



Federal Register

**Friday,
April 7, 2000**

Part II

Department of Health and Human Services

Health Care Financing Administration

42 CFR Parts 409, et al.

**Office of the Inspector General; Medicare
Program Prospective Payment System for
Hospital Outpatient Services; Final Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 409, 410, 411, 412, 413, 419, 424, 489, 498, and 1003

[HCFA-1005-FC]

RIN 0938-A156

Office of Inspector General; Medicare Program; Prospective Payment System for Hospital Outpatient Services

AGENCY: Health Care Financing Administration (HCFA), HHS, and Office of Inspector General (OIG), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period implements a prospective payment system for hospital outpatient services furnished to Medicare beneficiaries, as set forth in section 1833(t) of the Social Security Act. It also establishes requirements for provider departments and provider-based entities, and it implements section 9343(c) of the Omnibus Budget Reconciliation Act of 1986, which prohibits Medicare payment for nonphysician services furnished to a hospital outpatient by a provider or supplier other than a hospital, unless the services are furnished under an arrangement with the hospital. In addition, this rule establishes in regulations the extension of reductions in payment for costs of hospital outpatient services required by section 4522 of the Balanced Budget Act of 1997, as amended by section 201(k) of the Balanced Budget Refinement Act of 1999.

DATES: *Effective date:* July 1, 2000, except that the changes to § 412.24(d)(6), new § 413.65, and the changes to § 489.24(h), § 498.2, and § 498.3 are effective October 10, 2000.

Applicability date: For Medicare services furnished by all hospitals, including hospitals excluded from the inpatient prospective payment system, and by community mental health centers, the applicability date for implementation of the hospital outpatient prospective payment system is July 1, 2000.

Comment date: Comments on the provisions of this rule resulting from the Balanced Budget Refinement Act of 1999 will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on June 6, 2000. We will not consider comments concerning provisions that remain unchanged from the September

8, 1998 proposed rule or that were revised based on public comment.

See section VIII for a more detailed discussion of the provisions subject to comment.

ADDRESSES: Mail written comments (one original and three copies) to the following address ONLY: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA-1005-FC, P.O. Box 8013, Baltimore, MD 21244-8013.

If you prefer, you may deliver, by courier, your written comments (one 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 C5-14-03, Central Building, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Comments mailed to those addresses 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-1005-FC.

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 443-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (Phone (202) 690-7890).

For comments that relate to information collection requirements, mail a copy of comments to: 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, MD 21244-1850, Attn: John Burke, HCFA-1005-FC; and Lauren Oliven, HCFA Desk Officer, Office of Information and Regulatory Affairs, Room 3001, New Executive Office Building, Washington, DC 20503.

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FOR FURTHER INFORMATION CONTACT:

Janet Wellham, (410) 786-4510 or Chuck Braver, (410) 786-6719 (for general information)
Joel Schaer (OIG), (202) 619-0089 (for information concerning civil money penalties)
Kitty Ahern, (410) 786-4515 (for information related to the classification of services into ambulatory payment classification (APC) groups)
George Morey (410) 786-4653 (for information related to the determination of provider-based status)
Janet Samen (410) 786-9161 (for information on the application of APCs to community mental health centers)

SUPPLEMENTARY INFORMATION: To assist readers in referencing sections contained in this document, we are providing the following table of contents. Within each section, we summarize pertinent material from our proposed rule of September 8, 1998 (63 FR 47552) followed by public comments and our responses.

Table of Contents

- I. Background
 - A. General and Legislative History
 - B. Summary of Provisions of the Balanced Budget Act of 1997 (the BBA 1997)
 - 1. Prospective Payment System (PPS)
 - 2. Elimination of Formula-Driven Overpayment
 - 3. Extension of Cost Reductions
 - C. The September 8, 1998 Proposed Rule
 - D. Overview of Public Comments
 - E. Summary of Relevant Provisions in the Balanced Budget Refinement Act of 1999 (the BBRA 1999)
 - 1. Outlier Adjustment
 - 2. Transitional Pass-Through for Additional Costs of Innovative Medical Devices, Drugs, and Biologicals
 - 3. Budget Neutrality Applied to New Adjustments
 - 4. Limitation on Judicial Review
 - 5. Inclusion in the Hospital Outpatient PPS of Certain Implantable Items
 - 6. Payment Weights Based on Mean Hospital Costs
 - 7. Limitation on Variation of Costs of Services Classified Within a Group
 - 8. Annual Review of the Hospital Outpatient PPS Components
 - 9. Coinsurance Not Affected by Pass-Throughs

10. Extension of Cost Reductions
 11. Clarification of Congressional Intent Regarding Base Amounts Used in Determining the Hospital Outpatient PPS
 12. Transitional Corridors For Application of Outpatient PPS
 13. Limitation on Coinsurance for a Procedure
 14. Reclassification of Certain Hospitals
 - II. Prohibition Against Unbundling of Hospital Outpatient Services
 - A. Background
 - B. Office of Inspector General (OIG) Civil Money Penalty Authority and Civil Money Penalties for Unbundling Hospital Outpatient Services
 - C. Summary of Final Regulations on Bundling of Hospital Outpatient Services
 - D. Comments and Responses
 - III. Hospital Outpatient Prospective Payment System (PPS)
 - A. Hospitals Included In or Excluded From the Outpatient PPS
 - B. Scope of Facility Services
 1. Services Excluded from the Scope of Services Paid Under the Hospital Outpatient PPS
 - a. Background
 - b. Comments and Responses
 - c. Payment for Certain Implantable Items Under the BBRA 1999
 - d. Summary of Final Action
 2. Services Included Within the Scope of the Hospital Outpatient PPS
 - a. Services for Patients Who Have Exhausted Their Part A Benefits
 - b. Partial Hospitalization Services
 - c. Services Designated by the Secretary
 - d. Summary of Final Action
 3. Hospital Outpatient PPS Payment Indicators
 - C. Description of the Ambulatory Payment Classification (APC) Groups
 1. Setting Payment Rates Based on Groups of Services Rather than on Individual Services
 2. Packaging Under the APC System
 - a. Summary of Proposal
 - b. General Comments and Responses (Supporting or Objecting to Packaging)
 - c. Packaging of Casts and Splints
 - d. Packaging of Observation Services
 - e. Packaging Costs of Procuring Corneal Tissue
 - f. Packaging Costs of Blood and Blood Products
 - g. Packaging Costs for Drugs, Pharmaceuticals, and Biologicals
 - h. Summary of Final Action
 3. Treatment of Clinic and Emergency Department Visits
 - a. Provisions of the Proposed Rule
 - b. Comments and Responses
 4. Treatment of Partial Hospitalization Services
 5. Inpatient Only Procedures
 6. Modification of APC Groups
 - a. How the Groups Were Constructed
 - b. Comments on Classification of Procedures and Services Within APC Groups
 - c. Effect of the BBRA 1999 on Final APC Groups
 - d. Summary of APC Modifications
 - e. Exceptions to the BBRA 1999 Limit on Variation of Costs Within APC Groups
 - D. Discounting of Surgical Procedures
 8. Payment for New Technology Services
 - a. Background
 - b. Comments and Responses
 - D. Transitional Pass-Through for Innovative Medical Devices, Drugs, and Biologicals
 1. Statutory Basis
 2. Identifying Eligible Pass-Through Items
 - a. Drugs and Biologicals
 - b. Medical Devices
 3. Criteria to Define New or Innovative Medical Devices Eligible for Pass-through Payments
 4. Determination of "Not Insignificant" Cost of New Items
 5. Calculating the Additional Payment
 6. Process to Identify Items and to Obtain Codes for Items Subject to Transitional Pass-Throughs
 - E. Calculation of Group Weights and Conversion Factor
 1. Group Weights (Includes Table 1, Packaged Services by Revenue Center)
 2. Conversion Factor
 - a. Calculating Aggregate Calendar Year 1996 Medicare and Beneficiary Payments for Hospital Outpatient Services (Pre-PPS)
 - b. Sum of the Relative Weights
 - F. Calculation of Coinsurance Payments and Medicare Payments Under the PPS
 1. Background
 2. Determining the Unadjusted Coinsurance Amount and Program Payment Percentage
 - a. Calculating the Unadjusted Coinsurance Amount for Each APC Group
 - b. Calculating the Program Payment Percentage (Pre-deductible Payment Percentage)
 3. Calculating the Medicare Payment Amount and Beneficiary Coinsurance Amount
 - a. Calculating the Medicare Payment Amount
 - b. Calculating the Coinsurance Amount
 - G. Adjustment for Area Wage Differences
 1. Proposed Wage Index
 2. Labor-Related Portion of Hospital Outpatient Department PPS Payment Rates
 3. Adjustment of Hospital Outpatient Department PPS Payment and Coinsurance Amounts for Geographic Wage Variations
 4. Special Rules Under the BBRA 1999
 - H. Other Adjustments
 1. Outlier Payments
 2. Transitional Corridors/Interim Payments
 3. Cancer Centers and Small Rural Hospitals
 - I. Annual Updates
 1. Revisions to APC Groups, Weights and the Wage and Other Adjustments
 2. Annual Update to the Conversion Factor
 3. Advisory Panel for APC Updates
 - J. Volume Control Measures
 - K. Claims Submission and Processing and Medical Review
 - L. Prohibition Against Administrative or Judicial Review
 - IV. Provider-Based Status
 - A. Background
 - B. Provisions of the Proposed Rule
 - C. Comments and Responses
 - D. Requirements for Payment
 - V. Summary of and Response to MedPAC Recommendations
 - VI. Provisions of the Final Rule
 - VII. Collection of Information Requirements
 - VIII. Response to Comments
 - IX. Regulatory Impact Analysis
 - A. Introduction
 - B. Estimated Impact on the Medicare Program
 - C. Objectives
 - D. Limitations of Our Analysis
 - E. Hospitals Included In and Excluded From the Prospective Payment System
 - F. Quantitative Analysis of the Impact of Policy Changes on Payment Under the Hospital Outpatient PPS: Basis and Methodology of Estimates
 - G. Estimated Impact of the New APC System (Includes Table 2, Annual Impact of Hospital Outpatient Prospective Payment System in CY2000-CY2001)
 - X. Federalism
 - XI. Waiver of Proposed Rulemaking Regulations Text
- Addenda**
- Addendum A**—List of Hospital Outpatient Ambulatory Payment Classification Groups with Status Indicators, Relative Weights, Payment Rates, and Coinsurance Amounts
- Addendum B**—Hospital Outpatient Department (HOPD) Payment Rates and Payment Status by HCPCS, and Related Information
- Addendum C**—Hospital Outpatient Payment for Procedures by APC
- Addendum D**—1996 HCPCS Codes Used to Calculate Payment Rates That Are Not Active CY 2000 Codes
- Addendum E**—CPT Codes Which Will Be Paid Only As Inpatient Procedures
- Addendum F**—Status Indicators
- Addendum G**—Service Mix Indices by Hospital
- Addendum H**—Wage Index for Urban Areas
- Addendum I**—Wage Index for Rural Areas
- Addendum J**—Wage Index for Hospitals That Are Reclassified
- Addendum K**—Drugs, Biologicals, and Medical Devices Subject to Transitional Pass-Through Payment
- Alphabetical List of Acronyms Appearing in the Final Rule**
- APC Ambulatory payment classification
 APG Ambulatory patient group
 ASC Ambulatory surgical center
 AWP Average wholesale price
 BBA 1997 Balanced Budget Act of 1997
 BBRA 1999 Balanced Budget Refinement Act of 1999
 CAH Critical access hospital
 CAT Computerized axial tomography
 CCI [HCFA's] Correct Coding Initiative
 CCR Cost center specific cost-to-charge ratio
 CCU Coronary care unit
 CMHC Community mental health center
 CMP Civil money penalty
 CORF Comprehensive outpatient rehabilitation facility
 CPI Consumer Price Index
 CPT [Physicians'] Current Procedural Terminology, 4th Edition, 2000,

copyrighted by the American Medical Association
 DME Durable medical equipment
 DMEPOS DME, orthotics, prosthetics, prosthetic devices, prosthetic implants and supplies
 DRG Diagnosis-related group
 DSH Disproportionate share hospital
 EACH Essential access community hospital
 EBAA Eye Bank Association of America
 ED Emergency department
 EMS Emergency medical services
 EMTALA Emergency Medical Treatment and Active Labor Act
 ENT Ear/Nose/Throat
 ESRD End-stage renal disease
 FDA Food and Drug Administration
 FDO Formula-driven overpayment
 FQHC Federally qualified health center
 HCPCS HCFA Common Procedure Coding System
 HHA Home health agency
 HRSA Health Resources and Services Administration
 ICD-9-CM International Classification of Diseases, Ninth Edition, Clinical Modification
 ICU Intensive care unit
 IHS Indian Health Service
 IME Indirect medical education
 IOL Intraocular lens
 JCAHO Joint Commission on Accreditation of Healthcare Organizations
 LTH Long-term hospital
 MDH Medicare-dependent hospital
 MedPAC Medicare Payment Advisory Commission
 MRI Magnetic resonance imaging
 MSA Metropolitan statistical area
 NECMA New England County Metropolitan Area
 OBRA Omnibus Budget Reconciliation Act
 OT Occupational therapy
 PPO Preferred provider organization
 PPS Prospective payment system
 RFA Regulatory Flexibility Act
 RHC Rural health clinic
 RPCH Rural primary care hospital
 RRC Rural referral center
 SCH Sole community hospital
 SGR Sustainable growth rate
 SNF Skilled nursing facility
 TEFRA Tax Equity and Fiscal Responsibility Act of 1982
 TPA Tissue Plasminogen Activator
 Y2K Year 2000

I. Background

A. General and Legislative History

When the Medicare program was first implemented, it paid for hospital services (inpatient and outpatient) based on hospital-specific reasonable costs attributable to serving Medicare beneficiaries. Later, the law was amended to limit payment to the lesser of a hospital's reasonable costs or its customary charges. In 1983, section 601 of the Social Security Amendments of 1983 (Pub. L. 98-21) completely revised the cost-based payment system for most hospital inpatient services by enacting section 1886(d) of the Social Security Act (the Act). This section provided for

a prospective payment system (PPS) for acute hospital inpatient stays, effective with hospital cost reporting periods beginning on or after October 1, 1983.

Although payment for most inpatient services became subject to the PPS, Medicare hospital outpatient services continued to be paid based on hospital-specific costs, which provided little incentive for hospitals to furnish outpatient services efficiently. At the same time, advances in medical technology and changes in practice patterns were bringing about a shift in the site of medical care from the inpatient to the outpatient setting. During the 1980s, the Congress took steps to control the escalating costs of providing outpatient care. The Congress amended the statute to implement across-the-board reductions of 5.8 percent and 10 percent to the amounts otherwise payable by Medicare for hospital operating costs and capital costs, respectively, and enacted a number of different payment methods for specific types of hospital outpatient services. These methods included fee schedules for clinical diagnostic laboratory tests, orthotics, prosthetics, and durable medical equipment (DME); composite rate payment for dialysis for persons with end-stage renal disease (ESRD); and payments based on blends of hospital costs and the rates paid in other ambulatory settings such as separately certified ambulatory surgical centers (ASCs) or physician offices for certain surgery, radiology, and other diagnostic procedures. However, Medicare payment for services performed in the hospital outpatient setting remains largely cost-based.

In the Omnibus Budget Reconciliation Act of 1986 (OBRA 1986) (Pub. L. 99-509), the Congress paved the way for development of a PPS for hospital outpatient services. Section 9343(g) of OBRA 1986 mandated that fiscal intermediaries require hospitals to report claims for services under the HCFA Common Procedure Coding System (HCPCS). Section 9343(c) of OBRA 1986 extended the prohibition against unbundling of hospital services under section 1862(a)(14) of the Act to include outpatient services as well as inpatient services. The HCPCS coding enabled us to determine which specific procedures and services were being billed, while the extension of the prohibition against unbundling ensured that all nonphysician services provided to hospital outpatients would be billed only by the hospital, not by an outside supplier, and, therefore, would be reported on hospital bills and captured in the hospital outpatient data that

could be used to develop an outpatient PPS.

A proposed rule to implement section 9343(c) was published in the **Federal Register** on August 5, 1988. However, those regulations were never published as a final rule, so we included them in the hospital outpatient PPS proposed rule published in the **Federal Register** on September 8, 1998 (63 FR 47552) and will implement them as part of this final rule.

Section 1866(g) of the Act, as added by section 9343(c) of OBRA 1986, and amended by section 4085(i)(17) of the Omnibus Budget Reconciliation Act of 1987 (OBRA 1987) (Pub. L. 100-203), authorizes the Department of Health and Human Services' Office of Inspector General to impose a civil money penalty (CMP), not to exceed \$2,000, against any individual or entity who knowingly and willfully presents a bill in violation of an arrangement (as defined in section 1861(w)(1) of the Act).

In section 9343(f) of the OBRA 1986 and section 4151(b)(2) of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508), the Congress required that we develop a proposal to replace the current hospital outpatient payment system with a PPS and submit a report to the Congress on the proposed system.

The Secretary submitted a report to the Congress on March 17, 1995, summarizing the research we conducted searching for a way to classify outpatient services for purposes of developing an outpatient PPS. The report cited ambulatory patient groups (APGs), developed by 3M-Health Information Systems (3M-HIS) under a cooperative grant with HCFA, as the most promising classification system for grouping outpatient services and recommended that APG-like groups be used in designing a hospital outpatient PPS.

The report also presented a number of options that could be used, once a PPS was in place, for addressing the issue of rapidly growing beneficiary coinsurance. As a separate issue, we recommended that the Congress amend the provisions of the law pertaining to the blended payment methods for ASC surgery, radiology, and other diagnostic services to correct an anomaly that resulted in a less than full recognition of the amount paid by the beneficiary in calculating program payment (referred to as the formula-driven overpayment).

Three sections of the Balanced Budget Act of 1997 (the BBA 1997) (Pub. L. 105-33), enacted on August 5, 1997, affect Medicare payment for hospital outpatient services. Section 4521 of the BBA 1997 eliminates the formula-driven overpayment for ambulatory surgical

center procedures, radiology services, and diagnostic procedures furnished on or after October 1, 1997. In November 1998, we issued cost report instructions (Provider Reimbursement Manual, Part II, Chapter 36, Transmittal 4) that implemented this provision for services furnished on or after October 1, 1997. Section 4522 of the BBA 1997 amends section 1861(v)(1)(S)(ii) of the Act by extending cost reductions in payment for hospital outpatient operating costs and hospital capital costs, 5.8 percent and 10 percent respectively, before January 1, 2000. Section 4523 of the BBA 1997 amends section 1833 of the Act by adding subsection (t), which provides for implementation of a PPS for outpatient services. (Under Section 4523 of the BBA 1997 the outpatient PPS does not apply to cancer hospitals before January 1, 2000.) Set forth below in section I.B is a detailed description of the changes made by the BBA 1997.

On November 29, 1999, the Balanced Budget Refinement Act of 1999 (the BBRA 1999), Pub. L. 106-113, was enacted. This Act made major changes that affect the proposed hospital outpatient PPS. The legislative changes are summarized in section I.E, below. More specific details on individual provisions that we are implementing in this final rule with comment period are included under the various sections of this preamble.

B. Summary of Provisions in the Balanced Budget Act of 1997 (the BBA 1997)

1. Prospective Payment System (PPS)

Section 4523 of the BBA 1997 amended section 1833 of the Act by adding subsection (t), which provides for a PPS for hospital outpatient department services. (The following citations reflect the statute as enacted by the BBA 1997.) Section 1833(t)(1)(B) of the Act authorizes the Secretary to designate the hospital outpatient services that would be paid under the PPS. That section also requires that the hospital outpatient PPS include hospital inpatient services designated by the Secretary that are covered under Part B for beneficiaries who are entitled to Part A benefits but who have exhausted them or otherwise are not entitled to them. Section 1833(t)(1)(B)(iii) of the Act specifically excludes ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule.

Section 1833(t)(2) of the Act sets forth certain requirements for the hospital outpatient PPS. The Secretary is required to develop a classification

system for covered outpatient services that may consist of groups arranged so that the services within each group are comparable clinically and with respect to the use of resources.

Section 1833(t)(2)(C) of the Act specifies data requirements for establishing relative payment weights. The weights are to be based on the median hospital costs determined by 1996 claims data and data from the most recent available cost reports. Section 1833(t)(2)(D) of the Act requires that the portion of the Medicare payment and the beneficiary coinsurance that are attributable to labor and labor-related costs be adjusted for geographic wage differences in a budget neutral manner.

The Secretary is authorized under section 1833(t)(2)(E) of the Act to establish, in a budget neutral manner, other adjustments, such as outlier adjustments or adjustments for certain classes of hospitals, that are necessary to ensure equitable payments. Section 1833(t)(2)(F) of the Act requires the Secretary to develop a method for controlling unnecessary increases in the volume of covered outpatient services.

Section 1833(t)(3) of the Act specifies how beneficiary deductibles are to be treated in calculating the Medicare payment and beneficiary coinsurance amounts and requires that rules be established regarding determination of coinsurance amounts for covered services that were not furnished in 1996. The statute freezes beneficiary coinsurance at 20 percent of the national median charges for covered services (or group of covered services) furnished during 1996 and updated to 1999 using the Secretary's estimated charge growth from 1996 to 1999.

Section 1833(t)(3) of the Act also prescribes the formula for calculating the initial conversion factor used to determine Medicare payment amounts for 1999 and the method for updating the conversion factor in subsequent years.

Sections 1833(t)(4) and (t)(5) of the Act describe the method for determining the Medicare payment amount and the beneficiary coinsurance amount for services covered under the outpatient PPS. Section 1833(t)(5)(B) of the Act requires the Secretary to establish a procedure whereby hospitals may voluntarily elect to reduce beneficiary coinsurance for some or all covered services to an amount not less than 20 percent of the Medicare payment amount. Hospitals are further allowed to disseminate information on any such reductions of coinsurance amounts. Section 4451 of the BBA 1997 added section 1861(v)(1)(T) to the Act, which provides that any reduction in

coinsurance must not be treated as a bad debt.

Section 1833(t)(6) authorizes periodic review and revision of the payment groups, relative payment weights, wage index, and conversion factor.

Section 1833(t)(7) of the Act describes how payment is to be made for ambulance services, which are specifically excluded from the outpatient PPS under section 1833(t)(1)(B) of the Act.

Section 1833(t)(8) of the Act provides that the Secretary may establish a separate conversion factor for services furnished by cancer hospitals that are excluded from hospital inpatient PPS.

Section 1833(t)(9) of the Act prohibits administrative or judicial review of the hospital outpatient PPS classification system, the groups, relative payment weights, wage adjustment factors, other adjustments, calculation of base amounts, periodic adjustments, and the establishment of a separate conversion factor for those cancer hospitals excluded from hospital inpatient PPS.

Section 4523(d) of the BBA 1997 made a conforming

amendment to section 1833(a)(2)(B) of the Act to provide for payment under the hospital outpatient PPS for some services described in section 1832(a)(2) that are currently paid on a cost basis and furnished by providers of services, such as comprehensive outpatient rehabilitation facilities (CORFs), home health agencies (HHAs), hospices, and community mental health centers (CMHCs). This amendment provides that partial hospitalization services furnished by CMHCs be paid under the PPS.

2. Elimination of Formula-Driven Overpayment

Before enactment of section 4521(b) of the BBA 1997, using the blended payment formulas for ASC procedures, radiology, and other diagnostic services, the ASC or physician fee schedule portion was calculated as if the beneficiary paid 20 percent of the ASC rate or physician fee schedule amount instead of the actual amount paid, which was 20 percent of the hospital's billed charges. Section 4521(b), which amended sections 1833(i)(3)(B)(i)(II) and 1833(n)(1)(B)(i) of the Act, corrects this anomaly by changing the blended calculations so that all amounts paid by the beneficiary are subtracted from the total payment in the calculation to determine the amount due from the program. Effective for services furnished on or after October 1, 1997, payment for surgery, radiology, and other diagnostic services calculated by blended payment methods is now calculated by

subtracting the full amount of coinsurance due from the beneficiary (based on 20 percent of the hospital's billed charges).

3. Extension of Cost Reductions

Section 1861(v)(1)(S)(ii) of the Act was amended by section 4522 of the BBA 1997 to require that the amounts otherwise payable for hospital outpatient operating costs and capital costs be reduced by 5.8 percent and 10 percent, respectively, through December 31, 1999.

C. The September 8, 1998 Proposed Rule

We published a proposed rule in the **Federal Register** on September 8, 1998 (63 FR 47552) setting forth the proposed PPS for hospital outpatient services. In that proposed rule, we explained that, due to Year 2000 (Y2K) systems concerns, implementation of the new payment system would be delayed until after January 1, 1999. (The statement in the rule that the statute requires implementation "effective January 1, 1999," and other similar statements in other rules, were not intended to mean that the statute requires retroactive implementation of the hospital outpatient PPS. As noted elsewhere in this rule, the statute does not impose such a requirement.) As noted in that document, the scope of systems changes required to implement the hospital outpatient PPS is so enormous as to be impossible to accomplish concurrently with the critical work that we, our contractors, and our provider-partners had to perform to ensure that all of our respective systems were Y2K compliant. Section XI of the proposed rule (63 FR 47605) explains in greater detail the reasons for delaying implementation.

The proposed rule originally provided for a 60-day comment period. However, the comment period was extended four times, ultimately ending on July 30, 1999. (See 63 FR 63429, November 13, 1998; 64 FR 1784, January 12, 1999; 64 FR 12277, March 12, 1999; and 64 FR 36320; July 6, 1999.)

On June 30, 1999, we published a correction notice (64 FR 35258) to correct a number of technical and typographical errors contained in the September 8, 1998 proposed rule. The numerical values in the proposed rule reflected incorrect data and data programming. Among other corrections, the notice set forth revised numerical values for the current payment, total services (total units), relative weights, proposed payment rates, national unadjusted coinsurance, minimum unadjusted coinsurance, and service-mix index.

D. Overview of Public Comments

We received approximately 10,500 comments in response to our September 8, 1998 proposed rule. That count includes the numerous requests from hospital and other interested groups and organizations that we extend the public comment period to allow additional time for analysis of the impact of our proposals. As we explain above, we extended the comment period four times, to end finally on July 30, 1999.

In addition to receiving comments from a number of organizations representing the full spectrum of the hospital industry, we received comments from beneficiaries and their families, physicians, health care workers, individual hospitals, professional associations and societies, legal and nonlegal representatives and spokespersons for beneficiaries and hospitals, members of the Congress, and other interested citizens. The majority of comments addressed our proposals regarding payment for: Corneal tissue; payment for high-cost technologies, both existing and future; payment for blood and blood products; and payment for high cost drugs, including chemotherapy agents. We also received numerous comments addressing: Our approach to ratesetting using the ambulatory payment classification (APC) system; our method of calculating the payment conversion factor; and the potentially negative impact of the proposed hospital outpatient PPS on hospital revenues. In addition, we received many comments concerning the proposed regulations for provider-based entities.

We carefully reviewed and considered all comments received timely. The many modifications that we made to our proposed regulations in response to commenters' suggestions and recommendations are reflected in the provisions of this final rule. Comments and our responses are addressed by topic in the sections that follow.

E. Summary of Relevant Provisions in the Balanced Budget Refinement Act of 1999 (the BBRA 1999)

As noted above, subsequent to publication of the proposed rule, the BBRA 1999 was enacted on November 29, 1999. The BBRA 1999 made major changes that affect the proposed hospital outpatient PPS. Because these changes are effective with the implementation of the PPS, we have had to make some revisions from the September 8, 1998 proposed rule. The provisions of the BBRA 1999 that we are implementing in this final rule with comment period follow.

1. Outlier Adjustment

Section 201(a) of the BBRA 1999 amends section 1833(t) by redesignating paragraphs (5) through (9) as paragraphs (7) through (11) and adding a new paragraph (5). New section 1833(t)(5) of the Act provides that the Secretary will make payment adjustments for covered services whose costs exceed a given threshold (that is, an outlier payment). This section describes how the additional payments are to be calculated and caps the projected outlier payments at no more than 2.5 percent of the total projected payments (sum of both Medicare and beneficiary payments to the hospital) made under hospital outpatient PPS for years before 2004 and 3.0 percent of the total projected payments for 2004 and subsequent years.

2. Transitional Pass-Through for Additional Costs of Innovative Medical Devices, Drugs, and Biologicals

Section 201(b) of the BBRA 1999 adds new section 1833(t)(6) to the Act, establishing transitional pass-through payments for certain medical devices, drugs, and biologicals. This provision does the following: Specifies the types of items for which additional payments must be made; describes the amount of the additional payment; limits these payments to at least 2 years but not more than 3 years; and caps the projected payment adjustments annually at 2.5 percent of the total projected payments for hospital outpatient services each year before 2004 and no more than 2.0 percent in subsequent years. Under this provision, the Secretary has the authority to reduce pro rata the amount of the additional payments if, before the beginning of a year, she estimates that these payments would otherwise exceed the caps.

3. Budget Neutrality Applied to New Adjustments

Section 201(c) of the BBRA 1999 amends section 1833(t)(2)(E) of the Act to require that the establishment of outlier and transitional pass-through payment adjustments is to be made in a budget neutral manner.

4. Limitation on Judicial Review

Section 201(d) of the BBRA 1999 amends redesignated section 1833(t)(11) of the Act by extending the prohibition of administrative or judicial review to include the factors for determining outlier payments (that is, the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable total payment percentage), and the determination of additional payments for certain medical devices,

drugs, and biologicals, the insignificant cost determination for these items, the duration of the additional payment or portion of the PPS payment amount associated with particular devices, drugs, or biologicals, and any pro rata reduction.

5. Inclusion in the Hospital Outpatient PPS of Certain Implantable Items

Section 201(e) of the BBRA 1999 amends section 1833(t)(1)(B) of the Act to include as covered outpatient services implantable prosthetics and DME and diagnostic x-ray, laboratory, and other tests associated with those implantable items.

6. Payment Weights Based on Mean Hospital Costs

Section 201(f) of the BBRA 1999 amends section 1833(t)(2)(C) of the Act, which specifies data requirements for establishing relative payment weights, to allow the Secretary the discretion to base the weights on either the median or mean hospital costs determined by data from the most recent available cost reports.

7. Limitation on Variation of Costs of Services Classified Within a Group

Section 201(g) of the BBRA 1999 amends section 1833(t)(2) of the Act to limit the variation of costs of services within each payment classification group by providing that the highest median (or mean cost, if elected by the Secretary) for an item or service within the group cannot be more than 2 times greater than the lowest median (or mean) cost for an item or service within the group. The provision allows the Secretary to make exceptions in unusual cases, such as for low volume items and services.

8. Annual Review of the Hospital Outpatient PPS Components

Section 201(h) of the BBRA 1999 amends redesignated section 1833(t)(8) of the Act to require at least annual review of the groups, relative payment weights, and the wage and other adjustments made by the Secretary to take into account changes in medical practice, the addition of new services, new cost data, and other relevant information and factors. That section of the Act is further amended to require the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of provider representatives who will review the clinical integrity of the groups and weights and advise the Secretary accordingly. The panel may use data other than those collected or developed

by the Department of HHS for the review and advisory purposes.

9. Coinsurance Not Affected by Pass-Throughs

Section 201(i) of the BBRA 1999 amends redesignated section 1833(t)(7) of the Act to provide that the beneficiary coinsurance amount will be calculated as if the outlier and transitional pass-throughs had not occurred; that is, there will be no coinsurance collected from beneficiaries for the additional payments made to hospitals by Medicare for these adjustments.

10. Extension of Cost Reductions

Section 201(k) of the BBRA 1999 amends section 1861(v)(1)(S)(ii) of the Act to extend until the first date that the hospital outpatient PPS is implemented, the 5.8 and 10 percent reductions for hospital operating and capital costs, respectively.

11. Clarification of Congressional Intent Regarding Base Amounts Used in Determining the Hospital Outpatient PPS

Section 201(l) of the BBRA 1999 provides that, "With respect to determining the amount of copayments described in paragraph (3)(A)(ii) of section 1833(t) of the Social Security Act, as added by section 4523(a) of the BBA, Congress finds that such amount should be determined without regard to such section, in a budget neutral manner with respect to aggregate payments to hospitals, and that the Secretary of Health and Human Services has the authority to determine such amount without regard to such section." Pursuant to this provision, we are calculating the aggregate PPS payment to hospitals in a budget neutral manner.

12. Transitional Corridors for Application of Outpatient PPS

Section 202 of the BBRA 1999 amends section 1833(t) of the Act by redesignating paragraphs (7) through (11) as paragraphs (8) through (12), and adding a new paragraph (7), which provides for a transitional adjustment to limit payment reductions under the hospital outpatient PPS. More specifically, for the years 2000 through 2003, a provider, including a CMHC, will receive an adjustment if its payment-to-cost ratio for outpatient services furnished during the year is less than a set percentage of its payment-to-cost ratio for those services in its cost reporting period ending in 1996 (the base year). Two categories of hospitals, rural hospitals with 100 or fewer beds and cancer hospitals, will be held harmless under this provision.

Small rural hospitals, for services furnished before January 1, 2004, will be maintained at the same payment-to-cost ratio as their base year cost report if their PPS payment-to-cost ratio is less. The hold-harmless provision applies permanently to cancer centers. Section 202 also requires the Secretary to make interim payments to affected hospitals subject to retrospective adjustments and requires that the provisions of this section do not affect beneficiary coinsurance. Finally, this provision is not subject to budget neutrality.

13. Limitation on Coinsurance for a Procedure

Section 204 of the BBRA 1999 amends redesignated section 1833(t)(8) of the Act to provide that the coinsurance amount for a procedure performed in a year cannot exceed the hospital inpatient deductible for that year.

14. Reclassification of Certain Hospitals

Section 401 of the BBRA 1999 adds section 1886(d)(8)(E) to the Act to permit reclassification of certain urban hospitals as rural hospitals. Section 401 adds section 1833(t)(13) to the Act to provide that a hospital being treated as a rural hospital under section 1886(d)(8)(E) also be treated as a rural hospital under the hospital outpatient PPS.

II. Prohibition Against Unbundling of Hospital Outpatient Services

A. Background

Sections 9343(c)(1) and (c)(2) of OBRA 1986 amended sections 1862(a)(14) and 1866(a)(1)(H) of the Act, respectively. As revised, section 1862(a)(14) of the Act prohibits payment for nonphysician services furnished to hospital patients (inpatients and outpatients), unless the services are furnished by the hospital, either directly or under an arrangement (as defined in section 1861(w)(1) of the Act). As revised, section 1866(a)(1)(H) of the Act requires each Medicare-participating hospital to agree to furnish directly all covered nonphysician services required by its patients (inpatients and outpatients) or to have the services furnished under an arrangement (as defined in section 1861(w)(1) of the Act). Section 9338(a)(3) of OBRA 1986 affected implementation of the bundling mandate by amending section 1861(s)(2)(K) of the Act to permit services of physician assistants to be covered and billed separately. Sections 4511(a)(2)(C) and (D) of the BBA 1997 further revised sections 1862(a)(14) and 1866(a)(1)(H) of the Act, respectively, to exclude services of nurse practitioners

and clinical nurse specialists, described in section 1861(s)(2)(K)(ii) of the Act, from the bundling requirement.

B. Office of Inspector General (OIG) Civil Money Penalty Authority and Civil Money Penalties for Unbundling Hospital Outpatient Services

In order to deter the unbundling of nonphysician hospital services, section 9343(c)(3) of OBRA 1986 added section 1866(g) to the Act to provide for the imposition of civil money penalties (CMPs), not to exceed \$2,000, against any person who knowingly and willfully presents, or causes to be presented, a bill or request for payment for a hospital outpatient service under Part B of Medicare that violates the requirement for billing under arrangements specified in section 1866(a)(1)(H) of the Act. In addition, section 1866(g) includes authorization to impose a CMP, in the same manner as other CMPs are imposed under section 1128A of the Act when arrangements should have been made but were not. Section 4085(i)(17) of OBRA 1987 amended section 1866(g) of the Act by deleting all references to hospital outpatient services under Part B of Medicare. The result of this amendment is that the CMP is now applicable for services furnished to hospital patients, whether paid for under Medicare Part A or B.

In order to implement section 1866(g) of the Act, we proposed in our August 5, 1988 proposed rule that the OIG would impose a CMP against any person who knowingly and willfully presents, or causes to be presented, a bill or request for payment for a hospital outpatient service under Part B of Medicare that violates the billing arrangement under section 1866(a)(1)(H) of the Act or the requirement for an arrangement. The amount of the CMP is to be limited to \$2,000 for each improper bill or request, even if the bill or request included more than one item or service.

C. Summary of Final Regulations on Bundling of Hospital Outpatient Services

In our September 8, 1998 proposed rule, we proposed to make final most of the provisions of the August 5, 1988 proposed rule but with a number of revisions that we describe in detail in the proposed rule (63 FR 47558 through 47559). We are adopting as final regulations what we proposed in the September 8, 1998 rule with the following additional changes:

- We are adding a new paragraph (b)(7) to § 410.42 (Limitations on coverage of certain services furnished to

hospital outpatients) to provide an exception to the hospital bundling requirements for services hospitals furnish to SNF residents as defined in § 411.15(p). (Section 410.42 has been redesignated from § 410.39 in the proposed rule.)

- We are making a minor change to newly redesignated paragraph (m)(2) (this language was formerly included in paragraph (m)(1)) in § 411.15 (Particular services excluded from coverage) to make it clearer that the exclusion discussed in this section is referring to excluding certain services from coverage.

- Except for minor wording changes in introductory paragraph (b) of § 1003.102 (Basis for civil money penalties and assessments), that section remains as it appeared in the August 5, 1988 proposed rule. Paragraph (b)(15) is redesignated from proposed paragraph (b)(4) in the August 5, 1988 proposed rule and (b)(14) in the September 8, 1998 proposed rule. Paragraphs (b)(12) through (b)(14) of § 1003.102 are reserved.

- We are adding a new paragraph (k) to § 1003.103 (Amount of penalty) to indicate that the OIG may impose a penalty of not more than \$2,000 for each bill or request for items and services furnished to hospital patients in violation of the bundling requirements.

- We are also amending § 1003.105 (Exclusion from participation in Medicare, Medicaid and other Federal health care programs) by revising paragraph (a)(1)(i) to reflect that the basis for imposition of a CMP is also a basis for exclusion from participation in Medicare, Medicaid and other Federal health care programs.

D. Comments and Responses

Comment: One association requested that we clarify whether lab tests are subject to the bundling requirement or whether those services are included in the definition of diagnostic tests that are not required to be bundled. If lab tests are bundled, the association asked that we seek a legislative change to permit a provider, other than the lab that performs the test, to bill for the test.

Response: Laboratory tests, like all other services furnished to hospital patients, must be provided directly or under arrangements by the hospital and only the hospital may bill the program. Section 1833(h)(5)(A)(iii) of the Act provides an exception to the requirement that payment for a clinical diagnostic lab may be made only to the person or entity that performed or supervised the performance of the test. This section provides that in the case of a clinical diagnostic laboratory test

provided under arrangement made by a hospital or CAH, payment is made to the hospital.

All diagnostic tests that are furnished by a hospital, directly or under arrangements, to a registered hospital outpatient during an encounter at a hospital are subject to the bundling requirements. The hospital is not responsible for billing for the diagnostic test if a hospital patient leaves the hospital and goes elsewhere to obtain the diagnostic test.

Comment: The same association asked us to clarify that services billed to skilled nursing facilities (SNFs) under the consolidated billing requirement would be exempt from the bundling requirement for hospital outpatient services.

Response: We agree that in situations where a beneficiary receives outpatient services from a Medicare participating hospital or CAH while temporarily absent from the SNF, the beneficiary continues to be considered a SNF resident specifically with regard to the comprehensive care plan required under § 483.20(b). Such services are, therefore, subject to the SNF consolidated billing provision and should be exempt from the hospital outpatient bundling requirements. The final regulations at § 410.42(b)(7) reflect this exception.

We note that the SNF consolidated billing requirements, under § 411.15(p)(3)(iii), do not apply to a limited number of exceptionally intensive hospital outpatient services that lie well beyond the scope of care that SNFs would ordinarily furnish, and thus beyond the ordinary scope of SNF care plans. The hospital outpatient services that are currently included in this policy are: Cardiac catheterization; computerized axial tomography (CAT) scans; MRIs; ambulatory surgery involving the use of an operating room; emergency room services; radiation therapy; angiography; and lymphatic and venous procedures. When a hospital or CAH provides these services to a beneficiary, the beneficiary's status as a SNF resident ends, but only with respect to these services. The beneficiary is now considered to be a hospital outpatient and the services are subject to hospital outpatient bundling requirements. In November 1998, we issued Program Memorandum transmittal number A-98-37, which provides additional clarification on this exclusion as well as a list of specific HCPCS codes that identify the services that are excluded from SNF consolidated billing but subject to hospital outpatient bundling.

Comment: One commenter understood that the proposed rule

would permit payment for all diagnostic tests that are furnished by a hospital or other entity if the patient leaves the hospital and obtains the service elsewhere; however, the commenter requested clarification as to the treatment of "outsourced" hospital departments. The commenter stated that hospitals are increasingly outsourcing departments to providers that can furnish services efficiently. Often these providers do not operate as "under arrangements" providers to the hospital, but as free-standing providers offering outpatient services on hospital grounds. The commenter specifically asked whether a free-standing entity providing outpatient services on hospital grounds, but operated independently of the hospital is able to bill separately for services furnished or is the entity considered to be part of the hospital and required to furnish services "under arrangement."

Response: A free-standing entity, that is, one that is not provider-based, may bill for services furnished to beneficiaries who do not meet the definition of a hospital outpatient at the time the service is furnished. Our bundling requirements apply to services furnished to a "hospital outpatient," as defined in § 410.2, during an "encounter," also defined in § 410.2.

Comment: One commenter indicated that while the proposed revision to § 1003.102(b) accurately reflected the statutory directive that the basis for imposing a CMP is a "bill or request for payment," the proposed amendment to § 1003.103(a) regarding the appropriate penalty amount to be imposed for bundling violations was in error. The commenter indicated that the OIG lacks the authority to impose a CMP in the amount of \$10,000 for these violations, and that such a penalty should be not more than \$2,000 for each violation.

Response: The commenter is correct. While section 231(c) of the Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191, increased the CMP maximum amount from \$2,000 to \$10,000, the statute sets forth "items or services" as the basis upon which a higher CMP amount may be assessed. However, with regard to bundling violations, the Secretary may impose a CMP only on the basis of a "bill or request for payment" rather than "for each item and service" as stated in the proposed revision to § 1003.103. We are correcting this error by adding a new § 1003.103(k) to indicate that the OIG may impose a penalty of not more than \$2,000 for each bill or request for items and services furnished to hospital patients in violation of the bundling requirements.

III. Hospital Outpatient Prospective Payment System (PPS)

In this section, we designate the services for which Medicare will make payment under the hospital outpatient PPS, the payment rates set for those services, and the method by which we determined the outpatient PPS payment and coinsurance amounts.

We explain the structure of the hospital outpatient PPS, respond to comments that we received about the proposed PPS, and describe modifications that we made to the proposed PPS in response to comments, such as provisions we are making to expedite appropriate payment for new technologies and provisions to pay for blood and blood products.

In this section, we also discuss how we will implement requirements enacted by the BBRA 1999, including transitional payment corridors and other payment adjustments such as outliers and transitional pass-throughs.

A. Hospitals Included In or Excluded From the Outpatient PPS

This PPS applies to covered hospital outpatient services furnished by all hospitals participating in the Medicare program, except as noted below. Partial hospitalization services in community mental health centers (CMHCs) are also paid under this PPS. Exclusions from outpatient PPS are different and more limited than exclusions from inpatient PPS. Thus, hospitals or distinct parts of hospitals that are excluded from the inpatient PPS are included in the outpatient PPS, to the extent that the hospital or distinct part furnishes outpatient services. For example, we will make payment under the outpatient PPS for outpatient psychiatric services. The outpatient services provided by hospitals of the Indian Health Service (IHS) will continue to be paid under separately established rates which are published annually in the **Federal Register**. We intend to develop a plan that will help these facilities transition to the PPS and will consult with the IHS to develop this plan.

The following hospitals are excluded from the outpatient PPS:

- Certain hospitals in Maryland qualify under section 1814(b)(3) of the Act for payment under the State's payment system. The excluded services are limited to those paid under the State's payment system as described in section 1814(b)(3) of the Act. Any other outpatient services furnished by the hospital are paid under the outpatient PPS.
- Critical access hospitals that are paid under a reasonable cost based

system, as required under section 1834(g) of the Act.

Comment: National and State associations representing children's hospitals and a number of individual children's hospitals located across the country strongly recommended that their hospitals be excluded from the hospital outpatient PPS just as they have been excluded from the hospital inpatient PPS. These commenters argued that the exclusion should apply to outpatient services furnished by children's hospitals because these hospitals treat a unique patient group whose health needs are different from those of adult beneficiaries entitled to Medicare benefits. The commenters further argued that services to Medicare patients are, on average, only 1 percent of the total inpatient and outpatient services that children's hospitals furnish and that these services are largely ESRD services that are already excluded from the hospital outpatient PPS. The commenters were concerned that the resources required to implement and comply with the new system would be disproportionately high relative to the small number of patients who would be affected by the new system. In addition, the impact analysis that accompanied the proposed rule estimated that children's hospitals would lose more than 20 percent of their Medicare revenues under the new system. Commenters expressed great concern about this loss of revenue.

Response: Our most recent analysis of the impact on hospitals of the PPS shows a negative effect for children's hospitals of 11.9 percent, which is significantly less than what we estimated in the proposed rule. However, the transitional corridor payments provided by the BBRA 1999 will protect these hospitals from even this level of loss through 2004. The estimated loss for CY 2000-2001 for children's hospitals is only 3.2 percent. (See Table 2 in section IX of this preamble.) As we discuss in section III.H.2 below, we will conduct extensive analyses during the first years of implementation of the PPS to determine whether we should propose adjustments for certain types of hospitals, including children's hospitals, when the transitional corridor provision expires. In the meantime, we are not excluding any special class of hospital from the PPS.

B. Scope of Facility Services

Section 1833(t)(1)(B)(i) of the Act gives us the authority to designate the services to be covered under the hospital outpatient PPS. In this section of the final rule, we designate the types

of services included or excluded under the hospital outpatient PPS.

1. Services Excluded From the Scope of Services Paid Under the Hospital Outpatient PPS

a. Background

In developing a hospital outpatient PPS, we want to ensure that all services furnished in a hospital outpatient setting will be paid on a prospective basis. We have already been paying, in part, for some hospital outpatient services such as clinical diagnostic laboratory services, orthotics, and end-stage renal disease (ESRD) dialysis services based on fee schedules or other prospectively determined rates that also apply across other sites of ambulatory care. Rather than duplicate existing payment systems that are effectively achieving consistency of payments across different service delivery sites, we proposed to exclude from the outpatient PPS those services furnished in a hospital outpatient setting that were already subject to an existing fee schedule or other prospectively determined payment rate. The similar payments across various settings create a more level playing field in which Medicare makes virtually the same payment for the same service, without regard to where the service is furnished.

We therefore proposed to exclude from the scope of services paid under the hospital outpatient PPS the following:

- Services already paid under fee schedules or other payment systems including, but not limited to: screening mammographies, services for patients with ESRD that are paid for under the ESRD composite rate; the professional services of physicians and non-physician practitioners paid under the Medicare physician fee schedule; laboratory services paid under the clinical diagnostic laboratory fee schedule; and DME, orthotics, prosthetics, and prosthetics devices, prosthetic implants, and supplies (DMEPOS) paid under the DMEPOS fee schedule when the hospital is acting as a supplier of these items. An item such as crutches or a walker that is given to the patient to take home, but that may also be used while the patient is at the hospital, would be billed to the DME regional carrier rather than paid for under the hospital outpatient PPS.

- Hospital outpatient services furnished to SNF inpatients as part of his or her resident assessment or comprehensive care plan (and thus included under the SNF PPS) that are furnished by the hospital "under arrangements" but billable only by the

SNF, regardless of whether or not the patient is in a Part A SNF stay.

- Services and procedures that require inpatient care.

The statute excludes from the definition of "covered OPD services" ambulance services, physical and occupational therapy, and speech-language pathology services, specified in section 1833(t)(1)(B)(iii) of the Act (redesignated as section 1833(t)(1)(B)(iv) by section 201(e) of the BBRA 1999). These services are to be paid under fee schedules in all settings.

b. Comments and Responses

Comment: One commenter urged that we exclude services furnished to ESRD patients from the scope of the hospital outpatient PPS.

Response: Services furnished to ESRD patients include dialysis, Epoietin (EPO), drugs, and supplies provided outside the composite rate, surgery specific to access grafts, and many other medical services related to renal disease or to other coexisting conditions. We will continue to base payment for dialysis services on the composite rate, and we will continue to pay for EPO based on the current rate established for that service. The drugs and supplies that are used within a dialysis session, but for which payment is not included in the composite rate, are paid outside that rate. We have to conduct further analyses in order to develop appropriate APC groups upon which to base payment. In the meantime, we will continue to pay on a reasonable cost basis for dialysis related drugs and supplies that are paid outside the composite rate.

Comment: A hospital industry association took exception to the requirement that hospitals obtain a separate supplier number, post a bond, and bill separately to the DME regional carrier for DME supplies such as crutches. They believe that this is an unnecessary requirement that results in additional costs for small rural hospitals. The commenter recommended that we include within the PPS rate supplies such as crutches that are directly related to the provision of the hospital outpatient services or that we permit hospitals to bill under the DME fee schedule without having to obtain a DME supplier number or post a bond.

Response: Section 1834(j)(1)(A) of the Act provides that no payment may be made for items furnished by a supplier of medical equipment and supplies unless the supplier obtains a supplier number. Section 1834(a)(1)(C) of the Act provides that payment for DME can be made only under the DME fee schedule.

Therefore, to receive payment for DME under Medicare, a hospital must obtain a supplier number and must meet the other requirements set by applicable Medicare rules and regulations.

Comment: Several major hospital associations and a number of other commenters opposed our proposal to exclude from payment certain procedures that we designate as "inpatient only." Other commenters, including a physician professional society, agree that many of the procedures that we designated in the proposed rule as "inpatient only" are currently performed appropriately and safely only in the inpatient setting. However, these commenters believe that our explicit exclusion of individual procedures, besides being unnecessary, could have an adverse effect on advances in surgical care. Some commenters alleged that we provided no concrete support for designating procedures as "inpatient only." A number of commenters argued that medicine is not practiced uniformly across the nation and that some services listed among the exclusions are currently being performed on an outpatient basis in various parts of the country with positive outcomes.

An industry association stated that we failed to consider surgical judgment and patient choice in determining the appropriate treatment setting for certain services that we proposed to exclude from coverage. Other commenters believe that the appropriate site for performing a medical service is best determined by physicians and their patients. One professional society stated that case law including medical malpractice case law is sufficient to ensure that medical services are delivered in the appropriate treatment setting and in conformance with prevailing medical standards.

Response: We recognize and acknowledge that our assigning "inpatient only" status to certain services and procedures raises numerous questions and concerns, and that some individual determinations can be reasonably debated. However, section 1833(t)(1)(B) of the Act explicitly authorizes the Secretary to designate which hospital outpatient services are to be "covered OPD services" subject to payment under the hospital outpatient PPS. Therefore, we have had to select from the universe of possible services those that we determine are reasonable, necessary, and appropriate for Medicare payment under the hospital outpatient PPS. We note that our designation of a service as "inpatient only" does not necessarily preclude the service from being furnished in a hospital outpatient

setting, but means only that Medicare will not make payment for the service were it to be furnished to a Medicare beneficiary in that setting. This unfortunately leaves the beneficiary liable for payment if the procedure is in fact performed in the outpatient setting. We hope that hospitals will advise beneficiaries of the consequences if procedures on the inpatient list are provided as outpatient services (that is, denial of Medicare payment with concomitant beneficiary liability). In section III.C.5 of this preamble, we discuss in greater detail our rationale for designating specific procedures as "inpatient only." In response to comments, we have removed the "inpatient only" status from a number of services, which will allow them to be paid under the hospital outpatient PPS. We emphasize our intention to review annually, in consultation with hospital and professional societies and associations and the expert outside advisory panel mandated by the BBRA 1999, those procedures classified as "inpatient only" to ensure that the designation remains consistent with current standards of practice.

Comment: One industry association contends that the statutory and regulatory authorities that we cite in the proposed rule (section 1862(a)(1)(A) of the Act and 42 CFR 411.15(k)(1), respectively) do not support the proposed medical services exclusions. The commenter argues that those provisions are the basis for prohibiting coverage for services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. The commenter states that these provisions are not the basis upon which we identified services for the "inpatient only" list. The commenter further states that use of these provisions as a basis for denying coverage of the services would be confusing to beneficiaries.

Response: The commenter is correct that the proper citations are not section 1862(a)(1) of the Act and 42 CFR 411.15(k)(1). In fact, the basis for our designating certain procedures as "inpatient only" is dependent on medical judgment regarding the proper site of service, and the proper citation for such designation is section 1833(t)(1)(B) of the Act. In some instances, the identification of services to be included or excluded from this PPS was perfectly clear. For example, emergency departments (EDs) are outpatient departments of hospitals. Thus emergency services rendered in EDs qualify as outpatient services. On the other hand, coronary artery bypass

graft surgery (CABG) requires many hours in surgery, part of the time with the patient's life being sustained by artificial means; a period of hours, if not days, in the surgical intensive care unit (ICU); and further care in an inpatient unit with frequent nursing attention. It clearly cannot be an outpatient procedure, and it would not be reasonable to consider it for inclusion in this PPS. There are many procedures which require similar intensity of care, including periods in specialty ICUs and several days of intense nursing attention.

Some procedures formerly performed only in the inpatient setting, however, have moved to the outpatient site of service. This movement has taken place due to new, less-invasive surgical techniques, such as laparoscopy, or new anesthesia agents that clear from the body more rapidly, allowing some patients to have general anesthesia in the morning and return home that afternoon. Thus we have had to decide which procedures may reasonably be performed in the outpatient setting, and which cannot. We have been guided in this decision by our medical advisors' clinical judgment regarding what is reasonable in various settings, comments we received in response to the proposed rule, and bill data which shows movement from one site to another. In section III.C.5, we discuss the criteria we considered in defining "inpatient only" procedures.

Comment: One hospital asked how we would pay a hospital that routinely performs on an outpatient basis a procedure that we proposed to designate as "inpatient only." The commenter recommended that a specific billing mechanism be used to guarantee payment in these situations.

Response: Services designated as "inpatient only" will be excluded from Medicare payment under the hospital outpatient PPS. If the service is performed on an outpatient basis and a claim is submitted, the claim will be denied, and the beneficiary may be billed for the service. We would consider this a very poor policy on the hospital's part, and would hope that hospitals decide to abide by the constraints of the inpatient list.

Comment: One commenter noted that hospital outpatient departments have never been limited to a list of approved procedures as are Medicare participating ASCs. The commenter stated that the "inpatient only" policy would exclude payment for a significant number of procedures that have traditionally been performed in the hospital outpatient setting. The commenter stated that some of the

excluded procedures incorporate an observation stay in a recovery care center. The commenter contended that many of the excluded procedures could be safely performed in the outpatient setting particularly if a 24 to 72 hour recovery care center is part of the outpatient surgical care provided.

Response: Routinely billing an observation stay for patients recovering from outpatient surgery is not allowed under current Medicare rules nor will it be allowed under the hospital outpatient PPS. As we state in section III.C.5 of this preamble, one of the primary factors we considered as an indicator for the "inpatient only" designation is the need for at least 24 hours of postoperative care.

Comment: One commenter asked what option a hospital has if a beneficiary's secondary insurer requires that a procedure included on the Medicare inpatient only list be performed on an outpatient basis.

Response: Upon implementation, the provisions of this final rule will govern payment for Medicare covered outpatient services furnished by hospitals to Medicare beneficiaries. Medicare payment policy and rules are not binding on employer-provided retiree coverage that may supplement Medicare coverage. Medigap insurers, however, must follow Medicare's coverage determinations.

c. Payment for Certain Implantable Items Under the BBRA 1999

In the course of identifying items and services whose costs we proposed to designate for payment under the hospital outpatient PPS, we gave considerable thought to including implantable items and services because these items and services are such an integral part of the procedure by which they are inserted or implanted. However, a number of the more common implants such as aqueous shunts, hallux valgus implants, infusion pumps, and neurostimulators, are classified as implantable prosthetics or DME. The statutory language governing payment for DMEPOS provides that, notwithstanding any other provision of the Medicare statute, DMEPOS must be paid for using the DMEPOS fee schedule. Therefore, under the proposed rule, the scope of services paid under the hospital outpatient PPS did not include implantable prosthetics and DME paid under the DMEPOS fee schedule. However, we did propose to package payment for implanted items such as stents, vascular catheters, and venous ports within the APC payment rate for the procedure related to the insertion of these items because we

define these items as supplies rather than as prosthetic implants or implantable DME.

Section 201(e) of the BBRA 1999 amends section 1833(t)(1)(B) of the Act to provide that "covered OPD services" include implantable items described in paragraph (3), (6), or (8) of section 1861(s) of the Act. The conference report accompanying the BBRA 1999, H. R. Rep. No. 436 (Part I), 106th Cong., 1st Sess. (1999), expresses the belief of the conferees that the current DMEPOS fee schedule is not appropriate for certain implantable medical items such as pacemakers, defibrillators, cardiac sensors, venous grafts, drug pumps, stents, neurostimulators, and orthopedic implants as well as items that come into contact with internal human tissue during invasive medical procedures, but are not permanently implanted. In the conference report agreement, the conferees state their intention that payment for these items be made through the outpatient PPS, regardless of how these products might be classified on current HCFA fee schedules. The implantable items affected by this BBRA 1999 requirement include prosthetic implants (other than dental) that replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care and including replacement of these devices); implantable DME; and implantable items used in performing diagnostic x-rays, diagnostic laboratory tests, and other diagnostic tests.

Comment: A number of commenters disagreed with our proposal to pay under the DMEPOS fee schedule for implantable items and devices that require surgical insertion. We received comments on specific implantable items, including Vitrasert (a drug delivery system that is implanted in the eye); cochlear devices, which allow the profoundly deaf to hear sound and in some cases recognize speech; nerve stimulators that treat intractable epilepsy and other diseases; new technology intraocular lenses implanted following cataract surgery; and access devices for dialysis treatment. Commenters were also concerned that the costs of some implantable devices not paid under the DMEPOS fee schedule, which we packaged in our proposed rule, were not properly recognized in the APC payment.

Response: As we explain above, the amendments made to the statute by section 201(e) of the BBRA 1999 provide for payment to be made under the hospital outpatient PPS for implantable items that are part of diagnostic x-rays, diagnostic laboratory tests, and other

diagnostic tests; implantable durable medical equipment; and implantable prosthetic devices (other than dental). This BBRA 1999 provision requires that an implantable item be classified to the group that includes the service to which the item relates. Thus, under this final rule with comment period, we are including within the scope of the hospital outpatient PPS items such as aqueous shunts that would, absent the BBRA 1999 provision, have been paid under the DMEPOS fee schedule. Because implantable items are now packaged into the APC payment rate for the service or procedure with which they are associated, certain items may be candidates for the transitional pass-through payment, which is discussed in detail in section III.D of this preamble. The APC rates may not in every case perfectly recognize the cost of implantable items. We will continue to review the impact of packaging implantables in future updates.

d. Summary of Final Action

We are modifying proposed § 419.22 to remove prosthetic implants from the list of services excluded from payment under the hospital outpatient PPS. We are adding subparagraphs (9), (10), and (11) to proposed § 419.2(b), to include the following in the list of items and services whose costs are included in hospital outpatient PPS payment rates: prosthetic implants (other than dental) that replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), and including replacement of these devices; implantable DME; and implantable items used in performing diagnostic x-rays, diagnostic laboratory tests, and other diagnostic tests.

2. Services Included Within the Scope of the Hospital Outpatient PPS

We proposed to include three categories of services within the scope of the outpatient PPS, as follows:

a. Services for Patients Who Have Exhausted Their Part A Benefits

Section 1833(t)(1)(B)(ii) of the Act provides for Medicare payment under the hospital outpatient PPS for certain services designated by the Secretary that are furnished to inpatients who have exhausted their Part A benefits or who are otherwise not in a covered Part A stay. Examples of services covered under this provision include diagnostic x-rays and certain other diagnostic services and radiation therapy covered under section 1832 of the Act.

b. Partial Hospitalization Services

Section 1833(a)(2)(B) of the Act provides that partial hospitalization services furnished in CMHCs be paid under the hospital outpatient PPS. Partial hospitalization is a distinct and organized intensive psychiatric outpatient day treatment program, designed to provide patients who have profound and disabling mental health conditions with an individualized, coordinated, comprehensive, and multidisciplinary treatment program.

c. Services Designated by the Secretary

We proposed to designate the following services to be paid under the hospital outpatient PPS:

- All hospital outpatient services, except those that are identified as excluded, above, in section III.B.1 of this final rule. The types of services subject to payment under the hospital outpatient PPS include the following: surgical procedures; radiology, including radiation therapy; clinic visits; emergency department visits; diagnostic services and other diagnostic tests; partial hospitalization for the mentally ill; surgical pathology; and cancer chemotherapy.

- Specific hospital outpatient services furnished to a beneficiary who is admitted to a Medicare-participating SNF but who is not considered to be a SNF resident, for purposes of SNF consolidated billing, with respect to those services that are beyond the scope of SNF comprehensive care plans. The specific hospital outpatient services that are excluded from SNF consolidated billing are cardiac catheterization, computerized axial tomography (CAT) scans, MRIs, ambulatory surgery involving the use of an operating room, emergency room services, radiation therapy, angiography, and lymphatic and venous procedures.

- Supplies such as surgical dressings used during surgery or other treatments in the hospital outpatient setting that are also paid under the DMEPOS fee schedule. Payment for these supplies, when they are furnished in a hospital outpatient setting, is packaged into the APC payment rate for the procedure or service with which the items are associated.

- Certain preventive services furnished to healthy persons, such as colorectal cancer screening.

Section 4523(d)(3) of the BBA 1997 amended section 1833(a)(2)(B) of the Act to provide that we discontinue reasonable cost based payment and instead make Part B payment under the hospital outpatient PPS for certain medical and other health services when

they are furnished by other providers such as hospices, SNFs, and HHAs. Specifically, we proposed to pay under the hospital outpatient PPS for the following medical and other health services when they are furnished by a provider of services:

- Antigens (as defined in 1861(s)(2)(G) of the Act);
- Splints and casts (1861(s)(5) of the Act);
- Pneumococcal vaccine, influenza vaccine, hepatitis B vaccine (1861(s)(10) of the Act).

Upon implementation of the hospital outpatient PPS, we would make Part B payment for the above services under the outpatient PPS when they are furnished by an HHA or hospice program. We would also make payment for antigens and the vaccines under the PPS when they are furnished by CORFs. (Splints and casts furnished by CORFs are paid under the rehabilitation fee schedule.) However, this provision would not apply to services furnished by a CORF that fall within the definition of CORF services at section 1861(cc)(1) of the Act. It also would not apply to services furnished by a hospice within the scope of the hospice benefit. Nor would it apply to services furnished by HHAs to individuals under an HHA plan of treatment within the scope of the home health benefit.

d. Summary of Final Action

We received no comments about the services we proposed to include within the scope of the hospital outpatient PPS. As noted in the preceding section III.B.1, we added certain implantable items to § 419.2(b) to implement section 201(e) of the BBRA 1999.

3. Hospital Outpatient PPS Payment Indicators

In the September 8, 1998 proposed rule in the **Federal Register**, we proposed a payment status indicator for every code in the HCPCS to identify how the service or procedure described by the code would be paid under the hospital outpatient PPS. We received no comments on our proposal to assign a payment status indicator to every HCPCS code. (In section III.C.6, below, we respond to commenters who disagreed with the payment status indicator that we proposed for individual codes.) Therefore, we are implementing payment status indicators as part of the hospital outpatient PPS. Addendum B displays the final payment status indicator for each HCPCS code, including codes for incidental services that are packaged into APC payment rates. Addendum E identifies the HCPCS codes to which we have assigned payment status indicator "C" to identify inpatient services that are not payable under outpatient PPS as implemented by this final rule. We respond below, in section III.C.5, to public comments about the specific codes we classified as inpatient services in the proposed rule and our final determination regarding the payment status of those codes.

- The following are the payment status indicators and description of the particular services each indicator identifies:
- We use "A" to indicate services that are paid under some other method such as the DMEPOS fee schedule or the physician fee schedule.
 - We use "C" to indicate inpatient services that are not paid under the outpatient PPS.
 - We use "E" to indicate services for which payment is not allowed under the

hospital outpatient PPS. In some instances, the service is not covered by Medicare. In other instances, Medicare does not use the code in question, but does use another code to describe the service.

- We use "F" to indicate corneal tissue acquisition costs, which are paid separately.
 - We use "G" to indicate a current drug or biological for which payment is made under the transitional pass-through.
 - We use "H" to indicate a device for which payment is made under the transitional pass-through.
 - We use "J" to indicate a new drug or biological for which payment is made under the transitional pass-through.
 - We use "N" to indicate services that are incidental, with payment packaged into another service or APC group.
 - We use "P" to indicate services that are paid only in partial hospitalization programs.
 - We use "S" to indicate significant procedures for which payment is allowed under the hospital outpatient PPS but to which the multiple procedure reduction does not apply.
 - We use "T" to indicate surgical services for which payment is allowed under the hospital outpatient PPS. Services with this payment indicator are the only services to which the multiple procedure payment reduction applies.
 - We use "V" to indicate medical visits for which payment is allowed under the hospital outpatient PPS.
 - We use "X" to indicate ancillary services for which payment is allowed under the hospital outpatient PPS.
- The table below lists types of services, the hospital outpatient PPS payment status indicator assigned to each type of service, and the basis for Medicare payment for the service.

MEDICARE HOSPITAL OUTPATIENT PPS PAYMENT STATUS INDICATORS: HOW MEDICARE PAYS FOR VARIOUS SERVICES WHEN THEY ARE BILLED FOR HOSPITAL OUTPATIENTS

Indicator	Service	Status
A	Pulmonary Rehabilitation; Clinical Trial	Not paid.
C	Inpatient Procedures	Not paid.
A	Orthotics, and Non-implantable Durable Medical Equipment and Prosthetics.	DMEPOS Fee Schedule.
E	Nonallowed Items and Services	Not paid.
A	Physical, Occupational and Speech Therapy	Rehab Fee Schedule.
A	Ambulance	Reasonable cost or charge or, when implemented, Ambulance Fee Schedule.
A	EPO for ESRD Patients	National Rate.
A	Clinical Diagnostic Laboratory Services	Lab Fee Schedule.
A	Physician Services for ESRD Patients	Bill to Carrier.
A	Screening Mammography	Lower of Charge or National Rate.
N	Incidental Services, Packaged into APC Rate	Packaged; No Additional Payment Allowed.
P	Partial Hospitalization Services	Paid Per Diem.
S	Significant Procedure, Not Reduced When Multiple Procedures Performed.	Paid Under Hospital Outpatient PPS (APC Rate).
T	Significant Procedure, Multiple Procedure Reduction Applies ...	Hospital Paid Under Outpatient PPS (APC Rate).

MEDICARE HOSPITAL OUTPATIENT PPS PAYMENT STATUS INDICATORS: HOW MEDICARE PAYS FOR VARIOUS SERVICES WHEN THEY ARE BILLED FOR HOSPITAL OUTPATIENTS—Continued

Indicator	Service	Status
V	Visit to Clinic or Emergency Department	Paid Under Hospital Outpatient PPS (APC Rate).
X	Ancillary Service	Paid Under Hospital Outpatient PPS (APC Rate).
F	Acquisition of Corneal Tissue	Paid at reasonable cost.
G	Current Drug/Biological Pass-Through	Additional payment.
H	Device Pass-Through	Additional payment.
J	New Drug/Biological Pass-Through	Additional payment.

C. Description of the Ambulatory Payment Classification (APC) Groups

1. Setting Payment Rates Based on Groups of Services Rather Than on Individual Services

In our March 17, 1995 report to Congress, we recommended that groups similar to the ambulatory patient groups (APGs) developed by 3M Health Information Systems (3M) be used as the basis for the hospital outpatient PPS. We made this recommendation after examining a number of other payment systems that were already in place or under development, including DRGs that are the basis for Medicare payment for hospital inpatient services, the Medicare physician fee schedule that was implemented in 1992, and the payment groups that have been the basis for Medicare payments for ambulatory surgical center (ASC) facility services since 1982.

As provided by the BBA 1997, section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered outpatient services. Section 1833(t)(2)(B) provides that this classification system may be composed of groups, so that services within each group are comparable clinically and with respect to the use of resources. The statute refers to “each such service (or group of services),” confirming that the Secretary may choose or not choose to group services.

We explain in our proposed rule that we revised the APGs, based on more recent Medicare data than that used by 3M, to create the ambulatory payment classification (APC) system. We proposed to group services identified by HCPCS codes and descriptors within APC groups as the basis for setting payment rates under the hospital outpatient PPS. We indicated that we organized the APC groups so that the services within each group would be homogeneous both clinically and in terms of resource utilization. We invited comments on our proposal to set rates on the basis of groups of services rather than on individual codes.

Comments: Some commenters claimed that basing payment on APC

groups rather than on individual services would result in underpayment for services that are more resource intensive, causing hospitals with a more resource intensive case mix to lose money. An organization representing physicians strongly opposed the use of APCs, because it believes that it is not possible to achieve an incentive-neutral, “level playing field” payment system using groups of codes or services. This organization favored replacing the APC system with a fee schedule based on individual services, similar to the Medicare physician fee schedule, as MedPAC recommends in its 1999 report to Congress. (We address the MedPAC recommendation later in this section.) The same physician organization is concerned that the broad range of services included in each APC will create an incentive for hospitals to provide lower cost services, even though a patient might require higher cost services. This organization expressed concern about the negative impact on physicians if a payment methodology similar to the APC system were applied to payment for physician services. To facilitate pricing new codes using individual services rather than APC groups, the same organization suggested that we establish a “relative value relationship in direct costs” between the new code and a comparable code, or that we consult AMA’s Specialty Society RVS Updating Committee (RUC) for advice on relative cost relationships.

One major hospital association expressed its preference for a service-specific fee schedule because of the wide variation in costs represented by groups of codes. Another hospital association advocated using individual services rather than groups of services as the basis for ratesetting, but recommended, if we were to use some form of grouping, that we apply tight limits on the variations of costs for services within a group.

Response: We understand the concerns of commenters that setting payment weights using groups of services rather than individual services could result in payment for particular

services that might not fully offset the costs that hospitals incur when they furnish expensive, resource-intensive services. However, we believe these concerns are in large measure addressed by the provisions of this final rule. As we explain in section III.C.6, we significantly restructured the proposed APC groups, first in response to comments and, second, to comply with section 1833(t)(2) of the Act, as amended by the BBRA 1999, which limits the variation of costs of services classified within a group. The result is more APC groups with fewer codes and a narrower range of costs in each group. In addition, other provisions of the BBRA 1999, such as the transitional pass-throughs (see section III.D, below), and outlier payments and transitional corridors (see section III.H, below) protect hospital revenues while hospitals gain experience with the PPS.

Medicare Payment Advisory Commission (MedPAC) Recommendation

In both its March 1998 and March 1999 reports to the Congress on Medicare payment policy, MedPAC recommends that payment rates under the hospital outpatient PPS be based upon costs of individual services rather than groups of similar services to help ensure consistent payments across ambulatory settings. In its March 1999 report, MedPAC asserts its belief that the burden imposed by our proposed APC system outweighs its benefits in ambulatory settings. MedPAC gives several reasons to support its position.

- The use of groups to calculate weights masks questionable cost data for low volume and new procedures.
- Different classes of hospitals face disproportionate impacts, suggesting APC groups may not be as homogeneous as we believe.
- Grouping services will likely create additional administrative burdens for hospitals, because hospitals may have to purchase or develop new software and will experience additional education and training costs.

Response: We carefully reviewed the concerns about using groups of services

expressed by MedPAC in its March 1998 report, and we responded to those concerns in our proposed rule (63 FR 47562). Even though MedPAC concedes in its March 1999 report that using groups to set rates has certain potential advantages, MedPAC continues to oppose using groups because, according to MedPAC, they entail considerable costs and drawbacks and necessitate "a much more complicated design logic" than would be required using a service-level fee schedule.

We do not share MedPAC's concerns. We have a high level of confidence in the ratesetting method using APC groups that we implement in this final rule with comment period. As we explain below, in section III.C.6, we have extensively restructured the APC groups to respond to comments on the proposed rule, to incorporate specific provisions of the BBRA 1999, and to correct some errors that had come to our attention. We believe that by using median costs in the calculation of group weights, we limit the extent to which infrequently performed services with suspect costs can affect the payment rate of an APC group.

As discussed below in the impact analysis (section IX of this preamble), the provisions of this final rule with comment period, which include setting rates using APC groups, alleviate to a large extent the disproportionate impacts on different classes of hospitals estimated in our proposed rule. In addition, as we explain in section III.C.6, when we restructured the APC groups, we were particularly attentive to the degree of provider concentration associated with the individual services within a group in order to avoid biasing the payment system against any subset of hospitals.

Finally, none of the commenters cited increased administrative burden as an argument against using groups. Even though we are using APC groups to set rates under the hospital outpatient PPS, hospitals will bill for services using HCPCS codes (not APCs) using the same claims forms that they use currently. Although to receive payment under the new system, hospitals will have to more fully code the services they furnish, they will not have to know to which APC the service is assigned in order to determine the payment amount. We are publishing the payment rate applicable to each HCPCS code in Addendum B of this final rule. Any burdens on hospitals necessitating additional technical assistance, training, or systems changes are more a function of implementing an entirely new payment system than of our setting rates on the basis of groups of services.

Final Action: The payment rates implemented by this final rule with comment period are determined based on APC groups that use HCPCS codes to describe individual services. The codes assigned to an APC group are comparable clinically and in terms of resource use.

2. Packaging Under the APC System

a. Summary of Proposal

In our proposed rule, we described packaged services as those items or services that we recognized as contributing to the cost of the procedures or services in an APC group, and for which we would not make separate payment. We proposed to include as packaged services use of the operating room and recovery room, anesthesia, medical/surgical supplies, pharmaceuticals, observation, blood, intraocular lenses, casts and splints, the costs of acquiring tissue such as corneal tissue for surgical insertion and various incidental services such as venipuncture. We packaged the services (and their costs) within the APC group of procedures with which they were delivered in the base year. For a list of proposed packaged services grouped by hospital revenue centers, refer to the June 30, 1999 correction notice (64 FR 35258).

b. General Comments and Responses (Supporting or Objecting to Packaging)

Comment: Few commenters disagreed with our proposal to aggregate into one payment the costs for a "package" of services variously related to a procedure or to the principal service being furnished. However, many commenters did object to our packaging costs for certain specific items such as expensive drugs and pharmaceuticals, observation services in the emergency department, blood and blood products, corneal tissue acquisition costs, and chemotherapy and supportive drugs. Commenters, fearful that packaging items and services will result in lower payments that do not offset the high costs of particularly expensive items, raised the prospect of dire consequences such as forcing hospitals to use only the cheapest drugs, being unable to employ oncology nurses, eliminating otherwise clinically necessary ancillary services, or not being able to hold emergency room patients for observation.

Response: We are persuaded by commenters' arguments that packaging payment for certain expensive items and services into an APC group rate could have such a potentially negative impact as to jeopardize beneficiary access to these items and services in the hospital

outpatient setting. Therefore, in response to comments, we are not packaging within an APC payment rate the costs associated with certain specified items and services. Instead, we will make a separate APC payment for these particular items and services under the outpatient PPS. However, as we explain in section III.C.2.d, we do not concur with commenters who urge separate payment for observation services; rather, we are packaging the costs in the APC for each service with which observation services were billed in our 1996 database. We discuss in further detail below, in section III.C.2.d through section III.C.2.g, and in section III.C.6, the changes that we are making to the packaging we originally proposed. We address in section III.B.1, above, the BBRA 1999 provision that requires us to package into APC group rates payment for certain implantable items and devices. In section III.D, below, we describe additional payments for certain packaged medical devices, drugs, and biologicals that are provided as transitional pass-throughs under section 201(b) of the BBRA 1999.

As we gain experience with and collect additional cost data under the hospital outpatient PPS, we will review our policy to pay separately for certain items and services that would otherwise be packaged into the APC payment. Should we decide to modify this policy, we will do so through the rulemaking process as part of our annual hospital outpatient PPS update.

MedPAC Recommendation: In its March 1999 report to the Congress, MedPAC cites two models that Medicare uses to define a unit of payment: the DRG-based payment model for hospital inpatient services, and the Medicare physician fee schedule. MedPAC contends that services provided in the hospital outpatient setting more closely parallel those furnished in an office-based setting than those furnished as part of a hospital inpatient admission. Therefore, MedPAC recommends that, in establishing ambulatory care prospective payment systems in general, we define the unit of payment for ambulatory care facilities as an individually coded service, consisting of the primary service that is the reason for the encounter, and the necessary and essential ancillary services and supplies integral to it, including limited follow-up care if it is integral to the primary service, but not including physicians' services. MedPAC further recommends that the unit of payment be defined consistently across all ambulatory care settings.

Response: The packaging that we proposed as the basis for determining APC payment rates and that we will implement under the hospital outpatient PPS is generally consistent with MedPAC's recommendation. However, we did not propose to include "limited follow-up services" in our packaged groups under the hospital outpatient PPS because of the difficulty of matching in our database the costs of these services with their associated primary encounter. For now, hospitals are to bill follow-up care, such as suture removal, using an appropriate medical visit code. We did not propose, nor have we included in this final rule with comment period, provision for a global period for hospital outpatient services analogous to the global period affecting payments for professional services made under the Medicare physician fee schedule.

c. Packaging of Casts and Splints

Comment: One commenter stated that we should not package costs for casts and splints with other procedures.

Response: We proposed to assign payment status indicator "N" to CPT codes for strapping and casting services (CPT codes 29000-29750) to designate that these are incidental services for which payment is packaged into the APC rate for another service or procedure, in this case, the repair or reduction of a fracture or dislocation. After further review, we determined that strapping and casting services can be performed independently, for example, when a cast placed as a part of a procedure must later be replaced with another cast. Therefore, we have decided that strapping and casting services will not be packaged and we are creating two APCs (0058 and 0059) to pay for these services. The BBA 1997 required that we pay under the outpatient PPS for casting and strapping services furnished in HHAs and hospices, to the extent that these services are provided and are not within the patient's plan of care.

d. Packaging of Observation Services

We received many comments urging us to pay separately for observation services, particularly when patients are seen in the emergency department. Observation service is placing a patient in an inpatient area, adjacent to the emergency department, or, according to some comments, in the intensive care unit (ICU) or coronary care unit (CCU), in order to monitor the patient while determining whether he or she needs to be admitted, have further outpatient treatment, or be discharged. After 1983, many hospitals began to rely heavily on

the use of observation services when peer review organizations questioned admissions under the hospital inpatient prospective payment system. However, in some cases, patients were kept in "outpatient" observation for days or even weeks at a time. This resulted in excess payments both from the Medicare program and from beneficiaries who generally paid a higher coinsurance. In response to this practice, in November 1996, we issued instructions limiting covered observation services to no more than 48 hours except in the most extreme circumstances. However, the cost data upon which the APC system is based contain all costs for observation in 1996, including those that exceeded the 48-hour limit imposed at the end of that year. We have packaged those costs into the service with which they were furnished in the base year. Thus, APC payments for emergency room visits include the costs of observation within the payment.

Comment: Some commenters acknowledged that being paid separately for observation following a surgical procedure was not necessary; the packaged recovery room and observation services were sufficient. However, a major concern of commenters was observation of patients with chest pain who had equivocal results on initial diagnostic testing. Commenters were concerned that the APC payment for these cases would not be adequate.

Response: We assume that chest pain patients, such as those described by the commenters, are sent to the CCU or ICU for observation. We believe that, in general, if a patient needs to be monitored in the ICU or CCU for any length of time, then that patient should be admitted as an inpatient. Furthermore, we have never considered care furnished in an ICU or CCU to be outpatient services. Existing cost reporting instructions allow for the use of these specialty beds during a shortage of regular inpatient beds, but charges are to reflect routine care, not intensive care.

Although, as noted above, we received many comments urging that observation services be covered as a separate APC, we continue to believe that these services have been used so inappropriately in the past that we will have to gather data under the PPS before considering constructing a separate APC. We have packaged observation wherever it was billed. Roughly \$139 million was identified by revenue code 762 as representing observation services. An additional \$253 million was identified in revenue codes 760,

761, and 769, which could be used for either observation or treatment room use. That \$253 million is also packaged. (Both figures are in 1996 dollars.)

Further analyses will be necessary on the use of observation as an adjunct to emergency treatment, as in the case of chest pain. In order to ensure that we will have sufficient data for our future analyses, hospitals must continue to bill for observation using revenue center 762 and showing hours in the units field. Observation that is billed must represent some level of active monitoring by medical personnel. It must not be billed as a way to capture room and board for outpatients. During our first review of the APC groups, we will assess whether patients with certain conditions use observation services that should be separately recognized. Thus, correct diagnosis coding is required.

e. Packaging Costs of Procuring Corneal Tissue

Comment: We received about 2,000 comments from physicians, eye banks, and health care associations opposing our proposal to package corneal tissue acquisition costs into the APC payment for corneal transplant procedures. Most commenters argued that the payment for the procedures in proposed APC group 670, Corneal transplant, is grossly inadequate and that we have failed to recognize the high costs associated with tissue screening and testing procedures required by the Food and Drug Administration that are reflected in the fees charged by eye banks. In addition, commenters contended that we failed to recognize the wide variation in tissue acquisition costs resulting from the level of philanthropic contributions in different areas of the country and in different years. Commenters asserted that by packaging corneal tissue acquisition costs with the payment for corneal transplant surgery, we would limit beneficiary access to quality care, force eye banks that are nonprofit, low-cost operations to close, provide disincentives for philanthropic contributions, and impede our goal to increase tissue availability.

As part of their comments, the Eye Bank Association of America (EBAA) submitted a report of a study the EBAA commissioned on corneal tissue acquisition costs. The study was conducted by the Lewin Group which collected and analyzed data on corneal tissue acquisition costs incurred by 74 of EBAA's 100 members that are charitable nonprofit organizations. The report states that these 74 eye banks supplied approximately 82 percent of the corneal tissue distributed

throughout the United States in 1997. Based on the data that they collected, the Lewin Group found that the median gross acquisition cost per transplant is \$1,689 in 1999 dollars. Of this amount, approximately \$233 represents the national median value of donated in-kind services such as volunteer staff. The Lewin Group concluded that the proposed hospital outpatient PPS payment of \$1,583 did not adequately reflect the cost of procuring corneal tissue.

Additionally, the report states that "fund raising and in-kind service values are not as well centered on their median values as the underlying cost data. Variability in fund raising and in-kind contributions not only exists between eye banks, but from year to year, within the same eye bank." According to the study, charitable contributions in the form of cash and in-kind services represented 28 percent of the eye banks' total gross cost for tissues furnished in 1997. The Lewin Group finds that "If HCFA were to move to fee schedule or other fixed-payment rate, and pays the adjusted median Gross cost Per Transplant * * * payment of \$1689, HCFA would overpay some banks and underpay others, depending on philanthropy and in-kind services which varies from community to community and from year to year. The variation is too extreme to determine a fair rate-based system, without destroying the philanthropy the community is built upon."

Response: Based on the concerns raised by the commenters and the data presented in the Lewin Group study, we have decided not to package payment for corneal tissue acquisition costs with the APC payment for corneal transplant surgical procedures at this time. Instead, we will make separate payment, based on the hospital's reasonable costs incurred to acquire corneal tissue. Final payment will be subject to cost report settlement. To receive payment for corneal acquisition costs, hospitals must submit a bill using HCPCS code V2785, Processing, preserving and transporting corneal tissue, and indicate the acquisition cost rather than the hospital's charge on the bill. We intend to review this policy after we have acquired updated data on corneal procedures.

f. Packaging Costs of Blood and Blood Products

Comment: Many commenters, including the American Red Cross, a major medical association, teaching hospitals, and community oncology centers, believe that the payments we proposed for blood and blood-related

products and for APCs that required the use of blood and blood-related products, were too low. Commenters claimed that the proposed payments are so much lower than actual costs that hospitals might be forced to stop providing a range of blood services, especially those more complex than a simple transfusion. The commenters were concerned that our proposed payment would not allow hospitals to furnish the most clinically appropriate blood products and services. The commenters also stated that blood and blood product exchange were not assigned to appropriate APCs, thus skewing payment rates and not recognizing the true costs of services with which blood and blood product exchange are associated. Commenters attributed this deficiency to the fact that certain blood-related products were incorrectly billed in the 1996 data we used as the basis for pricing APCs. Commenters were also concerned that we excluded procedures whose costs fell outside 3 standard deviations of the mean cost. One major organization recommended that we separate payment for blood and blood products from the service with which it is associated. This commenter also recommended separate payment for infusible blood-derived drugs, and that we base payment for transfusable blood products on costs. Some commenters recommended a transition period prior to full implementation of the proposed PPS.

Response: Based on the recommendations of commenters, we have created separate APC groups to pay for blood and blood products. We agree with the commenters that blood use varies enough that packaging blood units with their administration could lead to inequities. Because we were not able to capture enough claims data in the base year to accurately price the blood and blood-product APCs, we have based payment rates for these APCs on data provided by commenters, including suppliers of blood and blood products. We have based payment on current costs rather than 1996 costs so that we recognize the costs of recently developed blood safety tests. The safety of the nation's blood supply is a major concern of the Department of Health and Human Services, and we want to encourage appropriate testing and follow-up care.

g. Packaging Costs for Drugs, Pharmaceuticals, and Biologicals

We proposed to package the cost of drugs, pharmaceuticals, and biologicals with APC groups because we believe drugs are usually provided in connection with some other treatment

or procedure. We collected aggregate cost data on all drugs that were billed with HCPCS codes and those billed with revenue center codes, whether or not a HCPCS was entered. By so doing, we captured historical patterns of drug use within the APC groups with which the drugs were billed during the base year. However, because we did not require HCPCS coding of drugs, we could not isolate costs associated with individual drugs, some of which are very expensive even though they are rarely used and may be used by only a few hospitals. As a result, we acknowledge that our proposed APC payment rates may not fully reflect costs of very expensive drugs or biologicals.

We also proposed to create separate drug groups for chemotherapeutic agents because those were separately identified in the APG system designed by 3M. However, because we did not have bills that were coded to identify drugs individually, we were concerned that the APC groups for chemotherapeutic groups may not have completely reflected the costs of these drugs.

Comment: Many commenters criticized the proposed APC payment rates because they were developed using cost data from 1996 that do not reflect the cost of many new drugs, pharmaceuticals, and biologicals. Some commenters expressed particular concern about oncology drugs such as paclitaxel (Taxol) and topotecan. Some advised that Taxol and carboplatin chemotherapy have become the standard treatment for ovarian carcinoma. A number of commenters believe that our proposal did not provide sufficient financial incentives to dissuade hospitals from using the older less effective chemotherapy regimens even though there is significantly greater toxicity and reduced chances of favorable outcomes associated with their use. Many commenters strongly suggested that we carve out new drugs and biologicals and those introduced after 1996 from the PPS and pay for them on a reasonable cost basis. Several commenters asserted that packaging drugs and pharmaceuticals within the APC groups understates their cost to hospitals and their value to patients.

Response: We believe the commenters' concerns have, to a great extent, been addressed by implementation of the BBRA 1999 pass-through provisions for drugs and biologicals. Addendum K includes a complete list of all drugs, biologicals, and medical devices that are eligible for pass-through payments. We encourage interested parties to follow the process outlined below in section III.I.4 of this

preamble to submit requests for consideration of drugs, biologicals, and medical devices that may be eligible for additional payment under the transitional pass-through provision but that are not listed in Addendum K.

h. Summary of Final Action

After consideration of comments received about packaging of services and of the requirements set forth in the amendments made to section 1833(t) of the Act by section 201(b) and section 201(e) of the BBRA 1999, we have revised the package of services directly related and integral to performing a procedure or furnishing a service on an outpatient basis whose costs will determine the national payment rate for that procedure or service under the hospital outpatient PPS.

- We will package into the APC payment rate for a given procedure or service any costs incurred to furnish the following items and services: Use of an operating suite, procedure room or treatment room; use of the recovery room or area; use of an observation bed; anesthesia; medical and surgical supplies and equipment; surgical dressings; supplies and equipment for administering and monitoring anesthesia or sedation; intraocular lenses; capital-related costs; costs incurred to procure donor tissue other than corneal tissue; and, various incidental services such as venipuncture.

- In general, we will package the cost of drugs, pharmaceuticals and biologicals into the APC payment rate for the primary procedure or treatment with which they are used. Additional payment for some drugs, pharmaceuticals, and biologics may be allowed under the transitional pass-through provisions, which we explain below, in section III.D.

- We will *not* package payment for corneal tissue acquisition costs into the payment rate for corneal transplant surgical procedures at this time. We will make separate payment for these acquisition costs based on the hospital's reasonable costs incurred to acquire corneal tissue.

- We will *not* package into the APC payment rate for another procedure or service costs incurred to furnish the following items and services: blood and blood products, including anti-hemophilic agents; casting, splinting, and strapping services; immunosuppressive drugs for patients following organ transplant; and certain other high cost drugs that are infrequently administered. We have created new APC groups for these items

and services, which allows separate payment to be made for them.

3. Treatment of Clinic and Emergency Department Visits

a. Provisions of the Proposed Rule

As we discussed in our proposed rule, determining payment for hospital clinic and emergency department (ED) visits requires a variety of considerations such as the following:

- The impact of packaging on setting payment rates.
- How to code visits in a manner that recognizes variations in service intensity and levels of resource consumption.
- How to keep the system administratively manageable.
- How to define critical care in terms of facility as opposed to physician input.
- Data problems associated with identifying costs from claims that list multiple services.
- How to move toward greater uniformity of payments across ambulatory settings so as to remove payment as an incentive for determining site of service.

The major issue we faced in determining payment for hospital clinic and ED visits is whether to include diagnosis as well as *Physicians' Current Procedural Terminology* (CPT) codes in setting payment rates.

In our proposed rule, we considered several approaches to setting prospective payment rates for hospital clinic and ED visits. Potential options included: (1) Using diagnosis codes only; (2) using CPT codes only; and (3) using a CPT-diagnosis code hybrid. We solicited comments on these approaches to setting payment rates for clinic and ED visits as well as comments on alternative approaches that we did not set forth in the proposed rule. In the proposed rule, we discussed in detail our assessment of the advantages and disadvantages of each approach.

In addition, we proposed to create a HCPCS code that would be used to bill when a patient presents to an ED, requests a screening, and is screened in accordance with section 1867(a) of the Act. Payment for this new code would be minimal because we included no treatment costs in the screening service. Payment for the screening APC would be made only when no additional services were furnished by the emergency department. If nonemergency treatment was furnished, the appropriate emergency department visit would be billed, and not the screening. Similarly, if the screening reveals that an emergency does exist

and treatment is instituted immediately, the screening would not be billed because we would consider payment to be subsumed into the payment for further treatment.

We proposed paying for critical care as the highest level of "visit." In our proposed rule, we stated that hospitals would use CPT code 99291 to bill for outpatient encounters in which critical care services are furnished.

We used the CPT definition of "critical care" which is the evaluation and management of the critically ill or injured patient. Under the outpatient PPS, we would allow the hospital to use CPT code 99291 in place of, but not in addition to, a code for a medical visit or for an emergency department service. Although the CPT system allows the physician to bill in 30-minute increments following the first 74-minute period of providing critical care, we proposed to pay separately for only the initial period (CPT code 99291), packaging the few instances in which the 30-minute increments (CPT code 99292) were billed. If other services, such as surgery, x-rays, or cardiopulmonary resuscitation, were furnished on the same day as the critical care services, we would allow the hospital to bill for them separately.

b. Comments and Responses

Comment: The major hospital associations argued that none of our three proposed approaches fully explains facility resource use in connection with clinic and emergency visits. Hospitals did not see a clear benefit in the payment ranges created by using the CPT and diagnosis hybrid approach. A major medical association adamantly opposed the use of diagnosis codes. One major HMO that does not currently use CPT codes was opposed to the use of CPT codes to describe clinic and emergency visits.

Response: In this final rule, we are not using patient diagnosis codes to compute payment rates for medical visits to clinics and emergency departments under the outpatient PPS because a number of concerns were raised about basing payment for medical visits on both HCPCS codes and ICD-9 diagnosis codes. The final payment groups for medical visits are constructed using CPT procedure codes only, which is consistent with our overall PPS grouping strategy and with the approach we have followed to establish payment groups for surgical and diagnostic services. However, we will continue to require hospitals to provide accurate diagnosis coding on claims for payment. We will continue to assess the value of using patient diagnosis for application

to our payment system for possible use in the future.

In developing medical visit APCs based on CPT procedure codes only (a change from the proposed rule), we are collapsing 31 CPT codes that define clinic and emergency visits into six groups, three each for the clinics and the emergency department. The final APC groups for clinic and emergency visits are as follows: APC 0600, Low Level Clinic Visits; APC 0601, Mid-Level Clinic Visits; APC 0602, High Level Clinic Visits; APC 0603, Interdisciplinary Team Conference; APC 0610, Low Level Emergency Visits; APC 0611, Mid-Level Emergency Visits; APC 0612, High Level Emergency Visits; and APC 0620, Critical Care.

When basing payment on CPT codes alone, the range of costs reflects hospitals' billing patterns in increasing level of intensity. However, those increasing increments are due largely to hospitals' use of "chargemaster" systems, which generate bills using predetermined charges for codes. Thus, billing patterns reflect standard bills, not the resources used in any particular case.

We had been concerned that certain hospitals' use of the lowest level code, CPT code 99201, to bill for all clinic visits would distort the data, causing inflation in both the volume and cost of low-level clinic visits, and a corresponding underreporting of mid- and high-level visits. (Costs for mid- and high-level visits would presumably have been correct, because individual hospitals would have reported appropriate charges with these codes; there simply would have been fewer reported visits at those levels.)

We have developed the weights for clinic visits by using claims data only from a subset of hospitals that billed a wider range of visits rather than relying solely on claims with CPT code 99201. We chose to use this subset of hospitals (for this purpose only) because we do not know what CPT code 99201 indicates when hospitals use it exclusively to bill all visits.

We emphasize the importance of hospitals assessing from the outset the intensity of their clinic visits and reporting codes properly based on internal assessment of the charges for those codes, rather than failing to distinguish between low- and mid-level visits "because the payment is the same." The billing information that hospitals report during the first years of implementation of the hospital outpatient PPS will be vitally important to our revision of weights and other adjustments that affect payment in future years. We realize that while these

HCPCS codes appropriately represent different levels of physician effort, they do not adequately describe nonphysician resources. However, in the same way that each HCPCS code represents a different degree of physician effort, the same concept can be applied to each code in terms of the differences in resource utilization. Therefore, each facility should develop a system for mapping the provided services or combination of services furnished to the different levels of effort represented by the codes. (The meaning of "new" and "established" pertain to whether or not the patient already has a hospital medical record number.)

We will hold each facility accountable for following its own system for assigning the different levels of HCPCS codes. As long as the services furnished are documented and medically necessary and the facility is following its own system, which reasonably relates the intensity of hospital resources to the different levels of HCPCS codes, we will assume that it is in compliance with these reporting requirements as they relate to the clinic/emergency department visit code reported on the bill. Therefore, we would not expect to see a high degree of correlation between the code reported by the physician and that reported by the facility.

Hospitals are required to use HCPCS code 99291 to report outpatient encounters in which critical care services are furnished. (See the American Medical Association's CPT 2000 coding manual for the definition of this code.) The hospital is required to use HCPCS code 99291 in place of, but not in addition to, a code for a medical visit or for an emergency department service.

We will work with the American Hospital Association and the American Medical Association to propose the establishment of appropriate facility-based patient visit codes in time for the next proposed rule.

Comment: Several commenters expressed concern that resources expended in the emergency department are not fully explained by the codes at their disposal. One commenter pointed out that some hospitals use internal coding systems to capture differing charges based on whether or not a case requires one-on-one nursing care.

Response: While we share commenters' concerns on this point, we remind hospitals that they can receive additional payment under the outpatient PPS for services such as diagnostic testing and administration of infused drugs, and for therapeutic procedures including resuscitation that

are furnished during the course of an emergency visit. We will also pay separately for certain high cost drugs, such as the expensive "clotbuster" drugs that must be given within a short period of time following a heart attack or stroke, if these drugs are furnished during an emergency visit. Even though some ED patients will be transferred to another hospital for inpatient treatment, the hospital that administers the drugs will be paid for them. Cases that fall far outside the normal range of costs will be eligible for an outlier adjustment established by section 201(a) of the BBRA 1999. (See section III.H, below.) In addition, one of the first topics of review to be addressed by the expert outside advisory panel, required by section 201(h)(1)(B) of the BBRA 1999, will be to determine if emergency department visits can be categorized in a way that better recognizes the underlying resources, especially nursing resources, involved in the visit.

Comment: Several commenters expressed concern about the appropriate level of payment for patients who die in the ED. One commenter believes that services furnished to these patients are resource-intensive and recommends that we continue to pay for the services on a reasonable cost basis.

Response: We are directing fiscal intermediaries to use the following guidelines in determining how to make payment when a patient dies in the ED or is sent directly to surgery and dies there.

- If the patient dies in the ED, make payment under the outpatient PPS for services furnished.
- If the ED or other physician orders the patient to the operating room for a surgical procedure, and the patient dies in surgery, payment will be made based on the status of the patient. If the patient had been admitted as an inpatient, pay under the hospital inpatient PPS (a DRG-based payment). If the patient was not admitted as an inpatient, pay under the outpatient PPS (an APC-based payment). If the patient was not admitted as an inpatient and the procedure is designated as an inpatient-only procedure (payment status indicator "C"), no Medicare payment will be made for the procedure, but payment will be made for ED services.

Comment: Some commenters objected to our proposal to restrict payment for critical care services to CPT code 99291 and not allow payment for CPT code 99292. One commenter recommended that we create an APC group for the additional increments of time a physician spends in critical care for which the physician may bill.

Response: We do not believe that paying hospitals for incremental time as critical care would better reflect facility resources. The most resource-intensive period for the hospital is generally the first hour of critical care. In addition, we believe it would be burdensome for hospitals to keep track of minutes for billing purposes. Therefore, we will pay for critical care as the most resource-intensive visit possible as defined by CPT code 99291. Critical care services will be assigned to APC 0620.

Comment: Several commenters advised that a screening code was not necessary because an emergency visit code could be billed for ED screening services.

Response: We agree with the commenters, and we will instead use the appropriate emergency department codes for screening services (as defined in section 1867(a) of the Act). If no treatment is furnished, we would expect screening to be billed with a low-level emergency department code.

Comment: Some commenters expressed concern about our proposal to allow hospitals to create a separate claim for each visit when two or more medical visits occur on the same day for different diagnoses. Commenters feared that this would result in our paying under the outpatient PPS for clinic care furnished at sites other than hospital outpatient departments, and that we are promoting fragmented care. One commenter was concerned that, to the extent that patients see multiple specialists, tests will be repeated unnecessarily, hospitalizations will rise, and beneficiaries and the Medicare program will be burdened with additional, unnecessary costs.

Response: Our decision not to use diagnosis codes as a factor in determining payment for clinic visits largely negates these concerns because the need to prepare different claims for visits for different diagnoses has been eliminated. When patients are seen in different clinics on the same day, hospitals should bill using the proper codes for the level of the visits, using the units field if appropriate to reflect more than one visit at the same level.

However, we note that the comment did prompt us to develop a code for billing those visits during which numerous physicians see a patient concurrently, for example, a surgeon, medical oncologist, and radiation oncologist for a cancer patient, to discuss treatment options and to ensure that the patient is fully informed. In this instance, each physician is addressing the patient's care from a unique perspective. If several physicians see a patient concurrently in the same clinic

for the same reason, the hospital would bill for one clinic visit using an appropriate visit code even though each physician would bill individually for his or her professional services. We have established a code for hospitals to use in reporting a scheduled medical conference with the patient involving a combination of at least three health care professionals, at least one of whom is a physician. That code is G0175, Scheduled interdisciplinary team conference (minimum of three, exclusive of patient care nursing staff) with patient present.

4. Treatment of Partial Hospitalization Services

As we explained in the proposed rule, partial hospitalization is an intensive outpatient program of psychiatric services provided to patients in lieu of inpatient psychiatric care. Partial hospitalization may be provided by a hospital to its outpatients or by a Medicare-certified community mental health center (CMHC). It is important to note that the services of physicians, clinical psychologists, clinical nurse specialists (CNSs), nurse practitioners (NPs), and physician assistants (PAs) furnished to partial hospitalization patients would continue to be billed separately to the carrier as professional services and are not considered to be partial hospitalization services. Thus, payment for partial hospitalization services represents the provider's overhead costs, support staff, and the services of clinical social workers (CSWs) and occupational therapists (OTs), whose professional services are considered to be partial hospitalization services for which payment is made to the provider. Including CSW and OT services reflects historical patterns of treatment billed during the base year.

Because a day of care is the unit that defines the structure and scheduling of partial hospitalization services, we proposed a per diem payment methodology for the partial hospitalization APC. We analyzed the service components billed by hospitals over the course of a billing period and determined the median hospital cost of furnishing a day of partial hospitalization. As noted in the June 30, 1999 correction notice, this analysis resulted in a proposed APC payment rate of \$206.71 per day, of which \$46.78 is the beneficiary's coinsurance.

We also solicited comments on a number of issues related to partial hospitalization. We asked for information on the mix of services that constitute a typical partial hospitalization day and average duration of a partial hospitalization

episode, whether we should impose a minimum number of services for each covered partial hospitalization day, and whether we should establish a limit on routine outpatient mental health services furnished on a given day to equal the partial hospitalization per diem amount. Finally, we indicated that we are considering specifying a timeframe for physician recertification of need for partial hospitalization services as a method of ensuring that a patient's condition continues to require the intensity of a partial hospitalization program.

We did not receive a significant number of public comments on this issue. A summary of the comments we received and our responses follow.

Comment: We received many similar comments from rural hospitals that operate partial hospitalization programs. The hospitals indicated that the proposed per diem amount does not cover their direct cost of providing services. Each commenter included an estimate of their partial hospitalization program cost (without depreciation or allocation of overhead costs). The estimates range from \$270 to \$325 per patient per day. The commenters indicated that approximately 65 to 70 percent of the costs are personnel-related.

Response: The commenters did not indicate why their costs were higher than the per diem amount, but only that a significant proportion of their costs are related to personnel. In the future, we are committed to assessing the extent to which the per diem reflects special needs of rural hospitals. In the meantime, the BBRA 1999 includes provisions that offer relief to rural hospitals during the early years of the outpatient PPS. (See section III.H of this preamble.)

Comment: We received several other comments regarding the proposed per diem amount. One commenter stated that the proposed per diem rate is equivalent to 3.3 psychotherapy units. The commenter believed this is an inadequate level of therapy for partial hospitalization patients and suggested that a per diem rate equal to 4 psychotherapy units would provide payment for a more appropriate level of service intensity. Several other commenters suggested that we set a single rate using a therapeutic hour of treatment (for example, the group psychotherapy APC rate) as the unit of service coupled with an overall aggregate limit for a course of treatment. These commenters estimated that a typical partial hospitalization day costs \$275. Another commenter, a national association, conducted a survey of its

member hospitals which showed that the median cost per day of treatment was approximately \$210. Other commenters urged us to establish separate per diem amounts for partial hospitalization programs serving geriatric beneficiaries and those serving disabled beneficiaries under age 65. They indicated that programs designed to serve geriatric beneficiaries consist of different treatment modalities that are costlier than programs that serve younger beneficiaries. One commenter stated that programs serving younger beneficiaries typically average high patient volume and therefore have much lower costs per patient day than do the programs that serve geriatric patients. Other commenters urged us to establish a half day rate, although some stated that a half-day benefit does not reduce administrative costs appreciably.

Response: In accordance with section 1833(t)(2)(C) of the Act, the proposed per diem amount represents the national median cost of providing partial hospitalization services. We used all the data from hospital bills that included the condition code 41, which identifies the claim as partial hospitalization. Because providers do not report on the claim the specific services provided each day, we do not currently have data that would permit us to establish an aggregate limit for a course of treatment or to analyze differences in the mix of services provided to various populations. As discussed in the preamble to the proposed rule and in Transmittal 7 of the CMHC Manual (issued November 1999) and Transmittal 747 of the Hospital Manual (issued December 1999), beginning April 1, 2000, hospitals and CMHCs will be required to indicate line item dates of service on claims. Once we have accumulated these data, we will be better able to determine if refinements to the per diem methodology are warranted, including the extent to which half-days are utilized.

Comment: Several commenters expressed concern that no CMHC data were used to establish the partial hospitalization per diem payment rate. The commenters stated that CMHC costs are significantly different from hospital-based programs and urged us to collect CMHC cost data and base payments to CMHCs on CMHC-specific information. Another commenter stated that implementing PPS for partial hospitalization services provided by CMHCs is intended to contain costs and urged us to track the impact of the PPS on CMHCs. Still another commenter expressed concern that the per diem amount is insufficient for CMHCs to provide quality services. The

commenter admitted, however, that historically their service area has had limited resources to provide minimum support for the persistent and chronically mentally ill. Two commenters expressed concern about certification requirements for CMHCs. One urged us to require accreditation by a national accrediting body and another commenter noted that reliance on the statutory definition established for CMHCs under the Public Health Service Act in 1963 is no longer appropriate and urged us to redefine a CMHC for Medicare certification purposes.

Response: Partial hospitalization services are covered services under the hospital outpatient PPS. Section 1833(a)(2)(B) of the Act provides that partial hospitalization services furnished by CMHCs are to be paid under the hospital outpatient PPS. And, section 1833(t)(2)(C) of the Act requires that we establish relative payment weights based on median (or mean, at the election of the Secretary) hospital costs determined by 1996 claims data and data from the most recent available cost reports. As stated above, we are committed to analyzing future data from hospitals and CMHCs to determine if refinements to the per diem are warranted. As we noted in the proposed rule, the Medicare partial hospitalization benefit is designed to furnish services to patients who have been discharged from inpatient psychiatric care, and partial hospitalization services are provided in lieu of continued inpatient treatment, and for patients who exhibit disabling psychiatric/psychological symptoms or experience an acute exacerbation of a severe and persistent mental disorder. Because the statute requires a physician to certify that the patient would otherwise require inpatient psychiatric care in the absence of the partial hospitalization services, we do not believe the Medicare partial hospitalization benefit was intended to provide support for the persistent and chronically mentally ill except when they are in an acute phase of their mental illness. With regard to accreditation requirements for CMHCs and substantively revising the definition of a CMHC, this final rule is not the appropriate vehicle in which to address these issues. We are, however, amending § 410.2 to remove an obsolete provision from the definition of a CMHC.

Comment: Several commenters questioned whether the proposed per diem approach meets the definition of an APC, that is, a group of services that are comparable clinically and in resource use. They believed that partial

hospitalizations vary widely in their treatment approach and cost. Therefore, creating one payment amount for all partial hospitalization days is not consistent with our proposed classification system.

Response: We continue to believe that the structure of the average partial hospitalization day is more similar than the commenters believe. We followed the basic analytical methodology used to establish all the APC payment amounts, except that we determined that, for partial hospitalization services, the unit of service is a day. Nonetheless, requiring providers to submit claims by date of service and by service provided will allow for future analysis to determine if the APC grouping for partial hospitalization can be improved.

Comment: One commenter expressed concern about the use of 1996 data as the basis for the per diem amount. They referenced testimony by the Inspector General that indicated a significant improvement in the accuracy of provider billing in 1998 audits. They urged us to use 1997 or 1998 cost reports by region to develop the APC rate.

Response: Section 1833(t)(2)(C) of the Act requires that we use 1996 claims data and the most recent cost reports as the basis for ratesetting under the hospital outpatient PPS. For purposes of the final rule, we primarily used cost reports for periods beginning in FY 1997.

Comment: Several commenters, including national industry associations, expressed concern that partial hospitalization programs are required by their individual fiscal intermediaries to meet different medical necessity and programmatic requirements. For this reason, programs vary widely in program content and resultant cost. The commenters urged us to establish national coverage criteria before implementing a PPS for partial hospitalization services. Another commenter urged us to rely on more recent claims data that identify all services provided on each date of service in order to determine the relative resource cost of various outpatient mental health treatment programs.

Response: Section 1833(a)(2)(B) of the Act provides that partial hospitalization services are paid under section 1833(t). We will refine the system, as needed, based on our review of more specific bill data. Movement to a per diem payment methodology will necessitate changes in the medical review approach used by fiscal intermediaries. It will become necessary to ensure that all patients receive the level of service their

individual condition requires. Some patients will require days of service that cost the provider more than the per diem payment amount. Other patients may require less intensive days of service during an acute episode of partial hospitalization care or as they transition out of the partial hospitalization program. We will be developing medical review guidance for fiscal intermediaries, which we believe will lead to more consistency in medical review.

Comment: One commenter noted that, in the past, a daily or partial-day payment approach was commonly used and was abandoned in favor of component billing for each partial hospitalization service. The commenter now believes that component billing provides a more accurate indication of the services provided to individual patients.

Response: We believe that a per diem payment approach is a more appropriate methodology than billing for each program component. This approach is supported by the major industry groups involved with partial hospitalization and is used by other governmental and private insurers to pay for partial hospitalization program services. A per diem approach also incorporates and recognizes the cost of services that are not separately billable as outpatient psychiatric services, such as nursing services, training and education services, activity therapy, and support staff costs.

Comment: Several commenters requested additional information on the HCPCS codes to which the partial hospitalization indicator applies and questioned how codes will group to APC 20 rather than grouping to psychotherapy APCs 91 through 94.

They also asked whether substance abuse day programs will group to APC 20.

Response: We issued revised billing instructions for partial hospitalization services provided by CMHCs in November 1999 and for hospital programs in December 1999. We instructed CMHCs to use HCPCS codes to bill for their partial hospitalization services; we required hospitals and CMHCs to report line item dates of service; and we established new HCPCS codes for occupational therapy and training and educational services furnished as a component of a partial hospitalization treatment program. We included in the instructions a complete listing of the revenue codes and HCPCS codes that may be billed as partial hospitalization services as follows:

Revenue codes	Description	HCPCS code
43X	Occupational Therapy (Partial Hospitalization)	G0129.
904	Activity Therapy (Partial Hospitalization)	Q0082.
910	Psychiatric General Services	90801, 90802, 90875, 90876, 90899, or 97770.
914	Individual Psychotherapy	90816, 90818, 90821, 90823, 90826, or 90828.
915	Group Psychotherapy	90849, 90853, or 90857.
916	Family Psychotherapy	90846, 90847, or 90849.
918	Psychiatric Testing	96100, 96115, or 96117.
942	Education Training (Partial Hospitalization)	G0172.

To bill for partial hospitalization services under the hospital outpatient PPS, hospitals are to use these HCPCS and revenue codes and are to specify condition code 41 on the HCFA-1450 claim form. Before assigning a claim for payment to APC 0033 (the final APC for partial hospitalization services), the outpatient code editor (OCE) will check for errors; for example, the OCE will verify that the claim includes a mental health diagnosis, and at least three partial hospitalization HCPCS codes for each day of service, one of which must be a psychotherapy HCPCS code (other than brief). Claims that do not pass the OCE edits will undergo further prepayment review.

With regard to the comments regarding substance abuse day programs, the Medicare benefit category is partial hospitalization services. Because there is no separate benefit category for substance abuse programs, any such program would have to meet requirements established for partial hospitalization programs in order for claims to group to APC 0033, including the requirements that a physician certify that the patient would otherwise require inpatient psychiatric care in the absence of the partial hospitalization services

and that the program provides active treatment.

Comment: In regard to physician recertification, we received several comments expressing support for establishing a specific timeframe and recommending a range from 7 to 31 days.

Response: We agree that physicians should initially certify a patient's need for partial hospitalization services and recertify continued need for this intensive level of treatment. Because partial hospitalization is the outpatient substitute for inpatient psychiatric care, we believe it is appropriate to adopt the standard currently used for inpatient psychiatric care. Therefore, in this final rule, we are amending § 424.24(e) to establish physician recertification requirements for partial hospitalization services. The initial physician certification establishing the need for partial hospitalization must be received by the partial hospitalization program upon admission. Thus, services provided to establish a patient's need for partial hospitalization services would continue to be billed to the carrier as professional services. The first recertification is required as of the 18th day of services and subsequent

recertifications are required no less frequently than every 30 days. Each recertification must address the patient's response to the intensive, therapeutic interventions provided by the active treatment program which make up partial hospitalization services, changes in functioning and status of the serious psychiatric symptoms that place the patient at risk of hospitalization, and treatment plan and goals for coordination of services such as community supports and less intensive treatment options to facilitate discharge from the partial hospitalization program.

Comment: We received several comments regarding our proposal to limit payment for less intensive outpatient mental health treatment at the partial hospitalization per diem rate. One commenter did not believe the law supports establishment of a payment ceiling and that any such action is arbitrary. Other commenters believe that treatment should be determined by the clinical needs of each patient. However, the commenters conceded that additional requirements may have to be added to the final rule to prevent duplication or overlap of partial

hospitalization and routine outpatient mental health services.

Response: Our rationale for this proposal was that the costs associated with administering a partial hospitalization program represent the most resource intensive of all outpatient mental health treatment and, therefore, we should not pay more for a day of individual services. We are also concerned that a provider may disregard a patient's need for the intensive active treatment offered by a partial hospitalization program and opt to bill for individual services. In addition, the per diem amount represents the cost of an average day of partial hospitalization because the data used to calculate the per diem were derived from all the partial hospitalization data and include the most and the least intensive days. It would not be appropriate for a provider to obtain more payment through component billing.

Comment: Several commenters expressed concern about staffing services that are bundled in the per diem payment and other staffing issues. One commenter stated that due to increased medical review by the fiscal intermediary, no partial hospitalization services may be furnished by unlicensed personnel. The commenter urged that the necessity for upgrades in staffing be taken into consideration in establishing a per diem rate. One commenter believes that all services, except for physician services, should be bundled into the per diem rate.

Response: The list of covered partial hospitalization services is located in section 1861(ff) of the Act. The list includes several services such as patient education and training and activity therapy that may be provided by unlicensed but qualified staff who are specifically trained to work with the mentally ill. We note that the billing instructions issued in November 1999 (for CMHCs) and in December 1999 (for hospitals) announced a new HCPCS code for patient training and education services as a component of a partial hospitalization program. (A HCPCS code for activity therapy as part of a partial hospitalization program has been in place for several years.) Although the list also specifically references the services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients, there are no specific HCPCS codes for these services. Certain other partial hospitalization services, for example, individual and group psychotherapy, family counseling, occupational therapy (OT), and diagnostic services, must be provided by

licensed staff, authorized by the State to provide these services.

With regard to the content and staffing of partial hospitalization programs, we believe that all the covered services listed in section 1861(ff) of the Act and the disciplines of the staff who provide the services, that is, the multidisciplinary team, are an important element in creating the therapeutic milieu that distinguishes partial hospitalization programs from other outpatient mental health treatment. We believe it would be inappropriate if providers no longer offered the full range of partial hospitalization services, especially services such as OT that continue to be bundled in the per diem amount. We plan to monitor the extent to which providers change their programming in response to implementation of the PPS. Because the data on which the per diem was based included the full range of services and the use of certain bundled professionals, we will monitor changes in services or increased use of unbundled practitioners to evaluate and update the per diem rate. In response to the comment recommending that we bundle more professional services into the per diem rate, we captured historical patterns of treatment and staffing during the base year. Thus, the partial hospitalization per diem amount is limited to the provider's overhead costs, support staff, and the services of clinical social workers and occupational therapists, whose professional services are defined as partial hospitalization services. We have amended § 410.43(b) to update the list of services that are not paid as partial hospitalization services.

Comment: One commenter took issue with our characterizing partial hospitalization to be the result of an acute exacerbation of a beneficiary's severe and persistent mental illness for which partial hospitalization services are provided in lieu of an inpatient psychiatric admission. They urged us to clarify that admission to a partial hospitalization is based on a physician certification that the patient would otherwise require inpatient psychiatric care, but continued stay in a partial hospitalization program would serve as a maintenance program for the chronically mentally ill. The commenter raised many other concerns about how we described partial hospitalization in the proposed rule, noting specific concern with regard to active treatment, community-based support, and frequency and duration of services.

Response: It was not our intention in the proposed rule to generate public comment on the nature and coverage of partial hospitalization under the

Medicare program. Rather, the information presented has appeared in various program memoranda and was included to describe the benefit and explain the per diem payment methodology. We continue to believe that partial hospitalization is a covered Medicare benefit category only when provided as an alternative to inpatient psychiatric care for acutely mentally ill beneficiaries.

Result of Evaluation of Comments

We are adopting as final our proposal to—

- Establish a per diem payment of \$202.19 for the partial hospitalization APC (APC 0033); and
- Limit the payment for outpatient mental health treatment furnished on a day of services to the partial hospitalization APC payment amount.

In addition, we are amending § 424.24(e) to establish requirements for physician recertification for partial hospitalization services.

5. Inpatient Only Procedures

In our proposed rule, we assigned payment status indicator "C" to 1,803 codes that represent procedures that our medical advisors and staff determined require inpatient care because of the invasive nature of the procedure, the need for postoperative care, or the underlying physical condition of the patient who would require the surgery. We did not assign these procedures to an APC group, and we proposed to make no payment for these services under the hospital outpatient PPS. Above, in section III.B.1.b of this preamble, we respond to the numerous general comments we received challenging both our classification of various procedures as inpatient procedures and our exclusion of these procedures from the scope of services paid under the hospital outpatient PPS.

Comment: Commenters objected on the grounds that medical practice and new technology have allowed many procedures that formerly were performed only in the inpatient setting to be safely and effectively performed on an outpatient basis. In addition, they believe we are making decisions that should be left to the discretion of surgeons and their patients. Finally, the commenters believe that it is better for the patient if procedures are performed on an outpatient basis whenever possible. Commenters requested that we remove the payment status indicator of "inpatient only" from 195 codes and include them in an appropriate APC.

Response: Under section 1833(t)(1)(B)(i) of the Act, the Secretary has broad authority to designate which

services fall within the definition of "covered OPD [outpatient department] services" that will be subject to payment under the prospective payment system. We believe that certain surgically invasive procedures on the brain, heart, and abdomen, such as craniotomies, coronary-artery bypass grafting, and laparotomies, indisputably require inpatient care, and therefore are outside the scope of outpatient services. Certain other procedures that we proposed as "inpatient only" may not be so clearly classified as such, but they are performed virtually always on an inpatient basis for the Medicare population. We acknowledge that emerging new technologies and innovative medical practice are blurring the difference between the need for inpatient care and the sufficiency of outpatient care for many procedures, although we are concerned that some of the procedures that commenters claim to be performing on an outpatient basis may actually have been performed with overnight postoperative care furnished in observation units. And, regardless of how a procedure is classified for purposes of payment, we expect, as we stated in our proposed rule, that in every case the surgeon and the hospital will assess the risk of a procedure or service to the individual patient, taking site of service into account, and will act in that patient's best interests.

After a careful review of comments by our medical advisors and staff, we have assigned to APC groups certain procedures that we had proposed as inpatient only. We made some changes because we were convinced by commenters' arguments that certain procedures are often performed safely in the outpatient setting; others because we believe that the simplest procedure described by the code may be performed safely in the outpatient setting; and yet others because they were related to codes we moved (for example, the radiologic part of an interventional cardiology procedure). The procedures we moved to the outpatient APCs include codes from within the following families: Explorations of penetrating wounds; repairs of some cranial and facial fractures; planned tracheostomies; diagnostic thoracoscopies; some insertion/removal/replacement of pacemakers, pulse generators, electrodes and cardioverter-defibrillators; embolectomies and thrombectomies; transluminal balloon angioplasty and peripheral atherectomy; transcatheter therapies; bone marrow transplantation; gastrostomies; percutaneous nephrostolithotomy; surgical laparoscopies, including

cholecystectomies; ovarian biopsies; and surgeries on the orbit. Although we are moving these procedures into APC groups and they can receive outpatient payment, we emphasize that we expect only the simplest and least resource intensive procedures of each type to be performed in the outpatient setting. For example, several codes could be used to describe initial insertion of a pacemaker or replacement of the pacemaker or its electrodes. We believe most initial pacemaker insertions are performed on an inpatient basis, so codes billed in this range are most likely to be for replacement of a pacemaker, which requires fewer facility resources.

Because of the risk involved with invasive cardiovascular procedures, including angioplasty and atherectomy, we are placing an additional requirement on their performance that we do not think is necessary with other procedures. That is, Medicare will pay for these procedures only in those settings in which the patient can immediately be placed on cardiopulmonary bypass in the event of a complication such as perforation of a coronary artery, which would require an immediate thoracotomy.

When our medical advisors and staff disagreed with the recommendation of commenters to reclassify a particular procedure, they based their decision to retain a procedure as "inpatient only" on several considerations. In general terms, as stated above, we define inpatient procedures as those that require inpatient care because of the invasive nature of the procedure, the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged, or the underlying physical condition of the patient who would require the surgery. In other words, inpatient procedures are those that, in the judgment of our medical advisors and staff, would not be safe, appropriate, or considered to fall within the boundaries of acceptable medical practice if they were performed on other than a hospital inpatient basis.

Among the procedures cited by commenters that we believe should remain as "inpatient only" are: Breast reconstruction using myocutaneous flaps; radical resections of tumors of the mandible; open treatment of certain craniofacial fractures; osteotomies of the femur and tibia; sinus endoscopy with repair of cerebrospinal fluid leaks; carinal reconstruction; surgical thoracoscopies; pacemaker procedures by thoracotomy; certain thromboendarterectomies; excision of mediastinal cysts and tumors; excisions of stomach tumors; enterostomies;

hepatotomies; ureterotomies and ureteral endoscopies through ureterotomies; transcranial approaches to the orbit; and laminectomies. Our medical advisors and staff, as well as consulting physicians, believe these procedures are too invasive (for example, thoracotomies), too extensive (for example, breast reconstruction with myocutaneous flaps), or too risky by virtue of proximity to major organs (for example, repairs of spinal fluid leaks and carinal reconstruction) to be performed on an outpatient basis. The procedures that we exclude from outpatient payment because we believe they should be performed on an inpatient basis are listed in Addendum E. This list represents national Medicare policy and is binding on fiscal intermediaries and peer review organizations as well as on hospitals and Medicare participating ASCs. Note, however, that services included in outpatient PPS and assigned to an APC may be performed on an inpatient basis when the patient's condition warrants inpatient admission.

In the future, as part of our annual update process, we will be working with professional societies and hospital associations, as well as with the expert outside advisory panel that we will be convening as required by new section 1833(t)(9)(A) of the Act, to reevaluate procedures on the "inpatient only" list and we will propose to move procedures to the outpatient setting whenever we determine it to be appropriate. For example, a decreasing length of inpatient stay for a procedure may signal that it is appropriate for consideration for payment under the outpatient PPS. If hospitals find that surgeons are discharging patients successfully on the day of surgery, they should bring this to our attention as well, because hospitals may become aware of this trend before our payment data disclose it. Thus, assignment of a "C" payment status indicator in this final rule should not be considered as a permanent or irrevocable designation.

Comment: One professional society recommended that we assign payment status indicator "C" to CPT codes 21343, open treatment of depressed frontal sinus fracture, 42842, radical resection of tonsil, tonsillar pillars, and/or retromolar trigone—without closure, and 69150, radical excision external auditory canal lesion—without neck dissection, because these procedures require inpatient care.

Response: We accepted the commenters' recommendation that these CPT codes should not be performed in an outpatient setting. We also reclassified as an inpatient procedure

CPT code 94762, noninvasive ear or pulse oximetry for oxygen saturation; by continuous overnight monitoring (separate procedure), because it requires an overnight stay.

Comment: One commenter noted that, to the extent that we require that certain surgical procedures be performed in an inpatient setting in order to receive Medicare payment, the beneficiary will incur the higher deductible associated with a hospital inpatient service.

Response: The commenter is correct that the Part A hospital inpatient deductible amount that a beneficiary will have to pay may be higher than coinsurance and deductibles the beneficiary would have paid as an outpatient for a surgical procedure. However, our decisions concerning whether to pay for certain surgical procedures under the PPS are based on patient safety concerns and the medical appropriateness of performing the procedures in the hospital inpatient versus outpatient setting.

Final Action

Under the hospital outpatient PPS, we will not make payment for procedures that are designated as "inpatient only." We have, however, revised the list of procedures that are designated as "inpatient only" based on comments. (See Addendum E.)

6. Modification of APC Groups

a. How the Groups Were Constructed

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered outpatient services. Within that classification system, the Secretary is given the authority under section 1833(t)(2)(B) of the Act to establish groups of covered services so that the services within each group are comparable clinically and with respect to the use of resources. In the proposed rule, we explain how we constructed the APC groups that are the basis for ratesetting under the hospital outpatient PPS.

Our medical advisors and staff used the ambulatory patient groups (APGs) developed by 3M-Health Information Systems as a starting point for the APC groups, but we modified the APGs to take into account 1996 outpatient claims data, data collected in a 1994 survey of ambulatory surgical center (ASC) costs and charges, data collected in 1995 and 1996 to establish resource-based practice expense relative values under the Medicare physician fee schedule, and comments offered by a broad range of professional and trade societies and associations. For a more detailed

discussion of this process, see section V.B of the proposed rule (63 FR 47561).

b. Comments on Classification of Procedures and Services Within APC Groups

In the proposed rule, we invited comments on the composition of the APC groups, and we requested that commenters support their recommendations for changes with resource cost data and clinical arguments. We received a large number of comments on our proposed grouping of individual procedures and services. The most common comment was that the APC groups generally lacked consistency in terms of clinical characteristics and resource utilization. Below, in section III.C.6.d of this preamble, we address recommendations from commenters that specific HCPCS codes be assigned to a group other than the one we proposed. In addition to reviewing the APC groups that were the subject of comments, our medical advisors and staff reviewed every APC group to take into account the effect across all related groups of commenters' recommended changes.

Criteria for Evaluating Changes Recommended by Commenters

In determining whether or not to accept a recommended change, we focused on five criteria that are fundamental to the definition of a group within the APC system. The decision to accept or decline a modification to an APC group was measured by whether the change enhanced, detracted from, or had no effect on the integrity of an APC group within the context of these five criteria. The five criteria are as follows:

- **Resource Homogeneity**

The amount and type of facility resources, for example, operating room time, medical surgical supplies, and equipment, that are used to furnish or perform the individual procedures or services within each APC should be homogeneous. That is, the resources used are relatively constant across all procedures or services even though resource use may vary somewhat among individual patients. If the procedures within an APC require widely varying resources, it would be difficult to develop equitable payment rates. Aggregated payments to a facility that performed a disproportionate share of either the expensive or inexpensive procedures within an APC would be distorted. Further, the facility might be encouraged to furnish only the less costly procedures within the APC, resulting in a potential access problem for the more costly services.

It is important to note that procedures within an individual HCPCS code can vary widely in resource use. The coefficient of variation of cost for the procedures within one HCPCS code can be as high as the overall coefficient of variation across all the HCPCS codes that comprise an APC group. Thus, a significant amount of the variability in resource use within some APC groups can be attributed to the variability of resources within individual HCPCS codes. Nevertheless, if resource use is reasonably homogeneous among the HCPCS codes within an APC group, the average pattern of resource use among a group of cases in an APC can be accurately predicted. In section III.C.6.c, below, we discuss the BBRA 1999 provision that sets limits on the variation in resource cost within an APC.

- **Clinical Homogeneity**

The definition of each APC group should be "clinically meaningful," that is, the procedures or services included within the APC group relate generally to a common organ system or etiology, have the same degree of extensiveness, and utilize the same method of treatment, for example, surgical, endoscopic, etc. The definition of clinical meaningfulness is, of course, dependent on the goal of the classification system. For APCs, the definition of clinical meaningfulness relates to the medical rationale for differences in resource use. If, on the other hand, classifying patient prognosis were the goal, the definition of patient characteristics that were clinically meaningful might be different.

- **Provider Concentration**

We considered the degree of provider concentration associated with the individual services that comprise the APC. If a particular service is offered only in a limited number of hospitals, then the impact of payment for the service is concentrated in a subset of hospitals. Therefore, it is particularly important to have an accurate payment level for services with a high degree of provider concentration. Conversely, the accuracy of payment levels for services that are routinely offered by most hospitals does not bias the payment system against any subset of hospitals. Thus, differences in the resource requirements for individual services within an APC are of less significance if all the services within the APC are routinely offered by most hospitals because the impact of the difference should average out at the hospital level.

- **Frequency of Service**

Unless we found a high degree of provider concentration, we avoided creating separate APC groups for

services that are infrequently performed. It is difficult to establish reliable payment rates for low volume APC groups. Therefore, we assigned the HCPCS codes to the APC that was the most similar in terms of resource use and clinical coherence.

Some procedures, such as craniotomies, are clearly inpatient procedures, and are rarely performed in an outpatient setting. However, there are some procedures that, while they are normally performed on an inpatient basis, can also be safely performed on an outpatient basis. The performance of those procedures on an outpatient basis is infrequent and is limited to the simplest cases. Therefore, when we included these procedures in APC groups, we assumed a level of resource use that would apply only to the simplest cases rather than that typical of more complex cases that would be performed on an inpatient basis.

- **Minimal Opportunities for Upcoding and Code Fragmentation**

The APC system is intended to discourage using a code in a higher paying group to define a case. That is, putting two related codes, such as the codes for excising a lesion of 1.1 cm and one of 1.0 cm, in different APC groups may create an incentive to exaggerate the size of the lesions in order to justify the incrementally higher payment. APC groups based on subtle distinctions would be susceptible to this kind of upcoding. Therefore, we kept the APC groups as broad and inclusive as possible without sacrificing resource or clinical homogeneity.

In general, HCPCS codes that are nonspecific (such as 20999, "unlisted procedure, musculoskeletal system, general") were assigned to the lowest paying APC that was consistent with the clinical characteristics of the service. In the case of 20999, the codes to which it is related are in the range 20000–20979. The APCs to which they group range from 0004, with a payment rate of \$89.22, to 0050, with a payment rate of \$1,024.53. We placed 20999 in the lowest paying, related group, 0004.

c. Effect of the BBRA 1999 on Final APC Groups

Section 201(g) of the BBRA 1999 amends section 1833(t)(2) of the Act to limit the variation in resource use among the procedures or services within an APC group. Specifically, section 1833(t)(2) of the Act now provides that the items and services within a group cannot be considered comparable with respect to the use of resources if the highest cost item or service within a group is more than 2 times greater than the lowest cost item or service within

the same group. The Secretary is to use either the mean or median cost of the item or service. We are using the median cost because we have continued to set the relative payment weights for each APC based on median hospital costs in this final rule. (See the discussion in section III.E of this preamble.)

Section 1833(t)(2) of the Act as amended also allows the Secretary to make exceptions to this limit on the variation of costs within each group in unusual cases such as low volume items and services, although we may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act. See the discussion of the classification of orphan drugs in section II.D of this preamble and the discussion of APC groups that we excepted from the "2 times" limit in section III.C.6.e.

We applied the limit on variation on median costs required by section 201(g) to the revised APC groups. (See section C.6.d, below.) As a result of our analysis of the array of median costs within the revised APC groups, we had to split some otherwise clinically homogeneous APC groups into smaller groups. We are concerned that this further subdivision of groups may create vulnerabilities for upcoding, which conflicts with one of the five criteria described above that we used to evaluate the construction of the APC groups. We will be examining the extent to which the APC reorganization due to the "2 times" rule results in upcoding.

d. Summary of APC Modifications

In this section, we summarize and explain our response to comments on individual or serial APCs. We use the APC number that appeared in the proposed rule to identify a group that was changed. In most instances, we moved a HCPCS code from its proposed APC group to a different APC group either in response to comments or to comply with section 1833(t)(2)(C) of the Act. In some cases, we moved codes when a change in response to a comment or the cost variation limit resulted in a grouping that seriously compromised one of the criteria we used to evaluate changes recommended by commenters. Because we made so many changes in the APC groups, we renumbered all the groups and, in many cases, renamed groups. In our response to comments in connection with an APC, the final designation for a HCPCS code corresponds to the renumbered APC group found in the addenda.

APC 121: Level I Needle Biopsy/Aspiration

Comment: One specialty society commented that there was significant variation in resource consumption for the procedures performed in this APC and that the proposed payment rate of \$33.95 for APC 121 does not accurately reflect the preparation, examination, and consultation expenses for a pathologist to thoroughly perform these procedures. The commenter recommended including CPT codes 85095, 85102, 88170, and 88171 in proposed APC 122.

Response: The procedures we proposed to classify in APC 121 were considered sufficiently similar from a clinical perspective. We found no provider concentration associated with the procedures proposed for this APC. Therefore, any variation in cost across the procedures in this APC should average out at the hospital level. However, to be consistent with the BBRA 1999 "two times" provision concerning comparable resources, we have moved CPT codes 85095 and 85102 to final APC 0003, and CPT codes 88170 and 88171 remain in final APC 0002.

APC 122: Level II Needle Biopsy/Aspiration

Comment: A number of commenters indicated that there was significant variation in resource consumption for the procedures proposed in this APC group. For example, one commenter stated that although all the codes within this group are needle biopsies, they range dramatically in complexity, they are quite dissimilar in terms of resource use, they are not clinically similar, and the proposed grouping results in inappropriate payment for the more complex procedures.

Response: We decided that CPT code 67415, Fine needle aspiration of orbital contents, was more appropriately grouped from a clinical perspective with ophthalmic procedures in final APC 0239. We further divided the codes in proposed APC groups 121 and 122 for needle biopsy/aspiration into final APC groups 0002, 0003, 0004, and 0005 to be consistent with the BBRA 1999 "two times" requirement.

APC 131: Level I incision & drainage

Although we received no comments on proposed APC group 131, based on internal review of this APC, we moved CPT code 11976, Removal, implantable contraceptive capsules, to final APC 019 because this procedure represents an excision rather than an incision. We divided proposed APC 131 into final

APC groups 0006, 0007, and 0008 to be consistent with the BBRA 1999 "two times" requirement.

APC 141: Level I Destruction of lesion

APC 142: Level II Destruction of lesion

Comment: One commenter questioned our proposed assignment of CPT codes 17106 through 17108, which describe destruction of cutaneous vascular proliferative lesions, to APC groups 141 and 142.

Response: We moved CPT code 17106 to final APC 0011 because its median cost is significantly higher than the other codes in 0010. However, the median cost for that code is greater than we would have expected it to be. We will review the appropriateness of this placement in the course of future updates of the APC groups.

APC 151: Level I debridement/
destruction

APC 152: Level II debridement/
destruction

Comment: We received general comments questioning the resource homogeneity of the proposed skin APC groups. One commenter recommended including removal of skin lesion with laser on other body parts in proposed APC 152 rather than restricting the APC to vulva, anus, and penis procedures. The commenter believes that removal of these benign lesions, including papillomas, should include other areas of the body.

Response: We agree with commenters' general concerns about resource homogeneity. We reclassified the codes in proposed APCs 151 and 152 into final APC groups 00012 through 00017 to better differentiate resource use and clinical characteristics and to be consistent with the "two times" BBRA 1999 requirement. We also moved CPT code 42809, Removal of foreign body from pharynx, to final APC 251 because it is an otorhinolaryngology (Ear/Nose/Throat (ENT)) procedure.

APC 161: Level I excision/biopsy

APC 162: Level II excision/biopsy

APC 163: Level III excision/biopsy

Comment: Numerous commenters were concerned about the variation of resource use among the procedures in proposed APC groups 161, 162, and 163. Commenters requested that we consider classifying procedures in these groups based on anatomic location where functionality is of high importance in combination with the size of excision.

Response: We made a number of modifications to the excision APC groups to satisfy the BBRA 1999 "two

times" requirement, resulting in final APC groups 0018 through 0022. We reclassified CPT codes 11043 and 11044 to APC groups 0016 and 0017 because these codes describe debridement of skin, subcutaneous tissue, muscle, and bone.

In the final excision/biopsy APC groups, we endeavored to make distinctions based on the location and size of the excision. For example, excisions of malignant lesions from the face, ears, eyelids, nose, lips greater than 4 cm were placed in an APC requiring more resource use than excisions of malignant lesions from the trunk, arms or legs greater than 4 cm because "functionality" is of greater importance when the site is the face, ears, eyelids, nose, or lips. We moved excisions involving the eye to ophthalmic procedure APCs. We did not make grouping distinctions between benign and malignant lesions of the same size and location because resource use for both types is similar.

We moved benign and malignant excisions larger than 2 cm to final APC group 0020 because these excisions require more resources than, for example, excisions smaller than 1 cm.

We moved CPT code 20220, superficial biopsy of bone (e.g., ilium, sternum, spinous process, ribs) with trocar or needle, to final APC 0019, because the resources used in connection with this procedure are similar to those required for excisions of small benign or malignant lesions.

As noted above, we classified two debridement procedures (CPT codes 11043 and 11044) to final APC groups 0016 and 0017, respectively.

We also moved seven codes from proposed APC 162 to the ophthalmic APC groups.

APC 181: Level I skin repair

APC 182: Level II skin repair

APC 183: Level III skin repair

APC 184: Level IV skin repair

Comment: We received numerous comments expressing concern about the consistency of resource use and clinical homogeneity of the procedures in the four proposed skin repair APC groups. Many commenters recommended moving more complex procedures, such as large layer closures, to an APC with a higher payment rate because the procedures require more operating room and recovery time. Some commenters recommended moving some of the skin repair codes to other body systems.

Response: Our review of proposed APC groups 181, 182, 183, and 184 resulted in our regrouping the skin repair codes based more on cost than on

clinical considerations. The volume of claims in most of the codes, however, is quite low. In addition, we moved CPT code 33222, Revision or relocation of skin pocket for pacemaker, from proposed APC 360 to final APC 0026, because this procedure is so similar to the other skin repair procedures in terms of clinical content and resource consumption. We will review these groups carefully as data become available.

APC 197: Incision/excision breast

APC 198: Breast reconstruction/
mastectomy

Comment: One commenter observed that the procedures in proposed APC group 198 are related both to the definitive treatment of breast cancer and to plastic and reconstructive operations of the breast. The commenter recommended moving CPT code 19162, Mastectomy, partial with axillary lymphadenectomy, and CPT code 19182, Mastectomy, subcutaneous, into an APC group with a higher payment rate because both procedures are more complex and involve more time and resources than the other procedures in proposed APC group 198. Another commenter stated that CPT code 19162, and CPT code 19318, Reduction mammoplasty, require significantly longer operating times than the other procedures in proposed APC group 198. The same commenter further observed that CPT code 19162 essentially involves performing two procedures.

Response: Our medical advisors and staff carefully reviewed the comments submitted in connection with the procedures in proposed APC group 198 within the context of the criteria that we discuss at the beginning of this section. They concluded that, although reduction mammoplasty (CPT code 19318) could require slightly more resources, a reduction mammoplasty is still fundamentally similar to other procedures in proposed APC 198 such as CPT code 19162, Partial mastectomy with axillary lymphadenectomy. Our medical advisors and staff concluded that the procedures in proposed APC groups 197 and 198 were sufficiently similar clinically and in terms of resource use to retain the proposed groupings. Therefore, we are retaining our proposed grouping in final APC groups 0029 and 0030.

APC 207: Closed treatment fracture
finger/toe/trunk

Although we did not receive comments about this APC group, our medical advisors and staff determined that treatment of closed fractures

pertaining to the larynx should be moved to the ENT APC groups because they are more similar from a clinical and resource use perspective to ENT procedures. The larynx procedures do not involve casts and, more importantly, they require completely different resources and ancillary personnel than, for example, the setting of a finger fracture. Proposed APC 207 is renumbered final APC 0043.

APC 209: Closed treatment fracture/dislocation except finger/toe/trunk

Comment: One commenter objected to including multiple procedures for dislocation and fractures in proposed APC group 209, when the cost of drugs and supplies alone for these procedures probably exceeds \$100. The commenter believed that the proposed payment rate for APC 209 was \$71.00.

Response: We note that the proposed payment for APC 209 was \$98.75, rather than \$71.00, as the commenter quoted. Although we included in proposed APC 209 some procedures that could involve considerable time and resources, only the simplest cases of these potentially more complex procedures would be performed on an outpatient basis, with proportionally lower costs than would be incurred when the procedures are performed in an inpatient setting. Therefore, we retained in final APC 0044 the codes in proposed APC 209, except we moved CPT code 31586, Treatment of closed laryngeal fracture, to final APC 0256, because this is primarily an ENT procedure.

APC 216: Open/percutaneous treatment fracture or dislocation

Comment: Numerous commenters took issue with the variation in resource use among the procedures that include the open treatment of almost all bone fractures, ranging from relatively simple finger and toe fractures to major long bone fractures.

Response: We expect that only the simplest of the procedures proposed in APC group 216 would be performed on an outpatient basis. Therefore, we kept open/percutaneous treatment of fractures in one APC rather than splitting these procedures into multiple APCs. We find it unlikely that one provider would specialize in, for example, only open fractures of fingers or only open fractures of long bones. Because the CPT code descriptors for so many procedures in this APC group indicate "with and/or without internal fixation," it is impossible to make distinctions based on whether or not internal fixation is applied. Proposed APC 216 is renumbered final APC 0046.

APC 226: Maxillofacial prostheses

APC 231: Level I skull and facial bone procedures

APC 232: Level II skull and facial bone procedures

Although we did not receive specific recommendations for these APCs, our medical advisors and staff determined that the procedures in these groups are more similar to ENT procedures from a clinical and resource use perspective. Therefore, we moved all of the procedures in these proposed APC groups to the final APCs 0251 through 0256, the ENT APCs.

APC 251: Level I Musculoskeletal Procedures

APC 252: Level II Musculoskeletal Procedures

Comment: One commenter expressed concerns about the clinical homogeneity of the codes in these two groups. The commenter stated that proposed APC 251 contains 77 widely disparate procedures, including CPT code 23100 and CPT code 24100, which describe arthrotomies with biopsies, CPT code 25248, Exploration with removal of deep foreign body, forearm or wrist, and CPT code 27704, Removal of ankle implant. The commenter further stated that proposed APC 252 contains equally diverse procedures ranging from: CPT code 20900, Bone graft, any donor area; minor or small, to CPT code 25251, Removal of wrist prosthesis; complicated, including "total wrist," to CPT codes 27396, 27580, and 27665, which are different types of tendon procedures. The commenter recommended that procedures that require specialized equipment and more operating room time be moved into a group with a higher payment rate.

Response: Our medical advisors and staff, after careful consideration of the commenter's concerns and after reviewing alternative groupings of the numerous codes in these two proposed musculoskeletal APC groups, concluded that splitting these groups to address the disparities cited by the commenter would result in too many small, low-volume groups for which we would be unable to establish reliable payment rates. The broad inclusiveness of these two APC groups is in part a reflection of the magnitude of the musculoskeletal system. Given the homogeneity of resource use across the many procedures within each group, we concluded that the factors supporting retention of the two groups outweighed the concerns raised by the commenter. We did, however, move CPT code 27086, Removal of foreign body, pelvis

or hip; subcutaneous tissue, to final APC 0019.

APC 280: Diagnostic Arthroscopy

APC 281: Level I Surgical Arthroscopy

APC 282: Level II Surgical Arthroscopy

Comment: A number of commenters expressed concerns about the homogeneity of codes in the proposed surgical arthroscopy APC groups. In particular, commenters stated that while an arthroscope is needed for all the procedures assigned to proposed APC group 281, the nature of the repair may mandate different additional equipment and differing times to complete. Commenters did not find the procedures in proposed APC 281 to be homogeneous with respect to the time required to perform the procedures nor their associated costs. Commenters specifically recommended transferring complex elbow and wrist procedures represented by CPT codes 29826, 29838, 29839, 29846, 29847, 29848, 29861, 29862, and 29863 into an APC group with a higher payment rate.

Response: Upon revisiting the assignment of codes to proposed APC groups 280, 281, and 282, and considering the concerns expressed by commenters, our medical advisors and staff concluded that collapsing the three proposed APC groups into a single group would result in a more homogeneous grouping in terms of resource use. Hence, final APC 0041 contains the codes proposed as APC groups 280, 281, and 282. The relatively low volume of many of the procedures in the proposed APCs supports combining them into a single group. Further, we found that, from a facility perspective, the resource use for all the codes in final APC 0041 is similar. For example, we had proposed to place CPT code 29881, Arthroscopy, knee, surgical; with meniscectomy (medial or lateral, including any meniscal shaving), and CPT code 29882, Arthroscopy, knee, surgical; with meniscus repair (medial or lateral), in two different APC groups. However, the resources required for these two procedures is sufficiently comparable to warrant placing both into the same APC.

APC 286: Arthroscopically-Aided Procedures

We considered including the procedures in proposed APC group 286 with the other arthroscopic procedures in final APC 0041 because they are so infrequently performed in an outpatient setting for Medicare beneficiaries. However, the resources required to perform the procedures in proposed

APC 286 are so strikingly distinct from those used in connection with the procedures in final APC group 0041 as to warrant being retained in a separate group. Further, it is unlikely that an individual provider specializes in the particular type of arthroscopic procedure contained in this APC, so separating all of the codes in final APC 042 from those in APC 041 should not disadvantage any one hospital.

APC 311: Level I ENT Procedures

APC 312: Level II ENT Procedures

APC 313: Level III ENT Procedures

APC 314: Level IV ENT Procedures

We received numerous comments about the composition of the four proposed ENT APC groups. After careful review of the comments, our medical advisors and staff recognized the need for a major reorganization of the groups we proposed for ENT procedures. The outcome of our review was the creation of five final APC groups for ENT procedures: APC groups 0251, 0252, 0253, 0254, and 0256. We moved a large number of bone procedures involving the facial and ENT areas from musculoskeletal groups to ENT groups. We transferred some codes out of the ENT groups altogether, and we shifted codes among the five final ENT groups to comply with the BBRA 1999 "two times" requirement. We respond to recommendations regarding specific codes below.

Comment: One commenter observed that CPT codes 31603 and 31605, emergency tracheostomy procedures, are risky and life-threatening no matter how quickly they are performed, and, as such, they should not be grouped with procedures for removing a foreign body from the ear canal or removing cerumen (proposed APC 311).

Response: We agree. We created new APC group 0340 to which we assigned CPT code 69200, removal of foreign body from external auditory canal; without general anesthesia, and CPT code 69210, Removal impacted cerumen (separate procedure), one or both ears. We shifted these two procedures to the Minor Ancillary Procedures APC group because of their relative high frequency, their low cost in terms of resource use with low disposable equipment cost, and because these procedures generally do not require scheduling. Removing CPT code 69210 from the final ENT groups also corrects any pricing distortions that may have resulted from the disproportionately high volume of that procedure.

We also moved the tracheostomy emergency procedures to final APC 0254.

We moved several other procedures such as CPT code 41870, Periodontal mucosal grafting, to final APC 0253, a group with higher cost procedures.

We moved several abscess drainage procedures such as CPT code 41800, Drainage of abscess, cyst, hematoma from dentoalveolar structures, to final APC group 0251 because of their relatively low cost.

Comment: One commenter stated that all the procedures in proposed APC 312 appear to be reasonably priced with the exception of CPT code 69436, Tympanostomy (requiring insertion of ventilating tube), general anesthesia. In the view of the commenter, the extra supplies and time required for this procedure necessitate a higher payment.

Response: We moved CPT code 69433, Tympanostomy (requiring insertion of ventilating tube, local or topical anesthesia), to final APC 0252 because of its lower resource use relative to CPT code 69436. CPT code 69436 is assigned to final APC 0253.

We moved a large number of procedures such as CPT code 42335, Sialolithotomy; submandibular (submaxillary), complicated, intraoral from original APC 313 to final APC 0253 to reflect a similarity of resource use. In terms of resource use, CPT code 30115, Excision, nasal polyp(s), extensive, is more similar to CPT code 42300, Drainage of abscess, parotid, simple, than it is to CPT 42410, Excision of parotid tumor or parotid gland; lateral lobe without nerve dissection.

We shifted CPT code 21040, Excision of benign cyst or tumor of mandible, from the musculoskeletal group to final APC 0253 with other ENT procedures.

Comment: One commenter stated that procedures directed towards cancer treatment were inappropriately assigned to proposed APC 313. As examples, the commenter cited CPT codes 30150 and 30160, rhinectomy procedures; CPT code 41120, Glossectomy; less than one-half tongue; and CPT code 69210, Excision external ear, complete amputation. The commenter also indicated concern that proposed APC group 313 includes a disproportionately large percentage of resource-consuming ENT procedures and commonly performed sinus procedures. Other commenters recommended that more complex otorhinolaryngology procedures in the group that have longer operating and recovery room times be moved to a group with a higher payment rate.

Response: We moved CPT code 69210 to final APC group 0340, and we assigned CPT codes 30150, 30160, and 41120 to final APC group 0256. We also moved CPT code 42215, Palatoplasty for

cleft palate; major revision to final APC group 0256.

Comment: One commenter suggested placing certain thyroid procedures in the ENT groups.

Response: While we agree that CPT code 60280, Thyroglossal cyst excisions, is somewhat similar to CPT code 42440, Excision of submandibular, submaxillary gland, we nonetheless believe that the former type of excision is more appropriately placed from a clinical perspective with other thyroid procedures.

APC 318: Nasal Cauterization/Packing

Comment: A number of commenters addressed generally the range of resource use among the procedures within this proposed APC. One commenter observed that CPT code 30901 is almost always a simple office procedure within the context of an otolaryngology practice. The same commenter indicated that CPT codes 30903, 30905, and 30906 frequently require several hours of direct physician contact and monitoring and recommended that we consider reclassifying CPT codes 30903, 30905, and 30906 to proposed APC group 332, Level II Endoscopy Upper Airway. Another commenter was concerned that CPT codes 30905 and 30906 stand out as inappropriate for this APC level because they require much more time and expertise and are used in more life-threatening situations than the other codes in the group.

Response: While there is a range of procedures in this APC pertaining to control of nasal hemorrhage, hospitals normally treat the entire range of these procedures, and there is no concentration of certain of these procedures in a subset of hospitals. Our medical advisors and staff also found that there can be a range of resource consumption within many of the procedures themselves as well as across procedures in this APC. We therefore are not reassigning the codes.

We did, however, move CPT codes 30999 and 42999 for unlisted procedures to final APC 0251 and 0252, respectively, to be consistent with our policy of placing unlisted codes in the lowest paid related group.

APC 331: Level I Endoscopy Upper Airway

Comment: One commenter noted that the relative weight and payment rate proposed for APC group 331 approximated the relative weight and payment rate proposed for APC groups 997 or 987. The commenter stated that CPT codes 31575 and 31579 should have a higher relative weight and

payment rate than that proposed for APC 331 because both procedures require more time, higher skill levels, and more equipment than the procedures in APC 997 or 987. A professional association, echoing the first commenter, noted that CPT codes 31575 and 31579 are the most complex of all noninvasive laryngeal diagnostic procedures performed by otolaryngologists and speech language pathologists, further justifying a higher relative weight and payment rate for these procedures.

Response: Proposed APC groups 997 and 987, Manipulation therapy and Subcutaneous chemotherapy, respectively, are clinically very different from proposed APC group 331. The professional skill and expertise of the physician performing the laryngoscopy are recognized separately and are not costs that are packaged with the payment rate for services furnished by the hospital in connection with the procedure. Further, it is very unlikely that there will be systematic differences among facilities with some only doing the most difficult of the basic laryngoscopies that are contained in this group and others only specializing in the simplest variety. However, we have reorganized the proposed endoscopy, upper airway groups into final APC groups 0071 through 0075 to be consistent with the BBRA 1999 "two times" requirement.

APC 341: Level I Needle and Catheter Placement

APC 342: Level II Needle and Catheter Placement

APC 343: Level III Needle and Catheter Placement

APC 347: Injection Procedures for Interventional Radiology

Based on our cost data, our medical advisors and staff determined that the codes in these proposed APC groups should be assigned status indicator "N," which designates incidental services whose costs are packaged into the APC payment rate. Injection procedures themselves are low cost but, more importantly, they are an integral portion of another procedure. The needle and catheter placement are typically an integral portion of interventional radiology procedures. An exception was made for CPT code 36420, cutdown on a child under age one, which was placed in final APC 0032, to recognize its infrequent use but high median cost.

APC 360: Removal/Revision, Pacemaker/Vascular Device

Comment: Most commenters recommended changing a number of

pacemaker codes from "inpatient only" payment status to allow payment under the hospital outpatient PPS. One commenter noted that whereas we proposed to exclude most pacemaker and implantable cardioverter defibrillator (ICD) replacement procedures from the outpatient PPS, we did include pacemaker revision/removal procedures in proposed APC 360 even though both types of procedures require very similar steps to perform. The commenter is concerned that by not paying for pacemaker replacement procedures under the outpatient PPS, we are forcing physicians to perform these replacement procedures on an inpatient basis. By so doing, the commenter suggested that we are adding costs to the entire system that could be saved, because the pacemaker replacement procedures can be safely performed in the outpatient setting, with less inconvenience to the patient.

Response: After careful consideration of commenters' recommendations, our medical advisors and staff agreed that paying for pacemaker insertion or replacement codes under the outpatient PPS is appropriate if the outpatient setting is determined to be reasonable and medically necessary for the individual beneficiary. We assigned procedures for revising or removing implanted infusion pumps and venous access ports in proposed APC 360 and pacemaker insertion or replacement codes payable under the outpatient PPS to final APCs 0089 and 0090. Also, we moved CPT code 33222, Revision or relocation of skin pocket for pacemaker, and CPT code 33223, Revision or relocation of skin pocket for implantable cardioverter-defibrillator, to final APC 0026 because the resource use for these two procedures is similar to that of the skin repair procedures in APC 0027.

APC 367: Vascular Ligation

Comment: One commenter wrote that the procedures in proposed APC 367 include ligation of major arteries and veins, which are usually performed as emergencies in the inpatient setting, and elective ligation and stripping of lower extremity varicose veins of variable complexity. The commenter contended that costs for these procedures vary dramatically, with simple ligation and division of the saphenous vein at the low end of the cost scale, and the stripping of long and saphenous veins at the high end.

Response: We split proposed APC 367 into two groups, final APCs 0091 and 0092, to conform with the BBRA 1999 "two times" requirement. Although we are not sure to which codes the comment refers, codes 37780 and 37730

are now in different groups. These represent ligation and division of the short saphenous vein, and ligation, division and stripping of long and short saphenous veins, respectively.

APC 368: Vascular Repair/Fistula Construction

Comment: Commenters disagreed with the codes assigned to proposed APC 368, especially services related to insertion of implantable hemodialysis access ports. Commenters did not find the services in APC 368 to be comparable clinically. In particular, they recommended moving cannula insertion and declotting procedures to proposed APC groups 341, 342, and 343, which consist of needle and catheter placement procedures.

Response: We split the codes in proposed APC 368 into APC groups 0088, 0090, 0092, and 0093. The resulting classifications are more clinically homogeneous, and they meet the BBRA 1999 "two times" requirement. We also moved CPT code 35875, Thrombectomy of arterial or venous graft (other than hemodialysis graft or fistula), into final APC 0088.

APC 369: Blood and Blood Product Exchange

Comments: As we noted in section III.C.2.f, above, many commenters disagreed with both our proposed payment rates and our proposed classification for blood and blood-related products. Most commenters disagreed with our classifying in one APC group therapeutic apheresis, stem cell procedures, and blood transfusion services. The commenters stated that therapeutic apheresis and stem cell procedures are very costly and resource intensive procedures which cost more than 3 times the proposed payment rate for APC 369, yet we are proposing to pay a median amount for these services that is appropriate for blood transfusions only. Commenters questioned whether we had taken into account the costs associated with the specialized equipment, supplies and personnel that are required to perform therapeutic apheresis and stem cell procedures. Commenters stated that the payment rate proposed for APC 369 would not offset the costs hospitals incur to furnish therapeutic apheresis services because outpatient apheresis procedures often combine dissimilar kinds and combinations of plasma replacement products, causing widely differing costs per service.

A major association representing community cancer centers stated that our data for stem cell harvesting claims (CPT 38231) include a range of costs so

large as to suggest that there are errors in the data. The commenter believes that the very small sample of claims (reduced by HCFA's exclusion of multiple procedure claims and claims without codes) further renders the data unreliable. The same commenter cited bone marrow harvesting (CPT 38230) as an example to argue that our data, which indicates a median cost of \$18.00 for what is normally a lengthy procedure performed under general anesthesia, are problematic.

Some commenters stated that the proposed payment rate was not sufficient for transfusion services if the rate was supposed to pay for both the blood product and the transfusion procedure, because even though outpatient transfusion services are relatively simple and low-cost, they are associated with a costly blood product that is far more variable.

Commenters expressed concern that the proposed payment rate for APC 369 was insufficient to pay for extracorporeal photopheresis (CPT 36522), whose actual cost is approximately \$1,000, and would have an especially negative impact for patients with cutaneous T-cell lymphoma.

A major organization recommended that we separate payment for a service from payment for the blood product associated with that service. The same commenter also recommends separate payment for infusible blood-derived drugs, and that payment for transfusable blood products be based on costs. This organization recommends that APC 369 be split into several APCs because payment for services such as transfusion services, therapeutic apheresis, stem cell collection, Staph column pheresis, and others are distinct, and deserve separate APC payments. The same commenter also recommended that we accelerate the HCPCS coding process for blood-related products.

Response: In response to commenters' recommendations, we are creating different APC groups for blood-related procedures and transfusions, and we are paying for blood and blood products separately, instead of packaging them with the procedures or services with which they are associated. We were convinced by commenters' illustrations of the variability in the use of blood and blood products in various procedures, and by our desire to recognize the costs of tests now being performed on donated blood that were not captured in our 1996 data. The procedures we proposed in APC 369 are split among final APC groups 0109, 0110, 0111, and 0112. We have also created individual APC groups for blood and blood related

products. The final APC 0109 that we created to capture bone marrow harvesting and bone marrow/stem cell transplant had a median cost of only \$15.00. This is due to the few, highly variable claims in our database. Based on the information available to us at this time, we have assigned a rate of \$200.00, and will adjust the rate to reflect actual claims as we collect data under PPS.

APC 407: Esophagoscopy

APC 417: Diagnostic Upper GI Endoscopy

APC 418: Therapeutic Upper GI Endoscopy

Comment: Commenters were concerned about low payment rates set for these three proposed APC groups.

Response: Our medical advisors reviewed the proposed groups and determined that combining the codes into a single APC group for upper gastrointestinal endoscopic procedures conformed with the criteria we used to define APC coherence and resulted in a reasonable payment rate supported by cost data. Resource use for all procedures in final APC 0141 is similar because each procedure involves an endoscopic examination. In addition, most of the procedures involve diagnostic and therapeutic tests such as brushings or fulgurations.

APC 426: Diagnostic Lower GI Endoscopy

APC 427: Therapeutic Lower GI Endoscopy

Comment: Commenters were concerned that the payment rates proposed for APC groups 426 and 427 were too low to offset costs incurred to perform these procedures. One commenter indicated that a diagnostic colonoscopy (CPT code 45379), without any mark up or consideration of room time and equipment use, costs \$350, with additional costs if a polyp has to be removed (\$155 just for a bicap). The commenter indicated that the current cost of a hot biopsy forceps is \$45. Given these costs, the provider would necessarily incur a loss when performing these procedures.

Response: Our medical advisors and staff, after reviewing the cost data for these two proposed groups, combined the diagnostic and therapeutic APCs into a single group, final APC 0143. Resource use for the procedures in this APC is similar because they all involve an endoscopic examination. More importantly, even though resource use may vary relative to the clinical requirements of individual cases, facilities are not likely to specialize in

just therapeutic or diagnostic endoscopic services. Therefore, costs should even out across all cases.

Comment: One commenter found the low rate proposed for CPT code 45378, Diagnostic colonoscopy, to be inconsistent with our major policy initiative to screen persons at high risk for colorectal cancer.

Response: We moved HCPCS code G0105, Colorectal Cancer Screening: Colonoscopy, to its own group, final APC 0158, because it is preventive rather than diagnostic or therapeutic in nature.

APC 446: Diagnostic Sigmoidoscopy

APC 447: Therapeutic Proctosigmoidoscopy

APC 448: Therapeutic Flexible Sigmoidoscopy

We reassigned the different types of sigmoidoscopy procedures into two groups, final APC 0146 and final APC 0147. The procedures within each group are similar both clinically and in terms of resource use. We moved HCPCS code G0104, CA screening; flexible sigmoidoscopy, to its own group, final APC 0159, because it is preventive rather than diagnostic or therapeutic in nature.

APC 451: Level I Anal/Rectal Procedures

APC 452: Level II Anal/Rectal Procedures

To conform with the BBRA 1999 "two times" requirement, our medical advisors and staff reclassified procedures in the proposed APC groups resulting in final APC groups 0148 and 0149. We believe the final APC groups are more consistent both clinically and in terms of resource use.

APC 470: Tube Procedures

Comments: We split the codes in proposed APC group 470 into final APC groups 0121, 0122, and 0123 to conform with the BBRA 1999 "two times" requirement. Also, we moved CPT code 50398, Change of nephrostomy or pyelostomy tube, from proposed APC 521 to final APC 0122.

APC 523: Level III Cystourethroscopy and Other Genitourinary Procedures

Comment: A number of commenters recommended moving CPT code 52240, Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; large bladder tumor(s), to the APC for Level IV Cystourethroscopy and other Genitourinary Procedures because the magnitude of the procedure most

closely resembles that of the codes in the higher payment group.

Response: We agree with commenters' recommendations; we moved CPT code 52240 to final APC group 0163 because of the extensive time and equipment required to perform the procedure.

Comment: One commenter recommended placing CPT codes 52335 through 52338 in their own group, given the complexity and technical demands of these ureteroscopic procedures. The same commenter suggested as an acceptable alternative placing these codes in the APC group for Level IV Cystourethroscopy and other Genitourinary Procedures, to reflect more accurately their cost, complexity, and need for expensive single use items such as dilation balloons, baskets and stents. Other commenters recommended moving CPT codes 51020 through 51880 (cystotomy procedures) to the APC group for Level IV Cystourethroscopy and other Genitourinary Procedures.

Response: After a careful review of comments and our cost data, our medical advisors and staff concluded that the cystotomy codes are similar enough in terms of equipment and the time required to perform the procedures to justify keeping them together in final APC 162. Our medical advisors and staff also concluded that the facility equipment and time duration for CPT code 52335, Cystourethroscopy, with ureteroscopy and/or pyeloscopy (includes dilation of the ureter and/or pyeloureteral junction by any method), was sufficiently similar to be retained with the other procedures in final APC 0162.

APC 524: Level IV Cystourethroscopy and other Genitourinary Procedures

Comment: Numerous commenters were concerned that the payment rate proposed for APC 524 was insufficient to offset the costs associated with CPT code 53850, Transurethral destruction of prostate tissue, by microwave thermotherapy (TUMT). The commenters argue that TUMT is a very expensive procedure due to its high capital equipment costs and the need to construct a special microwave area, the high cost of disposable probes and other disposable supplies required for the procedure, and the need for specially trained nursing staff. The commenters urged us to establish a unique APC group for this procedure and to provide a payment rate that is consistent with its anticipated costs, which they predict would total approximately \$2,200.

Response: After careful consideration of comments and available cost data, our medical advisors and staff determined that CPT code 53850

satisfies the criteria discussed below, in section III.C.8, as a new technology service. Payment for this procedure will be made under new technology APC 0980.

APC 529: Simple Urinary Studies and Procedures

Comment: A number of commenters proposed that we classify CPT code 51726, Complex cystometrogram, to its own unique APC and keep the other urinary study procedures together in proposed APC 529.

Response: After a careful review of comments and our data, our medical advisors and staff agreed with commenters' concerns and subdivided proposed APC group 529. The resulting final APC groups 0164 and 0165 are more homogeneous both in terms of clinical coherence and resource use. We also added simple anal procedures such as CPT code 91122, Anorectal manometry, to final APC 0165 because of the similarity of resource use.

APC 546: Testes/Epididymis Procedures

Comment: A number of commenters disagreed with our classification of scrotal procedures with inguinal procedures in proposed APC group 546. The commenters observed that the scrotal procedures vary considerably from the inguinal procedures in terms of resource usage. The commenters recommended that we move CPT codes 54530, 54550, 54640, 55520, 55530, 55535 and 55540 to proposed APC 466, Hernia/Hydrocele Procedures, because they all involve operating on vessels at the internal ring, and are therefore similar to a hernia repair.

Response: We agree with comments that these procedures are similar to hernia repairs. We moved CPT codes 54530, 54550, 54640, 55535, and 55540 to final APC group 0154.

APC 551: Level I Laparoscopy

APC 552: Level II Laparoscopy

Comment: We received two categories of comments pertaining to laparoscopic procedures: Numerous commenters disagreed with our proposal to define certain laparoscopic procedures as inpatient only, and numerous commenters claimed that the resource costs among the procedures within proposed APC groups 551 and 552 varied too greatly for the groups to be considered homogeneous. Most commenters stated that the costs associated with the procedures in proposed APC groups 551 and 552 exceed their respective proposed payment rates because of the expensive equipment and disposable supplies and

the length of time required to perform laparoscopic procedures.

Response: Our medical advisors and staff, after a thorough review and consideration of comments, agreed with commenters who claimed that most laparoscopic procedures can and are being safely and appropriately performed in an outpatient setting. We therefore moved most of the laparoscopic codes to which we proposed to assign a payment status indicator "C," indicating that the procedures would not be covered under the hospital outpatient PPS, into an APC group with a payment status indicator "T" (significant procedure, multiple procedure reduction applies, payable under the outpatient PPS). In order to absorb these additional procedures within the APC system, we created a third laparoscopic APC group in order to accommodate the wide range of resource use and time that is required to perform the expanded list of laparoscopic procedures.

Although the AMA revised the coding of laparoscopic procedures in CPT 2000, in order to set rates for the laparoscopy APC groups, we used the codes that were in our database of 1996 claims. That is, we moved CPT codes 56362 and 56363 to the Level I laparoscopic group, final APC group 0130, because the resources used in connection with these procedures are less compared to the Level II procedures generally. For example, CPT code 56362, Laparoscopy with guided transhepatic cholangiography, primarily involves the laparoscopy without any associated removal of tissue. Conversely, we shifted CPT codes 56303 and 56304 from Level I to Level II (final APC 0131). CPT code 56303, Laparoscopy, surgical, with fulguration or excision of lesions of the ovary, pelvic viscera, or peritoneal surface, requires more resources than, for example, CPT code 56300, Diagnostic laparoscopy, the most common laparoscopic procedure within Level I, final APC group 0130.

The new Level III laparoscopy group, final APC group 0132, consists largely of laparoscopic procedures that we had proposed to classify as inpatient. In addition, we moved CPT code 56312, Laparoscopy, surgical; with bilateral total pelvic lymphadenectomy, and CPT code 56313, Laparoscopy, surgical; with bilateral total pelvic lymphadenectomy and peri-aortic lymph node sampling (biopsy), single or multiple, to final APC group 0132 because of the extensive resources and time involved in performing these procedures. Refer to Current Procedural Terminology 2000, published by the American Medical Association, for a summary of coding

changes and crosswalks for laparoscopic procedures.

APC 561: Level I Female Reproductive Procedures

APC 562: Level II Female Reproductive Procedures

APC 563: Level III Female Reproductive Procedures

Comment: One commenter expressed concern that the payment rate for proposed APC group 563 would have a negative effect on certain treatment options for women suffering with incontinence. The commenter contrasted the proposed payment of \$848 with a current median cost calculated at \$1,931 for CPT code 57288, Sling operation for stress incontinence (e.g., fascia or synthetic).

Response: After reviewing the procedures in proposed APCs 561, 562, and 563, and to be consistent with the BBRA 1999 "two times" requirement, we split the proposed groups into final APCs 0191 through 0195. The cost of CPT code 57288, to which the commenter refers, is still at the high end of the highest weighted group, but the volume of claims for that service is so low that splitting the group again would be problematic. If these more intense surgeries move to the outpatient setting in greater numbers, we will be able to price them more precisely.

APC 601: Level I Nervous System Injections

APC 602: Level II Nervous System Injections

Comment: Commenters contended that there are no similarities among the procedures in the proposed APC groups for nervous system injections.

Response: We disagree. We find the range of services included within each APC group to be generally consistent from a clinical perspective. And, even though an injection into the subarachnoid space may be a more complex injection than some of the others in the group, no institution is likely to specialize solely in one kind of injection. Because all the services within the APC group are offered by most hospitals, the impact of the variation in resource consumption among the different codes should average out at the hospital level. Therefore, we are keeping intact in final APC groups 0211 and 0212 the two levels of nervous system injections that we proposed, with the exception of CPT codes 62194 and 62225, which we moved to final APC group 0121 because they are catheter replacement procedures.

APC 616: Implantation of Neurostimulator Electrodes

APC 617: Revision/Removal Neurological Device

APC 618: Implantation of Neurological Device

Comment: One commenter was concerned that the payment rate proposed for APC group 616 falls far short of the costs incurred to implant a neurostimulator system that embodies a vagus nerve stimulator for the treatment of patients with refractory epilepsy. The commenter estimated that hospitals incur costs between \$2,000 and \$5,000 to surgically insert the Neurocybernetic Prosthesis system (NCP), which includes an implantable neurostimulator, pulse generator, and implantable electrodes. The commenter stated that the NCP costs \$9,100. The commenter recommended that we create a separate APC group for the procedure to ensure appropriate payment. The commenter also expressed concern that the broad range of procedures in proposed APC 618 results in inappropriate payment rates. The commenter noted that the median cost of the procedures in proposed APC group 618 varies from a low of \$269.44 to a high of \$3,890.70, with a proposed payment rate of \$1,274.

Another commenter stated that vagus nerve stimulation, approved by the FDA in 1997, which can sometimes be performed as an outpatient procedure, would be inappropriately paid under our PPS. The commenter stated that the reported cost for the device is \$6,900 for the implantable neurostimulator pulse generator and \$2,030 for the implantable vagus nerve stimulator leads. A manufacturer of this new system, which is used in treating intractable epilepsy, also expressed concern that the proposed PPS will underpay hospitals for new technologies such as its system and deny beneficiaries access to them.

Response: In response to these and other comments, we made several changes in proposed APC groups 616, 617, and 618. We moved CPT code 63650, Percutaneous implantation of neurostimulator electrodes, peripheral, to final APC 0224 because the procedure is less time intensive and uses fewer facility resources than the implant procedures in final APC 0225. We also shifted CPT codes 64585 and 64595 to final APC 0225. We will re-evaluate APCs 0223, 0224, and 0225 as we accumulate data and will incorporate our findings in a subsequent hospital outpatient PPS rule. Additionally, we will determine whether the implantable neurostimulator system is eligible for

treatment as a "pass-through" device under section 201(b) of the BBRA 1999. The criteria for assessing a medical device's eligibility for additional payment under this provision are discussed in section III.D.4, below.

Ophthalmic Procedures: We received numerous comments concerning the APC groups proposed for eye procedures. Based on their analysis of these comments and recommended changes, a review of our data, and consideration of the limit on variation within a group required by section 201(g) of the BBRA 1999, our medical advisors and staff have significantly restructured the ophthalmic APC groups. Eye procedures and services are assigned to final APC groups 0230 through 0248.

APC 930: Minor Eye Examinations

APC 931: Level I Eye Tests

APC 932: Level II Eye Tests

We assigned to final APC groups 0230 and 0231 the procedures in proposed APC groups 930, 931, and 932 in addition to codes from proposed APC groups 681, 682, and 683 that are either tests or minor ophthalmologic procedures requiring relatively low resource use.

APC 651: Level I Anterior Segment Eye Procedure

APC 652: Level II Anterior Segment Procedure

Comment: We received a number of comments about these proposed APC groups. Commenters were primarily concerned that the payment rates proposed for the two levels of anterior segment eye procedures are significantly less than the costs incurred to perform the procedures assigned to these groups, especially those for glaucoma surgery (CPT codes 66150 through 66170). One commenter indicated that the rate proposed for CPT 66180 is acceptable only if separate payment is made for the aqueous shunt and patch graft.

Response: Based on their review of comments and to be consistent with the BBRA 1999 "two times" requirement, our medical advisors and staff added a third APC group for anterior segment eye procedures. The anterior segment eye procedures are assigned to final APC groups 0232, 0233, and 0234. We made a number of code changes among the three groups. We moved CPT codes 66155, 66160, 66165, and 66170 for glaucoma surgery to final APC group 0234. We shifted CPT code 65800, Paracentesis of anterior chamber of eye (separate procedure) with diagnostic aspiration of aqueous, from proposed APC 683 to final APC 0232 because the

instruments used in connection with CPT code 65800 are similar to those used in all procedures that are primarily paracentesis and because operating room time is likewise similar.

APC 667: Cataract Procedures

APC 668: Cataract Procedures With IOL Insert

Based on our data, the median cost for final APC group 0245 (cataract extraction without lens insert) was slightly higher than that for final APC group 0246 (cataract extraction with lens insertion). We attribute the discrepancy to poor coding, and we have increased the payment rate for APC group 0246 to equal the payment rate for APC group 0245. Proper coding in the future should result in better differentiated costs between these two groups.

Comment: One commenter objected to assigning payment status indicator "T," Significant procedure, multiple procedure reduction applies, to the procedures in proposed APC group 668. The commenter contended that CPT code 66984, Cataract removal with lens insertion, is often performed in conjunction with other procedures such as CPT code 67010, partial removal of eye fluid, CPT code 65875, incise inner eye adhesions, and 66170, Glaucoma surgery, which also have a "T" payment status indicator. The commenter believes that the multiple procedure reduction would undercompensate for these services and that all these procedures should be given an "S" payment status indicator, which would not subject them to the multiple procedure discount.

Response: We disagree. When more than one surgical procedure is performed during a single operative session, full Medicare payment and the full beneficiary coinsurance payment are made for the procedure that has the highest payment rate. The costs associated with anesthesia, operating and recovery room use, and other services for any additional procedures are incremental and are accounted for within the discounted additional payment.

APC 670: Corneal Transplant

Comment: The numerous comments that we received about this proposed APC focused on our proposal to package the cost of procuring corneal tissue as part of the costs associated with corneal transplant surgery. Commenters feared that this fixed payment method would underpay some hospitals while overpaying others because hospitals acquire corneal tissue from eye banks

whose charges are dependent upon the amount of philanthropic contributions the bank receives during the course of a year. A national association representing eye banks reported that fee data from different member facilities show that the corneal tissue acquisition fee alone nearly consumes or, in some cases, exceeds, the entire payment rate proposed for APC group 670. Commenters expressed great concern that we would significantly reduce the supply of corneas available for transplant if we were to package corneal tissue acquisition costs within the APC rate.

Response: Given the current basis for pricing corneal tissue, we are accepting commenters' recommendations that corneal tissue acquisition costs be paid separately and in addition to the payment rate for corneal transplant procedures. At least until we gather data regarding costs associated with the acquisition of corneal tissue, this will ensure that individual hospital's reasonable corneal tissue procurement costs are covered under the PPS. Corneal transplant procedures are in final APC group 0244.

APC 676: Posterior Segment Eye Procedures

Comment: Commenters were concerned that the payment rate for proposed APC group 676 was too low given the costs incurred to perform a number of procedures in the group. For example, one commenter noted that CPT code 67005 requires the same draping as a cataract extraction.

Response: In response to commenters' concerns and to be consistent with the BBRA 1999 "two times" requirement, we split the procedures in proposed APC group 676 into final APC groups 0235 through 0237. We also moved procedures such as CPT code 67025, Replace eye fluid, and CPT code 67027, Implant eye drug system, to final APC 0237 because of the similarity of resource use. CPT code 67025 involves injection of a vitreous substitute, usually gas, silicone, or a similar substance, and the procedure may also involve an aspiration.

APC 681: Level I Eye Procedure

APC 682: Level II Eye Procedure

APC 683: Level III Eye Procedure

APC 684: Level IV Eye Procedure

Comment: Commenters were concerned about the wide variation of resource use and clinical characteristics among the procedures within proposed APC groups 681, 682, 683, and 684. Commenters noted that the surgical complexity of individual procedures in

proposed APC group 684 ranges from simple suturing (CPT code 67914, Repair of ectropion; suture) to complex eyelid reconstructions with full thickness tarsoconjunctival flap transfer (CPT code 67971). Commenters recommended that these proposed APC groups be revised and that the more complex procedures that require longer operating room time be paid a higher rate.

Response: We agree. Guided by commenters' recommendations as well as the "two times" limit on cost variation required by the BBRA 1999, we created several new groups and we completely reorganized the procedures in proposed APC groups 681, 682, 683, and 684 into the final APC groups 0230 through 0234 and 0238 through 0242.

APC 690: Vitrectomy

Comment: Several commenters were concerned that the cost of an intravitreal implant (\$4,000, according to one commenter) would not be adequately recognized if payment for the device were to be packaged with payment for the insertion procedure (CPT code 67027, Implant eye drug system). Commenters were concerned that beneficiary access to this implant would be restricted if we did not make adequate payment. Commenters supported our proposal to make separate payment for the intravitreal implant.

Response: We assigned all of the procedures in proposed APC 690 to final APC group 0237. As we explain in section III.B.1.c, above, section 201(e) of the BBRA 1999 requires us to classify implantable items to the group that includes the service to which the item relates. However, the intravitreal implant that dispenses ganciclovir is an orphan drug that qualifies for a transitional pass-through payment under the BBRA 1999, which is explained in section III.D, below. Thus, we have assigned the entire drug delivery system to its own APC, 0913. We believe that the payment rate set for CPT code 67027 combined with the additional payment for ganciclovir results in an appropriate payment for this service.

APC 700: Plain Film

Comment: We received numerous comments about the structure of proposed APC group 700. Commenters recommended breaking down the proposed APC group into a number of smaller, more congruous groups. For example, one commenter found no justification for the assumption that resource costs are the same for all plain films listed in APC 700, noting that

there is a significant difference in capital costs, room costs, and maintenance costs between an x-ray room that is designed to take chest x-rays compared to an x-ray room with a table used to take abdominal x-rays. The commenter pointed out that there is a substantial increase in cost when cineradiography capabilities are added. The same commenter questioned our assumption that therapeutic radiology port films are clinically similar to diagnostic radiology films or that bone density studies are clinically similar to and have the same resource costs as plain film radiography.

Response: We agree with commenters' concerns about the composition of proposed APC group 700. In response to commenters' recommendations and applying the "two times" limit on cost variation required by the BBRA 1999, we split proposed APC group 700 into final APC groups 0260 through 0262. We assigned CPT code 70300, Radiologic examination, teeth; single view; CPT code 70310, Radiologic examination, teeth; partial examination, less than full mouth; and, CPT code 70320, Radiologic examination, teeth; complete, full mouth, to their own group, final APC group 0262, because these procedures require minimal time and relatively little radiographic film and technical equipment. We classified the remaining codes to final APC groups 0260 and 0261. We believe that these two groups are sufficient to distinguish clinical consistency and similar resource use. Facilities perform, relatively, a similar proportion of the different plain film procedures, and hospitals do not systematically use one type of plain film over another type, with the exception of dental films, which we moved to a separate group. The absolute magnitude of the difference in resource use among different plain films is not as significant as the difference between dental and other types of plain film. Additionally, our data indicate minimal differences in the amount of resource use between bone density measurement tests and plain films.

APC 706: Miscellaneous Radiological Procedures

Comment: A number of commenters found the tests grouped in proposed APC group 706 to vary significantly in the amount of time, effort, and costs required to provide the service.

Response: As a result of applying the "two times" limit on cost variation required by the BBRA 1999, we divided proposed APC 706 into two levels: final APC 0263 and final APC 0264. We also moved CPT code 76075, Bone Density

Study, one or more sites, to final APC 0261. We explain below, in section III.C.6.e, why we are making an exception to the BBRA 1999 "two times" limit on cost variation in the case of final APC group 264.

APC 710: Computerized Axial Tomography

APC 720: Magnetic Resonance Angiography

APC 726: Magnetic Resonance Imaging

Comment: A number of commenters believe that assigning all computerized axial tomography (CAT) to a single group and all magnetic resonance imaging (MRI) to a single group results in a lack of homogeneity among the procedures within each group. These commenters were concerned that we ignored the cost of contrast materials, labor, and equipment within proposed APC group 710 and proposed APC group 726 and that combining contrast and non-contrast studies represents an inconsistency in resource use because an examination that uses contrast will be more costly than one without contrast. One commenter observed that an MRI examination with the use of contrast material requires approximately 30 percent more time and effort than an examination performed without contrast material and that a bilateral examination requires 50 percent more staff time and effort to complete. The same commenter expressed concern that proposed APC 720 consists of only one procedure, CPT code 70541, Magnetic image, head (MRA). The commenter recommended that we place this code and the other MRA codes that we now cover into two APC groups, one with and the other without contrast. A number of commenters recommended that we pay separately for contrast material, as a cost pass-through. One commenter believes that including diagnostic studies with placement of radiation therapy fields in proposed APC 710 violates the "clinically similar" criterion.

Response: Our medical advisors and staff carefully reviewed our data for the procedures in proposed APC group 710, proposed APC group 720, and proposed APC group 726 in light of commenters' concerns about the extent to which these groups take into account the costs associated with the use of contrast material. We concluded that costs associated with the use of contrast material are reflected in the payment rate in proportion to its frequency of use. We believe it is reasonable to have the CAT scans and MRIs with and without contrast together in their respective APC groups because facilities do not specialize based on whether or

not they use contrast material. Further, the cost of contrast material relative to the overall inherent cost of CAT scans and MRI procedures alone is small. Moreover, the use of contrast material with CAT scans and MRI procedures differs significantly when compared to the use of contrast with plain films. Contrast comprises a significant portion of the cost of plain film services, and not all facilities perform plain films with contrast. A plain film can be ordered without being scheduled, but any plain film with contrast has to be scheduled. This scheduling distinction does not apply to a CAT or MRI scan with or without contrast. We did find that applying the "two times" limit on cost variation required by the BBRA 1999 resulted in the creation of two CAT groups, final APC groups 0282, to which we assigned CPT codes 70486, 76370, 76375, and 76380, and final APC 0283, to which the remaining codes in proposed APC group 710 are assigned. We further eliminated proposed APC group 720 and combined CPT code 70541, Magnetic image, head (MRA), with the other MRI procedures in final APC group 0284 because the base procedure, magnetic resonance imaging, is the same.

APC 716: Fluoroscopy

Comment: A number of commenters recommended that we pay separately for the fluoroscopy portion of procedures that include this radiologic service.

Response: We have assigned payment status indicator "X" to the procedures in final APC groups 0272 and 0273 to indicate that these are ancillary services that are paid separately under the hospital outpatient PPS.

Comment: A professional society commented that CPT code 74340, X-ray guide for GI tube, requires approximately 10 times the amount of radiologic technologist and room time, approximately 15 times the amount of film and many more supplies than does CPT code 71023, Chest x-ray and fluoroscopy. The commenter recommended that we divide proposed APC 716 into three separate and distinct levels based on the extent of the procedures and that we recalculate the relative weight and associated payment rate for the resulting groups.

Response: We disagree with the commenter. Our medical advisors and staff, after reviewing the procedures in proposed APC group 716, concluded that the fluoroscopic portion of these procedures is sufficiently similar in terms of clinical characteristics and resource requirements to be grouped together. However, applying the "two times" limit on cost variation required

by the BBRA 1999 results in the formation of two groups, final APC groups 0272 and 0273.

APC 728: Myelography

Comment: Commenters objected to assigning the same payment amount to procedures regardless of whether or not a contrast agent is used. One commenter was concerned that this payment policy will dissuade hospitals from utilizing contrast agents even in cases where the use of contrast is medically appropriate.

Response: We agree that median costs vary more among the procedures in proposed APC 728 than their clinical similarities would suggest. However, although we found that final APC group 0274 did not satisfy the "two times" limit on cost variation required by the BBRA 1999, we are making an exception in this case as we explain below, in section III.C.6.e., and we are retaining all myelographic procedures in final APC 0274.

APC 730: Arthrography

Comment: Some commenters suggested reassigning various arthrographic procedures that were assigned to proposed APC 730.

Response: We find the procedures in this group to be sufficiently homogeneous in terms of clinical definition and resource use. The procedures are comparable with respect to the use of resources in that the highest median cost procedure is less than twice the lowest median cost procedure, consistent with the standard set by the BBRA 1999. Therefore, we are retaining the proposed grouping of arthrographic procedures in final APC 0275.

APC 736: Digestive Radiology

To be consistent with the limit on cost variation required by section 201(g) of the BBRA 1999, we divided the procedures in proposed APC 736 into final APC groups 0276 and 0277.

APC 738: Therapeutic Radiologic Procedures

To be consistent with the limit on cost variation required by section 201(g) of the BBRA 1999, we split the procedures in proposed APC 738 into final APC groups 0296 and 0297.

APC 739: Diagnostic Angiography and Venography

Comment: Numerous commenters expressed concern about the lack of homogeneity among procedures in proposed APC 739. One commenter recommended that we divide proposed APC 739 into three groups: one for CPT code 75790, Angiography, arteriovenous

shunt; one for all other angiography procedures; and one for venography procedures.

Response: In response to these comments, we created final APC group 0281, Venography of Extremity, to reflect the significant clinical and resource consumption differences between venographic procedures performed on extremities and diagnostic angiography and venography performed on other parts of the body. Venographic procedures on the extremities consume less time and fewer resources than other angiography and venography procedures. To be consistent with the limit on cost variation required by the BBRA 1999, we split the other procedures in proposed APC 739 into final APC groups 0279 and 0280. With respect to final APC group 0279, we explain in section III.C.6.e why we are making an exception to the BBRA 1999 limit on cost variation.

APC 747: Diagnostic Ultrasound Except Vascular

Comment: A number of commenters suggested that we restructure proposed APC group 747 according to body site because the APC criterion of clinical homogeneity is violated by including within one group body sites that range from the eye to the pregnant uterus to the scrotum and contents.

Response: Our medical advisors and staff carefully weighed the suggestion of commenters that clinical homogeneity would be better served if the procedures in proposed APC group 747 were divided into groups according to body site. We concluded that resource costs based on the type of technology used are what primarily dictates the definition of groups for various diagnostic services. Thus, we did not assign plain film of the chest in the same APC group with MRI of the chest. Because ultrasound is the type of technology common to all procedures in proposed APC group 747 and because resource use for the various procedures is similar irrespective of body site, we did not break this group up according to body site. However, to be consistent with the limit on cost variation required by the BBRA 1999, we split the procedures in proposed APC 747 into final APC groups 0265 and 0266.

APC 749: Guidance Under Ultrasound

Although there is a range of sites for the procedures in proposed APC group 749, as we explain above in our response to the comments submitted in connection with proposed APC 747, we are keeping this group intact in final APC group 0268 because the base procedure, ultrasonography, is the same

for all procedures. Also, the procedures in final APC group 0268 are comparable with respect to the use of resources in accordance with the "two times" limit on cost variation.

APC 750: Therapeutic Radiation Treatment Planning

Comment: Commenters were concerned that radiation physics services are not appropriately recognized in proposed APC group 750. One commenter observed that proposed APC 750 lacks clinical homogeneity by including HCPCS codes for calculations and computer-based treatment planning with codes for the construction of treatment devices. Another commenter objected to including CPT codes 77261, 77262, 77263, 77431, and 77432 in proposed APC 750 because these codes are for professional services only and do not include a technical or facility component. As such, there are no facility costs associated with the codes. The commenter noted that if these codes were removed from proposed APC group 750, three medical physics consultation codes, CPT codes 77336, 77370, and 77399 would remain in the group. The commenter suggested that the resource requirements for two of the three remaining codes are dramatically different.

Response: We agree with commenters' concerns about proposed APC group 750, and we modified this group accordingly. First, we assigned payment status indicator "E," which designates certain items and services that are not paid under the hospital outpatient PPS, to five codes that describe professional services, which would not be billed by hospitals: CPT code 77261, Therapeutic radiology treatment planning; simple; CPT code 77262, Therapeutic radiology treatment planning; intermediate; CPT code 77263, Therapeutic radiology treatment planning; complex; CPT code 77431, Radiation therapy management with complete course of therapy consisting of one or two fractions only; and CPT code 77432, Stereotactic radiation treatment management of cerebral lesion(s) (complete course of treatment consisting of one session).

We renamed the remaining group of codes as final APC 0311, Radiation Physics Services. The codes specific to radiation physics that we classified in this APC are CPT code 77336, Continuing medical physics consultation, including assessment of treatment parameters, quality assurance of dose delivery, and review of patient treatment documentation in support of the radiation oncologist, reported per week of therapy; CPT code 77370, Special medical radiation physics

consultation; and CPT code 77399, Unlisted procedure, medical radiation physics, dosimetry and treatment devices, and special services.

APC 751: Level I Therapeutic Radiation Treatment Preparation

APC 752: Level II Therapeutic Radiation Treatment Preparation

Comment: One commenter objected to including CPT code 77295, Therapeutic radiology simulation-aided field setting; three-dimensional, in proposed APC 752 because this service has dramatically different resource requirements than the other CPT codes in group. Another commenter believes that the resources used in connection with simple intracavitary applications, which are normally performed with re-usable Cs-137 sources, are totally dissimilar from the resources required for remote afterloading high intensity brachytherapy in proposed APC 751. This commenter noted that the equipment and room costs associated with remote afterloading high intensity brachytherapy may well exceed \$500,000.

Response: We agree. In response to commenters' concerns, we made a number of modifications to proposed APC group 751 and proposed APC group 752. First, we assigned payment status indicator "E," which designates certain items and services that are not paid under the hospital outpatient PPS, to CPT code 77299, Unlisted procedure, therapeutic radiology clinical treatment planning, thereby removing it from an APC group.

We created final APC group 0303, which consists of the following three codes: CPT code 77332, Unlisted procedure, therapeutic radiology clinical treatment planning; CPT code 77333, Treatment devices, design and construction; intermediate (multiple blocks, stents, bite blocks, special bolus); and, CPT code 77334, Treatment devices, design and construction; complex (irregular blocks, special shields, compensators, wedges, molds or casts). We created final APC 0303 because the resources needed for device construction are unique. We decided to put these three codes together in one group rather than assigning each to its own individual group because we could make no clear cost distinctions among the three codes and because we expect that facilities do not specialize in one type of device over another, but rather construct all of the types of devices encompassed within the three codes.

We created final APC group 0310, to which we assigned CPT code 77295,

Therapeutic radiology simulation-aided field setting, three-dimensional. We assigned CPT code 77295 to its own individual APC group because it requires significantly greater resource consumption than the procedures in either final APC group 0304 or final APC group 0305.

We assigned the codes remaining in proposed APC groups 751 and 752 to final APC groups 0304 and 0305. Both APC groups 0304 and 0305 are comparable with respect to the use of resources in accordance with the "two times" requirement set by the BBRA 1999.

APC 757: Radiation Therapy

Comment: We received a number of comments about the assignment to proposed APC 757 of CPT code 61793, Stereotactic radiosurgery, particle beam, gamma ray or linear accelerator, one or more sessions. Commenters indicated that CPT code 61793 is clinically distinct from other forms of radiation treatment delivery and that this service generally involves significantly greater treatment time and costs. One commenter stated that if we were to keep CPT code 61793 in proposed APC 757, we would be prejudicing use of this new, proven technology. Another commenter contended that radiation therapy is not the same as a surgical procedure. The commenter urged us to separate stereotactic radiation therapy (SRT) and intensity-modulated radiation therapy (IMRT) services from the conventional radiation therapy procedures in APC 757 and to assign them a higher payment rate due to their higher cost.

Response: We created final APC group 0302, to which we assigned stereotactic radiosurgery, which requires significantly more costly resources than the procedures assigned to final APC groups 0300 and 0301. Note that we have created two codes, G0173 and G0174, to use in place of CPT code 61793. They represent stereotactic radiosurgery completed in one session, and that which requires multiple sessions, respectively. We also assigned CPT code 77470 to APC 0302, since we believe it requires resources similar to those required for radiosurgery. We will continue to track the data for these codes to ensure their proper placement. The procedures in final APC group 300 and in final APC group 301 are comparable with respect to the use of resources in accordance with the "two times" limit on cost variation.

APC 759: Brachytherapy and Complex Radioelement Applications

Comment: One commenter expressed concern because we did not identify a payment amount for the radioactive seeds used in brachytherapy. Another commenter referred to low dose rate interstitial brachytherapy that is used to treat complex gynecologic tumors, prostate cancers, and head and neck cancers, noting that this type of radiation therapy employs single-use radioactive sources (iodine, gold, iridium, and palladium seeds) and various disposable applicators. The commenter pointed out that only a limited number of vendors produce these radioactive sources and that the seeds cost as much as \$200 each with the number of implants varying depending on the size, stage, and location of the cancer. The commenter stated that some patients with prostate cancer may require as many as 100 to 150 seeds. The commenter asserted that we have not captured the costs of these radiopharmaceuticals in the APC payment.

Response: We have changed how we pay for brachytherapy and the other services we proposed to classify to APC 759 in response both to comments and to the provisions of section 201(b) of the BBRA 1999, which provide for an additional payment to be made for innovative medical devices, including "a (current) device of brachytherapy." (See section III.D., below.) Within this framework, we recognize the seeds provided during brachytherapy. For bill processing purposes, we have assigned brachytherapy seeds to APC 0918. We will make payment for brachytherapy seeds under the transitional pass-through rules explained in section III.D., below.

Based on commenters' suggestions, a review of our data, and the BBRA 1999 "two times" requirement, we have classified the procedures in proposed APC 759 in final APC 0312, Radioelement Applications, and final APC 0313, Brachytherapy. APC 0313 consists of CPT code 77781, Remote afterloading high intensity brachytherapy; 1-4 source positions or catheters; CPT code 77782, Remote afterloading high intensity brachytherapy; 5-8 source positions or catheters; CPT code 77783, Remote afterloading high intensity brachytherapy; 9-12 source positions or catheters; CPT code 77784, Remote afterloading high intensity brachytherapy; over 12 source positions or catheters; and, CPT code 77799, Unlisted procedure, clinical brachytherapy. Because these

procedures are all different types of brachytherapy, final APC 313 is more coherent clinically than was proposed APC 759.

We moved CPT code 77750, Infusion or instillation of radioelement solution, to final APC 301, Level II Radiation Therapy, and CPT code 77789, Surface application of radioelement, were moved to final APC 300, Level I Radiation Therapy. The remaining procedures from proposed APC 759 constitute final APC 312, Radioelement Applications. The procedures in final APC group 312 and in final APC group 313 are comparable with respect to the use of resources in accordance with the "two times" limit on cost variation.

APC 761: Standard Non-Imaging Nuclear Medicine

APC 762: Complex Non-Imaging Nuclear Medicine

APC 771: Standard Planar Nuclear Medicine

APC 772: Complex Planar Nuclear Medicine

APC 781: Standard SPECT Nuclear Medicine

APC 782: Complex SPECT Nuclear Medicine

APC 791: Standard Therapeutic Nuclear Medicine

APC 792: Complex Therapeutic Nuclear Medicine

Comment: We received numerous comments about the proposed nuclear medicine APC groups. Commenters addressed what they believe to be discrepancies in the payment weights among the proposed groups. Commenters also asserted that the proposed payment levels are inadequate to offset the cost of radiopharmaceuticals. They believe, in part, that our use of single-procedure claims in constructing our database failed to capture the costs associated with the various radiopharmaceuticals that may be used in combination during multiple procedures performed during a single session on various patients. One commenter disagrees with our decision to consider therapeutic radiopharmaceuticals and radionuclides as incidental services, bundling their costs into nuclear medicine and radiation therapy procedures. The commenter recommended that we develop unique APC groups for radiopharmaceuticals and radionuclides. One manufacturer expressed particular concern about our proposed payment for a radiopharmaceutical used to relieve the pain of bone metastasis (CPT code

79400) that we proposed to package into APC 791 for which the proposed payment was \$758. The commenter stated that this new radiopharmaceutical, which has generated a very high clinical response rate, costs more than \$2,000 per dose.

Response: In response to these and other comments, as well as the changes made by the BBRA 1999 to the outpatient PPS, our medical advisors and staff have reconstructed the nuclear medicine APC groups. First, we have placed radiopharmaceuticals into a separate set of APC groups that are listed in Addendum K. As we state above, new section 1833(t)(6) of the Act provides for additional payment for current and new radiopharmaceuticals. We list in Addendum K those radiopharmaceuticals that are eligible for additional payment effective with services furnished on or after July 1, 2000. In accordance with the process outlined below, in section III.D.4, we invite requests to consider other radiopharmaceuticals as potential candidates for additional pass-through payments.

Next, we reconfigured the nuclear medicine APC groups based on the resources required for the procedures themselves, exclusive of costly radiopharmaceuticals. We took into account the fact that SPECT equipment, which costs significantly more than the non-SPECT equipment that was initially used most frequently for planar medicine, is now commonly used to conduct planar studies. As a final step, we further reorganized the groups to satisfy the requirement set by the BBRA 1999 "two times" requirement, resulting in final APC groups 0286, 0290, 0291, 0292, 0294, and 0295.

Comment: We received a number of comments concerning the clinical efficacy of iodine 131 tositumomab in the treatment of cancer. One commenter stated that iodine 131 tositumomab, which was reported to be pending final FDA approval, has the potential to be the first radioimmunotherapeutic agent to be approved for the treatment of cancer. The commenter expected this pharmaceutical to be the first in its class, and characterized it as neither a chemotherapeutic agent nor a radiopharmaceutical. The commenter stated that the cost of this pharmaceutical will be significantly higher than the payment amount proposed for any of the APC groups containing drugs used for cancer therapies. The commenter believes that we should have proposed an outlier policy to ensure equitable payment for pharmaceuticals such as iodine 131 tositumomab.

Response: If iodine 131 tositumomab receives final FDA approval, we strongly encourage interested parties to submit the appropriate materials to us for determination of this product's eligibility for additional payment under the pass-through provision as described below in section II.D.6.

Comment: One commenter finds our method of paying for new products to be flawed. The commenter sees it as highly probable that a new product will be inserted into an APC procedure category where the payment rate is significantly lower than the actual cost of the newly developed product. The commenter cites our proposed payment for a new product, In-111 Octreo Scan, which is used for tumor imaging. The product costs four times the payment rate for proposed APC 772, Complex Planar Nuclear Medicine. The commenter believes that this enormous discrepancy will discourage hospital outpatient departments from utilizing procedures that require this product and that Medicare beneficiaries may be denied access to the most appropriate care available as a result.

Response: We are firmly committed to ensuring that the provisions of the hospital outpatient PPS do not in any way obstruct or limit Medicare beneficiaries' access to reasonable medically necessary and appropriate care. We further recognize that the development of new technology and products is a highly dynamic enterprise that is constantly evolving and changing the character and cost of current diagnostic and treatment modalities. New section 1833(t)(6) of the Act provides for an additional transitional pass-through payment for certain innovative medical devices, drugs, and biologicals. We are also creating a series of transitional APCs for the express purpose of providing appropriate payment for new technology services when they emerge into the marketplace while we collect data to enable us ultimately to incorporate the new technology service within an APC group, making payment adjustments as needed. We expect to continue working closely with hospitals and their representatives throughout this process to ensure that payment does not inhibit beneficiary access to appropriate care. We discuss the transitional pass-through payment groups in greater detail in section III.D and provisions for payment for new technology in section III.C.8.

APC 881: Level I Pathology

APC 882: Level II Pathology

APC 883: Level III Pathology

Comment: We received numerous comments on the proposed pathology APC groups. One commenter expressed concern that our proposed assignment of tests among the three groups may create an incentive for physicians to order complex and unnecessary tests when simpler, less comprehensive tests may be adequate, because we have grouped together and are paying the same amount for tests that are clinically similar but that are comprehensively more difficult than one another.

Response: Our medical advisors and staff reviewed and completely reorganized the grouping of pathology tests in light of commenters' concerns and the BBRA 1999 "two times" requirement. Pathology tests are in final APC groups 0342, 0343, and 0344.

APC 906: Infusion Therapy Except Chemotherapy

APC 907: Intramuscular Injections

Comment: We received many comments about proposed APC groups 906 and 907. The commenters were generally concerned that packaging payment for nonchemotherapeutic infused and injected drugs in the payment rates for the administration of nonchemotherapy drugs does not take into account the great variation among these products with regard to their indication/application and cost nor the cost of new drugs that have been introduced since 1996. Commenters fear that we will underpay hospitals and inhibit the introduction of new drugs into the system.

Response: In response to the concerns expressed by commenters, we have created additional groups for certain expensive pharmaceuticals. These high-cost, nonchemotherapy, nonorphan drugs are captured in the following APCs: 0886–0891, 0907, 0908, 0911, 0914, 0915, 0917, 7007, 7036, and 7042. We have set the rates for these high-cost drug APCs based on data we obtained from a contracted study of drug costs. In section III.D, below, we discuss the process for pricing new high cost drugs as they are introduced into the marketplace to assure adequate payment until these new drugs can be assigned to an appropriate APC. Final APC 120, Infusion Therapy Except Chemotherapy, and final APC 359, Intramuscular injections, are priced based on the resources used to perform the procedures, including many less expensive drugs that are packaged into the two APCs.

APC 957: Echocardiography

Comment: Numerous commenters remarked on the lack of homogeneity in resource consumption in this APC. One commenter objected to our not distinguishing between procedures performed with or without contrast agents. Another commenter contends that proposed APC 957 does not account for the diversity of services in costs based on type of equipment, use of conscious sedation medication, and use of contrast agents.

Response: Conscious sedation and contrast media were packaged where they were used in the base year. We believe that packaging of items into the payment amount is appropriate because hospitals do not specialize in providing only services with or only services without sedation or contrast. To the extent that different equipment is used for different procedures, and has different costs, those differing costs are captured and recognized in our payment algorithm.

Comment: Several commenters referred to the fact that some of the echocardiograms are part of more comprehensive codes pertaining to echocardiograms that are in the same APC. For example, one commenter noted that CPT code 93880, the basic vascular ultrasound service, is defined as a "duplex scan." The commenter stated that all duplex vascular ultrasound codes involve three components and that, to the extent all three components are incorporated into this single vascular code, a provider is paid for only one procedure. On the other hand, CPT code 93307, the basic echocardiography service, incorporates only one of the three types of services included in the basic vascular service, CPT code 93880. Other codes, CPT 93320 and 93325 are used to bill for the other services that are a standard part of all vascular ultrasound procedures like CPT code 93880. This approach results in a provider receiving three separate payments for an echocardiogram with Doppler and color flow mapping as compared to a single payment for an equivalent vascular study.

Response: We agree that duplex vascular ultrasound scanning procedures include two dimensional and doppler signal display. However, for the example cited by the commenter, there is no separate code that includes both the two dimensional and the doppler ultrasound spectral analysis. To report a duplex vascular ultrasound of the heart, the only codes available are CPT codes 93307, 93320 and 93325, unlike the duplex vascular ultrasound scan of the extracranial arteries, which

is coded with CPT code 93880. We agree that this limitation of the coding system affects the payment system, since the APC system is based on charges associated with each of the codes. We will bring this issue to the attention of the American Medical Association's CPT Editorial Panel.

However, in those instances where there is a code for the comprehensive service and separate codes for services that are inherent components of the comprehensive service, the Correct Coding Initiative (CCI) edits, which we are incorporating into the hospital outpatient PPS claims processing system, will address this concern. The CCI edits have been in place in the Part B claims processing system since January 1996. These edits detect when codes representing component services are reported with the code for the more comprehensive service. For example, there is an edit that prohibits the payment of CPT code 93875, a doppler study of the extracranial arteries when reported with CPT code 93880, the duplex scan of the extracranial arteries.

APC 960: Cardiac Electrophysiologic Tests/Procedures APC

Comment: Many commenters cited extreme variations in resource use among the procedures in proposed APC 960. One commenter noted that the procedures involve the use of one or more catheters, and argued that the proposed payment does not cover the cost of even one catheter. Another commenter claims that, at a minimum, the total cost of the four diagnostic catheters and one ablation catheter used in performing these procedures is \$1,955.

Response: In response to these concerns, we moved CPT code 93660, Evaluation of cardiovascular function with tilt table evaluation, with continuous ECG monitoring and intermittent blood pressure monitoring, with or without pharmacological intervention, to final APC 0101, and CPT code 93724, Electronic analysis of antitachycardia pacemaker system, to final APC 0100. We reclassified the remaining procedures in proposed CPT 960 into final APC groups 0084, 0085, 0086, and 0087 to be consistent with the BBRA 1999 "two times" requirement.

APC 966: Electronic Analysis of Pacemakers/Other Devices

Comment: A number of commenters stated that the procedures in proposed APC 966 are not related clinically or in terms of resource cost. One commenter indicated that analyzing a spine infusion pump or neuroreceiver is a very different process from analyzing a

pacemaker or cardio/defibrillator and hence uses very different resources.

Response: Although the devices that are the subject of electronic analysis in proposed APC group 966 differ, we believe that the resource use among the services in the group is, on average, relatively similar. We determined that the procedures in proposed APC 966 meet the "two times" test for comparability with respect to the use of resources set by the BBRA 1999. In addition, we find it unlikely that facilities will specialize in one particular type of electronic analysis of pacemakers/other devices to the exclusion of others. Therefore, we did not change the procedures in final APC group 102 from what we had proposed.

APC 968: Vascular Ultrasound

Comment: One commenter recommended removing CPT code 93875, Non-invasive physiologic studies of extracranial arteries, complete bilateral study (for example, periorbital flow direction with arterial compression, ocular pneumoplethysmography, Doppler ultrasound spectral analysis), from proposed APC 968 because this study is a physiologic procedure and should be in the same group with other noninvasive physiologic vascular studies.

Response: We agree. We moved CPT code 93875 to final APC 0096.

Comment: One commenter recommended creating additional APC groups for CAT, MRI, and general ultrasound procedures to distinguish between diagnostic procedures that utilize contrast media and those that do not. The commenter believes that additional APC groups that properly recognize the resources required for contrast agents will encourage hospitals to use the procedures most suitable for the clinical needs of different patients.

Response: As we explained above, in our response to comments about proposed APC groups 710, 720, and 726, our medical advisors and staff carefully reviewed our data and concluded that costs associated with the use of contrast material are reflected in the payment rate for vascular ultrasound procedures in proportion to its frequency of use. We believe it is reasonable to have vascular ultrasound procedures with and without contrast together in one group because facilities do not specialize based on whether or not they use contrast material. Further, the cost of contrast material is small relative to the overall cost of the ultrasound. Moreover, facilities are not likely to schedule ultrasound according to whether or not contrast is used. Therefore, with the

exception of moving CPT code 93875, we did not further change the procedures in final APC group 0267. Final APC group 0267 is within the limit on cost variation required by the BBRA 1999.

APC 969: Hyperbaric Oxygen

Comment: Many commenters were concerned that our cost data for hyperbaric oxygen therapy are flawed because of poor coding, and that the proposed payment rate is, as a consequence, inadequate. One commenter suggested that we did not use a common definition of hyperbaric oxygen therapy across all hospitals and that, due to ambiguity in codes, there is wide variation in how hyperbaric oxygen therapy services are defined for billing purposes.

Response: We cannot subdivide final APC 0031 because we have no mechanism for creating clinically distinct groups related to differences in resource consumption among facilities within a single CPT code. However, we explain below, in section III.H, that we intend to make adjustments in future years to APC group weights, once the hospital outpatient PPS is implemented. If commenters believe that current codes are inadequate to describe these services, they should seek new CPT codes from the American Medical Association.

Comment: One commenter was concerned about not only the low payment rate proposed for hyperbaric oxygen therapy, but also the fact that the proposed national unadjusted coinsurance amount exceeds the proposed total payment rate for the service.

Response: We calculated the payment rate and coinsurance amount for APC 0031 using the same method that we followed for the other APC groups. Charges for hyperbaric oxygen are much higher than their costs, which accounts for the unusually high national unadjusted coinsurance rate relative to the total payment rate for CPT code 99183. Note, however, that hospitals may elect to offer a reduced coinsurance rate for the service as described below in section III.F.4.

APC 971: Level I Pulmonary Tests

APC 972: Level II Pulmonary Tests

APC 973: Level III Pulmonary Tests

Comment: Commenters generally questioned the clinical consistency of procedures in the proposed pulmonary test APC groups and expressed concern about the variability of resources required to perform the procedures within each group. One commenter

disagreed with our combining procedures before and after medication with procedures before rest and after exercise.

Response: After carefully reviewing the assignment of codes among the three proposed pulmonary test groups, our medical advisors and staff made a number of changes. To better recognize their median costs, we moved CPT code 94060, Bronchospasm evaluation before and after bronchodilator, and CPT code 94260, Thoracic gas volume, to final APC group 0368, and classified CPT code 94720, Carbon monoxide diffusing capacity, to final APC group 0367. We made additional changes among the three groups to ensure comparability of resources within each pulmonary test APC group in accordance with the "two times" standard set by the BBRA 1999.

APC 976: Pulmonary Therapy

Comment: Commenters generally questioned the clinical consistency of procedures in the proposed pulmonary therapy APC group and expressed concern about the variability of resources required to perform the procedures within the group. One professional association wrote that the respiratory therapy procedures in proposed APC group 976 are significantly different in complexity and require significantly different equipment and expertise to perform. The same commenter noted that CPT code 94657, Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing, subsequent days; CPT code 94660, Continuous positive airway pressure ventilation (CPAP), initiation and management; and, CPT code 94662, Continuous negative pressure ventilation (CNP), initiation and management, all require close monitoring, more costly equipment, and, often, more expertise than do other therapies in proposed APC group 976.

Response: We agree with the commenter. We moved the CPT codes describing ventilation initiation and management (CPT codes 94657, 94660, 94662) into their own APC, final APC 0079, Ventilation Initiation and Management, to recognize that these procedures represent a completely different type of clinical service and because they utilize resources that are materially different from those used in connection with other pulmonary therapy procedures. We further divided the procedures in proposed APC 976 to meet the definition of comparable resources required by the BBRA 1999, resulting in final APC groups 0077 and 0078.

APC 979: Extended EEG Studies and Sleep Studies

APC 980: Electroencephalogram

APC 981: Level I Nerve and Muscle Tests

APC 982: Level II Nerve and Muscle Tests

Comment: One commenter expressed concern about our grouping sleep medicine services in proposed APC 979 with EEG and Epilepsy diagnostic services. Another commenter is concerned about the clinical homogeneity of our proposed groups for the numerous different neurologic and neuromuscular diagnostic codes that are encompassed within the range of services described by CPT code 95805 through CPT code 95958. The commenter believes that our proposed groups do not make appropriate distinctions among the many different tests relating to different parts of the body, taking different amounts of time, using different equipment, and measuring different outcomes. One commenter asked that we add two codes created in 1998 for sleep services to the list of procedures in the APC system. The commenter recommended assigning CPT 95811, Polysomnography with CPAP, to proposed APC group 979. The commenter also recommended that CPT code 95806, Sleep study, unattended by a technologist, *not* be assigned to proposed APC group 979 to avoid creating an incentive for hospitals to use that procedure, which the commenter asserts is both less costly and less conclusive than other studies in proposed APC 979, in place of more comprehensive tests. One commenter claimed that the variety of neurological and neuromuscular diagnostic tests warrants an expansion of the number of APCs for these procedures to six, because the resources used vary widely. The commenter prefers that payments be made on a per service rather than on a per group basis. However, if we retain groups, the commenter recommended, on the basis of cost-based practice expenses, separate APCs for sleep and polysomnography services, for EEG studies, for EEG monitoring codes, for EMG codes, for nerve conduction and H reflex tests, and for sensory evoked potential and autonomic nerve function tests.

Response: Our medical advisors and staff decided that CPT codes 95806 and 95811 are both most appropriately assigned to final APC 0213. While sleep studies unattended by a technologist may consume less resources than those studies which involve the presence of a technologist, we believe that physicians

are likely to order a mix of sleep studies, and that institutions are unlikely to specialize in sleep studies with or without the presence of a technologist. We added CPT code 95951 to APC group 0213. We believe the codes we proposed in APC groups 979 and 980 are sufficiently comparable clinically and in terms of resource use not to require further subdivision into smaller groups. Therefore, we retained our proposed classification in final APC groups 213 and 214.

We created a third APC group for the nerve and muscle test codes, and we split the codes in proposed APCs 981 and 982 among final APC groups 0215, 0216, and 0217 to ensure comparability of resources within each of the three nerve and muscle test APC groups in accordance with the "two times" requirement set by section 201(g) of the BBRA 1999.

APC 987: Subcutaneous or Intramuscular Chemotherapy

APC 988: Chemotherapy except by Extended Infusion

APC 989: Chemotherapy by Extended Infusion

APC 990: Photochemotherapy

Comments: We received numerous comments that criticized our proposed payments for chemotherapy services. The commenters argued that the proposed payment for chemotherapy and radiation therapy would severely reduce payments to hospitals and create perverse incentives for hospitals to substitute the older, less effective therapies for the newer ones. The commenters asserted that the proposed payment would not cover the costs of supportive care such as drugs to control nausea and vomiting. They expected that low payment rates to hospitals would force them to discontinue chemotherapy services, and that patients would be faced with trips to distant facilities to obtain services.

Response: We believe that the concerns raised by the commenters have been addressed through the transitional pass-through provision set forth in section 1833(t)(6) of the Act, as added by section 201(b) of the BBRA 1999. In accordance with that provision, we have separately identified current drugs and biologicals used in the treatment of cancer. These are listed in Addendum K of this final rule, and are eligible for additional payment under this provision. We have obtained codes for any anticancer, supportive, or adjunctive drugs we could identify. Thus, we will pay for chemotherapy by recognizing the mode(s) of administration and each of the covered

drugs given, whether they are to treat the cancer, to protect the patient against the toxic effects of the treatment, or to relieve the side effects of treatment. In section III.D.4, below, we discuss how to request codes for new drugs.

Note that we moved CPT-based chemotherapy infusion codes into the "E" (noncovered) category because HCPCS "Q" codes for these services will be used to identify chemotherapy infusions. Hospitals had been instructed in the past not to bill using the CPT codes.

APC 999: Therapeutic Phlebotomy

Comment: One commenter is concerned that facilities will lose money because the proposed payment rate does not cover the cost incurred to provide the nursing care, phlebotomy bag and other supplies, overhead, scheduling time and disposal of hazardous waste that are all required to furnish this service.

Response: We have carefully reviewed the costs associated with APC 999 and believe that the CPT code 99195 was mistakenly used to report simple venipuncture in some cases, thus lowering the cost of proposed APC 999. However, we believe it is appropriate to base payment for this APC on the median amount billed, since CPT code 99195 was billed more than 20,000 times. Hospitals must use this code only when *therapeutic* phlebotomy is furnished, and charge an appropriate rate for the resources involved. Appropriate reporting will enable us to determine a more precise weight for this APC in future years.

Final APC 081: Non-Coronary Angioplasty or Atherectomy

Final APC 082: Coronary Atherectomy

Final APC 083: Coronary Angioplasty

We created these three new APC groups to accommodate atherectomy and angioplasty procedures that we originally proposed to classify as inpatient only. We discuss in section III.C.5 our response to commenters' concerns about our proposing to designate certain procedures as "inpatient only" and our final decision to change the status of these atherectomy and angioplasty procedures.

Final APC 058: Strapping

Final APC 059: Casting

We proposed to assign the procedures in these new APC groups a payment status indicator "N" as incidental services for which payment is packaged into the APC rate for another service or procedure. However, we determined

that the procedures in the final APC groups 0058 and 0059 could be performed independently, that is, the procedures for which a strapping has been previously applied and/or a new cast has previously been placed. We explain in more detail in section III.C.2.c our rationale for not packaging the costs associated with these services. We therefore created APC groups 0058 and 0059 for these codes to which we assigned payment status indicator "S" to indicate that these are significant procedures paid under the hospital outpatient PPS to which the multiple procedure discount does not apply.

e. Exceptions to BBRA 1999 Limit on Variation of Costs Within APC Groups

As we note above, section 201(g) of BBRA 1999 amends section 1833(t)(2) of the Act to define what constitutes comparable use of resources among the procedures or services within an ambulatory payment classification group under the hospital outpatient PPS. The standard set by section 1833(t)(2) of the Act is that the items and services within a group cannot be considered comparable with respect to the use of resources if the highest median (elected by the Secretary, as opposed to the mean) cost item or service within a group is more than 2 times greater than the lowest median cost item or service within the same group (the "two-times" requirement).

Section 1833(t)(2) of the Act allows the Secretary to make exceptions to the "two-times" requirement in unusual cases, such as low volume items and services, although the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act. As we explain in the preceding section of this preamble, after we had modified the composition of the APC groups based on the recommendations of commenters, we made numerous additional changes to the APC groups to conform with the BBRA 1999 "two times" requirement. In the resulting groups, we found certain anomalies that were irreconcilable with the principles underlying formation of the APC groups. After carefully evaluating the various combinations resulting from further subdividing groups or reassigning codes to other groups to resolve the anomalies, and after reviewing our data, we decided to maintain the composition of certain APC groups, as exceptions to the "two times" requirement. We based exceptions on factors such as low procedure volume, suspect or incomplete cost data, concerns about

inaccurate or incorrect coding, or compelling clinical arguments. We believe that as hospitals gain experience under the hospital outpatient PPS, and as they refine their coding of services, a number of the apparent anomalies within the groups that we are treating as exceptions to the "two times" will be resolved.

Below we list the APC groups that are exceptions to the "two times" requirement, and our reasons for the exception. We use the final APC number to identify the group.

APC 0016: Level IV Debridement and Destruction

We are retaining CPT code 56501 in final APC group 0016, even though its median cost exceeds the "two times limit." We believe the higher costs that are reflected in the data are the result of incorrect coding. The descriptor for CPT code 56501 defines the procedure as the simple destruction of skin and superficial subcutaneous tissues. In the judgment of our medical advisors, costs associated with simple destruction of skin and superficial subcutaneous tissues are typically within the range of costs associated with the other procedures in final APC group 0016, and the median cost that our data attribute to CPT code 56501 is higher than the code description warrants.

APC 0030: Breast Reconstruction/Mastectomy

Although the range of costs for procedures in final APC group 0030 exceeds the "two times limit," we believe that only the simplest breast procedures will be done in the outpatient setting. Most of the procedures with median costs over \$1000 used observation services in order to provide an overnight stay. We expect these cases to revert to the more appropriate inpatient setting.

APC 0058: Level I Strapping/Casting

The codes in final APC group 0058 are the simpler casting, splinting, and strapping procedures. Costs associated with the more resource-intensive procedures in final APC group 0059 are fairly uniform, but the median costs of procedures in final APC group 0058 vary widely. We are excepting final APC group 0058 from the "two times limit" until we can review the data for the first year of the outpatient PPS.

APC 0060: Manipulation Therapy

Taken collectively, the codes in final APC group 0060 are low in volume and erratically priced. For example, although the number of areas treated increases within the range of CPT codes

98925 through 98929, suggesting progressively increasing resource utilization, our data show median costs associated with the codes in the range 98925–98929 as \$38, \$11, \$16, \$17, and \$19, respectively. Although costs associated with treating 9 to 10 body regions might not be 5 to 10 times greater than treating one or two regions, we would still expect costs for the more extensive procedures to be higher than those for the less extensive procedures, and certainly not lower as suggested by our data. Nor do we expect a hospital to specialize in treating more or fewer body areas. Therefore, the median payment set for final APC 0060 should average out, providing adequate payment for any number of body areas treated.

APC 0079: Ventilation Initiation and Management

These codes all represent respiratory treatment and support within the outpatient setting. Their costs should be roughly the same, even though our data suggest otherwise. We are excepting final APC group 0079 from the "two times limit" at this time, pending the collection of more conclusive cost data.

APC 0080: Diagnostic Cardiac Catheterization

The data for CPT code 93524 reflect costs that are lower than we would expect. We can find no apparent explanation for the wide variation in costs among the cardiac catheterization codes, although we suspect that the accuracy of the chargemaster system, when assigning charges in other than the surgical suite, may be problematic. We expect costs to even out once hospitals decide which cases may be handled on an outpatient basis without requiring an overnight stay.

APC 0081: Non-Coronary Angioplasty

We are excepting final APC group 0081 from the "two times limit" because of the low volume of cases for the codes in the group. For some of the codes in this group, the data reflect lower than expected median costs, which we attribute to low volume and to miscoding, which would account for the erratic sequences of costs found in our data.

APC 0093: Vascular Repair/Fistula Construction

We believe the median costs for CPT codes 36530 and 36810 are aberrant. These codes are very similar clinically to the other codes in APC 0093, and we would expect their costs to be similar. We believe low volume may account for the variability in cost.

APC 0094: Resuscitation and Cardioversion

We believe the median costs for CPT codes 92953 and 31500 are aberrant, perhaps due to misuse of the codes. Therefore, we are excepting this APC group from the "two times limit," until we collect and analyze more accurate data once the hospital outpatient PPS is implemented.

APC 210: Spinal Tap

The two CPT codes that comprise this group are essentially the same procedure, one performed for diagnostic reasons and the other therapeutic. We suspect the disparity in median costs is attributable to the much higher volume of diagnostic spinal taps. Therefore, we are excepting this APC group from the "two times limit," until we collect and analyze more accurate data once the hospital outpatient PPS is implemented.

APC 0233: Level II Anterior Segment Eye

We are excepting final APC group 233 from the "two times limit" because many of the codes in this APC are low volume and the coding seems erratic. For example, CPT designates a number of codes that are in final APC group 0233 as "relatively small" surgical procedures, which suggests that miscoding may have resulted in inflated cost data.

APC 0251: Level I ENT Procedures

A combination of low volume and unlisted codes obscures the fact that this APC represents the least intense ENT procedures. Because there are so many ENT codes, consistent agreement on what the codes represent may be difficult to achieve. Therefore, we are excepting this APC group from the "two times limit," until we collect more accurate data under outpatient PPS.

APC 0264: Level II Miscellaneous Radiology Procedures

In the judgment of our medical advisors, the median costs for CPT codes 74740 and 76102 are aberrant. These procedures would be underpaid if they were paid separately and on the basis of what our data show to be their median cost. Therefore, we are excepting this APC group from the "two times limit," until we collect more accurate cost data under outpatient PPS.

APC 0274: Myelography

In the judgment of our medical advisors, the median costs for CPT codes 70010 and 70015 are aberrant. These codes would be underpaid if they were moved to their own APC and paid on the basis of their median cost. All

codes in this APC should cluster around the same cost. Therefore, we are excepting this APC group from the "two times limit," until we collect more accurate cost data under outpatient PPS.

APC 0279: Level I Diagnostic Angiography

We believe the median costs for the codes at the low end of this APC may be inaccurate, because, clinically, these codes are homogeneous. Therefore, we are excepting this APC group from the "two times limit," until we collect more accurate cost data under outpatient PPS.

APC 0302: Level III Radiation Therapy

We are retaining CPT code 77470 in final APC group 302, because the median cost seems low for the code description, possibly because this code may have been billed improperly in the past. We are also uncertain of the appropriate median cost of CPT code 61793, because we have been told that CPT code 61793 was used for both single-session gamma knife procedures and for each of multiple sessions of treatment with linear accelerators. Therefore, we have created two codes to be used in place of CPT code 61793, in order to collect more reliable data: G0173 (Stereotactic radiosurgery, complete course of therapy in one session), and G0174 (Stereotactic radiosurgery, requiring more than one session).

We will initially pay both codes at the same rate; however, we expect differences in cost would become apparent during the first year or 18 months of the outpatient PPS.

APC 0311: Radiation Physics Services

We are retaining CPT code 77370 in final APC group 0311, because we believe a special medical radiation physics consultation (outside the weekly management of a patient) is probably more costly than our data indicate.

APC 0341: Immunology Tests

We think the variation in costs among the procedures within final APC group 0341 may be the result of erratic coding. Because these services are so similar clinically, we would expect their individual costs to cluster around the median. Therefore, we are excepting this APC group from the "two times limit," until we collect more accurate cost data under outpatient PPS.

APC 0371: Allergy Injections

We attribute the variation in median costs among the procedures within final APC group 0371 to erratic coding. Because these services are so similar

clinically, we would expect their individual costs to cluster around the median. Therefore, we are excepting this APC group from the "two times limit," until we collect more accurate cost data under outpatient PPS.

APC 0373: Neuropsychological Testing

With one exception, the codes in final APC group 0373 are billed per hour, so facility costs should all cluster around the median. Therefore, we are excepting this APC group from the "two times limit," until we collect more accurate cost data under outpatient PPS.

7. Discounting of Surgical Procedures

To be consistent with Medicare policy and regulations governing payment for ambulatory surgical services furnished in a physician's office and in an ASC, we proposed under the hospital outpatient PPS to discount payment amounts when more than one procedure is performed during a single operative session or when a surgical procedure is terminated prior to completion. Specifically, we proposed that when more than one surgical procedure with payment status indicator "T" is performed during a single operative session, we would pay the full Medicare payment and the beneficiary would pay the coinsurance for the procedure having the highest payment rate. Fifty percent of the usual Medicare PPS payment amount and beneficiary coinsurance amount would be paid for all other procedures performed during the same operative session to reflect the savings associated with having to prepare the patient only once and the incremental costs associated with anesthesia, operating and recovery room use, and other services required for the second and subsequent procedures.

We also proposed to require hospitals to use modifiers on bills to indicate procedures that are terminated before completion. Modifier -73 (Discontinued Outpatient Procedure Prior to Anesthesia Administration) would identify a procedure that is terminated after the patient has been prepared for surgery, including sedation when provided, and taken to the room where the procedure is to be performed, but before anesthesia is induced (for example, local, regional block(s), or general anesthesia). Modifier-52 (Reduced Services) would be used to indicate a procedure that did not require anesthesia, but was terminated after the patient has been prepared for the procedure, including sedation when provided and taken to the room where the procedure is to be performed. We proposed to pay 50 percent of the usual Medicare PPS payment amount and

beneficiary coinsurance amount for a procedure terminated before anesthesia is induced. Modifier-74 (Discontinued Procedure) would be used to indicate that a surgical procedure was started but discontinued *after* the induction of anesthesia (for example, local, regional block, or general anesthesia), or *after* the procedure was started (incision made, intubation begun, scope inserted) due to extenuating circumstances or circumstances that threatened the well-being of the patient. To recognize the costs incurred by the hospital to prepare the patient for surgery and the resources expended in the operating room and recovery room, the hospital will receive full payment for a procedure that was started but discontinued after the induction of anesthesia or after the procedure was started, as indicated by a modifier-74. The elective cancellation of procedures would not be reported. If multiple procedures were planned, only the procedure actually initiated would be billed.

Comment: Some commenters asked us to clarify how the policy would be applied. For example, one commenter asked whether the surgical discounting methodology would apply in the following situation: Contrast x-ray of lower spine (CPT code 72265) is followed by contrast CAT of the spine (CPT code 72132). Both procedures have related surgical codes (CPT codes 62270 and 62284). Other commenters provided examples that were similar in nature but involved other codes.

Response: We proposed to apply the reduced payment for multiple procedures to surgical procedures only, that is, those CPT codes that have a payment status indicator "T." Therefore, services such as CPT codes 72265 and 72132 that have a payment status indicator of "S" would not be subject to the multiple procedure discount, whereas CPT codes 62270 and 62284, which are surgical procedures and have a payment status indicator of "T," would be subject to the multiple procedure discount. Hypothetically, if all four codes were provided in a single operative session, as suggested by this commenter, then the reduced payment would apply only to the surgical procedure with the lower payment rate. (For the record, we have responded to the commenter's example in order to clarify how the multiple procedure discount would apply in a hypothetical situation. However, we question whether the suggested combination of codes would be covered if actually performed during the course of a single patient encounter.)

Comment: Commenters asked what factors guided our assignment of payment status indicator "T" to a code.

Response: We generally assigned the payment status indicator "T" to surgical services. Our medical advisors and staff will continue to review the designation of status indicators and we may propose revisions in the future.

Comment: A variety of commenters stated that the reduced payments for multiple procedures would inappropriately reduce payments for a second procedure. Some were concerned that application of the multiple procedure discount could result in hospitals being less likely to offer procedures assigned the payment status indicator "T." These commenters recommended that we change all "T" payment indicators to a different indicator such as "S," which we define as a significant procedure not reduced when multiple, until we have had an opportunity to collect reliable cost data upon which to base payment decisions about discounting.

Response: We continue to believe that the proposed reduced payment for multiple surgical procedures is reasonable. We disagree that hospitals would be less likely to provide these services. We believe there clearly are savings achieved when more than one surgical procedure is performed during a single operative session. The patient has to be prepared for surgery only once, and the costs associated with anesthesia, operating and recovery room use, and other services required for the second procedure are incremental.

Comment: Some commenters questioned whether the reduced payment for multiple procedures applied to the beneficiary coinsurance as well as to the Medicare program payment. Others did not understand how this reduced payment was accounted for in determining the conversion factor.

Response: The reduced payment for multiple procedures would apply to both the beneficiary coinsurance and the Medicare payment. In order to do this in a "budget neutral" manner, we increased the conversion factor to account for the reduced payments for multiple procedures. In this way, total payments in the aggregate are not affected.

Comment: One commenter believes we should exclude from the multiple-procedure discount those procedures that were subject to a 50 percent reduction under the previous cost-based system because those procedures were recognized as being an adjunct to a primary procedure. The commenter believes that we had already factored

these discounts into our cost determinations and would therefore be inappropriately reducing payment even further for these procedures.

Response: We disagree with the commenter. In determining the weights for the APC groups, we included only single procedure claims. Multiple procedure reductions existing under the previous cost-based system would not have been reflected in these single procedure claims, and, therefore, do not affect the APC payment weights.

Final Action

Under the hospital outpatient PPS, we will discount payment amounts for surgical procedures when more than one procedure is performed during a single operative session or when a surgical procedure is terminated prior to completion. Parallel discounts will apply to beneficiary coinsurance amounts.

8. Payment for New Technology Services

a. Background

We proposed to price a new item or service that was assigned a new HCPCS code by classifying the new code to whichever existing APC group most closely resembled the item or service in terms of its clinical characteristics and estimated resource use. We proposed to use the group weight, payment rate, and coinsurance amount established for the existing APC to price the new code for at least 2 years to give us an opportunity to collect cost data for the new item or service.

After we published our proposed rule, the Congress expressed concern in the conference report accompanying the BBRA 1999, that our proposed PPS does not adequately address "issues pertaining to the treatment of * * * new technology." (See H. R. Rep. No. 436 (Part I), 106th Cong., 1st Sess. 868 (1999).) Therefore, the Congress enacted "transitional pass-throughs" in section 201(b) of the BBRA 1999 that provide an additional payment for "new medical devices, drugs, and biologicals" that do not otherwise meet the definition of current orphan drugs, or current cancer therapy drugs and biologicals and brachytherapy, or current radiopharmaceutical drugs and biological products. (See section III.D of this preamble for a discussion of how we are implementing the transitional pass-throughs.)

b. Comments and Responses

Comment: The most frequent commenters regarding our treatment of new technology under the proposed

hospital outpatient PPS were device manufacturers and pharmaceutical companies and their trade associations. Commenters were concerned because the proposed APC payment rates were developed using 1996 cost data that do not reflect the cost of many new technologies introduced subsequent to 1996. Commenters believe that the proposed method of ratesetting under the APC system lacks the flexibility needed to recognize emergent technologies in a timely manner. In the view of the commenters, assigning new technologies to existing APC groups pending the collection of cost data would result in underpayment, thereby discouraging the adoption of new technologies.

Commenters further stated that the proposed payment rates for current yet relatively new devices were too low and would favor continued use of older, less effective regimens on the basis of financial pressures rather than on the improved clinical outcomes of newer technology. Some commenters, concerned that we will not update codes or payment rates quickly enough to allow hospitals to pay for new technologies, recommended that we assign HCPCS codes as soon as products become available and alter APC group weights to account for a new technology. These commenters believe that the time lapse between coding updates is a barrier to innovation because it can take several years for a code to be issued for a new surgical technique, and until a new code is issued, facilities must bill for new surgical techniques as "unlisted procedures" resulting in the lowest payment rate for the category of surgery.

One commenter urged that we implement a payment carve-out for certain drug and biological therapies and pay for these items on a reasonable cost basis in order to provide timely patient access to many new pharmaceutical and biotechnology products. The same commenter recommended that if we reject a complete carve-out, then, at a minimum, we should pay for new products introduced after 1996 on a reasonable cost basis for 1 year to adequately compensate companies for developing new and more effective products. Another commenter recommended that we increase the number of APC groups to better reflect services with similar cost structures.

One professional association recommended abandoning the APC group system altogether and pricing services individually because assigning new technology and most costly procedures to APC groups with

established lower cost procedures creates a strong disincentive for hospitals to provide new or improved items or services and, in the case of newer, higher cost drugs, encourages hospitals to develop formularies and practice patterns based on financial considerations rather than on the medical value of drugs.

Technologies that commenters cited as being inadequately addressed by the proposed outpatient PPS include new technologies based on molecular genetics; gamma knife procedures used in radiation surgery; and prostatic microwave thermotherapy (transurethral microwave thermotherapy (TUMT)) which a commenter said has a direct cost of \$1,918 and, factoring in indirect costs, a total cost of \$2,623.

Response: The concerns expressed by commenters regarding new technology items and services highlight two issues. The first is specific to the data used to construct APC groups and calculate their prices at the start of the PPS. As required by section 1833(t)(2)(C) of the Act, we are using claims data from 1996 as the basis for determining APC group weights and payment rates under the new system. The 1996 data do not capture items and services that have emerged since that time and that are now in use. The second issue relates to new items and services that will be introduced in the future, after the outpatient PPS is implemented. Postponing the adjustment of APC groups and weights for several years to allow for the collection of cost data would potentially inhibit the dissemination of medically desirable innovations.

We recognize the concerns raised by commenters about our proposed treatment of new codes under the hospital outpatient PPS. We therefore have developed a process that we believe will allow us to recognize new technologies on an ongoing basis as expeditiously as our systems permit. We expect that this process, which we explain below, combined with the transitional pass-throughs established by section 201(b) of the BBRA 1999 (which we describe in section III.D of this preamble), will provide additional payment for a significant share of new technologies.

In this final rule, we have created special APC groups to accommodate payment for new technology services. In contrast to the other APC groups, the new technology APC groups do not take into account clinical aspects of the services they are to contain, but only their costs. We will assign new items and services that we determine cannot appropriately be placed in existing APC

groups for established procedures and services to the new technology APC groups.

The new technology APC groups, which are now largely unpopulated, are already defined in our claims processing system for the outpatient PPS, and we have established payment rates for the APC groups based on the midpoint of ranges of possible costs, for example, the payment amount for a new technology APC group reflecting a range of costs from \$300 to \$500 would be set at \$400. The cost range for the groups reflects current cost distributions, and we reserve the right to modify the ranges as we gain experience under the outpatient PPS. The final APC groups for new technology are groups 0970 through 0984 and cover a range of costs from less than \$50 to \$6,000. Upon implementation of the outpatient PPS, we will make payment for the following new technology services under the new technology APCs:

- 53850 Transurethral destruction of prostate tissue; by microwave thermotherapy
- 53852 Transurethral destruction of prostate tissue; by radiofrequency thermotherapy
- 96570 Photodynamic therapy, first 30 minutes
- 96751 Photodynamic therapy, each additional 15 minutes
- G0125 PET lung imaging of solitary pulmonary nodules, using 2-(Fluorine-18)-Fluoro-2-Deoxy-D-Glucose (FDG), following CT (71250/71260 or 71270)
- G0126 PET lung imaging of solitary pulmonary nodules, using 2-(Fluorine-18)-Fluoro-2-Deoxy-D-Glucose (FDG), following CT (71250/71260 or 71270); initial staging of pathologically diagnosed non-small cell lung cancer
- G0163 Positron emission tomography (PET), whole body, for recurrence of colorectal metastatic cancer
- G0164 Positron emission tomography (PET), whole body, for staging and characterization of lymphoma
- G0165 Positron emission tomography (PET), whole body, for recurrence of melanoma or melanoma metastatic cancer
- G0166 External counterpulsation, per treatment session
- G0168 Wound closure by adhesive

The new technology APC groups give us a mechanism for initiating payment at an appropriate level within a relatively short timeframe, and certainly less than the 2 or 3 years that we contemplated in our proposed rule. As in the case of items qualifying for the transitional pass-through payment, placement in a new technology APC will be temporary. After we gain information about actual hospital costs incurred to furnish a new technology service, we will move it to a clinically-related APC group with comparable resource costs. If we cannot move the new technology service to an existing

APC because it is dissimilar clinically and with respect to resource costs from all other APCs, we will create a separate APC for such service. We will retain a service within a new technology APC group for at least 2 years, but no more than 3 years, consistent with the time duration allowed for the transitional pass-through payments. Movement from a new technology APC to a clinically-related APC would occur as part of the annual update of APC groups. Beneficiary coinsurance amounts for items and services in the new technology APC groups are 20 percent of the payment rate set for the new technology APCs.

We ask that interested parties take the following steps to bring to our attention services that they believe merit consideration for pricing using the new technology APC groups. Mail requests for consideration of possible new technology services that have established HCPCS codes to the following address ONLY: PPS New Tech/Pass-Throughs, Division of Practitioner and Ambulatory Care, Mailstop C4-03-06, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244-1850.

To be considered, requests MUST include the following information:

- Trade/brand name of item.
- A detailed description of the clinical application of the item, including HCPCS code(s) to identify the procedure(s) with which the item is used.
- Current cost of the item to hospitals (*i.e.*, actual cost paid by hospitals net of all discounts, rebates, and incentives in cash or in-kind). In other words, submit the best and latest information available that provides evidence of the hospital's actual cost for a specific item.
- If the item is a service, itemize the costs required to perform the procedure, *e.g.*, labor, equipment, supplies, overhead, etc.
- If the item requires FDA approval/clearance, submit information that confirms receipt of FDA approval/clearance and the date obtained.
- If the item already has an assigned HCPCS code, include the code and its descriptor in your submission plus a dated copy of the HCPCS code "recommendation application" previously submitted for this item.
- If the item does not have an assigned HCPCS code, follow the procedure discussed, below, for obtaining HCPCS codes and submit a copy of the application with our payment request.
- Name, address, and telephone number of the party making the request.

- Other information as HCFA may require to evaluate specific requests.

We believe some items not yet known to us do not yet have assigned HCPCS codes. We expect to use national HCPCS codes in the hospital outpatient PPS to the greatest extent possible. These codes are established by a well-ordered process that operates on an annual cycle, starting with submission of information by interested parties due by April 1 and leading to announcement of new codes in October of each year. This process is described, and relevant application forms are available, on the following HCFA website: <http://www.hcfa.gov/medicare/hcpcs.htm>.

Considering the exigencies of implementing a new system, we intend to establish temporary codes in 2000 to permit implementation of additional payments for other eligible items effective beginning October 1, 2000. The process for submitting information will be the same as for national codes.

For new technology services that DO NOT have established HCPCS codes, submit the regular application for a national HCPCS code in accordance with the instructions found on the internet at <http://www.hcfa.gov/medicare/hcpcs.htm>. Send applications for national HCPCS codes to: C. Kaye Riley, HCPCS Coordinator, Health Care Financing Administration, Mailstop C5-08-27, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. A fuller discussion of the HCPCS process and schedule is in section III.D.6 of this preamble.

Because of staffing and resource limitations, we cannot accept requests by facsimile (FAX) transmission. Because of claims processing systems constraints, a new technology payment rate can only be initiated at the start of a calendar quarter. Since we will update our outpatient PPS quarterly to include new technology additional services, October 1, 2000 is the earliest date that we will implement payment for additional new technology services other than for those items beginning on July 1, 2000. In general, we expect to be able to complete action on requests to assign an item or service to a new technology APC group in about 6 months from the date we receive the request.

In order to be considered for assignment to a new technology APC group, an item or service must meet the following criteria:

- The item or service is one that could not have been billed to the Medicare program in 1996 or, if it was available in 1996, the costs of the item or service could not have been adequately represented in 1996 data.

- The item or service does not qualify for an additional payment under the transitional pass-through provided for by section 1833(t)(6) of the Act, as amended by section 201(b) of the BBRA 1999, and 42 CFR 419.43(e) as a current orphan drug, as a current cancer therapy drug or biological or brachytherapy, as a current radiopharmaceutical drug or biological product, or as a new medical device, drug, or biological.

- The item or service has a HCPCS code. (See section III.D for additional information about obtaining HCPCS codes.)

- The item or service falls within the scope of Medicare benefits under section 1832(a) of the Act.

- The item or service has been determined to be reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act.

Final Action

We are initiating a method to pay for new technology services that are not addressed by the transitional pass-through provisions of the BBRA 1999.

D. Transitional Pass-Through for Innovative Medical Devices, Drugs, and Biologicals

1. Statutory Basis

Section 201(b) of the BBRA 1999 amended section 1833(t) of the Act by adding a new section 1833(t)(6). This provision requires the Secretary to make additional payments to hospitals for a period of 2 to 3 years for specific items. The items designated by the law are the following: current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs, biologic agents, and brachytherapy devices used for treatment of cancer; current radiopharmaceutical drugs and biological products; and new medical devices, drugs, and biologic agents, in instances where the item was not being paid for as a hospital outpatient service as of December 31, 1996, and where the cost of the item is "not insignificant" in relation to the hospital outpatient PPS payment amount. In this context, "current" refers to those items for which hospital outpatient payment is being made on the first date the new PPS is implemented.

Section 1833(t)(6)(C)(i) of the Act sets the additional payment amounts for the drugs and biologicals as the amount by which the amount determined under section 1842(o) of the Act (95 percent of the average wholesale price (AWP)) exceeds the portion of the otherwise applicable hospital outpatient department fee schedule amount that

the Secretary determines to be associated with the drug or biological. Section 1833(t)(6)(C)(ii) provides that the additional payment for medical devices be the amount by which the hospital's charges for the device, adjusted to cost, exceed the portion of the otherwise applicable hospital outpatient department fee schedule amount determined by the Secretary to be associated with the device. Under section 1833(t)(6)(D), the total amount of pass-through payments for a given year cannot be projected to exceed an "applicable percentage" of total payments. For a year (or a portion of a year) before 2004, the applicable percentage is 2.5 percent; for 2004 and subsequent years, the applicable percentage is 2.0 percent. If the Secretary estimates that total pass-through payments would exceed the caps, the statute requires the Secretary to reduce the additional payments uniformly to ensure the ceiling is not exceeded.

Section 201(c) of the BBRA amended section 1833(t)(2)(E) of the Act to require that these pass-through payments be made in a budget neutral manner. In accordance with section 1833(t)(7) of the Act, as amended by section 201(i) of the BBRA 1999, these additional payments do not affect the computation of the beneficiary coinsurance amount.

Implementation of this pass-through provision requires us to—

- Identify eligible pass-through items;
- Designate a Billing Code for each;
- Determine the term "not insignificant" in the context of determining whether an additional payment is appropriate;
- Determine an appropriate cost-to-charge ratio to use to adjust the hospital's charges for a new medical device to cost;
- Determine the portion of the applicable APC that would be associated with the drug, biological or device; and
- Determine the additional payment amount.

As with other provisions of this final rule that reflect implementation of the BBRA 1999, we are soliciting comments on our implementation of the transitional pass-through payments, as set forth below.

2. Identifying Eligible Pass-Through Items

a. Drugs and Biologicals

Section 1833(t)(6)(A) of the Act establishes definitions and examples of the drugs and biologicals that are candidates for pass-through payments.

As indicated above, these drugs and biologicals are characterized as both current and new. Current refers to those drugs and biologicals for which payment is made on the first date the hospital outpatient PPS is implemented, that is, on July 1, 2000. They include the following:

1. Orphan drugs. These are drugs or biologicals that have been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act.

2. Cancer therapy drugs, biologicals, and brachytherapy. These items are those drugs or biologicals that are used in cancer therapy, including (but not limited to) chemotherapeutic agents, antiemetics, hematopoietic growth factors, colony stimulating factors, biological response modifiers, bisphosphonates, and a device of brachytherapy.

3. Radiopharmaceutical drugs and biological products. These are radiopharmaceutical drug or biological products used in nuclear medicine for diagnostic, monitoring, or therapeutic purposes.

A new drug or biological is defined as a product that was not paid as a hospital outpatient service prior to January 1, 1997 and for which the cost is not insignificant in relation to the payment for the APC to which it is assigned. These items are not reflected in the 1996 claims data we are required to use in developing the outpatient PPS. Before payment can be made for these new drugs and biologicals, a determination must be made that these items are reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member as required by section 1862(a)(1)(A) of the Act. Drugs that can be self-administered are not covered under Part B of Medicare (with specific exemptions for certain oral chemotherapeutic agents and antiemetics, blood-clotting factors, immunosuppressives, and erythropoietin for dialysis patients).

b. Medical Devices

Under section 201(b) of the BBRA 1999, for purposes of making pass-through payments, a new or innovative medical device is one for which payment as a hospital outpatient service was not being made as of December 31, 1996 and for which the cost of the device "is not insignificant" in relation to the hospital outpatient department fee schedule amount payable for the service involved. For the purpose of identifying "new medical devices" that may be eligible for pass-through payments, we are excluding equipment, instruments, apparatuses, implements

or items that are generally used for diagnostic or therapeutic purposes, that are not implanted or incorporated into a body part, and that are used on more than one patient (that is, are reusable). This material is generally considered to be hospital overhead costs and the depreciation expenses associated with them are reflected in the APC payments. The unit of payment for the outpatient PPS is a service or procedure. Equipment or instrumentation is a method or means of delivering that service. We are not establishing separate APC payments for equipment, instruments, apparatuses, implements, or items because payment for these types of devices is packaged in the APC payment for the service or item with which they are used. However, as we discuss above in section III.C.8, we have created new technology APCs to accommodate new technology services that may be performed using equipment or instrumentation that is capitalized and depreciated and used on more than one patient. An example of a new technology service is CPT code 53850, Transurethral destruction of prostate tissue; by microwave thermotherapy. We have assigned this procedure to new technology APC 0980. (See section III.C.8 of this preamble for further discussion of payment for new technology under the hospital outpatient PPS.)

Section 201(e) of the BBRA 1999 amends section 1833(t)(1)(B) of the Act to include as "covered OPD services" implantable items described in paragraphs (3), (6), or (8) of section 1861(s) of the Act. Paragraph (3) refers to diagnostic tests including diagnostic x-rays, mammographies, laboratory tests, and other diagnostic tests. Paragraph (6) refers to implantable durable medical equipment (DME), and paragraph (8) refers to prosthetic devices that replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care). Implantables are not mentioned specifically in these paragraphs, but we consider a prosthetic device that replaces all or part of an internal body organ that is mentioned in section 1861(s)(8) to be an implantable. The BBRA 1999 Conference Report lists pacemakers, defibrillators, cardiac sensors, venous grafts, drug pumps, stents, neurostimulators, and orthopedic implants, as well as items that come in contact with human tissue during invasive procedures as examples of implantable items.

Implantable items covered under section 201(e) of the BBRA 1999 may be considered eligible for the transitional pass-through payments allowed under

section 201(b) of the BBRA 1999 to the extent that these implantables meet the statutory requirements set forth in section 201(b) and the criteria established in this final rule for payment of these devices.

Although we are recognizing the implantable items identified in section 201(e) of the BBRA 1999 for possible pass-through payments, we are not applying the pass-through provision to any DME, orthotics, and prosthetic devices that are not covered under section 201(e) of the BBRA 1999. Rather, we will pay for these items under the DMEPOS fee schedule when the hospital is acting as a supplier.

3. Criteria To Define New or Innovative Medical Devices Eligible for Pass-Through Payments

In summary, we will make pass-through payment for new or innovative medical devices that meet the following criteria:

a. They were not recognized for payment as a hospital outpatient service prior to 1997.

b. They have been approved/cleared for use by the FDA.

c. They are determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as required by section 1862(a)(1)(A) of the Act. We recognize that some investigational devices are refinements of existing technologies or replications of existing technologies and may be considered reasonable and necessary. We will consider devices for coverage under the outpatient PPS if they have received an FDA investigational device exemption (IDE) and are classified by the FDA as Category B devices. (See §§ 405.203 to 405.215.) However, in accordance with § 405.209, payment for a nonexperimental investigational device "is based on, and may not exceed, the amount that would have been paid for a currently used device serving the same medical purpose that has been approved or cleared for marketing by the FDA."

d. They are an integral and subordinate part of the procedure performed, are used for one patient only, are surgically implanted or inserted, and remain with that patient after the patient is released from the hospital outpatient department.

e. The associated cost is not insignificant in relation to the APC payment for the service in which the innovative medical equipment is packaged. (See section III.D.4 below for the definition of "not insignificant.")

f. They are not equipment, instruments, apparatuses, implements,

or such items for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (HCFA Pub. 15-1). (As indicated above, these costs are considered overhead expenses that have been factored into the APC payment.)

g. They are not materials and supplies such as sutures, clips, or customized surgical kits furnished incident to a service or procedure.

h. They are not materials such as biologicals or synthetics that may be used to replace human skin.

Comment: Some commenters asked how we would pay for new technology intraocular lenses (IOLs) under the hospital outpatient PPS.

Response: We will use the same criteria established in the June 16, 1999 final rule (64 FR 32198) titled "Medicare Program; Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers" to identify IOLs that may be considered new technology and eligible for pass-through payments. In accordance with that rule, IOLs must first be approved by the FDA before they can be considered as a new technology IOL. The rule establishes only one criterion for distinguishing new technology IOLs from other IOLs. Specifically, all claims of the IOL's clinical advantages and superiority over existing IOLs must have been approved by the FDA for labeling and advertising purposes. For further discussion on the reasons for relying on the FDA's determination, we refer the reader to the IOL proposed rule published on September 4, 1997 (62 FR 46700 through 46701). We recognize that this criterion has been developed to define the characteristics that distinguish a new technology IOL from other IOLs in order to comply with section 141(b) of the Social Security Act Amendments of 1994 (Pub. L. 103-432) that is specific to IOLs furnished in ASCs and not hospital outpatient departments. However, we believe that it is appropriate to rely on an established approach to assist us in distinguishing this new technology since more than 1 million IOLs are inserted annually during or subsequent to cataract surgery performed in the outpatient setting. Moreover, we believe that consistent application of the criterion in both the ASC and hospital outpatient prospective payment systems is less burdensome to those requesting recognition of new technology IOLs. Therefore, when IOLs that are recognized as "new technology IOLs" in accordance with the provisions of the

June 16, 1999 final rule are furnished in a hospital outpatient setting, we will pay for such new technology IOLs in accordance with the hospital outpatient PPS method for determining additional payments under the pass-through provision set forth in this final rule.

Comment: We received many comments urging that we establish appropriate payments for brachytherapy seeds used in the treatment of prostate cancer.

Response: In accordance with section 1833(t)(6)(A)(ii), as added by section 201(b) of the BBRA 1999, we will provide additional payments for brachytherapy seeds as an implanted device. The brachytherapy device is assigned to APC 0918.

4. Determination of "Not Insignificant" Cost of New Items

Section 1833(t)(6)(A)(iv)(II) of the Act, as added by section 201(b) of the BBRA 1999 provides that the transitional pass-throughs apply to new drugs, biologicals, and devices whose cost is not insignificant in relation to the hospital outpatient PPS payment amount. Section 1833(t)(6)(C) defines the additional payment as the difference between an amount specified by the law and the portion of the applicable fee schedule amount determined to be associated with the item. The objective of this section is to prevent the hospital outpatient PPS from creating disincentives for the diffusion of valuable new technology by initially paying a rate significantly below the costs of these items. We believe that the "not insignificant" criterion was included in recognition that: (1) The costs of some new technologies would not be large enough relative to the fee schedule amount to provide disincentives for their use in the short run; and (2) that an excessive number of pass-through items could place a substantial burden on the claims processing systems of both HCFA and individual hospitals in a way that could hamper the rapid processing of pass-through payments for those items that would be significantly more costly than the applicable fee schedule amount. Therefore, in order to be consistent with the objectives of this section, we are establishing the following criteria for determining whether the costs of drugs, biologicals, and devices are "not insignificant" relative to the hospital outpatient department fee schedule amount:

(1) Its expected reasonable cost exceeds 25 percent of the applicable fee schedule amount for the associated service.

(2) The expected reasonable cost of the new drug, biological, or device must exceed the portion of the fee schedule amount determined to be associated with the drug, biological, or device by 25 percent.

(3) The difference between the expected, reasonable cost of the item and the portion of the hospital outpatient department fee schedule amount determined to be associated with the item exceed 10 percent of the applicable hospital outpatient department fee schedule amount.

The following illustrates the application of these three criteria.

Example: Let us assume that the reasonable cost of the new device ZZ is \$32.00. ZZ is associated with HCPCS code 00000 assigned to APC 0001. The fee schedule amount for APC 0001 is \$100.00. The portion of the fee schedule amount included in APC 0001 that represents the cost associated with the former device is \$25.00.

1. (a) Multiply the fee schedule amount for APC 0001 by 25 percent
 $\$100.00 \times .25 = \25.00

(b) Compare the reasonable cost for ZZ to the product derived in Step 1
 $\$32.00 > \25.00

Finding: The first criterion is met.

2. (a) Multiply the portion of the fee schedule amount for APC 0001 that is associated with a device by 25 percent
 $\$25.00 \times .25 = \6.25

(b) Subtract the portion of the fee schedule amount for APC 0001 attributable to a device from the reasonable cost for ZZ
 $\$32.00 - \$25.00 = \$7.00$

(c) Compare the remainder in Step 4 to the product in Step 2(a)
 $\$7.00 > \6.25

Finding: The second criterion is met.

3. (a) Multiply the fee schedule amount for APC 0001 by 10 percent
 $\$100.00 \times .10 = \10.00

(b) Compare the remainder in Step 3 to the product derived in Step 3(a)
 $\$7.00 < \10.00

Finding: The third criterion is not met. Therefore, new device ZZ is not eligible for transitional pass-through payment.

5. Calculating the Additional Payment

Section 1833(t)(6)(C)(i) of the Act requires that for drugs, biologicals, and radiopharmaceuticals, the additional payment be determined as the difference between the amount determined under section 1842(o) of the Act (95 percent of AWP) and the portion of the hospital outpatient department fee schedule amount determined by the

Secretary to be associated with those items. For devices, the additional payment is the difference between the hospital's charges adjusted to costs and the portion of the applicable hospital outpatient department fee schedule amount associated with the device. Under section 1833(t)(7) of the Act, as added by section 201(i) of the BBRA 1999, the coinsurance amounts for beneficiaries are not affected by pass-through payments.

We will determine, on an item-by-item basis, the amount of the applicable fee schedule amount associated with the relevant drug, biological, or device. To the extent possible, hospital outpatient department claims data will be used to make these estimates. When necessary, external data pertaining to the costs of the drugs, biologicals and devices already included in the fee schedule amounts will be used to make these determinations.

Before January 1, 2002, charges for devices eligible for pass-throughs will be adjusted to cost on each claim by applying the individual hospital's average cost-to-charge ratio across all outpatient departments. The 1996 data do not allow for determination of which revenue center-specific ratios might be used for this purpose. We will examine claims for the latter half of 2000 and for 2001 in order to determine if a revenue center-specific set of cost-to-charge ratios should be used for 2002 and beyond.

A one-time exception to the general methodology described above pertains to current drugs and biologicals that will be eligible for transitional pass-throughs when the PPS is implemented. For this final rule, we revised many APC groups by removing, to the extent possible, many of these drugs and radiopharmaceuticals. Therefore, the payment rates for the APC groups with which these drugs are associated exclude the costs of these drugs and the total amount paid to hospitals for the drugs will be 95 percent of the applicable AWP. In order to be able to determine a coinsurance amount for these drugs, we needed to estimate what portion of this payment would have been included as part of the APC payment amount associated with these drugs and what portion would be the pass-through amount. Using an external survey of hospitals' drug acquisition costs, we determined the APC payment amount for many of these drugs as their average acquisition cost adjusted to year 2000 dollars. Where valid cost data were not available for individual drugs, we applied the following average ratios of acquisition cost to AWP calculated from the survey to determine the fee schedule

amount: .68 for drugs with one manufacturer, .61 for multi-source drugs, and .43 multi-source drugs with generic competitors. In either case, the coinsurance amounts were determined as 20 percent of these fee schedule amounts. It is important to note that these estimates do not affect the total payment to hospitals for these drugs (95 percent of AWP).

Because claims data are not available for most items that will be eligible for transitional pass-through payments for 2000 and 2001, it is extremely difficult to project expenditures under this provision. For this reason, and because many eligible items will be added after the system's implementation, we cannot estimate if, and to what extent, these payments would exceed 2.5 percent of total payments in 2000 and 2001. Therefore, there will be no uniform reduction factor applied to these payments during this period.

6. Process To Identify Items and To Obtain Codes for Items Subject to Transitional Pass-Throughs

We have identified a large number of items subject to the transitional pass-through payment through our own data-gathering activities or through comments on the proposed rule. Many of them already have HCPCS codes, and we are taking steps to establish temporary codes for the remaining items. We will make additional payments for these items when the hospital outpatient PPS system is implemented on July 1. A list of the items already known to us is set forth in Addendum K.

Other items potentially eligible for additional pass-through payments may not be known to us at this time. Because of systems limitations, if we do not know about an item, we will not be able to make additional payments for those items beginning on July 1, 2000. However, we will update our outpatient PPS on a quarterly basis beginning October 1, 2000 to add other items that are eligible for pass-through payments. Therefore, implementation of additional payment for any such item must wait until a later release of systems instructions, that is, in October 2000, January 2001 (annual update), or later.

A manufacturer or other interested party who wishes to bring items that may be eligible for additional transitional pass-through payments to our attention should mail requests for consideration of items to the following address ONLY: PPS New Tech/Pass-Throughs, Division of Practitioner and Ambulatory Care, Mailstop C4-03-06, Health Care Financing Administration,

7500 Security Boulevard, Baltimore, MD 21244-1850.

To be considered, requests MUST include the following information:

- Trade/brand name of item.
- A detailed description of the clinical application of the item, including HCPCS code(s) to identify the procedure(s) with which the item is used. If the item replaces or improves upon an existing item, identify the predecessor item by trade/brand name and HCPCS code.

- Current cost of the item to hospitals (*i.e.*, actual cost paid by hospitals net of all discounts, rebates, and incentives in cash or in-kind). In other words, submit the best and latest information available that provides evidence of the hospital's actual cost for a specific item.

- Date of sale of first unit.
- For drugs, submit the most recent average wholesale price (AWP) of the drug and the date associated with the AWP quote.

- If the item requires FDA approval/clearance, submit information that confirms receipt of FDA approval/clearance and the date obtained.

- If the item already has an assigned HCPCS code, include the code and its descriptor in your submission plus a dated copy of the HCPCS code "recommendation application" previously submitted for this item.

- If the item does not have an assigned HCPCS code, follow the procedure discussed, below, for obtaining HCPCS codes and submit a copy of the application with your payment request.

- Name, address, and telephone number of the party making the request.
- Other information as HCFA may require to evaluate specific requests.

We believe some items not yet known to us do not yet have assigned HCPCS codes. We expect to use national HCPCS codes in the hospital outpatient PPS to the greatest extent possible. These codes are established by a well-ordered process that operates on an annual cycle, starting with submission of information by interested parties due by April 1 and leading to announcement of new codes in October of each year. This process is described, and relevant application forms are available, on the following HCFA website: <http://www.hcfa.gov/medicare/hcpcs.htm>.

Considering the exigencies of implementing a new system, we intend to establish temporary codes in 2000 to permit implementation of additional payments for other eligible items effective beginning October 1, 2000. The process for submitting information will be the same as for national codes.

For items that might be candidates for additional transitional pass-through payments but that DO NOT have established HCPCS codes, submit the regular application for a national HCPCS code in accordance with the instructions found on the internet at <http://www.hcfa.gov/medicare/hcpcs.htm>. Send applications for national HCPCS codes to: C. Kaye Riley, HCPCS Coordinator, Health Care Financing Administration, Mailstop C5-08-27, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Because of staffing and resource limitations, we cannot accept requests by facsimile (FAX) transmission.

As indicated in the instructions posted at our website address cited above, the deadline for submission of applications for a national HCPCS code for the CY 2001 cycle is April 1, 2000. The HCPCS process will proceed to assign national codes as warranted, and we expect these codes will be used in the hospital outpatient PPS starting January 1, 2001. Because the coding application will contain information vital to determining a specific item or product's eligibility for pass-through payments, we are requesting that a copy of the application be sent concurrently to ATTN: PPS New Tech/Pass-Throughs at the address shown above.

This year, we plan to implement additional payment for appropriate items on October 1, 2000. Requests submitted to us with appropriate information will be evaluated for payment effective October 1. We will use the same submissions made for national HCPCS codes as the basis for making temporary code assignments. However, a very large volume of requests or systems constraints could affect our ability to achieve this goal.

Any applications for HCPCS codes that are received after April 1 will be retained for the next cycle of the national HCPCS code assignment process starting the following April 1. We will also consider these items for assignment of temporary codes that might take effect in January or later in the next year.

How quickly additional payment for a new item can be implemented will depend on processing and systems constraints; it will in general require at least 6 months and may require as many as 9 or more months. Thus, a submission that we receive in May (which is too late for October implementation) might be assigned a temporary code to be used for implementing additional payments starting the following January.

As previously stated, pass-through payment for each item is temporary.

After we obtain information about actual hospital costs incurred to furnish a pass-through item, we will package it into the service with which it is clinically associated.

Comment: A number of commenters expressed concern about the extensive amount of time required to obtain HCPCS codes for new items or services. They argued that the lag-time in coding updates creates a barrier to innovation, claiming that it can be several years before a code is issued for a new surgical technique or product. Some commenters noted that when facilities are forced to code new surgical techniques as "unlisted procedures," pending issuance of a specific code for the procedure, it would result in the facility receiving payment for the lowest related APC group. Some commenters recommended that we assign HCPCS codes as soon as products become available.

Response: We recognize the urgency expressed by commenters. We believe the process we have outlined above will assist interested parties in obtaining HCPCS codes for new items and services in the most expeditious manner possible within the constraints imposed by our system requirements.

E. Calculation of Group Weights and Conversion Factor

1. Group Weights (Includes Table 1, Packaged Services by Revenue Center)

Section 1833(t)(2)(C) of the Act requires the Secretary to establish relative payment weights for covered hospital outpatient services. That section requires that the weights be developed using data on claims from 1996 and data from the most recent available hospital cost reports. Before enactment of the BBRA 1999, we were required to base the relative payment weights on median hospital costs. Section 201(f) of the BBRA 1999 amended section 1833(t)(2)(ii) of the Act to authorize the Secretary to base the relative payment weights on either the median or mean hospital costs. In constructing the database for the outpatient PPS proposed rule group weights and conversion factor, we used a universe of approximately 98 million calendar year 1996 final action claims for hospital outpatient department services received through June 1997 to match to the most recent hospital cost reports available. We have decided to continue to base the relative payments weights in this final rule on median (as opposed to mean) costs because, among other things, reconstructing our database to evaluate the impact of using mean costs after the BBRA 1999 was