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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–AI56

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.

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Addenda

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 provison 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 paclitaxil (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 factions 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 intracavitatory 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 1 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 CPAPP, 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 × .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 × .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 × .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

enacted would have delayed implementation of the hospital outpatient PPS.

To derive weights based on median hospital costs for services in the hospital outpatient APC groups, we converted billed charges to costs and aggregated them to the procedure or visit level. To accomplish this, we first identified the cost-to-charge ratio that was specific to each hospital's cost centers (''cost center specific cost-to-charge ratios'' or CCRs). We then developed a crosswalk to match the hospital's CCRs to revenue centers used on the hospital's 1996 outpatient bills. The CCRs included operating and capital costs but excluded costs associated with direct graduate medical education and allied health education.

To determine the hospital CCRs, the most recent available cost report from each hospital was identified. For the proposed rule, we used cost reports from cost reporting periods beginning on or after October 1, 1994 and before October 1, 1995 (referred to as PPS–12) or earlier. For this final rule, more recent cost reports were available for hospitals. We used cost reports from cost reporting periods beginning on or after October 1, 1996 and before October 1, 1997 (PPS–14) for approximately 94 percent of the hospitals in our database.

If the most recent available cost report for a hospital was one that had been submitted but not settled, we calculated a factor to adjust for the differences that generally exist between settled and ''as submitted'' cost reports. The adjustment factor was determined by dividing the outpatient department cost-to-charge ratio from the hospital's most recent settled cost report by the outpatient department cost-to-charge ratio from the hospital's ''as submitted'' cost report for the same period. The resulting ratio was used to adjust each of the CCRs in the hospital's most recent ''as submitted'' cost report. We repeated this process for every hospital for which the most recent available cost report was a cost report that had not been settled.

The Office of Inspector General (OIG) for DHHS is concerned that the cost reports we are using may reflect some unallowable costs. Therefore, the OIG, in conjunction with HCFA, is proposing to examine the extent to which the cost reports used reflect costs that were inappropriately allowed. If this examination reveals excessive inappropriate costs, we will address this issue in a future proposed rule, or perhaps seek legislation to adjust future payment rates downward.

We next eliminated from the hospital CCR database 258 hospitals that we have identified as having reported charges on their cost reports that were not actual charges (for example, they make uniform charges for all services). These excluded hospitals were Kaiser, New York Health and Hospital Corporation, and all-inclusive rate hospitals. After removing these hospitals, we calculated the geometric mean of the total operating CCRs of hospitals remaining in our CCR database. We identified 58 hospitals whose total operating CCR exceeded the geometric mean by more than 3 standard deviations. These hospitals were also removed from our CCR database.

After assembling and editing our new CCR database, we matched revenue centers from approximately 80 million claims to CCRs of approximately 5,700 hospitals. We excluded from the crosswalk approximately 15 million claims in which the bill type denoted services that would not be covered under the PPS (for example, bill type 72X for dialysis services for patients with ESRD). We also excluded almost 3 million claims from the hospitals that we had removed or trimmed from the hospital CCR database. The table below shows the five cost reporting periods used and the percentage of the cost reports within each PPS period for which we were able to match 1996 claims.

Reporting period	Percentage of cost reports matched
PPS–15 (cost reporting period beginning on or after 10/1/97 and before 10/1/98)	0.1
PPS–14 (cost reporting period beginning on or after 10/1/96 and before 10/1/97)	94.2
PPS–13 (cost reporting period beginning on or after 10/1/95 and before 10/1/96)	3.7
PPS–12 (cost reporting period beginning on or after 10/1/94 and before 10/1/95)	1.7
PPS–11 (cost reporting period beginning on or after 10/1/93 and before 10/1/94)	0.3
Total	100.0

Next, we took the estimated 80 million claims that we had matched with a cost report and separated them into two distinct groups: Single-procedure claims and multiple-procedure claims. Single-procedure claims were those that included only one HCPCS code (other than laboratory and incidentals such as packaged drugs and venipuncture) that could be grouped to an APC. Multiple-procedure claims included more than one HCPCS code that could be mapped to an APC. There were approximately 45.4 million single-procedure claims and 34.6 million multiple-procedure claims.

To calculate median costs for services within an APC, we used only the single-procedure bills. (Of the roughly 45.4 million single-procedure claims, about 24 million were excluded from the conversion process largely because the only HCPCS codes reported on the claims were for laboratory procedures or other outpatient services not paid under the outpatient PPS.) This approach was taken because the information on claims does not enable us to specifically allocate charges or costs for packaged items and services such as anesthesia, recovery room, drugs, or supplies to a particular procedure when more than one significant procedure or medical visit was billed on a claim. Use of the single-procedure bills minimizes the risk of improperly assigning costs to the wrong procedure or visit. Although we used only single-procedure/visit bills to determine APC relative payment weights, we used multiple-procedure bills in the conversion factor and service mix calculations, regressions, and impact analyses.

For each single-procedure claim, we calculated a cost for every billed line item charge by multiplying each revenue center charge by the appropriate hospital-specific CCR. If the appropriate cost center did not exist for a given hospital, we crosswalked the revenue center to a secondary cost center when possible, or to the hospital's overall cost-to-charge ratio for outpatient department services. We excluded from this calculation all charges associated with HCPCS codes previously defined as not paid under this PPS (for example, laboratory, ambulance, and therapy services).

To calculate the per-procedure or per-visit costs, we used the charges shown in the revenue centers that contained items integral to performing the procedure or visit. These included those items that we previously discussed as being subject to our proposed packaging provision. For instance, in calculating the surgical procedure cost, we included charges for the operating room, treatment rooms, recovery, observation, medical and surgical supplies, pharmacy, anesthesia, casts and splints, and donor tissue, bone, and organ. For medical visit cost estimates, we included charges for items such as medical and surgical supplies, drugs, and observation. A complete listing of the revenue centers that we used is shown below in Table 1, Packaged Services by Revenue Center.

TABLE 1.—PACKAGED SERVICES BY REVENUE CENTER

ASC AND OTHER SURGERY

250 PHARMACY
251 GENERIC
252 NONGENERIC
257 NONPRESCRIPTION DRUGS
258 IV SOLUTIONS
259 OTHER PHARMACY
260 IV THERAPY, GENERAL CLASS
262 IV THERAPY/PHARMACY SERVICES
263 IV THERAPY/DRUG/SUPPLY/DELIVERY
264 IV THERAPY/SUPPLIES
269 OTHER IV THERAPY
270 M&S SUPPLIES
271 NONSTERILE SUPPLIES
272 STERILE SUPPLIES
276 INTRAOCULAR LENS
279 OTHER M&S SUPPLIES
370 ANESTHESIA
379 OTHER ANESTHESIA
390 BLOOD STORAGE AND PROCESSING
399 OTHER BLOOD STORAGE AND PROCESSING
630 DRUGS REQUIRING SPECIFIC IDENTIFICATION, GENERAL CLASS
631 SINGLE SOURCE DRUG
632 MULTIPLE SOURCE DRUG
633 RESTRICTIVE PRESCRIPTION
700 CAST ROOM
709 OTHER CAST ROOM
710 RECOVERY ROOM
719 OTHER RECOVERY ROOM
720 LABOR ROOM
721 LABOR
723 CIRCUMCISION
762 OBSERVATION ROOM
810 ORGAN ACQUISITION
819 OTHER ORGAN ACQUISITION
890 OTHER DONOR BANK
891 BONE
892 ORGAN
893 SKIN
899 OTHER DONOR BANK

MEDICAL VISIT

250 PHARMACY
251 GENERIC
252 NONGENERIC
257 NONPRESCRIPTION DRUGS
258 IV SOLUTIONS
259 OTHER PHARMACY
270 M&S SUPPLIES
271 NONSTERILE SUPPLIES
272 STERILE SUPPLIES
279 OTHER M&S SUPPLIES
630 DRUGS REQUIRING SPECIFIC IDENTIFICATION, GENERAL CLASS
631 SINGLE SOURCE DRUG
632 MULTIPLE SOURCE DRUG
633 RESTRICTIVE PRESCRIPTION
700 CAST ROOM
709 OTHER CAST ROOM
762 OBSERVATION ROOM

OTHER DIAGNOSTIC (BLENDED SERVICES)

254 PHARMACY INCIDENT TO OTHER DIAGNOSTIC
372 ANESTHESIA INCIDENT TO OTHER DIAGNOSTIC
622 SUPPLIES INCIDENT TO OTHER DIAGNOSTIC

TABLE 1.—PACKAGED SERVICES BY REVENUE CENTER—Continued

710 RECOVERY ROOM
719 OTHER RECOVERY ROOM
762 OBSERVATION ROOM

RADIOLOGY SUBJECT TO THE FEE SCHEDULE AND OTHER RADIOLOGY

255 PHARMACY INCIDENT TO RADIOLOGY
371 ANESTHESIA INCIDENT TO RADIOLOGY
621 SUPPLIES INCIDENT TO RADIOLOGY
710 RECOVERY ROOM
719 OTHER RECOVERY ROOM
762 OBSERVATION ROOM

ALL OTHER APC GROUPS

250 PHARMACY
251 GENERIC
252 NONGENERIC
257 NONPRESCRIPTION DRUGS
258 IV SOLUTIONS
259 OTHER PHARMACY
260 IV THERAPY, GENERAL CLASS
262 IV THERAPY PHARMACY SERVICES
263 IV THERAPY DRUG/SUPPLY/DELIVERY
264 IV THERAPY SUPPLIES
269 OTHER IV THERAPY
270 M&S SUPPLIES
271 NONSTERILE SUPPLIES
272 STERILE SUPPLIES
279 OTHER M&S SUPPLIES
630 DRUGS REQUIRING SPECIFIC IDENTIFICATION, GENERAL CLASS
631 SINGLE SOURCE DRUG
632 MULTIPLE SOURCE DRUG
633 RESTRICTIVE PRESCRIPTION
762 OBSERVATION ROOM

We then applied to these cost estimates an adjustment to calibrate the costs to calendar year 1996 for those services in hospitals whose CCRs were calculated using FY 1997 or later cost reports. On average, hospital charges were rising faster than costs in FY 1997. We therefore made this adjustment for the calculation of the weights, as well as for the hospital costs used in the conversion factor and impact model, to ensure that we did not underestimate costs and payments. We based this hospital specific CCR adjustment on the observed change in each hospital's overall CCR (total operating + total capital) from the proposed rule cost report database to the new final rule database. If applicable, we then calculated a monthly rate of change and applied it based on the number of months past 1996 encompassed in a hospital's cost reporting period; if a hospital's period coincided completely within calendar year 1996, no adjustment was made.

After calibrating the costs to calendar year 1996, we standardized costs for geographic wage variation by dividing the labor-related portion of the operating and capital costs for each billed item by the FY 2000 hospital inpatient prospective payment system wage index published in the **Federal Register** on July 30, 1999 (64 FR 41585). As in the proposed rule and correction notice, we used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. A more detailed discussion of wage index adjustments is found below in section III.G of this document.

The standardized labor-related cost and the nonlabor-related cost component were summed for each billed item to derive the total standardized cost for each procedure or medical visit. Extremely unusual costs that appeared to be errors in the data were trimmed from standardized procedure and visit costs. This trimming methodology is analogous to that used in calculating the DRG weights for the inpatient PPS: eliminate any bills with costs outside of 3 standard deviations from the geometric mean. We used the geometric mean and the associated standard deviation because the distribution of costs more closely resembles a lognormal distribution than a normal distribution: There are no negative costs, and the average cost is greater than the median cost. Use of the geometric mean minimizes the impact of the most unusual bills in the determination of the mean. The geometric mean is calculated by taking the mean of the natural logarithm cost. Because the distribution of the natural logarithms of a set of numbers is more compact than the distribution of the numbers themselves, bills with extreme costs do not appear as extreme as they would if non-logged costs were examined. This ensures that only the most aberrant data will be removed from the calculation.

After trimming the procedure and visit level costs, we mapped each procedure or visit cost to its assigned APC and calculated the median cost for each APC weighted by procedure volume. Using the median APC costs, we calculated the relative payment weights for each APC. We scaled all the relative payment weights to APC 601, a mid-level clinic visit, because it is one of the most frequently performed services. This approach is consistent with that used in developing relative value units for the Medicare physician fee schedule. By assigning APC 601 a relative payment weight of 1.0, hospitals can easily compare the relative relationship of one APC to another. Next, we divided the median cost for each APC by the median cost for a mid-level clinic visit, APC 601, to derive the relative payment weight for each APC.

The median cost for APC 601 is $47.00. In the proposed rule, we also used a mid-level clinic visit, APC 91336, which had a median cost of $54.00, as the scaler of APC weights. On average, due to the reduced value of the scaler used for this notice, the final weights will be higher than those published in the proposed rule.

Comment: Some commenters believe that the ratesetting methodology does not reflect complex cases because we eliminate statistical ''outlier'' claims from the calculation of the median costs and the weights.

Response: As noted above, we trimmed claims with estimated costs that were outside of three standard deviations from the geometric mean. Because we removed claims above or below the mean, we corrected for data errors that would have skewed the estimates of median costs and group weights upward or downward. We believe this trim is a valid method of removing extremely unusual costs that are most likely associated with data submission errors and do not represent actual costs. In addition, it is consistent with the method we use to set inpatient hospital diagnosis-related group (DRG) weights.

Comment: Numerous commenters disagreed with our use of single-procedure claims only in the calculation of the relative payment weights. One commenter was concerned that we could be masking differences in resource use attributable to patient characteristics by using only single-procedure claims to calculate relative weights.

Response: We used single-procedure claims to calculate the relative weight for each APC because we could not accurately allocate costs to a particular procedure when the costs were part of a bill for multiple procedures. Bills with a single major procedure provided are, in most cases, the best estimate of relative procedure costs. It is important to note that for all other calculations, including calculation of the conversion factor, we used both single-procedure and multiple-procedure bills.

We do not believe that using single-procedure bills biases the relative cost of any particular procedure. Although patients with more complex healthcare needs might have several procedures performed, hospital charges for an individual procedure would not be greater. Our most significant concern was that distribution of single bill procedures within an APC would not reflect the correct distribution of those procedure on all bills. However, careful statistical analyses demonstrated that the distribution of procedures within an APC group did not differ when single bill procedure frequencies were compared with all bills. It is also important to note that when items or services were to be packaged with a major procedure, we added their costs to that procedure prior to making the single bill determination. Therefore, the costs of contrast media, for example, are included in the relative weights. In some cases, we agreed with the commenters that this approach needed to be modified. For example, for chemotherapy, we are not grouping drugs, but rather paying for each one separately. Moreover, as a result of the transitional pass-through provisions of the BBRA 1999, radiopharmaceuticals will be paid separately from the nuclear medicine APCs.

Comment: Several commenters expressed concern that the 1996 claims data are insufficient or inadequate to develop the PPS model. For example, some commenters asserted that the 1996 data are not recent enough to reflect the current mix of outpatient services. Some commenters also argued that undercoding in the data would lead to underestimates of median costs. Other commenters recommended that we address alleged inadequacies in the data by gathering cost data on new procedures and by basing payment on these data until we can determine whether to place a new procedure in an existing APC or create a new APC.

Response: While we acknowledge limitations of setting payment rates with historical claims data, section 1833(t)(2)(C) of the Act requires us to use 1996 claims in developing the PPS. We discuss how we will price new procedures that are not reflected in our database in section III.C.8 of this preamble.

Comment: Commenters were concerned about the cost-to-charge ratios used to estimate median APC costs and pre-BBA payments. For example, one medical organization recommended that we account for the capital-intensive nature of radiology services by adjusting the cost-to-charge ratios applicable to these services for the step-down methodology that allocates capital expenses by square footage. The belief is that these allocation methods underestimate radiological equipment costs and certain cost-to-charge ratios, leading to underestimates of the median costs for relevant APC groups.

Response: Although capital-related costs may be allocated to routine and ancillary service cost centers using the step-down methodology based on square footage, as an alternative, the ''dollar value'' method may be used by hospitals. This method is made available to hospitals in Worksheet B–1 of the hospital cost report (HCFA 2552–96). The dollar value method more accurately distributes the capital costs associated with equipment to the revenue-producing cost center to which the equipment is assigned. We are not able to adjust the cost-to-charge ratios of those hospitals that allocate equipment based on square footage because we have no way of knowing which specific equipment costs should be allocated to revenue-producing cost centers in each hospital.

2. Conversion Factor

Section 1833(t)(3)(C)(i) of the Act requires that we establish a conversion factor for 1999 to determine the Medicare payment amounts for each covered group of services. For the proposed rule as corrected, we derived the conversion factor from a base amount of payments described in section 1833(t)(3)(A) of the Act, as enacted in the BBA 1997. Such base amount was calculated for the services included in the outpatient PPS as an estimate of the sum of (1) total payments that would be payable from the Trust Fund under the current (non-PPS) payment system in 1999, plus (2) the beneficiary coinsurance that would have been paid under the new (PPS) system in 1999. For the final rule, however, we derived the conversion factor from a base amount that includes beneficiary coinsurance that would have been made under the current (non-PPS) system rather than the proposed (PPS) system. Section 201(l) of the BBRA 1999 states: ''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.''

Section 1833(t)(2)(C) of the Act requires us to project utilization for hospital outpatient services. We were unable to make precise projections of increases in the volume and intensity of services because we were not able to quantify some of the factors that affect utilization. For instance, we would anticipate that Medicare beneficiaries who choose to migrate to managed care plans may be healthier than those who choose to stay in fee-for-service plans. Thus, we could assume a decrease in the volume of services coupled with an increase in the intensity of services

furnished for Medicare beneficiaries in the fee-for-service program. Another factor that we believe will affect future utilization is the incentive to code billed services more accurately. Currently, hospitals are paid for the majority of the outpatient services they furnish on a cost basis, and inaccurate or improper coding does not necessarily affect the amount of payment. In contrast, under the PPS, hospitals are required to use HCPCS codes in order to receive payment. We expect that the frequency of some services may increase as a result of the coding requirements. We believe each of these assumptions will affect the reporting of volume and intensity of services, although we are not able to quantify them individually to project 1999 utilization. Therefore, we used what we believe to be a more reliable and valid approach to computing the conversion factor under the methodology described below.

Comment: A large national trade association commented that the exclusion of claims for unclassified services (for example, those claims for which we cannot identify the service to be paid) from the PPS model could bias the conversion factor downward if the excluded claims have a disproportionate number of services with high payment to cost ratios, such as clinic and emergency room visits.

Response: In order to set the conversion factor as accurately as possible, we used only claims for which the costs and volume of services could be identified on the bill. As noted by the commenter, this decision resulted in the exclusion of claims with unclassifiable services. Upon examination of these claims, we have determined that services with high payment to cost ratios (those that would gain under the PPS system) were not disproportionately represented. Therefore, we believe the exclusion of unclassifiable services does not bias the conversion factor.

Setting the Rates

In order to convert the relative weights determined for each APC (see section III.E.1) into payment rates, we calculated a conversion factor that would result in total estimated payments to hospitals under the PPS in 1999 equal to the total estimated payments that would have been payable from the Trust Fund in 1999 if PPS had not been enacted plus estimated beneficiary coinsurance for the same services during the same period. The prospective payment rate for each APC is calculated by multiplying the APC's relative weight by the conversion factor. For the calculation of the conversion factor, we have excluded all data from the 58 Maryland providers that qualify under section 1814(b)(3) of the Act for payment under the State's payment system. We computed the conversion factor by first adding together the aggregate Medicare hospital outpatient payments made under the cost-based payment system (referred to in this section as pre-PPS payments) for calendar year 1996, plus the estimated beneficiary coinsurance amounts made under pre-PPS law for the same services. We then divided that amount by a wage-adjusted sum of the relative weights for all APCs under the hospital outpatient PPS. The methodology we used to determine current law Medicare hospital outpatient payments and beneficiary coinsurance is discussed below in section III.E.2.a. A discussion of the sum of the relative weights follows in section III.E.2.b.

a. Calculating Aggregate Calendar Year 1996 Medicare and Beneficiary Payments for Hospital Outpatient Services (Pre-PPS)

To calculate Medicare hospital outpatient payment amounts before implementation of the PPS, we first identified calendar year 1996 single and multiple procedure bills for all the services that we will recognize under the outpatient PPS. As we identified services that will be paid under the outpatient PPS, we eliminated invalid or noncovered HCPCS codes.

Hospital payments include both operating and capital costs for the HCPCS coded services for which payment is to be made under the outpatient PPS. We summed these two types of costs by HCPCS code at the provider level. Consolidating the data in this manner allowed us to simulate provider payment on an aggregate basis. Then (as required by section 1861(v)(1)(S)(ii) of the Act as amended by section 201(k) of the BBRA 1999), we applied the capital cost reductions of 10 percent and operating cost reductions of 5.8 percent.

We determined for each HCPCS code the applicable payment methodology under the current system. Payment before implementation of PPS for procedures in the baseline was calculated using one of the following equations, as appropriate:

- For radiology procedures paid for under the radiology fee schedule, we determined payment in the aggregate for each provider as the lower of the cost, charge, or blended amount. We use the following equation to determine the radiology blended amount: (0.42 × lower of cost or charge minus beneficiary coinsurance) + (0.58 × ((0.62 × global physician fee schedule amount) − beneficiary coinsurance)).
- For surgical procedures for which Medicare pays an ASC facility fee, we determined payment in the aggregate for each provider as the lower of the cost, charge, or blended amount. We used the following equation to determine the ASC blended amount: (0.42 × lower of cost or charge minus beneficiary coinsurance) + (0.58 × (ASC payment rate − beneficiary coinsurance)).
- For diagnostic procedures paid for under the diagnostic fee schedule, we determined payment in the aggregate for each provider as the lower of the cost, charge, or blended amount. We used the following equation to determine the blended amount for diagnostic procedures: (0.50 × lower of cost or charge minus beneficiary coinsurance) + (0.50 × ((0.42 × global physician fee schedule amount) − beneficiary coinsurance)).

For all other covered services not subject to one of the blended payment method categories, we determined payment as the lower of costs or charges less beneficiary coinsurance. Because the formula-driven overpayment (FDO) was corrected beginning October 1, 1997, the blended equations eliminate FDO.

We then determined the Medicare payment amount for each provider by summing the aggregate amounts computed for each of the four types of payment methodologies discussed above. In addition, we determined the amount of the beneficiary coinsurance for each provider using the beneficiary coinsurance amounts that would have been paid before implementation of PPS. The total amount (Medicare and beneficiary payments) reflects the amount hospitals would be paid under the PPS and is the numerator in the equation for calculating the unadjusted conversion factor.

b. Sum of the Relative Weights

Next we summed the discounted relative weights for services that are within the scope of the outpatient PPS. (See discussion of discounting for surgical procedures in section III.C.7.) Specifically, we multiplied (using single and multiple procedure claims in a hospital) the discounted volume of procedures or visits in each APC group by the relative weights for each APC group; we wage-adjusted 60 percent of this total by each hospital's wage index, and we then summed the wage-adjusted and nonadjusted weights across all hospitals. (The wage indices used are included in Addenda H, I, and J.) The resulting sum equals the denominator in the calculation of the conversion factor.

We calculated the conversion factor by dividing the sum of the discounted relative weights into the total payment explained in section III.E.2.a, above, including both Medicare payment and beneficiary coinsurance. We then adjusted the conversion factor so that the outlier and pass-through payments are implemented in a budget neutral manner, as described in sections III.H.1 and III.D. The adjusted calendar year 1996 conversion factor is $43.023. To inflate the 1996 conversion factor to 1999, our Office of the Actuary estimated an update factor of 1.106. Therefore, the adjusted 1999 conversion factor is $47.583.

For calendar year 2000, we updated the conversion factor as specified in section 1833(t)(3)(C)(iii) of the Act. The update is the market basket percentage increase applied to hospital discharges occurring during the fiscal year ending in calendar year 2000 minus 1 percentage point. For 2000, the updated conversion factor is $48.487.

Comment: A number of commenters suggested that we remove the behavioral offset that we proposed to apply to the conversion factor. As proposed, the intent of the offset was to adjust for hospital coding changes that take place in response to reductions in beneficiary coinsurance.

Response: We have decided not to include a behavioral offset to the conversion factor in this final rule. Hospital coding changes are expected to occur under the outpatient PPS; however, we believe changes that occur during the first PPS years will result from hospitals billing more accurately under the new system. A behavioral offset implemented in the initial PPS years may distort the incentives to bill accurately. We may reconsider implementation of a behavioral offset in future years as we gather data and gain experience under the new system.

Comment: A large national trade association expressed concern that application of the 5.8 percent and 10.0 percent reduction to costs for all hospital outpatient services included in the PPS model underestimates the conversion factor. They recommended that we exclude the Part B services provided to inpatients who exhaust their Part A benefits from the reductions.

Response: Our analysis shows that fewer than 5,000 of the more than 80 million claims used to set the conversion factor were associated with these types of services. Total costs associated with these claims were less than $1.4 million, which is too small to have a measurable effect on the conversion factor.

Comment: Many commenters strongly argued that we misinterpreted the provisions of section 1833(t)(3) of the Act in calculating beneficiary coinsurance for purposes of setting the base amount of the conversion factor. The commenters noted that this methodology contributed significantly to the estimated 5.7 percent reduction in Medicare outpatient payments to hospitals reflected in the proposed rule. Most commenters further argued that the Congress did not intend for this loss to occur and that we had the authority to interpret the methodology described in the statute so that no net change in payments would result from the conversion factor.

Response: Section 1833(t)(3)(A) of the Act, as added by the BBA 1997, states that, for purposes of calculating the base amount used to determine the conversion factor, the Secretary shall calculate ''the total amount of copayments estimated to be paid *under this subsection.* * * *'' (Emphasis added.) For the proposed rule, we estimated the coinsurance that would be paid under PPS. In section 201(l) of the BBRA 1999, the Congress addressed the calculation of the base amount, stating, ''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 the Secretary of Health and Human Services has the authority to determine such amount without regard to such section.'' Therefore, for this final rule, we estimated the coinsurance that would have been paid if PPS had not been enacted.

F. Calculation of Coinsurance Payments and Medicare Program Payments Under the PPS

1. Background

In section III.E, above, we explained how we determined APC group weights, calculated an outpatient PPS conversion factor, and determined national prospective payment rates, standardized for area wage variations, for the APC groups. We will now explain how we calculated beneficiary coinsurance amounts for each APC group.

The outpatient PPS established by section 1833(t) of the Act includes a mechanism designed to eventually achieve a beneficiary coinsurance level equal to 20 percent of the prospectively determined payment rate established for the service. As discussed in the proposed rule, for each APC we calculate an amount referred to in section 1833(t)(3)(B) of the Act as the ''unadjusted copayment amount.'' The unadjusted coinsurance amount is calculated by taking 20 percent of the national median charges billed in 1996 for the services that are in the APC, trended forward to 1999; however, the coinsurance amount cannot be less than 20 percent of the APC payment rate. The unadjusted coinsurance amount for an APC remains frozen, while the payment rate for the APC is increased by adjustments based on the Medicare market basket. As the APC rate increases and the coinsurance amount remains frozen, the unadjusted coinsurance amount will eventually become 20 percent of the payment rate for all APC groups. Once the unadjusted coinsurance amount is 20 percent of the payment amount, both the APC payment rate and the unadjusted coinsurance amount will be updated by the annual market basket adjustment.

In the proposed rule, we proposed to not adopt new APCs for new procedures or services for at least 2 years, but instead assign them to existing groups while accumulating data on their costs. In the final rule we do provide for APCs for new procedures that do not fit well into another APC. When an APC is added that consists of HCPCS codes for which we do not have 1996 charge data upon which to calculate the unadjusted coinsurance amount, coinsurance will be calculated as 20 percent of the APC payment amount.

There is an exception to the coinsurance provisions for screening colonoscopies and screening sigmoidoscopies. Section 4104 of the BBA 1997 provided coverage for colorectal screening. This section, in part, added new sections 1834(d)(2) and (3) to the Act, which provide that for covered screening sigmoidoscopies and colonoscopies performed in hospital outpatient departments and ambulatory surgical centers (ASCs), payment is to be based on the *lesser* of the hospital or the ASC payment rates and coinsurance for both screening colonoscopies and screening sigmoidoscopies is to be 25 percent of the rate used for payment.

Section 4104 of the BBA 1997 also allows, at the Secretary's discretion, coverage of screening barium enemas as a colorectal cancer screening tool. We are including screening barium enemas as a covered service under the hospital outpatient PPS. The payment rate for screening barium enemas is the same as for diagnostic barium enemas. Coinsurance for a screening barium enema is based on 20 percent of the APC payment rate.

Sections 201(a) and (b) of the BBRA 1999 amend section 1833(t) of the Act to provide for additional payments to hospitals for outlier cases and for certain medical devices, drugs, and biologicals. These additional payments to hospitals will not affect coinsurance amounts. Redesignated section 1833(t)(8)(D) of the Act, as amended by section 201(i) of the BBRA 1999, provides that the coinsurance amount is to be computed as if outlier adjustments, adjustments for certain medical devices, drugs, and biologicals, as well as any other adjustments we may establish under section 1833(t)(2)(E) of the Act, had not occurred. Section 202 of the BBRA 1999 adds a new section 1833(t)(7) to the Act to provide transitional corridor payments to certain hospitals through calendar year 2003 and indefinitely for certain cancer centers.

Section 1833(t)(7)(H) of the Act provides that the transitional corridor payment provisions will have no effect on determining copayment amounts.

Section 204(a) of the BBRA 1999 amended redesignated section 1833(t)(8)(C) of the Act to provide that the coinsurance amount for a hospital outpatient procedure cannot exceed the amount of the inpatient hospital deductible for that year. The inpatient hospital deductible for calendar year 2000 is $776.00. We will apply the limitation to the wage adjusted coinsurance amount (not the unadjusted coinsurance amount) after any Part B deductible amounts are taken into account. Therefore, although the published unadjusted coinsurance amount for any APC may be higher or lower than $776.00 in 2000, the actual coinsurance amount for an APC, determined after any deductible amounts and adjustments for variations in geographic areas are taken into account, will be limited to the Medicare inpatient hospital deductible. Any reductions in copayments that occur in applying the limitation will be paid to hospitals as additional program payments. (See section III.F.3.a, below, for discussion of calculating the Medicare payment amount.)

MedPAC Comment: In its March 1999 report to the Congress, MedPAC expressed concern that the statute's approach to addressing the reduction in coinsurance could mean that it will be decades before coinsurance is 20 percent of all APC payment rates. MedPAC recommended that the Secretary seek and the Congress legislate a more rapid phase-in and that the cost be financed by increases in program spending, rather than through additional reductions in payments to hospitals. MedPAC agrees that the approach to calculating the coinsurance delineated in section 1833(t) of the Act is methodologically sound, but they recommend a shorter period to complete the coinsurance reduction.

Response: The coinsurance reductions enacted by the BBA 1997 already provide significantly higher levels of financial protection for beneficiaries than have existed in the past. While an acceleration of this protection might be desirable, the costs of such a policy must be balanced against other needs for increased Medicare spending and protection of the trust funds. The President's budget for FY 2001 does not contain such a proposal.

Comment: Three commenters discussed the delay in implementing the outpatient PPS until after January 1, 2000. A hospital association stated that it strongly believes that the outpatient PPS should not be implemented until all systems are ready, and suggested that implementation occur at the start of a calendar year so that Medigap insurers did not receive an unearned windfall by reason of a midyear decrease in beneficiary coinsurance amounts. Stating that the delay in implementation was of serious concern to it, an insurance group strongly urged us to implement the outpatient PPS as soon as possible. Finally, a beneficiary advocacy group stated that it is deeply concerned about the delay in implementation. While stating that it understood the magnitude of the Y2K problem, this group urged us to find a way to proceed with the phase-down of beneficiary coinsurance or, failing that, to offer our assurance that the phase-down will not be delayed beyond January 1, 2000.

Response: As noted elsewhere in this final rule, we intend to implement the outpatient PPS effective for services furnished on or after July 1, 2000. As noted in the proposed rule, we concluded that attempting to make the massive computer changes required to implement PPS at the same time we were trying to ensure that Medicare's computers were Y2K compliant would have jeopardized the compliance effort, which was HCFA's highest priority. Now that HCFA's efforts to make its computer systems, and those of its contractors, Y2K compliant are complete, we believe that July 1, 2000 is the earliest date on which we can feasibly implement the PPS. Pursuant to HCFA's contracts with the contractors responsible for maintaining its computer systems, HCFA makes programming changes such as those required to implement the outpatient PPS at the beginning of fiscal quarters. Thus, pursuant to this practice, after January 1, 2000, there are only three dates in 2000 on which the programming changes necessary to implement outpatient PPS can be put into effect—April 1, 2000, July 1, 2000 and October 1, 2000.

The first step in changing HCFA's computer systems to allow for implementation of the outpatient PPS is to expand the claim record of several HCFA and contractor systems to accept and retain specific information related to how a service is being paid or why it is denied. The claim record expansion is an indispensable prerequisite to implementation of outpatient PPS. Once expansion of the claim form is completed, we can then make the remaining programming changes necessary to implement the outpatient PPS. As we noted in the proposed rule, 63 FR 47605, these are massive changes that will require extensive testing. We anticipate that these software coding changes cannot be completed before the end of the second quarter of 2000. Therefore, the earliest possible date on which they can be installed and made operational is July 1, 2000.

We do not believe that it is technically feasible to complete installation of both the claims-form line item expansion and the coding changes needed to implement PPS any sooner than July 1, 2000. Each of these two stages of preparing HCFA's computer system for PPS constitutes major systems changes in and of itself. To attempt to make both changes simultaneously would be to run the risk that the system would not function properly at all, potentially requiring implementation to be delayed beyond July 1, 2000. We believe that the two-stage approach discussed above is the only feasible way to make the systems changes necessary to implement PPS and to be certain that they will work. The soonest date on which PPS can be implemented after the millennium is therefore July 1, 2000.

Despite one commenter's request that we implement the outpatient PPS at the start of a calendar year, we do not believe it would be appropriate to delay implementation beyond July 1, 2000. We see no reason to delay implementation beyond the time necessary for HCFA to have completed its Y2K efforts and make all the systems changes necessary for PPS. As with all of the other aspects of PPS, we believe that the beneficiary coinsurance reform contained in the outpatient PPS should be put into effect as soon as possible, so that beneficiaries can be subject to the lower coinsurance amounts under the new payment methodology at the

earliest date. We believe that this consideration outweighs any concern that Medigap insurers might receive a windfall because they set premiums for a given year assuming coinsurance amounts would be at one level only to see those amounts decrease in the middle of the year. In addition, we note that, if insurers received a large enough windfall for the reasons described by the commenter, the insurers might be required to refund premiums to beneficiaries or offer them a credit on premiums pursuant to section 1882(r) of the Act.

While none of the commenters specifically requested that we do so, we have considered the possibility of applying the outpatient PPS payment methodology retroactively to services furnished on or after January 1, 1999. We have decided not to make these retroactive payments for the reasons described below.

The first reason is the practical problem that the information needed to implement PPS retroactively does not exist in a usable form. Under current payment methodologies for many outpatient services, hospitals submit bills for furnished services based on their charges for the services. For these services, HCFA does not require hospitals to submit bills containing the HCPCS code for the furnished service and other data (such as the dates of service of multiple services submitted on the same bill) necessary to process bills under the new prospective payment methodology. Without the HCPCS code for a given service, we would be unable to determine retroactively into which APC group the service should be placed for payment under PPS. In turn, that would mean that we could not determine the appropriate payment amount for the service. Thus, given the information currently available to us, we could not now simply reprocess bills for outpatient services that had been furnished between January 1, 1999 and July 1, 2000 and recompute payment and coinsurance amounts for these services. As a result, the data needed to implement PPS retroactively do not exist in a form that would allow for such implementation.

Nor would it have been feasible to attempt to capture the information necessary for retroactive application during 1999. As noted above, we concluded that it would not have been prudent to make the computer programming changes necessary to implement PPS until our Y2K efforts were complete. Those same changes would have been necessary to allow us to capture the more detailed claims data needed to perform a retroactive application of PPS back to January 1, 1999 once the system was implemented prospectively. Because we delayed those changes out of concern that they would interfere with our Y2K efforts, no automated process existed for the period January 1, 1999 through July 1, 2000 by which we could have captured the more detailed claims data necessary to effect an eventual retroactive implementation of PPS. Publication of a final rule before January 1, 1999 would not have altered this situation. Even if we had published such a rule, it could not have become effective until we could make the computer changes necessary to implement PPS—the functional equivalent of what we have done through publication of the proposed rule and this final rule—and until we could make those changes, we could not compile by computer the data needed to later reprocess claims under PPS.

In theory, we might have been able to implement PPS retroactively despite the lack of an automated method of compiling the data necessary to do so. But it simply would not have been practicable to maintain and later process by hand such data for the period between January 1, 1999 and July 1, 2000, given the millions of claims for outpatient services submitted during that period. (Based on the latest data available, we process approximately 160 million claims for outpatient services over an 18-month period.) Neither HCFA nor its contractors have the staff needed to accomplish such a task.

We might also have conceivably required hospitals to maintain the data required for a later retroactive implementation of PPS, but this approach has practical difficulties. First, during the interim period between January 1, 1999 and implementation of PPS, hospitals themselves were exerting significant efforts to ensure the Y2K compliance of their own automated Medicare billing systems, and it is doubtful that those systems could have accommodated the necessary programming changes any more than Medicare's systems could have. Even if hospitals could have maintained the information (or if HCFA could have maintained it by hand or could obtain it from any source now), the burden associated with attempting to implement the new prospective payment methodology both retroactively and prospectively at the same time would have been prohibitive. As noted in the proposed rule and in this final rule, effecting the transition between the old payment methodologies and the new prospective payment methodology constitutes a massive programmatic undertaking. Any effort to reprocess the huge number of bills for outpatient services that would be involved in any attempt to retroactively implement PPS would compete for the same resources needed to implement PPS prospectively, and would compromise our ability to ensure the smoothest prospective implementation.

This is especially so if paper records of claims from the interim period would have to be manually input into Medicare's automated payment systems in order to make retroactive payments for services furnished on or after January 1, 1999. Undertaking an effort, once PPS is implemented, to review hospital records of every outpatient service furnished between January 1, 1999 and July 1, 2000; translate those records into the data needed to process a Medicare claim for the service under PPS; and issue a retroactive payment reflecting the PPS rate for the service would cause a huge backlog of current bills to be processed (and of other carrier tasks), and thus would not be practicable. Therefore, there was no feasible way to have captured the information necessary to make PPS apply retroactively.

In addition to the practical problems described above, the statute does not require retroactive application of PPS. The statutory requirement to implement the PPS for services furnished on or after January 1, 1999 is ambiguous. While section 1833(t)(1)(A)'s reference to outpatient services ''furnished during a year beginning with 1999'' might be read as imposing such a requirement, it is also true that section 1833(t)(1)(B)(i) does not expressly set a time limit for HCFA to designate which services are ''covered'' outpatient services for purposes of payment under PPS. Nor does it set a deadline for HCFA to issue regulations implementing the outpatient PPS. As a result, the statute can also be read to require implementation of PPS for services furnished in a year beginning in 1999 *if* HCFA has designated in its implementing regulations those services as covered services for purposes of PPS. The better reading is that the system applies prospectively only.

We recognize that, under section 1833(a)(2)(B), Congress arguably made the old payment methodologies for outpatient services inapplicable to services furnished on or after January 1, 1999. Again, though, Congress imposed no corresponding limit on the time within which HCFA must designate the services that would be ''covered'' services for purposes of PPS. While it is therefore possible to read the statute in such a way that an outpatient service

furnished after January 1, 1999 but not yet designated as a covered outpatient service by HCFA for purposes of PPS would have no payment methodology applicable to it, we do not believe that Congress intended such a result. We believe that where HCFA, because of significant Y2K concerns, has not yet designated a given outpatient service as a covered service for purposes of PPS, the most appropriate reading of section 1833(t)(1)(A) is that it authorizes the Secretary to continue to pay for the service under the existing methodology until PPS can be implemented. If the Congress had known about the Y2K problem at the time it enacted the PPS statute, this is the only rational approach it could have adopted.

We believe that a clear expression of Congressional intent not to require retroactive application of PPS can be found in the legislative history of amendments to section 1833(t) of the Act, enacted as sections 201, 202, and 204 of the BBRA 1999. In each instance, the legislation provides that the ''amendments made by this section shall be effective as if included in the enactment of the BBA,'' that is, the original enactment of PPS in section 1833(t) (sections 201(m), 202(b), and 204(c) of the BBRA 1999). This language was taken from the House version of the bill (H.R. Rep. No. 436 (Part I), 106th Cong., 1st Sess. 14, 16 (1999)). The House Report stated that the outpatient payment reforms contained in the BBRA 1999 (and hence in the BBA 1997) were intended to take effect ''upon implementation of the hospital prospective payment system'' by HCFA, *id.* at 52, 55, 56, not on January 1, 1999. The House Conference Committee Report reiterated the understanding that the payment and coinsurance provisions of the BBA and BBRA do not take effect until after implementation by HCFA. H. Conf. Rep. No. 479, 106th Cong., 1st Sess. 866 (1999) (''[c]urrently, beneficiaries pay 20% of charges for outpatient services,'' but ''[u]nder the outpatient PPS, beneficiary coinsurance will be limited to frozen dollar amounts based on 20% of national median charges for services in 1996, updated to the year of implementation of the PPS''); *id.* at 867 (''[t]he conferees fully expect that the beneficiary coinsurance phase-down will commence, as scheduled, on July 1, 2000''); 870 (''[h]ospital outpatient PPS is to be implemented simultaneously and in full for all services and hospitals (estimated for July 2000)'').

Both the House Report and the Conference Report expressly acknowledge, without disapproval, HCFA's decision to delay implementation of the outpatient PPS until after January 1, 2000. H.R. Rep. No. 436 (Part I) at 51 (stating that Secretary ''delayed implementation of the new system until after the start of CY 2000 in order to ensure that 'year 2000' data processing problems are fully resolved before the new system is implemented'' and that ''HCFA currently estimates that the outpatient department prospective payment system will be implemented in July 2000''); 145 Cong. Rec. at H12529 (daily ed. Nov. 17, 1999) (H. Conf. Rep. No. 479) (acknowledging ''[t]here has already been a one-year delay in implementation of the BBA 97 provision'' and stating that conferees ''fully expect'' that the outpatient prospective payment system ''will commence, as scheduled, on July 1, 2000''). These statements indicate Congressional intent that payments and coinsurance for covered hospital outpatient services would be governed prospectively by PPS only after HCFA promulgated and made effective final implementing regulations.

Finally, there is a serious question as to whether retroactive implementation of PPS might constitute prohibited retroactive rulemaking. In *Bowen* v. *Georgetown University Hospital*, 488 U.S. 204, 208 (1988), the Supreme Court stated that a statutory grant of legislative rulemaking authority does not encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms, even where some substantial justification for retroactive rulemaking might exist. The Court then declined to find this express authorization for retroactive rulemaking in the Medicare statute's general grant of rulemaking authority.

We do not find this express authorization in section 1833(t) or any other statutory provision concerning the outpatient PPS. Section 1833(t)(1) requires that payment for outpatient services that are furnished during any calendar year beginning after January 1, 1999 and that are designated by HCFA as ''covered'' outpatient services shall be made under a prospective payment system. While Congress may have presumed, when it enacted section 1833(t) as part of the BBA, that HCFA would be able to designate covered outpatient services and implement the outpatient PPS by January 1, 1999, Congress did not foresee at that time that Y2K concerns would prevent the agency from doing so. As a result, the statute is silent as to what was to occur if HCFA was unable to designate covered outpatient services and implement PPS by January 1, 1999. We do not believe that this silence constitutes the express authorization of retroactive rulemaking required by the Supreme Court's *Georgetown* decision.

Comment: Several commenters contended that the proposed rules for beneficiary coinsurance are overly complex and that the phase-in period is too long. One commenter asked HCFA to consider a less involved method and a more aggressive time period for implementation. Another commenter suggested using a 5-year phase-in period. One commenter requested that we recommend a legislative change to the Congress to reduce beneficiary coinsurance to 20 percent by January 1, 2003. Still another commenter expressed concern that calculations of coinsurance amounts for each hospital will be particularly burdensome to Medicare fiscal intermediaries and, as a result of the increased workload, errors may occur. The commenter also recommended a more rapid reduction of coinsurance to 20 percent of the payment amount.

Response: We agree that the rules governing how coinsurance is to be calculated under the PPS are complex, and the phase-in to 20 percent coinsurance is a lengthy one. However, the methods for calculating coinsurance are dictated by the statute. The legislative changes were made in order to put some control on rapidly increasing beneficiary coinsurance payments, to begin to decrease the proportion of beneficiary liability for hospital outpatient services, and to continue to reduce beneficiary liability over time. As we have stated, the impetus to accelerate the reduction of beneficiary coinsurance has to be viewed within the context of other needs for increased Medicare expenditures and long-term protection of the trust funds. The delay in implementing the hospital outpatient PPS past the statutory effective date was unavoidable due to systems constraints imposed by Y2K compliance requirements.

Comment: One commenter noted that the proposed rule set beneficiary coinsurance at 20 percent of *median* charges, but the commenter believes that coinsurance amounts should be recalculated to equal 20 percent of the *average* charge for the applicable APC group. The commenter indicates that such a change would provide some financial relief to hospitals.

Response: Section 1833(t)(3)(B)(i) of the Act requires that unadjusted coinsurance amounts be calculated as 20 percent of the national *median* of the charges for services within the APC group.

Comment: One commenter stated that because coinsurance is based on the median charges of the APC, some beneficiaries would pay a higher coinsurance than they would under the current system. The commenter believes that beneficiaries who require less intensive services in an APC group will essentially subsidize other beneficiaries who receive more intensive services within the group. The commenter asserted that fairness would dictate beneficiaries be charged coinsurance amounts that more appropriately reflect the services received, not an amount based on a median of multiple services they did not receive.

Response: Section 1833(t)(3)(B)(ii) of the Act provides that the unadjusted coinsurance amounts are based on the national median of the charges for the ''services within'' an APC. Because an APC group consists of services that are both clinically similar and similar with respect to the resources required to perform the service, we would expect that charges for the services should also be fairly homogeneous. We believe that services within a group are homogeneous enough to warrant a single payment amount and a single coinsurance amount.

In the following sections, we describe how we determined the beneficiary coinsurance amount and the Medicare program payment amount for services paid for under the hospital outpatient PPS.

2. Determining the Unadjusted Coinsurance Amount and Program Payment Percentage

To calculate Medicare program payment amounts and beneficiary coinsurance amounts, we first determined for each APC group two base amounts, in accordance with statutory provisions:

- An unadjusted copayment amount, described in section 1833(t)(3)(B) of the Act; and
- The predeductible payment percentage, which we call the program payment percentage, described in section 1833(t)(3)(E) of the Act.

a. Calculating the Unadjusted Coinsurance Amount for Each APC Group

In the proposed rule, we described the specific steps used to calculate the unadjusted coinsurance amounts for each APC group as follows:

(i) We determined the national median of the charges billed in 1996 for the services that constitute an APC group after standardizing charges for geographic variations attributable to labor costs. (To determine the labor adjustment, we divided the portion of each charge that we estimated was attributable to labor costs (60 percent) by the hospital's inpatient wage index value and added the result to the nonlabor portion of the charge (40 percent)).

(ii) We updated charge values to projected 1999 levels by multiplying the 1996 median charge for the APC group by 13.0 percent (increased to 14.7 percent in this final rule), which the HCFA Office of the Actuary estimates to be the rate of growth of charges between 1996 and 1999.

(iii) To obtain the unadjusted coinsurance amount for the APC group, we multiplied the estimated 1999 national median charge for the APC group by 20 percent. The unadjusted coinsurance amount is frozen at the 1999 level until such time as the program payment percentage (as determined below) equals or exceeds 80 percent (section 1833(t)(3)(B)(ii) of the Act).

b. Calculating the Program Payment Percentage (Predeductible Payment Percentage)

In the proposed rule and in this final rule, we use the term ''program payment percentage'' to replace the term ''predeductible payment percentage,'' which is referred to in section 1833(t)(3)(E) of the Act. The program payment percentage is calculated annually for each APC group, until the value of the program payment percentage equals 80 percent. To determine the program payment percentage for each APC group, we—

(i) Subtract the APC group's unadjusted coinsurance amount from the payment rate set for the APC group; and

(ii) Divide the difference (APC payment rate minus unadjusted coinsurance amount) by the APC payment rate, and multiply by 100.

The program payment percentage will be recalculated each year because APC payment rates will change when APC rates are increased by annual market basket updates and whenever we revise an APC.

Comment: One commenter expressed concern about how the coinsurance amounts are determined. The commenter stated that the calculation is flawed and penalizes beneficiaries in those States where charges for services tend to be lower than in other States. The commenter alleged that if the hospitals in those States where charges for services tend to be lower accept a reduced coinsurance in order to hold beneficiaries harmless, the hospitals will be penalized. The commenter also asserted that Medigap policies and Medicaid programs will also be affected. The commenter further stated that coinsurance should be based on regional, not national, charges. The commenter contended that the provision does not achieve the intended outcome of equalizing payment across the nation.

Response: Sections 1833(t)(3) and (t)(8) of the Act prescribe how coinsurance amounts are to be calculated under the PPS. Our method of calculating unadjusted coinsurance amounts for each APC group based on 20 percent of national median charges follows the requirements of section 1833(t)(3)(B) of the Act.

Comment: A number of commenters believe that the payment system as proposed would create gross anomalies in coinsurance for particular chemotherapy drugs. For example, the proposed $36.61 coinsurance for fluorouracil is 10 times the hospital's cost to purchase that drug. The commenters asserted that this excessive coinsurance represents an abuse of patients and would undermine beneficiary confidence in the new system. They recommended that coinsurance be limited to 20 percent of the payment amount for each drug.

Several other commenters noted that classifying drugs with widely varying costs in the same APC will have a significant negative effect on beneficiary coinsurance, and in some cases beneficiaries could be required to pay a greater percentage of coinsurance for less effective therapies. For example, one commenter alleged that the coinsurance for the drug 5–FU, which the commenter believes has a current coinsurance of approximately $1, would increase to $40 under the proposed system.

Response: The coinsurance anomalies for chemotherapy drugs that appeared in the proposed rule are not an issue under this final rule. Unlike the proposed chemotherapy drug APCs, which grouped all chemotherapy drugs under four APCs, in this final rule, each chemotherapy drug is assigned to a separate APC. As discussed in section III.D.5 of this preamble, the unadjusted coinsurance amounts for these APCs is calculated as 20 percent of the APC payment rate.

Comment: One commenter noted that the proposed national unadjusted coinsurance amounts for cardiovascular stress testing and perfusion imaging result in beneficiaries bearing 85 percent of the total payment for stress testing and 60 percent for perfusion imaging, which many beneficiaries will be unable to afford. Another commenter

requested that we either exclude cataract procedures and angioplasty from the hospital outpatient PPS or create an outlier policy that affords special treatment for these procedures in order to protect beneficiaries from excessive coinsurance amounts.

Response: Coinsurance amounts, by law, are based on 20 percent of the median of the charges actually billed in 1996 (updated to 1999) for the services within an APC. The fact that coinsurance is a larger proportion of the total payment for some APCs than for others reflects the differences in hospital charging practices for different services. For example, in examining departmental cost-to-charge ratios reflected on hospital cost reports, we have found that most hospitals have higher mark-ups in charges for radiology and diagnostic services than they do for clinic visits.

3. Calculating the Medicare Payment Amount and Beneficiary Coinsurance Amount

a. Calculating the Medicare Payment Amount

The national APC payment rate that we calculate for each APC group is the basis for determining the total payment (subject to wage-index adjustment) the hospital will receive from the beneficiary and the Medicare program. (A hospital that elects to reduce coinsurance, as described below in section III.F.4, may receive a total payment that is less than the APC payment rate.) The Medicare payment amount takes into account the wage index adjustment and the beneficiary deductible and coinsurance amounts. In addition, the amount calculated for an APC group applies to all the services that are classified within that APC group. The Medicare payment amount for a specific service classified within an APC group under the outpatient PPS is calculated as follows:

(i) Apply the appropriate wage index adjustment to the national payment rate that is set annually for each APC group.

(ii) Subtract from the adjusted APC payment rate the amount of any applicable deductible as provided under § 410.160.

(iii) Multiply the adjusted APC payment rate, from which the applicable deductible has been subtracted, by the program payment percentage determined for the APC group or 80 percent, whichever is lower. This amount is the *preliminary Medicare payment amount.*

(iv) If the wage-index adjusted coinsurance amount for the APC is reduced because it exceeds the inpatient deductible amount for the calendar year, add the amount of this reduction to the amount determined in (iii) above. The resulting amount is the *final Medicare payment amount.*

b. Calculating the Coinsurance Amount

A coinsurance amount is calculated annually for each APC group. The coinsurance amount calculated for an APC group applies to all the services that are classified within the APC group. The beneficiary coinsurance amount for an APC is calculated as follows:

Subtract the APC group's Medicare payment amount from the adjusted APC group payment rate less deductible; for example, coinsurance amount = (adjusted APC group payment rate less deductible)—APC group *preliminary Medicare payment amount.* If the resulting amount does not exceed the annual hospital inpatient deductible amount for the calendar year, the resulting amount is the beneficiary coinsurance amount. If the resulting amount exceeds the annual inpatient hospital deductible amount, the beneficiary coinsurance amount is limited to the inpatient hospital deductible. For example, assume that the wage-adjusted payment rate for an APC is $300; the program payment percentage for the APC group is 70 percent; the wage-adjusted coinsurance amount for the APC group is $90; and the beneficiary has not yet satisfied any portion of his or her $100 annual Part B deductible.

(A) Adjusted APC payment rate: $300.

(B) Subtract the applicable deductible:

$300–$100 = $200

(C) Multiply the remainder by the program payment percentage to determine the preliminary Medicare payment amount:

$0.7 \times \$200 = \$140$

(D) Subtract the Medicare payment amount from the adjusted APC payment rate less deductible to determine the coinsurance amount, which cannot exceed the inpatient hospital deductible for the calendar year:

$200 − $140 = $60

(E) Calculate the final Medicare payment amount by adding the preliminary Medicare payment amount determined in step (C) to the amount that the coinsurance was reduced as a result of the inpatient hospital deductible limitation.

$140 + $0 = $140

In this case, the beneficiary pays a deductible of $100 and a $60 coinsurance, and the program pays $140, for a total payment to the hospital of $300. Applying the program payment percentage ensures that the program and the beneficiary pay the same proportion of payment that they would have paid if no deductible were taken.

If the annual Part B deductible has already been satisfied, the calculation is:

(A) Adjusted APC payment rate: $300.

(B) Subtract the applicable deductible:

$300 − 0 = $300

(C) Multiply the remainder by the program payment percentage to determine the preliminary Medicare payment amount:

$0.7 \times \$300 = \$210$

(D) Subtract the Medicare payment amount from the adjusted APC payment rate less deductible to determine the coinsurance amount. The coinsurance amount cannot exceed the amount of the inpatient hospital deductible for the calendar year:

$300 − $210= $90

(E) Calculate the final Medicare payment amount by adding the preliminary Medicare payment amount determined in step (C) to the amount that the coinsurance was reduced as a result of the inpatient hospital deductible limitation.

$210 + $0 = $210

In this case, the beneficiary makes a $90 coinsurance payment, and the program pays $210, for a total payment to the hospital of $300.

The following example illustrates a case in which the inpatient hospital deductible limit on coinsurance amounts applies. Assume that the wage-adjusted payment rate for an APC is $2,000; the wage-adjusted coinsurance amount for the APC is $900; the program payment percentage is 55 percent; the inpatient hospital deductible amount for the calendar year is $776 and the beneficiary has not yet satisfied any portion of his or her $100 Part B deductible.

(A) Adjusted APC payment rate: $2,000.

(B) Subtract the applicable deductible:

$2000 − $100 = $1,900

(C) Multiply the remainder by the program payment percentage to determine the preliminary Medicare payment amount:

$0.55 \times \$1,900 = \$1,045$

(D) Subtract the preliminary Medicare payment amount from the adjusted APC payment rate less deductible to determine the coinsurance amount. The coinsurance amount cannot exceed the inpatient hospital deductible amount of $776:

$1,900 − $1,045 = $855, but coinsurance limited to $776

(E) Calculate the final Medicare payment amount by adding the

preliminary Medicare payment amount determined in step (C) to the amount that the coinsurance was reduced as a result of the inpatient hospital deductible limitation ($855 − $776 = $79).

$1,045 + $79 = $1,124

In this case, the beneficiary pays a deductible of $100 and coinsurance that is limited to $776. The program pays $1,124 (which includes the amount of the reduction in beneficiary coinsurance due to the inpatient hospital deductible limitation) for a total payment to the hospital of $2,000.

4. Hospital Election To Offer Reduced Coinsurance

For most APCs, the transition to the standard Medicare coinsurance rate (20 percent of the APC payment rate) will be gradual. For those APC groups for which coinsurance is currently a relatively high proportion of the total payment, the process will be correspondingly lengthy. The law offers hospitals, but not CMHCs, the option of electing to reduce coinsurance amounts and permits hospitals to disseminate information on their reduced rates. In this section, we discuss the procedure by which hospitals can elect to offer a reduced coinsurance amount, and the effect of the election on calculation of the program payment and beneficiary coinsurance.

Section 1833(t)(5)(B) of the Act, as added by section 4523 of the BBA 1997, requires the Secretary to establish a procedure under which a hospital, before the beginning of a year, may elect to reduce the coinsurance amount otherwise established for some or all hospital outpatient services to an amount that is not less than 20 percent of the hospital outpatient prospective payment amount. The statute further provides that the election of a reduced coinsurance amount will apply without change for the entire year, and that the hospital may disseminate information on its reduced copayments. Section 1833(t)(5)(C) of the Act, as added by the BBA 1997, provides that deductibles cannot be waived. Finally, section 1861(v)(1)(T) of the Act (as added by section 4451 of the BBA 1997) provides that no reduction in coinsurance elected by the hospital under section 1833(t)(5)(B) of the Act may be treated as a bad debt. We note that section 1833(t)(5) of the Act has been redesignated as section 1833(t)(8) of the Act by sections 201(a) and 202(a) of the BBRA 1999.

Elections to reduce coinsurance will not be taken into account in calculating transitional corridor payments to hospitals (discussed in section III.H.2 of this preamble). That is, a hospital's transitional corridor payment will be determined as if the hospital received unreduced coinsurance amounts from beneficiaries.

In the proposed rule, we stated that we would require that hospitals make the election to reduce coinsurance on a calendar year basis. The proposed rule required that the hospital must notify its fiscal intermediary of its election to reduce coinsurance no later than 90 days prior to the date the PPS is implemented or 90 days prior to the start of any subsequent calendar year and that the hospital's notification must be in writing. It must specifically identify the APC groups to which the hospital's election will apply and the coinsurance amount (within the limits identified below) that the hospital has elected for each group. The election of reduced coinsurance must remain in effect and unchanged during the year for which the election is made. Because the law states that hospitals may disseminate information on any reduced coinsurance amounts, we provided in the proposed rule that hospitals would be allowed to publicly advertise this information.

The proposed regulations provided that a hospital may elect to reduce the coinsurance amount for any or all APC groups. A hospital may *not* elect to reduce the coinsurance amount for some, but not all, services within the same APC group.

As proposed, a hospital may not elect a coinsurance amount for an APC group that is less than 20 percent of the adjusted APC payment rate for that hospital. In determining whether to make such an election, hospitals should note that the national coinsurance amount under this system, based on 20 percent of national median charges for each APC, may yield coinsurance amounts that are significantly higher or lower than the coinsurance that the hospital previously has collected. This is because the median of the national charges for an APC group, from which the coinsurance amount is ultimately derived, may be higher or lower than the hospital's historic charges. Therefore, in determining whether to elect lower coinsurance and the level at which to make the election, we advise that hospitals carefully study the wage-adjusted coinsurance amounts for each APC group in relation to the coinsurance amount that the hospital has previously collected.

As discussed in section III.F.1, under sections 1834(d)(2)(C)(ii) and 1834(d)(3)(C)(ii) of the Act the coinsurance for screening sigmoidoscopies furnished by hospitals and screening colonoscopies furnished by hospital outpatient departments and ASCs is 25 percent of the applicable payment rate. The payment rate for these colorectal cancer screening tests is the lower of the hospital outpatient rate or the ASC payment rate. The payment rate for screening barium enemas is the same as that for diagnostic barium enemas. However, the coinsurance amount for screening barium enemas is 20 percent of the APC payment rate. Hospitals may *not* elect to reduce coinsurance for screening sigmoidoscopies, screening colonoscopies, or screening barium enemas.

Calculation of coinsurance amounts on the basis of a hospital's election of reduced coinsurance is similar to the formula described in section III.F.3. For example, assume that the adjusted APC payment rate is $300; the program payment percentage for the APC group is 60 percent; the hospital has elected a $60 *reduced* coinsurance amount for the APC group; and the beneficiary has not satisfied the annual Part B deductible.

(A) Adjusted APC payment rate: $300.

(B) Subtract the applicable deductible:

$300 − $100 = $200

(C) Multiply the remainder by the program payment percentage to determine the Medicare payment amount:

$0.6 \times \$200 = \$120$

(D) Beneficiary's coinsurance is the difference between the APC payment rate reduced by any deductible amount and the Medicare payment amount, but not to exceed the lesser of the reduced coinsurance amount or the inpatient hospital deductible amount:

$200 − $120 = $80 (limited to $60 because of the hospital-elected reduced coinsurance amount)

(E) Calculate the final Medicare payment amount by adding the preliminary Medicare payment amount determined in step (C) to the amount that the coinsurance was reduced as a result of the inpatient hospital deductible limitation.

$120 + $0 = $120

In this case, Medicare makes its regular payment of $120, and the beneficiary pays a $100 deductible and a reduced coinsurance amount of $60. The hospital receives a total payment of $280 instead of the $300 that it would have received if it had not made its election to reduce coinsurance.

Comment: One commenter stated that it is currently illegal to accept lower coinsurance amounts from beneficiaries and asked for an explanation as to how

we could propose to encourage hospitals to lower coinsurance.

Response: Although Medicare, in general, has prohibitions against reducing beneficiary coinsurance, redesignated section 1833(t)(8)(B) of the Act specifically provides the legal authority for hospitals to make elections to reduce coinsurance amounts for purposes of the outpatient PPS. However, those coinsurance amounts cannot be reduced below 20 percent of the adjusted APC payment rate for the hospital.

Comment: One commenter asked whether, in view of our proposal to allow hospitals to elect lower coinsurance, Medigap insurance plans will be permitted to offer a waiver of a participating hospital's coinsurance. That is, can a Medigap plan act as a preferred provider organization (PPO) with a financial incentive to select those hospitals that elect to reduce coinsurance?

Response: There are two kinds of Medigap policies—regular Medigap and Medicare SELECT. While regular Medigap policies must pay full supplemental benefits on all claims that are submitted by all Medicare providers and are approved by Medicare carriers and intermediaries, Medicare SELECT plans, which are a managed care form of Medigap, may restrict payment of supplemental benefits to network providers. Thus, by design, Medicare SELECT plans are permitted to negotiate selectively with hospitals. Ordinarily, Medicare SELECT plans contract with certain hospitals to waive the hospital deductible for inpatient services.

Since the Congress has expressly permitted hospitals to reduce outpatient coinsurance to no less than 20 percent of the PPS payment amount, a Medicare SELECT plan is free to contract selectively with these hospitals. We note that a hospital's election to reduce coinsurance under redesignated section 1833(t)(8)(B) of the Act requires that the reduction be across-the-board for some or all APC groups. Thus, an agreement between a Medicare SELECT plan and a hospital to reduce coinsurance would result in coinsurance reductions for all beneficiaries who receive those APC group services at the hospital, whether or not they are enrolled in the Medicare SELECT plan.

Comment: One commenter requested that we seek a legislative change to offer hospitals more flexibility under the coinsurance reduction provision by permitting them to review and revise coinsurance amounts every 3 months.

Response: We believe that there would be a significant impact on contractors if hospitals were allowed to revise their reduced coinsurance more often than annually. More frequent coinsurance changes may also be confusing to beneficiaries. Because we do not have a good estimate of how many hospitals will make the elections and we do not yet know whether those hospitals that do make elections will elect to reduce coinsurance for just a few or for a significant number of APCs, we do not support allowing hospitals to make or change elections more often than annually. However, we may reconsider our position after we gain more experience under the PPS and can better assess what the impact of more frequent elections would be on hospitals, beneficiaries, and HCFA and its contractors.

Comment: One commenter noted that if we intend to publish a final rule no more than 90 days before implementation of the PPS, hospitals would not have sufficient time to make coinsurance election decisions. The commenter recommended that hospitals be permitted to make the election 60 days before implementation of the system.

Response: This final rule will not be published more than 90 days before the date of implementation of the PPS. Therefore, the final regulations require that hospitals inform their fiscal intermediaries (FIs) of their elections to reduce coinsurance not later than June 1, 2000. Beginning with elections for calendar year 2001, elections are required to be made by December 1 preceding the calendar year. At this time, we do not know how many hospitals will choose to reduce coinsurance or for how many APCs these hospitals will elect reductions. While we want to provide hospitals sufficient time to make their elections, we also must provide fiscal intermediaries with enough time to incorporate the elections into their systems.

Comment: Several commenters disagreed with our proposal to allow hospitals to advertise reduced coinsurance amounts. They noted that, although the BBA 1997 provision with respect to hospitals' election to reduce coinsurance amounts provides that hospitals may ''disseminate information'' on their reductions, we have interpreted that to mean that hospitals may ''advertise'' their reductions. Two commenters stated that disseminating information is not synonymous with granting one category of hospitals the unique opportunity to advertise to attract customers. They believe that this interpretation is antithetical to the spirit underlying provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) that prohibit beneficiary inducements and may conflict with State anti-kickback laws. Some commenters were also concerned that under our proposal to allow hospitals to advertise, hospitals may issue a general advertisement of reduced coinsurance when the reduction may apply only to certain services. Other commenters were concerned that hospital advertising may lead Medicare beneficiaries to believe that hospital outpatient care is more economical than other ambulatory settings, even when that is not the case, or beneficiaries may become confused and believe that all ambulatory providers have the ability to reduce coinsurance. These commenters asked us to reconsider our proposal to allow hospitals to advertise rather than to disseminate information. In addition, they asked us to establish additional requirements for hospitals' dissemination of information concerning coinsurance reductions so that beneficiaries are made aware that reduced coinsurance applies only to certain specified services, that it applies only to coinsurance billed by hospitals for those services, and that the law does not permit reduced coinsurance for other Part B services such as physician services.

Several other commenters stated that for the election to reduce coinsurance to be effective, hospitals must have the right to advertise and, therefore, the commenters supported our proposal to permit hospitals to advertise coinsurance reductions.

Response: We believe that hospitals must be able to advertise their coinsurance reductions in order to achieve what we believe to be the intent of the BBA provision, that is, to provide hospitals with some ability to compete with other ambulatory settings (where coinsurance is already 20 percent of the applicable Medicare payment rate) and to reduce beneficiary coinsurance liability.

Hospitals would have less incentive to reduce coinsurance if they could not advertise. In addition, beneficiaries need to be fully informed so that they can make informed decisions. We believe that advertising as a way of disseminating information has merit.

We were persuaded by some commenters' concerns that beneficiaries may not understand that reduced coinsurance applies to specific hospital outpatient services furnished by specific hospitals that choose to elect reductions and that similar reductions cannot be made by other providers of ambulatory services. We, therefore, are amending the regulations to require that all

advertisements or other information furnished to beneficiaries must specify that the coinsurance reductions advertised apply only to the specified services of that hospital and that these coinsurance reductions are available only where a hospital elects to reduce coinsurance for hospital outpatient services and reductions are not allowed in other ambulatory settings or physician offices.

Comment: One commenter, noting the complexity of the PPS coinsurance requirements, requested that we provide a phase-in period in the final rule to allow hospitals sufficient time to implement the changes necessary to meet the requirements.

Response: The method required to be used in calculating coinsurance under the PPS results in an overall decrease in the total coinsurance amounts beneficiaries pay for hospital outpatient services. Total coinsurance is somewhat reduced in the first year of implementation and will be reduced even more in future years, until coinsurance for all PPS services equal 20 percent of the applicable APC payment rate. It is only by fully implementing the coinsurance provisions under section 1833(t)(3)(B) of the Act that beneficiaries will realize these reductions. We, therefore, do not support a phase-in period.

Comment: One commenter recommended that we include, as part of the public record, year by year estimates of the total economic burden placed on beneficiaries by the prolonged coinsurance phase-in period, assuming hospitals charge the maximum and minimum coinsurance amounts. The commenter believes these estimates would be useful as a basis for future discussions of how to remedy the coinsurance problem.

Response: As a rule, we develop estimates of impacts for legislative proposals that are under consideration by the Congress and for final legislation as we are developing regulations to implement the law. Although we do not have the resources available to model any number of other data analyses that may have merit, our data are made available to the public, so the commenter and any other interested party may perform the coinsurance analysis.

Comment: One commenter stated that the proposed PPS creates new complexities for Medicare beneficiaries in that they will have to wait for hospitals to do the calculations necessary to determine coinsurance. The beneficiaries will also receive multiple bills and explanations of benefits for multiple hospital visits occurring on the same day. The commenter stated that we will need to have an extensive process in place to explain why, in most cases, beneficiaries are paying 50 to 70 percent of their outpatient services and why they are receiving separate statements when they have multiple visits on the same day.

Response: In the proposed rule, we assigned medical visits, that is, clinic and emergency room visits, to APCs based on both the level of visit as defined by a HCPCS code and the diagnosis of the patient. In order to implement that type of APC assignment, we would have to require hospitals to submit a separate bill for each medical visit that occurred on the same day; however, under the final rule, medical visits are assigned to APCs based solely on the HCPCS code, and it will be possible for hospitals to bill for multiple medical visits on the same bill. We agree that the way coinsurance is determined under the PPS is a significant change. We are developing a brochure for beneficiaries that will explain the new system and the policies under the outpatient PPS that will affect them.

Comment: One commenter recommended that we make information available to beneficiaries that compares the average coinsurance for high volume procedures performed at hospitals in a particular geographic area so that beneficiaries can make informed health care decisions about their care.

Response: We believe that beneficiaries will be informed about the coinsurance reductions elected by hospitals in their area through advertisements and other information made available by hospitals.

Comment: One commenter asked whether the EOMB (Explanation of Medicare Benefits) notice to the beneficiary will clearly explain that a hospital's decision to reduce coinsurance applies to a specific service furnished at that specific hospital.

Response: We are reviewing the EOMB in light of the changes in Medicare payments and coinsurance amounts under the PPS, but we have not yet finalized our work. We will take the commenter's suggestion into consideration as we investigate changes we will make to the EOMB.

G. Adjustment for Area Wage Differences

1. Proposed Wage Index

Under section 1833(t)(2)(D) of the Act, the Secretary is required to determine a wage adjustment factor to adjust, in a budget-neutral manner, the portion of the payment rate and the coinsurance amount that is attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions. As stated in the proposed rule, we considered several options and we proposed using the hospital inpatient PPS wage index as the source of an adjustment factor for geographic wage differences for the hospital outpatient department PPS. We believe that using the hospital inpatient PPS wage index is both reasonable and logical, given the inseparable, subordinate status of the outpatient department within the hospital overall. Use of a hospital outpatient-specific wage index was not required by the Congress and we did not have either the time or resources necessary to construct one. We explained in our proposed rule that there are several possible versions of the hospital inpatient wage index that can be developed by extracting the basic wage and salary data from hospital cost reports, depending on the methodology that is applied to the data. For the hospital outpatient PPS, we proposed to adopt the same version that is used to determine payments to hospitals under the hospital inpatient PPS to adjust for relative differences in labor and labor-related costs across geographic areas. This version reflects the effect of hospital redesignation under 1886(d)(8)(B) of the Act and hospital reclassification under 1886(d)(10) of the Act.

By statute, we implement the annual updates of the hospital inpatient PPS on a fiscal year basis. However, we proposed to update the hospital outpatient department PPS on a calendar year basis. Therefore, the hospital inpatient PPS wage index values that are updated annually on October 1 would be implemented for the hospital outpatient department PPS on the January 1 immediately following. We proposed this schedule so that wage index changes will be implemented on a calendar year basis concurrently with other revisions and updates, such as the conversion factor update or changes in the APC groups resulting from new or deleted CPT codes. Subsequent to our proposal, section 201(h) of the BBRA 1999 amended section 1833(t)(8)(A) of the Act (as redesignated by section 201(a) of the BBRA 1999) to require the Secretary to review and revise the outpatient PPS wage index adjustment factor at least annually rather than on a periodic basis. (This section of the Act was further redesignated as section 1833(t)(9)(A) by section 202(a) of the BBRA 1999.)

2. Labor-Related Portion of Hospital Outpatient Department PPS Payment Rates

We proposed to recognize 60 percent of the hospital's outpatient department costs as labor-related costs that would be standardized for geographic wage differences. We initially estimated this percentage by comparing the percentage of costs attributed to labor by other systems (that is, hospital inpatient PPS and ASC) and by considering health care market factors such as the shift in more complex services from the inpatient to the outpatient setting, which could influence labor intensity and costs. We stated that 60 percent represented a reasonable estimate of outpatient costs attributable to labor, as it fell between the hospital inpatient PPS operating cost labor factor of 71.1 percent and the ASC labor factor of 34.45 percent, and is close to the labor-related costs under the hospital inpatient operating cost PPS attributed directly to wages, salaries, and employee benefits (61.4 percent) under the rebased 1992 hospital market basket that was used to develop the fiscal year 1997 update factor for inpatient PPS rates (published August 30, 1996 at 61 FR 46187).

We confirmed our estimate through regression analysis. Using this approach, we analyzed the percentage change in hospital costs attributable to a 1 percent increase in the wage index as expressed by the hospital wage index coefficient. The coefficient from a fully specified payment regression of the hospital cost per unit, standardized for the service mix on the wage index, disproportionate share patient percentage, modified teaching, rural, and urban variables, is approximately 0.60, suggesting a labor share of 60 percent. Even though we decided not to propose additional adjustments, we believed that the coefficient from this specification provided the best estimate of the labor share for the proposed PPS. This judgment was based on a policy to use a labor share that reflects the relationship between the wage index and costs, rather than the effects of correlated factors.

After calculating 60 percent of each hospital's total operating and capital costs, we divided that amount by the hospital's FY 1998 hospital inpatient PPS wage index value to standardize costs to remove the differences that are attributable to geographic wage differences. Therefore, as we explained in the proposed rule, the total cost of performing a procedure or visit would include standardized operating and capital costs, as well as related costs (for example, operating room time, medical/surgical supplies, anesthesia, recovery room, observation) and minor ancillary procedures such as venipuncture that we packaged.

Comment: Some commenters urged that we annually update the wage index applied to the outpatient PPS as we do under the hospital inpatient PPS.

Response: We proposed to update the wage index annually, on a calendar year basis. In addition, section 1833(t)(9)(A) of the Act, redesignated and amended by the BBRA 1999, requires us to review and revise the wage adjustment at least annually.

Comment: A professional society recommended eliminating the ''regional variation for radiologic technologists working in small and rural practices'' and applying the ''same wage scale'' used for their urban counterparts. The commenter asserted that our wage index methodology is biased against rural hospital radiology departments that must compete with the urban areas to attract and retain radiologic technologists. The commenter stated that hospitals are operating in a very competitive labor market in which rural facilities are forced to match or exceed wages paid in the urban areas for reduced workloads. The commenter further stated that the impact of higher hourly technologist wages does not result in a corresponding increase in a higher wage index for radiologic technologists in rural hospitals because these wages are averaged with those for all other hospital inpatient personnel working in the same area.

Response: The commenter is correct that the wage index is calculated based upon all of the wages paid and hours worked of hospital personnel within areas of the hospital that are paid under the inpatient PPS. The wages and hours are then totaled for a particular labor market area (defined as a Metropolitan Statistical Area [MSA] or all of the counties of a State that are not part of an MSA). We believe the inpatient wage index is an appropriate measure of the relative costs of labor across geographic areas for purposes of outpatient PPS.

Currently, we do not have data available that would allow us to calculate the wage index for the costs of employing staff in particular occupational categories. Collecting these data would require significant recordkeeping and reporting efforts for hospitals, and the impacts of adjusting the wage index using the data are uncertain. Although some analyses have indicated that the wage indices of rural areas could rise as a result of such an adjustment, these findings are limited by the lack of a national database through which to fully assess the impacts.

Comment: Several commenters viewed our proposal to establish a 60 percent labor share as an arbitrary decision for which we provided no rational support. One commenter stated that ''Congress did not expect HCFA to invent a number.''

Response: As we explained in the proposed rule (63 FR 47581), we used a statistical tool, that is, regression analysis, to validate the percentage of costs that we had initially estimated could be attributed to labor and, therefore, subject to the wage adjustment. We adopted this approach because we did not have adequate and appropriate data readily available through a reputable source from which we could derive a hospital outpatient labor share within the time allotted to develop our new system. While hospital outpatient costs, including labor costs, are reported annually on the hospital cost report, they are not reported in a manner and format that allow us to capture the statistical and cost data necessary to calculate a precise hospital outpatient labor share. Therefore, we decided to use regression analysis to test our estimate of that labor share. Within the constraints imposed by a lack of accessible, reliable data and the compressed timeframe under which we were working to develop the outpatient PPS, we believe our approach was appropriate and the best available option.

Comment: Several commenters urged us to use more current hospital cost report data to determine the appropriate hospital outpatient labor share.

Response: As stated above, at this time the Medicare hospital cost report is not a feasible data source for determining a hospital outpatient labor share.

Comment: One commenter asserted that setting the labor-related share at 60 percent fails to recognize all labor costs associated with the delivery of hospital outpatient services. The commenter stated that the labor-related percentage for the outpatient PPS should be the same as that used for the hospital inpatient PPS, that is, 71.1 percent. Another commenter supported 60 percent as a ''maximum'' labor percentage on an interim basis and suggested that we reconsider our decision to use the inpatient PPS hospital wage index to adjust the outpatient PPS payments because of the commenter's concerns about flaws inherent in the system used to derive the inpatient PPS wage index values. A third commenter proposed that the

labor-related portion should be closer to the 34.45 percent currently applied to adjust ASC payment for wage variation. The latter commenter contended that apportioning 60 percent of the outpatient PPS payment rate for wage adjustment would adversely affect rural hospitals because the wage index values for these areas are generally below 1.0.

Response: We note that commenters' opinions regarding an appropriate labor percentage are mixed. However, beyond expressing a preference for a percentage other than 60 percent, none of the commenters provided data to assist us in re-evaluating our proposal. We realize that rural hospitals would benefit from using a labor share that is less than 60 percent and that some other hospitals would derive advantages from a labor share greater than 60 percent. However, we believe the approach that we used to determine the labor share that will be applied to all hospitals paid under our new system is reasonable and the best option available at this time. We will re-evaluate our decision as we gain more experience with the new system and as new data become available.

3. Adjustment of Hospital Outpatient Department PPS Payment and Coinsurance Amounts for Geographic Wage Variations

In the proposed rule, we noted our intent to use fiscal year 1999 hospital inpatient PPS wage index values to compute the initial outpatient PPS rates. However, we have decided to use fiscal year 2000 inpatient PPS wage index values in determining the payment rates set forth in this final rule. The rationale for using the fiscal year 2000 wage index includes availability of the more recent wage index, that it is more current than the 1999 wage index would have been, and that it is being used to calculate FY 2000 payments under the hospital inpatient PPS.

We proposed to use the annually updated hospital inpatient PPS wage index values to adjust both program payment and coinsurance amounts under the outpatient PPS for area wage variations. Under our proposal, when intermediaries calculate actual payment amounts, they would multiply the prospectively determined APC payment rate and coinsurance amount by that labor-related percentage to determine the labor-related portion of the base payment rate and coinsurance amount that is to be adjusted using the applicable wage index factor. We proposed that the labor-related portion would then be multiplied by the hospital's inpatient PPS wage index factor, and the resulting wage-adjusted labor-related portion would be added to the nonlabor-related portion, resulting in wage-adjusted payment and coinsurance rates. The wage-adjusted coinsurance amount would then be subtracted from the wage-adjusted APC payment rate, and the remainder would be the Medicare payment amount for the service or procedure. Note that even if a hospital elects to reduce the coinsurance or if the coinsurance is capped at the inpatient deductible, the full coinsurance is assumed for purposes of determining the Medicare payment percentage. (See section III.F.3 for a discussion on how Medicare program payments are calculated when the Part B deductible applies.)

The following is an example of how an intermediary would calculate the Medicare payment for a surgical procedure with a hypothetical APC payment rate of $300 that is performed in the outpatient department of a hospital located in Heartland, USA. The coinsurance amount for the procedure is $120. The hospital inpatient PPS wage index value for hospitals located in Heartland, USA is 1.0234. The labor-related portion of the payment rate is $180 ($300 × 60 percent), and the nonlabor-related portion of the payment rate is $120 ($300 × 40 percent). The labor-related portion of the unadjusted coinsurance amount is $72 ($120 × 60 percent), and the nonlabor-related portion of the unadjusted coinsurance amount is $48 ($120 × 40 percent). It is assumed that the beneficiary deductible has been met.

Wage-Adjusted Payment Rate (rounded to nearest dollar):
= ($180 × 1.0234) + $120
= $184 + $120
= $304

Wage-Adjusted Coinsurance Amount (rounded to nearest dollar):
= ($72 × 1.0234) + $48
= $74 + $48
= $122

Calculate Medicare Program Payment Amount:
$304 − $122 = $182

4. Special Rules Under the BBRA 1999

We issued the federal fiscal year (FY) 2000 hospital inpatient PPS wage index values in the **Federal Register** on July 30, 1999, in a final rule titled ''Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2000 Rates'' (64 FR 41490). Subsequent to that publication, section 152 of the BBRA 1999 reclassified certain counties and labor market areas for purposes of payment under the Medicare hospital inpatient PPS; section 153 of the BBRA 1999 enacted a ''wage index correction''; and section 154 of the BBRA 1999 provided for the calculation and application of a wage index floor for a specified area. These changes are effective for FY 2000 and will be explained in detail in an interim final rule with comment that we expect to issue in the **Federal Register** shortly. The wage index values in Addendum H, Addendum I, and Addendum J reflect the changes made by the BBRA 1999.

H. Other Adjustments

1. Outlier Payments

Section 1833(t)(2)(E) of the Act, as enacted by the BBA 1997, authorized, but did not require, an outlier adjustment. In the proposed rule, we discussed our reasons for not implementing an outlier adjustment policy. We explained that we had reached that decision after carefully evaluating several factors. For the following reasons, we believed an outlier policy was not necessary: (a) in the proposed PPS, unlike the hospital inpatient PPS, we would use limited packaging of services and allow payment for multiple services delivered to a given patient on a given day; (b) payment for critical care services would reflect the intensity and higher costs associated with providing this type of medical care; and (c) we would make higher payment for serious medical cases even if critical care were not provided and additional payments would be made for any other laboratory work, x-rays, or surgical interventions resulting from medical visits to the emergency room.

Section 201(a) of the BBRA 1999 amended section 1833(t) of the Act by adding an outlier adjustment provision, section 1833(t)(5). Under this new provision, the statute now requires that we make an additional payment (that is, an outlier adjustment) for outpatient services for which a hospital's charges, adjusted to cost, exceed a fixed multiple of the outpatient PPS payment as adjusted by pass-through payments. The Secretary determines this fixed multiple and the percent of costs above the threshold that is to be paid under this outlier provision. The statute sets a limit on projected aggregate outlier payments. Under the statute, projected outlier payments may not exceed an ''applicable percentage'' of projected total payments. The applicable percentage means a percentage specified by the Secretary (projected percentage of outlier payments relative to total payments), subject to the following limits: for years before 2004, the projected percentage that we specify cannot exceed 2.5 percent; for 2004 and later, the projected percentage cannot

exceed 3.0 percent. Section 201(c) of the BBRA 1999 amended section 1833(t)(2)(E) of the Act to require that these payments be budget neutral.

Section 1833(t)(5)(D) of the Act grants the Secretary authority until 2002 to identify outliers on a bill basis rather than on a specific service basis and to use an overall hospital cost-to-charge ratio (CCR) to calculate costs on the bill rather than using department-specific CCRs for each hospital.

To set the threshold or fixed multiple and the payment percent of costs above that multiple for which an outlier payment would be made, we first had to determine what specified percentage of total program payment, up to 2.5 percent, we should select. We decided to set the outlier target at 2.0 percent. In order to set the fixed multiple outlier threshold and payment percentage, we simulated PPS payments, as described below in section G of the preamble. As explained further below, we calibrated the threshold and the payment percentage applying an iterative process so that the simulated outlier payments were 2.5 percent of simulated total payments. *For purposes of the simulation,* we set a ''target'' of 2.5 percent (rather than 2.0 percent), because we believe that *a given set of numerical criteria* would result in a higher percentage of outlier payments under the simulation using 1996 data than under the PPS. This is because we believe that the 1996 data reflects undercoding of services, which means simulated total payments would likely be understated and it in turn means the percentage of outlier payments would be overstated. In addition, we are unable to fully estimate the amount and distribution of pass-through payments using the 1996 data. Our inability to make these estimates further understates the total payments under the simulation. We believe that a set of numerical criteria that results in simulated outlier payments of 2.5 percent using the 1996 data would result in outlier payments of 2.0 percent under PPS. The difference arises from the effect of undercoding in the historical data and the payment of pass-throughs under PPS. Under the budget neutrality requirement in section 1833(t)(2)(E) of the Act, as amended by section 201(c) of the BBRA 1999, we make a corresponding 2.0 percent reduction to the otherwise applicable conversion factor. We will monitor outlier payment and make any necessary refinements to the outlier methodology when we set outlier policies for CY 2002.

After setting the outlier target percentage and reducing the unadjusted conversion factor to reflect the 2 percent outlier reduction and the 2.5 percent pass-through adjustment (see discussion in section III.D), we identified those claims in our 1996 database with at least one payable service under the PPS system. For these bills, we first calculated the total PPS payment for the bill using the reduced conversion factor. Next, we calculated for each claim the total charges attributed to services being paid under the PPS system. These charges were then adjusted to cost, using a hospital-specific CCR. We used the sum of the hospital's total operating CCR and total capital CCR as the hospital specific CCR. These CCRs were calculated from the most current cost report data available and were adjusted to calendar year 1996.

We also identified all bills for the 1,800-plus hospitals that we had previously identified as having coded only the lowest level clinic visit code (CPT code 99201) for all visits. For these hospitals, we isolated those claims with at least one service with the CPT code 99201 and one or more additional PPS covered service. Due to the undercoding on these bills and the inherent problem in determining a possible outlier condition, we excluded these bills from the calculation process but set aside a proportional amount of outlier payments based on the proportional cost of these bills to the total cost of all bills used in the outlier calculation.

After determining the PPS payment and the cost for all 42 million claims for which there was at least one billable service under the PPS system, we experimented with several combinations of thresholds or fixed multiples and payment percent of costs over these multiples. We found that the combination of using a multiple of 2.5 for the threshold and the use of a payment percent of 75 percent of cost over this threshold achieved our target of a 2.5 percent outlier payment. Approximately 1.6 million claims in our 1996 claims database had calculated bill costs that exceeded the PPS payments on the claim by more than 2.5 times and thus qualified for an outlier payment in our model.

Comment: We received several comments that supported our proposal not to create outlier payments. However, most commenters opposed it and supported including an outlier policy. Several commenters disagreed that multiple payment for multiple services furnished during a given visit would absolve the need for outliers. One commenter stated that outlier payments are necessary because of the limited number of APC groups. Several commenters believe that outlier payments are necessary to recognize variability in APC groups stemming from treatment options and patient complexity. Some argued that our own data demonstrate that an outlier policy is necessary to ensure equitable payments. Several commenters stated that the data trimming algorithm that we used, excluding from our PPS database claims that were greater than three standard deviations from the geometric mean, probably eliminated claims that included high cost items and services that should have been reflected in our data and that may have been associated with the later technologies. A professional association noted that an examination of our PPS data indicated that ''20 percent of outpatient services subject to the PPS (excluding clinic and emergency room visits) include maximum costs that are at least 10 times higher than the corresponding rate; 100 services have maximum costs that are at least 40 times higher than the corresponding payment rate.''

One commenter believes that an outlier policy is necessary for a payment system based on averaging to provide additional payments for potentially variable and expensive items such as pharmaceuticals and supplies. Several commenters suggested that outlier payments would be necessary if we did implement their option to carve out all pharmaceuticals and certain supplies from the hospital outpatient PPS and pay them separately based on reasonable costs or average wholesale price (AWP). Most commenters who urged establishing outlier payments advocated them for high cost drugs, supplies, and new technologies. Some commenters advised that a drug such as Activase administered to a cardiac patient in the emergency room prior to inpatient admission or transfer to another hospital for inpatient admission would be costly. One commenter estimated that the cost for two doses of the drug would exceed $4,000. One commenter urged an outlier policy that would adequately pay for iodine I 131 tositomomab. Another commenter recommended that we make an outlier payment for Hemophilia Factor Concentrate that could be packaged in APC 906 (Infusion Therapy, except Chemotherapy) or APC 907 (Intramuscular Injections) and Tissue Plasminogen Activator (TPA) and IV therapy drugs as outliers.

A professional association expressed the need for an outlier policy for tests whose costs exceed a reasonable range of costs for similar procedures. They identified CPT codes 95951 and 95956 as examples of those tests. Another association recommended adoption of

an outlier policy to recognize higher costs associated with new technologies. The commenter suggested that the policy remain in effect a full year after the hospital outpatient PPS is implemented to allow us adequate time to collect the appropriate data for use in updating the payment rates. Several other commenters believe that we may need to adopt an outlier policy on an interim basis while data are collected to determine the appropriate assignment of certain services and items to an APC. One commenter advocated outlier payments for hospitals whose aggregate costs exceed total payments under the hospital outpatient PPS in a given year. A number of other commenters stated that the hospital outpatient PPS outlier policy should be similar to that currently used for the inpatient PPS.

Response: As we discussed above, section 201(a) of the BBRA 1999 amended the Act by adding a new section 1833(t)(5). This provision now requires the Secretary to make an additional outlier payment for outpatient services for which a hospital's or a CMHC's charges, adjusted to cost, exceed a fixed multiple of the new PPS payment as adjusted by pass-through payments. The Secretary is required to determine the fixed multiple and the percent of costs above the threshold that is to be paid under the outlier provision. As we explain above, to implement the outlier adjustment, we have determined that an outlier payment will be made when calculated bill costs exceed the PPS payments on a claim by more than 2.5 times. In addition, the provision of transitional pass-throughs under section 201(b) of the BBRA 1999, which requires the Secretary to make an additional payment for certain high cost medical devices, drugs, and biologicals, constitutes a kind of outlier adjustment (see section III.D of this preamble), and our decision to create special transitional payments for new technology items and services (see section III.C.8) will also provide additional payments to hospitals that incur higher costs under the outpatient PPS.

2. Transitional Corridors/Interim Payments

As we developed the proposed rule, we conducted extensive regression analysis of the relationship between outpatient hospital costs and several factors that affect costs, such as teaching intensity and disproportionate share percentage, as part of the analysis to determine whether payment adjustments should be proposed for the outpatient PPS. Ultimately, we did not propose any adjustments other than the wage index used to adjust for local variation in labor costs. One of the main reasons we did not propose any special adjustments was that the estimated effects of measured factors on costs were small and, in most cases, not statistically significant. In addition, we believe that the negative impacts estimated in the proposed rule for certain classes of hospitals were partially attributable to undercoding and coding variations in the data because coding did not affect the payment of many services under the current payment system, especially medical visits.

Since publication of our proposed policy, section 202(a)(3) of the BBRA 1999 added new paragraph (7) to section 1833(t) of the Act to require the Secretary to make payment adjustments during a transition period to limit the decline in payments under PPS for hospitals. These additional payments are to be implemented without regard to budget neutrality and are in effect through 2003.

Under paragraphs (A), (B), and (C) of section 1833(t)(7) of the Act, the amount of the payment adjustment for an individual hospital depends on the difference between the hospital's ''PPS amount'' and the hospital's ''pre-BBA amount.'' Section 1833(t)(7)(E) of the Act defines the ''PPS amount'' as the amount payable under PPS for the hospital's covered outpatient department services, excluding the effects of the transitional corridor and including coinsurance and deductibles. For purposes of calculating the PPS amount, we include the full copayment amounts; if a hospital chooses to reduce the copayment for some or all of the services that it furnishes, we will count the full copayment amounts rather than the reduced copayment amounts. Section 1833(t)(7)(F) of the Act defines the ''pre-BBA amount'' for a period as the amount equal to the product of (1) the hospital's reasonable cost for covered outpatient department services, and (2) the base outpatient department payment-to-cost ratio for the hospital. The statute defines ''base payment-to-cost ratio'' as the ratio of (1) the hospital's reimbursement for covered outpatient department services during the cost reporting period ending in 1996, to (2) the reasonable cost of the services for the period. The base payment-to-cost ratio will be calculated as if the amendments to sections 1833(i)(3)(B)(i)(II) and 1833(n)(1)(B)(i) of the Act made by section 4521 of the BBA 1997, to require that the full amount beneficiaries paid as coinsurance under section 1862(a)(2)(A) of the Act are taken into account in determining Medicare Part B Trust Fund payment to the hospital, were in effect in 1996.

For calendar years 2000 and 2001, payment to hospitals whose PPS payment is less than 100 percent, but is at least 90 percent, of the pre-BBA payment, is increased by 80 percent of the difference. Hospitals whose PPS payment is less than 90 percent, but is at least 80 percent, of the pre-BBA payment, will receive additional payment equal to the amount by which 71 percent of the estimated pre-BBA payment exceeds 70 percent of the PPS payment. Hospitals whose PPS payment is less than 80 percent, but is at least 70 percent, of the pre-BBA payment will receive additional payment equal to the amount by which 63 percent of the pre-BBA payment exceeds 60 percent of the PPS payment. Payments to hospitals whose PPS payment is less than 70 percent of the pre-BBA payment will be increased by 21 percent of the pre-BBA payment. For calendar years 2001 through 2003, the number of corridors and the associated percentage increases decline over time. As required by statute, interim payments will be made subject to retrospective adjustments. Section 1833(t)(7) of the Act provides special transition payments for cancer centers and small rural hospitals, which are discussed below in section III.H.3.

Comment: Hundreds of commenters, including associations, hospitals, and entities providing goods and services to hospitals, expressed grave concerns about the estimated impact of our proposed system on certain classes of hospitals. Many commenters noted that the case mix and service mix for specific classes of hospitals such as rehabilitation, cancer, children's, rural, and teaching hospitals are different than for other hospitals. They argued that a number of these hospitals deal with patients who typically require more resources. The commenters noted that we have authority under the statute to make adjustments for specific classes of hospitals. Some reasoned that given our estimates of substantial losses for certain classes of hospitals under the proposed hospital outpatient PPS, we should use our authority to exclude these classes of hospitals from the outpatient PPS for 2 years, require proper coding of bills from those hospitals, and have an opportunity to analyze the results of the improved coding. These commenters urged that we examine reasons other than coding that may contribute to the disparity. Many commenters recommended that a separate conversion factor be developed

for the hospitals whose payments are adversely affected by the new system.

Response: As discussed above, section 1833(t)(7) of the Act, as added by section 202(a) of the BBRA 1999, provides that, for several years, additional payments be made to any facility for which the PPS payment is less than an estimate of the hospital's pre-PPS payment and that these payments are in addition to the total payments under the PPS. Our estimate of the impacts of this change in policy along with other payment-related provisions of the BBRA 1999 (discussed in further detail in section IX) show improved payments under PPS relative to pre-BBRA law for nearly all classes of hospitals. Our simulations show that hospitals overall receive an additional 4.6 percent in payments under PPS compared to pre-PPS law. Long-term care and children's hospitals show losses (1.7 percent and 3.2 percent, respectively). Moreover, urban hospitals with no indirect teaching or disproportionate share inpatient adjustments show a loss of 0.3 percent. In addition, we reexamined and reestimated the multivariate regression specifications described in the proposed rule to reflect the changes described in this rule. Based on the results of regression analysis, we believe further adjustments are not warranted at this time. We found, for example, the disproportionate share percentage did not have a statistically significant effect on unit costs standardized by service mix. In addition, positive and significant results did not occur for most teaching variables that we specified. For instance, positive and significant results did not occur for hospitals whose ratio of residents to inpatient and outpatient days was less than .28. Hospitals with a large number of residents to inpatient and outpatient days did demonstrate slightly higher standardized costs, but only when the regression model included independent variables for urban/rural location. Moreover, the parameter estimate was small and payment was not greatly improved when a corresponding adjustment was made to these teaching hospitals. Therefore, we are not making such adjustments for these hospital groups. We do not believe that this action will restrict beneficiary access to care because the projected losses are relatively small and could reflect undercoding on the part of these hospitals before PPS.

We will begin comprehensive analyses of cost and payment differentials between different classes of hospitals as soon as there is a sufficient amount of claims data submitted under the PPS. We will use data from the initial years of the PPS to conduct regression and simulation analyses. In addition, we will carefully track and analyze the additional payment made to hospitals under section 1833(t)(7) of the Act. These analyses will be used to consider and possibly propose adjustments in the system, particularly beginning in 2004 when the BBRA 1999 transition provisions expire.

Comment: Commenters from organizations representing teaching hospitals recommended that we include a budget-neutral payment adjustment for certain classes of hospitals such as teaching hospitals. For example, the concern is that PPS payments are not adequate for academic medical centers because they provide more resource-intensive outpatient services than other hospital types.

Response: As noted above, we are not making adjustments for specific classes of hospitals in this final rule. The primary reason for this decision is that section 1833(t)(7) of the Act requires additional payments through 2003 to all hospitals whose PPS payment falls below estimates of pre-PPS payment. We will conduct analyses and studies of cost and payment differential among different classes of hospitals, including teaching facilities, when sufficient data under the PPS have been submitted. We will carefully consider whether permanent adjustments should be made in the system once the BBRA 1999 transition provisions expire.

3. Cancer Centers and Small Rural Hospitals

Cancer Centers

In the BBA 1997, the Congress did not exclude from the hospital outpatient PPS the 10 cancer centers that are currently excluded from the inpatient PPS, but section 1833(t)(8) of the Act (as enacted in the BBA 1997) provides special consideration for these hospitals under the outpatient PPS. More specifically, that section provides that the outpatient PPS would not apply to the 10 cancer centers before January 1, 2000, and that the Secretary may establish a separate conversion factor for cancer centers to take into account the unique costs they incur due to their patient population and the intensity of their services.

In the proposed rule, we stated that, because we had no choice but to delay implementation of the PPS for all hospitals until sometime after January 1, 2000 due to Y2K concerns, we would begin paying cancer centers under hospital outpatient PPS at the same time. Also, we did not propose a separate conversion factor for cancer centers. Although our proposed impact analysis indicated that, under the PPS, the cancer centers could lose 32 percent of their current outpatient Medicare payments, we proposed to do additional work to try to explain the impact before we provided for a separate conversion factor or other payment adjustment.

Section 1833(t)(7)(D)(ii) of the Act, as added by the BBRA 1999, provides that the 10 cancer centers excluded from the inpatient PPS are permanently held harmless with respect to their pre-BBA 1997 amount.

Comment: The cancer centers commented that they are unlike other hospitals in that they treat the most difficult cases (patients often referred by community hospitals) and they are usually the first hospitals to use the latest technology related to cancer treatments. They also pointed out that their clinic visits often involve consultations with a number of physicians and therefore are longer and require more hospital resources than clinic visits in other hospitals. They believe that our proposed payments for clinic visits would seriously underpay them for their more comprehensive visits. The cancer centers also stated that any delay in recognizing and paying appropriately for new technology would affect them more adversely than it would other hospitals.

During the comment period for the proposed rule, the cancer centers submitted for our consideration an alternative payment methodology. Under their methodology, we would calculate a separate conversion factor for each of the 10 centers based on their individual base year Medicare payments and service mix. Subsequently, the conversion factors would be updated using the Congressionally determined update factor applicable to all hospitals. Hospitals would be paid interim payment amounts during the year, but payment would ultimately be based on the lesser of—

- The PPS payments they would receive using their individual conversion factor; or
- The payments they would receive based on their cost reports by applying the current (that is, pre-PPS) outpatient services payment methodology.

Capital costs would be excluded from this comparison and be paid on a reasonable cost pass-through basis. The proposal also envisioned some payment penalties and incentives similar to the penalties and incentives provided under the reasonable payment cost limit methodology applicable to hospitals excluded from the inpatient PPS.

Response: As noted above, new section 1833(t)(7)(D)(ii) of the Act holds cancer centers harmless on a permanent basis by providing that, in instances where Medicare payment to a cancer center under the hospital outpatient PPS would be lower than a specified pre-BBA Medicare payment for the same services, we are to pay the full pre-BBA amount. Therefore, an alternative approach to paying cancer centers under the hospital outpatient PPS is no longer needed.

Small Rural Hospitals

We noted in the proposed rule that rural hospitals generally receive a relatively high percentage of their Medicare income from outpatient services (greater than the national average), which compounds the impact of the reduction in Medicare payments to rural hospitals that we projected would result upon implementation of the hospital outpatient PPS. We attributed these reduced revenues to undercoding, lack of economies of scale, and reliance on the median instead of the geometric mean in the calculation of APC weights. Because our impact analysis revealed that low-volume rural hospitals that are sole community hospitals or Medicare-dependent hospitals could experience a considerable reduction in revenues under the outpatient PPS, we solicited comments in the proposed rule on two possible approaches to phasing in the outpatient PPS for these types of hospitals.

Section 1833(t)(7)(D)(i) of the Act provides that hospitals located in a rural area with 100 or fewer beds are held harmless with respect to their pre-BBA 1997 amount for outpatient services furnished before January 1, 2004. For purposes of implementing this provision, bed size will be determined in the same way it is for inpatient PPS for the indirect medical education adjustment as defined in § 412.105(b), Determination of number of beds. A hospital's location in a rural area will also be determined as it is in the inpatient PPS; see § 412.63(b), Geographic classifications.

Comment: Many commenters were concerned that the projected negative impact of the proposed outpatient PPS on rural hospitals would be magnified because outpatient revenues make up such a large part of rural hospitals' total revenues. Some commenters believe that our proposed PPS ratesetting method favors high volume, urban hospitals. Some commenters supported phasing in the outpatient PPS for rural disproportionate share hospitals because those facilities may not have the resources to improve their coding in the near future. One association opposed phasing in the PPS because doing so would postpone but not resolve the financial jeopardy imposed on rural hospitals by the hospital outpatient PPS. Some commenters recommended that we provide an ''add-on'' to the prospective rate for emergency services in low-volume sole community and rural disproportionate share hospitals. One commenter expressed concern about the numerous factors contributing to rural hospitals' negative margins that limit their ability to absorb losses, including a disproportionately high share of Medicare, Medicaid, and indigent patients, significant problems recruiting practitioners, low population density, and limited patient volume. Numerous commenters recommended that we establish a payment floor for low-volume rural hospitals. One association requested that we either revise the payment methodology or put in place a payment floor that guarantees health care services will continue to be available to Medicare beneficiaries served by rural hospitals.

Response: As we discuss above, in order to limit potential reductions in payment to hospitals under the outpatient PPS, section 1833(t)(7) of the Act, as added by section 202(a)(3) of the BBRA 1999, requires us to establish payment adjustments for hospitals whose PPS payments are less than our estimate of the hospital's pre-BBA payments. These additional payments are to be implemented in a non-budget neutral manner and are to be paid through 2003. Section 1833(t)(7)(D)(i) of the Act includes a special ''hold harmless'' provision, which is to be paid through 2003, for hospitals that are located in a rural area and that have no more than 100 beds. Under section 1833(t)(7)(D)(i) of the Act, as added by the BBRA 1999, small rural hospitals will be paid a predetermined pre-BBA amount for services covered under the outpatient PPS if payment under the PPS would be less than the pre-BBA amount. This hold harmless provision establishes a payment floor until January 1, 2004 for small rural hospitals. During this period, we will collect and analyze data under the PPS in order to assess whether any special adjustments will need to be made for rural hospitals once the hold harmless provision expires.

I. Annual Updates

1. Revisions to APC Groups, Weights and the Wage and Other Adjustments

Prior to enactment of the BBRA 1999, section 1833(t)(6)(A) of the Act required the Secretary to periodically review and revise the APC groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

In the proposed rule, we described our plan to update the various components of the outpatient PPS. We proposed to keep the composition of all the APC groups essentially intact from one year to the next, with the exception of the few changes that may be necessary as a consequence of annual revisions to HCPCS and ICD–9–CM (International Classification of Diseases, Ninth Edition, Clinical Modification) codes. We stated that we did not plan to routinely reclassify services and procedures from one APC to another. We proposed to make these changes based on evidence that a reassignment would improve the group(s) either clinically or with respect to resource consumption. However, we specifically solicited comments on how frequently to recalibrate the APC weights and on the method and data that should be used. We defined recalibration as the updating of all the APC group weights based on more recent information.

We proposed to update the wage index values used to calculate program payment and coinsurance amounts on a calendar year basis, adopting, effective for services furnished each January 1, the wage index value established for a hospital under the inpatient PPS the previous October 1. The first update to the wage index values will be effective for calendar year 2001 beginning January 1, 2001.

Section 201(h)(1)(A) of the BBRA 1999 amended section 1833(t)(8)(A) of the Act (as redesignated by section 201(a) of the BBRA 1999) to require the Secretary to review the components of the outpatient PPS not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, and the addition of new services, new cost data, and other relevant information and factors. (Section 202(a) of the BBRA 1999 further redesignated section 1833(t)(8) as section 1833(t)(9).)

Section 201(h)(1)(B) of the BBRA 1999 further amended this section of the Act to require that the Secretary consult

with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the groups and weights. This provision allows these experts to use data other than those collected or developed by us during our review of the APC groups and weights. Section 201(h)(2) of the BBRA 1999 requires the Secretary to initiate the annual review process beginning in 2001 for the PPS payments that would take effect January 1, 2002.

Comment: A number of commenters urged that we adopt an annual update cycle for APC recalibration. Some commented that the APC update frequency should not be less often than the annual cycles that we have instituted for both the hospital inpatient PPS and physician fee schedule payment system. Many commenters maintained that annual updating is necessary to ensure that the APCs appropriately reflect changes in new technologies, standards of care, and other marketplace patterns. Several commenters stated that an annual update cycle is needed to take into account changes in drug prices and appropriately reflect advancements in nuclear medicine. Some commenters believe that updating the APCs less frequently than annually would adversely impact hospitals that would incur financial losses attributable to inappropriate payment for new technologies. Some commenters contended that infrequent updating would be a disincentive for manufacturers to develop new outpatient therapies.

Response: In accordance with the amendments enacted by the BBRA 1999, we will review and update annually, for implementation effective January 1 of each year, the APC groups, the relative payment weights, and the wage and other adjustments that are components of the outpatient PPS, beginning with the update to be effective January 1, 2002.

2. Annual Update to the Conversion Factor

We stated in the proposed rule that section 1833(t)(3)(C)(ii) of the Act requires us to update annually the conversion factor used to determine APC payment rates. Section 1833(t)(3)(C)(iii) of the Act provides that the update be equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act, reduced by one percentage point for the years 2000, 2001, and 2002. The Secretary also has the option (under section 1833(t)(3)(C)(iii) of the Act) of developing a market basket that is specific to hospital outpatient services. We advised in our proposed rule that we are considering this option, and specifically invited comments on possible sources of data that are suitable for constructing a market basket specific to hospital outpatient services. We did not receive any comments regarding potential data sources for constructing a hospital outpatient-specific market basket. Therefore, we will update the conversion factor annually by the hospital inpatient market basket increase (as specified in section 1886(b)(3)(B) of the Act), reduced by one percentage point for the years 2000, 2001, and 2002.

3. Advisory Panel for APC Updates

As stated above, section 1833(t)(9)(A) of the Act (as redesignated by section 201(a) of the BBRA 1999 and further redesignated by section 202(a) of the BBRA 1999) requires the Secretary, beginning in 2001, to consult with an expert outside advisory panel of appropriately selected provider representatives when annually reviewing and updating the APC groups and the relative group weights. The statute specifies that the expert panel will act in an advisory capacity on matters pertaining to the clinical integrity of the groups and weights and that it may use data other than those developed or collected by us in executing this function. We will initiate this review process in 2001 for the hospital outpatient PPS payments that will take effect for services furnished on or after January 1, 2002. We will adopt a process for identifying and appropriately selecting provider representatives to serve as members of an expert advisory panel. We anticipate informing the hospital community of the formation of an expert advisory panel through timely notice in the **Federal Register**.

J. Volume Control Measures

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 department services. Section 1833(t)(6)(C) of the Act, as added by the BBA 1997, authorizes the Secretary to adjust the update of the conversion factor if we determine that the volume of services paid for under the outpatient PPS increases beyond amounts we establish under section 1833(t)(2)(F) of the Act.

In the proposed rule, we proposed a volume control measure for services furnished in CY 2000 only. We discussed several long-term alternatives to control volume for services furnished in subsequent years, and we solicited comments on those options. We stated that we would propose an appropriate volume control mechanism for services furnished in CY 2001 and beyond after we completed further analysis. Given the complexities of developing an appropriate volume control mechanism for hospital outpatient services, we believed additional study was necessary.

For CY 2000, we proposed to use a modified version of the physician sustainable growth rate system (SGR), which is required under section 1848(d)(3) of the Act, for purposes of the hospital outpatient PPS. As we stated in the proposed rule, this appeared to be the most feasible initial approach. Using this approach, we proposed to update the target amount specified under section 1833(t)(3)(A) for CY 1999 as an expenditure target for services furnished in CY 2000. We stated that we would update the CY 1999 target for inflation (based on the projected change in the hospital market basket minus one percentage point), estimate changes in the volume and intensity of hospital outpatient services, and estimate Part B fee-for-service changes in enrollment. If volume exceeded the target for CY 2000, we proposed to adjust the update to the conversion factor for CY 2002. We further stated that we would compare the CY 2000 target to an estimate of CY 2000 actual payments to hospitals as determined by our Office of the Actuary using the best available data. We proposed that if unnecessary volume increases, as reflected by expenditure levels, caused payment to exceed the target, we would determine the percentage by which the target is exceeded, and adjust the CY 2002 update to the conversion factor by the same percentage.

We indicated that we would respond in the final rule to comments on our proposed volume control measure for services furnished in CY 2000, but not to comments about volume control options for services furnished after CY 2000, which will be addressed in a later proposed rule.

Comment: We received many comments opposing our proposed use of an SGR-like system to control unnecessary volume increases under the hospital outpatient PPS. Most commenters strongly urged us to exercise the discretionary authority allowed under section 1833(t)(9)(C) of the Act (as redesignated) not to adjust the update to the conversion factor. A few commenters endorsed the provision

of the ''President's Plan to Modernize and Strengthen Medicare for the 21st Century'' (issued July 2, 1999) to delay adoption of a volume control measure in order to give hospitals additional time to adjust to the new system. Several commenters, including one national physicians' association, contended that we did not have the statutory authority to establish and use an expenditure target in the manner that we had proposed. The physicians' association stated that the law limits use of the SGR system to physician services. Some commenters believe that we lack the expertise needed to set an accurate target amount. Others argued that an expenditure target is not a reliable way to distinguish the growth of necessary versus unnecessary services and that our proposal would therefore have consequences not intended by the statute (that is, affecting all services rather than only those that would be considered unnecessary). Some commenters stated that expenditure caps only work when they directly affect those who control the volume. These commenters contended that a volume control measure is unfair to hospitals because it is physicians, not hospitals, who order services and therefore control volume. Some commenters were concerned that adopting a volume control measure would penalize hospitals for increases in outpatient volume attributable to technological changes that appropriately shift service delivery from the inpatient to outpatient setting. In addition, numerous organizations recommended that we not implement the volume expenditure targets and control measures because payments would be reduced to inadequate levels and affect beneficiary access to care.

Response: We are delaying implementation of a volume control mechanism as suggested by the ''President's Plan to Modernize and Strengthen Medicare for the 21st Century'' (the statute does not specify an implementation date). This delay gives hospitals time to adjust to the PPS, and it gives us additional time to study appropriate methods of controlling outpatient volume over the long term. We are currently working with a contractor to study options for volume control measures for outpatient services. In the future, before we make any final decision, we will publish a notice in which we will discuss our proposal and will provide a public comment period.

K. Claims Submission and Processing and Medical Review

Comment: Numerous commenters expressed a variety of concerns related to information exchange processes required by the new PPS. Several commenters stated that the remittance advice documents will need to reflect all of the components used in calculating payment for each claim, as well as possible coinsurance reductions. The commenters also were concerned that, with the complexity of the APC system, hospitals will need the ability to verify payment. One health system that had experience with 3M's APGs offered the experience of their member hospitals to assist us by providing input on the data needed by hospitals to manage APCs. This same commenter stated that hospitals must be given detailed instructions on claims submission, changes to the UB–92, and changes to the Correct Coding Initiative (CCI) in advance to ensure that systems and personnel can comply with Medicare requirements.

Response: We released specific hospital billing instructions that address line item reporting and reporting of service units on December 23, 1999 (Transmittals 1787 and 747). We will be issuing final instructions for implementation of this PPS in a program memorandum to fiscal intermediaries. The program memorandum addresses a range of issues such as appropriate use of revenue center/HCPCS codes for compliance with Medicare requirements and changes to Remittance Advice messages and Medicare Summary Notices/EOMBs.

All current correct coding initiative (CCI) edits with the exception of laboratory and anesthesiology edits have been incorporated in the outpatient code editor (OCE) that fiscal intermediaries use to process claims for hospital outpatient services for payment. We will address OCE changes in a program memorandum to fiscal intermediaries. The effective date of these edits is July 1, 2000.

We have decided not to pursue changes to the UB–92 claim form to allow line item diagnosis because, as we discuss in section III.C.3, we will not be using diagnosis to determine payments for clinic and emergency visits when the PPS is first implemented. Diagnosis codes, however, are still required to be reported on hospital outpatient bills.

Medical Review Under the Hospital Outpatient PPS

We have received inquiries regarding the anticipated medical review process for hospital outpatient PPS claims. The methodology of review for outpatient claims does not change under the PPS. The goal of medical review is to identify inappropriate billing and to ensure that payment is not made for noncovered services. Contractors may review any claim at any time, including requesting medical records, to ensure that payment is appropriate. In accordance with this final rule, Medicare will make payment under the PPS for hospital outpatient services including partial hospitalization services; certain Part B services furnished to inpatients who have no Part A coverage; partial hospitalization services furnished by CMHCs; vaccines, splints, casts and antigens provided by HHAs and CORFs that provide medical and other health services; and splints, casts and antigens provided to hospice patients for the treatment of a nonterminal illness. In addition, we expect focused reviews will include the adjustments we have made to the hospital outpatient PPS as a result of the enactment of the BBRA 1999, especially the transitional pass-through payments for innovative drugs, biologicals, and medical devices that are discussed in section III.D. Fiscal intermediaries will continue focused and random review of services such as ambulance, clinical diagnostic laboratory, orthotics, prosthetics, take home surgical dressings, chronic dialysis, screening mammographies, and outpatient rehabilitation (physical therapy including speech language pathology and occupational therapy) even though these services are excluded from the scope of services paid under the hospital outpatient PPS.

L. Prohibition Against Administrative or Judicial Review

Section 1833(t)(9) of the Act, as added by the BBA 1997, prohibits administrative or judicial review of the development of the PPS classification system, the groups, relative payment weights, wage adjustment factors, other adjustments, volume control methods, calculation of base amounts, periodic control methods, periodic adjustments, and the establishment of a separate conversion factor for cancer hospitals. Section 201(a) of the BBRA 1999 redesignates this section as section 1833(t)(11) of the Act, and section 201(d) of the BBRA 1999 amends the section by adding the following to the list of adjustments subject to the limitation on judicial review: the factors used to determine 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 factors used to determine additional payments for certain medical devices, drugs, and biologicals such as the determination of insignificant cost, the duration of the additional payments, the portion of the outpatient PPS

payment amount associated with particular devices, drugs, or biologicals, and any pro rata reduction. Section 202(a) of the BBRA 1999 further redesignates section 1833(t)(11) as section 1833(t)(12).

IV. Provider-Based Status

A. Background

The Medicare law (section 1861(u) of the Act) lists the types of facilities that are regarded as providers of services, but does not use or define the term ''provider-based.'' However, from the beginning of the Medicare program, some providers, which we refer to in this section as ''main providers,'' have owned and operated other facilities, such as SNFs or HHAs, that were administered financially and clinically by the main provider. The subordinate facilities may have been located on the main provider campus or may have been located away from the main provider. In order to accommodate the financial integration of the two facilities without creating an administrative burden, we have permitted the subordinate facility to be considered provider-based. The determination of provider-based status allowed the main provider to achieve certain economies of scale. To the extent that overhead costs of the main provider, such as administrative, general, housekeeping, etc., were shared by the subsidiary facility, these costs were allowed to flow to the subordinate facility through the cost allocation process in the cost report. This was considered appropriate because these facilities were also operationally integrated, and the provider-based facility was sharing the overhead costs and revenue producing services controlled by the main provider.

Before implementation of the hospital inpatient PPS in 1983, there was little incentive for providers to affiliate with one another merely to increase Medicare revenues or to misrepresent themselves as being provider-based, because at that time each provider was paid primarily on a retrospective, cost-based system. At that time, it was in the best interest of both the Medicare program and the providers to allow the subordinate facilities to claim provider-based status, because the main providers achieved certain economies, primarily on overhead costs, due to the low incremental nature of the additional costs incurred.

In the proposed rule, we pointed out the increase of provider-based facilities and the financial and organizational incentives for that increase since 1983. A variety of factors such as the emergence of integrated delivery systems and the pressure to enhance revenues have combined to create incentives for providers to affiliate with one another and to acquire control of nonprovider treatment settings, such as physician offices.

We noted in the proposed rule that it is essential that we make decisions regarding provider-based status appropriately, and that we have clear rules for identifying provider-based entities. By failing to distinguish properly between provider-based and free-standing facilities or organizations, we risk increasing program payments and beneficiary coinsurance with no commensurate benefit to the Medicare program or its beneficiaries and we jeopardize the delivery of safe and appropriate health care services to our beneficiaries.

Although there is no direct statutory requirement to maintain explicit criteria for determination of provider-based status, there are statutory references acknowledging the existence of this payment outcome. For example, section 1881(b) of the Act provides for separate payment rates for hospital-based ESRD facilities. There is currently no general definition of ''provider-based facility'' in the CFR. However, in the proposed rule, we cited issuances that do contain provisions for recognition of specific types of entities as provider-based, including Program Memorandum A–96–7, published on August 27, 1996, which pulled together instructions for specific entity types from previously published documents and consolidated them into a general instruction for the designation of provider-based status for all facilities or organizations. That Program Memorandum was subsequently reissued, without substantive change, as Program Memoranda A–98–15 and A–99–24 and, in October 1999, was manualized by the Provider Reimbursement Manual, Part I, Transmittal 411 (adding new section 2446), and the State Operations Manual, Transmittal 11 (replacing previous section 2003 and adding new section 2004). Our policy will continue to follow the principles we articulated in Program Memorandum A–96–7 and the Provider Reimbursement Manual and State Operations Manual sections cited above until October 10, 2000. After that date, we shall apply the policies set forth in these final regulations.

B. Provisions of the Proposed Rule

We announced our intention to implement §§ 413.24(d)(6)(i) and (ii), 413.65, 489.24(b), and 498.3, as revised based on our consideration of public comments, with respect to services furnished on or after 30 days following publication of a final rule. We describe these sections below and explain that we have now provided a 6-month delay in the effective date of the regulations on provider-based status.

We proposed to add a new § 413.65 on the determination of provider-based status. In paragraph (a), we proposed to define the following terms: department of a provider, free-standing facility, main provider, provider-based entity, and provider-based status. In paragraph (b), we proposed that a facility or organization would not be entitled to be treated as provider-based simply because it or the provider believe it to be provider-based. The facility or organization, or the provider, would have to contact HCFA and obtain an affirmative provider-based determination before billing of the facility's or organization's costs through the main provider, or inclusion of those costs on the main provider's cost report, is initiated. Further, we proposed to presume a facility not located on the campus of a hospital and used as a site of physician services of the kind ordinarily furnished in physician offices to be a free-standing facility unless we determined it to have provider-based status.

We proposed to require, in paragraph (c), that a main provider that acquires a facility or organization for which it wishes to claim provider-based status must report its acquisition of the facility or organization to us if the facility or organization is off the campus of the main provider, or is located on the campus of the main provider and, if acquired, would increase the main provider's costs by 5 percent or more. The main provider must also furnish all information needed for a determination as to whether the facility or organization meets the criteria in this section for provider-based status. A main provider that has had one or more facilities or organizations determined to have provider-based status also must report to us any material change in the relationship between it and any department or provider-based entity, such as a change in ownership of the entity or entry into a new or different management contract, that could affect the provider-based status of the department or entity.

In paragraph (d), we proposed the requirements for a determination of provider-based status. In paragraph (d)(1), we proposed to set forth licensure requirements for facilities or organizations seeking provider-based status.

In paragraph (d)(2), we proposed to require that a facility or organization be

under the ownership and control of the main provider.

In paragraph (d)(3), with respect to administration and direct supervision of the main provider, we proposed to require that a facility or organization seeking provider-based status have a reporting relationship to the main provider that is characterized by the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and one of its departments.

In paragraph (d)(4), we proposed that a facility or organization seeking provider-based status and the main provider share integrated clinical services, as evidenced by privileging of the professional staff of the department or entity at the main provider, and the main provider's maintenance of the same monitoring and oversight of the department or entity as of other departments. Also, the medical director of the department or entity would be required to maintain a day-to-day reporting relationship with the chief medical officer (or equivalent) of the main provider, and be under the same supervision as any other director of the main provider.

In paragraph (d)(5), we proposed to require that the department or entity and the main provider be fully financially integrated within the main provider's financial system, as evidenced by the sharing of income and expenses. The department's or entity's costs should be reported in a cost center of the provider, and the department's or entity's financial status should be incorporated into, and readily identifiable in, the main provider's trial balance.

In paragraph (d)(6), we proposed to require that the main provider and the facility seeking status as a department of the provider be held out to the public as a single entity, so that when patients enter the department they are aware that they are entering the provider and will be billed accordingly. (This requirement would not apply to a provider-based entity that is itself a provider, such as a SNF.)

In paragraph (d)(7), we proposed to require that the department of a provider or provider-based entity and the main provider be located on the same campus, except where requirements relating to service to the same patient population are met.

Paragraph (e) would specifically prohibit the approval of provider-based status for any proposed department or entity that is owned by two or more providers engaged in a joint venture.

In proposed paragraph (f), we proposed to state that facilities or organizations operated under management contracts would be considered provider-based only if specific requirements are met related to: Staff employment, administrative functions, day-to-day control of operations, and holding of the management contract by the provider itself rather than by a parent organization.

In proposed paragraph (g), we proposed to specify nine obligations of hospital outpatient departments and hospital-based entities. We explained that these obligations ensure that facilities seeking recognition as hospital outpatient departments or hospital-based entities are in fact what they represent themselves to be, and are not simply the private offices of individual physicians or of physicians in group practices.

We also proposed to preclude any facility or organization that furnishes all services under arrangements from qualifying as provider-based. We believe the provision of services under arrangement was intended to be allowed only to a limited extent, in situations where cost-effectiveness or clinical considerations, or both, necessitate the provision of services by someone other than the provider's own staff. The ''under arrangement'' provision in section 1861(w)(1) of the Act and § 409.3 is not intended to allow a facility merely to act as a billing agent for another.

Proposed paragraph (h) states that, if we learn of a provider that has inappropriately treated a facility or organization as provider-based, before obtaining our determination of provider-based status, we would reconsider all payments to that main provider for those periods subject to reopening, and we would investigate to determine whether the designation was appropriate.

In proposed paragraph (i), we would apply the principles in paragraph (h) to situations involving inappropriate billing for services furnished in a physician's office or other facility or organization as if they had been furnished in a hospital outpatient or other department of a provider or in a provider-based entity.

We also proposed to add a new paragraph (j) that would allow us to review past determinations. If we find that a designation was in error, and the facility or organization in question does not meet the requirements of this section, we will notify the main provider that the provider-based status will cease as of the first day of the next cost report period following notification of the redetermination.

In addition, we proposed to add to § 413.24(d) new paragraphs (6)(i) and (6)(ii) to clarify that main providers, in completing their Medicare cost reports, may not allocate overhead costs to the provider-based or other cost centers that incur similar costs directly through management contracts or other arrangements. These changes are needed to prevent misallocation of management costs, which would result in excessive payment to those types of providers paid on a reasonable cost basis.

To provide an administrative appeals process for entities that have been denied provider-based status, we proposed to revise the regulations on provider appeals at § 498.3. As revised, these rules would specify that a provider seeking a determination that a facility or an organization is a department of the provider or a provider-based entity under proposed § 413.65 would be included in the definition of ''prospective provider'' for purposes of part 498, and would be afforded the same appeal rights as a prospective provider, such as a hospital or SNF, that we have found not to qualify for participation as a provider.

C. Comments and Responses

In response to our proposals, we received approximately 120 letters of comment, most of which raised a number of issues. Included among the commenters were hospitals and hospital and other provider associations, physicians, attorneys, and other individuals. Here we respond to comments submitted on the proposed rule.

General Comments

Many comments were not directed to a specific provision or criterion, but concerned the implementation of the regulations or the application of provider-based criteria to specific types of facilities. These are summarized below.

Effective Date

Comment: A commenter requested clarification as to when the parts of the final rule setting forth criteria for provider-based status would be effective, and a number of commenters requested an extended grace period or a delay in effective date of the final rules, with some commenters requesting delays as long as 12 to 18 months. Various reasons were cited, including the pressures on providers to prepare their systems and staff for the outpatient PPS, the need to bring operations into compliance with the provider-based criteria, and the anticipated workloads of HCFA regional offices that may

receive a large number of requests for provider-based determinations. Commenters argued that it is unrealistic to expect that a hospital would engage in a full-blown analysis of its provider-based arrangements and modify each arrangement until it knows against which exact criteria it is measuring those arrangements. Any changes in status will require hospitals to implement billing and other operational changes. Thus, commenters argued that it is not reasonable to expect hospitals to complete such steps within a 30-day period.

Response: We agree, and are providing a delay in the effective date until October 10, 2000. Moreover, as stated in our response to comments on proposed § 413.65(j) below, any redetermination of provider-based status that finds the facility or organization not to be provider-based will not take effect for at least 6 months after the date the provider is notified of the redetermination.

Application to Specific Facilities

Comment: One commenter stated that under the Balanced Budget Act of 1997 (the BBA 1997) long-term hospitals established on or before September 30, 1995 are entitled to retain their long-term hospital classification notwithstanding their location in the same building or campus of another hospital. In the commenter's view, these hospitals should not now have this classification revoked by this proposed regulation.

Response: The provision referred to by the commenter, section 4417(a) of the BBA 1997, is codified in section 1886(d)(1)(B) of the Act and is implemented under regulations at § 412.22(f). That provision authorizes certain hospitals to continue being excluded from the Medicare hospital inpatient prospective payment system (PPS) based on their exclusion status and configuration on or before September 30, 1995, even though they would not otherwise qualify for this exclusion. The criteria for provider-based status do not conflict with or even directly relate to the section 4417(a) provision, and we have therefore not made any change in the regulations based on this comment.

Comment: The commenter believes that rural health clinics (RHCs) should be exempted from provider-based designation requirements if they meet the intent of the enabling regulation. The commenter requested that an RHC be granted provider-based status if it meets one of the following criteria: Is the sole source of primary care for the community; has traditionally served the community with an open door policy; or treats a disproportionate share of the community's Medicare and Medicaid population.

Response: We share the commenter's concern, but believe the criteria suggested are overly inclusive and could lead to a proliferation of RHCs in areas where there are no true shortages of care. While we do not believe a blanket exemption from the criteria is warranted, we have developed a special provision for RHCs affiliated with small rural hospitals, as described below in our responses to comments on § *415.65(d)(7), Location in immediate vicinity.*

Comment: A commenter stated that there may be instances where the Medicare regulations related to provider-based definitions conflict with the Medicaid provider-based regulations, and asked whether Medicaid will be required to comply with the new Medicare provider-based regulations.

Response: Because hospitals under Medicaid are required to meet the same standards as Medicare facilities, these final rules would affect the Medicaid definition of these facilities as well as the Medicare definitions.

Comment: Commenters stated that the reasons cited for establishing provider-based requirements that are found in the preamble do not apply to clinical laboratories and thus these requirements should not apply. The commenters asked that we explicitly state in the final regulations that the provider-based requirements are not applicable to clinical laboratories. They believe the regulations have little bearing where, as with clinical laboratory services, reimbursement is under a fee schedule amount, and neither the Medicare program nor the beneficiary will pay anyone differently as a result of the treatment of the laboratory in the manner proposed.

Response: As explained more fully in the preamble to the proposed rule, our objective in issuing specific criteria for provider-based status is to ensure that higher levels of Medicare payment and increases in beneficiary liability for deductibles or coinsurance (which can all be associated with provider-based status) are limited to situations where the facility or organization is clearly and unequivocally an integral and subordinate part of a provider. Under this principle, we agree with the commenter's view that it would not be either necessary or appropriate to make provider-based determinations with respect to facilities or organizations if by law their status (that is, provider-based or free-standing) would not affect either Medicare payment levels or beneficiary liability. However, we believe that it is not necessary to specify in the regulations that specific facility types are excluded, since these facilities or organizations are unlikely to seek a provider-based determination. We will be careful to clarify this policy in program operating instructions.

Comment: A commenter stated that the proposed provider-based requirements seem to preclude the possibility of a Comprehensive Outpatient Rehabilitation Facility (CORF) meeting these new requirements. The commenter believes that in the past, CORFs have been permitted to be either provider-based or free-standing and asked whether the final rules will give CORFs the option of being either free-standing or provider-based.

Response: As explained more fully in the preamble to the proposed rule, our objective in issuing specific criteria for provider-based status is to ensure that higher levels of Medicare payment and increases in beneficiary liability for deductibles or coinsurance (which can all be associated with provider-based status) are limited to situations where the facility or organization is clearly and unequivocally an integral and subordinate part of a provider. We are aware that, under the cost-based payment system that applied to CORFs prior to January 1, 1999, approximately 17 percent of participating CORFs claimed provider-based status. However, effective January 1, 1999, in accordance with the BBA 1997, payment for all CORF services is made no longer on the basis of cost reimbursement but on the basis of the physician fee schedule. Beneficiary liability is also determined under the fee schedule, regardless of the organizational structure or affiliations of the CORF. The switch to fee schedule payment from a cost-based system eliminates or removes any payment incentives to be a provider-based rather than a free-standing CORF. Thus, as in the case of the preceding comment, we agree with the commenter's view that it would not be either necessary or appropriate to make provider-based determinations with respect to facilities or organizations if by law their status (that is, provider-based or free-standing) would not affect either Medicare payment levels or beneficiary liability. We also note that existing regulations at § 413.174 specify rules for determining whether ESRD facilities are independent or hospital-based, and we have revised § 413.65(a) to state that determinations with respect to ESRD facilities will continue to be made under § 413.174,

not § 413.65. However, we believe that it is not necessary to specify in the regulations that most specific facility types are excluded, since these facilities or organizations are unlikely to seek a provider-based determination. We will be careful to clarify this policy in program operating instructions.

Application to Specific Facilities—Indian Health Service (IHS)

Comment: Several commenters requested an exception or exemption from the rules for IHS and tribal facilities. One commenter was concerned that the implementation of these proposed regulations will have the effect of denying Medicare participation as provider-based entities to a number of IHS facilities that are currently operated by Indian tribes under the auspices of Public Law 93–638. They will also cause a disruption of the coordinated health care delivery system(s) that exist between IHS and numerous tribes, and jeopardize statutorily authorized contracting and compacting relationships between the IHS and these tribes due to the conflict between these proposed regulations and the statutory opportunities for self-determination by the Indian tribes. The IHS strongly recommended that these proposed regulations not apply to IHS and tribal health systems as written. Recommendations were also made to deem satellite facilities within a discrete Indian reservation as meeting the definition of a provider-based entity as well as satellite facilities within a historical service unit. Finally, the IHS recommended that the current system be ''grandfathered'' to meet the definition of provider-based entity.

Response: We share many of these concerns and have provided special treatment for IHS and tribal facilities as described below.

Comment: A commenter was concerned that the proposed regulations would severely restrict a number of IHS satellite clinics from receiving reimbursement for the provision of Medicare Part B services. The commenter believes that a number of the requirements that must be met before an entity can be designated as provider-based for Medicare payment purposes are unrealistic for IHS satellite clinics, which are often the only Medicare providers on remote tribal lands. The commenter recommended that HCFA provide for an exemption for IHS satellite facilities that are generally located on a main hospital campus or within a short distance of a hospital. Also, the commenter recommended that the final rule clarify that IHS and tribal outpatient departments or satellite clinics are eligible to receive designation as a department of a provider or a provider-based entity and are eligible for Part B reimbursement.

Response: We share many of these concerns and have provided special treatment for IHS and tribal facilities as described below.

Comment: Many tribes have acquired operations of outpatient facilities and are in the process of acquiring the affiliated hospitals. The commenter stated that this trend, coupled with the complexities of the Indian Self-Determination Act (Pub. L. 93–638), the Indian Health Care Improvement Act (Pub. L. 94–437), and a moratorium on tribal compacting and contracting, requires special consideration by HCFA. The commenter requested that facilities be recognized as provider-based if—

(1) The outpatient facility is owned and operated by the tribe that owns the majority of the tribal shares utilized in funding the main hospital;

(2) The tribe has previously compacted programs that were historically administered by the hospital and are now administered through a committee or board comprised of medical staff of both facilities;

(3) The outpatient facility is in the same State as the hospital;

(4) There is coordination and integration of services, to the extent practicable, between the outpatient facility seeking provider-based status and the main provider.

Response: We recognize that the provision of health services to members of Federally recognized Tribes is based on a special and legally recognized relationship between Indian tribes and the United States Government. To address this relationship, the IHS has developed an integrated system to provide care that has its foundation in IHS hospitals. Because of these special circumstances, not present in the case of private, non-Federal facilities and organizations that serve patients generally, we agree that it would not be appropriate to apply the provider-based criteria to IHS facilities or organizations or to most tribal facilities or organizations. Therefore, we have revised the final rule to state that facilities and organizations operated by the IHS or Tribes will be considered to be departments of hospitals operated by the Indian Health Service or Tribes if, on or before April 7, 2000, they furnished only services that were billed as if they had been furnished by a department of a hospital operated by the Indian Health Service or a Tribe and they are: (1) owned and operated by the IHS; (2) owned by the Tribe but leased from the Tribe by the IHS under the Indian Self-Determination Act in accordance with applicable regulations and policies of the Indian Health Service in consultation with Tribes: or (3) owned by the IHS but leased and operated by the Tribe under the Indian Self-Determination Act in accordance with applicable regulations and policies of the Indian Health Service in consultation with Tribes. Facilities or organizations that are neither leased nor owned by the IHS would not be eligible for this special treatment, even if operated on Tribal land by members of the Tribe. These facilities would, of course, be eligible to participate in Medicare as FQHCs if applicable requirements in our regulations at 42 CFR part 405, subpart X are met. We did not adopt the conditions recommended by one commenter because we believe they may not apply to all Tribes.

Application to Specific Facilities—Federally Qualified Health Centers (FQHCs)

Comment: A commenter stated that despite specific acknowledgment of the eligibility of FQHCs to qualify as provider-based entities, certain proposed ownership, governance, and supervision criteria in connection with the determination of provider-based status would effectively prohibit entities from maintaining concurrent provider-based and FQHC designations. The commenter believe the criteria should be modified, or some other special provision created, to allow FQHCs to be departments of a provider.

Response: We understand the commenter's concerns and have provided special treatment for FQHCs as described below.

Comment: The commenter, a hospital that is affiliated with a number of off-site community health centers, believes the criteria in the proposed rule would deny provider-based status to community controlled, urban tax-exempt health centers operated under the license of a ''main provider.'' Several of the commenter's health centers are FQHCs that must fulfill certain criteria to maintain this status. In the commenter's view, it is not feasible to require the ''main provider'' to own and control these health centers or to require that the health centers and the ''main provider'' strictly meet all of the requirements set forth in the proposed rule. The commenter asked that the final rule be revised to take into account these historical relationships and ''grandfather'' the provider-based status of health centers that have been on the license of a disproportionate share hospital for at least 10 years. The recommended ''grandfathering''

provisions also could, in the commenter's view, require common Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accreditation, integration of clinical care committees, main provider approval of clinical guidelines and protocols, and financial oversight and review by the main provider.

Response: We share many of these concerns and have provided special treatment for FQHCs as described below.

Comment: A commenter requested that we provide a transition period of at least five years for health centers that have been treated as provider-based entities for a significant period of time (for example, 10 years or more), so that the centers will have adequate time to achieve compliance with the provider-based criteria. In the commenter's view, an extended time period for compliance would permit continuity of care to the populations served by the health centers while granting the affected health centers an opportunity to find alternative funding streams.

Response: We recognize that FQHC qualification criteria effectively require these facilities to be governed by community-based boards independent of hospitals and other providers, while our provider-based criteria require facilities seeking provider-based status to be operated under the ownership and control of the main provider, and to be under the direct supervision of that provider. This does not preclude an FQHC from participating in Medicare as a free-standing entity; on the contrary, this participation is entirely appropriate. However, it does preclude the facility from qualifying as a department of a hospital or other provider under our criteria.

Despite the difference between HRSA and HCFA requirements, we are aware that some FQHCs may have been treated by hospitals as departments for purposes of Medicare and Medicaid billing, and we are concerned that an abrupt change in status for them could force some or all to close, leading to shortages of care in some areas. Therefore, we plan to establish special provisions for FQHCs and FQHC ''look-alikes'' (facilities that are structured like FQHCs and meet all requirements for grant funding, but have not actually received these grants). Specifically, we have revised the regulations to state that if a facility has since April 7, 1995 furnished only services that were billed as if they had been furnished by a department of a provider and either (1) received a grant before 1995 under section 330 of the Public Health Service Act or, before 1995, received funding from such a grant under a contract with the recipient of such a grant and meets the requirements to receive a grant under section 330 of the Public Health Service Act; or (2) based on the recommendation of the PHS, was determined by HCFA before 1995 to meet the requirements for receiving such a grant, the facility will continue to be treated, for purposes of this section, as a department of the provider without regard to whether it complies with the criteria for provider-based status in § 413.65. We note that both types of facilities would be obligated, for as long as they are treated as a department of a provider, to comply with the applicable requirements for departments of providers as stated in § 413.65(g).

Application of Standards

Comment: One commenter believes that the proposed rule did not make clear how it would apply to existing entities, because some language in the rule could be read to require that existing entities would not receive provider-based status until we have issued a determination letter. Another commenter requested that we clarify whether we expect to review all clinics prospectively or just new clinics. The commenter stated that requirements that only new clinics seek designation does not preclude us from auditing currently designated clinics. Another commenter asked if there will be a set time frame during which current providers with provider-based departments or entities under Program Memorandum A–96–7 must contact us and receive an official designation in order to continue billing as they currently do. More specifically, the commenter asked whether, if there is such a time frame, compliance with the criteria in the Program Memorandum would constitute a good faith effort as referred to in § 413.65(i)(2). Additional guidance was also requested as to what providers should do now to demonstrate that they have made a good faith effort.

Response: We plan to review all new requests for provider-based status. At present, we have no plans to systematically review all providers to determine whether they may be claiming provider-based status for some facilities or organizations inappropriately. However, we will review the status of specific facilities or organizations in response to complaints or any other credible information that indicates that provider-based status requirements are not being met. If the regional office determines that this is the case, it will take action in accordance with the rules in new § 413.65(h) and (i). In response to the comment about possible retroactive application of the new regulations, we note that they will apply only on or after their effective date of October 10, 2000. We will not apply the provider-based criteria in the new regulations to periods prior to that date; on the contrary, decisions for such periods will be reviewed only under the criteria in effect at the time, as stated in Program Memoranda and the Provider Reimbursement Manual and State Operations Manual.

Comment: Two commenters pointed out the proposed rules do not state whether the required approval status is retroactive to when the provider applied or to when we granted approval. These commenters believe it should be retroactive to the date of the provider's application for the determination.

Response: We plan to make provider-based status applicable as of the earliest date on which a request for provider-based status has been made and all requirements for provider-based status are shown to have been met, not on the date of our determination. Thus, if a provider requests provider-based status for a facility on May 1 and demonstrates that applicable criteria were met on that date, but the regional office did not make a formal determination until June 1, the determination would be effective on May 1.

Comment: The commenter stated that we should not have published important provider-based policies in a **Federal Register** document that some providers, such as skilled nursing facilities and home health agencies, may not have read. The commenter recommended that we re-issue these proposed rules separately from the proposed hospital outpatient prospective payment rules.

Response: We do not agree that the proposed rules were published in an obscure location. On the contrary, the number of written comments received, many of them from providers other than hospitals, indicates that our proposals were widely known among providers that could be affected. Therefore, we do not intend to republish the proposed rules.

Comment: A commenter expressed concern that these provider-based provisions are unnecessarily restrictive and will unreasonably limit practice arrangements. The commenter went on to state that in the current health care environment, physicians and hospitals need flexibility to adapt to local market conditions and participate in a variety of practice arrangements to provide cost effective, high quality care. An unnecessary strict definition of

''provider-based entity'' could have a chilling effect on the evolution of new care delivery structures that would expand access to care, especially in rural areas.

Response: We share the commenter's concern with preserving Medicare beneficiaries' access to care, but do not agree that the provider-based rules will limit access. We note that the rules do not prohibit hospitals from purchasing physician practices or taking other actions to enhance access to care in remote rural areas; they only set minimum standards for the type of affiliations that will be recognized for provider-based designation.

For example, an institutional provider such as a hospital or SNF may elect to use part of its institutional complex to house physician offices or other facilities that provide services complementing those of the provider. Those facilities'costs will have to be included in the trial balance of the institutional complex, in order to allow costs to be allocated accurately to all parts of the complex, and permit the costs of the provider to be determined. However, inclusion of such facilities' costs on the institutional complex trial balance does not make the facilities provider-based. On the contrary such facilities would have to meet the criteria in § 413.65 to qualify for provider-based status.

Comment: Different views were expressed on how much

discretion regional offices should have in applying the provider-based criteria. One commenter asked that we make the rules as clear and concise as possible. The commenter argued that rules allowing for great latitude in interpretation could be dangerous for the provider community. On the other hand, another commenter stated that we should allow Medicare regional offices greater latitude for determining when sufficient integration exists for a facility to qualify as provider-based, and should avoid adopting regulations that ''micro-manage'' a hospital's operations. Another commenter suggested that rather than requiring that *all* criteria must be met to achieve provider-based status, we change the test to *substantially all.* There may be circumstances where criteria are not fully met, but an overall assessment supports a provider-based determination. This same commenter recommended that a ''pending'' status be incorporated into the evaluation process, whereby hospitals not meeting the criteria for provider-based status would be afforded an opportunity to make the modifications necessary. Another commenter asked that instead of meeting all criteria, we permit the regional offices to evaluate a facility's status with respect to the main provider with input from local government and the fiscal intermediary. Another commenter also suggested that the standards only be enforced to the extent that they are applicable and relevant, consistent with state laws, and relate to practices that are subject to the control of the particular provider.

Response: We have tried to balance the need to apply standards that can be adapted to fit particular circumstances, and agree that the standards should not be overly prescriptive, but rely on regional judgment to ensure appropriate decision making. Because provider-based status is a matter of extreme importance to many facilities, published standards provide a basis for advance assessment and planning of particular organizational and financial arrangements. Therefore, we have decided that a facility or organization will be found to be provider-based only when it is in compliance with *all* standards set forth in these final rules.

With respect to the comment regarding situations in which all but a few criteria for provider-based status are met, we note that nothing prohibits the main provider from re-applying for approval of provider-based status for a facility or organization after having made the changes necessary to come into compliance. Regional offices would in such cases only need to verify compliance with whatever criteria had not been previously met, unless the amount of time that elapses between requests, or other factors, make a full re-evaluation necessary. Because facilities have this flexibility under the rules as proposed, we did not make any changes based on this comment.

Comment: One commenter believes that we had not fully addressed the impact of these rules on service delivery. The commenter suggested that changes would affect deemed status, survey and certification requirements, state licensure requirements, physician referral requirements, and a host of related issues. Another commenter stated that the new requirement regarding administration and supervision found in § 413.65(d)(3) could impact more than our estimated 105 providers. The commenter believes that if providers are required to convert management firm employees to hospital employees and then revert back when outpatient PPS becomes effective, this could impact 5,000 inpatient PPS hospitals.

Response: We again reviewed our requirements, but do not believe they will have the far-reaching effects envisioned by these commenters. In particular, to the extent a facility or organization that claims to be a department of a provider must be accredited, surveyed, or licensed as a part of that provider, or must adapt to the physician referral requirements of the main provider, that result does not flow from the existence of criteria for provider-based status, but instead is a direct result of the provider's decision to claim the facility or entity as a department. We also do not think it is reasonable to assume that any significant number of hospitals will restructure themselves repeatedly because of the final rules set forth below. As noted earlier, both the proposed and final rules closely parallel policies that have been stated explicitly on program instructions since 1996, and we are providing a 6-month delay in effective date for the final rule. Thus, hospitals and other providers have had ample time to assess the impact of any changes and to make necessary adjustments in an orderly way.

Comment: A commenter requested clarification as to how the proposed rules would apply to two hospitals seeking consolidation into a single provider. The commenter also asked whether two small PPS hospitals located approximately 15 to 25 miles apart in separate towns within a metropolitan statistical area (MSA) who wish to consolidate would be prohibited from doing so because of patient population or licensure requirements. Furthermore, if these two hospitals are already certified as a single provider, would the proposed rules require them to separate and create separate providers? Another commenter requested that the final regulatory text state that the provider-based requirements do not apply to any facility where there are inpatient beds since such a facility would be viewed as a ''main provider.'' The provider-based requirements should apply only to facilities or organizations other than main providers.

Response: Although the Program Memorandum and proposed rules were issued in response to situations primarily involving outpatient facilities, we believe the policies set forth in these documents are equally applicable to inpatient facilities, and should be applied in the many cases in which a determination about inpatient facilities must be made. The rules would not prohibit two previously separate hospitals from merging to become a single provider. However, for either facility to be considered provider-based with respect to the main provider, the facility would have to meet the criteria

in this final rule. To clarify the scope of application of these regulations, we have added a definition of ''remote location of a hospital'' and a reference to hospital satellite facilities to § 413.65(a) Definitions, and have clarified the wording of several later sections by including references to remote locations and satellites. We have defined a ''remote location of a hospital'' as a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A remote location of a hospital may not be licensed to provide inpatient hospital services in its own right, and Medicare conditions of participation do not apply to a department as an independent entity. The term ''remote location of a hospital'' does not include a satellite facility as defined in § 412.22(h)(1) and § 412.25(e)(1). Hospitals may acquire remote locations by various means, but often do so by mergers or acquisitions, in which a single hospital purchases other, previously separate hospitals, and operates them as remote locations that are not separately organized as departments, but instead furnish the same types of services as the original hospital. For example, a long-term care or other specialty hospital might acquire one or more other hospitals, terminate their separate participation in Medicare, but continue to use them as sites of the same type of care as the original hospital. Satellite facilities are currently defined in our regulations at § 412.22(h)(1) (for hospitals) and § 412.25(e)(1) (for units). In general, a satellite facility is a part of a hospital (or of a hospital unit) that provides services in a building also used by another hospital, or in one or more buildings on the same campus as buildings also used by another hospital. Satellite status always involves co-location with another hospital, while remote locations are not co-located with other hospitals' facilities.

Comment: A commenter requested clarification that the provider-based requirements apply only to providers who are paid under the reasonable cost methodology. The preamble language in section VI implies that these requirements would also apply to providers under the outpatient PPS. The commenter believe that if this were the case, the requirements found in §§ 413.24(d)(6) and 413.65 would be appropriately placed in Subchapter E (for example, Part 482, Conditions of Participation for Hospitals).

Response: The rules set forth below are not limited in their scope to providers paid on a reasonable cost basis but, except where specifically stated in the text of the rules, apply to all providers and facilities seeking Medicare payment. While many of the problems associated with inappropriate accordance of provider-based status relate to cost reimbursement, the different payment systems used for various providers may produce some unintended incentives for one type of facility to gain an unfair payment advantage by misrepresenting itself. The specific requirements cited do not, like the Medicare conditions of participation, implement section 1861(e) of the Act, nor do they primarily concern patient health and safety. Therefore, we did not adopt the suggestion that the section be relocated to part 482.

Comment: A commenter would support a provision that prohibits hospitals from acquiring free-standing physician practices and converting them to hospital-based entities.

Response: We understand the commenter's concern, but do not have authority under the Medicare law to prohibit this practice. We do believe that the rules set forth below will keep hospitals from misrepresenting physicians' practices as hospital outpatient departments.

Section 413.24(d)(6) Adequate cost data and cost finding: Management contracts

Comment: The proposed cost reporting requirements state that if an overhead administrative cost center does not perform services for the off-site clinic or department, no costs should be allocated to that function. The commenter pointed out that this contradicts generally established Medicare cost reporting principles that have always required that the administrative costs be allocated to allowed and nonallowed cost centers.

Response: Our position, as expressed in the Provider Reimbursement Manual, Part II, Chapter 36 for hospitals, is to allow the provider to bypass the allocation of overhead through the cost report to avoid inappropriate allocations. An example of this would be lab services under arrangement, where there is obviously no administrative activity by the main provider. Our electronic cost report systems are set up to ''skip'' that particular cost center and to re-allocate the costs to the remaining cost centers. Likewise, where administrative costs such as billing are performed by the subordinate provider, no billing cost from the main provider should be allocated to that cost center from the main provider.

Comment: Several commenters suggested clarification of ''like'' costs by adding a definition or providing examples. Also, a commenter stated that since the main concern is costs, this provision should be applied when management costs exceed the hospital's operating costs of the department by 10 percent on a comparable basis. Another commenter stated that: (1) Management services benefit only the specific department to which they are expensed, and provide no direct services to other hospital departments; (2) A department under the management contract receives necessary services from other hospital overhead departments; (3) such overhead departments do not represent duplicate services provided under the management contract. Since management agreements can be drastically diverse, the commenter believes this clarification would assist in avoiding any confusion, as well as allow for consistency with generally accepted cost finding principles. Another commenter stated that most entities that contract to manage an area of a hospital manage just that area. Therefore, if they offer assistance with a particular function, it is only for that area and not for the whole hospital. The commenter believes the same principles of reimbursement should be applied whether the hospital provides the service directly or contracts for the service to be provided.

Response: Examples of similar costs when management contracts provide services also available through the main provider are the following: billing services, computer services, accounting services, and, possibly, general administrative staff. When the same services are included in the administrative and general costs of the main provider, and allocated down to subordinate cost centers or providers incurring and reporting these same costs in the trial balance, the result is a duplication of costs to the subordinate cost center or provider. As long as the main provider has the ability to identify these ''like'' service costs, these costs should be re-allocated to the remaining reimbursable and non-reimbursable cost centers in proportion to each cost center's total costs as prescribed in the Provider Reimbursement Manual, Part II, Chapter 36. However, if the main provider is not able to identify the costs of these same services to permit the exclusion of allocation to the subordinate providers or cost centers,

the cost of the management contract of the subordinate provider or cost center must be reclassified to the main provider's administrative and general cost center, and allocated down to *all* reimbursable and non-reimbursable cost centers in proportion to each cost center's total cost.

Comment: With regard to the language in paragraph (d)(6)(ii), Medicare principles of reimbursement require that, when two entities are related, and one contracts from the other, reimbursement for these services is at cost due to the ''related party principle.'' The commenter stated that the cost of a service is both direct and indirect; Medicare reimbursement has a longstanding methodology concerning nonrevenue producing costs and their allocation on a provider's cost report. A separate work paper should not be required. The appropriate methodology for stepping down administrative costs should be based on the cost of the entity utilizing the service. The cost of the free-standing entity must be placed on the main provider's cost report to step down cost appropriately. Additional work papers would allow room for error and would delay any necessary adjustments.

Response: The intent of § 413.24(d)(6)(ii) was to require the main provider to report costs of related party entities that would not be reported through their accounting system on the main provider's books and records, for example, trial balance. Consequently, when there is a sharing of administrative services, for example, managerial staff, the related entity escapes any administrative overhead allocation when that same related entity is not reported on the main provider's trial balance of the cost report. While the commenter is correct regarding the proper reporting of related transactions at cost of the related entity, this regulation section goes further to require the main provider to develop the total cost of the related entity, utilizing and maintaining workpapers to justify the amount to be reported, and to report those costs by the main provider on the cost report trial balance.

Section 413.65(a) Definitions (retitled in this final rule as Section 413.65(a) Scope and definitions)

Comment: Two commenters requested that a definition be provided for ''a provider's campus.'' A definition would be important since the proposed regulation specifies additional requirements for off-campus locations.

Response: We agree that location on or off a hospital's campus is important. To provide a clear standard, we have revised the final rule to define ''campus'' as ''the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by our regional office, to be part of the provider's campus.'' This definition would encompass not only institutions that are located in self-contained, well-defined settings, but other locations, such as in central city areas, where there may be a group of buildings that function as a campus but are not strictly contiguous and may even be crossed by public streets. This would also allow the regional offices to determine, on a case-by-case basis, what comprises a hospital's campus. We believe allowing regional office discretion to make these determinations will allow us to take a flexible and realistic approach to the many physical configurations that hospitals and other providers can adopt.

Comment: The commenter expressed concern regarding the definition of provider-based facilities as many hospital-owned outpatient services are often provided with leased employees with ambulatory care experience. It is not clear that such an arrangement would satisfy the intent of the regulation.

Response: The regulations do not explicitly prohibit the use of leased employees, and each situation will be evaluated relative to the criteria in the regulations set forth below.

Comment: One commenter stated that the difference between ''department of a provider'' and ''provider-based entity'' is not clear from the definitions given of those terms. The commenter requested that we clarify in the regulations text whether a provider-based entity must be certified in its own right, and what type of certification this encompasses. The commenter also requested clarification in the regulations text concerning whether the term ''provider'' in the definition is intended to mean only entities that satisfy the Medicare definition of ''provider'' contained in § 400.202.

Response: We have clarified § 413.65(a) to state that a ''department of a provider'' is a facility or organization that could not by itself be qualified to participate in Medicare as a provider under § 489.2, while a ''provider-based entity'' could be so qualified. For example, a skilled nursing facility (SNF) could be a ''provider-based entity,'' whereas an entity that furnishes ambulatory surgical services could not be a provider-based entity, and could participate in Medicare (for example, receive Medicare payment for services furnished to beneficiaries), only as a department of a provider, as a physician office, or as an ambulatory surgical center approved by Medicare under part 416, if at all. We have further revised the final rule to clarify that a department of a provider furnishes services of the same type as the main provider (for example, a department of a hospital furnishes hospital services), while a provider-based entity furnishes services of a different type from those of the main provider (for example, a hospital-based RHC furnishes RHC services, not hospital services).

Comment: A commenter believes the proposed rule should be revised for medically underserved populations and health manpower shortage areas to allow the referral of beneficiaries back to their community for treatment of community-based therapy providers. Therapy services provided under such a referral would be included under the provider-based designation.

Response: We do not oppose use of such referrals where they are medically appropriate, but believe that referral arrangements should not be equated to provider-based status.

Comment: A commenter questioned the requirement that services be furnished ''under the name'' of the main provider entity. The commenter argued that the requirement is inconsistent with the commenter's view that health care in the late 1990s is, and in many markets must be, ''marketed'' in a highly competitive environment. The commenter's view is that having provider-based status turn on the names used will inevitably invite micro-management of the way the main provider's name is used by the department or other hospital-based entity.

Response: We disagree with any suggestion that health care is merely a generic commodity that can be repackaged under another name for marketing purposes. On the contrary, we believe that operating under the name of the main provider, and holding oneself forward to patients under that name, is an important indicator of status as an integral and subordinate part of that provider. Therefore, we did not make any changes in the regulation based on this comment.

Section 413.65(b) Responsibility for obtaining provider-based determinations

Comment: A commenter stated that the proposed rule does not state clearly enough whether our approval is required in order to permit billing each

time a provider sets up a new service, regardless of whether the service is acquired, managed, new, located on the main campus, or off the main campus. Some commenters stated that if approval is required in all instances, it will cause a significant paperwork backlog and will be quite costly to administer.

Response: Section 413.65(b) states explicitly that a determination by us that a facility or organization is provider-based is required before the main provider may treat the facility or organization as provider-based for billing or cost reporting purposes. We recognize that this may generate some administrative cost, but believe the cost will be much less than the amounts that would be spent improperly if payment were made to a free-standing facility as if it were provider-based.

Comment: A commenter urged that the new determination process be applied to all current as well as new hospital-based services.

Response: We have no plans at present to review all hospitals and other providers with respect to provider-based criteria, but will look into any situations that come to our attention in which it appears that a facility does not meet the requirements of the new regulations but is being treated as provider-based. If the facility or organization does not qualify as provider-based, action will be taken as described later in this preamble and in § 413.65(i).

Comment: A commenter stated that there should be some mechanism in place for a long-term hospital (LTH) to seek an advance determination or advisory ruling that a proposed LTH satellite will be granted provider-based status. Because establishing an LTH requires a huge expenditure of time and human resources, an LTH main provider needs to know in advance whether or not its proposed satellite will receive a favorable provider-based determination. It is suggested that we institute a system by which advance rulings or determinations are available before the satellite is established.

Response: We understand the commenter's concern, but do not have the staff or facilities to provide advance approvals of restructuring proposals. We suggest that providers review the new criteria carefully and avoid forms of organization that are not clearly in compliance with them.

Comment: Two commenters suggested that we provide guidance on the application process providers must complete in order to receive a provider-based determination. In addition, time limits for approval of these determinations should be established. Furthermore, existing provider-based entities should not be required to change their billing and accounting procedures. A commenter also asked for clarification as to whether the intermediary and regional office is to be the contact, and who will make the actual determination of provider-based status.

Response: We are developing an application process and intend to have it in place and ready for use before the effective date of the regulation. We expect that determinations of provider-based status will be made by our regional offices. Involvement by other entities, such as fiscal intermediaries or State survey agencies, will be for information-gathering purposes and under the direction of the regional office.

Comment: A commenter suggested that if a determination goes against the provider, the provider should be given the option to come into compliance with the requirements or file an appeal.

Response: As noted earlier, the regulations do not prohibit a provider that meets most but not all criteria from taking action to fully meet the criteria, thus qualifying a facility or organization for provider-based status. In the case of a provider that believes that the determination of the regional office is incorrect, an appeals process is provided under part 498.

Comment: A commenter stated that the requirement in paragraph (b)(3) establishes an adverse presumption against provider status for ''off-campus'' physician practice sites, and that the focus on ''campus'' boundaries will prove elusive, and serve no real policy purpose.

Response: As explained later, we believe location in the immediate vicinity is an important indicator of provider-based status, and that location can be a good basis for identifying facilities for further scrutiny.

Section 413.65(c) Reporting

Comment: Several commenters pointed out that the regulatory language does not reflect the preamble language regarding off-campus entities and the five percent increase in a provider's costs.

Response: We have revised the final rule to correct this oversight.

Comment: One commenter asked whether this language applies only to entities that are applying for provider-based status, or also applies to entities that have already achieved provider-based status.

Response: The requirement applies to both types of providers, but providers that have entities with provider-based status are required to report only newly created or acquired facilities or organizations.

Comment: Two commenters stated that the five percent and off-campus criteria with regard to provider-based status do not take into account the characteristics of rural and frontier areas, and could lead to lower payments to some facilities, thus reducing the flow of Federal money into rural areas and possibly creating a shortage of care. In addition, considering the small budget of RHCs and other rural facilities, 5 percent is an inappropriately low and unreasonable growth limit.

Response: We understand the commenter's concern but do not agree that a 5 percent threshold for reporting is too low. Therefore, we made no change based on this comment.

Comment: A commenter asked whether this reporting requirement also applies to all newly developed services (that is, department on the campus of the hospital).

Response: The requirement applies to all newly developed on-campus services that could increase the costs of the provider by 5 percent or more.

Comment: A commenter requested clarification that a main provider that ''creates'' as well as ''acquires'' a facility or organization is responsible for reporting to us. The commenter also suggested specific items to be included in the reporting and approval process. These include specific data elements to be reported by the main provider, specifying our component with primary responsibility; specifying our approval process; adding a preliminary conditional approval process; adding a specific time period for our approval; and adding requirements for the effective date that the costs of the provider-based entity can be included on the main provider's cost report.

Response: We have revised the regulation to clarify that it applies to facilities or organizations created by the main provider, as well as those ongoing operations acquired by purchase or other means. We have not included the procedural detail requested by the commenter in regulations, but will consider including it in program instructions.

Comment: A commenter stated that the use of the phrase ''any material change'' in paragraph (c)(2) of this section is too vague and open to interpretation. It is suggested that the section be revised to clearly designate changes of ownership and new management agreements as the only two material changes that require reporting by provider-based entities.

Response: We do not agree that the range of reportable events should be limited in this way. On the contrary, we intend to require reporting of any change that could have a significant (''material'') effect on compliance with the provider-based criteria.

Comment: A commenter asked if the reporting requirements are coordinated with the notification of change of ownership requirements at § 489.18(b), where notice is to be given in advance, and whether there should be a cross reference or clarification with respect to the change in ownership regulation and this proposed regulation.

Response: We believe this suggestion has merit, and will consider revising our program instructions to specify that a report under § 489.18(b) should be reviewed for its applicability to provider-based determinations.

Section 413.65(d) Requirements

Comment: A commenter suggested that we clarify whether all requirements, or only a majority of the requirements, must be met to obtain provider-based status.

Response: We have revised the first sentence of paragraph (d) to state that all of the stated requirements must be met by a facility or organization that wishes to be classified as provider-based.

Section 413.65(d)(1) Licensure

Comment: Many commenters objected to the requirement that provider-based facilities share a common license with the main provider unless the State requires separate licensure for the subordinate facility. One commenter listed several reasons for this concern. First, in the commenter's opinion, licensure determinations may be made based on factors that are different from those that would be important for provider-based determinations. Another reason cited by the commenter is that State licensure laws may vary from State to State. Some State hospital licensure definitions are building specific, and do not include off-site outpatient facilities, thus giving what the commenter argues is undue weight to physical location in evaluating provider-based status. Finally, the commenter believes that requiring common licensure will create a situation where some States may have a large number of provider-based entities and others will have few or none, thus leading to inconsistent application of our rules. One commenter recommended that the same licensure requirement be waived for States with idiosyncratic licensure requirements. An alternative would be accreditation with the provider as a deemed status for meeting a common license requirement. The commenter suggested that the proposed language could be reworded to clarify that offsite clinics would not have to be licensed or operated under the same license as the provider in those States that do not license them.

Response: We recognize that licensure may not be an appropriate indicator of provider-based status in all States, and have therefore revised the regulations to require common licensure only in States with laws that permit common licensure of the provider and the prospective provider-based department under a single license. This means that in States that do not allow licensure of certain types of facilities, such as those providing ambulatory care or those located off the provider's main campus, the licensure criterion would not be applied. We do not agree that JCAHO or other accreditation should be accepted in lieu of licensure, since such accreditation may not necessarily reflect an on-site evaluation of the prospective provider-based department. In recognition of the fact that some hospitals are not licensed by the State because they are Indian Health Service (Federal) hospitals or are located on Tribal lands, we also will not apply the licensure requirement to departments of those hospitals.

Comment: Under paragraph (d)(1) as proposed, clinics in another State from the main provider could not be under the hospital's license. Several commenters argued that this requirement would arbitrarily affect rural and urban health care delivery, where the main provider is close to a State line. A commenter recommended that close proximity be used instead, where a hospital-based clinic is in another State from the main provider. For urban hospitals in large metropolitan statistical areas that cross State boundaries, the commenter believes that the market area of the main provider should be the primary determinant of the potential for integration with the main provider.

Response: Under the regulations as revised based on the comments summarized above, common licensure would not be required of facilities located across State lines if the law of the State in which the main provider is located does not allow such licensing. However, see the discussion, later in this preamble, of § 413.65(d)(7)(ii).

Comment: A commenter pointed out that the proposed rule appears to limit the licensure requirement to ''departments'' of the main provider. The commenter asked whether this requirement only applied to ''provider-based entities.'' The commenter also suggested that where a State has two licensure schemes for the same type of facility, we should not prefer one licensure scheme over the other for purposes of determining the provider-based status of the facility.

Response: The commenter is correct in noting that the common licensure requirement in the proposed rule would have applied only to provider-based departments. We did not propose to apply a common licensure requirement to provider-based entities such as SNFs and HHAs, because they are providers of services in their own right, and typically would be separately licensed without regard to their affiliation with the provider. We disagree with the commenter's view that licensure should not be viewed as an indicator of integration. On the contrary, our view is that if a facility could be licensed as part of a main provider but chooses not to be, the facility cannot reasonably be seen as an integral and subordinate part of that provider.

Comment: With regard to the proposed requirement that states that our determination regarding provider-based status will be based on a State health facilities' review commission, one commenter argued that relying on the commission's criteria for purposes of making provider-based determinations is arbitrary and inappropriate. The commenter believes imposing this criterion could disadvantage providers and discourage expansion to off-site locations, thus indirectly leading to shortages of care. Another commenter requested that there be a delay in implementation during which time changes can be made to the commission's definition of what rates it can regulate.

Response: We continue to believe it would be inappropriate for a facility to claim to be separate from the provider for State rate-setting purposes while also claiming to be an integral and subordinate part of the provider for Medicare purposes. To allow this practice would authorize providers to misrepresent their structures and affiliations in whatever way will yield the highest payment. Thus, we did not make changes to reflect the comment.

Section 413.65(d)(2) Operation under the ownership and control of the main provider

Comment: Regarding § 413.65(d)(2), the commenter suggested that the regulations provide a separate set of criteria that would allow a provider that is operated within one legal entity to be provider-based to a provider that is operated within another legal entity, as long as the two entities are under common control. Another commenter

stated that this ownership and control requirement is unnecessarily rigid, since a hospital-based clinic, which was strictly an administrative division of the hospital, might qualify while another similar clinic, wholly owned by the hospital with slightly different governing bodies and documents, would not be eligible.

Response: We do not agree that common control of two separate entities by the same parent organization should be sufficient to meet a requirement for ownership and control by the main provider. While this arrangement may be an appropriate way to manage two separate entities, it does not establish provider-based status for either. With respect to the second comment, we agree that the form of administration of an entity can determine whether or not the entity is found to be provider-based. We believe this would be an appropriate result, since it would help ensure that only facilities that are organized as provider-based entities or departments of a provider are given this status.

Comment: One commenter believes it is unrealistic to require a potential provider-based facility or organization to be owned by the main provider and share bylaws and an identical governing body. The commenter stated that in the present business climate an entity can operate as a provider-based entity without meeting these criteria. It is recommended that we replace the proposed 100 percent ownership standard with a majority standard, require only overlapping governing bodies, and eliminate the requirement for organization under the same organizational documents. Another commenter believes that the key consideration should be whether the provider is in control of the day-to-day operations of that portion of the facility in which the provider seeks provider-based status, and not necessarily whether the building is 100 percent owned by the provider. The commenter believes we should rephrase this provision to require that the operations of that portion of the facility or organization in which the provider is seeking provider-based status be controlled by the provider.

Response: In response to the first comment, we recognize that many organizations enter into business relationships that involve overlapping of ownership, governance, and applicability of bylaws. However, this degree of collaboration does not mean that one facility is an integral and subordinate part of another. Therefore, we made no change based on this comment. Regarding the second comment, we wish to clarify that it is ownership of the business enterprise, not of the buildings or other physical assets of the enterprise, that is required under paragraph (b)(1). We have therefore revised the regulation text to refer to ownership of the business enterprise.

Comment: A commenter stated that the requirements contained in paragraph (d)(2) would preclude entities that are jointly owned through legitimate joint ventures or those separately organized subordinate facilities from qualifying for provider-based status. Additionally, to require the level of integration suggested by our proposed rule would prevent providers from establishing efficient systems of delegation and management, solely to qualify for provider-based status.

Response: We agree that this criterion would have the stated effect. As explained further in our discussion of comments on proposed § 413.65(e), facilities operated jointly by two or more providers cannot appropriately be considered integral and subordinate parts of either provider. With respect to the second comment, we do not oppose systems of operation that stress separate, decentralized operation where this leads to greater efficiency. However, we believe such facilities or organizations should be recognized as the separate enterprises that they are, not considered integral and subordinate parts of another institution.

Comment: A commenter suggested that the requirement under paragraph (d)(2) be modified for medically underserved populations and health manpower shortage areas.

Response: We are also concerned that our criteria not limit access to care for any vulnerable populations and have, to avoid this potential problem, created special provisions for FQHCs and IHS and tribal facilities. As described later in this preamble, we have also created an exception to the location requirements in paragraph (d)(7), which is designed to help avoid restricting access to primary care furnished by RHCs in remote, underserved areas. In view of these provisions, we do not believe it is necessary to also modify our requirement relating to ownership of the facility or organization.

Comment: A commenter stated that the proposed requirements in paragraph (d)(2) are inherently inconsistent with section 330 of the Public Health Service Act statutory and regulatory requirements and the Bureau of Primary Health Care expectations necessary to obtain and maintain section 330 funding (and FQHC status). The commenter believes HCFA should not require FQHCs to be 100 percent owned by the main provider or share a common governing body and common bylaws with the main provider. The commenter also suggested that we accept appropriate reporting relationships and satisfaction of other criteria (for example, licensure, quality assurance, integration of certain administrative and clinical functions, such as billing, purchasing, retention of medical records, quality assurance and utilization review procedures; and public awareness of the relationship between the health center and the main provider) as a sufficient basis for provider-based status.

Response: As described earlier, we have provided a special transition period for FQHCs. We believe this period will be adequate to avoid the problems envisioned in this comment.

Section 413.65(d)(3) Administration and supervision

Comment: A commenter recommended that the daily reporting relationship stated in § 413.65(d)(3) should be replaced with the standard of having the reporting relationships have the same intensity as on-site departments. The commenter stated that in practice at the hospital, there may be very little day-to-day contact between medical directors of various hospital services. Also, the commenter believes it is unlikely that departmental directors report directly to the chief executive officer, but rather to a chief operating officer or other designee. Finally, the commenter argued that under the common governance requirement, while all hospital employees are theoretically accountable to the governing body, the accountability may be directed through the CEO, and multiple executives may not have an independent reporting with the board. Another commenter also believes that the standards for the provider-based entity should mirror those of the main facility; personnel reporting structure needs to be respected within the regulations. Still another commenter found ''intensity'' to be a subjective standard and asked how it will be measured.

Response: We agree that reporting need not be daily in all cases, and have revised the final rule to state that the reporting relationship between the facility or organization seeking provider-based status and the main provider must have the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and one of its departments. We agree with the commenter that the intensity of supervision will have to be assessed on a case-by-case basis, but do not believe

this will lead to imprecise or poorly reasoned decisions.

Comment: Several commenters believe that this requirement limits the flexibility of the entity to operate efficiently and effectively in the current environment, since hospitals frequently turn to many specialized management companies to operate more efficiently and effectively than with hospital resources. Another commenter stated that whether the administrative department utilizes employees at one location and contracts at another location should be irrelevant as long as the function is integrated with the main provider, follows the policies and procedures of the main provider, and is accountable to the governing body of the main provider as is any other department. Still another disagreed, and believes that it may be appropriate to require that the main provider manage such contracts.

Response: We do not agree that the provision unreasonably limits hospital flexibility. Paragraph (3)(iii)(B) explicitly allows different management contracts to be used for the facility or organization and the main provider, as long as the provider manages the contracts. Thus, we did not make any changes in the proposal based on these comments.

Comment: A commenter asked whether the administrative functions listed in paragraph (d)(3)(iii) are the only services that must be integrated between the main provider and the subordinate facility.

Response: The commenter was correct in understanding that the functions listed are the only administrative functions that must be integrated. There are also requirements for integration of certain financial functions, as described below.

Comment: One commenter posed several questions concerning this proposed requirement. First, in a certain situation, the facility fee is billed to the intermediary by the hospital billing department using the provider number, while the professional fee is billed to the Part B carrier by the faculty practice billing organization under its physician group number. The commenter asked if the different provider number and tax identification impact on the provider-based status, and if there is a more appropriate way to obtain billing numbers for hospital-based clinics. Also, the commenter asked if clinic space can be shared by two clinics, when one is provider-based and one is free-standing, without impacting the provider-based status of the first clinic.

Response: In the circumstances described, the use of separate billing and tax identification numbers for provider and physician services would not adversely affect a facility's request for provider-based status, since such billings are required under Medicare to be separate in the case of services in hospitals. The question regarding sharing of space, however, can be answered only in the context of a specific case, and we expect that such decisions will be made by our regional offices.

Comment: With respect to the oversight of contracts under paragraph (3)(B)(iii)(B), several commenters stated that it is common for hospitals to subcontract out the billing for different departments, especially the hospital outpatient department, due to the complexity and number of claims. These commenters stated that while it may be appropriate to require the main provider to manage such contracts, departments other than the billing department should be permitted to perform this management function. One commenter suggested revising the criterion on billing under the integration of administrative functions to state, ''common billing or the contract for billing services is held by the provider where it is based.''

Response: We agree that departments other than the main provider's billing department may appropriately manage billing contracts, and have revised the criterion to state that the contract for a provider-based facility or organization must be managed by the main provider.

Section 413.65(d)(4) Clinical services

Comment: A commenter asked for clarification of paragraph (4)(iv) of this section, specifically concerning whether this language would require a Medicare certified HHA's improvement activities to be overseen by hospital medical staff, rather than the advisory committee as is now being done. The commenter believes that having the hospital medical staff overseeing the quality assurance activities of a HHA may not be appropriate or cost effective and may even slow the process of performance changes.

Response: The commenter is correct in understanding that compliance with this criterion would require oversight of a hospital-based HHA's quality improvement activities by the hospital's medical staff. We do not agree with the commenter that the outcome would be to substitute the judgment of the hospital for the HHA's own committee or that it would be inappropriate. The hospital conditions of participation contain a number of separate requirements that must be read together to make complete sense of this provision. Conditions spelled out at § 482.12 (Governing body), § 482.21 (Quality assurance), and § 482.22 (Medical staff) establish a chain of accountability in a hospital for the quality of care it provides. The requirements are clearly applicable to any activity (for example, provider-based entity) that is an integral part of the hospital. Thus, a quality improvement activity of the HHA is likely to be firmly grounded in the hospital's operating and governance fabric even when the group is ''established'' by the HHA, and staffed by employees and physicians who work primarily in home health. We would expect the linkages to be formal (that is, known to the governing bodies and medical staffs of both providers), and the quality assurance mechanisms interrelated to the extent that shared patients are the subject of the effort.

Comment: Regarding paragraph (d)(4)(v) of this provision, some commenters requested clarification of what is meant by a ''unified retrieval system,'' or for guidance as to what types of cross referencing are acceptable. Another commenter asked for an explanation of the practical expectations regarding the maintenance of medical records. Finally, a commenter expressed support for the requirement for a unified retrieval system (or cross references), saying the latter system would be used in States that mandate a unified system.

Response: We would like to clarify that what is intended is that a system be maintained under which both the potential provider-based entity or department of a provider and the main provider have access to the beneficiary's record, so that practitioners in either location can obtain relevant medical information about care in the other setting. We did not, however, make any changes in the requirement based on these comments.

Comment: A commenter believes that functions of operations should not be regulated to dissuade cost efficiency, and that laundry and housekeeping would be examples where shared services may not be the most effective manner of operation.

Response: We agree that in some cases it may be less expensive for a facility to obtain services independently, but continue to believe such separateness is an indicator that the facility is not an integral and subordinate part of a provider.

Comment: With regard to paragraph (d)(4)(vi) requiring integration of services of the main and provider-based entity, the commenter expressed concern about the potential impact of

this section on a patient's freedom of choice. The commenter believes that the entity's efforts to meet this standard would limit a patient's freedom of choice. The commenter suggested that we clarify our position so that providers acting in good faith will not be sanctioned for attempting to comply with this requirement.

Response: Paragraph (d)(4)(vi) requires only that patients have access to the services of the main provider and that they be referred to it where the referral is appropriate. We wish to clarify that these criteria are not intended to restrict patient freedom of choice or the practitioner's freedom to refer patients to other locations, where doing so will result in better care for the patient.

Section 413.65(d)(5) Financial integration

Comment: A commenter believes that § 413.65(d)(5), which requires full integration of financial operations, is too rigid. An alternative approach is suggested that would allow managers of provider-based entities to retain some control over both the resources and information required to administer these units.

Response: Section 413.65(d)(5) requires that there be financial integration of the potential provider-based facility or organization and the main provider, but does not preclude normal management control of resources. Thus, we made no change in the regulation based on this comment.

Comment: A commenter stated that the criteria for common resource usage of building, equipment, and service personnel is not even relevant for multi-campus systems or even buildings that are across the street from each other, much less off-site hospital outpatient departments.

Response: Although the provider-based program memoranda required that there be significant common resource usage of buildings, equipment, and service personnel on a daily basis, this requirement does not appear in the proposed rule. Thus, we made no change in the regulation based on this comment.

Comment: One commenter stated that the requirement for financial integration seems unnecessary in light of the requirement for 100 percent ownership by the main provider. The commenter stated that some providers may wish to segregate the operations of certain departments in their financial systems, and expressed the view that as long as the costs of a department can be adequately identified on the cost report, the practice should be acceptable.

Response: We do not believe that these two requirements are duplicative. On the contrary, in some cases a provider may own 100 percent of another facility or organization, but not be financially integrated with it, either because the other facility or organization is engaged in a different, non-health care activity, or because it is organized and operated separately from the main provider. In these circumstances, we believe the criteria on financial integration apply appropriately to deny provider-based status to separate facilities or organizations.

Section 413.65(d)(6) Public awareness

Comment: Section 413.65(d)(6) requires that provider-based entities be identified as part of the main provider organization. The commenter did not understand the importance of this criterion, particularly when the provider-based organization is licensed and Medicare certified separately from the main provider.

Response: The proposed rule would not apply this criterion to provider-based entities (which may participate separately as providers), but only to provider-based departments. In the latter case, we think it is not unreasonable for such a department to be expected to identify itself with the provider of which it claims to be a part.

Section 413.65(d)(7) Location in immediate vicinity

Comment: A commenter stated that if off-site RHCs cannot be considered provider-based, it will be much harder to deliver care in rural areas. The commenter asked that RHCs be allowed to continue as provider-based RHCs even though they are off campus.

Response: We continue to believe close physical proximity is an important indicator of provider-based status. We note, however, that paragraph (d)(7) does allow off-campus facilities to be treated as provider-based if they meet the criterion relating to service to the same patient population.

Comment: Many commenters believe that more specific tests of service to the same patient population are needed. One commenter suggested that an appropriate criterion would be that the proposed provider-based facility or organization be located within the same geographic area that accounts for a high percentage of patients in the main provider. The commenter believes this test is consistent with Program Memorandum No. 96–7 and with the qualification requirements for sole community hospitals. Other commenters suggested that the main provider's geographical service area be considered the area from which the main provider drew 80 percent of its Medicare inpatients for the previous three years.

Response: We agree that more precise criteria are needed. Therefore, we have revised the regulations to provide that a prospective provider-based facility or organization will be considered to serve the same patient population as the main provider if, during the 12-month period immediately preceding the first day of the month in which the application for provider-based status is filed with us, at least 75 percent of the patients served by the facility or organization seeking provider-based status reside in the same zip code areas as at least 75 percent of the patients served by the main provider. As an alternative, we would consider a facility or organization to serve the same patient population if, during the same 12-month period described above, at least 75 percent of the patients served by the prospective provider-based facility or organization who required the type of care furnished by the main provider received that care from the main provider. We require this ''same patient population'' test to be met for the 12-month period used to support an initial determination of provider-based status, and it must continue to be met for each subsequent 12-month period to justify a continuation of provider-based status. Application of population/geographic standards to newly established facilities or organizations is discussed below.

Comment: Commenters suggested we show some flexibility with regard to the definition of patient population for teaching hospitals. The commenter stated that it will not always be the case that the patient populations for the teaching program will be the same as the overall mix or patient population for the main provider.

Response: We recognize that patient populations will not be identical in all cases, and thus have adopted a patient population criterion under which there may be a divergence of up to 25 percent between the main provider and the facility or organization seeking provider-based status. We believe this provides a reasonable allowance for differences in patient population. Moreover, we note that under section 1886 of the Act, Medicare provides much flexibility for teaching hospitals in other ways, for example, under section 1886(h)(4)(E), permitting the counting of residents for purposes of payment to teaching hospitals for the time the residents spend in nonhospital settings.

Comment: Two commenters suggested that the criterion on service to the same patient population be dropped. One commenter believes the criterion is overly vague, could limit access to care as facilities seek to control their service patterns, and, in general, represents a geographically based approach that is out of keeping with modern technology and communications. Another commenter stated that the criterion is unclear, and providers could find it burdensome to assemble the data to show compliance. Other commenters shared the second commenter's concern, but instead of recommending elimination of the criterion, they suggested that a more administrable solution would be to use regional or state standards to define ''same geographic area,'' such as, health systems area, a specified mileage amount, or our wage area.

Response: As described above, we have developed a more precisely stated test of service to the same patient population. We believe that test will be clear and understandable, not impose unrealistic burdens on providers, and allow provider-based designations that parallel service patterns.

Comment: With respect to paragraph (d)(7)(i), a commenter asserted that many currently operating facilities that are treated as provider-based by us provide types of service that are the same as those of the main provider, but serve patient populations from different geographic areas. The commenter believes these entities provide care under the direction of, and utilize substantial services from, the main provider. An example would be the geographically separate campuses of a single parent hospital that are located at various sites throughout a region. The commenter suggested that such campuses be presumed to be provider-based if they provide substantially the same services as the main provider, do not exceed the size of the main provider, and comply with all other provider-based requirements. Another commenter stated that the ''same patient population'' requirement should not apply to multi-campus long term care hospital locations. These locations are fundamentally different from other provider-based entities that the regulation addresses, since a long-term care hospital main provider and its remote campus furnish the same services, and offer the same programs of care, but operate in slightly different geographic areas. The commenter suggested that so long as all of the strict financial and administrative integration requirements of the proposed provider-based regulation are satisfied, the ''same patient population'' requirements should not apply to long-term care hospitals. The result of this criterion would be that satellites will not be established in many underserved areas where long term services are needed. Another commenter believes a specialty facility, such as a long-term care hospital, should be exempt from the geographic proximity requirement if it can demonstrate that it will improve the quality of patient care, and offer services that are not otherwise provided in that area.

Response: We recognize that there may be some cases in which a hospital and another facility seeking provider-based status as a remote location of that hospital may meet most or all other criteria in § 413.65, yet not qualify because the two facilities serve different patient populations. However, we do not agree that this result should lead us to abandon the ''same patient population'' test. On the contrary, we continue to believe that criterion is a valid indicator of provider-based status. Thus, we did not revise the regulation based on this comment. In this context, we note that there is no Medicare rule that would prohibit a hospital from setting up another hospital in another area. We do not agree with the commenter's assumption that because the program memorandum and proposed rule were issued in response to situations primarily involving outpatient facilities, they can apply only to such facilities. On the contrary, we believe the policies set forth in these documents are equally applicable to inpatient facilities, and should be applied in the many cases in which a determination about inpatient facilities must be made. In particular, the rules apply to remote locations of long-term care and other hospitals that are main providers, as well as to satellite facilities of hospitals and hospital units that are excluded from the hospital inpatient prospective payment system. Remote locations and satellite facilities are discussed more fully earlier in this preamble, and ''satellite facilities'' are specifically described in our regulations in §§ 412.22(h) and 412.25(e). (As explained in that document, we are concerned that establishment of satellites by hospitals and units excluded from the inpatient PPS could lead to payment abuses, such as circumvention of certain payment caps mandated by section 4414 of the Balanced Budget Act of 1997, and we have therefore established special payment rules for those facilities. Facilities seeking to qualify as ''satellites'' under the inpatient payment criteria in §§ 412.22(h) and 412.25(e) would first need to comply with the provider-based requirements before being eligible for satellite status.) We have revised the final rule to clarify its application to remote locations of hospitals and satellite facilities.

Comment: The commenter believes that flexibility in the definition of ''located in the immediate vicinity'' needs to be met with additional considerations when viewing rural and underserved areas; for example, it should not be our intention to eliminate the provider-based designation of a rural health clinic (RHC), when the purpose of the RHC is to be an outreach to geographically isolated areas.

Response: We share the commenter's concern and have developed a special provision for RHCs, as described below.

Comment: A commenter believes that the requirement that provider-based entities serve the same population as the main provider could cause significant problems for RHCs. The unique situations addressed by hospital-based RHCs attempting to satisfy the health care needs of medically underserved areas should be considered as exceptions to the proposed rule.

Response: We continue to believe close physical proximity is an important indicator of provider-based status; however, we recognize that small rural hospitals and their RHCs may not be able to demonstrate that a substantial number of clinic patients receive services from the main provider. Small rural hospitals typically provide limited inpatient care compared to their urban counterparts, which may cause the RHC patients to seek inpatient service from other providers. In light of this, we believe small rural hospitals (less than 50 beds) that own and operate RHCs should not be expected to demonstrate that they serve the same patient population as the main provider. Therefore, we are revising the regulation to allow off-campus RHCs affiliated with small rural hospitals (less than 50 beds) to retain their provider-based status without satisfying that requirement.

Comment: Several commenters opposed the inclusion of paragraph (d)(7)(ii), since they view a State border as an arbitrary boundary inhibiting a hospital's ability to serve patients, which seems counterproductive. They also argued that a regulation that fails to recognize the operation of health care systems that function across State lines is unrealistic. Another commenter suggested that we rely on the proposal concerning serving the same patient population. It was also stated that in one case a provider can be located in a city

split by the State border with its related facility located one mile away, but in another state, while in another case, the provider and its subordinate facility can be a mile apart and in the same State. Another commenter believes that, since Medicare beneficiaries often cross borders for health care services, disallowing hospitals in these areas from establishing provider-based entities eliminates choices and prohibits the development of new services. The commenter recommended that we revise or eliminate this criterion. Another commenter suggested that LTHs and their satellites not be subject to this requirement if the main provider and its satellite are located in two contiguous States. Alternatively, the commenter suggested that we consider using the wage index areas as guidelines for the areas to be served by provider-based entities even if that area crosses State lines.

Response: After reviewing these comments, we have decided to revise the regulations to allow providers in one State to have provider-based facilities in an adjacent State, if doing so is not inconsistent with the law of either State, and other criteria are met, including those related to service to the same patient population.

Comment: With regard to paragraph (d)(7)(i), while the proposed rule permits a provider to show that a ''high percentage'' of patients of the main provider and the facility come from the same geographic region, new facilities would not have any historical data upon which to base this assertion, and therefore would fail to be able to demonstrate the criteria prior to operation. Another commenter believes the requirement may pose an impediment to new facilities being located in underserved or outlying areas. Thus, the commenters believe the same patient population requirement should not apply to new facilities, including new long-term care hospital satellites.

Response: We agree that it would be appropriate to establish a criterion that could be met by new facilities or organizations, and therefore have revised the final rule to include a special provision for new facilities or organizations. Under this revision, a new facility or organization, (one that has not been in operation for all of the 12-month period immediately preceding the first day of the month in which the application for provider-based status is filed with us), may be considered to meet the criterion on service to the same patient population, if it is located in a zip code area included among those that (during the 12-month period described above) accounted for at least 75 percent of the patients served by the main provider. We note that this provision would not be limited to long-term care hospitals' satellites or their remote locations, but would be available to all new facilities or organizations.

Section 413.65(e) Provider-based status not applicable to joint ventures

Comment: Several commenters expressed concern that this criterion would prohibit the use of joint ventures for entities that want to participate as provider-based entities, and argued that such a prohibition would unnecessarily restrict hospital flexibility. One believes this provision should be eliminated. Another commenter suggested modification of paragraph (d)(2) of the rule to establish majority ownership as the standard rather than 100 percent ownership. Still other commenters suggested that provider-based status for facilities or organizations run as joint ventures should be permitted, as long as the hospital at which the facility is located has the equipment or service under its control.

Response: We reviewed these comments carefully, but did not make any changes in the regulations based on them. When a facility or organization is run as a joint venture of two or more providers, it is by definition under their joint control, and therefore cannot be an integral and subordinate part of any individual provider. We have no interest in discouraging such ventures, but continue to believe they do not qualify as provider-based.

Section 413.65(f) Management contracts

Comment: Several commenters expressed the view that the criterion under which the staff of the facility or organization must be employed by the provider or another organization other than a management company is too restrictive, and should be deleted. One commenter argued that, if the written contract maintains the responsibility and control for services in the hands of the main provider, the employer of the staff working at the site is not relevant. Another believes the criterion will discourage economic efficiencies. If a provider is able to demonstrate integration and subordination of the off-site facility based upon other provider-based criteria, the fact that a hospital chooses to provide certain services either directly through its own employees or indirectly through an independent contractor/management arrangements is irrelevant. Another commenter argued that the proposed criterion is inconsistent with: the provision of the Medicare statute that expressly permits coverage of ''services under arrangement''; with the hospital conditions of participation that recognize that contractors may be used to furnish patient care services; and with the Provider Reimbursement Manual, which recognizes that providers commonly contract for management services and the costs of the contract services may be allowed under Medicare principles of reimbursement. Still another commenter believes the proposed criterion would negatively impact the therapy profession, and could impact the health and safety of Medicare beneficiaries.

Response: We do not believe the criterion is overly restrictive, nor do we agree that employment of the staff of a facility or organization is irrelevant to the question of whether that facility or organization is an integral and subordinate part of a provider. On the contrary, employment of the staff of such a facility or organization will normally give the provider significant control over it, thus promoting integration. Conversely, if a facility or organization is staffed by personnel who are employed by another entity that has only a contractual relationship with the provider, the facility or organization may well be an integral and subordinate part of the management company, not of the provider.

We also do not agree that the criterion is inconsistent with section 1861(w)(1) of the Act, which permits providers to make arrangements for the provision of specific health services, nor do we believe adopting this criterion will undercut the ability of providers to have selective services provided under arrangements. In this regard, we point out that existing Medicare policy, stated in section 207 of the Medicare Hospital Manual (HCFA Publication 10), emphasizes the need for the hospital to exercise professional responsibility for the arranged-for services, not merely to serve as a billing mechanism for the other party. This is consistent with our view that section 1861(w)(1) was intended to allow specific health care services to be furnished under arrangements, but was never meant to be a vehicle by which a provider could nominally operate a facility or organization, but, in fact, contract out its operation to another entity. Finally, we note that while there are various sections of the hospital conditions of participation and the Provider Reimbursement Manual that recognize the possibility that specialized health care services or management services may be provided under contract, this does not indicate that providers may

contract out entire departments or services while claiming them as provider-based. To clarify the scope of the requirement on contracted services, we have revised it to state that management staff of the facility or organization (rather than health care or support staff) need not be employed directly by the provider. We have also revised the rule to clarify that if staff of the facility or organization (other than management staff) are employed by an organization other than the management company or the provider, it must be the same organization that also employs the staff of the main provider.

Section 413.65(g) Obligations of hospital outpatient departments and hospital-based entities

Section 413.65(g)(1)

Because of the direct relationship between the proposed changes in this section and those in § 489.24(b), comments on both proposals are discussed later, under § 489.24(b), ''Special responsibilities of Medicare hospitals in emergency cases.''

Comment: A commenter requested clarification as to the application of the anti-dumping requirement in the home health setting.

Response: Section 413.65(g)(1) states that the EMTALA requirements apply to hospital outpatient departments. EMTALA requirements would not apply to off-campus provider-based entities that are not hospital departments, such as home health agencies.

Section 413.65(g)(2)

Comment: While one commenter agreed with the requirement under § 413.65(g)(2) for billing of physician services with the appropriate site-of-service indicator, another commenter also believes there should be clarification that correct billing is the responsibility of the entity performing the billing function. Both commenters suggested that the hospital notify physicians who do their own billing that they must use the correct indicator; they agree that it should not be the responsibility of the hospital.

Response: We agree that physicians (or those to whom they assign their billing privileges) are responsible for appropriate billing, but note that physicians who practice in hospitals, including off-site hospital departments, do so under privileges granted by the hospital. Thus, we believe the hospital has a role in ensuring proper billing.

Section 413.65(g)(5)

Comment: Presently, provider-based clinics bill Medicare for the facility charge on a UB–92 form, and the physician fee is billed separately on a HCFA–1500 form, while other payers may accept a single bill for both charges. A commenter believes it is inappropriate to mandate that two bills be submitted for all patients, as long as charges for similar services are uniform regardless of payer.

Response: As explained further below, we have revised the final rule to eliminate the part of this criterion relating to billing of services to non-Medicare patients. We believe this responds to this commenter's concern.

Comment: Many commenters stated that Medicare should treat a facility that claims a facility fee as being provider-based even when other payers do not do so, reasoning that as long as the hospital claims that the patient is an outpatient for Medicare purposes, the practices of other payers, with respect to similar patients, are not significant, and should be ignored. Another commenter believes this requirement should be eliminated, because, in the commenter's view, it has no bearing on the outpatient services delivered to Medicare beneficiaries, and therefore does not affect Medicare reimbursement. To illustrate, a large commercial insurer does not have the capability to accept certain types of outpatient claims from hospitals; therefore, it requires claims for those services to be billed on a physician claim form, so hospitals will receive the proper reimbursement. If this criteria is retained as proposed, many hospital-based departments would not meet our criteria due to the nuances of other payers' policies, that are often contractual issues with providers. Still another commenter believes that we should reexamine the proposal made in paragraph (g)(5), and at a minimum, clarify what it means by its proposal mandating uniform ''treatment of all patients, for billing purposes, as hospital outpatients.'' If we are proposing to mandate that all outpatients be billed on the same basis, this would effectively extend Medicare direct billing or rebundling rules to all payers. In addition, this proposed requirement would not only be contrary to past policy and practice, but would affect departments that have differentiated billing practices. Another commenter stated that payers typically determine payments based upon how they define a particular service or their individual market power; Medicare certification of outpatient departments should not be influenced by how unrelated third parties pay for services to the patients they cover at these sites. Moreover, this criterion would be very difficult to implement, because hospitals can have hundreds of contracts with insurance companies and the providers that subcontract for part of the risk for plans.

Response: After review of the comments on this section, we have decided to revise it to restrict the requirement for uniform billing to Medicare patients only, thus allowing hospitals to bill other payers in whatever manner is appropriate under those payers' rules. As revised, § 413.65(g)(6) states that hospital outpatient departments (other than RHCs) must treat all Medicare patients, for billing purposes, as hospital outpatients. The department must not treat some Medicare patients as hospital outpatients and others as physician office patients.

Comment: A commenter stated that there appears to be some confusion as to whether this requirement applies to ''departments'' or all facilities and organizations seeking provider-based status. Also, the commenter asked if there is a provision of the proposed rule that mandates that a facility fee be charged to patients of facilities and organizations receiving provider-based status.

Response: As noted earlier, the proposed rule would not apply this criterion to provider-based entities (which may participate separately as providers) but only to provider-based departments. Regarding the second issue, we have, as described in response to the preceding comment, revised the final rule to eliminate the criterion regarding billing of payers other than Medicare.

Section 413.65(g)(7)

Comment: A commenter stated that requiring written notice for each patient (presumably signed by the patient), would be an overly burdensome requirement, and requested that the requirement allow for a clear, prominently displayed sign in lieu of individual notice. Another commenter believes that the proposed requirement would apply a standard to hospital outpatient departments that is not applied to any other site of service.

Response: First, we emphasize that notice is required only for Medicare beneficiaries, not for all patients. We recognize that providing notice will generate some burden for the provider, but believe that the protection it affords to patients warrants the requirement. We considered allowing the notice requirement to be satisfied through the posting of signs, as recommended by one commenter, but concluded that use of individual written notices would more effectively ensure that each

beneficiary receives the necessary information. In response to the comment concerning settings other than hospital outpatient departments, we note that in other settings, a patient is unlikely to be misled as to what type of facility is the site of treatment, so provision of notice is not required. To avoid confusion as to when the requirement applies, we have revised the final rule to state that notice is required only if the hospital outpatient department or provider-based entity is not located on the campus of the hospital that is the main provider. We have revised this final rule to specify that the notice must be in writing, must be one the beneficiary can read and understand, and must be given to the beneficiary's authorized representative if the beneficiary is unconscious, under great duress, or for any other reason unable to read a written notice and understand and act on his or her own rights.

Section 413.65(g)(9) (redesignated in this final rule as Section 413.65(h), Furnishing all services under arrangement)

Comment: A commenter observed that § 413.65(g)(9) does not preclude an outpatient facility from obtaining a certain type of service from an off-site supplier. If this is correct, if the service is provided on-site in the hospital's outpatient facility, it is not clear how the proposed regulations are intended to be applied. It would appear that if the facility is looked at as a whole, all services are not provided ''under arrangements''; therefore, paragraph (g)(9) of this section would not preclude the facility from being recognized as provider-based. However, in this case, the commenter stated that both licensure and ownership requirements would be difficult to satisfy. In most cases, that portion of the facility that is operated ''under arrangements'' with the hospital will not be on the hospital's license, nor will that portion necessarily be owned by the hospital. Thus, the commenter urged that the ''under arrangements'' portion of an outpatient facility be excluded from the licensure and ownership analyses.

Response: We agree that where a facility offers a variety of services, provision of a single type of service under arrangement would not prevent the facility from meeting this criterion. The criterion could not, of course, be met by a facility that furnished only a specific type of service (such as physical therapy), and provided that service only under arrangement. In the case envisioned by the second commenter, the facility would be out of compliance with licensure and ownership requirements, as well as the requirement involving services under arrangement, and we would agree that it could not be provider-based.

Comment: A commenter asked for clarification of ''under arrangements'', in reference to our other regulations that contain these terms. Also, the commenter requested clarification on the types of services to which this standard applies, that is, direct patient care as opposed to facility related services.

Response: The term ''arrangements'' is defined in section 1861(w)(1) of the Act and the Medicare regulations § 409.3, in that ''arrangements'' refers to arrangements that provide that Medicare payment made to the provider that arranged for the services discharges the liability of the beneficiary or any other person to pay for the services. We wish to emphasize that the provision will apply to patient care services, not housekeeping, security, billing, or other services that are not patient care services but are needed to support their provision.

Section 413.65(h) Inappropriate treatment of a facility or organization as provider-based (redesignated in this final rule as paragraph (i))

Comment: This section establishes sanctions that may be used to address a main provider that has treated an entity as provider-based without our review and approval. A commenter believes that the investigation phase should precede the review of payments to the main provider. A commenter was also concerned that the individuals involved in these reviews and investigations are properly trained to make the required determinations.

Response: We believe review of payments will encompass two activities—investigation to determine whether applicable provider-based requirements were met, and a calculation of the amount of overpayment if they were not. Thus, investigation necessarily precedes recovery, but is a part of the overall effort, which is to reconsider payment amounts. To respond more effectively to concerns about how the review and recovery activities will occur, and to clarify the specific actions we will take in cases of inappropriate billing, we have reorganized paragraph (i) to deal separately with the processes of determination and review, recovery of overpayments, and the good faith effort exception. With respect to determination and review, we state that if we learn that a provider has treated a facility or organization as provider-based and the provider had not obtained a determination of provider-based status under this section, we will review current payments and, if necessary, take action in accordance with the rules on inappropriate billing in paragraph (j), investigate and determine whether the requirements for provider-based status in paragraph (d) of § 413.65 (or, for periods prior to October 10, 2000, the requirements in applicable program instructions) were met, and review all previous payments to that provider for all cost reporting periods subject to re-opening in accordance with § 405.1885 and § 405.1889 of this chapter. With respect to recovery of overpayments and the good faith exception, we have clarified that we will recover only the difference between the amount of payments that actually were made and the amount of payments that we estimate should have been made in the absence of a determination of provider-based status, and that recovery will not be made for any period prior to the effective date of these final rules if during all of that period the management of the entity made a good faith effort to operate it as a provider-based facility or organization, as described in paragraph (h)(3) of § 413.65. In response to the comment about the competence of individuals involved in these activities, we wish to emphasize that we will ensure that staff involved in these activities have the necessary expertise.

Comment: A commenter believes that it would be unfair to apply the proposed regulations retroactively, that is, to periods before the effective date of the final rule. Even though paragraphs (h) and (i) provide for a good faith exception, it is still unfair to provide that the conditions for this exception will apply prior to the effective date of the final regulation. The commenter requested that these sections be revised to provide that the period of recovery will not extend to any period prior to the effective date of the final regulations. Another commenter also believes that any payment changes be prospective (unless the hospital did not make a good faith effort to operate the site as provider-based).

Response: We agree that it would be inappropriate to apply the rules in paragraph (h) to any period prior to their effective date, and have revised the final rule to clarify that for such periods, we will make determinations based on the program memoranda or other instructions in effect at the time. However, the criteria in paragraph (i) that form the basis for a good faith exception were in effect prior to the issuance of these regulations. Regarding

the last comment, we cannot agree to ignore possible overpayments resulting from noncompliance with published criteria in effect at that time.

Comment: A commenter believes that the term ''good faith effort'' should be defined to provide more direction and opportunity to comply. Also, entities making ''good faith efforts'' should be given an opportunity to correct those factors or criteria that render it out of compliance with the provider-based requirements.

Response: The conditions under which a provider will be found to have made a good faith effort were clarified in § 413.65(i)(2), and have been restated in the final rule.

Section 413.65(i) Inappropriate billing (redesignated in this final rule as paragraph (j))

Comment: A commenter believes that suspending all payments for outpatient services to facilities that have billed inappropriately as provider-based entities until the provider can demonstrate that payments are proper is too onerous. Instead, the commenter suggested that we consider suspending the reimbursement differential between a provider-based entity and a nonprovider-based entity until a determination is made or the facility has had a reasonable opportunity to comply.

Response: We understand the commenter's concern and have revised the final rule to authorize partial suspension of payment (that is, a reduction in payment) to the extent needed to prevent creation of an overpayment to the provider. This rule will allow payment to continue at a reduced rate, thus avoiding creation of financial hardship for the provider. To describe more clearly how we will deal with instances of inappropriate billing, we have reorganized paragraph (j) of § 413.65 to spell out more clearly the actions we will take, and the extent to which payment will be adjusted. Specifically, we state that if we find that a facility or organization is being treated as provider-based without having obtained a determination of provider-based status under this section, we will notify the provider, adjust future payments, review previous payments, determine whether the facility or organization qualifies for provider-based status under this paragraph, and continue payments only under specific conditions. The notice to the provider will explain that payments for past cost reporting periods may be reviewed and recovered, that future payments for services in or of the facility or organization will be adjusted, and that a determination of provider-based status will be made.

We further state that we will not stop all payment in such cases, but instead, will adjust future payments to approximate as closely as possible the amounts that would be paid in the absence of a provider-based determination, if all other requirements for billing were met. We also explain that we will review previous payments and, if necessary, take action in accordance with the rules on inappropriate treatment of a facility or organization described above. The regulation states that we will determine whether the facility or organization qualifies for provider-based status under the criteria in this section. If we determine that the facility or organization qualifies for provider-based status, future payment for services at or by the facility or organization will be adjusted to reflect that determination. Even if the facility or organization does not qualify for provider-based status, however, we will continue paying, at an appropriately adjusted level, for a limited time period in order to avoid disruption of services to program beneficiaries at that site and to allow an orderly transition to freestanding status.

The notice of denial of provider-based status sent to the provider will ask the provider to notify us in writing, within 30 days of the date the notice is issued, as to whether the facility or organization (or, where applicable, the practitioners who staff the facility or organization) will be seeking to enroll and meet other requirements to bill for services in a free-standing facility. If the provider indicates that the facility, organization, or practitioners will not be seeking to enroll, or if we do not receive a response within 30 days of the date the notice was issued, all payment will end as of the 30th day after the date of notice. If the provider indicates that the facility or organization, or its practitioners, will be seeking to enroll and meet other requirements for billing for services in a free-standing facility, payment for services of the facility or organization will continue, at the adjusted amounts described in paragraph (j)(2) of this section for as long as is required for all billing requirements to be met (but not longer than 6 months) if—

- The facility or organization, or its practitioners, submit a complete enrollment application and provide all other required information within 90 days after the date of notice, and
- The facility or organization, or its practitioners, furnish all other information we need to process the enrollment application and verify that other billing requirements are met.

If the necessary applications or information are not provided, we will terminate all payment to the provider, facility, or organization as of the date we issue notice that necessary applications or information have not been submitted. We have clarified the final rule to state that these reductions will occur where inappropriate billing is or has been taking place.

Comment: A commenter believes that there are already existing mechanisms for overpayment and recoupment that may be used in the situations described in this section. At the very least, administrative actions of this type should be subject to time frames in order to protect providers from the impact of extended investigations.

Response: We plan to conduct any recovery efforts in accordance with applicable law and regulations on overpayment recovery. However, investigations may be complex and require examination of many records, and we do not agree that they should be limited by additional, self-imposed restrictions.

Comment: A commenter stated that a facility or organization that requests a provider-based determination prior to the effective date of the final rule, and meets the good faith requirements, should not be subject to recovery of overpayment for periods either before or after the effective date of the final rule. This will prevent disruptions to existing arrangements that meet the good faith exception during the time that the request is being processed.

Response: If we were to adopt this proposal, we would be guaranteeing an overpayment to providers who, for a specific time period, knowingly billed for services as those of provider-based entities, even though they met only a few of the provider-based criteria. Thus, we did not adopt this comment.

Comment: A commenter requested that the requirement found at paragraph (i)(2)(iii) be clarified to state that management is only responsible for professional services billed by the hospital.

Response: As explained earlier, we believe hospitals' privileging mechanisms give them adequate leverage to prevent inappropriate billing by practitioners using their facilities. Therefore, we did not adopt this comment.

Comment: As to the good faith criteria found in paragraph (i)(2), a commenter questioned why requirements related to public awareness were chosen for inclusion. An organization can represent itself to the public in any number of inaccurate ways in order to mislead our officials and others. The

commenter believes that we should focus our attention on more tangible expressions of good faith efforts to operate a provider based entity.

Response: We believe inclusion of this requirement is needed to help ensure that beneficiaries are protected from unexpected deductible and coinsurance liability. While we agree with the commenter that some providers may misrepresent the status of off-site facilities, we believe such providers cannot reasonably be said to have acted in good faith, and should not receive favorable treatment with respect to past overpayments.

Section 413.65(j) Correction of errors (redesignated in this final rule as paragraph (k))

Comment: A commenter disagreed with the language in this subsection that would allow us to review and rescind, if appropriate, any past determinations. The commenter believes that this subsection should be removed and any previous determinations should be grandfathered in under the new regulations. Other commenters recommended that we grandfather facilities or organizations that had previously been determined by the regional office to be provider-based, or that have not received such a determination but have been billing as provider-based without a determination for a period of at least ten years, so that those facilities or organizations could retain provider-based status even though they do not meet the criteria in the regulations.

Response: We do not agree that it would be appropriate to grandfather existing facilities or organizations, since this would in effect create an ongoing double standard, under which some facilities or organizations are held to higher standards than others. Moreover, the fact that improper billing may have continued undetected for a long period is not a reason to continue to permit such billing. As explained in the response to the following comment, however, any adverse determination regarding provider-based status of facilities or organizations which we previously determined were provider-based will not be effective until the start of the cost reporting period after the period in which the provider is notified of the redetermination, or for at least 6 months, whichever date is later.

Comment: A commenter believes that our proposal that we may review past provider-based determinations inserts needless uncertainty into the process for making provider-based designations. The commenter is concerned that providers may file before the final rule is published in order to avoid a crush of applications and subsequent disruption in payment, if they do not have a determination within 30 days of the rule becoming final. The commenter stated that providers need to be able to receive prompt determinations on which they can rely.

Response: We understand the concern about avoiding the need to process a large number of applications in a short time, and agree that it would not be appropriate to make abrupt changes in provider-based status. To avoid a possible crush of applications within a 30-day period, as envisioned by the commenter, we are providing the delayed effective date described earlier in this document. In addition, under § 413.65(j) of these regulations, when a facility or organization that previously was determined to be provider-based is found to no longer qualify for provider-based status, treatment of the facility or organization as provider-based will not cease until the first day of the first cost reporting period following notification of the redetermination, but not less than 6 months after the date the provider is notified of the redetermination. If there has been no prior determination of provider-based status, and a facility or organization is later found not to meet the criteria, that determination may be effective up to 6 months after the date the provider is notified of the determination, if within 30 days of the determination, the provider indicates that the facility or organization, or its practitioners, will enroll separately and, within 90 days, the facility or organization, or its practitioners, take other necessary action to enroll.

Section 489.24(b) Special responsibilities of Medicare hospitals in emergency cases

Comment: One commenter disagreed strongly with the proposed revisions to the regulation defining ''comes to the emergency department,'' and in particular expressed the view that patients arriving on the campus, sidewalk, driveway, or parking lot of hospital facilities should not be considered to have come to the emergency department. The commenter stated the view that an obligation under section 1867 of the Act (sometimes referred to as the Emergency Medical Treatment and Active Labor Act (EMTALA), after the original title of the legislation adding section 1867) and our regulations at §§ 489.20(l), (m), (q), and (r), and § 489.24 should be triggered only by a presentation to the emergency department, and that only in exceptional situations should EMTALA apply to someone not technically in the emergency department. The commenter recommended that the regulations be revised to state that in these cases, the hospital may rely on a variety of transport options, consistent with the individual's condition and established policies that are applied in a nondiscriminatory manner. The commenter also recommended that the statute be interpreted as requiring only that hospitals with emergency departments have policies and procedures to assure that a person who presents to the hospital requesting emergency services is provided a medical screening examination and, if needed, stabilization or an appropriate transfer.

Another commenter raised several arguments against the proposed change. The commenter stated that there is a legal and ethical conflict in requiring hospital personnel to leave an area of patient care and furnish assistance to another patient in a remote area of the hospital. The commenter also believes that ED personnel are not well-trained or practiced in immobilization or scene safety, and patients and staff may be put at risk if staff are asked to go into the field and render aid to a victim who needs the expert care and experience for which field emergency medical services (EMS) personnel are trained. Finally, the commenter expressed concern about possible increases in the liability insurance cost to hospitals as a result of the proposed change.

Response: We do not agree that the proposed language inappropriately extends the scope of hospitals' EMTALA responsibilities. On the contrary, existing regulations at § 489.24 make it clear that EMTALA applies to hospitals that offer services for emergency medical conditions, and we believe it would defeat the purpose of EMTALA if we were to allow hospitals to rely on narrow, legalistic definitions of ''comes to the emergency department'' or of ''emergency department'' to escape their EMTALA obligations. We would also note, as discussed further below, that there is no requirement that all areas of the hospital be equipped to provide emergency care or that treatment always be provided outside the emergency area or department. Similarly, there is no prohibition of appropriate transfers to other facilities where such a transfer is conducted in accordance with § 489.24. On the contrary, the intent of the revised regulation is to ensure that patients who come to the hospital and request examination or treatment for what may be an emergency medical condition are not denied EMTALA protection simply because they enter the

wrong part of the hospital or fail to make their way to the emergency room.

Comment: Two commenters recommended clarification of the applicability of section 1867 of the Act regarding transfer requirements to scheduled patients at an ''off-campus'' hospital site, to ensure that the movement of scheduled patients unexpectedly requiring a higher level of care to another site of the same hospital is not construed as a ''transfer'' under the emergency access law, and that only those patients taken from one hospital's off-campus facility to another hospital's emergency department or inpatient unit be considered ''transfers'' that must be in accordance with the requirements of section 1867.

Response: We agree that movement of a patient from one part of a hospital to another, including movement from a remote location to a main hospital campus, does not constitute a ''transfer'' for EMTALA purposes, nor does it require compliance with the appropriate transfer requirements in § 489.24(d). The final regulations at § 489.24(i)(3)(i) clarify this policy.

Comment: A commenter expressed the view that the proposed revision to § 489.24 does not recognize the role that EMS personnel play in emergency situations and the true medical benefit provided by EMS personnel to patients in emergency situations. The commenter recommended that language be included in the regulation to authorize hospitals' use of EMS in responding to emergency situations on hospital grounds.

Response: We agree that EMS personnel can play a valuable role in transporting patients to appropriate sources of emergency care. A hospital may not, however, meet its EMTALA obligations merely by summoning EMS personnel. EMS may be used appropriately in conjunction with an appropriate hospital response to treat and move an individual who is already on hospital property. We therefore did not make any change to these regulations to authorize exclusive use of EMS to respond to emergency situations on hospital property.

Comment: A number of commenters stated that the anti-dumping rules implemented under section 1867 of the Act (EMTALA requirements) and our regulations at §§ 489.20(l), (m), (q), and (r), and § 489.24 should apply to the hospital's main campus and to all emergency departments. However, they argued that it is not reasonable to apply these rules to outpatient departments located off-campus that would not be set up to provide emergency services. In the commenters' view, it should suffice that patients in an emergency situation be directed to the hospital's emergency room. Another commenter stated that EMTALA obligations should be limited to those hospital entities that hold themselves out as providing emergency services, and should not be enforceable anywhere outside the emergency department or anywhere on hospital property, including an outpatient department or provider-based entity. Another commenter stated that the enforcement of this requirement would lead to the elimination of service-specific outpatient departments located off a main campus, and asked that we reconsider our policy. One commenter expressed concern that patients identifying a facility as a hospital-based department could mistakenly assume it is equipped to handle emergency cases. Another commenter believes that hospitals should be required to have policies and procedures in place to assure that all parts of the hospital are prepared to deal with getting an individual the appropriate medical screening.

Response: Existing regulations at § 489.24(b) define ''hospital with an emergency department'' to include all hospitals that offer services for emergency medical conditions, not just those that have organized emergency rooms or departments. To the extent a hospital acquires or creates an off-campus location, identifies it to us and to the public as a part of that hospital, and claims payment for services at that location as hospital services, we believe it is not unreasonable to expect that hospital also to assume the obligations, including compliance with EMTALA requirements, which flow from hospital status. This principle does not mean, of course, that a hospital must have a fully equipped and staffed emergency department at each location. It also does not mean that every appearance by an individual at an off-campus hospital department that does not offer services for emergency medical conditions will necessarily trigger an EMTALA obligation on the part of the hospital. Individuals come to these departments for many medical purposes which may not involve potential emergency medical conditions. Under these circumstances, the hospital would not have an EMTALA obligation with respect to that individual. This principle does mean, however, that if an individual comes to an off-campus department of a hospital and a request is made for examination or treatment for a potential emergency medical condition, the hospital incurs an obligation to provide, *within its capability,* an appropriate medical screening examination and necessary stabilizing treatment. In some cases, the patient may need to be taken back to the main hospital campus for a full screening and/or stabilizing treatment. Under these circumstances, the hospital is responsible for moving the patient or arranging his or her safe transport, but this movement would not be considered a ''transfer'' under § 489.24(b), since the patient is merely going from one part of the hospital to another. If it is necessary to transfer the patient to another medical facility, the hospital must provide an appropriate transfer in accordance with § 489.24(d).

After review of the comments on this issue, we have decided to revise the regulations to state more clearly the extent of a hospital's EMTALA obligations with respect to patients who come to a hospital department located off the hospital's main campus. Provider-based entities, such as SNFs or HHAs, located off the hospital campus would not, of course, be subject to EMTALA since a patient coming to such an entity would not have come to the hospital. We will require that each off-campus hospital department, during its regular hours of operation, have in effect procedures for: (1) assessing the possibility that an emergency medical condition exists, and providing such screening (as defined in § 489.24(a) and (b)) and necessary stabilization (as defined in § 489.24(c)) at the off-campus site); (2) transporting the patient to the hospital's emergency room or department for screening and necessary stabilization meeting the requirements of § 489.24; or (3) providing an appropriate transfer to another facility in accordance with the requirements in § 489.24(c). To meet these requirements, the hospital will need to develop procedures that permit staff of the off-campus department to contact emergency physicians or other qualified emergency practitioners at the main hospital campus, to obtain advice and direction regarding the handling of any potential emergencies, and to obtain prompt medical transport, by hospital-owned or other ambulance or other appropriate vehicle, either to the main hospital campus or, where an appropriate transfer is being provided, to another medical facility.

Specifically, we are adding new paragraph (i) to § 489.24 to describe a hospital's obligations. The paragraph states that, if an individual comes to a facility or organization that is located off the main hospital campus as defined in § 413.65(b), but has been determined under § 413.65 of this chapter to be a department of the hospital, and a

request is made on the individual's behalf for examination or treatment of a potential emergency medical condition as otherwise described in paragraph (a) of § 489.24, the hospital is obligated to provide the individual with an appropriate medical screening examination and any necessary stabilizing treatment.

The capability of the hospital includes that of the hospital as a whole, not just the capability of the off-campus facility or organization. Except for cases described in paragraph (i)(3)(iii) (those in which the main hospital campus does not have the specialized capability or facilities needed to treat the individual, or the individual's condition is deteriorating so rapidly that transport to the main campus would significantly jeopardize the life or health of the individual), the obligation of a hospital under this section must be discharged within the hospital as a whole. However, the hospital is not required to locate additional personnel or staff to off-site locations to be on standby for possible emergencies.

In § 489.24(i)(2), Protocols for off-campus departments, we further state that the hospital must establish protocols for the handling of potential emergency cases at off-campus departments. These protocols must include provision for direct contact between personnel at the off-campus department and emergency personnel at the main hospital campus, and may provide for dispatch of practitioners, when appropriate, from the main hospital campus to the off-campus department to provide screening or stabilization services. The intent of these requirements is to ensure timely exchange of information between the two sites, and to allow the hospital the flexibility to bring emergency personnel to the patient, rather than the opposite, where doing so is the best medical approach to meeting the patient's needs.

Under the final rule, if the off-campus department is an urgent care center, primary care center, or other facility that is routinely staffed by physicians, RNs, or LPNs, these personnel must be trained, and given appropriate protocols, for the handling of emergency cases. At least one individual on duty at the off-campus department during its regular hours of operation must be designated as a qualified medical person as described in paragraph (d). The qualified medical person must initiate screening of individuals who come to the off-campus department with a potential emergency medical condition, and may be able to complete the screening and provide any necessary stabilizing treatment at the off-campus department, or to arrange an appropriate transfer.

The final rule further states that if the off-campus department is a physical therapy, radiology, or other facility not routinely staffed with physicians, RNs, or LPNs, the department's personnel must be given protocols that direct them to contact emergency personnel at the main hospital campus for direction. Under this direction, and in accordance with protocols established in advance by the hospital, the personnel at the off-campus department must describe patient appearance and reported symptoms and, if appropriate, arrange transportation of the individual to the main hospital campus (if the main hospital campus has the capability required by the individual, and movement to the main campus would not significantly jeopardize the individual's life or health), or assist in an appropriate transfer. Movement of the individual to the main campus of the hospital is not considered a transfer under this section, since the individual is simply being moved from one department of a hospital to another department or facility of the same hospital.

Finally, specific rules apply if the individual's condition warrants movement to a facility other than the main hospital campus, either because the main hospital campus does not have the specialized capability or facilities required by the individual, or because the individual's condition is deteriorating so quickly that taking the time required to move the individual to the main hospital campus could place the life or health of the individual in significant jeopardy. Under these circumstances, personnel at the off-campus department must, in accordance with protocols established in advance by the hospital, assist in arranging an appropriate transfer of the individual to a medical facility other than the main hospital. The hospital must have protocols to ensure that the movement is an appropriate transfer in accordance with paragraph (d)(2) of this section. The protocol must include procedures and agreements established in advance with other hospitals or medical facilities in the area of the off-campus department to facilitate these anticipated transfers. We note that the interpretive guidelines for enforcement of EMTALA requirements will be revised to conform to these new rules.

Section 498.3 Scope and applicability

Comment: A commenter asked for clarification as to whether appeal rights would be available in the event of revocation by us of provider-based status.

Response: We have revised § 489.3(b)(2) to specify that a determination that a facility or organization no longer qualifies for provider-based status is an initial determination, thus providing an administrative appeals mechanism for these decisions.

D. Requirements for Payment

We proposed to revise § 410.27, Outpatient Hospital Services and Supplies Incident to a Physician Service: Conditions, to require that services furnished at a location other than an RHC or an FQHC that we designate as having provider-based status under § 413.65 must be under the direct supervision of a physician as defined in § 410.32(b)(3)(ii).

Comment: Several commenters requested clarification of what we mean by ''direct supervision.'' One commenter asked that we further define the nature and extent of the supervision needed to comply with our proposal. One commenter asked whether the supervision requirement would be met if a physician is in the hospital or whether the physician must be in the department while the procedure is being performed. The same commenter asked whether the physician billing for the incident to services must be of the same specialty as the procedure being performed. A large trade association stated that we appear to be replacing our current policy in section 3112.4(A) of the Intermediary Manual, which states that we assume the physician supervision requirement to be met when incident to services are furnished on hospital premises, with a policy requiring direct physician supervision at all times, in all outpatient departments, regardless of whether or not they are located on the hospital campus. The commenter recommended that if we retain a direct supervision requirement, it should be limited to outpatient departments located off-site of the main provider. One commenter stated that facilities and organizations accorded provider-based status that are located on the main provider's campus should be subject to the same physician supervision requirements that apply to ''incident to'' services provided elsewhere on the campus.

Response: We regret that our proposal to define ''direct supervision'' by referring to the definition of ''direct supervision of a physician'' given at § 410.32(b)(3)(ii) may have been confusing to some commenters. Section 410.32(b)(3)(ii) defines ''direct supervision'' within (a physician) office

setting as meaning that the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. The definition at § 410.32(b)(3)(ii) goes on to state that ''direct supervision'' does not mean that the physician must be present in the room when the procedure is performed.

Our intention in the proposed rule was to define ''direct supervision'' of hospital outpatient services incident to physician services when they are furnished at a department of a hospital to mean that a physician must be present on the premises of the entity accorded status as a department of the hospital and, therefore, immediately available to furnish assistance and direction for as long as patients are being treated at the site. By ''direct supervision'' we do not mean that the physician must physically be in the room where a procedure or service is furnished. Nor does the supervising physician necessarily have to be of the same specialty as the procedure or service that is being performed. We emphasize that our proposed amendment of § 410.27 to require direct supervision of hospital services furnished incident to a physician service to outpatients applies to services furnished at an entity that is located off the campus of a hospital that we designate as having provider-based status as a department of a hospital in accordance with the provisions of § 413.65. Our proposed amendment of § 410.27 to require direct supervision of hospital services furnished incident to a physician service to outpatients does not apply to services furnished in a department of a hospital that is located on the campus of that hospital. For hospital services furnished incident to a physician service to outpatients in a department of a hospital that is located on the campus of the hospital, we assume the direct supervision requirement to be met as we explain in section 3112.4(A) of the Intermediary Manual. The requirement at § 410.27 does not affect the definition of physician supervision in section 3112.4(A) of the Intermediary Manual. In response to these comments, we have revised our definition of ''direct supervision by a physician'' in the final regulation.

Comment: A major trade association asserted that requiring a physician to be on-site at a provider-based entity throughout the performance of all ''incident to'' services would be burdensome and costly for hospitals where there are a limited number of physicians available to provide coverage, particularly in rural settings. Another commenter believes that entities with provider-based status should not be subject to physician supervision requirements that are more stringent than those applicable to free-standing facilities. A third commenter believes that this requirement is unnecessary because the requirements for integration with the hospital and other requirements for provider-based status include adequate checks and balances to ensure quality care. The commenter recommended that this proposal be omitted from the final rule with the potential for a separate, better defined, proposal at a later date.

Response: We disagree with commenters who believe the proposed supervision requirement is not necessary or that it would be burdensome to the hospital. First, the supervision requirement is separate from and independent of the provider-based requirements, and hospitals and physicians already have to meet a direct supervision of ''incident to'' services requirement that is unrelated to provider-based issues. That is, we require that hospital services and supplies furnished to outpatients that are incident to physician services be furnished on a physician's order by hospital personnel and under a physician's supervision (Intermediary Manual, section 3112.4(A)). We assume the physician supervision requirement is met on hospital premises because staff physicians would always be nearby within the hospital. The effect of the regulations in this final rule is to extend this assumption to a department of a provider that is located on the campus of a hospital. However, the regulation *does not* extend the assumption of supervision to a department of a hospital that is located off the campus of the hospital. We would not extend this assumption to a provider-based entity, regardless of its location, because the ''incident to'' requirement in § 410.27(a)(1)(iii) applies only to hospitals. Also, as we state above, satisfying the requirements to be designated provider-based is unrelated to our requirement that hospital services furnished incident to a physician service to outpatients at an entity that has provider-based status be under the direct supervision of a physician. Finally, this supervision requirement is entirely consistent with the direct supervision requirements currently set forth in the Medicare Carriers Manual, Part 3, section 2050.1(B).

Comment: One commenter suggested that partial hospitalization services furnished by a hospital to its outpatients be exempt from the outpatient department ''incident to'' requirements, or that other requirements be drafted that would, in the commenter's opinion, be more appropriate to the nature of this care.

Response: Section 1861(s)(2)(B) restricts coverage of partial hospitalization services furnished by a hospital to its outpatients to services that meet ''incident to'' requirements. We do not have the discretion to ignore this statutory restriction.

Comment: One commenter asked that we provide an exception to the direct supervision requirement in the case of physical therapy services. The commenter questioned why therapists who furnish the same services in a provider-based entity that they would furnish in an independent practice should be subject to direct physician supervision in one setting and not the other.

Response: The provision on coverage for outpatient physical therapy and occupational therapy services does not require that they be ''incident to'' physician services (see section 1861(s)(2)(D) of the Act). Therefore, there is no need to exempt them from the supervision requirement for outpatient hospital services incident to a physician service that is furnished at a provider-based entity. We therefore made no change in the final regulation based on this comment.

Comment: One commenter suggested that we modify our proposed regulation to waive the direct supervision requirement in entities with provider-based status for certain procedures for which we already waive the direct supervision requirement when the procedures are performed on homebound patients, as set forth in section 2051 of the Medicare Carriers Manual. The commenter believes that general supervision is sufficient for these waived services, for example, the physician need not be present, but the services must be performed under a physician's overall supervision and control, and ordered by a physician.

Response: Under section 2050.2 of the Medicare Carriers Manual, subject to certain requirements, we waive the direct supervision requirement when the following services are furnished to homebound patients: injections; venipuncture; EKGs; therapeutic exercises; insertion and sterile irrigation of a catheter; changing of catheters and collection of catheterized specimen for urinalysis and culture; dressing changes, for example, the most common chronic conditions that may need dressing changes are decubitus care and gangrene; replacement and/or insertion of nasogastric tubes; removal of fecal

impaction, including enemas; sputum collection for gram stain and culture, and possible acid-fast and/or fungal stain and culture; paraffin bath therapy for hands and/or feet in rheumatoid arthritis or osteoarthritis; and, teaching and training the patient for the care of colostomy and ileostomy, the care of permanent tracheostomy, testing urine and care of the feet (diabetic patients only), and blood pressure monitoring. While we believe the commenter's suggestion has merit, we do not believe it would be appropriate to adopt it before we have had time to analyze the issue further. Therefore, we did not revise the final rule based on this comment.

In our proposed rule, we proposed to require that the same supervision levels established for diagnostic x-ray and other diagnostic tests in accordance with § 410.32(b)(3) be required when these tests are furnished at an entity that has been accorded provider-based status by us.

Comment: A large industry federation generally favored our requiring that diagnostic tests be furnished at provider-based entities under levels of physician supervision that we specify, consistent with the definitions of general, direct, and personal supervision established at § 410.32(b)(3). The commenter suggested that we modify the definition of general supervision to make it clear that the training of nonphysician personnel and the maintenance of necessary equipment and supplies are the responsibility of the hospital, not the physicians.

Response: We agree and we will modify our regulation accordingly.

Comment: Numerous commenters, including radiology and imaging specialty groups, neurologists, vascular technologists, and sonographers, questioned the level of supervision required for various specific diagnostic tests and services.

Response: Our model for this proposed requirement was the requirement for physician supervision for diagnostic tests payable under the Medicare physician fee schedule that was issued in the October 31, 1997 physician fee schedule final rule (for CY 1998) (62 FR 59048). There have been issues raised about the appropriate level of supervision for some specific diagnostic services, similar to the comments we received about our proposed regulation. We have not yet resolved these issues, and this final rule is not the place to convey decisions about appropriate supervision levels for specific diagnostic tests and services by individual HCPCS code. In January 1998, we sent a memorandum to all Associate Regional Administrators advising them to instruct carriers to follow their existing policies on physician supervision of diagnostic tests until we provide further instruction. We intend to instruct hospitals and intermediaries to use the October 31, 1997 physician supervision requirements as a guide, pending issuance of updated requirements. In the meantime, fiscal intermediaries, in consultation with their medical directors, will define appropriate supervision levels for services not listed in the October 31, 1997 final rule when those services are furnished at an entity with provider-based status in order to determine whether claims for these services are reasonable and necessary.

V. Summary of and Response to MedPAC Recommendations

The following are additional recommendations contained in the report on Medicare payment policy that the Medicare Payment Advisory Commission submitted to the Congress in March 1999. (MedPAC, *Report to the Congress: Medicare Payment Policy,* March 1999.) We respond to recommendations that are specifically related to a particular component of the hospital outpatient PPS in the appropriate section of this preamble.

MedPAC Recommendation: MedPAC recommends that the Secretary evaluate payment amounts under the hospital outpatient PPS and the ambulatory surgical center (ASC) PPS along with the practice expense payments under the Medicare physician fee schedule for services furnished in physicians' offices to ensure that the differing payments made under the three payment systems do not create unwarranted financial incentives regarding site of care.

Response: We agree that the three payment systems should avoid creating unnecessary financial incentives to deliver care in particular settings. We will consider this matter further and evaluate differences in payments.

MedPAC Recommendation: MedPAC recommends that the Secretary study means of adjusting base prospective payment rates across ambulatory settings for patient characteristics such as age, frailty, comorbidities and coexisting conditions, and other measurable traits. Under this approach, payment would be less dependent on the type of facility and more dependent on the relative costliness of furnishing specific services to individual patients. MedPAC notes that no viable patient-level adjuster currently exists that could be used in this fashion.

As an interim measure, MedPAC recommends, with reservations, that HCFA evaluate facility-level adjustments in order to preserve access to care for particularly vulnerable segments of the Medicare population.

Response: The underlying premise in this recommendation, as MedPAC states, is that HCFA should move toward development of a more unified and rational payment system for ambulatory care. Many powerful arguments favor such a system, but the challenges of creating and implementing it are substantial. We will give further consideration to the recommendation to study possible adjustments that could be used in various settings.

We agree that we should evaluate the need for facility-level adjustments. We believe the best course is to evaluate the need for these adjustments during the next several years as we gain actual experience with the operation of the hospital outpatient PPS and are able to observe the effects on particular provider groups. In consideration of the transitional protections provided by the BBRA 1999, we have not adopted facility-level adjustments, other than an adjustment for local labor costs, at this time.

MedPAC Recommendation: MedPAC recommends that the Secretary seek legislation to develop and implement a single update mechanism that would link conversion factor updates to volume growth across all ambulatory care settings. These settings include hospital outpatient departments, physicians' offices, and ASCs, as well as other specific settings mentioned.

Response: We believe that this proposal requires further study to determine its feasibility and possible impact. Therefore, we are not prepared to seek legislation at this time.

MedPAC Recommendation: MedPAC recommends that we not use patient diagnosis to calculate relative weights or make payments for medical visits, ''given the current state of the available data and the lack of definitive rules for reporting patients' diagnoses under the proposed system.''

Response: As discussed in section III.C.3, we have dropped diagnosis from our characterization of medical visit APCs. We hope to develop procedure codes for medical visits that are more descriptive of hospital outpatient resource use, rather than physician services. Once we revise procedure coding to better reflect hospital services, we will assess whether accurate diagnosis coding further improves recognition of resources.

MedPAC Recommendation: MedPAC recommends that the Secretary closely

monitor the use of hospital outpatient services to ensure that beneficiary access to care is not compromised.

Response: We plan to evaluate the operation of the new PPS to address a variety of issues, including beneficiary access to care. We note that the provisions of the BBRA 1999 should mitigate substantially any payment reductions and hence the possibility of reduced access.

MedPAC Recommendation: MedPAC recommends that the Secretary consider making payment adjustments in addition to the proposed adjustment for local area wages under the new system. These adjustments should be tied to patient characteristics. The facility-level adjustments that are made until the time that a patient-level adjuster is available should reflect the population of Medicare patients treated by facilities identified to receive the adjustments.

MedPAC points out that HCFA, in setting Medicare payment rates for hospital inpatient services, adjusts payments based on the costs or provider characteristics of hospitals (for example, sole community hospitals). Rather than continuing this practice in the outpatient setting, MedPAC recommends that HCFA move toward making adjustments based on patient characteristics and the relative costliness of resources required in furnishing care to differing patients. Any differences in the payment of the same ambulatory care service should be based on patient characteristics, rather than on the setting. MedPAC recommends that HCFA evaluate any relationships between immutable patient characteristics and the cost of furnishing care.

Response: Other than those adjustments specified in sections 201 and 202 of the BBRA 1999, we have made no additional adjustments in this final rule. We will consider the possibility of adjustments in the future once we have actual experience with operation of the hospital outpatient PPS and can examine its effects. The extent to which adjustments at the level of patient characteristics will be feasible is unclear and would require further study.

VI. Provisions of the Final Rule

The provisions of this final rule reflect the provisions of the September 8, 1998 proposed rule, except as noted elsewhere in this preamble. Following is a synopsis of the major changes we have made, either in response to comments or in order to implement provisions of the BBRA 1999 that apply to the hospital outpatient prospective payment system.

For our proposal to adjust the CY 2002 update of the conversion factor by the percentage that actual CY 2000 payments exceed the estimated CY 2000 expenditure target, we are delaying implementation of the volume control mechanism for 2 years.

For our proposal to package costs that are directly related and integral to performing a procedure or furnishing a service on an outpatient basis, we are making the following changes:

- We are creating separate APC groups to pay for blood, blood products, and anti-hemophilic factors, for splints and casts, and for certain very costly drugs that are not included in the transitional pass-through payment provision.
- We are paying separately, at cost, for the acquisition of corneal tissue.
- As required by section 201(e) of the BBRA 1999, we are *not* paying for certain implantable items under the DMEPOS fee schedule, but are including them as covered outpatient services. We are packaging the costs of these items into the APC payment rate for the procedures or services with which they are associated. These include implantable items used in connection with diagnostic tests, implantable DME, and implantable prosthetic devices.

For our proposal to base payment for medical visits to clinics and emergency departments on diagnosis codes as well as HCPCS codes, we are not using diagnosis codes at this time.

For our proposal to classify a new technology procedure or service within the APC group that it most closely resembles in terms of clinical characteristics and resource utilization, pending collection of additional pricing data, we are creating separate APC groups to which we can temporarily classify new technology services while we gather additional data and gain pricing experience. We are also creating a process under which interested parties may submit requests for consideration of services that may be eligible for payment as new technology.

For our proposal to pay for drugs, pharmaceuticals, and biologicals (except for cancer therapy drugs and certain infrequently used but very expensive drugs) as part of the APC payment for the service or procedure with which they are used, we are establishing transitional pass-through payments, as directed by section 201(b) of the BBRA 1999. Under this provision, an additional payment will be made for current orphan drugs, current cancer therapy drugs, biologicals, and brachytherapy, and current radiopharmaceutical drugs and biological products.

For our proposal to classify a new or innovative medical device, drug or biological (for which we were not making payment as of December 31, 1996) within the APC group that it most closely resembles in terms of clinical characteristics and resource utilization, pending collection of additional pricing data, we are establishing transitional pass-through payments. Under this provision, as directed by section 201(b) of the BBRA 1999, an additional payment will be made for new or innovative devices, drugs, and biologicals whose cost is not insignificant in relation to the APC payment for the group of services with which they are used.

For our proposal not to establish an outlier adjustment, as directed by section 201(a) of the BBRA 1999, we will make an outlier payment when calculated bill costs exceed 2.5 times the PPS payment for a service.

For our proposal to determine comparability of resources and clinical characteristics among the codes within an APC group based on our claims data and the analyses and judgment of our medical advisors, supported by comments from medical specialty societies and trade associations, as provided in section 201(g) of the BBRA 1999, we are limiting the variation so that the highest median cost of an item or service in an APC group is no more than two times the lowest median cost of an item or service within that group. We will also consult with an expert outside advisory panel regarding the clinical integrity of the APC groups and weights as part of our update of the PPS.

For our proposal to periodically review and update payment weights, APC groups, and other elements of the hospital outpatient PPS, as required by section 201(h) of the BBRA 1999, we will annually review the groups, relative payment weights, and the wage and other adjustments that are a part of the PPS.

For our proposal to implement the hospital outpatient PPS fully and in its entirety for all hospitals beginning as early as possible in CY 2000, with no phase-in period, as required by section 202(a) of the BBRA 1999, we are establishing transitional corridors for services furnished before January 1, 2004 to limit losses facilities might otherwise face.

For our proposal not to make any adjustments for any specific classes of hospitals, we are holding small rural hospitals harmless through CY 2003 in accordance with the requirements set by section 202(a)(3) of the BBRA 1999,

which added section 1833(t)(7)(D)(i) to the Act. Also, we are holding cancer centers permanently harmless in accordance with the requirements set by section 202(a)(3) of the BBRA 1999.

For our proposal on beneficiary coinsurance payment amounts, we are limiting the coinsurance amount for a procedure to be no more than the hospital inpatient deductible, as specified in section 204(a)(3) of the BBRA 1999.

The following is a synopsis of the principal changes that we are making in the provider-based requirements:

For our proposal to require main providers and provider-based entities to share a common license, we will require common licensure only where State law permits it. Where State law prohibits it or is silent, we will not apply the licensure requirement. We will also exempt IHS facilities and facilities located on Tribal lands from this requirement.

For our proposal requiring a main provider and a provider-based entity to serve a common service area indicated largely by overlapping patient populations, we have redefined ''common service area'' to mean a 75 percent threshold of patients who reside in a zip code area that is common to the main provider and the provider-based entity.

For our proposal to require provider-based entities to be in the same State as the main provider, we will allow providers in one State to have provider-based facilities in an adjacent State, if doing so is consistent both with the law of the affected States and with other criteria, including those related to a common service area.

For our proposal to require that a provider-based outpatient department bill all payers as an outpatient department, we have rescinded this requirement.

For our proposal to require FQHCs that have been billing Medicare as hospital outpatient departments to comply with the provider-based requirements, we are grandfathering both FQHCs and FQHC ''look-alikes'' (facilities that are organized as FQHCs but do not receive grants) so that these facilities will be considered departments of providers without having to meet § 413.65 requirements.

For our proposal to apply the provider-based requirements to Indian Health Service (including tribally operated) entities, we are creating a permanent exception for those entities that were billing as departments of IHS or Tribal hospitals on or before October 10, 2000.

For our proposal to consider provider-based entities to be part of the hospital for Emergency Medical Treatment and Active Labor Act (EMTALA) (''anti-dumping'' purposes), we are maintaining the principle that off-site hospital facilities are subject to EMTALA. We have clarified the obligations of hospitals with respect to these locations to ensure they are consistent with staffing patterns and resources.

For our proposal to apply provider-based criteria to inpatient facilities such as multi-campus hospitals created by mergers and satellites of PPS-excluded hospitals that are created by hospitals leasing space in other hospitals, we have clarified the applicability of provider-based criteria to remote locations of hospitals and hospital satellite facilities.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

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

We are soliciting public comment on each of these issues for the provisions summarized below that contain information collection requirements:

Section 413.24 Adequate cost data and cost finding

Section 413.24(d)(6)(ii) states that a provider must develop detailed work papers showing the exact cost of the services (including overhead) provided to or by the free-standing entity and show those carved out costs as nonreimbursable cost centers in the provider's trial balance. While these information collection requirements are subject to the PRA, the burden associated with these requirements is captured under §§ 413.65(c)(1) and (c)(2) below.

Section 413.65 Requirements for a determination that a facility or an organization is a department of a provider or a provider-based entity

Section 413.65(b)(2) states that a provider or a facility or organization must contact HCFA and the facility or organization must be determined by HCFA to be provider-based before the main provider begins billing for services of the facility or organization as if they were furnished by a department of the provider-based entity, or before it includes costs of those services on its cost report. While these information collection requirements are subject to the PRA, the burden associated with these requirements is captured under §§ 413.65(c)(1) and (c)(2) below.

Sections 413.65(c)(1) and (c)(2) state that a main provider that acquires a facility or organization for which it wishes to claim provider-based status, including any physician offices that a hospital wishes to operate as a hospital outpatient department or clinic, must report its acquisition of the facility or organization to HCFA and must furnish all information needed for a determination as to whether the facility or organization meets the requirements in paragraph (d) of this section for provider-based status, if the facility or organization is located off the campus of the provider or would increase the provider's total costs by at least 5 percent. Furthermore, a main provider that has had one or more entities considered provider-based also must report to HCFA any material change in the relationship between it and any provider-based facility or organization, such as a change in ownership of the facility or organization or entry into a new or different management contract that could affect the provider-based status of the facility or organization.

The burden associated with this requirement is the time for the main provider to report its acquisition to HCFA, furnish all information needed for a determination, report to HCFA any material change in the relationship between it and any provider-based facility or organization, such as a change in ownership of the facility or organization or entry into a new or different management contract that could affect the provider-based status of the facility or organization. It is estimated that 105 main providers will take 10 hours for a total of 1,050 hours.

Section 413.65(d)(4)(v) states that medical records for patients treated in a facility or organization must be integrated and maintained into a unified retrieval system (or cross reference) of the main provider. The burden

associated with this requirement is the time required for the main provider to maintain medical records in a unified retrieval system. While this requirement is subject to the PRA, we believe this requirement is a usual and customary business activity and the burden associated with this requirement is exempt from the PRA, as stipulated under 5 CFR 1320.3(b)(2) and (b)(3).

Section 413.65(d)(7)(i) requires that for a facility or organization and the main provider that is not located on the same campus, the facility or organization must demonstrate a high level of integration with the main provider by showing that it meets all of the other provider-based criteria, and demonstrates that it serves the same patient population as the main provider, by submitting records showing that, during the 12-month period immediately preceding the first day of the month in which the application for provider-based status is filed with HCFA, and for each subsequent 12-month period meet the requirements of paragraphs (d)(7)(i)(A), (B), or (C) of this section. While the information collection requirements listed below are subject to the PRA, the burden associated with these requirements is captured under §§ 413.65(c)(1) and (c)(2).

Section 413.65(g)(7) states that when a Medicare beneficiary is treated in a hospital outpatient department or hospital-based entity, the hospital has a duty to notify the beneficiary, prior to the delivery of services, of the beneficiary's potential financial liability (that is, a coinsurance liability for a facility visit as well as for the physician service).

The burden associated with this requirement is the time for the provider to disseminate information to each beneficiary of the beneficiary's potential financial liability (that is, a coinsurance liability for a facility visit as well as for the physician service). It is estimated that 750 providers will make on average 667 disclosures on an annual basis, at 3 minutes per disclosure, for a total annual burden of 25,013 hours.

Section 413.65(j)(5) requires that upon notice of denial of provider-based status sent to the provider by HCFA, the notice will ask the provider to notify HCFA in writing, within 30 days of the date the notice is issued, of whether the facility or organization (or, where applicable, the practitioners who staff the facility or organization) will be seeking to enroll and meet other requirements to bill for services in a free-standing facility. This requirement is exempt from the PRA as stipulated under 5 CFR 1320.4(a)(2).

Further, if the provider indicates that the facility or organization, or its practitioners, will be seeking to meet enrollment and other requirements for billing for services in a free-standing facility, the facility or organization must submit a complete enrollment application and provide all other required information within 90 days after the date of notice; and the facility or organization, or its practitioners, furnish all other information needed by HCFA to process the enrollment application and verify that other billing requirements are met. The requirements and burden associated with the provider enrollment process are currently approved under OMB control number 0938–0685, with a current expiration date of September 30, 2001.

Section 424.24 Requirements for Medical and Other Health Services Furnished by Providers Under Medicare Part B

Section 424.24(e)(3)(i) requires that when a partial hospitalization service occurs the physician recertification must be signed by a physician who is treating the patient and has knowledge of the patient's response to treatment. While this signature requirement is subject to the PRA, the overall requirements associated with physician recertification, as currently referenced in HCFA regulation number HCFA–1006, published in the **Federal Register** on June 5, 1998, have not yet been approved by OMB under the PRA. Therefore, we continue to solicit comment on all of the requirements and associated burden referenced in § 424.24.

Section 419.42 Hospital Election To Reduce Copayment

Sections 419.42(b) and (c) state that a hospital must notify its fiscal intermediary of its election to reduce copayments no later than June 1, 2000 prior to the date the PPS is implemented or for subsequent calendar years, beginning with elections for calendar year 2001, no later than December 1 of the preceding calendar year. The hospital's election must be properly documented. It must specifically identify the ambulatory payment classification to which it applies and the coinsurance amounts (within the limits identified within this regulation) that the hospital has elected for each group.

The burden associated with these requirements is the time it takes a hospital to compile, review, and analyze data for both revenues and coinsurance; prepare and present the data to the hospital board; make a business decision as to whether the hospital would elect to reduce coinsurance; and then notify its fiscal intermediary of its election. A hospital would notify its fiscal intermediary of its election to reduce coinsurance only if there were other providers, in close proximity, that would attract a majority of the hospital's business if they did not reduce their coinsurance. Since hospitals do not want to lose money by absorbing coinsurance, we anticipate that this requirement will affect 750 hospitals and take them 10 hours each for a total of 7,500 hours.

Section 419.42(e) states that the hospital may advertise and otherwise disseminate information concerning the reduced level(s) of coinsurance that it has elected. All advertisements and information furnished to Medicare beneficiaries must specify that the coinsurance reductions advertised apply only to the specified services of that hospital and that these coinsurance reductions are available only for hospitals that choose to reduce coinsurance for hospital outpatient services and are not applicable in any other ambulatory settings or physician offices.

The burden associated with this requirement is the time for the hospital to disseminate information concerning its coinsurance election. It is estimated that 750 hospitals will each take 10 hours annually to disseminate this information via newsletters and information sessions at senior citizen centers for a total of 7,500 hours.

We have submitted a copy of this final rule to OMB for its review of the information collection requirements. These requirements are not effective until they have been approved by OMB. A notice will be published in the **Federal Register** when approval is obtained.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Health Care Financing Administration, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Room C2–26–17, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn: John Burke HCFA–1005–FC/R–240,

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn.: Allison Herron Eydt, HCFA–1005–FC.

VIII. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. Comments on the provision of this final rule that implement provisions of the BBRA 1999 will be considered if we receive them by the date and time specified in the DATES section of this preamble. We will not consider comments concerning provisions that remain unchanged from the September 8, 1998 proposed rule or that were changed based on public comments.

IX. Regulatory Impact Analysis

A. Introduction

Section 804(2) of title 5, United States Code (as added by section 251 of Pub. L. 104–121), specifies that a ''major rule'' is any rule that the Office of Management and Budget finds is likely to result in—

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment productivity, innovation, or on the ability of United States based enterprises to compete with foreign-based enterprises in domestic and export markets.

We estimate, based on a simulation model, that the effect on hospitals participating in the Medicare program associated with this final rule would be to increase Medicare payments by $600 million in calendar year 2000. This figure includes beneficiary copayments. We estimate that the additional expenditures to hospitals from the Part B Trust Fund associated with this final rule will be $490 million in fiscal year 2000. Therefore, this rule is a major rule as defined in Title 5, United States Code, section 804(2).

We have examined the impacts of this final rule as required by Executive Order 12866, the Unfunded Mandates Reform Act of 1995, and the Regulatory Flexibility Act (RFA) (Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). Because the projected spending resulting from this final rule is expected to exceed $100 million, it is considered a major rule for purposes of the RFA.

The Unfunded Mandates Reform Act of 1995 also requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits for any rule that may result in an expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million. This final rule does not mandate any requirements for State, local, or tribal governments.

We generally prepare a regulatory flexibility analysis that is consistent with the RFA (5 U.S.C. 601 through 612), unless we certify that a final rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we consider all hospitals to be small entities.

Also, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital with fewer than 100 beds that is located outside of a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA). Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent NECMA. Thus, for purposes of the proposed prospective payment system, we classify these hospitals as urban hospitals.

B. Estimated Impact on the Medicare Program

Our Office of the Actuary projects that the additional benefit expenditures from the Part B Trust Fund resulting from implementation of the hospital outpatient PPS for hospital outpatient services furnished on or after July 1, 2000, and the hospital outpatient provisions enacted by the BBRA 1999, are as follows:

Fiscal year	Impact (In millions of dollars)
2000	490
2001	3,030
2002	3,520
2003	4,230
2004	4,670

C. Objectives

The primary objective of the hospital outpatient prospective payment system is to simplify the payment system and encourage hospital efficiency in providing outpatient services, while at the same time ensuring that payments are sufficient to compensate hospitals adequately for their legitimate costs. Another important goal of the new system is to reduce beneficiaries' share of outpatient payment to hospitals by freezing coinsurance amounts at an absolute level until they equal 20 percent of the total payment amounts.

We believe that implementation of the final PPS will ultimately further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that the provisions of this final rule with comment period will ensure that the outcomes of the PPS are reasonable and equitable while avoiding or minimizing unintended adverse consequences.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our policy changes resulting from comments, as well as statutory changes enacted by the BBRA 1999, on various hospital groups. We use the best data available. In addition, we do not make adjustments for future changes in such variables as volume and intensity. For this final rule with comment period, we are soliciting comments and information about the anticipated effects of the changes on hospitals resulting from implementation of the hospital outpatient provisions of the BBRA 1999, and our methodology for estimating them.

E. Hospitals Included In and Excluded From the Prospective Payment System

The outpatient prospective payment system encompasses nearly all hospitals that participate in the Medicare program. However, Maryland hospitals that are paid under a cost containment waiver in accordance with section 1814(b)(3) of the Act are excluded from the PPS. Critical access hospitals (CAHs) are also excluded and are paid at cost under section 1834(g) of the Act.

F. Quantitative Analysis of the Impact of Policy Changes on Payment Under the Hospital Outpatient PPS: Basis and Methodology of Estimates

We have analyzed the impact on hospital payment under the outpatient PPS. Our analysis compares the payment impact of PPS compared to current law. The definition and calculation of current law used in the impact analysis is the same used in estimating the conversion factor. That is, current law reflects pre-PPS payment methodologies in effect on January 1, 2000, and prior to July 1, 2000, which include the elimination of the formula-driven overpayment and application of the capital and operating cost reductions. A detailed explanation of the current law calculation can be found in section III.E.2.a.

The data used in developing the quantitative analyses presented below are taken from the CY 1996 cost and charge data and the most current provider-specific file that is used for payment purposes. Our analysis has several qualifications. First, we draw upon various sources for the data used to categorize hospitals in Table 2, below. In some cases, there is a degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. For individual hospitals, however, some miscategorizations are possible.

Using CY 1996 cost and charge data, we simulated payments using the pre-PPS and PPS payment methodologies. Although we used only single-procedure/visit bills to determine APC relative payment weights, we used both single and multiple-procedure bills in the conversion factor and service mix calculations, regressions, and impact analyses. Both pre-PPS and PPS payment estimates include operating and capital costs, adjusted to the calendar year 1996 cost reporting period. We excluded Kaiser, New York Health and Hospital Corporation, and all-inclusive providers because reported charges on their cost reports are not actual charges. Cost-to-charge ratios for these hospitals are not comparable to all other hospitals. The excluded Maryland hospitals were not included in the calculation of the conversion factor and the simulations; however, we did include the 10 cancer hospitals that will be paid under the PPS.

We also trimmed outlier hospitals from the impact analysis because inclusion of hospitals with extremely high and low unit costs would not allow us to assess the impacts among the various classes of hospitals accurately. First, we identified all of the outlier hospitals by using an edit of 3 standard deviations from the mean of the logged unit costs. Trimming the data in this manner ensures that only the hospitals with aberrantly high and low costs are eliminated from the impact analysis. In doing this, we removed 97 hospitals of which 41 hospitals had extremely low unit costs and 56 hospitals had extremely high unit costs. We conducted a thorough analysis of these hospitals to ensure that we did not remove any particular type of hospital (for example, teaching hospitals) that would further harm the integrity of the data. We speculate that many of these hospitals are not coding accurately, and we will continue to perform further analysis in this area following implementation of the PPS.

After we removed the 58 excluded Maryland hospitals, the all-inclusive rate hospitals, the statistical outlier hospitals, and hospitals for which we could not identify payment variables, we used the remaining 5,362 hospitals as the basis for our analysis. Table 2, Annual Impact of Outpatient Prospective Payment System in CY2000–CY2001, below, demonstrates the results of our analysis. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The first column represents the number of hospitals in each category. The second column shows the hospitals' Medicare outpatient payments under the current (non-PPS) payment system as a percentage of the hospitals' total Medicare payment. The third and fourth columns show the impact of the PPS *excluding* the transitional corridor payments enacted by the BBRA 1999. Column three shows the percentage change in total Medicare outpatient payments comparing pre-PPS payments with payments under the PPS. The fourth column shows the change in *total* (outpatient and inpatient) Medicare payments resulting from implementation of the PPS for outpatient services. The fifth and sixth columns show the impact of the PPS *including* the transitional corridor payments enacted by the BBRA 1999. Column five shows the percentage change in Medicare outpatient payments comparing pre-PPS payments with payments under the PPS. Column six shows the change in total (outpatient and inpatient) Medicare payments resulting from implementation of the PPS for outpatient services.

The first row of Table 2 shows the overall impact on the 5,362 hospitals included in the analysis. We included as much data as possible to the extent that we were able to capture all the provider information necessary to determine payment. Our estimates include the same set of services for both pre-PPS and PPS payments so that we could determine the impact of the PPS as accurately as possible. Because payment under the hospital outpatient PPS can only be determined if bills are accurately coded, the data upon which the impacts were developed do not reflect all CY 1996 hospital outpatient services, but only those that were coded using valid HCPCS codes.

The second row of Table 2 shows the overall impact of the PPS on the 4,828 hospitals that remain when we exclude psychiatric, long-term care, children's, and rehabilitation hospitals.

The next four rows of the table contain hospitals categorized according to their geographic location (all urban, which is subdivided into large urban and other urban, and rural). We include 2,665 hospitals located in urban areas (MSAs or NECMAs) in our analysis. Among these, 1,505 hospitals are located in large urban areas (populations over 1 million), and 1,160 hospitals are located in other urban areas (populations of 1 million or less). In addition, we include 2,160 hospitals located in rural areas in our analysis. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The next category groups urban and rural hospitals by volume of outpatient services. We then show the distribution of urban and rural hospitals by regional census divisions.

The next three categories group hospitals according to whether or not they have residency programs (teaching hospitals that receive an indirect medical education (IME) adjustment), receive disproportionate share hospital (DSH) payments, or some combination of these two adjustments. In our analysis we show the impact of the PPS on the 3,738 nonteaching hospitals, the 821 teaching hospitals with fewer than 100 residents, and the 269 teaching hospitals with 100 or more residents.

In the DSH categories, hospitals are grouped according to their DSH payment status. The next category groups hospitals considered urban after geographic reclassification, in terms of whether they receive the IME adjustment, the DSH adjustment, both, or neither. The next five rows examine the impacts of the changes on rural hospitals by special payment groups (rural referral centers (RRCs), sole community hospitals/essential access community hospitals (SCHs/EACHs), Medicare dependent hospitals (MDHs), and hospitals that are both SCHs and

RRCs), as well as rural hospitals not receiving a special payment designation. The RRCs (164), SCH/EACHs (634), MDHs (358), and SCH and RRCs (56) shown here were not reclassified for purposes of the standardized amount.

The next grouping is based on type of ownership. These data are taken primarily from the FY 1996 Medicare cost report files, if available; otherwise, earlier cost report data are used.

The final two groups are specialty hospitals. The first set includes eye and ear hospitals, trauma hospitals (hospitals having a level one trauma center), and cancer hospitals, which are TEFRA hospitals. The last group lists all other TEFRA hospitals, specifically, rehabilitation, psychiatric, long-term care, and children's hospitals.

G. Estimated Impact of the New APC System (Includes Table 2, Annual Impact of Hospital Outpatient Prospective Payment System in CY2000–CY2001)

Column 3 compares our estimate of PPS payments without application of the BBRA 1999 transitional corridors, but incorporating policy changes and all other BBRA 1999 provisions contained in this final rule, to our estimate of payments under the current system. The percent differences shown in columns 3 and 4 between current and PPS payment (without the BBRA 1999 transitional corridors) reflect the impact of the BBRA 1999 outlier and pass-through payment adjustments and nonbudget-neutral hold-harmless provisions for cancer hospitals, as well as distributional differences attributable to variation in cost and charge structures among hospitals.

The percent changes in columns 5 and 6 are the result of comparing our estimate of PPS payments with application of the BBRA 1999 transitional corridors, as well as the statutory and policy changes contained in this final rule, to our estimate of payments under the pre-PPS system. Percent differences between the pre-PPS and the PPS payment (with the BBRA 1999 transition) reflect the combined impact of the transitional corridor adjustments, outlier and pass-through payment adjustments and the hold-harmless provision for cancer hospitals, in addition to distributional differences attributable to variation in cost and charge structures among hospitals.

Basing the conversion factor on pre-PPS program and pre-PPS beneficiary payments and on budget-neutral outlier and pass-through adjustments results in no net change in payments to hospitals overall relative to pre-PPS payments. (As noted above, in section III.E.2 of this preamble, pursuant to section 201(l) of the BBRA 1999, we set the conversion factor by estimating pre-PPS rather than PPS copayments.) However, the BBRA hold-harmless provision for cancer hospitals results in a 0.2 percent increase in payments to hospitals overall because this provision is not budget neutral. Including the BBRA 1999 transitional corridor adjustments further increases payment to hospitals overall. We estimate that in calendar year 2000, payment will increase by an annual rate of 4.6 percent under the PPS compared to the pre-PPS payments.

Without the BBRA 1999 transitional corridor payments, the impact on short-term acute care hospitals is negative for a substantial number of hospital classifications. That is, for certain groups of hospitals, payments under the PPS without the transitional corridor payments would be several percentage points below pre-PPS payments. For nearly all of these hospital groups, the BBRA 1999 transitional corridor payments mitigate this negative impact. In addition, hospital groups that experience net gains without the BBRA 1999 transitional corridor payments experience even greater gains with them. The reason is that even though the average impact for hospitals in these groups is positive, some individual hospitals experience net losses in payments and, thus, benefit from the transitional corridor payments. The hospital groups that gain without the transitional corridor payments receive even greater increases in payments with the transitional corridor payments. The following discussion highlights some of the changes in payments among hospital classifications.

Comparing the pre-PPS and PPS payment estimates, payment to low-volume hospitals would decrease substantially without the BBRA 1999 transitional corridor payments (12.2 percent annually for rural and 7.7 percent annually for urban hospitals with fewer than 5,000 units of service). These hospitals experience a net gain with the BBRA 1999 transitional corridor payments (2.5 percent annually and 0.2 percent annually for low-volume rural and urban hospitals, respectively), although these payment increases are relatively small compared to the 4.6 percent annual increase for hospitals overall. We believe several factors contribute to this outcome, including undercoding, lack of economies of scale, and the reliance on the median instead of the geometric mean in the calculation of APC weights. The majority of these hospitals (about 75 percent) are rural. For these small hospitals, some of the higher standardized unit costs could be attributed to economies of scale. These low-volume rural hospitals also receive a greater percentage of their Medicare income (18.5 percent) from outpatient services than the national average (9.9 percent).

Major teaching hospitals, whose payments would decrease annually by 3.7 percentage points without the BBRA 1999 transitional corridor payments, gain 2.6 percent annually with the BBRA 1999 transitional corridor payments relative to pre-PPS payments. Major teaching hospitals receive less of their total Medicare income (9.1 percent) from outpatient services than the national average. This results in a 0.2 percent annual gain in their total Medicare payments. Minor teaching and nonteaching hospitals would experience marginal gains in outpatient payment without the BBRA 1999 transitional corridor payments. Payment to both hospital groups increases by 5.0 percent annually relative to the pre-PPS payment system.

Without the BBRA 1999 transitional corridor payments, hospitals with a high percentage of low-income patients (disproportionate share patient percentage greater than or equal to 0.35) would have a 2.5 percent annual decrease in payment relative to pre-PPS payments. But payments to these hospitals increase annually by 3.5 percent relative to pre-PPS payments with the BBRA 1999 transitional corridor payments. These hospitals have lower than average volume, and, like major teaching hospitals, receive a smaller than average percentage of their Medicare income from outpatient services. Thus, their total Medicare payments increase marginally, by 0.3 percent, with the BBRA 1999 transitional corridor payments.

Without the BBRA 1999 adjustments, payment to rural hospitals would decrease 1.8 percent annually and payment to large urban hospitals would decrease 0.3 percent annually, while payment to other urban hospitals would increase 1.8 percent annually relative to pre-PPS payments. These hospitals all experience net gains in PPS payment with the BBRA 1999 transitional corridor payments, at an annual rate of 4.4 percent, 4.3 percent, and 5.1 percent, respectively. Even though rural hospitals receive a greater percentage of their Medicare income (14.7 percent) from outpatient services compared to the national average, their total Medicare payments increase by only a fraction, 0.6 percent.

Negative impacts for urban hospitals in the Mid-Atlantic and the West North Central regions are also reversed under

the BBRA 1999 transitional corridor payments, changing from −3.4 percent to 2.4 percent on an annual basis, and from −3.5 percent to 2.5 percent on an annual basis, respectively. Similarly, rural hospitals in nearly all census regions experience net increases in payment relative to pre-PPS payments with the BBRA 1999 transitional corridor payments.

The impact on TEFRA hospitals is shown separately at the end of the table. The TEFRA hospitals were not included in determining the impact on any of the other categories discussed above (for example, geographic location, bed size, volume, etc.). These hospitals demonstrated a very low service mix, but an average unit cost that approximates the national average. We believe that undercoding or billing an all-inclusive rate could account for their low-volume, low-service mix, and average cost per unit. We expect that once these hospitals begin to code services accurately under the PPS, payments will more closely approximate pre-PPS payments.

If the effect of the BBRA 1999 transition payments were removed, differences between pre-PPS payments and PPS payments among hospitals would still exist. These distributional differences are the result of many factors. First, cost variations among hospitals result in differences between pre-PPS payments and PPS payments, and charge structure variations result in differences between pre-PPS payments and PPS beneficiary copayment amounts. Hospitals whose costs are low relative to payment would gain under the PPS even without the BBRA 1999 transitional corridor payments. Because the transitional corridor payments are not budget neutral, these hospitals continue to gain relative to pre-PPS payments.

Redistributions may also occur as a result of current payment methods. Total Medicare outpatient payments are less than reported total costs because (in addition to the 5.8 and 10 percent reductions for operating and capital costs) the blended payment methods applicable to many surgical and diagnostic services often result in payments that are less than reported costs. Other services such as medical visits, chemotherapy services, and non-ASC approved surgeries are paid based on hospital costs. The new system redistributes the current total Medicare payments, based in part on cost-based payments and in part on blended payment amounts, across all services. Hospitals, in the aggregate, will receive proportionately less for services that are currently paid based on costs, and more for services that had been paid under blended payment methods.

TABLE 2. ANNUAL IMPACT OF HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM IN CY2000–CY2001

	Number of hospitals	Outpatient percent	Excluding BBRA transitional corridors [1]		Including BBRA transitional corridors	
			Percent change in Medicare outpatient payments [3]	Percent change in total Medicare payments	Percent change in Medicare outpatient payments [3]	Percent change in total Medicare payments
	(1)	(2)	(3)	(4)	(5)	(6)
ALL HOSPITALS	5,362	9.9	0.2	0.0	4.6	0.5
NON-TEFRA HOSPITALS	4,828	10	0.1	0.0	4.6	0.5
URBAN HOSPS [2]	2,665	9.3	0.6	0.1	4.6	0.4
LARGE URBAN [2] (GT 1 MILL.)	1,505	9.1	−0.3	0.0	4.3	0.4
OTHER URBAN [2] (LE 1 MILL.)	1,160	9.7	1.8	0.2	5.1	0.5
RURAL HOSPS	2,160	14.7	−1.8	−0.3	4.4	0.6
BEDS (URBAN): [2]						
0—99 BEDS	672	14.9	0.6	0.1	4.6	0.7
100–199 BEDS	924	10.5	1.3	0.1	5.2	0.5
200–299 BEDS	533	9.2	0.8	0.1	4.4	0.4
300–499 BEDS	399	8.5	1.8	0.2	5.2	0.4
500 + BEDS	137	8.4	−2.9	−0.2	2.8	0.2
BEDS (RURAL):						
0—49 BEDS	1,170	19.5	−8.5	−1.7	3.3	0.6
50–99 BEDS	615	15.5	−2.7	−0.4	4.4	0.7
100–149 BEDS	223	13.3	−0.2	0.0	3.8	0.5
150–199 BEDS	81	13	2.5	0.3	5.5	0.7
200 + BEDS	71	11.6	2.7	0.3	6.1	0.7
VOLUME (URBAN):						
LT 5,000	349	12	−7.7	−0.9	0.2	0.0
5,000–10,999	504	9.8	0.0	0.0	4.2	0.4
11,000–20,999	596	9.1	0.1	0.0	4.4	0.4
21,000–42,999	773	8.8	1.3	0.1	4.9	0.4
GT 42,999	443	9.7	0.4	0.0	4.6	0.4
VOLUME (RURAL):						
LT 5,000	1,049	18.5	−12.2	−2.3	2.5	0.5
5,000–10,999	595	15.2	−5.2	−0.8	2.9	0.4
11,000–20,999	322	13.8	0.1	0.0	4.7	0.6
21,000–42,999	173	13.6	2.4	0.3	5.7	0.8
GT 42,999	21	13.2	3.0	0.4	6.8	0.9
REGION (URBAN): [3]						
NEW ENGLAND	146	10.7	3.8	0.4	6.7	0.7
MIDDLE ATLANTIC	393	8.4	−3.4	−0.3	2.4	0.2
SOUTH ATLANTIC	401	8.6	0.3	0.0	4.2	0.4
EAST NORTH CENT.	465	10.7	1.0	0.1	4.5	0.5

TABLE 2. ANNUAL IMPACT OF HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM IN CY2000–CY2001—Continued

	Number of hospitals	Outpatient percent	Excluding BBRA transitional corridors [1]		Including BBRA transitional corridors	
			Percent change in Medicare outpatient payments [3]	Percent change in total Medicare payments	Percent change in Medicare outpatient payments [3]	Percent change in total Medicare payments
	(1)	(2)	(3)	(4)	(5)	(6)
EAST SOUTH CENT.	161	7.9	1.8	0.1	4.6	0.4
WEST NORTH CENT.	183	9.5	0.9	0.1	4.9	0.5
WEST SOUTH CENT.	335	9.7	−2.7	−0.3	2.5	0.2
MOUNTAIN	123	10.2	3.1	0.3	6.1	0.6
PACIFIC	423	9.4	5.6	0.5	8.6	0.8
PUERTO RICO	35	6.6	10.8	0.7	13.2	0.9
REGION (RURAL):						
NEW ENGLAND	53	17.2	−3.2	−0.6	3.3	0.6
MIDDLE ATLANTIC	80	13.6	7.1	1.0	10.1	1.4
SOUTH ATLANTIC	285	11.8	−1.8	−0.2	3.6	0.4
EAST NORTH CENT.	282	15.7	−1.2	−0.2	4.3	0.7
EAST SOUTH CENT.	260	11.1	0.1	0.0	4.9	0.5
WEST NORTH CENT.	508	19.8	−5.2	−1.0	3.0	0.6
WEST SOUTH CENT.	337	14.2	−5.7	−0.8	3.0	0.4
MOUNTAIN	213	16.9	−3.4	−0.6	4.7	0.8
PACIFIC	140	15.9	0.7	0.1	6.3	1.0
PUERTO RICO	2	6.6	32.1	2.1	32.1	2.1
TEACHING STATUS:						
NON-TEACHING	3,738	11.3	0.5	0.1	5.0	0.6
MINOR	821	9.1	1.6	0.1	5.0	0.5
MAJOR	269	9.1	−3.7	−0.3	2.6	0.2
DSH PATIENT PERCENT:						
0	101	10.9	−5.8	−0.6	0.7	0.1
GT 0—0.10	1,139	10.5	0.8	0.1	4.6	0.5
0.10–0.16	986	11	2.0	0.2	5.6	0.6
0.16–0.23	880	10.1	0.8	0.1	4.9	0.5
0.23–0.35	855	9.5	−1.5	−0.1	3.7	0.4
GE 0.35	867	9.2	−2.5	−0.2	3.5	0.3
URBAN IME/DSH: [2]						
IME & DSH	994	9	−0.4	0.0	4.1	0.4
IME/NO DSH	17	9.2	−3.6	−0.3	1.1	0.1
NO IME/DSH	1,611	9.9	1.9	0.2	5.4	0.5
NO IME/NO DSH	43	14.7	−8.2	−1.2	−0.3	0.0
RURAL HOSP. TYPES:						
NO SPECIAL STATUS	864	15	−2.2	−0.3	4.4	0.7
RRC	164	12.3	5.0	0.6	7.3	0.9
SCH/EACH	634	16.5	−7.7	−1.3	2.2	0.4
MDH	358	18.3	−5.4	−1.0	3.5	0.6
SCH AND RRC	56	13.9	−1.4	−0.2	3.1	0.4
TYPE OF OWNERSHIP:						
VOLUNTARY	2,816	9.9	0.6	0.1	4.7	0.5
PROPRIETARY	752	8.3	−0.1	0.0	4.7	0.4
GOVERNMENT	1,260	12.2	−2.3	−0.3	3.6	0.4
SPECIALTY HOSPITALS:						
EYE AND EAR	10	31.1	20.1	6.3	20.2	6.3
TRAUMA	159	9.1	−1.2	−0.1	4.0	0.4
CANCER	10	22	0.8	0.2	0.8	0.2
TEFRA HOSPITALS (NOT INCLUDED ON OTHER LINES):						
REHAB	147	3.7	−9.4	−0.3	1.7	0.1
PSYCH	281	9	21.3	1.9	27.9	2.5
LTC	65	3.7	−15.3	−0.6	−1.7	−0.1
CHILDREN	41	16.5	−11.9	−2.0	−3.2	−0.5

Notes:

[1] Includes all BBRA provisions except the transitional corridor provisions that expire 01/01/04.

[2] Does not include impact of reclassifications as allowed under section 401 of the BBRA 1999.

[3] Estimate of change compared to pre-PPS payments, which reflect the payment methodologies in effect as of January 1, 2000, and prior to July 1, 2000.

X. Federalism

We have examined this rule in accordance with Executive Order 13132, Federalism, and have determined that this final rule will not have any negative impact on the rights, roles, and responsibilities of State, local or Tribal governments.

XI. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and its reasons in the rule. We find that the circumstances surrounding this rule make it impracticable to pursue a process of notice-and-comment rulemaking before the provisions of this rule take effect.

The BBRA 1999 was enacted on November 29, 1999. This final rule incorporates the following hospital outpatient PPS provisions in the BBRA 1999: outlier adjustment for high cost cases; transitional pass-through payment adjustments for additional costs (over the payments for APCs otherwise made) for new medical devices, drugs, and biologicals; definition of APCs so that the variation of costs of items within an APC is subject to certain limits; establishment of ''transitional corridors'' for the first 3½ years of the new system that limit losses hospitals might otherwise face; payment for implantable devices under the hospital outpatient PPS, rather than under the Durable Medical Equipment Fee Schedule; limitation of the copayment on an outpatient procedure to the amount of the inpatient hospital deductible; requirement to review annually the APC groups, relative weights, and wage and other adjustments; and calculation of the conversion factor in a budget-neutral manner, eliminating the 5.7 percent reduction indicated in the proposed rule.

As discussed earlier in this rule, July 1, 2000 is the earliest date on which we can feasibly implement the PPS. The provisions of the BBRA 1999, enacted on November 29, 1999, made numerous refinements to the PPS. With respect to the BBRA 1999 provisions, it would have been impracticable to complete notice and comment procedures by July 1, 2000. Given the limited timeframe, given the nature and scope of the BBRA 1999 refinements, and given the time required to complete notice and comment rulemaking (to develop proposed policies, draft the proposed rule, provide a 60-day public comment period, consider public comments, develop final policies, draft a final rule), it would not have been possible to issue this document as a proposed rule and issue a final rule by July 1.

In addition, it would not be feasible to implement the hospital outpatient PPS *without* the BBRA 1999 provisions, not only because of the nature of the BBRA 1999 provisions, but also because section 201(m) of the BBRA 1999 states: ''Except as provided in this section, the amendments made by this section shall be effective as if included in the enactment of BBA.'' Therefore, if we undertook prior notice and comment procedures with respect to the BBRA 1999 provisions, then (because such procedures could not be completed by July 1, 2000) the PPS would not be implemented by July 1, 2000.

Accordingly, we find good cause to waive the procedures for *prior* notice and comment with respect to the provisions of this document that implement the BBRA 1999 refinements to hospital outpatient PPS. We are providing a 60-day period for public comment with respect to the provisions of this final rule with comment period that implement the BBRA refinements. We are not accepting comments with respect to the other aspects of this document (for which the public has already had an extensive opportunity to comment).

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Rural areas, X-rays.

42 CFR Part 411

Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 412

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

42 CFR Part 413

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

42 CFR Part 419

Health facilities, Hospitals, Medicare.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 498

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

42 CFR Part 1003

Administrative practice and procedure, Archives and records, Grant program—social programs, Maternal and Child Health, Medicaid, Medicare, Penalties.

For the reasons set forth in the preamble, 42 CFR chapter IV is amended as follows:

PART 409—HOSPITAL INSURANCE BENEFITS

A. Part 409 is amended as set forth below:

1. The authority citation for part 409 continues to read as follows:

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

Subpart B—Inpatient Hospital Services and Inpatient Critical Access Hospital Services

2. In § 409.10, paragraph (b) is revised to read as follows:

§ 409.10 Included services.

* * * * *

(b) *Inpatient hospital services* does not include the following types of services:

(1) Posthospital SNF care, as described in § 409.20, furnished by a hospital or a critical access hospital that has a swing-bed approval.

(2) Nursing facility services, described in § 440.155 of this chapter, that may be furnished as a Medicaid service under title XIX of the Act in a swing-bed hospital that has an approval to furnish nursing facility services.

(3) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(4) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(5) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(6) Certified nurse mid-wife services, as defined in section 1861(gg) of the Act.

(7) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(8) Services of an anesthetist, as defined in § 410.69 of this chapter.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

B. Part 410 is amended as set forth below:

1. The authority citation for part 410 continues to read as follows:

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

Subpart A—General Provisions

2. In § 410.2, the introductory text is republished, the definition of ''Community mental health center (CMHC)'' is revised, and the definitions of ''Encounter'' and ''Outpatient'' are added in alphabetical order to read as follows:

§ 410.2 Definitions.

As used in this part—

Community mental health center (CMHC) means an entity that—

(1) Provides outpatient services, including specialized outpatient services for children, the elderly, individuals who are chronically mentally ill, and residents of its mental health service area who have been discharged from inpatient treatment at a mental health facility;

(2) Provides 24-hour-a-day emergency care services;

(3) Provides day treatment or other partial hospitalization services, or psychosocial rehabilitation services;

(4) Provides screening for patients being considered for admission to State mental health facilities to determine the appropriateness of this admission; and

(5) Meets applicable licensing or certification requirements for CMHCs in the State in which it is located.

Encounter means a direct personal contact between a patient and a physician, or other person who is authorized by State licensure law and, if applicable, by hospital or CAH staff bylaws, to order or furnish hospital services for diagnosis or treatment of the patient.

* * * * *

Outpatient means a person who has not been admitted as an inpatient but who is registered on the hospital or CAH records as an outpatient and receives services (rather than supplies alone) directly from the hospital or CAH.

* * * * *

Subpart B—Medical and Other Health Services

3. In § 410.27:

A. The section heading is revised;

B. The introductory text to paragraph (a) is revised;

C. The introductory text to paragraph (a)(1) is republished;

D. The word ''and'' at the end of paragraph (a)(1)(i) is removed; and

E. New paragraphs (a)(1)(iii), (e), and (f) are added to read as follows:

§ 410.27 Outpatient hospital services and supplies incident to a physician service: Conditions.

(a) Medicare Part B pays for hospital services and supplies furnished incident to a physician service to outpatients, including drugs and biologicals that cannot be self-administered, if—

(1) They are furnished—

* * * * *

(iii) In the hospital or at a location (other than an RHC or an FQHC) that HCFA designates as a department of a provider under § 413.65 of this chapter; and

* * * * *

(e) Services furnished by an entity other than the hospital are subject to the limitations specified in § 410.42(a).

(f) Services furnished at a location (other than an RHC or an FQHC) that HCFA designates as a department of a provider under § 413.65 of this chapter must be under the direct supervision of a physician. ''Direct supervision'' means the physician must be present and on the premises of the location and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

4. In § 410.28, paragraph (a)(4) is removed, paragraph (c) is redesignated as paragraph (d), and new paragraphs (c) and (e) are added to read as follows:

§ 410.28 Hospital or CAH diagnostic services furnished to outpatients: Conditions.

* * * * *

(c) Diagnostic services furnished by an entity other than the hospital or CAH are subject to the limitations specified in § 410.42(a).

* * * * *

(e) Medicare Part B makes payment under section 1833(t) of the Act for diagnostic services furnished at a facility (other than an RHC or an FQHC) that HCFA designates as having provider-based status only when the diagnostic services are furnished under the appropriate level of physician supervision specified by HCFA in accordance with the definitions in § 410.32(b)(3)(i), (b)(3)(ii), and (b)(3)(iii). Under general supervision at a facility accorded provider-based status, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the facility.

5. A new § 410.42 is added to read as follows:

§ 410.42 Limitations on coverage of certain services furnished to hospital outpatients.

(a) *General rule.* Except as provided in paragraph (b) of this section, Medicare Part B does not pay for any item or service that is furnished to a hospital outpatient (as defined in § 410.2) during an encounter (as defined in § 410.2) by an entity other than the hospital unless the hospital has an arrangement (as defined in § 409.3 of this chapter) with that entity to furnish that particular service to its patients. As used in this paragraph, the term ''hospital'' includes a CAH.

(b) *Exception.* The limitations stated in paragraph (a) of this section do not apply to the following services:

(1) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(3) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(4) Certified nurse mid-wife services, as defined in section 1861(gg) of the Act.

(5) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(6) Services of an anesthetist, as defined in § 410.69.

(7) Services furnished to SNF residents as defined in § 411.15(p) of this chapter.

6. In § 410.43, paragraph (b) is revised to read as follows:

§ 410.43 Partial hospitalization services: Conditions and exclusions.

* * * * *

(b) The following services are separately covered and not paid as partial hospitalization services:

(1) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(3) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(4) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(5) Services furnished to SNF residents as defined in § 411.15(p) of this chapter.

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

C. Part 411 is amended as set forth below:

1. The authority citation for part 411 continues to read as follows:

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

Subpart A—General Exclusions and Exclusion of Particular Services

2. In § 411.15:

A. The introductory text is republished;

B. The section heading to paragraph (m) is revised;

C. Paragraph (m)(1) is revised;

D. Paragraph (m)(2) is redesignated as paragraph (m)(3);

E. The introductory text to newly redesignated paragraph (m)(3) is republished;

F. Newly redesignated paragraphs (m)(3)(iii), (m)(3)(iv), and (m)(3)(v) are redesignated as paragraphs (m)(3)(iv), (m)(3)(v), and (m)(3)(vi), respectively; and

G. New paragraphs (m)(2) and (m)(3)(iii) are added to read as follows:

§ 411.15 Particular services excluded from coverage.

The following services are excluded from coverage:

* * * * *

(m) *Services to hospital patients*—(1) *Basic rule.* Except as provided in paragraph (m)(3) of this section, any service furnished to an inpatient of a hospital or to a hospital outpatient (as defined in § 410.2 of this chapter) during an encounter (as defined in § 410.2 of this chapter) by an entity other than the hospital unless the hospital has an arrangement (as defined in § 409.3 of this chapter) with that entity to furnish that particular service to the hospital's patients. As used in this paragraph (m)(1), the term ''hospital'' includes a CAH.

(2) *Scope of exclusion.* Services subject to exclusion from coverage under the provisions of this paragraph (m) include, but are not limited to, clinical laboratory services; pacemakers and other prostheses and prosthetic devices (other than dental) that replace all or part of an internal body organ (for example, intraocular lenses); artificial limbs, knees, and hips; equipment and supplies covered under the prosthetic device benefits; and services incident to a physician service.

(3) *Exceptions.* The following services are not excluded from coverage:

* * * * *

(iii) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

* * * * *

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

D. Part 412 is amended as set forth below:

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

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

Subpart C—Conditions for Payment Under the Prospective Payment Systems for Inpatient Operating Costs and Inpatient Capital-Related Costs

2. In § 412.50, paragraphs (a) and (b) are revised to read as follows:

§ 412.50 Furnishing of inpatient hospital services directly or under arrangements.

(a) The applicable payments made under the prospective payment systems, as described in subparts H and M of this part, are payment in full for all inpatient hospital services, as defined in § 409.10 of this chapter. Inpatient hospital services do not include the following types of services:

(1) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(3) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(4) Certified nurse mid-wife services, as defined in section 1861(gg) of the Act.

(5) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(6) Services of an anesthetist, as defined in § 410.69 of this chapter.

(b) HCFA does not pay any provider or supplier other than the hospital for services furnished to a beneficiary who is an inpatient, except for the services described in paragraphs (a)(1) through (a)(6) of this section.

* * * * *

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

E. Part 413 is amended as set forth below:

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

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

Subpart A—Introduction and General Rules

§ 413.1 [Amended]

2. In § 413.1, paragraph (a)(2)(viii) is removed.

Subpart B—Accounting Records and Reports

3. In § 413.24, the heading to paragraph (d) is republished, and a new paragraph (d)(6) is added to read as follows:

§ 413.24 Adequate cost data and cost finding.

* * * * *

(d) *Cost finding methods.* * * *

(6) *Management contracts.* (i) If the main provider purchases services for a department of the provider or a provider-based entity through a management contract or otherwise directly assigns costs to the department or entity, the like costs of the main provider must be carved out to ensure that they are not allocated to the department of the provider or provider-based entity. However, if the like costs of the main provider cannot be separately identified, the costs of the services purchased through a management contract must be included in the main provider's administrative and general costs and allocated among the provider's overall statistics.

(ii) Costs of free-standing entities may not be shown in the provider's trial balance for purposes of stepping down overhead costs to these entities. The provider must develop detailed work papers showing the exact cost of the services (including overhead) provided to or by the free-standing entity and show those carved out costs as

nonreimbursable cost centers in the provider's trial balance.

* * * * *

Subpart E—Payments to Providers

4. A new § 413.65 is added to read as follows:

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

(a) *Scope and definitions.* (1) *Scope.* This section applies to all facilities or organizations for which provider-based status is sought, including remote locations of hospitals, as defined in paragraph (a)(2) of this section and satellite facilities as defined in § 412.22(h)(1) and § 412.25(e)(1) of this chapter, other than ESRD facilities. Determinations for ESRD facilities are made under § 413.174 of this chapter.

(2) *Definitions.* In this subpart E, unless the context indicates otherwise—

Campus means the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the HCFA regional office, to be part of the provider's campus.

Department of a provider means a facility or organization or a physician office that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A department of a provider may not be licensed to provide health care services in its own right, may not by itself be qualified to participate in Medicare as a provider under § 489.2 of this chapter, and Medicare conditions of participation do not apply to a department as an independent entity. For purposes of this part, the term ''department of a provider'' does not include an RHC or, except as specified in paragraph (m)(1) of this section, an FQHC.

Free-standing facility means an entity that furnishes health care services to Medicare beneficiaries and that is not integrated with any other entity as a main provider, a department of a provider, remote location of a hospital, satellite facility, or a provider-based entity.

Main provider means a provider that either creates, or acquires ownership of, another entity to deliver additional health care services under its name, ownership, and financial and administrative control.

Provider-based entity means a provider of health care services, or an RHC or an FQHC as defined in § 405.2401(b) of this chapter, that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of a different type from those of the main provider under the name, ownership, and administrative and financial control of the main provider, in accordance with the provisions of this section.

Provider-based status means the relationship between a main provider and a provider-based entity or a department of a provider, remote location of a hospital, or satellite facility, that complies with the provisions of this section.

Remote location of a hospital means a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A remote location of a hospital may not be licensed to provide inpatient hospital services in its own right, and Medicare conditions of participation do not apply to a remote location of a hospital as an independent entity. For purposes of this part, the term ''remote location of a hospital'' does not include a satellite facility as defined in § 412.22(h)(1) and § 412.25(e)(1) of this chapter.

(b) *Responsibility for obtaining provider-based determinations.* (1) A facility or organization is not entitled to be treated as provider-based simply because it or the main provider believe it is provider-based.

(2) A main provider or a facility or organization must contact HCFA and the facility or organization must be determined by HCFA to be provider-based before the main provider bills for services of the facility or organization as if the facility or organization were provider-based, or before it includes costs of those services on its cost report.

(3) A facility that is not located on the campus of a hospital and is used as a site of physician services of the kind ordinarily furnished in physician offices will be presumed to be a free-standing facility, unless it is determined by HCFA to have provider-based status.

(c) *Reporting.* (1) A main provider that creates or acquires a facility or organization for which it wishes to claim provider-based status, including any physician offices that a hospital wishes to operate as a hospital outpatient department or clinic, must report its acquisition of the facility or organization to HCFA if the facility or organization is located off the campus of the provider, or inclusion of the costs of the facility or organization in the provider's cost report would increase the total costs on the provider's cost report by at least 5 percent, and must furnish all information needed for a determination as to whether the facility or organization meets the requirements in paragraph (d) of this section for provider-based status.

(2) A main provider that has had one or more facilities or organizations considered provider-based also must report to HCFA any material change in the relationship between it and any provider-based facility or organization, such as a change in ownership of the facility or organization or entry into a new or different management contract that could affect the provider-based status of the facility or organization.

(d) *Requirements.* An entity must meet all of the following requirements to be determined by HCFA to have provider-based status.

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

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

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

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

(iii) The facility or organization is operated under the same organizational documents as the main provider. For

example, the facility or organization seeking provider-based status must be subject to common bylaws and operating decisions of the governing body of the provider where it is based.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(5) *Financial integration.* The financial operations of the facility or organization are fully integrated within the financial system of the main provider, as evidenced by shared income and expenses between the main provider and the facility or organization. The costs of the facility or organization are reported in a cost center of the provider, and the financial status of the facility or organization is incorporated and readily identified in the main provider's trial balance.

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

(7) *Location in immediate vicinity.* The facility or organization and the main provider are located on the same campus, except where the following requirements are met:

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

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

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

(C) If the facility or organization is unable to meet the criteria in paragraph (d)(7)(i)(A) or (d)(7)(i)(B) of this section because it was not in operation during all of the 12-month period described in the previous sentence, the facility or organization is located in a zip code area included among those that, during all of the 12-month period described in the previous sentence, accounted for at least 75 percent of the patients served by the main provider.

(ii) A facility or organization is not considered to be in the ''immediate vicinity'' of the main provider unless the facility or organization and the main provider are located in the same State or, where consistent with the laws of both States, adjacent States.

(iii) A rural health clinic that is otherwise qualified as a provider-based entity of a hospital that is located in a rural area, as defined in § 412.62(f)(1)(iii) of this chapter, and has fewer than 50 beds, as determined under § 412.105(b) of this chapter, is not subject to the criterion in this paragraph (d)(7).

(e) *Provider-based status not applicable to joint ventures.* A facility or

organization cannot be considered provider-based if the entity is owned by two or more providers engaged in a joint venture. For example, where a hospital has jointly purchased or jointly created free-standing facilities under joint venture arrangements, neither party to the joint venture arrangement can claim the free-standing facility as a provider-based entity.

(f) *Management contracts.* Facilities and organizations that otherwise meet the requirements of paragraph (d) of this section, but are operated under management contracts, must also meet all of the following criteria:

(1) The staff of the facility or organization, other than management staff, are employed by the provider or by another organization, other than the management company, which also employs the staff of the main provider.

(2) The administrative functions of the facility or organization are integrated with those of the main provider, as determined under criteria in paragraph (d)(3)(iii) of this section.

(3) The main provider has significant control over the operations of the facility or organization as determined under criteria in paragraph (b)(3)(ii) of this section.

(4) The management contract is held by the main provider itself, not by a parent organization that has control over both the main provider and the facility or organization.

(g) *Obligations of hospital outpatient departments and hospital-based entities.* (1) Hospital outpatient departments located either on or off the campus of the hospital that is the main provider must comply with the anti-dumping rules in §§ 489.20(l), (m), (q), and (r) and § 489.24 of this chapter. If any individual comes to any hospital-based entity (including an RHC) located on the main hospital campus, and a request is made on the individual's behalf for examination or treatment of a medical condition, as described in § 489.24 of this chapter, the hospital must comply with the anti-dumping rules in § 489.24 of this chapter.

(2) Physician services furnished in hospital outpatient departments or hospital-based entities (other than RHCs) must be billed with the correct site-of-service indicator, so that applicable site-of-service reductions to physician and practitioner payment amounts can be applied.

(3) Hospital outpatient departments must comply with all the terms of the hospital's provider agreement.

(4) Physicians who work in hospital outpatient departments or hospital-based entities are obligated to comply with the non-discrimination provisions in § 489.10(b) of this chapter.

(5) Hospital outpatient departments (other than RHCs) must treat all Medicare patients, for billing purposes, as hospital outpatients. The department must not treat some Medicare patients as hospital outpatients and others as physician office patients.

(6) In the case of a patient admitted to the hospital as an inpatient after receiving treatment in the hospital outpatient department or hospital-based entity, payments for services in the hospital outpatient department or hospital-based entity are subject to the payment window provisions applicable to PPS hospitals and to hospitals and units excluded from PPS set forth at § 412.2(c)(5) of this chapter and at § 413.40(c)(2), respectively.

(7) When a Medicare beneficiary is treated in a hospital outpatient department or hospital-based entity (other than an RHC) that is not located on the main provider's campus, the hospital has a duty to provide written notice to the beneficiary, prior to the delivery of services, of the amount of the beneficiary's potential financial liability (that is, of the fact that the beneficiary will incur a coinsurance liability for an outpatient visit to the hospital as well as for the physician service, and of the amount of that liability). The notice must be one that the beneficiary can read and understand. If the beneficiary is unconscious, under great duress, or for any other reason unable to read a written notice and understand and act on his or her own rights, the notice must be provided, prior to the delivery of services, to the beneficiary's authorized representative.

(8) Hospital outpatient departments must meet applicable hospital health and safety rules for Medicare-participating hospitals in part 482 of this chapter.

(h) *Furnishing all services under arrangement.* A facility or organization may not qualify for provider-based status if all patient care services furnished at the facility are furnished under arrangement.

(i) *Inappropriate treatment of a facility or organization as provider-based.* (1) *Determination and review.* If HCFA learns that a provider has treated a facility or organization as provider-based and the provider had not obtained a determination of provider-based status under this section, HCFA will—

(i) Review current payments and, if necessary, take action in accordance with the rules on inappropriate billing in paragraph (j) of this section;

(ii) Investigate and determine whether the requirements in paragraph (d) of this section (or, for periods prior to October 10, 2000, the requirements in applicable program instructions) were met; and

(iii) Review all previous payments to that provider for all cost reporting periods subject to re-opening in accordance with § 405.1885 and § 405.1889 of this chapter.

(2) *Recovery of overpayments.* If HCFA finds that payments for services at the facility or organization have been made as if the facility or organization were provider-based, even though HCFA had not previously determined that the facility or organization qualified for provider-based status, HCFA will recover the difference between the amount of payments that actually were made and the amount of payments that HCFA estimates should have been made in the absence of a determination of provider-based status, except that recovery will not be made for any period prior to October 10, 2000 if during all of that period the management of the entity made a good faith effort to operate it as a provider-based facility or organization, as described in paragraph (h)(3) of this section.

(3) *Exception for good faith effort.* HCFA determines that the management of a facility or organization has made a good faith effort to operate it as a provider-based entity if—

(i) The requirements regarding licensure and public awareness in paragraphs (d)(1) and (d)(6) of this section are met;

(ii) All facility services were billed as if they had been furnished by a department of a provider, remote location of a hospital, satellite facility, or a provider-based entity of the main provider; and

(iii) All professional services of physicians and other practitioners were billed with the correct site-of-service indicator, as described in paragraph (g)(2) of this section.

(j) *Inappropriate billing.* If HCFA finds that a facility or organization is being treated as provider-based without having obtained a determination of provider-based status under this section, HCFA will notify the provider, adjust future payments, review previous payments, determine whether the facility or organization qualifies for provider-based status under this paragraph, and continue payments only under specific conditions, as described in paragraphs (j)(1), (j)(2), (j)(3), and (j)(4) of this section.

(1) *Notice to provider.* If HCFA finds that inappropriate billing has occurred or is occurring since no provider-based

determination has been made by HCFA, HCFA will issue written notice to the provider that payments for past cost reporting periods may be reviewed and recovered as described in paragraph (i) of this section, that future payments for services in or of the facility or organization will be adjusted as described in paragraph (j)(2) of this section, and that a determination of provider-based status will be made.

(2) *Adjustment of payments.* If HCFA finds that inappropriate billing has occurred or is occurring since no provider-based determination has been made by HCFA, HCFA will adjust future payments to the provider, the facility or organization, or both, to approximate as closely as possible the amounts that would be paid, in the absence of a provider-based determination, if all other requirements for billing were met.

(3) *Review of previous payments.* If HCFA finds that inappropriate billing has occurred or is occurring since no provider-based determination has been made by HCFA, HCFA will review previous payments and, if necessary, take action in accordance with the rules on inappropriate treatment of a facility or organization as provider-based in paragraph (h) of this section.

(4) *Determination regarding provider-based status.* If HCFA finds that inappropriate billing has occurred or is occurring since no provider-based determination has been made by HCFA, HCFA will determine whether the facility or organization qualifies for provider-based status under the criteria in this section. If HCFA determines that the facility or organization qualifies for provider-based status, future payment for services at or by the facility or organization will be adjusted to reflect that determination. If HCFA determines that the facility or organization does not qualify for provider-based status, future payment for services at or by the facility or organization will be made only in accordance with the rules in paragraph (i)(5) of this section.

(5) *Continuation of payment.* The notice of denial of provider-based status sent to the provider will ask the provider to notify HCFA in writing, within 30 days of the date the notice is issued, of whether the facility or organization (or, where applicable, the practitioners who staff the facility or organization) will be seeking to enroll and meet other requirements to bill for services in a free-standing facility. If the provider indicates that the facility, organization, or practitioners will not be seeking to enroll, or if HCFA does not receive a response within 30 days of the date the notice was issued, all payment under this paragraph (i)(5) will end as of the 30th day after the date of notice. If the provider indicates that the facility or organization, or its practitioners, will be seeking to meet enrollment and other requirements for billing for services in a free-standing facility, payment for services of the facility or organization will continue, at the adjusted amounts described in paragraph (j)(2) of this section for as long as is required for all billing requirements to be met (but not longer than 6 months) if the facility or organization, or its practitioners, submit a complete enrollment application and provide all other required information within 90 days after the date of notice; and the facility or organization, or its practitioners, furnish all other information needed by HCFA to process the enrollment application and verify that other billing requirements are met. If the necessary applications or information are not provided, HCFA will terminate all payment to the provider, facility, or organization as of the date HCFA issues notice that necessary applications or information have not been submitted.

(k) *Correction of errors.* HCFA may review a past determination of provider-based status for a facility or organization or may review the status of a facility or organization (that is, whether the facility or organization is provider-based) if no determination regarding provider-based status has previously been made, if HCFA believes that status may be inappropriate, based on the provisions of this section. If HCFA determines that a previous determination was in error, and the entity should not be considered provider-based, HCFA notifies the main provider. Treatment of the facility or organization as provider-based ceases with the first day of the next cost report period following notification of the redetermination, but not less than 6 months after the date of notification.

(l) *Status of Indian Health Service and Tribal facilities and organizations.* Facilities and organizations operated by the Indian Health Service or Tribes will be considered to be departments of hospitals operated by the Indian Health Service or Tribes if, on or before April 7, 2000, they furnished only services that were billed as if they had been furnished by a department of a hospital operated by the Indian Health Service or a Tribe and they are:

(1) Owned and operated by the Indian Health Service;

(2) Owned by the Tribe but leased from the Tribe by the IHS under the Indian Self-Determination Act (Pub. L. 93–638) in accordance with applicable regulations and policies of the Indian Health Service in consultation with Tribes: or

(3) Owned by the Indian Health Service but leased and operated by the Tribe under the Indian Self-Determination Act (Pub. L. 93–638) in accordance with applicable regulations and policies of the Indian Health Service in consultation with Tribes.

(m) *FQHCs and ''look-alikes''.* A facility that has, since April 7, 1995, furnished only services that were billed as if they had been furnished by a department of a provider will continue to be treated, for purposes of this section, as a department of the provider without regard to whether it complies with the criteria for provider-based status in this section, if the facility—

(1) Received a grant before 1995 under section 330 of the Public Health Service Act, or is receiving funding from such a grant under a contract with the recipient of such a grant and meets the requirements to receive a grant under section 330 of the Public Health Service Act; or

(2) Based on the recommendation of the Public Health Service, was determined by HCFA before 1995 to meet the requirements for receiving such a grant.

(n) *Effective date of provider-based status.* Provider-based status for a facility or organization is effective on the earliest date on which a request for provider-based status has been made, and all requirements of this part have been met.

Subpart F—Specific Categories of Costs

5. In § 413.118, the heading to paragraph (d) is republished, and a new paragraph (d)(5) is added to read as follows:

§ 413.118 Payment for facility services related to covered ASC surgical procedures performed in hospitals on an outpatient basis.

* * * * *

(d) *Blended payment amount.* * * *

(5) For portions of cost reporting periods beginning on or after October 1, 1997, for purposes of calculating the blended payment amount under paragraph (d)(4) of this section, the ASC payment amount is the sum of the standard overhead amounts reduced by deductibles and coinsurance as defined in section 1866(a)(2)(ii) of the Act.

* * * * *

6. In § 413.122:

A. The heading to paragraph (b) is republished

B. A new paragraph (b)(5) is added

C. The heading to paragraph (c) is republished; and

D. A new paragraph (c)(4) is added to read as follows:

§ 413.122 Payment for hospital outpatient radiology services and other diagnostic procedures.

* * * * *

(b) *Payment for hospital outpatient radiology services.* * * *

(5) For hospital outpatient radiology services furnished on or after October 1, 1997, the blended payment amount is equal to the sum of—

(i) 42 percent of the hospital-specific amount; and

(ii) 58 percent of the fee schedule amount calculated as 62 percent of the sum of the fee schedule amounts payable for the same services when furnished by participating physicians in their offices in the same locality, less deductible and coinsurance as defined in section 1866(a)(2)(A)(ii) of the Act.

(c) *Payment for other diagnostic procedures.* * * *

(4) For other diagnostic services furnished on or after October 1, 1997, the blended payment amount is equal to the sum of—

(i) 50 percent of the hospital-specific amount; and

(ii) 50 percent of the fee schedule amount calculated as 42 percent of the sum of the fee schedule amounts payable for the same services when furnished by participating physicians in their offices in the same locality less deductible and coinsurance as defined in section 1866(a)(2)(A)(ii) of the Act.

7. In § 413.124, paragraph (a) is revised to read as follows:

§ 413.124 Reduction to hospital outpatient operating costs.

(a) Except for sole community hospitals, as defined in § 412.92 of this chapter, and critical access hospitals, the reasonable costs of outpatient hospital services (other than capital-related costs of these services) are reduced by 5.8 percent for services furnished during portions of cost reporting periods occurring on or after October 1, 1990 and until the first date that the prospective payment system under part 419 of this chapter is implemented.

* * * * *

Subpart G—Capital-Related Costs

8. In § 413.130, the heading to paragraph (j) and the introductory text to paragraph (j)(1) are republished, and paragraph (j)(1)(ii) is revised to read as follows:

§ 413.130 Introduction to capital-related costs.

* * * * *

(j) *Reduction to capital-related costs.* (1) Except for sole community hospitals and critical access hospitals, the amount of capital-related costs of all hospital outpatient services is reduced by—

* * * * *

(ii) 10 percent for portions of cost reporting periods occurring on or after October 1, 1991 and until the first date that the prospective payment system under part 419 of this chapter is implemented.

* * * * *

F. A new part 419, consisting of §§ 419.1, 419.2, 419.20, 419.21, 419.22, 419.30, 419.31, 419.32, 419.40, 419.41, 419.42, 419.43, 419.44, 419.50, 419.60, and 419.70, is added to read as follows:

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

Subpart A—General Provisions

Sec.

Subpart B—Categories of Hospitals and Services Subject to and Excluded From the Hospital Outpatient Prospective Payment System

Subpart C—Basic Methodology for Determining Prospective Payment Rates for Hospital Outpatient Services

Subpart D—Payments to Hospitals

Subpart E—Updates

Subpart F—Limitations on Review

Subpart G—Transitional Corridors

Authority: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395l(t), and 1395hh).

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

Subpart A—General Provisions

§ 419.1 Basis and scope.

(a) *Basis.* This part implements section 1833(t) of the Act by establishing a prospective payment system for services furnished on or after July 1, 2000 by hospital outpatient departments to Medicare beneficiaries who are registered on hospital records as outpatients.

(b) *Scope.* This subpart describes the basis of payment for outpatient hospital services under the prospective payment system. Subpart B sets forth the categories of hospitals and services that are subject to the outpatient hospital prospective payment system and those categories of hospitals and services that are excluded from the outpatient hospital prospective payment system. Subpart C sets forth the basic methodology by which prospective payment rates for hospital outpatient services are determined. Subpart D describes Medicare payment amounts, beneficiary copayment amounts, and methods of payment to hospitals under the hospital outpatient prospective payment system. Subpart E describes how the hospital outpatient prospective payment system may be updated. Subpart F describes limitations on administrative and judicial review. Subpart G describes the transitional payment adjustments that are made before 2004 to limit declines in payment for outpatient services.

§ 419.2 Basis of payment.

(a) *Unit of payment.* Under the hospital outpatient prospective payment system, predetermined amounts are paid for designated services furnished to Medicare beneficiaries. These services are identified by codes established under the Health Care Financing Administration Common Procedure Coding System (HCPCS). The prospective payment rate for each service or procedure for which payment is allowed under the hospital outpatient prospective payment system is

determined according to the methodology described in subpart C of this part. The manner in which the Medicare payment amount and the beneficiary copayment amount for each service or procedure are determined is described in subpart D of this part.

(b) *Determination of hospital outpatient prospective payment rates: Included costs.* The prospective payment system establishes a national payment rate, standardized for geographic wage differences, that includes operating and capital-related costs that are directly related and integral to performing a procedure or furnishing a service on an outpatient basis. In general, these costs include, but are not limited to—

(1) Use of an operating suite, procedure room, or treatment room;

(2) Use of recovery room;

(3) Use of an observation bed;

(4) Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations;

(5) Supplies and equipment for administering and monitoring anesthesia or sedation;

(6) Intraocular lenses (IOLs);

(7) Incidental services such as venipuncture;

(8) Capital-related costs;

(9) Implantable items used in connection with diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests;

(10) Durable medical equipment that is implantable;

(11) Implantable prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of these devices; and

(12) Costs incurred to procure donor tissue other than corneal tissue.

(c) *Determination of hospital outpatient prospective payment rates: Excluded costs.* The following costs are excluded from the hospital outpatient prospective payment rates:

(1) Medical education costs for approved nursing and allied health education programs.

(2) Corneal tissue acquisition costs incurred by hospitals that are paid for on a reasonable cost basis.

(3) Costs for services listed in § 419.22.

Subpart B—Categories of Hospitals and Services Subject to and Excluded From the Hospital Outpatient Prospective Payment System

§ 419.20 Hospitals subject to the hospital outpatient prospective payment system.

(a) *Applicability.* The hospital outpatient prospective payment system is applicable to any hospital participating in the Medicare program, except those specified in paragraph (b) of this section, for services furnished on or after July 1, 2000.

(b) *Hospitals excluded from the outpatient prospective payment system.* (1) Those services furnished by Maryland hospitals that are paid under a cost containment waiver in accordance with section 1814(b)(3) of the Act are excluded from the hospital outpatient prospective payment system.

(2) Critical access hospitals (CAHs) are excluded from the hospital outpatient prospective payment system.

§ 419.21 Hospital outpatient services subject to the outpatient prospective payment system.

Except for services described in § 419.22, effective for services furnished on or after July 1, 2000, payment is made under the hospital outpatient prospective payment system for the following:

(a) Medicare Part B services furnished to hospital outpatients designated by the Secretary under this part.

(b) Services designated by the Secretary that are covered under Medicare Part B when furnished to hospital inpatients who are either not entitled to benefits under Part A or who have exhausted their Part A benefits but are entitled to benefits under Part B of the program.

(c) Partial hospitalization services furnished by community mental health centers (CMHCs).

(d) The following medical and other health services furnished by a comprehensive outpatient rehabilitation facility (CORF) when they are provided outside the patient's plan (of care); or by a home health agency (HHA) to patients who are not under an HHA plan or treatment; or by a hospice program furnishing services to patients outside the hospice benefit:

(1) Antigens.

(2) Splints and casts.

(3) Pneumococcal vaccine, influenza vaccine, and hepatitis B vaccine.

§ 419.22 Hospital outpatient services excluded from payment under the hospital outpatient prospective payment system.

The following services are not paid for under the hospital outpatient prospective payment system:

(a) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(b) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(c) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(d) Certified nurse-midwife services, as defined in section 1861(gg) of the Act.

(e) Services of qualified psychologists, as defined in section 1861(ii) of the Act.

(f) Services of an anesthetist as defined in § 410.69 of this chapter.

(g) Clinical social worker services as defined in section 1861(hh)(2) of the Act.

(h) Outpatient therapy services described in section 1833(a)(8) of the Act.

(i) Ambulance services, as described in section 1861(v)(1)(U) of the Act, or, if applicable, the fee schedule established under section 1834(l).

(j) Except as provided in § 419.22(b)(11), prosthetic devices, prosthetics, prosthetic supplies, and orthotic devices.

(k) Except as provided in § 419.2(b)(10), durable medical equipment supplied by the hospital for the patient to take home.

(l) Clinical diagnostic laboratory services.

(m) Services for patients with ESRD that are paid under the ESRD composite rate and drugs and supplies furnished during dialysis but not included in the composite rate.

(n) Services and procedures that the Secretary designates as requiring inpatient care.

(o) Hospital outpatient services furnished to SNF residents (as defined in § 411.15(p) of this chapter) as part of the patient's 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.

(p) Services that are not covered by Medicare by statute.

(q) Services that are not reasonable or necessary for the diagnosis or treatment of an illness or disease.

Subpart C—Basic Methodology for Determining Prospective Payment Rates for Hospital Outpatient Services

§ 419.30 Base expenditure target for calendar year 1999.

(a) HCFA estimates the aggregate amount that would be payable for

hospital outpatient services in calendar year 1999 by summing—

(1) The total amounts that would be payable from the Trust Fund for covered hospital outpatient services without regard to the outpatient prospective payment system described in this part; and

(2) The total amounts of coinsurance that would be payable by beneficiaries to hospitals for covered hospital outpatient services without regard to the outpatient prospective payment system described in this part.

(b) The estimated aggregate amount under paragraph (a) of this section is determined as though the deductible required under section 1833(b) of the Act did not apply.

§ 419.31 Ambulatory payment classification (APC) system and payment weights.

(a) *APC groups.* (1) HCFA classifies outpatient services and procedures that are comparable clinically and in terms of resource use into APC groups. Except as specified in paragraph (a)(2) of this section, items and services within a group are not comparable with respect to the use of resources if the highest median cost for an item or service within the group is more than 2 times greater than the lowest median cost for an item or service within the group.

(2) HCFA may make exceptions to the requirements set forth in paragraph (a)(1) in unusual cases, such as low volume items and services, but 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.

(3) The payment rate determined for an APC group in accordance with § 419.32, and the copayment amount and program payment amount determined for an APC group in accordance with subpart D of this part, apply to every HCPCS code classified within an APC group.

(b) *APC weighting factors.* (1) Using hospital outpatient claims data from calendar year 1996 and data from the most recent available hospital cost reports, HCFA determines the median costs for the services and procedures within each APC group.

(2) HCFA assigns to each APC group an appropriate weighting factor to reflect the relative median costs for the services within the APC group compared to the median costs for the services in all APC groups.

(c) *Standardizing amounts.* (1) HCFA determines the portion of costs determined in paragraph (b)(1) of this section that is labor-related. This is known as the ''labor-related portion'' of hospital outpatient costs.

(2) HCFA standardizes the median costs determined in paragraph (b)(1) of this section by adjusting for variations in hospital labor costs across geographic areas.

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

(a) *Conversion factor for 1999.* HCFA calculates a conversion factor in such a manner that payment for hospital outpatient services furnished in 1999 would have equaled the base expenditure target calculated in § 419.30, taking into account APC group weights and estimated service frequencies and reduced by the amounts that would be payable in 1999 as outlier payments under § 419.43(d) and transitional pass-through payments under § 419.43(e).

(b) *Conversion factor for calendar year 2000 and subsequent years.* (1) Subject to paragraph (b)(2) of this section, the conversion factor for a calendar year is equal to the conversion factor calculated for the previous year adjusted as follows:

(i) For calendar years 2000, 2001, and 2002, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act reduced by one percentage point.

(ii) For calendar years 2003 and subsequent years, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act.

(2) Beginning in calendar year 2000, HCFA may substitute for the hospital inpatient market basket percentage in paragraph (b) of this section a market basket percentage increase that is determined and applied to hospital outpatient services in the same manner that the hospital inpatient market basket percentage increase is determined and applied to inpatient hospital services.

(c) *Payment rates.* The payment rate for services and procedures for which payment is made under the hospital outpatient prospective payment system is the product of the conversion factor calculated under paragraph (a) or paragraph (b) of this section and the relative weight determined under § 419.31(b).

(d) *Budget neutrality.* HCFA adjusts the conversion factor as needed to ensure that updates and adjustments under § 419.50(a) are budget neutral.

Subpart D—Payments to Hospitals

§ 419.40 Payment concepts.

(a) In addition to the payment rate described in § 419.32, for each APC group there is a predetermined beneficiary coinsurance amount as described in § 419.41(a). The Medicare program payment amount for each APC group is calculated by applying the program payment percentage as described in § 419.41(b).

(b) For purposes of this section—

(1) *Coinsurance percentage* is calculated as the difference between the program payment percentage and 100 percent. The coinsurance percentage in any year is thus defined for each APC group as the *greater* of the following: the ratio of the APC group unadjusted copayment amount *to* the annual APC group payment rate, or 20 percent.

(2) *Program payment percentage* is calculated as the *lower* of the following: the ratio of the APC group payment rate minus the APC group unadjusted coinsurance amount, *to* the APC group payment rate, *or* 80 percent.

(3) *Unadjusted coinsurance amount* is calculated as 20 percent of the wage-adjusted national median of charges for services within an APC group furnished during 1996, updated to 1999 using an actuarial projection of charge increases for hospital outpatient department services during the period 1996 to 1999.

(c) *Limitation of coinsurance amount to inpatient hospital deductible amount.* The coinsurance amount for a procedure performed in a year cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year.

§ 419.41 Calculation of national beneficiary coinsurance amounts and national Medicare program payment amounts.

(a) To calculate the unadjusted coinsurance amount for each APC group, HCFA—

(1) Standardizes 1996 hospital charges for the services within each APC group to offset variations in hospital labor costs across geographic areas;

(2) Identifies the median of the wage-neutralized 1996 charges for each APC group; and

(3) Determines the value equal to 20 percent of the wage-neutralized 1996 median charge for each APC group and multiplies that value by an actuarial projection of increases in charges for hospital outpatient department services during the period 1996 to 1999. The result is the unadjusted beneficiary coinsurance amount for the APC group.

(b) HCFA calculates annually the program payment percentage for every APC group on the basis of each group's unadjusted coinsurance amount and its payment rate after the payment rate is adjusted in accordance with § 419.32.

(c) To determine payment amounts due for a service paid under the hospital

outpatient prospective payment system, HCFA makes the following calculations:

(1) Makes the wage index adjustment in accordance with § 419.43.

(2) Subtracts the amount of the applicable Part B deductible provided under § 410.160 of this chapter.

(3) Multiplies the remainder by the program payment percentage for the group to determine the preliminary Medicare program payment amount.

(4) Subtracts the program payment amount from the amount determined in paragraph (c)(2) of this section to determine the coinsurance amount.

(i) The coinsurance amount for an APC cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year.

(ii) The coinsurance amount is computed as if the adjustments under § 419.43(d) and (e) (and any adjustment made under § 419.43(f) in relation to these adjustments) had not been paid.

(5) Adds the amount by which the coinsurance amount would have exceeded the inpatient hospital deductible for that year to the preliminary Medicare program payment amount determined in paragraph (c)(3) of this section to determine the final Medicare program payment amount.

§ 419.42 Hospital election to reduce coinsurance.

(a) A hospital may elect to reduce coinsurance for any or all APC groups on a calendar year basis. A hospital may *not* elect to reduce copayment for some, but not all, services within the same group.

(b) A hospital must notify its fiscal intermediary of its election to reduce coinsurance no later than—

(1) June 1, 2000, for coinsurance elections for the period July 1, 2000 through December 31, 2000; or

(2) December 1 preceding the beginning of each subsequent calendar year.

(c) The hospital's election must be properly documented. It must specifically identify the APCs to which it applies and the coinsurance amount (within the limits identified below) that the hospital has selected for each group.

(d) The election of reduced coinsurance remains in effect unchanged during the year for which the election was made.

(e) In electing reduced coinsurance, a hospital may elect a level that is less than that year's wage-adjusted coinsurance amount for the group but not less than 20 percent of the APC payment rate as determined in § 419.32.

(f) The hospital may advertise and otherwise disseminate information concerning the reduced level of coinsurance that it has elected. All advertisements and information furnished to Medicare beneficiaries must specify that the coinsurance reductions advertised apply only to the specified services of that hospital and that coinsurance reductions are available only for hospitals that choose to reduce coinsurance for hospital outpatient services and are not allowed in any other ambulatory settings or physician offices.

§ 419.43 Adjustments to national program payment and beneficiary coinsurance amounts.

(a) *General rule.* HCFA determines national prospective payment rates for hospital outpatient department services and determines a wage adjustment factor to adjust the portion of the APC payment and national beneficiary coinsurance amount attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner.

(b) *Labor-related portion of payment and copayment rates for hospital outpatient services.* HCFA determines the portion of hospital outpatient costs attributable to labor and labor-related costs (known as the ''labor-related portion'' of hospital outpatient costs) in accordance with § 419.31(c)(1).

(c) *Wage index factor.* HCFA uses the hospital inpatient prospective payment system wage index established in accordance with part 412 of this chapter to make the adjustment referred to in paragraph (a) of this section.

(d) *Outlier adjustment*—(1) *General rule.* Subject to paragraph (d)(4) of this section, HCFA provides for an additional payment for each hospital outpatient service (or group of services) for which a hospital's charges, adjusted to cost, exceed the following:

(i) A fixed multiple of the sum of—

(A) The applicable Medicare hospital outpatient payment amount determined under § 419.32(c), as adjusted under § 419.43 (other than for adjustments under this paragraph (d) or paragraph (e) of this section); and

(B) Any transitional pass-through payment under paragraph (e) of this section.

(ii) At the option of HCFA, a fixed dollar amount.

(2) *Amount of adjustment.* The amount of the additional payment under paragraph (d)(1) of this section is determined by HCFA and approximates the marginal cost of care beyond the applicable cutoff point under paragraph (d)(1) of this section.

(3) *Limit on aggregate outlier adjustments*—(i) *In general.* The total of the additional payments made under this paragraph (d) for covered hospital outpatient department services furnished in a year (as estimated by HCFA before the beginning of the year) may not exceed the applicable percentage specified in paragraph (d)(3)(ii) of this section of the total program payments (sum of both the Medicare and beneficiary payments to the hospital) estimated to be made under this part for all hospital outpatient services furnished in that year. If this paragraph is first applied to less than a full year, the limit applies only to the portion of the year.

(ii) *Applicable percentage.* For purposes of paragraph (d)(3)(i) of this section, the term ''applicable percentage'' means a percentage specified by HCFA up to (but not to exceed)—

(A) For a year (or portion of a year) before 2004, 2.5 percent; and

(B) For 2004 and thereafter, 3.0 percent.

(4) *Transitional authority.* In applying paragraph (d)(1) of this section for hospital outpatient services furnished before January 1, 2002, HCFA may—

(i) Apply paragraph (d)(1) of this section to a bill for these services related to an outpatient encounter (rather than for a specific service or group of services) using hospital outpatient payment amounts and transitional pass-through payments covered under the bill; and

(ii) Use an appropriate cost-to-charge ratio for the hospital or CMHC (as determined by HCFA), rather than for specific departments within the hospital.

(e) *Transitional pass-through for additional costs of innovative medical devices, drugs, and biologicals*—(1) *General rule.* HCFA provides for an additional payment under this paragraph for any of the following that are provided as part of a hospital outpatient service (or group of services):

(i) *Current orphan drugs.* A drug or biological that is used for a rare disease or condition with respect to which the drug or biological has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act if payment for the drug or biological as an outpatient hospital service under this part was being made on the first date that the system under this part is implemented.

(ii) *Current cancer therapy drugs and biologicals and brachytherapy.* A drug or biological that is used in cancer therapy, including, but not limited to, a chemotherapeutic agent, an antiemetic,

a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, a bisphosphonate, and a device of brachytherapy, if payment for the drug, biological, or device as an outpatient hospital service under this part was being made on the first date that the system under this part is implemented.

(iii) *Current radiopharmaceutical drugs and biological products.* A radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine procedures if payment for the drug or biological as an outpatient hospital service under this part was being made on the first date that the system under this part is implemented.

(iv) *New medical devices, drugs, and biologicals.* A medical device, drug, or biological not described in paragraph (e)(1)(i), (e)(1)(ii), or (e)(1)(iii) of this section if—

(A) Payment for the device, drug, or biological as an outpatient hospital service under this part was not being made as of December 31, 1996; and

(B) The cost of the device, drug, or biological is not insignificant (as defined in paragraph (e)(1)(iv)(C) of this section) in relation to the hospital outpatient fee schedule amount (as calculated under § 419.32(c)) payable for the service (or group of services) involved.

(C) The cost of the device, drug, or biological is considered not insignificant if it meets all of the following thresholds:

(*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 current 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 fee schedule amount determined to be associated with the item exceeds 10 percent of the applicable hospital outpatient fee schedule amount.

(2) *Limited period of payment.* The payment under this paragraph (e) with respect to a medical device, drug, or biological applies during a period of at least 2 years, but not more than 3 years, that begins—

(i) On the first date this section is implemented in the case of a drug, biological, or device described in paragraphs (e)(2)(i), (e)(2)(ii), or (e)(2)(iii) of this section and in the case of a device, drug, or biological described in paragraph (e)(1)(iv) of this section and for which payment under this part is made as an outpatient hospital service before the first date; or

(ii) In the case of a device, drug, or biological described in paragraph (e)(1)(iv) of this section not described in paragraph (e)(2)(i) of this section, on the first date on which payment is made under this part for the device, drug, or biological as an outpatient hospital service.

(3) *Amount of additional payment.* Subject to paragraph (e)(4)(iii) of this section, the amount of the payment under this paragraph is—

(i) In the case of a drug or biological, the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare hospital outpatient fee schedule amount that HCFA determines is associated with the drug or biological; or

(ii) In the case of a medical device, the amount by which the hospital's charges for the device, adjusted to cost, exceeds the portion of the otherwise applicable Medicare hospital outpatient fee schedule amount that HCFA determines is associated with the device.

(4) *Limit on aggregate annual adjustment*—(i) *General rule.* The total of the additional payments made under this paragraph for hospital outpatient services furnished in a year, as estimated by HCFA before the beginning of the year, may not exceed the applicable percentage specified in paragraph (e)(4)(ii) of this section of the total program payments estimated to be made under this section for all hospital outpatient services furnished in that year. If this paragraph is first applied to less than a full year, the limit applies only to the portion of the year.

(ii) *Applicable percentage.* For purposes of paragraph (e)(4)(i) of this section, the term ''applicable percentage'' means—

(A) For a year (or portion of a year) before 2004, 2.5 percent; and

(B) For 2004 and thereafter, a percentage specified by HCFA up to (but not to exceed) 2.0 percent.

(iii) *Uniform prospective reduction if aggregate limit projected to be exceeded.* If HCFA estimates before the beginning of a year that the amount of the additional payments under this paragraph (e) for the year (or portion thereof) as determined under paragraph (e)(4)(i) of this section without regard to this paragraph (e)(4)(iii) would exceed the limit established under this paragraph (e)(4)(iii), HCFA reduces pro rata the amount of each of the additional payments under this paragraph for that year (or portion thereof) in order to ensure that the aggregate additional payments under this paragraph (as so estimated) do not exceed the limit.

(f) *Budget neutrality.* Outlier adjustments under paragraph (d) of this section and transitional pass-through payments under paragraph (e) of this section are established in a budget-neutral manner.

§ 419.44 Payment reductions for surgical procedures.

(a) *Multiple surgical procedures.* When more than one surgical procedure for which payment is made under the hospital outpatient prospective payment system is performed during a single surgical encounter, the Medicare program payment amount and the beneficiary copayment amount are based on—

(1) The full amounts for the procedure with the highest APC payment rate; and

(2) One-half of the full program and the beneficiary payment amounts for all other covered procedures.

(b) *Terminated procedures.* When a surgical procedure is terminated prior to completion due to extenuating circumstances or circumstances that threaten the well-being of the patient, the Medicare program payment amount and the beneficiary copayment amount are based on—

(1) The full amounts if the procedure is discontinued after the induction of anesthesia or after the procedure is started; or

(2) One-half of the full program and the beneficiary coinsurance amounts if the procedure is discontinued after the patient is prepared for surgery and taken to the room where the procedure is to be performed but before anesthesia is induced.

Subpart E—Updates

§ 419.50 Annual review.

(a) *General rule.* Not less often than annually, HCFA reviews and updates groups, relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

(b) *Consultation requirement.* HCFA will consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise HCFA concerning) the clinical integrity of the groups and weights. The panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting the review.

(c) *Effective dates.* HCFA conducts the first annual review under paragraph (a) of this section in 2001 for payments made in 2002.

Subpart F—Limitations on Review

§ 419.60 Limitations on administrative and judicial review.

There can be no administrative or judicial review under sections 1869 and 1878 of the Act or otherwise of the following:

(a) The development of the APC system, including—

(1) Establishment of the groups and relative payment weights;

(2) Wage adjustment factors;

(3) Other adjustments; and

(4) Methods for controlling unnecessary increases in volume.

(b) The calculation of base amounts described in section 1833(t)(3) of the Act.

(c) Periodic adjustments described in section 1833(t)(9) of the Act.

(d) The establishment of a separate conversion factor for hospitals described in section 1886(d)(1)(B)(v) of the Act.

(e) The determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under § 419.43(d) or the determination of insignificance of cost, the duration of the additional payments (consistent with § 419.43(e)), the portion of the Medicare hospital outpatient fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under § 419.43(e).

Subpart G—Transitional Corridors

§ 419.70 Transitional adjustment to limit decline in payment.

(a) *Before 2002.* Except as provided in paragraph (d) of this section, for covered hospital outpatient services furnished before January 1, 2002, for which the prospective payment system amount (as defined in paragraph (e) of this section) is—

(1) At least 90 percent, but less than 100 percent, of the pre-BBA amount (as defined in paragraph (f) of this section), the amount of payment under this part is increased by 80 percent of the amount of this difference;

(2) At least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this part is increased by the amount by which the product of 0.71 and the pre-BBA amount exceeds the product of 0.70 and the prospective payment system amount;

(3) At least 70 percent, but less than 80 percent, of the pre-BBA amount, the amount of payment under this part is increased by the amount by which the product of 0.63 and the pre-BBA amount, exceeds the product of 0.60 and the PPS amount; or

(4) Less than 70 percent of the pre-BBA amount, the amount of payment under this part shall be increased by 21 percent of the pre-BBA amount.

(b) *For 2002.* Except as provided in paragraph (d) of this section, for covered hospital outpatient services furnished during 2002, for which the prospective payment system amount is—

(1) At least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this part is increased by 70 percent of the amount of this difference;

(2) At least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this part is increased by the amount by which the product of 0.61 and the pre-BBA amount exceeds the product of 0.60 and the prospective payment system amount; or

(3) Less than 80 percent of the pre-BBA amount, the amount of payment under this part is increased by 13 percent of the pre-BBA amount.

(c) *For 2003.* Except as provided in paragraph (d) of this section, for covered hospital outpatient services furnished during 2003, for which the prospective payment system amount is—

(1) At least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this part is increased by 60 percent of the amount of this difference; or

(2) Less than 90 percent of the pre-BBA amount, the amount of payment under this part is increased by 6 percent of the pre-BBA amount.

(d) *Hold harmless provisions*—(1) *Temporary treatment for small rural hospitals.* For covered hospital outpatient services furnished in a calendar year before January 1, 2004 for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by the amount of that difference if the hospital—

(i) Is located in a rural area as defined in § 412.63(b) of this chapter or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act; and

(ii) Has 100 or fewer beds as defined in § 412.105(b) of this chapter.

(2) *Permanent treatment for cancer hospitals.* In the case of a hospital described in § 412.23(f) of this chapter for which the prospective payment system amount is less than the pre-BBA amount for covered hospital outpatient services, the amount of payment under this part is increased by the amount of this difference.

(e) *Prospective payment system amount defined.* In this paragraph, the term ''prospective payment system amount'' means, with respect to covered hospital outpatient services, the amount payable under this part for these services (determined without regard to this paragraph or any reduction in coinsurance elected under § 419.42), including amounts payable as copayment under § 419.41, coinsurance under section 1866(a)(2)(A)(ii) of the Act, and the deductible under section 1833(b) of the Act.

(f) *Pre-BBA amount defined*—(1) *General rule.* In this paragraph, the ''pre-BBA amount'' means, with respect to covered hospital outpatient services furnished by a hospital or a community mental health center (CMHC) in a year, an amount equal to the product of the reasonable cost of the provider for these services for the portions of the provider's cost reporting period (or periods) occurring in the year and the base provider outpatient payment-to-cost ratio for the provider (as defined in paragraph (f)(2) of this section).

(2) *Base payment-to-cost-ratio defined.* For purposes of this paragraph, HCFA shall determine these ratios as if the amendments to sections 1833(i)(3)(B)(i)(II) and 1833(n)(1)(B)(i) of the Act made by section 4521 of the BBA, to require that the full amount beneficiaries paid as coinsurance under section 1862(a)(2)(A) of the Act are taken into account in determining Medicare Part B Trust Fund payment to the hospital, were in effect in 1996. The ''base payment-to-cost ratio'' for a hospital or CMHC means the ratio of—

(i) The provider's payment under this part for covered outpatient services furnished during the cost reporting period ending in 1996, including any payment for these services through cost-sharing described in paragraph (e) of this section; and

(ii) The reasonable cost of these services for this period, without applying the cost reductions under section 1861(v)(1)(S) of the Act.

(g) *Interim payments.* HCFA makes payments under this paragraph to hospitals and CMHCs on an interim basis, subject to retrospective adjustments based on settled cost reports.

(h) *No effect on coinsurance.* No payment made under this section affects the unadjusted coinsurance amount or the coinsurance amount described in § 419.41.

(i) *Application without regard to budget neutrality.* The additional payments made under this paragraph—

(1) Are not considered an adjustment under § 419.43(f); and

(2) Are not implemented in a budget neutral manner.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

G. Part 424 is amended as set forth below:

1. The authority citation for part 424 continues to read as follows:

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

2. In § 424.24, the heading to paragraph (e) is republished, and a new paragraph (e)(3) is added to read as follows:

§ 424.24 Requirements for medical and other health services furnished by providers under Medicare Part B.

* * * * *

(e) *Partial hospitalization services: Content of certification and plan of treatment requirements*—

* * * * *

(3) *Recertification requirements.*

(i) *Signature.* The physician recertification must be signed by a physician who is treating the patient and has knowledge of the patient's response to treatment.

(ii) *Timing.* The first recertification is required as of the 18th day of partial hospitalization services. Subsequent recertifications are required at intervals established by the provider, but no less frequently than every 30 days.

(iii) *Content.* The recertification must specify that the patient would otherwise require inpatient psychiatric care in the absence of continued stay in the partial hospitalization program and describe the following:

(A) The patient's response to the therapeutic interventions provided by the partial hospitalization program.

(B) The patient's psychiatric symptoms that continue to place the patient at risk of hospitalization.

(C) Treatment goals for coordination of services to facilitate discharge from the partial hospitalization program.

* * * * *

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

H. Part 489 is amended as set forth below:

1. The authority citation to part 489 continues to read as follows:

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

Subpart B—Essentials of Provider Agreements

2. In § 489.20, the introductory text to the section is republished; the introductory text to paragraph (d) is revised; paragraphs (d)(3), (d)(4), and (d)(5) are redesignated as paragraphs (d)(4), (d)(5), and (d)(6), respectively; and a new paragraph (d)(3) is added to read as follows:

§ 489.20 Basic commitments.

The provider agrees to the following:

* * * * *

(d) In the case of a hospital or a CAH that furnishes services to Medicare beneficiaries, either to furnish directly or to make arrangements (as defined in § 409.3 of this chapter) for all Medicare-covered services to inpatients and outpatients of a hospital or a CAH except the following:

* * * * *

(3) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

* * * * *

3. In § 489.24, the definition for ''Comes to the emergency department'' in paragraph (b) is revised, and a new paragraph (i) is added to read as follows:

§ 489.24 Special responsibilities of Medicare hospitals in emergency cases.

* * * * *

(b) * * *

Comes to the emergency department means, with respect to an individual requesting examination or treatment, that the individual is on the hospital property. For purposes of this section, ''property'' means the entire main hospital campus as defined in § 413.65(b) of this chapter, including the parking lot, sidewalk, and driveway, as well as any facility or organization that is located off the main hospital campus but has been determined under § 413.65 of this chapter to be a department of the hospital. The responsibilities of hospitals with respect to these off-campus facilities or organizations are described in paragraph (i) of this section. Property also includes ambulances owned and operated by the hospital even if the ambulance is not on hospital grounds. An individual in a nonhospital-owned ambulance on hospital property is considered to have come to the hospital's emergency department. An individual in a nonhospital-owned ambulance off hospital property is not considered to have come to the hospital's emergency department even if a member of the ambulance staff contacts the hospital by telephone or telemetry communications and informs the hospital that they want to transport the individual to the hospital for examination and treatment. In these situations, the hospital may deny access if it is in ''diversionary status,'' that is, it does not have the staff or facilities to accept any additional emergency patients. If, however, the ambulance staff disregards the hospital's instructions and transports the individual on to hospital property, the individual is considered to have come to the emergency department.

* * * * *

(i) *Off-campus departments.* If an individual comes to a facility or organization that is located off the main hospital campus but has been determined under § 416.35 of this chapter to be a department of the hospital and a request is made on the individual's behalf for examination or treatment of a potential emergency medical condition as otherwise described in paragraph (a) of this section, the hospital is obligated in accordance with the rules in this paragraph to provide the individual with an appropriate medical screening examination and any necessary stabilizing treatment or an appropriate transfer.

(1) *Capability of the hospital.* The capability of the hospital includes that of the hospital as a whole, not just the capability of the off-campus department. Except for cases described in paragraph (i)(3)(ii) of this section, the obligation of a hospital under this section must be discharged within the hospital as a whole. However, the hospital is not required to locate additional personnel or staff to off-campus departments to be on standby for possible emergencies.

(2) *Protocols for off-campus departments.* The hospital must establish protocols for the handling of individuals with potential emergency conditions at off-campus departments. These protocols must provide for direct contact between personnel at the off-campus department and emergency personnel at the main hospital campus and may provide for dispatch of practitioners, when appropriate, from the main hospital campus to the off-campus department to provide screening or stabilization services.

(i) If the off-campus department is an urgent care center, primary care center, or other facility that is routinely staffed by physicians, RNs, or LPNs, these department personnel must be trained, and given appropriate protocols, for the handling of emergency cases. At least one individual on duty at the off-campus department during its regular hours of operation must be designated

as a qualified medical person as described in paragraph (d) of this section. The qualified medical person must initiate screening of individuals who come to the off-campus department with a potential emergency medical condition, and may be able to complete the screening and provide any necessary stabilizing treatment at the off-campus department, or to arrange an appropriate transfer.

(ii) If the off-campus department is a physical therapy, radiology, or other facility not routinely staffed with physicians, RNs, or LPNs, the department's personnel must be given protocols that direct them to contact emergency personnel at the main hospital campus for direction. Under this direction, and in accordance with protocols established in advance by the hospital, the personnel at the off-campus department must describe patient appearance and report symptoms and, if appropriate, either arrange transportation of the individual to the main hospital campus in accordance with paragraph (i)(3)(i) of this section or assist in an appropriate transfer as described in paragraphs (i)(3)(ii) and (d)(2) of this section.

(3) *Movement or appropriate transfer from off-campus departments*—(i) If the main hospital campus has the capability required by the individual and movement of the individual to the main campus would not significantly jeopardize the life or health of the individual, the personnel at the off-campus department must assist in arranging this movement. Movement of the individual to the main campus of the hospital is not considered a transfer under this section, since the individual is simply being moved from one department of a hospital to another department or facility of the same hospital.

(ii) If transfer of an individual with a potential emergency condition to a medical facility other than the main hospital campus is warranted, either because the main hospital campus does not have the specialized capability or facilities required by the individual, or because the individual's condition is deteriorating so rapidly that taking the time needed to move the individual to the main hospital campus would significantly jeopardize the life or health of the individual, personnel at the off-campus department must, in accordance with protocols established in advance by the hospital, assist in arranging an appropriate transfer of the individual to a medical facility other than the main hospital. The protocols must include procedures and agreements established in advance with other hospitals or medical facilities in the area of the off-campus department to facilitate these appropriate transfers. Such a transfer would require—

(A) That there be either a request by or on behalf of the individual as described in paragraph (d)(1)(ii)(A) of this section or a certification by a physician or a qualified medical person as described in paragraph (d)(1)(ii)(B) or (d)(1)(ii)(C) of this section; and

(B) That the transfer comply with the requirements described in paragraph (d)(2) of this section.

(iii) If the individual is being appropriately transferred to another medical facility from the off-campus department, the requirement for the provision of medical treatment in paragraph (d)(2)(i) of this section would be met by provision of medical treatment within the capability of the transferring off-campus department.

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/MR AND CERTAIN NFs IN THE MEDICAID PROGRAM

I. Part 498 is amended as set forth below:

1. The authority citation for part 498 continues to read as follows:

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

2. In § 498.2, the introductory text is republished, and the definition of ''Provider'' is revised to read as follows:

§ 498.2 Definitions.

As used in this part—

* * * * *

Provider means a hospital, critical access hospital (CAH), skilled nursing facility (SNF), comprehensive outpatient rehabilitation facility (CORF), home health agency (HHA), or hospice, that has in effect an agreement to participate in Medicare, that has in effect an agreement to participate in Medicaid, or a clinic, rehabilitation agency, or public health agency that has a similar agreement but only to furnish outpatient physical therapy or outpatient speech pathology services, and *prospective provider* means any of the listed entities that seeks to participate in Medicare as a provider or to have any facility or organization determined to be a department of the provider or provider-based entity under § 413.65 of this chapter.

* * * * *

3. In § 498.3, the introductory text to paragraph (b) is republished; paragraphs (b)(2) through (b)(15) are redesignated as paragraphs (b)(3) through (b)(16), respectively; and a new paragraph (b)(2) is added to read as follows:

§ 498.3 Scope and applicability.

* * * * *

(b) *Initial determinations by HCFA.* HCFA makes initial determinations with respect to the following matters:

* * * * *

(2) Whether a prospective department of a provider, remote location of a hospital, satellite facility, or provider-based entity qualifies for provider-based status under § 413.65 of this chapter, or whether such a facility or entity currently treated as a department of a provider, remote location of a hospital, satellite facility, or a provider-based entity no longer qualifies for that status under § 413.65 of this chapter.

* * * * *

PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

J. Part 1003 is amended as set forth below:

1. The authority citation for part 1003 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1320–7, 1320a–7a, 1320a–7e, 1320b–10, 1395u(j), 1395u(k), 1395cc(g), 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396(m), 11131(c), and 11137(b)(2).

2. Section 1003.100 is amended by revising paragraph (a), by republishing the introductory text to paragraphs (b) and (b)(1), by revising paragraphs (b)(1)(xi) and (b)(1)(xii), and by adding paragraph (b)(1)(xiii) to read as follows:

§ 1003.100 Basis and purpose.

(a) *Basis.* This part implements sections 1128(c), 1128A, 1128E, 1140, 1866(g), 1876(i), 1877(g), 1882(d) and 1903(m)(5) of the Social Security Act, and sections 421(c) and 427(b)(2) of Pub. L. 99–660 (42 U.S.C. 1320a–7, 1320a–7a, 1320a–7e, 1320a–7c, 1320b–10, 1395cc(g), 1395mm, 1395ss(d), 1396(m), 11131(c), and 11137(b)(2)).

(b) *Purpose.* This part—

(1) Provides for the imposition of civil money penalties and, as applicable, assessments against persons who—

* * * * *

(xi) Are physicians or entities that enter into an arrangement or scheme that they know or should know has as a principal purpose the assuring of referrals by the physician to a particular entity that, if made directly, would violate the provisions of § 411.353 of this title;

(xii) Violate the Federal health care programs' anti-kickback statute as set forth in section 1128B of the Act; or

(xiii) Knowingly and willfully present, or cause to be presented, a bill or request for payment for nonphysician services furnished to hospital patients (unless the services are furnished by the hospital, either directly or under an arrangement) in violation of sections 1862(a)(14) and 1866(a)(1)(H) of the Act.

* * * * *

3. Section 1003.102 is amended by republishing the introductory text to paragraph (b), by adding and reserving paragraphs (b)(12) through (b)(14), and by adding a new paragraph (b)(15) to read as follows:

§ 1003.102 Basis for civil money penalties and assessments.

* * * * *

(b) The OIG may impose a penalty, and where authorized, an assessment against any person (including an insurance company in the case of paragraphs (b)(5) and (b)(6) of this section) whom it determines in accordance with this part—

* * * * *

(15) Has knowingly and willfully presented, or caused to be presented, a bill or request for payment for items and services furnished to a hospital patient for which payment may be made under the Medicare or another Federal health care program, if that bill or request is inconsistent with an arrangement under section 1866(a)(1)(H) of the Act, or violates the requirements for such an arrangement.

* * * * *

4. Section 1003.103 is amended by revising paragraph (a), by adding and reserving paragraphs (i) and (j), and by adding a new paragraph (k) to read as follows:

§ 1003.103 Amount of penalty.

(a) Except as provided in paragraphs (b) and (d) through (k) of this section, the OIG may impose a penalty of not more than $10,000 for each item or service that is subject to a determination under § 1003.102.

* * * * *

(k) For violations of section 1862(a)(14) of the Act and § 1003.102(b)(15), the OIG may impose a penalty of not more than $2,000 for each bill or request for payment for items and services furnished to a hospital patient.

5. Section 1003.105 is amended by republishing the introductory text to paragraph (a)(1) and by revising paragraph (a)(1)(i) to read as follows:

§ 1003.105 Exclusion from participation in Medicare, Medicaid and other Federal health care programs.

(a)(1) Except as set forth in paragraph (b) of this section, in lieu of or in addition to any penalty or assessment, the OIG may exclude from participation in Medicare, Medicaid and other Federal health care programs the following persons for a period of time determined under § 1003.107—

(i) Any person who is subject to a penalty or assessment under § 1003.102(a), (b)(1) through (b)(4), or (b)(15).

* * * * *

(Catalog of Federal Domestic Assistance 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: March 3, 2000.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Dated: March 28, 2000.

June G. Brown,

Inspector General, Department of Health and Human Services.

Approved: March 29, 2000.

Donna E. Shalala,

Secretary.

Note: The following addenda will not appear in the Code of Federal Regulations.

Note to Addenda A, B, C, E and F: Addenda A, B, and C have a number of errors in the following columns: APC, status indicator, payment rate, and national unadjusted coinsurance and minimum unadjusted coinsurance. We identified these errors too late in preparing this rule for publication to correct them. Some of the errors are related to the status codes assigned to the HCPCS codes and APCs.

Some errors affect addenda B, C, and E. Several of these errors involve procedures incorrectly identified as inpatient procedures, and one inpatient procedure incorrectly identified as an outpatient procedure. Certain PET scan codes and other codes are shown in incorrect APCs. Screening sigmoidoscopy and colonoscopy APCs have the wrong HCPCS codes and incorrect payment rates and coinsurance amounts. Certain dental codes were inadvertently identified as errors, so their correct APC assignments, payment rate and coinsurance amounts were not shown in the addenda. Two breath tests are subject to the clinical diagnostic lab fee schedule. We have listed below the corrections that have payment implications.

Addendum F does not include status indicators G and H which identify items that are eligible for pass-through payments. (See section III.B.3 of the preamble for a complete description of all status indications used in conjunction with this final rule.)

We also note that the word ''proposed'' should not appear on any Addenda contained in this final rule such as on Addendum A or C.

The fiscal intermediaries will receive the necessary changes to process outpatient PPS claims correctly. We will post the corrected Addendum B on our Website and publish a correction document in the **Federal Register**.

Our Website address is *http://www.hcfa.gov/medicare/hopsmain.htm.*

LIST ACCOMPANYING NOTE TO ADDENDA A, B, C, E AND F

CPT/ HCPCS	HOPD Status Indicator	Description	APC	Relative Weight	Proposed Payment Rate	National Unadjusted Coinsurance	Minimum Unadjusted Coinsurance
20979	E	US bone stimulation.					
31375	C	Partial removal of larynx.					
35481	T	Atherectomy, open	0081	19.36	$938.71	$434.25	$187.74
61795	S	Brain surgery using computer	0302	8.21	$398.08	$216.55	$79.62
61886	T	Implant neurostim arrays	0222	25.48	$1,235.45	$780.07	$247.09
75945	S	Intravascular us	0267	2.72	$131.88	$80.06	$26.38
75946	S	Intravascular us add-on	0267	2.72	$131.88	$80.06	$26.38
78267	A	Breath test attain/anal, c-14.					
78268	A	Breath test analysis, c-14.					
92978	S	Intravasc us, heart add-on	0267	2.72	$131.88	$80.06	$26.38
92979	S	Intravasc us, heart add-on	0267	2.72	$131.88	$80.06	$26.38
96570	T	Photodynamic Tx, 30 min	0973	5.16	$250.19	.....	$50.04
96571	T	Photodynamic Tx, addl 15 min	0973	5.16	$250.19	.....	$50.04
D0277	S	Vert bitewings-sev to eight	0330	1.51	$73.22	$14.64	$14.64
D0472	S	Gross exam, prep & report	0330	1.51	$73.22	$14.64	$14.64