



# Federal Register

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**Monday,  
November 13, 2000**

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## **Part II**

### **Department of Health and Human Services**

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**Health Care Financing Administration**

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**42 CFR Part 419**

**Medicare Program; Prospective Payment  
System for Hospital Outpatient Services;  
Interim Final Rule**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Care Financing Administration**

**42 CFR Part 419**

[HCFA-1005-IFC]

RIN 0938-A156

**Medicare Program; Prospective Payment System for Hospital Outpatient Services**

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

**ACTION:** Interim final rule with comment period.

**SUMMARY:** This interim final rule with comment period provides for the annual update to the Medicare hospital outpatient prospective payment system conversion factor that is used to calculate the payment amount for each payment group, effective January 1, 2001. It also updates the wage index values and incorporates the year 2001 changes in the procedure codes that are used to make payments under this system. In this rule, we are also responding to public comments received on those portions of the April 7, 2000 final rule with comment period (which established the hospital outpatient prospective payment system) that implemented related provisions of the Balanced Budget Refinement Act (BBRA) of 1999. In addition, we are responding to public comments on the August 3, 2000 interim final rule with comment period that modified the April 7, 2000 final rule with comment period by revising the criteria used to define new or innovative medical devices, drugs, and biologicals eligible for transitional pass-through payments and correcting the criteria for grandfathering provider-based Federally Qualified Health Centers (FQHC) into the prospective payment system.

**DATES:**

*Effective Date:* These regulations are effective on January 1, 2001.

*Comment Period:* We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on January 12, 2001.

**ADDRESSES:** Mail written comments (1 original and 3 copies) to the following address:

Health Care Financing Administration,  
Department of Health and Human Services, Attention: HCFA-1005-IFC,  
P.O. Box 8013, Baltimore, MD 21244-8013.

To ensure that mailed comments are received in time for us to consider them,

please allow for possible delays in delivering them.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 443-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or  
Room C5-14-03, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Comments mailed to the above addresses may be delayed and received too late for us to consider them. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-1005-IFC. of the 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 office at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 to 5 p.m. (phone: (202) 690-7890).

**FOR FURTHER INFORMATION CONTACT:**

Janet Wellham (410) 786-4510, Chuck Braver, (410) 786-6719, or Jana Petze (410) 786-9374, (for general information).

Kity Ahern, (410) 786-4515 (for information related to ambulatory payment classification groups and transitional pass-through payments related to drugs and biologicals).  
Majorie Baldo, (410) 786-4617 or Barry Levi, (410) 786-4529 (for information related to transitional pass-through payments for medical devices).  
George Morey (410) 786-4653 (for information related to the criteria for grandfathering provider-based FQHCs into the prospective payment system).

**SUPPLEMENTARY INFORMATION:**

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#### Alphabetical List of Acronyms Appearing in the Interim Final Rule With Comment Period

- 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
- CAT Computerized axial tomography
- CCI [HCFA's] Correct Coding Initiative
- CCR Cost center specific cost-to-charge ratio
- CMHC Community mental health center
- 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, prosthetics (which include prosthetic devices and implants) orthotics, and supplies
- DRG Diagnosis-related group
- FDA Food and Drug Administration
- FQHC Federally qualified health center
- HCPCS HCFA Common Procedure Coding System
- HHA Home health agency
- ICD-9-CM International Classification of Diseases, Ninth Edition, Clinical Modification
- IME Indirect medical education
- JCAHO Joint Commission on Accreditation of Healthcare Organizations
- MRI Magnetic resonance imaging
- MSA Metropolitan statistical area
- NECMA New England County Metropolitan Area
- PPS Prospective payment system
- RFA Regulatory Flexibility Act
- RHC Rural health clinic
- RRC Rural referral center
- SCH Sole community hospital
- SNF Skilled nursing facility

#### I. Background

*A. General Summary of April 7, 2000 Final Rule With Comment Period That Implemented Amendments Enacted by the Balanced Budget Act of 1997 and the Balanced Budget Refinement Act of 1999*

On April 7, 2000, we published in the **FEDERAL REGISTER** (65 FR 18434) a final

rule with comment period to implement a new prospective payment system for hospital outpatient services. This new system establishes prospective payment rates for covered outpatient hospital services using ambulatory payment classification (APC) groups. The April 7, 2000 final rule with comment period implemented section 4523 of the Balanced Budget Act of 1997 (the BBA 1997), Public Law 105-33, and related sections of the Balanced Budget Refinement Act of 1999 (the BBRA 1999), Public Law 106-113. Section 4523 of the BBA 1997 amended section 1833 of the Social Security Act (the Act) by adding subsection (t) to provide for implementation of a prospective payment system for hospital outpatient services furnished to Medicare beneficiaries. Section 1833(t) of the Act, as added by the BBA 1997—

- Authorizes the Secretary to designate the hospital outpatient services that would be paid under the prospective payment system and requires that the hospital outpatient prospective payment system include hospital inpatient services designated by the Secretary that are covered under Medicare Part B for beneficiaries who are entitled to Part A benefits but who have exhausted them or are otherwise entitled to them.

- Sets forth certain requirements for the hospital outpatient prospective payment system, including the requirement that a classification system for covered outpatient services be developed that may consist of groups arranged so that the services within each group are comparable clinically and with respect to the use of resources.

- 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. (This provision has subsequently been changed by the BBRA 1999, as discussed later in this preamble.)

- 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.

- Authorizes the Secretary 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 the Secretary determines to be necessary to ensure equitable payments.

- Requires the Secretary to develop a method for controlling unnecessary

increases in the volume of covered outpatient services.

- Specifies how beneficiary deductibles are to be treated when 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 a group of covered services) furnished during 1996 and updated to 1999 using the Secretary's estimated charge growth from 1996 to 1999.

- Prescribes the formula for calculating the initial conversion factor used to determine 1999 Medicare payment amounts and the method for updating the conversion factor in subsequent years.

- Describes the method for determining the Medicare payment amount and the beneficiary coinsurance amount for services covered under the outpatient prospective payment system. (This section was amended by the BBRA 1999, as discussed later in this preamble.)

- Requires the Secretary to establish a procedure whereby hospitals may voluntarily elect to reduce beneficiary copayment for some or all covered services to an amount no less than 20 percent of the Medicare payment amount. Hospitals are further allowed to disseminate information on any such reductions of copayment amounts. Section 4451 of the BBA 1997 added section 1861(v)(1)(T) to the Act, which provides that any reduction in copayment, must not be treated as a bad debt.

- Authorizes periodic review and revision of the payment groups, relative payment weights, wage index, and conversion factor. (This section was amended by the BBRA 1999, as discussed later in this preamble.)

- Describes how payment is to be made for ambulance services, which are specifically excluded from the hospital outpatient prospective payment system under section 1833(t)(1)(B) of the Act.

- Provides that the Secretary may establish a separate conversion factor for services furnished by cancer hospitals that are excluded from the hospital inpatient prospective payment system.

- Prohibits administrative or judicial review of the hospital outpatient prospective payment system classification system, the payment 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 prospective payment system. (This section was expanded by the BBRA 1999, as discussed later in this preamble.)

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 prospective payment system for some services described in section 1832(a)(2) of the Act 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 hospital outpatient prospective payment system.

Before enactment of section 4521(b) of the BBA 1997, the blended payment formulas for ambulatory surgery centers (ASC) procedures, radiology, and other diagnostic services, the ASC or physician fee schedule portion were 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) of the BBA 1997, which amended sections 1833(i)(3)(B)(i)(II) and 1833(n)(1)(B)(i) of the Act, corrected 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 ASC 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).

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. (This section was further amended by the BBRA 1999.)

(Refer to the April 7, 2000 hospital outpatient prospective payment system final rule with comment period for a more in-depth description of how the changes made by the BBA 1997 and the BBRA 1999 were implemented.)

On November 29, 1999, after we had published a proposed rule to implement section 4253 of the BBA 1997, the BBRA

1999 was enacted. The BBRA 1999 made major changes that affected the hospital outpatient prospective payment system that was established by the BBA 1997 and implemented in the April 7, 2000 final rule with comment period. Therefore, in the April 7, 2000 final rule with comment period, we also implemented 14 provisions of the BBRA 1999 that affected the hospital outpatient prospective payment system and solicited public comments on those provisions. The BBRA 1999 provisions on which we solicited comments included the following:

#### 1. Outlier Adjustment

Section 201(a) of the BBRA 1999 amended section 1833(t) of the Act by adding a new paragraph (5) to provide that the Secretary must make payment adjustments (that is, an outlier payment) for covered services whose costs exceed a threshold determined by the Secretary. 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 the hospital outpatient prospective payment system 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 added new section 1833(t)(6) to the Act, establishing transitional pass-through payments for certain medical devices, drugs, and biologicals. This provision specifies the types of items for which additional payments must be made; describes the amount of the additional payments; limits these payments to at least 2, 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 must reduce pro rata the amount of the additional payments if, before the beginning of a year, he or she estimates that these payments would otherwise exceed the caps.

#### 3. Budget Neutrality Applied to New Adjustments

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

#### 4. Limitation on Judicial Review

Section 201(d) of the BBRA 1999 amended 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 prospective payment system payment amount associated with particular devices, drugs, or biologicals, and any pro rata reduction.

#### 5. Inclusion in the Hospital Outpatient Prospective Payment System of Certain Implantable Items

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

#### 6. Payment Weights Based on Median or Mean Hospital Costs

Section 201(f) of the BBRA 1999 amended 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 amended 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 cost (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 Prospective Payment System Components

Section 201(h) of the BBRA 1999 amended redesignated section 1833(t)(8) of the Act to require at least an annual review of the payment 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. Section 201(h)(2) provides that the first annual review must be conducted in 2001 for application in 2002. The section was 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 Health and Human Services (HHS) for review and advisory purposes.

#### 9. Coinsurance Not Affected by Pass-Throughs

Section 201(i) of the BBRA 1999 amended 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 additional 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 amended section 1861(v)(1)(S)(ii) of the Act to extend, until the first date that the hospital outpatient prospective payment system 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 Prospective Payment System

Section 201(l) of the BBRA 1999 provided 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 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."

#### 12. Transitional Corridors for Application of Outpatient Prospective Payment System

Section 202 of the BBRA 1999 amended section 1833(t) of the Act by redesignating paragraphs (7) through (11) as paragraphs (8) through (12),

respectively, and adding a new paragraph (7), which provides for a transitional adjustment to limit payment reductions under the hospital outpatient prospective payment system. More specifically, from the date the prospective payment system is implemented through 2003, a provider, including a CMHC, will receive an adjustment if its prospective payment system payments for outpatient services furnished during the year is less than a set percentage of its "pre-BBA" amount for that year. The pre-BBA amount is the product of the reasonable costs the hospital incurs for prospective payment system services during the year and the payment-to-cost ratio for covered prospective payment system services furnished during the cost report period ending during 1996. Two categories of hospitals, rural hospitals with 100 or fewer beds and cancer hospitals, will be held harmless under this provision. Small rural hospitals will be held harmless for services furnished before January 1, 2004. 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 amended redesignated section 1833(t)(8) of the Act to provide that the copayment 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 added section 1886(d)(8)(E) to the Act to permit reclassification of certain urban hospitals as rural hospitals for purposes of section 1886(d) of the Act. Section 401 added section 1833(t)(13) to the Act to provide that a hospital being treated as a rural hospital under section 1886(d)(8)(E) is also to be treated as a rural hospital under the hospital outpatient prospective payment system.

A discussion of how each of these BBRA 1999 provisions was implemented in the April 7, 2000 final rule with comment period appears in section II of this preamble preceding our summary of the public comments received and our responses to those comments.

*B. June 30, 2000 Notice of Delay of Effective Date for the April 7, 2000 Final Rule With Comment Period*

On June 30, 2000, we published a notice in the **Federal Register** (65 FR 40535) announcing a delay in the effective date of the April 7, 2000 hospital outpatient prospective payment system final rule with comment period from July 1, 2000 to August 1, 2000. This delay was based on our determination that the appropriate claims processing changes could not feasibly be made to our computer systems and properly tested in time to ensure that proper payments would be made for Medicare hospital outpatient services under the new prospective payment system by the original July 1, 2000 effective date.

*C. August 3, 2000 Interim Final Rule With Comment Period*

On August 3, 2000, we published an interim final rule with comment period in the **Federal Register** (65 FR 47670) that changed one criterion and postponed the effective date for two other criteria that a new device, drug, or biological must meet in order for its cost to be considered "not insignificant" for purposes of determining its eligibility for transitional pass-through payments from the hospital outpatient prospective payment system. It also changed the transitional pass-through payment policy to include new single use medical devices that come in contact with human tissue and are surgically implanted or inserted into patients, whether or not the devices remain with the patients following their release. These policies were a departure from those presented in the April 7, 2000 final rule with comment period.

The August 3, 2000 rule also corrected a trigger date for grandfathering of provider-based FQHCs to conform with the intent not to disrupt existing FQHCs with longstanding provider-based treatment that we discussed in the April 7, 2000 rule. Under the criteria in the April 7, 2000 final rule with comment period, FQHCs would have been treated as departments of a provider without regard to the criteria for provider-based status if they continued to qualify as FQHCs and were designated as FQHCs before 1995. In accordance with the August 3, 2000 interim final rule with comment period and this interim final rule with comment period, facilities that continue to qualify as FQHCs and were designated as FQHCs or "look-alikes" on or before April 7, 2000 would continue to be treated as provider-based facilities. In addition, we clarified how

the requirement for prior notices to beneficiaries is to be applied in emergency situations. We also clarified the protocols for off-campus departments in emergency situations.

*D. Summary of This Interim Final Rule With Comment Period*

In section II of this preamble, we—

- Respond to public comments received timely on the 14 BBRA 1999 provisions that were included in the April 7, 2000 final rule with comment period. (We received numerous public comments on other aspects of the April 7, 2000 final rule with comment period that were not open for comment. We will not address those comments in this rule.)

- Respond to public comments on the August 3, 2000 interim final rule with comment period that revised the criteria for defining new or innovative medical devices, drugs, and biologicals eligible for pass-through payments and corrected the criteria for the grandfathering provision for certain FQHCs as provider-based.

In section III of this preamble, we are updating, for services furnished during calendar year 2001, the wage index values and the conversion factor, and revising the APCs to reflect new codes for 2001 effective January 1, 2001. As required under section 1833(t)(8)(A) of the Act, in 2001, we will begin our annual review process of the APC groups, relative weights, and the wage and other adjustments for the prospective payment systems payments that will become effective on January 1, 2002. The statute requires the Secretary to 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.

**II. Analysis of, and Responses to, Public Comments on the BBRA 1999 Provisions and the August 3, 2000 Interim Final Rule With Comment Period**

We received a total of 747 pieces of timely correspondence containing public comments on the April 7, 2000 final rule with comment period. In addition to receiving comments from various organizations throughout the hospital industry, we also 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 the comments addressed the BBRA 1999 provisions relating to the limitation on variation of costs of services classified within a group, the transitional pass-through provision for devices, drugs, and biologicals, and the inclusion of implantable items.

We received 13 comments in response to the August 3, 2000 interim final rule with comment period. These comments were submitted by major associations, drug and device manufacturers, providers, a private citizen, and a law firm. More than half of the comments addressed issues for which we did not solicit comments in the August 3, 2000 interim final rule with comment period. Those comments specifically addressed payment policy and typographical errors present in the April 7, 2000 final rule with comment period. The remaining commenters addressed the revisions to the criteria to define new or innovative medical devices, drugs, and biologicals eligible for pass-through payments and corrections to the criteria for the grandfathering provision for certain FQHCs. These commenters took issue with some of the provisions and raised additional concerns regarding our actions. A summary of the public comments and our responses to them appears following the discussion of the April 7, 2000 final rule with comment period.

We have carefully reviewed and considered all comments received timely. The modifications that we are making in response to commenters' suggestions and recommendations are summarized in section III.A of this preamble and, as appropriate, reflected in the regulation text.

*A. April 7, 2000 BBRA 1999 Provisions*

Below we discuss the implementation of the BBRA 1999 provisions addressed in the April 7, 2000 final rule with comment period and modified in the August 3, 2000 interim final rule with comment period, the public comments received on each provision, and our response to those comments.

**1. Outlier Adjustment**

Section 1833(t)(5) of the Act, as added by section 201(a) of the BBRA 1999, required that the Secretary 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 sum of the outpatient prospective payment system payment and the transitional pass-through payments. The Secretary is

authorized to determine the amount of this fixed multiple and the percent of costs above the threshold that is to be paid under this outlier provision. Under the statute, projected outlier payments may not exceed an "applicable percentage" of projected total program 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 the Secretary specifies cannot exceed 2.5 percent; for 2004 and later, the projected percentage cannot exceed 3.0 percent. Section 1833(t)(2)(E) of the Act requires 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.

In the April 7, 2000 final rule with comment period, in accordance with the statute, we presented how the additional outlier payments are to be calculated.

To set the threshold or fixed multiple and the payment percentage 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 the prospective payment system payments. 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 believed 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 prospective payment system. This is because we believe that the 1996 data reflects undercoding of services, which means simulated total payments would likely be understated and, in turn, the percentage of outlier payments would be overstated. In addition, we were not able to fully estimate the amount and distribution of pass-through payments using the 1996 data. Our inability to make these estimates further understated 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 the prospective payment system. The difference arises from the effect of undercoding in the historical data and the payment of pass-throughs under prospective payment system. We set the outlier threshold at 2.5 times the prospective payment system payments.

*Comment:* Several commenters asked us to clarify how series bills for services such as chemotherapy that are billed monthly for multiple sessions are treated in determining outlier payments. They also asked that we clarify how bills for multiple clinic visits on the same day are treated in calculating the outlier payment.

*Response:* In accordance with section 1833(t)(5)(D) of the Act, until 2002, outliers will be determined on a bill basis rather than on a specific service basis. Therefore, the charges (converted to costs) associated with all services under the hospital outpatient prospective payment system reported on series bills or all payable multiple clinic visits billed on a single claim would be used to determine whether the outlier threshold is exceeded and to calculate the outlier payment.

*Comment:* One commenter suggested that we prospectively adjust the conversion factor if we determine that the actual outlier expenditures are less than estimated in a given year.

*Response:* Consistent with our outlier policies in other prospective payment systems, we will not adjust the conversion factor for a given year to account for an underestimation (or overestimation) of outlier payments in a previous year. The statute does not provide for such an adjustment to the conversion factor. We set outlier policies prospectively, using the best available data. Outlier payments, like many aspects of a prospective payment system, reflect estimates, and we believe it would be inappropriate to adjust the conversion factor (upward or downward) for a given year simply because an estimate for a previous year ultimately turned out to be inaccurate. If we underestimate or overestimate the percentage of outlier payments, the divergence of our estimate from actual experience might provide information that might help us improve estimates in the future, but it would have no direct effect on the conversion factor for any following year.

*Comment:* One commenter urged us to provide additional information about the cost-to-charge ratios that will be used to determine whether a claim exceeds the outlier threshold for payment. The commenter stated that the

preamble language on page 18498 of our April 7, 2000 final rule with comment period conflicts with statements contained in Program Memorandum Transmittal No. A-00-23 regarding which cost-to-charge ratio would be used to determine whether a claim meets the outlier threshold requirements for payment. According to the commenter, we stated in the final rule with comment period that we will use a hospital's overall cost-to-charge ratio to make this determination, but stated in the program memorandum that we will use an outpatient cost-to-charge ratio. The commenter asked us to clarify the conflicting statements.

*Response:* On September 8, 2000, we issued Program Memorandum Transmittal No. A-00-63, titled "Cost-to-Charge Ratios (CCRs) for Calculating Certain Payments Under the Hospital Outpatient Prospective Payment System" which describes how we calculated the cost-to-charge ratios that are used to determine payments for outliers, interim transitional corridors, and device pass-throughs for calendar year 2000. That program memorandum defined the cost-to-charge ratio that is used to calculate these payments as the overall hospital outpatient cost-to-charge ratio. This is consistent with what we stated in our April 7, 2000 final rule with comment period. The September program memorandum contains the latest and most complete information available on cost-to-charge ratio calculation for the hospital outpatient prospective payment system.

*Comment:* One commenter assumed that we will use department level cost-to-charge ratios after 2002 to determine if a particular outpatient service qualifies for outlier payment. The commenter asked if we will use a "national cost-to-charge mapping procedure" to determine the appropriate department cost-to-charge ratios to use. The commenter expressed concern about the appropriateness of that approach because of the variability among providers in assigning costs to departments. For this reason, the commenter recommended, if we use a national cost-to-charge mapping procedure, we permit providers to request outlier payments if they can demonstrate that the actual department cost-to-charge ratio to which they assign costs for a service results in a cost calculation that meets the outlier threshold.

*Response:* We plan to address this issue and seek comments on it in the rulemaking process for the annual update for 2002.

*Comment:* One commenter urged us to publish annually the "cost reporting

year” used to determine the cost-to-charge ratios that will be used in determining outlier payments. The commenter also asked that we explain how we computed cost-to-charge ratios for hospitals that have merged or been acquired.

*Response:* On September 8, 2000, we issued Program Memorandum Transmittal No. A-00-63 that describes the specific criteria we used and provides detailed instructions for calculating the cost-to-charge ratios for hospitals that have merged or been acquired. It also identifies the specific cost reporting year end that was used to calculate each provider’s cost-to-charge ratio.

*Comment:* One commenter asked that we lower the outlier threshold from 2.5 to 2.0. The commenter strongly recommended that we permanently retain the lowered threshold to ensure appropriate patient care and adequate provider reimbursement.

*Response:* We oppose lowering the outlier threshold to 2.0. As discussed in our April 7, 2000 final rule with comment period, we set the outlier threshold at 2.5 by simulating total prospective payment system payments (using 1996 hospital outpatient data) and using an iterative process to calculate a threshold under which outlier payments are projected to equal 2.0 percent of total payments. If we lowered the threshold as the commenter suggests, then the projected percentage of outlier payments would increase and we would have to reduce the conversion factor correspondingly (thus reducing the payment for all non-outlier cases.)

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

Section 1833(t)(6) of the Act, as added by section 201(b) of the BBRA 1999, requires the Secretary to make additional payments to hospitals, outside the hospital outpatient prospective payment system 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 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 prospective payment system payment

amount. In this context, “current” refers to those items for which hospital outpatient payment is being made on the first date the new prospective payment system 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) of the Act 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.

These pass-through payments must be made in a budget neutral manner. In addition, these additional payments do not affect the computation of the beneficiary coinsurance amount.

In the April 7, 2000 final rule with comment period, we specified the types of items for which additional payments would be made; described the amount of the additional payments; announced that these payments would be limited to at least 2 years but not more than 3 years; and announced a cap of 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.

### a. Definition of a Device

*Comment:* Some commenters argued that we have adopted a very narrow definition of a device that restricts pass-through payments to prosthetic devices and excludes valuable new nonprosthetics from pass-through consideration. They asserted that the definition of a device should mirror the

definition set forth in the Federal Food, Drug, and Cosmetic Act. They agreed that such a definition should exclude capital equipment, reusable items, and incidental supplies. However, they argued that we should clarify and revise our definition of devices to those that are “implanted or inserted” and “remain with the patient after the patient is released from the hospital outpatient department.”

*Response:* The definition of a device under the Food, Drug, and Cosmetic Act is extremely broad. In summary, it refers to a device as an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component, part, or accessory, which is—

- Recognized in the official national formulary, or the U.S. Pharmacopeia, or any supplement to them;
- Intended for the use of the diagnosis of conditions other than diseases such as pregnancy;
- Intended to affect the structure or any function of the body of man or other animals; or
- Considered an *in vitro* diagnostic product, including those previously regulated as drugs, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

This definition is inappropriate for use in the context of the transitional pass-through payments for several reasons: It would include (as the commenters noted) items that are treated as supplies, reusable items, or capital equipment by Medicare payment systems, including the outpatient prospective payment system. It has a number of inappropriate elements, including reference to pharmaceuticals and to use in animals. Further, it is insufficiently specific for Medicare purposes, as it does not mention medical necessity or the test of whether the cost of a device is “not insignificant” relative to the associated APC.

We have instead provided a definition of a device specific to the purposes of the transitional pass-through provision. This definition was presented in the preamble to the April 7, 2000 final rule with comment period and revised in the August 3, 2000 interim final rule with comment period, which added § 413.43(e)(4).

In the August 3, 2000 interim final rule with comment period, we revised the criteria that we had set forth in the



April 7, 2000 final rule with comment period to define a device. Among the changes included is a revision of the criterion relating to whether a device must remain with the patient. The new criterion (§ 419.43(e)(4)(iv)) includes devices that are surgically implanted or inserted in a patient "whether or not they remain with the patient when the patient is released from the hospital outpatient department." This change allows pass-through payments for devices that are surgically implanted or inserted even temporarily in a patient providing the devices meet all other requirements for pass-through payments. As a result, nonprosthetic devices, such as cardiac catheters, guidewires, or stents that commenters noted would be excluded, may be eligible for pass-through status.

In § 419.43(e)(4)(iv), we have retained the limitation to devices that are surgically implanted or inserted because we believe this offers the best interpretation of section 201(e) of the BBRA 1999, which indicates that implantable devices are to be included in the APCs. To further clarify how we interpret § 419.43(e)(4)(iv), we consider that a device is surgically implanted or inserted if it is introduced into the human body through a surgically created incision. We do not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted. We consider items used to create incisions, such as scalpels, electrocautery units, biopsy apparatuses, or other commonly used operating room instruments, to be supplies or capital equipment, and hence, in accordance with § 419.43(e)(4)(vi) or (vii), we consider these items not eligible for transitional pass-through payments. We believe the function of these items is different and distinct from that of devices that are used for surgical implantation or insertion. Generally, we would expect that surgical implantation or insertion of a device occurs after the surgeon uses certain primary tools, supplies, or instruments to create the surgical path or site for implanting the device.

We have discovered some items that do not meet the requirement of being surgically implanted or inserted were erroneously approved for pass-through payments. Consequently, we will eliminate these items from the list of items eligible for pass-through payments, effective January 1, 2001.

*Comment:* One commenter claimed that it was inappropriate for us to change the definition of devices through letters to manufacturers. The commenter believed that this was done outside the rulemaking process.

*Response:* We did not make a change to our policy through a letter. As we began to evaluate the hundreds of applications for approval of numerous devices, it was apparent that our definition for new medical devices as published in our April 7, 2000 final rule with comment period would have resulted in denials for items that we believe might warrant pass-through payments. Examples of such potential denials are many types of general and specialty catheters. Based on our experience in reviewing these applications, we decided to change three of the eight specific criteria that a new device must meet in order to be eligible for pass-through payments. We published these changes in our August 3, 2000 interim final rule with comment period.

#### b. Eligibility Criteria

*Comment:* Some commenters believed that we should accept and process applications for items while they are undergoing the FDA review process.

*Response:* We have accepted and begun processing all applications, including those for which items are pending FDA approval or clearance. However, in those instances where the FDA approval or clearance documentation is missing, the application is considered incomplete. In order for an item to be eligible for transitional pass-through payments, it must have been approved or cleared by the FDA for marketing. We will not make a final determination on any applications that are pending FDA approval or clearance until all the required documentation is submitted. Resources permitting, we will commence preliminary processing of the applications when received. The applying party is responsible for providing us with proper evidence of FDA approval or clearance for any item, once approval or clearance has been obtained. Once we receive documentation of FDA approval or clearance and determine the item is determined to be eligible for transitional pass-through payments, payment for the item will commence at the start of the next quarterly update of pass-through items.

*Comment:* Some commenters asked that we clarify that items must meet Medicare coverage requirements in order to qualify for pass-through status.

*Response:* As stated in both our April 7, 2000 final rule with comment period and our August 3, 2000 interim final rule with comment, items that qualify for pass-through payments must be covered by Medicare. They must have been 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. (See § 419.43(e)(4)(iii).)

#### c. Investigational Device Exemption (IDE) Devices

*Comment:* Some commenters recommended that we automatically define as "new" any device that receives an investigational device exemption (IDE) from the FDA, with a Category B designation. They believed that we should pay for IDE devices through the pass-through payment methodology rather than limit the payment to no more than what is currently paid for an equivalent device.

*Response:* As stated in our August 3, 2000 interim final rule with comment period, we have changed the payment methodology for eligible IDE Category B devices so that they will be paid using the transitional pass-through methodology. Since these noninvestigational devices are required to meet the same eligibility criteria as other devices, we determined that they should be paid in a similar manner. However, we do not accept the commenter's recommendation that all IDE Category B devices "automatically" be considered as new. The statute defines "new" medical device on the basis of a date certain (that is, payment for the device was not being made as an hospital outpatient service as of December 31, 1996) rather than based on a class of devices (such as IDEs).

#### d. Removing Cost of Predicate Item

*Comment:* Some commenters stated that we did not have adequate data to ensure appropriate removal of the costs for predecessor items (particularly radiopharmaceuticals and devices) from their relevant APCs. They advocated that we reevaluate this provision as soon as possible after implementation of our new system and make necessary changes.

*Response:* We will be continuously evaluating our data to remove the costs of predecessor items from the pass-through payments. As of January 1, 2001, a specific dollar amount will be deducted from selected devices (see explanation below). Over time, such deductions will be made, as we are able to make appropriate estimates from the data.

#### e. Excluded Costs

*Comment:* A number of commenters stated that the APC construction excluded costs for implantable devices billed with revenue codes 274, 275 and 278. The commenters recommended

that implantable devices associated with these revenue codes be included on the pass-through list until data is collected to adequately reflect the cost of such devices. In addition to claims that revenue codes 274, 275 and 278 were not represented in the data, some commenters alleged that implant procedures were infrequently performed on an outpatient basis prior to 1997 and therefore the costs associated with them were not represented in the data used to develop the APC rates. Some commenters recommended, on that basis, that all implantable devices be included for pass-through payment regardless of FDA approval dates.

*Response:* Following enactment of the BBRA of 1999, we did not have sufficient time to re-run our data to package the costs of implantable device revenue centers into the APC weights and still be able to publish a final rule in time to implement the prospective payment system by July 1, 2000.

As of January 1, 2001, the APC rates will reflect the inclusion of revenue codes 274, 275 and 278. While the aggregate amount of these revenue centers is small (0.3 percent of total charges in 1996), the costs of certain procedures such as implantation of cardiac pacemakers did increase substantially. As detailed in section III.B.1 of this interim final rule, some APC groups were modified because of the inclusion of these revenue centers, and rates for some procedures will increase to reflect these costs. A reduction in an amount equal to the increase in the APC rates will be deducted from the relevant devices that are either eligible for pass-through payments or that can be billed for additional payment through the new technology APCs.

#### f. Effect on Conversion Factor

*Comment:* Some commenters believed that lowering the outpatient prospective payment system conversion factor to reflect the 2.5 percent transitional pass-through adjustment could affect hospitals' financial health. They asserted that any risks to the financial health of hospitals resulting from reducing the conversion factor should be balanced against any benefits that would be gained from higher payments for new drugs and devices. Another commenter advocated that we increase the conversion factor if we find that the transitional pass-through payments do not comprise 2.5 percent of the total outpatient prospective payment system payments.

*Response:* Section 1833(t)(2)(E), as amended by section 201(c) of the BBRA 1999, requires that transitional pass-

through payments be implemented in a budget neutral manner. We set prospective payment system rates prospectively and, consistent with our policies in other aspects of the prospective payment system, we will not adjust (upward or downward) the conversion factor for a given year to account for the difference between 2.5 percent and the actual percentage of pass-through payments in a previous year.

#### g. Cost Significance Tests

*Comment:* Some commenters asserted that we could preclude some worthwhile technologies from achieving pass-through status if we set the "not insignificant" cost threshold at 25 percent of the APC payment rate for the relevant procedure with which it is used. They contend that technologies associated with higher payment APCs would be more likely to be disqualified.

*Response:* We have lowered the cost threshold from 25 percent to 10 percent of the applicable fee schedule amount for the service associated with the item. This change is effective for services furnished on or after August 1, 2000.

*Comment:* A hospital association asked that we clarify how the "not insignificant" criteria will be applied when a new device, drug, or biological is associated with more than one APC. The commenter stated that, under the current provisions of the rule, an item could be determined to be eligible for pass-through payment when used in performing a procedure in one APC, but not another. The commenter suggested that an item that meets the criteria for one APC be treated as a pass-through item for all APCs in which it is used.

*Response:* We agree with the stated approach. This has been the policy that we have applied in processing applications.

*Comment:* One manufacturer stated that we did not make information available on the "not insignificant" rule in sufficient time for applicants to take the criteria into account in preparing applications for payment effective August 1, 2000. The commenter alleged that the term "not insignificant" can be interpreted widely and caused manufacturers not to apply for all potentially eligible pass-through items. The commenter recommended that we review applications submitted for the following HCPCS codes to be certain that they meet the published cost criteria and remove them from the pass-through list if they do not. The commenter also advocated that we allow other manufacturers to submit applications retroactive to July 1, 2000, to assure that we are not promoting a

competitive disadvantage for some companies.

#### HCPCS Codes

C1029  
C1034  
C1061  
C1072  
C1073  
C1074  
C1100  
C1101  
C1155

*Response:* In order for a device to be included on the pass-through list, it must meet the criteria for transitional pass-through payments. These criteria include a test of whether the cost of a device is "not insignificant" relative to the payment for the associated APC. This test was first put forth in the April 7, 2000 final rule with comment period, and subsequently revised in the August 3, 2000 interim final rule with comment period. All the devices denoted by the HCPCS codes listed above were tested and met the 10-percent "not insignificant" test as well as the other applicable criteria. The "not insignificant" test was applied uniformly to all applications that had been received timely. We believe that permitting retroactive applications is unwarranted (and would be inconsistent with principles of prospectivity); moreover, resource and systems constraints would make it infeasible to give retroactive effect to determinations of eligibility for pass-through payments.

#### h. Brand-Specific Versus Categorization Approaches

*Comment:* Many commenters criticized us for implementing a brand-specific approach to items on the pass-through list. Device manufacturers in particular recommended a category scheme to classify pass-through devices. Representatives of the device industry also offered to assist us in creating the categories. They argued that a category system would allow devices to be added immediately upon FDA approval. They stated that under a category approach manufacturers would only approach us to obtain new pass-through categories and codes when items reflect a technological advance and are significantly more costly than existing payment amounts.

*Response:* We adopted a trade-name specific approach for several reasons. First, such an approach provides better information. Codes that are largely item-specific allow us to track what procedures the items are used with and costs of the items. When the pass-through payments for an item ends, we would expect to have good information

for assigning it to relevant APCs and ensuring appropriate payment for these APCs. Adopting a scheme with a significant degree of categorization would require use of averages in making assignments and setting payment rates. Decisions based on these more limited data would be likely to lead to intensified concerns about the appropriateness of APC assignment and payment.

Second, this approach permits finer discrimination in eligibility decisions. An item-by-item approach allows us to be sure individual items in fact meet the criteria for eligibility. Of major concern in this instance is whether a device is "new" using the standard of the statute. Section 1833(t)(6)(A) of the Act limits transitional pass-through payment to those devices for which "\* \* \* payment for the device \* \* \* as an outpatient hospital service under this part was not being made as of December 31, 1996." Adopting categories would in some cases mix "old" and "new" devices. In these instances, either some old devices would get special treatment that they would not be eligible for if they were examined on an item-specific basis, or an entire category could be considered old, thus depriving some new devices from special treatment they would be eligible for if they were examined on an item-specific basis.

Third, an item-specific scheme avoids issues associated with the design of categories needed for purposes of transitional pass-through payments. It largely avoids concerns about what items should be in what category or whether new categories should be created to accommodate items that may appear to be little different from those in existing categories.

Fourth, an item-specific approach allows us to assure that a newly arriving device can obtain the full period of pass-through status it is arguably eligible for under the statute. A categorization approach would likely lead to latecomers being eligible for pass-through payments for a shorter period. Insofar as revision to APC payment rates reflected the costs of items in the category by the time the category was terminated, the shorter period would be of little consequence. However, if the costs of the late-coming item were significantly higher, this procedure could appear objectionable. A solution in this case would be to create a new code, which could be specific to that item, thus departing from a categorization approach.

We recognize that a category approach would lessen concerns about competitive disadvantages that may have been inadvertently created by an

item specific approach and about access to specific items by hospitals and their patients. However, we found no satisfactory way of establishing categories that would not run into difficulty regarding the test of whether a device is "new" as described above. Consequently, we are making no change in our approach.

*Comment:* Many commenters argued that competitive advantages have resulted and will continue to result from using a brand-specific approach to implementing transitional pass-through payments for devices. Some commenters alleged that our use of the FDA approval date as a proxy for determining payment in concert with the brand-specific approach causes further competitive disadvantages. Some hospitals claimed that the brand-specific approach would create winners and losers if a device that one hospital uses obtains pass-through status, but one that another hospital uses does not. A number of commenters asserted that a category approach would decrease the administrative burden on hospitals, manufacturers, and us that a brand-specific approach for application and approval of new devices now incurs.

*Response:* It was never our intent to competitively disadvantage anyone or any product. To the maximum extent possible, given the limitations under the BBRA 1999 and our resource constraints, we have worked closely with the pharmaceutical and medical device industries to identify and resolve such issues. By October 1, 2000, we had determined that more than 700 devices are eligible for pass-through payments. Therefore, we believe that hospitals will receive additional payments for many of the devices they use.

#### i. Issues Pertaining to Specific Items

*Comment:* A medical association advocated pass-through status for the following devices: new pacemakers, implantable cardioverter defibrillators, insertable loop recorders, electrophysiology catheters (ablation and diagnostic), intracardiac echocardiography ultrasound catheters, and advanced three-dimensional mapping system catheters.

*Response:* All of these items are already on the pass-through list. For a complete list of items approved on the pass-through list, refer to Addendum B of this rule for short descriptions of the items. Refer to Program Memoranda Transmittals Nos. A-00-42, A-00-61 and A-00-72 for the long descriptors for each of the C-codes listed in Addendum B. We are developing an additional program memorandum that we expect to issue shortly. This additional program

memorandum will contain a list of additional devices, drugs, and new technology services that will be effective January 1, 2001.

*Comment:* Several device manufacturers alleged that the following devices were not included on the pass-through list:

PALMAZ Balloon-Expandable Stent  
Corinthian IQ Biliary Stent  
SMART Cordis Nitinol Stent  
CARTO EP Navigation System Catheters  
HYDROLYSER Catheter  
Indigo Prostate Seeding Needle  
Lioresal Intrathecal  
SynchroMed and SynchroMed EL infusion pumps

*Response:* All of these devices have been approved for pass-through payments and assigned C-codes. They have been assigned the following codes: the PALMAZ Balloon-Expandable Stent, C8522; Corinthian IQ Biliary Stent, C5004; SMART Cordis Nitinol Stent, C1372; CARTO EP Navigation System Catheters, C1047; HYDROLYSER Catheter, C1054; Indigo Prostate Seeding Needle, C1706; Lioresal Intrathecal, C9007, C9008, C9009, and C9010; SynchroMed and SynchroMed EL infusion pumps, C8505 and C3800, respectively.

*Comment:* Another device manufacturer claimed that the following devices were not included on the pass-through list:

Mitek Bone Anchors  
Innovative Bone Anchors  
VAPR and VAPR Thermal T Electrode  
Gynecare TVT Tension-Free Support for Incontinence System (TVT)  
Gynecare Thermachoice Uterine Balloon Therapy System

*Response:* Many of the items above have been approved for pass-through status and assigned C-codes. The Mitek and Innovative Bone Anchors have been assigned to C1109; VAPR and VAPR Thermal T Electrode, to C1323; TVT Single-Use Tension-Free Vaginal Tape, to C1370; and the Gynecare Thermachoice II Catheter, to C1056. However, some of the items included in the Gynecare TVT Tension-Free Support for Incontinence System and the Gynecare Thermachoice Uterine Balloon Therapy System did not meet the criteria for pass-through status and, therefore, are ineligible for additional payments. The eligible pass-through items are listed in Addendum B.

*Comment:* A device manufacturer believed that we should have approved the Targis System, which provides prostatic microwave thermotherapy, for pass-through payments.

*Response:* We assigned the prostatic microwave thermotherapy procedure to

a new technology APC, that is, APC 0980. In making this assignment, we took into account the costs associated with performing this procedure, including the cost of the Targis system. Therefore, we would not also make a pass-through payment for the system.

*Comment:* A number of commenters contended that only 39 of the more than 70 eligible radiopharmaceuticals have been given pass-through status. They recommended that we approve the following radiopharmaceuticals for pass-through payments:

Strontium Sr 82 Rubidium Rb 82  
Generator  
Sodium Chromate Cr-51  
Co 57 Cobaltous Chloride  
Co 57 Cyanocobalamin  
Ferrous Citrate Fe59  
Fludeoxyglucose F 18  
Intrinsic Factor Concentrate Capsules  
In 111 Imciromab (Myoscint)  
In 111 Labeled WBCs, Platelets  
I 123 and I 131 Hippurate  
Iodinated I 131 Albumin (I 131  
Albumin)  
Iodinated I 125 Albumin (I 125  
Albumin)  
Iothalamate Sodium I 125 Albumin  
(I125 Iothalamate)  
Technetium Tc 99m Perchnetate  
Technetium Tc 99m Albumin Colloid  
Technetium Tc 99m Lidofenin  
Technetium Tc 99m Tebroxime  
Technetium Tc 99m Nofetumomab  
(Verluma)  
Technetium Tc 99m HMPAO labeled  
WBCs  
Technetium Tc 99m Human Serum  
Albumin  
Technetium Tc 99m Serum Albumin  
(Tc 99m HSA kit)  
Xenon XE 127 Gas

*Response:* While a number of radiopharmaceuticals are already on the pass-through list, we are unable to add some of the ones listed above because we do not have AWP's for them. The AWP's are the basis for payment for these items and without the AWP's we cannot approve them for pass-through payments. As soon as the AWP's are made available to us, we will complete our review to determine their pass-through status. If eligible, they will be added to the pass-through list during the appropriate quarterly update cycle.

*Comment:* One commenter stated that our transitional pass-through policy for devices precludes pass-through eligibility for capital equipment and therefore does not provide a mechanism under our new system for recognizing the incremental costs associated with capital equipment. The commenter recommended that we recognize capital-equipment costs through our new technology APCs.

*Response:* Under our new outpatient prospective payment system, capital costs are not paid separately. Payment for these costs are included in the total APC payment amount for each procedure or medical visit and will be updated through our annual updating process. Therefore, the new technology APCs will not be used to make separate payments for capital related costs.

*Comment:* A number of commenters claimed that we denied pass-through status for the contrast agents.

*Response:* As clarified in our August 3, 2000 interim final rule with comment, contrast agents other than radiopharmaceuticals are considered supplies and are not eligible for pass-through payments. (See § 419.43(e)(4)(vii).)

*Comment:* A medical association claimed that we denied pass-through status requests for high dose rate brachytherapy. Another industry group alleged that many brachytherapy related items that manufacturers applied for were excluded from the pass-through list.

*Response:* Since publishing our initial list of potentially eligible pass-through items to our website on March 9, 2000, we have added 38 brachytherapy items to our pass-through list. High-dose rate brachytherapy will be eligible for pass-through payment effective for services furnished on or after January 1, 2001.

#### j. Pass-Through Applications Process

*Comment:* Some commenters urged that we process transitional pass-through applications in a more timely manner. A few other commenters believed that we should have chosen a date later than July 14, 2000 as the application deadline for the October 1, 2000 quarterly update for pass-through items.

*Response:* We have committed considerable resources to process pass-through applications in a timely manner. Since publication of our preliminary list of 149 potentially eligible pass-through items on our website on March 9, 2000, we have approved nearly 1000 additional items for pass-through payments. We have instituted a coding strategy that allows us to assign a temporary HCPCS code immediately to an eligible pass-through item if a national HCPCS code has not been assigned. We have committed to making quarterly updates to the pass-through list, a commitment that is unprecedented in Medicare's history. We have reviewed all applications timely submitted for each update cycle. Unfortunately, however, we have had to defer items with significantly unclear applications or for which sufficient

information was not included to determine that the item meets the statutory criteria. We have endeavored to work closely with the applicants to obtain this information and respond timely to their questions.

Regarding objections to setting a July 14, 2000 deadline for receipt of pass-through applications for the October 1 update, this deadline was established in order to evaluate the applications and make the necessary systems modifications in time for the October release to our fiscal intermediaries and standard systems maintainers.

*Comment:* One commenter believed that we should update our transitional pass-through list more frequently than quarterly. Some other commenters were concerned that the quarterly updating process could potentially create systems problems for both HCFA and hospitals that would delay payments. They believed that such a delay would, in turn, create cash flow difficulties for hospitals. They urged that we develop contingency plans to address cash flow problems resulting from the transitional pass-through process.

*Response:* Because of the complexity of our new system, we cannot institute systems changes more frequently than quarterly for pass-through payments. While we believe that making quarterly updates to the pass-through list will present challenges both for HCFA and the hospital industry, we have not been advised that any hospital is experiencing cash flow problems attributable to the transitional pass-through process.

*Comment:* One commenter urged us to issue guidelines that detail the planned methodologies, data sources, and associated timelines for updating the pass-through list.

*Response:* Since March 10, 2000, we have published information on our website which provides detailed instructions and deadlines for submitting transitional pass-through applications. These instructions have been revised as needed in order to clarify and update information and may be found on the following HCFA website: <http://www.hcfa.gov/medlearn/refopps.htm>.

*Comment:* One commenter claimed that our method and timing of assigning HCPCS codes to eligible transitional pass-through items would preclude Medicare beneficiaries from receiving appropriate treatment. The commenter also alleged that hospitals will not always be adequately reimbursed for their costs for such items and that they will have an incentive to switch to more invasive treatment options with higher costs.

*Response:* We have expedited the process of assigning HCPCS codes to pass-through items. When an item is determined eligible for pass-through status, a temporary HCPCS code is assigned immediately in order that hospitals may begin billing the item as soon as it is effective for payment.

In addition, section 1833(t)(6)(C)(i) of the Act requires that the hospital's additional payment for drugs and biologicals 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 hospitals' charges adjusted to costs and the portion of the applicable hospital outpatient department fee schedule amount associated with the device. We believe that this payment method will appropriately reimburse hospitals for eligible pass-through items and that hospitals will act in a prudent manner and not compromise their patients' safety and care.

#### k. Payment for Pass-Through Items

*Comment:* Several commenters questioned how payment would be made when a pass-through item is included on an outpatient claim. Another commenter stated that our April 7, 2000 final rule with comment period does not state the actual payment amount that will be made for each pass-through item, or provide a good reason for not updating drug and biological average wholesale prices quarterly, or pledge timely correction of payment amount errors. The latter commenter believed that we should make available the actual APC payment rates for pass-through items and institute quarterly pricing-updates for drug and biological APCs.

*Response:* Transitional pass-through payments for devices are established by taking the hospital charges for each billed item (on an item-by-item basis), reducing them to cost by use of the hospital's cost-to-charge ratio, and subtracting an amount representing the device cost contained in the APC payments for procedures involving that device. Note that for services furnished prior to January 1, 2001, we have not subtracted an amount for the predicate device that is packaged in the relevant APC. However, we will implement this policy beginning with services furnished on or after January 1, 2001. These calculations are all done in the outpatient prospective payment system pricer. Because there are no

predetermined APC payment rates for eligible pass-through devices, we cannot publish them in the same manner as we publish the APC payment rates for other services.

For drugs and biologicals, pass-through payments are determined based on 95 percent of the AWP for the eligible drug or biological. We described in our April 7, 2000 final rule (65 FR 18481) the process we used to subtract the cost of the eligible drug or biological contained in the APC payments for procedures involving that drug, radiopharmaceutical or biological. The year 2000 AWP's for pass-through drugs and biologicals on which payments are currently based will be updated annually at the beginning of the next quarter following publication of the updated values. Due to the complexity of our new system, we cannot update AWP's quarterly as requested.

*Comment:* A number of commenters stated that the codes for drugs in Addendum K of our April 2000 final rule are specific to the dosage amount dispensed and asked what happens if the dosage dispensed to a patient is not equal to the amount associated with the eligible codes. The commenters requested additional information about how providers should account for these situations. They asked if we would allow providers to bill for the product amount associated with the container opened to treat the patient and round up to the nearest whole billing unit.

*Response:* The APC payment amount for drugs and biologicals is established at the lowest dosage level for the specific drug or biological. If the dosage required in treating the patient exceeds the lowest level specified in the HCPCS code descriptor for the drug or biological, providers may bill the number of units necessary to treat the patient and round them up to the nearest unit. To determine the payment for the drug or biological, multiply the number of billed units by the APC payment amount.

*Comment:* One commenter stated that the APC payment amount for Eptifibatide, a drug on the pass-through list, does not equal 95 percent of the average wholesale price (\$6.28 per 5-mg. service unit). The commenter claimed that the APC payment is 42 percent lower than 95 percent of the AWP. The commenter asked that we correct the payment immediately.

*Response:* The correct APC payment amount for Eptifibatide injection, 5 mg. is \$12.57, of which \$1.68 is the minimum unadjusted coinsurance.

*Comment:* One commenter stated that the APC payment amount for Quadramet, a pass-through drug, is

incorrect. The commenter claimed the AWP for this drug is \$2,975 rather than \$2,875, which the commenter believed is the basis for our APC payment amount. The commenter stated that the pass-through payment should be \$942.08 instead of \$910.42.

*Response:* The correct APC payment amount for Quadramet is \$942.09. Of this amount, \$134.87 is the minimum unadjusted coinsurance.

*Comment:* A commenter stated that the APC payment amount for Thyrogen, a pass-through drug, should be \$494.00 rather than \$404.18 per vial.

*Response:* The APC payment amount of \$404.18 is for 0.9 mg. units of Thyrogen rather than 1.1 mg., which appears to be the standard vial dosage. However, because Thyrogen is not available in a vial dosage less than 1.1 mg., we are eliminating the APC payment for 0.9 mg. units (HCPCS code J3240) effective for outpatient prospective payment system services furnished on or after January 1, 2001. We have established a new code, C9108, for Thyrogen, 1.1 mg. with an APC payment amount of \$494.00. This new code is effective for outpatient prospective payment system services furnished on or after January 1, 2001.

*Comment:* A medical association acknowledged our short lead-time for implementing the transitional pass-through provision and urged that we hold a series of face-to-face meetings with physicians and suppliers to clarify and revise our pass-through policies.

*Response:* Since publishing our April 7, 2000 final rule with comment period, we have met on numerous occasions with physicians and representatives of hospitals, pharmaceutical companies and device manufacturers. During these meetings, we have discussed our transitional pass-through policies and clarified information regarding the pass-through applications process.

*Comment:* One commenter stated that the April 7, 2000 final rule with comment period requiring the submittal of applications for national HCPCS codes to bill eligible transitional pass-through was published after the application deadline had passed. The commenter alleged that some manufacturers obtained information about the pass-through provisions prior to publication of the final rule, submitted their applications timely, and thus dominated the hospital outpatient market.

*Response:* On March 9, 2000, we posted information on our website similar to that contained in the April 7, 2000 final rule with comment period about applying for national HCPCS codes for pass-through items. We also

discussed the coding deadline with representatives of the pharmaceutical and device manufacturers associations as well as with hospital industry representatives through conference calls, meetings, and e-mails. We note that the instructions and deadline for submitting applications for a national HCPCS code are well established and were published on HCFA's website (<http://www.hcfa.gov/medicare/hcpcs.htm>) more than a year prior to publication of our April 7, 2000 final rule with comment period. Subsequent to these publications, we adopted a new system for assigning codes exclusively for pass-through items to expedite their availability to the hospital industry and Medicare beneficiaries. Therefore, interested parties applying for pass-through status for items have not been required to obtain national HCPCS codes for these items unless they want to bill other payment systems in addition to the hospital outpatient prospective payment system.

#### 1. Focus Medical Review

*Comment:* One commenter asked that we clarify why we intend to conduct focused medical review of pass-through eligible drugs, biologicals and medical devices.

*Response:* Our goal is to identify inappropriate billing for these services and to ensure that payment is not made for noncovered services.

#### 3. Budget Neutrality Applied to New Adjustments

In the April 7, 2000 final rule with comment period, in accordance with section 1833(t)(2)(E) of the Act, as amended by section 201(c) of the BBRA 1999, we made the outlier and transitional pass-through payment adjustments under section 1833(t)(5) and section 1833(t)(6) of the Act, respectively, budget neutral. We did not receive any public comments on this provision.

#### 4. Limitation on Judicial Review

In the April 7, 2000 final rule with comment period (65 FR 18503-18504), in accordance with section 1833(t)(12) of the Act (as amended by section 201(d) of the BBRA 1999 and redesignated by section 202(a) of the BBRA 1999), we implemented the extension of 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 factors used to determine 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 prospective payment system payment amount associated with particular devices, drugs, or biologicals, and any pro rata reduction.

We did not receive any public comments on this provision.

#### 5. Inclusion in the Hospital Outpatient Prospective Payment System of Certain Implantable Items

In the April 7, 2000 final rule with comment period, we specified that section 1833(t)(1)(B) of the Act, as amended by section 201(e) of the BBRA 1999, provides that "covered OPD services" include implantable items described in section 1861(s)(3), (6), or (8) of the Act.

The conference report accompanying the BBRA 1999, H.R. Rept. No. 479, 106th Cong., 1st Sess. at 869-870, (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 hospital outpatient prospective payment system, regardless of how they might be classified on current HCFA fee schedules.

In the April 7, 2000 final rule with comment period, we included the following in the list of items and services whose costs are included in hospital outpatient prospective 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. In accordance with the BBRA 1999 provision, we require that an implantable item be classified to the group that includes the service to which the item relates. We indicated that we would continue to review the impact of packaging implantables in future updates. For more detailed information on this provision, refer to the April 7, 2000 final rule with comment period (65 FR 18443-18444).

*Comment:* Two commenters (hospitals) expressed concern that the APC for the Cyberonics-NeuroCybernetic Prosthesis (NCP) System, an implantable device used to treat epilepsy patients with partial-onset seizures, will not adequately reimburse hospitals for the cost of the device and the implantation procedure cost. The hospitals recommended that HCFA create a separate APC group for the NCP System implantation.

*Response:* The NCP System was approved for pass-through status effective for services furnished on or after August 1, 2000 (see Program Memorandum Transmittal No. A-00-42 issued on July 26, 2000). The two components of this system, the NeuroCybernetic Prosthesis Generator and the NeuroCybernetic Prosthesis Lead, will be paid based on the hospital's charges that are converted to cost using the hospital's assigned cost-to-charge ratio. These devices have been assigned to two separate pass-through APCs (1048 and 1306, respectively) and should be billed using HCPCS code C1048 for the generator and C1306 for each lead.

*Comment:* Several commenters from physician practices and a device manufacturer raised concerns that the APC payment level for the Contigen Implant procedure is inadequate to cover the facility costs and the Contigen Implant supplies. According to the commenters, the APC reimbursement amount only covers the 2-3 Contigen Implant syringes used per procedure. The commenters recommended that we map the Contigen Implant procedure and the collagen skin test to higher paying completely new APCs, to more adequately reflect reasonable costs for syringes and skin tests used in the procedure, in addition to appropriate facility fees.

Other commenters raised concerns that the separate APC reimbursement for the pre-Contigen Implant procedure testing is inadequate to reimburse for the reasonable cost of the supply. They recommended that we allow payment of Contigen Implant syringes according to the DMEPOS fee schedule.

One commenter recommended that we create a special ancillary APC to cover Contigen Implant syringes and the collagen skin test.

*Response:* While we understand the commenters' concerns, Contigen Implant syringes do not qualify for transitional pass-through status because they do not meet all of the device criteria set forth in § 419.43(e)(4). Specifically, they are not items that are surgically implanted or inserted in a patient. However, both collagen implant

material and the collagen skin test are paid as APCs (that is, APCs 6012 through 6016 and 343, respectively). We will examine data after the first year of billing under the prospective payment system to determine if we are adequately capturing the cost of performing these procedures.

As stated in our April 7, 2000 final rule with comment period, we will initiate the annual review process for the various components of our system, including the APC groupings, in calendar year 2001 for services furnished on or after January 1, 2002. We expect to publish our proposed rule for 2002 in the spring of 2001.

*Comment:* A device manufacturer inquired as to what will happen when devices are taken off the transitional pass-through list after 2 to 3 years. The commenter stated that the additional expense of these implantable devices will require that HCFA reassign these CPT codes to an APC that is comparable clinically and in terms of resources used at the close of the transition period. If this does not occur, the commenter indicated that hospitals would be seriously underpaid for the use of these technologies and other technologies in similar circumstances.

*Response:* As stated above, the BBRA 1999 allows for 2 to 3 years of transitional pass-through payments to be made for new devices, drugs, and biologicals. After the temporary payment period expires for any item, its cost will be packaged with the relative procedure code or medical visit and assigned to the APC group that is clinically related and comparable in resources used. Thus, the APC groupings, weights, and payments will be updated in a subsequent year to include costs associated with former pass-through items.

*Comment:* A coalition of health care providers and insurers indicated that providers should be allowed to report all DME, orthotics, and prosthetic devices, both implantable and nonimplantable, on the UB-92 to the fiscal intermediary. The fiscal intermediary should be able to either pay for the item via the DMEPOS fee schedule or through the APC. This also would allow a tracking system for future ratesetting, and consolidate the billing into one claim. This would consolidate all charges on one bill per encounter, which simplifies processing and is consistent with other third party payer claims processing as well as Medicare inpatient claims processing.

*Response:* Section 201(e) of the BBRA 1999 amended section 1833(t)(1)(B) of the Act to require that covered outpatient prospective payment system

services include implantable medical items, described in section 1861(s)(3), (6), or (8) of the Act. These items were formerly paid under the DMEPOS fee schedule. The statute is explicit in defining which DME items are payable under the hospital outpatient prospective payment system.

Also, we cannot adopt the suggested billing changes for DME as the commenter suggested. All services that are billed through the fiscal intermediaries, whether they are paid under the hospital outpatient prospective payment system or DMEPOS, may be submitted on the UB-92 (or the equivalent electronic transaction). However, there are numerous, very exacting, specific criteria and rules that govern Medicare coverage and payment for nonimplantable DME and oxygen. The DME regional carriers are exclusively qualified to deal with these issues. Therefore, claims for nonimplantable DME and oxygen cannot be billed to the fiscal intermediaries. Instead, providers must continue to submit claims for nonimplantable DME and oxygen to the DME regional carriers using form HCFA-1500 (or the equivalent electronic transaction).

It should be noted that if a health care provider submits an electronic claim for these services, the transaction must comply with the standards adopted by the Secretary in the August 17, 2000 final rule (65 FR 50312) Standards for Electronic Transactions. The compliance date of that rule is October 16, 2002.

*Comment:* A device manufacturer expressed concern about how the new system will change the payment mechanism for cochlear implants. Under the DMEPOS fee schedule, payments were fixed and unrelated to hospital charges. Now, under the new system, hospitals must properly establish charges that, when multiplied by the ratio of cost to charges, provide an accurate reflection of cost. This manufacturer was concerned that they will have to collect data to determine the charges hospitals have set for these devices and the applicable ratio of cost to charges. They believe the charges may not have been set appropriately to be consistent with the ratio of cost to charges. If not, pass-through payments might be substantially less than the actual cost for these medical devices.

This manufacturer indicated that it is working to obtain the required charge and cost report data from providers of cochlear implant procedures and will report back to us once it has these data. The manufacturer requested that we agree to work with them in setting any

future update to the payment allowance recognizing the short timeframe available to collect the data.

*Response:* We appreciate the commenter's offer to assist us in collecting cost and charge data on cochlear implants billed by hospitals. However, for purposes of making transitional pass-through payments for new medical devices such as cochlear implants, it is not necessary for manufacturers to obtain cost report data from hospitals to assist us in developing hospital-specific, cost-to-charge ratios to calculate these payments. We have already calculated these ratios and assigned them to providers. Each provider is responsible for accurately reporting its charges in order that we may calculate the appropriate payment for the pass-through device.

#### 6. Payment Weights Based on Median or Mean Hospital Costs

Section 1833(t)(2)(C) of the Act requires the Secretary to establish relative payment weights for covered hospital outpatient services. This section requires that the weights be developed using data on claims from 1996 and data from the most recent available hospital cost reports.

As specified in the April 7, 2000 final rule with comment period (65 FR 18482), section 201(f) of the BBRA 1999 amended section 1833(t)(2)(C) of the Act to authorize the Secretary to base the relative payments weights on median or mean hospital costs. In implementing the BBRA 1999 provision, we decided to adopt as final our previously proposed policy to base the relative payment weights on median (as opposed to mean) costs. We had already used median costs to reconstruct our database for the outpatient prospective payment system group weights and conversion factors in a proposed rule and we believe that this method is still valid, especially considering the time constraints for implementation of the BBRA 1999 provision. We indicated that, 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 prospective payment system rule.

*Comment:* A group of hospitals urged us to adopt a mean-based APC relative weight system to implement section 201(f) of the BBRA 1999, which authorizes, but does not require, the Secretary to use mean (rather than median) costs in determining the APC payment weights. The commenters contend that use of the geometric mean is standard in the industry as the basis

for calculating payment weights for prospective payment systems. They pointed out that the geometric mean is used because costs are not distributed "normally" (that is, there are no negative costs) and that for APCs that include low volume, high costs procedures, the geometric mean is preferable for adequately accounting for these costs. The commenters believed that our use of median costs also forced us to select an arbitrary value for relative weight 1.0, because finding the median of medians is meaningless. The commenters believed that, given the Congress' clarification in section 201(f) of the BBRA 1999, we should at least evaluate the impact of a mean-based system in our system review for 2001.

*Response:* We plan to further evaluate the feasibility of using mean rather than median costs for calculating APC payment weights in future updates. In order to make a decision about whether we should change the basis we are using for determining payment weights, we have to analyze and rerun claims data and conduct extensive impact analyses to assess the impact such a change would have on different types of providers and different types of services.

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

Section 1833(t)(2) of the Act was amended by section 201(g) of the BBRA 1999 to limit the variation in resource use among the procedures or services within an APC group. Specifically, section 1833(t)(2) of the Act 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.

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.

In the April 7, 2000 final rule with comment period, we elected to use the median cost because we have continued to set the relative payment weights for each APC based on median hospital costs. We modified the composition of the APC groups and then made additional changes to the APC in

response to public comments on individual or serial APCs.

In determining whether or not to accept changes recommended by commenters, 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 determined based on whether the change enhanced, detracted from, or had no effect on the integrity of an APC group within the context of the following five criteria:

- Resource homogeneity;
- Clinical homogeneity;
- Provider concentration;
- Frequency of services; and
- Minimal opportunity for upcoding and code fragmentation.

For a full explanation of these criteria, refer to the April 7, 2000 final rule with comment period (65 FR 18457).

After we modified the composition of the APC groups based on the recommendations of commenters, we applied the median cost variation limit required by section 201(g) of the BBRA 1999 to the revised APC groups. 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 listed the APC groups that we had designated as exceptions to the "two times" requirement and our reasons for granting the exception. We based the exceptions on factors such as low procedure volume, suspect or incomplete cost data, concerns about inaccurate or incorrect coding, or compelling clinical arguments. We indicated that we would be examining the extent to which the APC reorganization due to the "two times" rule results in upcoding (refer to the April 7, 2000 final rule with comment period (65 FR 18458–18475)).

*Comment:* We received requests to examine 51 APCs that commenters alleged violated the "two times" rule.

*Response:* We reevaluated the APCs listed below, upon which we received comments, and found that most of them did not warrant revision. We received no new information about these APC groups that would alter our previous decision. These APCs are identified below under numbers 1 and 2.

Our review also revealed that a few APC groups did warrant revision and we have reconfigured these APCs accordingly. We have listed these APCs under number 3. In addition, our review identified some APCs that are additional exceptions to the "two times" requirement. These APC groups and our

reasons for the exception are listed below under number 4.

In reviewing the APC groups for conformance to the "two times" requirement, we exempted from the analysis codes for unlisted services and procedures and those codes that represent less than 2 percent of the claims in the APC (our test for low volume).

1. Taking into account the exemptions mentioned above, the following APC groups that we reviewed based on comments have not been reconfigured:

- 0005 Level II Needle Biopsy/  
Aspiration Except Bone Marrow
- 0076 Endoscopy Lower Airway
- 0088 Thrombectomy
- 0090 Level II Implantation/Removal/  
Revision of Pacemaker, AICD or  
Vascular Device
- 0111 Blood Product Exchange
- 0112 Extracorporeal Photopheresis
- 0121 Level I Tube changes and  
Repositioning
- 0143 Lower GI Endoscopy
- 0146 Level I Sigmoidoscopy
- 0149 Level II Anal/Rectal Procedure
- 0150 Level III Anal/Rectal Procedure
- 0151 Endoscopic Retrograde  
Cholangio-Pancreatography (ERCP)
- 0162 Level III Cystourethroscopy and  
other Genitourinary Procedures
- 0260 Level I Plain Film Except Teeth
- 0262 Plain Film of Teeth
- 0265 Level I Diagnostic Ultrasound  
Except Vascular
- 0268 Guidance Under Ultrasound
- 0269 Echocardiogram Except  
Transesophageal
- 0278 Diagnostic Urography
- 0280 Level II Diagnostic Angiography  
and Venography Except Extremity
- 0282 Level I Computerized Axial  
Tomography
- 0283 Level II Computerized Axial  
Tomography
- 0284 Magnetic Resonance Imaging
- 0286 Myocardial Scans
- 0290 Standard Non-Imaging Nuclear  
Medicine
- 0291 Level I Diagnostic Nuclear  
Medicine Excluding Myocardial  
Scans
- 0292 Level II Diagnostic Nuclear  
Medicine Excluding Myocardial  
Scans
- 0294 Level I Therapeutic Nuclear  
Medicine
- 0297 Level II Therapeutic Radiologic  
Procedures
- 0301 Level II Radiation Therapy
- 0303 Treatment Device Construction
- 0304 Level I Therapeutic Radiation  
Treatment Preparation
- 0305 Level II Therapeutic Radiation  
Treatment Preparation

2. The following APC groups were listed in the April 7, 2000 final rule



with comment period as exceptions to the "two times" rule and our review found no factual basis for modifying our decision:

0030 Breast Reconstruction/  
Mastectomy

0264 Level II Miscellaneous Radiology  
Procedures

0274 Myelography

0279 Level I Diagnostic Angiography  
and Venography Except Extremity

0311 Radiation Physics Services

0371 Allergy Injections

3. We have reconstructed the four APCs shown below as a result of adding the cost of certain devices used in performing procedures included in these APCs. We discuss this change in section III.B. of this preamble.

0080 Diagnostic Cardiac

Catheterization

0081 Non-Coronary Angioplasty or  
Atherectomy

0082 Coronary Atherectomy

0083 Athrectomy

4. Following are additional exceptions to the "two times" rule and our reasons for the exceptions. We are excepting these APCs from the "two times limit" on an interim basis, until we can review data from the first year of billing under the hospital outpatient prospective payment system.

0142 Small Intestine Endoscopy: The codes in APC 0142 are clinically similar and should show a relative progression of cost with slight increases in complexity. This effect does not occur, presumably due to low volume (although exceeding our low volume threshold) or inconsistent coding. Splitting this APC into two, based on current data, would be unjustified.

0145 Therapeutic Anoscopy: The costs of the codes in this APC are aberrant, with several of them exceeding the costs of more extensive procedures such as sigmoidoscopy and colonoscopy.

0152 Percutaneous Biliary Endoscopic Procedures: The codes in this APC have so few occurrences that we cannot justify splitting the group. Several of the codes call for the use of devices such as stents that may be paid for separately.

0161 Level II Cystourethroscopy and other Genitourinary Procedures: The costs of the codes in this APC are aberrant, with more comprehensive codes costing less than the base codes.

0195 Level V Female Reproductive Procedures: This is a low volume APC, with aberrant cost data. In several instances, codes that are more comprehensive cost less than the related, simpler code.

0296 Level I Therapeutic Radiologic Procedures: We believe the codes at the

lower end of the median cost in this APC would be underpaid if we were to move them to a lower-paying APC.

0300 Level I Radiation Therapy: We believe we would underpay codes at the lower end of median cost in this APC if we were to move them to a lower-paying APC.

0312 Radioelement Applications: We believe the costs in this very low volume APC are aberrant. However, the group is completely coherent clinically. The radioactive elements related to these codes would receive separate payment.

0313 Brachytherapy: We believe the costs in this very low volume APC are aberrant. The group is coherent clinically. The radioactive elements related to these codes would receive separate payment.

0314 Hyperthermic Therapies: This APC has an extremely low volume, with aberrant costs.

#### 8. Annual Review of the Components of the Hospital Outpatient Prospective Payment System

In the April 7, 2000 final rule with comment period (65 FR 18501-18502), we indicated that, in accordance with section 1833(t)(9) (as redesignated and revised by sections 201(h) and 202(a) of the BBRA 1999), we would 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 hospital outpatient prospective payment system. In accordance with section 201(h)(2) of the BBRA 1999, an annual review process will begin in calendar year 2001 for the hospital outpatient prospective payments that would take effect for services furnished on or after January 1, 2002. This review process will involve consultation with an expert advisory panel. We will provide notice of the formation of the expert advisory panel in the **Federal Register**. The expert outside advisory panel will review and make recommendations to us on the clinical integrity of the groups and weights and may use data other than those collected or developed by us for their review and advisory functions.

We note that in section III of this preamble, we are updating the wage index values and the conversion factor under the hospital outpatient prospective payment system effective for calendar year 2001. We also are making appropriate changes to the APC groups to reflect additions and deletions of CPT codes and changes to a limited number of APCs to incorporate the cost of certain devices used in performing

those procedures that were excluded from our initial ratesetting methodology.

*Comment:* One commenter stated that the wage index for the Hattiesburg, Mississippi Metropolitan Statistical Area (MSA), .7306, was printed incorrectly in our April 7, 2000 final rule with comment period. The commenter stated that use of this value would result in an underpayment for that area. The commenter further stated that, "the appropriate wage index for the Hattiesburg, Mississippi MSA for the fiscal year 2000 is .7634." The commenter was concerned that we had previously acknowledged this error and promised to correct it via a program memorandum to fiscal intermediaries dated April 2000 (Transmittal Number A-00-17), but had failed to do so in our April 7, 2000 final rule with comment period.

*Response:* We apologize for the confusion. The fiscal year 2000 hospital inpatient prospective payment system wage index value for the Hattiesburg, Mississippi (MSA) was changed from .7306 to .7634 in accordance with section 153 of the BBRA 1999 that required us to include wage data from Wesley Medical Center in calculating the wage index for this MSA. On August 1, 2000, we published in the **Federal Register** an interim final rule with comment period (65 FR 47026) that included Hattiesburg's new hospital inpatient prospective payment system wage index. For services paid under the hospital outpatient prospective payment system, the new wage index value is effective for services furnished on or after August 1, 2000.

#### 9. Copayment Amounts Not Affected by Pass-Throughs

Section 1833(t) of the Act, as established by the BBA of 1997, includes a mechanism designed to achieve a beneficiary coinsurance level equal to 20 percent of the prospectively determined payment rate established for the service. In the April 7, 2000 final rule with comment period, we specified how a copayment amount is calculated annually for each APC group under the hospital outpatient prospective payment system.

We also explained that sections 201(a) and (b) of the BBRA 1999 amended section 1833(t) of the Act to provide for additional payments to hospitals for outlier cases and for certain medical devices, drugs, and biologicals and that these additional payments to hospitals will not affect copayment amounts. Redesignated section 1833(t)(8)(D) of the Act, as amended by section 201(i) of the BBRA 1999, provides that the copayment 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.

In addition, we specified that section 202 of the BBRA 1999 added 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.

We specified that copayment from beneficiaries will not be collected for the additional payments made to hospitals (outlier and transitional pass-throughs) by Medicare. Beneficiary copayment amounts will be calculated as if the outlier and transitional pass-throughs had not occurred (65 FR 18487–18488).

When a drug or device pass-through payment is reduced by the otherwise applicable APC payment amount that is associated with the drug or device, it is only the portion of the payment that represents an additional pass-through payment that is not subject to copayment. The portion that does not represent an additional pass-through payment will be subject to copayment.

We did not receive any public comments on this provision.

#### 10. Extension of Cost Reductions

In the April 7, 2000 final rule with comment period (65 FR 18439), we announced that, in accordance with section 1861(v)(1)(S)(ii) of the Act (as amended by section 201(k) of the BBRA 1999), the 5.8 and 10 percent reductions for hospital operating and capital costs, respectively, would extend until the first date that the hospital outpatient prospective payment system is implemented (which was August 1, 2000).

We did not receive any public comments on this provision.

#### 11. Clarification of Congressional Intent Regarding Base Amounts Used in Determining the Hospital Outpatient Prospective Payment System

Section 201(l) of the BBRA 1999 provided that, “With respect to determining the amount of copayments described in paragraph (3)(A)(ii) of section 1833(t) of the Act, as added by section 4523(a) of 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.” In accordance with this provision, in the April 7, 2000 final rule with comment period (65 FR 18482–18493), we explained how we determined APC group weights, calculated an outpatient prospective payment system conversion factor, and determined national prospective payment rates, standardized for area wage variations, for the APC groups. We then explained how we calculated the aggregate hospital outpatient prospective payment to hospitals in a budget neutral manner and how we calculated beneficiary coinsurance amounts for each APC group.

We did not receive any public comments on this provision.

#### 12. Transitional Corridors for Application of Outpatient Prospective Payment System

Section 1833(t)(7) of the Act, as added by section 202(a)(3) of the BBRA 1999, provides for payment adjustments during a transition period to limit the decline in payments under the outpatient prospective payment system for hospitals. These additional payments are to be implemented without regard to budget neutrality and are in effect through 2003.

In the April 7, 2000 final rule with comment period (65 FR 18499–18500), we specified that, from the date the prospective payment system is implemented through 2003, a provider, including a CMHC, will receive an adjustment if its prospective payment system payments for outpatient services furnished during the year is less than a set percentage of its pre-BBA amount for that year. The pre-BBA amount is the product of the reasonable cost the hospital incurs for prospective payment system services furnished during the year and the payment-to-cost ratio for covered prospective payment system services furnished during the cost reporting period ending in calendar year 1996. Additionally, we provided that small rural hospitals with 100 or fewer beds and cancer hospitals will be held harmless under this provision. Small rural hospitals will be held harmless for services furnished before January 1, 2004. The hold-harmless provision applies permanently to cancer centers. We announced that we will make interim payments to the affected hospitals subject to retrospective adjustments and that these provisions do not affect beneficiary coinsurance. Finally, we specified that this provision is not subject to budget neutrality.

#### a. Interim Payment Versus Final Settlement

*Comment:* One commenter recommended that we make retroactive payments to hospitals in those “situations where underpayments have been made between the prospective payment system payments as compared to the pre-prospective payment system amounts.” Another commenter asked that we set forth the process that would be used to determine retroactive payment adjustments if the hospital’s interim payments are higher or lower than its actual experience. The commenter further asks that we state whether the interim payments will be compared to outpatient payments shown on settled or audited cost reports.

*Response:* Final transitional corridor payments are determined based on a provider’s settled cost report. At the time the cost report is settled, the reasonable costs incurred by the provider to furnish outpatient prospective payment system services during the calendar year are known and that amount is then multiplied by the provider’s 1996 payment-to-cost ratio to calculate the pre-BBA amount. The pre-BBA amount for a calendar year is compared to the actual prospective payment system payments the provider received to determine whether the provider may be entitled to a transitional corridor payment. Although the final transitional corridor payment is based on a settled cost report, beginning in October 2000, we have been making monthly interim payments to providers based on estimates of what their transitional corridor payments should be based on the monthly bills the provider submits. The monthly payments are designed to maintain some additional cash flow to providers that may otherwise realize significant losses on services that are being paid under the prospective payment system.

#### b. Payment-to-Cost Ratios

*Comment:* One commenter argued that our formula for calculating the base payment-to-cost ratio for the transitional corridor payments does not comport with the statutory requirements. The commenter stated that we define the denominator of the base payment-to-cost ratio to be “[the] reasonable cost of these services for the period, without applying the cost reductions under section 1861(v)(1)(S) of the Act.” The commenter contends that the phrase “without applying the cost reductions under section 1861(v)(1)(S) of the Act” is not included in section 1833(t)(7)(F)(ii)(II) of the Act, as

amended by section 212 of the BBRA 1999. The commenter claimed that by defining the denominator in this manner, the payment-to-cost ratio is understated and transitional corridors payments to hospitals would be reduced. The commenter stated that such a reduction is contrary to Congressional intent and urged us to modify our base payment-to-cost denominator set forth in § 419.70(f)(2)(ii) to exclude the phrase "without applying the cost reduction under section 1861(v)(1)(S) of the Act."

*Response:* The phrase "without applying the cost reductions under section 1861(v)(1)(S) of the Act" was intended to make clear that a hospital's 1996 "reasonable costs" do not include the effects of the reductions in section 1861(v)(1)(S) of the Act. We did not mean to suggest that we were taking the hospital's 1996 "reasonable costs" and then adding back the reductions for purposes of determining the denominator of the base payment-to-cost ratio. We view the hospital's 1996 reasonable costs as the unreduced amount; thus, the denominator of the hospital's base payment-to-cost ratio (1996 reasonable costs) does not reflect the reductions. We believe that our policy is consistent with the purpose of the transitional corridor provision. Under this policy, if a hospital incurs the same amount of costs during the transitional corridor as in 1996, then its pre-BBA amount (the amount that estimates what the hospital would have received in the current year if payments were calculated under the pre-prospective payment system) would be the same as the payments the hospital received in 1996. Under the methodology suggested by the commenter, if a hospital incurs the same amount of costs during the transitional corridor as in 1996, then its pre-BBA amount would be *higher* than the payments the hospital received in 1996. The language in § 419.70(f)(2)(ii) as set forth in the April 7, 2000 final rule with comment period was intended to clarify, not revise, the definition of 1996 reasonable costs, but we recognize that the phrase at issue may have inadvertently caused confusion to the extent it is redundant; accordingly, we are revising that section to remove the phrase.

*Comment:* One commenter asked us to clarify the term "payment-to-cost ratio" and the data that will be used to compute the ratio. Several commenters asked why we did not give the 1996 outpatient prospective payment system-specific amounts required to compute the payment-to-cost ratio and the methodology for calculating it.

*Response:* The statutory definition of base "payment-to-cost ratio" is fairly straightforward. Under section 1833(t)(7)(F) of the Act, the base payment-to-cost ratio for a given hospital is the ratio of (1) the hospital's Medicare Part B reimbursement for covered OPD services for the cost reporting period ending during 1996, to (2) the hospital's reasonable costs for that period. We are in the process of developing program instructions for fiscal intermediaries (for notification to providers) to provide detailed information on how payment-to-cost ratios are calculated. These instructions will be made available as soon as possible.

*Comment:* One hospital association recommended that we revise our regulations to explicitly state that we will adjust the provider's 1996 payment-to-cost ratio "whenever subsequent developments occur that affect the data used in the calculation." The commenter cited final audit adjustments and appeal determinations as examples of adjustments that would warrant changing the 1996 cost data used to calculate the provider's payment-to-cost ratio. The commenter stated that this policy is consistent with similar adjustments made under the prospective payment systems for both inpatient operating and capital-related costs.

*Response:* We agree with the commenter. In the event final audit adjustments or appeals result in a change in outpatient costs or payments for the provider's 1996 cost report, the provider's payment-to-cost ratio would be recalculated.

*Comment:* One commenter asked for clarification on the treatment of direct graduate medical education costs and education costs for nursing and allied health programs in calculating the payment-to-cost ratio. The commenter assumed that such costs are excluded from the pre-BBA amount because they will continue to be paid on a cost pass-through basis.

*Response:* The commenter is correct that direct graduate medical education costs and certain costs of nursing and allied health programs are paid on a cost pass-through basis and will not be included in calculating a provider's pre-BBA amount.

*Comment:* One commenter asked that we explain our reasons for basing the transitional corridor interim payments on a 0.8 payment-to-cost ratio. The commenter suggested that a provider be allowed to modify its interim transitional corridor payment if it can show that its payment-to-cost ratio is higher or lower than the 0.8 level.

Several commenters questioned why we chose to use a standard 0.8 payment-to-cost ratio for all providers in calculating the interim payment if provider-specific payment-to-cost ratios were available. They stated that 9 of the 10 cancer centers have payment-to-cost ratios that exceed 0.8.

*Response:* The standard payment-to-cost ratio of 80 percent is an average value that we calculated for payment-to-cost ratios across all hospitals. We decided to use 80 percent for all providers to permit us to make interim payments as soon as possible following the implementation of the outpatient prospective payment system. If we had attempted to calculate individual payment-to-cost ratios for all providers, it would have delayed, perhaps for several months, the introduction of interim payments. Final transitional corridor payments will be calculated using each provider's payment-to-cost ratio for the relevant year at the time of settlement of the cost report. In the future, as we gain more experience with interim payments, we will consider permitting modification of payment-to-cost ratios to reflect particular circumstances.

#### c. Cost-to-Charge Ratios

*Comment:* One commenter stated that the April 7, 2000 final rule with comment period did not explain how the transitional corridor payments would be implemented for the 10 cancer hospitals. The commenter noted that while Program Memorandum Transmittal No. A-00-23 issued by us on April 7, 2000, does describe how these payments are to be calculated it does not clarify how we derived the hospital-specific cost-to-charge ratios used to compute the transitional corridor payments.

Several commenters representing the 10 cancer centers stated that the cost-to-charge ratios for their centers that will be used in calculating their transitional corridor, outlier, and transitional pass-through payments are significantly lower than their estimates. They requested that we explain how we determined their ratios and comment on the appropriateness of our methodology. They also asked that we respond to a number of specific questions to allow hospitals to determine whether the cost-to-charge ratios accurately reflect the hospital's cost and provide a fair base for calculating their transitional corridor payments.

*Response:* On September 8, 2000, we issued a Program Memorandum Transmittal No. A-00-63, which provides a detailed explanation of how hospital cost-to-charge ratios were

calculated. This program memorandum is available on HCFA's internet website at [www.hcfa.gov/Medicare](http://www.hcfa.gov/Medicare).

d. Interim Payments Limited to 85 Percent of the Estimated Transitional Corridor Payment

*Comment:* One commenter asked why we will only pay 85 percent of the estimated transitional corridor payment as an interim payment. Another commenter recommended that we reconsider our policy to pay providers only 85 percent of their transitional corridor payments on the interim basis. The commenter stated that our policy to withhold 15 percent of each provider's payment until the fiscal intermediary finalizes the provider's cost report is contrary to Congressional intent to preserve hospitals' cash flow and ensure them of an ability to provide outpatient services to beneficiaries, especially those in rural areas. Another commenter stated that retaining 15 percent of each provider's estimated transitional corridor payments until the provider's cost report is settled is contrary to Congressional intent and defers relief provided by statute for several years.

*Response:* We limited the interim payment to less than 100 percent of the estimated payment in order to minimize the risk of overpayment. If interim payments exceed the final settled amounts, we would need to initiate recoupment procedures that place additional burden both on the agency and on providers. Eighty-five percent was chosen as a reasonable percentage that prudently balances the cash flow needs of some providers with concerns regarding possible difficulties in the recovery of overpayments. We have used comparable figures in other situations in which we make interim or advance payments. One example where we specified 85 percent for advance payments is in the contingency plan that we published to address the possibility that either our contractors or individual providers would be unable to process claims at the initiation of the outpatient prospective payment system. In the future, as cost reports are settled and we are able to determine how well interim transitional corridor payments relate to final transitional corridor payments, we will reevaluate this aspect of our interim payment policy.

e. Providers Having More Than One 1996 Cost Report

*Comment:* Several commenters stated that we did not discuss in our final rule how we would calculate the 1996 payment-to-cost ratio in cases where a provider has more than one cost report that is less than 12 full months during

the fiscal year ending in 1996. The commenters asked which would be the appropriate cost report to use in calculating the transitional corridor payments. One commenter explained that this situation may occur if ownership changed during the provider's fiscal year ending in 1996.

*Response:* The 1996 cost report that will be used to calculate a payment-to-cost ratio is the cost report period that ends in calendar year 1996. If a provider has two cost reports that end in 1996, we will make a decision about which cost report to use on a case-by-case basis, depending on which appeared to be the most representative of the provider's experience in 1996. For example, if one cost report covers a longer period, we would likely use that one.

f. Providers Having No 1996 Cost Report

*Comment:* One commenter expressed concern about insufficient guidance from us about how transitional corridor payments would be determined for providers that did not file cost reports during 1996. The commenter believed that because the statute is silent on this issue, we have the discretion to develop such policy. The commenter strongly opposed any decisions by us to preclude providers without 1996 cost reports from being eligible to receive transitional corridor payments.

Another commenter requested that we treat new hospitals that did not file a 1996 cost report the same as rural hospitals. The commenter contended that the pre-BBA payment level for these hospitals should be based on the hospital's first full cost reporting period, and would be guaranteed at that level through December 31, 2003. Another commenter suggested as an option that we assign a regional average payment-to-cost ratio for existing providers to providers without a 1996 cost report.

*Response:* Under the statute, the amount of transitional payments to providers depends on the provider's reimbursement for the 1996 cost reporting period. We intend to monitor the adequacy of payments to providers not having a 1996 cost report, but we believe that a statutory change is required in order to provide transitional payments to providers that did not have a 1996 cost report.

g. Prospective Payment System Delay and Transitional Corridor Payments

*Comment:* One commenter expressed concern about the potential effect of delaying implementation of the hospital outpatient prospective payment system on the duration of the transitional corridor payments as provided by law.

The commenter stated that our decision to delay implementation of the prospective payment system for 1 month, from July 1, 2000 to August 1, 2000, should not result in a 1-month loss of transitional corridor payments for providers. The commenter believed that the 3½ years of corridor payments required by law for non-cancer hospitals paid under the outpatient prospective payment system should not be reduced due to delayed implementation of the prospective payment system. The commenter urged us to seek a legislative change if we determine the 3½ year period for transitional corridor payments must coincide with the first 3½ years of actual prospective payment system implementation.

*Response:* For hospitals that do not qualify for the permanent hold-harmless provision applicable to cancer hospitals, the statute provides for transitional corridor payments through the end of calendar year 2003. We will monitor and evaluate prospective payment system payments and will consider whether it would be appropriate to recommend that Congress legislate an extension of transitional corridor payments.

h. Rural Hold-Harmless Provision

*Comment:* One commenter suggested that we reevaluate the definition of rural outpatient hospitals eligible for the hold-harmless provision and consider including rural hospitals that have 100 to 200 beds, "but whose outpatient volumes are not sufficient to maintain the facilities' finances."

*Response:* The bed size for hospitals to qualify for the rural hospital hold-harmless provision is limited by statute, under section 1833(t)(7)(D)(i) of the Act, to hospitals that have no more than 100 beds.

*Comment:* One commenter stated that on page 18501 of the April 7, 2000 final rule with comment period, we state that bed size under the rural hospital hold-harmless provision will be determined in the same manner as it is for the hospital inpatient prospective payment system indirect medical education adjustment. The commenter contended that we have not provided these instructions to fiscal intermediaries. The commenter questioned whether the fiscal intermediaries are using the number of beds reported on the hospital cost reports to determine the bed size. Still another commenter stated that we failed to specify how beds are to be counted under the hospital outpatient prospective payment system. The commenter further stated that our impact analysis published in the April 7, 2000 final rule with comment period

suggests that available bed counts shown on the HCFA-2552 cost report S-3 Worksheet are used to determine if a hospital has 100 or fewer beds to qualify for the rural hold-harmless transitional corridor payment provision. The commenter urged us to clarify this issue.

*Response:* In Program Memorandum Transmittal No. A-00-23, later revised in June 2000 as Program Memorandum Transmittal No. A-00-36, we provided instructions to fiscal intermediaries concerning how to calculate interim transitional corridor payments. As indicated in the April 7, 2000 final rule with comment period, the bed size used for transitional corridor payments will be the same bed size defined in and used to calculate indirect medical education costs and disproportionate share adjustments under the hospital inpatient prospective payment system. Fiscal intermediaries are instructed to obtain certain provider-specific information needed to make the calculation from the outpatient provider-specific file that they maintain. Certain items on the outpatient provider-specific file, including bed size, are taken directly from the provider file used in processing inpatient claims.

*Comment:* One commenter urged that we revise policy for determining bed size for purposes of defining rural providers eligible for the hold-harmless provision. The commenter advocated that we adjust a provider's count of acute inpatient days to account for observation patients occupying acute inpatient beds.

*Response:* The commenter did not provide a rationale for their recommendation. We believe that it is appropriate to adopt a policy for purposes of the outpatient prospective payment system that is consistent with the policy for purposes of the inpatient prospective payment system; therefore, we are not making a change at this time.

*Comment:* A commenter specifically asked that, for purposes of determining bed size for rural providers, we clarify what year is used to determine bed size. The commenter also asked what our policy is regarding providers that changed their inpatient capacity prior to July 1, 2000, and those that may change this capacity during the 3½ year transition period. The commenter suggested that we permit hospitals to downsize capacity without affecting their eligibility for hold-harmless status.

*Response:* Under § 412.105(b), to determine bed size for the rural hold-harmless provision, we calculated bed size on the basis of the provider's cost reporting period. A rural hospital's bed

size and, therefore, its eligibility for hold-harmless treatment may change from one cost reporting period to the next.

*Comment:* Several commenters asked us to clarify whether a hospital's reclassification for either the wage index area or standardized amount affects its eligibility for the rural hold-harmless payment. The commenter believed that, because the BBRA 1999 statutory provision relevant to the rural hold-harmless provision refers to providers "located in a rural area" rather than the provider's payment status, a provider's geographic reclassification for wages or standardized amount has no bearing on its rural hold-harmless status. A few commenters argued that a geographic reclassification under inpatient prospective payment system for the wage index or the standardized amount is not relevant for purposes of the hold-harmless rural payment provision and that these reclassified hospitals should be included in the rural hold-harmless payment.

*Response:* If a hospital is located in a rural area, it will not lose its eligibility for hold-harmless payments if it obtains a geographic reclassification under the inpatient prospective payment system for purposes of determining its wage index or standardized amount.

*Comment:* A number of commenters expressed concern about the various aspects of the hold-harmless provision, referring to sections 1886(d)(8)(E) and 1833(t)(13) under section 401 of the BBRA 1999, and asked about a hospital's eligibility for the rural hold-harmless provision.

*Response:* Under section 1886(d)(8)(E) of the Act, as added by section 401 of the BBRA 1999, if a hospital submits an application and meets certain criteria, the Secretary treats the hospital as being located in a rural area for purposes of section 1886(d) of the Act. Under section 1833(t)(13) of the Act, as added by section 401(b) of the BBRA 1999, if a hospital is treated as being located in a rural area under section 1886(d)(8)(E) of the Act, then the Secretary shall treat the hospital as being located in a rural area for purposes of the outpatient prospective payment system. Therefore, if a hospital is treated as being located in a rural area under section 1886(d)(8)(E) of the Act, then the hospital is treated as a rural hospital for purposes of the hold-harmless provision.

*Comment:* One commenter stated that the 2-month waiting period for interim transitional payments may adversely affect a large number of small rural hospitals. The commenter also believed these hospitals will require a higher

interim payment than planned. The commenter asked that we use a hospital-specific impact analyses to create a process for interim payments for these small rural hospitals that would begin concurrently with the start of the prospective payment system.

*Response:* In order to calculate interim transitional corridor payments for any hospital, we needed to have some amount of claims that had been processed under the prospective payment system. For this reason, we were not able to begin transitional corridor payments concurrently with the implementation of the prospective payment system. Because of our concerns discussed earlier about having to initiate recoupment procedures in cases of overpayments, we are not increasing interim payments at this time. However, as cost reports are settled and we are able to determine how well interim payments predict final transitional corridor payments, we will be able to reevaluate this policy.

#### i. Covered Charges

*Comment:* Several commenters asked that we clarify the definition of "covered charges" used to compute the rural hold-harmless transitional corridor payment. One commenter stated that total procedures and thus the hold-harmless payment will be understated should we eliminate from these calculations the charges for incidental procedures or procedures that the Outpatient Code Editor consolidates into the main procedures.

*Response:* In the preamble and the regulation text of the April 7, 2000 final rule with comment period, we refer to "covered hospital outpatient services" to describe the services that are paid under the prospective payment system and, therefore, subject to the transitional corridor provision. To determine a provider's costs for purposes of calculating the pre-BBA amount for both interim payments and for final cost report settlement, we will take into account all costs encompassed under the prospective payment system, including the cost of incidental services that are packaged into the APC rate. These services are identified as those having HCPCS codes with a status indicator of "N" (as listed in Addendum B) and incidental services that may not be billed with HCPCS codes, but which are billed under revenue codes that indicate a packaged service such as observation services, recovery room, supplies and many drugs.

*Comment:* One commenter asked us to clarify how charges for packaged services, for example observation services, should be billed when they are

the only service provided. The commenter stated that inclusion of charges for these packaged services in the total bill charges are necessary to calculate the proper transitional corridor payment.

*Response:* Packaged services will not be the only items that appear on a bill. Packaged services will appear on a bill with the service to which they are incidental. For example, observation services are properly billed with the clinic visit, emergency room visit, surgery, etc., that results in the need for the incidental observation service.

#### j. Cancer Hospitals and Transitional Corridor Payments

*Comment:* Several commenters believed that the process described in Program Memorandum Transmittal No. A-00-23 for calculating the hold-harmless transitional corridor payments should be revised because it does not reflect Congressional intent and will not provide the relief to the 10 cancer centers that the Congress intended. These commenters contended that the method described in the program memorandum for calculating the transitional corridor payments will result in a 22 percent loss in outpatient patient revenues for the cancer centers compared to those received in 1998. The commenters further claimed that their revenue losses under the new outpatient prospective payment system may increase an additional 2 percent, or 24 percent in total, because we will not pay claims for any medical visits that are billed in conjunction with related significant procedures.

In addition, these commenters urged us to:

- Establish an appeal process for providers with cash flow problems that would permit fiscal intermediaries to adjust a provider's cost-to-charge ratio "to rectify ongoing OPSS losses prior to reconciliation."

- Reduce interim payments to the 10 cancer centers by only 5 percent rather than 15 percent. (The commenters contended that this approach would be consistent with the method currently used to determine their inpatient interim payments under the TEFRA cost limits system.)

- Pay the 10 cancer centers the balance of the hold-harmless payments due at the time the cost report is subjected to desk review rather than at the time it is settled. (The commenters stated that settlement of the centers' cost reports is completed within 2 to 4 years after a completed cost report is filed, whereas the cost report desk review is generally completed 90 days after it is filed.)

*Response:* Medical visits may be billed with significant procedures as long as the medical visit is a separate and distinct service from the significant procedure, even though the significant procedure is related to the medical visit. For example, as a result of an examination performed as part of a clinic or emergency room visit, a patient is determined to need a CT scan or MRI, or as a result of a dermatology examination performed as a clinic visit, a patient also has a surgical procedure to remove a mole. In these types of situations, payment will be made for both a medical visit and a significant procedure.

Program Memorandum Transmittal No. A-00-63 provides for adjustment of a provider's cost-to-charge ratio in certain specific situations. In the future, in order to reflect changes in hospital costs and charges, we will allow fiscal intermediaries to make additional updates of a provider's cost-to-charge ratio to ensure that interim payments accurately reflect our best estimates of final transitional corridor payments.

Although we limited the interim payment to 85 percent of the estimated payment in order to minimize the risk of overpayment, in the future, as cost reports are settled and we are able to determine how well interim payments predict final transitional corridor payments, we will be able to reevaluate this aspect of our interim payment policy and we will consider permitting modification of payment-to-cost ratios to reflect particular circumstances.

The statute indicates that interim payments are made subject to retrospective adjustments based on settled cost reports. However, it is current practice that, depending on the provider's specific situation, a fiscal intermediary may make additional payments as part of a tentative settlement action prior to final settlement of the cost report.

#### k. Teaching Hospitals and Transitional Corridor Payments

*Comment:* One commenter urged that we retain the transitional corridor payments permanently for major teaching hospitals.

*Response:* Section 1833(t)(7) of the Act provides permanent transitional corridor payments only for cancer hospitals described in section 1886(d)(1)(B)(v) of the Act. As indicated earlier, we will monitor and evaluate the prospective payment system payments and will consider whether it would be appropriate to recommend that Congress extend transitional corridor payments.

*Comment:* One commenter stated that while the transitional corridor payments will mitigate some of the losses to teaching hospitals under the prospective payment system compared to the former cost-based payment system, these payments are temporary. The commenter believed that we underestimated the losses that some teaching hospitals will experience. Another commenter urged us to monitor closely the impact of the prospective payment system on major teaching hospitals during the 3½ year transitional corridor payments. The commenter believed that these hospitals will require a payment adjustment after the transitional corridor payment period expires to mitigate their potential financial losses under the prospective payment system.

*Response:* As we stated in the preamble of the April 7, 2000 final rule with comment period, we will perform further comprehensive analyses of cost and payment differences between different classes of hospitals as soon as there is a sufficient amount of claims data submitted under the prospective payment system. We will use data from the initial years of the prospective payment system to conduct regression and simulation analyses. In addition, we will carefully track and analyze the additional payments made to hospitals under the transitional corridor provision. These analyses will be used to consider and possibly propose adjustments in the system, particularly beginning in 2004 when the transitional corridor provisions expire.

#### 13. Limitation on Coinsurance for a Procedure

In the April 7, 2000 final rule with comment period (65 FR 18488), we specified that, in accordance with section 1833(t)(8) of the Act (as amended by section 204(a) of the BBRA 1999), the coinsurance amount for a procedure performed in a year cannot exceed the hospital inpatient deductible for that year. We specified that we would 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 unadjusted coinsurance amount for any APC may be higher or lower than the inpatient hospital deductible, 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 reduction in coinsurance that occurs in applying the limitation will be paid to

hospitals as additional program payments.

*Comment:* One commenter disagreed with our interpretation of the BBRA 1999 provision that amended section 1833(t)(8) of the Act to limit the coinsurance amount for a procedure to the amount of the inpatient hospital deductible. The commenter believed that our interpretation that applies the limitation to coinsurance on an APC by the APC basis is too narrow.

The commenter concluded that, at a minimum, the limitation should be more broadly interpreted to apply to the total coinsurance incurred by a beneficiary in connection with an outpatient visit, that is, from the time the beneficiary walks into an outpatient department until he or she is released. However, to implement the provision as envisioned by the Congress, the commenter suggested that we also consider developing a service period unit for outpatient procedures that is similar to the "spell of illness" concept used to define the set of services to which a single inpatient hospital deductible applies. Therefore, when a patient comes to an outpatient department for treatment of a particular condition, his or her coinsurance liability for all the services required for that condition should not exceed the inpatient hospital deductible. The commenter recommended that we apply the limitation regardless of how many or which APCs are billed or the number of visits required for such treatment.

*Response:* APCs are based on CPT codes. We believe that the most plausible meaning for "procedure" in this context is a CPT code or, by extension, an APC. Thus we interpret the limitation of coinsurance for a procedure in section 1833(t)(8)(C) of the Act as added by section 204 of the BBRA 1999 to apply in general to APCs.

We do not believe that it was the intent of the Congress to apply the coinsurance limitation to the beneficiary's aggregate coinsurance amounts for all outpatient services received during the entire service period for a specific condition or even to the services a beneficiary receives in one day. During the Congressional committee deliberations on this provision before it was enacted, we held technical discussions with committee staff. At their request, we identified the specific 10 APCs in the September 1998 proposed rule that would be likely to have a coinsurance that exceeded the inpatient hospital deductible. The Congressional Budget Office also used that information to project the cost of this statutory provision. Therefore, we believe that our interpretation in the

April 7, 2000 final rule with comment period of how the coinsurance limitation is to be applied is consistent with the intent of Congress.

*Comment:* Several commenters pointed out that because APCs for drugs and biologicals are defined based on HCPCS codes for the lowest unit of the drug or biological, if we intend to apply the inpatient deductible limit at the APC level, we might disadvantage beneficiaries who receive multiple units. For example, the coinsurance for a specific drug APC may not exceed the inpatient deductible amount. However, if multiple units of the same drug are administered, the coinsurance based on the multiple APCs may, in fact, exceed the inpatient deductible. The commenters believed that the total coinsurance amount for a drug or biological based on the amount administered should be subjected to the inpatient deductible limit. The commenters believed that constructing APCs for drugs based on the lowest unit of the drug is solely a payment convention and does not mean that each dose is a separate "procedure." Therefore, the commenters contended, a better reading of the statute is that the administration of a drug or biological, regardless of the dose, is one procedure for purposes of applying the hospital outpatient prospective payment system and it would be inappropriate to compare the inpatient deductible limit to anything but the total coinsurance amounts.

*Response:* In the case of services that involve the administration of drugs and biologicals in separate APCs, we have concluded that we should apply the limitation on coinsurance to include both the drug or biological (in whatever units it is administered) and the service that leads to its administration. We constructed separate APCs for drugs and biologicals, and established pricing on the basis of the lowest dose, not to reflect CPT codes, but solely as a matter of convenience in administering the payment system. Consequently, we think that the interpretation with the most clinical relevance in this instance is to treat a drug or biological and the service that leads to its administration as a single procedure. We had not proposed separate APCs for drugs and biologicals in the proposed rule for the outpatient prospective payment system and the Congress did not know we would segment APCs at the time it passed the BBRA 1997.

Effective for drugs and biologicals furnished on or after January 1, 2001, when multiple units of a drug or biological are furnished to a beneficiary during one day, resulting in multiple

APC payments for the same drug, we will aggregate the total coinsurance applicable to the drug or biological, and the aggregated amount cannot exceed the inpatient hospital deductible for the calendar year. In order to accomplish this change in our bill processing systems, we are assigning a new status indicator designated as "K" to APCs for nonpass-through drugs and biologicals (as reflected in Addendum D of this interim final rule with comment period). Effective for services furnished on or after July 1, 2001, in the same circumstances, we will aggregate the total coinsurance applicable to the drug or biological and to the service that resulted in the administration of the drug, and the aggregated amount cannot exceed the inpatient hospital deductible for the calendar year. We are unable to make the latter provision effective earlier because of systems constraints.

*Comment:* One commenter stated that the BBRA 1999 requirement that coinsurance for a procedure cannot exceed the inpatient hospital deductible for that year adds confusion to an already complicated formula for determining coinsurance. The commenter stated that the monitoring of coinsurance needed to ensure the limitation is being applied on a procedure basis will add undue burden and increase a provider's costs. To make the hospital outpatient prospective payment system less complicated, the commenter believed that we should consider eliminating the threshold.

*Response:* The coinsurance limitation is required by statute. Therefore, a statutory change would be required to eliminate this provision.

#### 14. Reclassification of Certain Hospitals

In the August 1, 2000 **Federal Register** (65 FR 47029), we implemented section 401 of the BBRA 1999 for the hospital inpatient prospective payment system. Section 401(a) of the BBRA 1999, which amended section 1886(d)(8) of the Act by adding a new paragraph (E), directs the Secretary to treat any subsection (d) hospital located in an urban area as being located in the rural area of the State in which the hospital is located if the hospital files an application (in the form and manner determined by the Secretary) and meets certain statutorily specified criteria. Additionally, section 401(a) of the BBRA 1999 includes hospitals "\* \* \* located in an area designated by any law or regulation of such State as a rural area (or is designated by such State as a rural hospital)." A hospital also may seek to qualify for reclassification premised on the fact that, had it been located in a

rural area, it would have qualified as a rural referral center or as a sole community hospital.

Section 401(b) of the BBRA 1999 made a conforming change to section 1833(t) of the Act. Specifically, section 401(b) added section 1833(t)(13) to the Act which provides that if a hospital is being treated as being located in a rural area under section 1886(d)(8)(E) of the Act (for purposes of section 1886(d) of the Act), the hospital will also be treated under section 1833(t)(13) of the Act as being located in a rural area.

In the April 7, 2000 final rule with comment period, we explained that we use the same yearly version of the hospital inpatient prospective payment system wage index (which takes effect each October 1) to adjust the portion of the outpatient prospective payment system payment rate and the coinsurance amount that is attributable to labor-related costs for relative differences in labor and labor-related costs across geographic areas (and that will be applied effective each January 1). This wage index reflects the effects of hospital designations under section 1886(d)(8)(B) of the Act and hospital reclassifications under section 1886(d)(10) of the Act.

We did not receive any comments on this conforming change.

#### *B. August 3, 2000 Interim Final Rule With Comment Period*

Following are the issues addressed in the August 3, 2000 interim final rule with comment period, the public comments received on each issue, and our response to those comments. In that interim final rule, we—

- Revised the regulation at § 419.43(e)(1)(iv) to change one criterion and postpone the effective date for two other criteria that a new device, drug, or biological must meet in order for its cost to be considered “not insignificant” for purposes of determining its eligibility for transitional pass-through payments;
- Changed our interpretation for three of the eight criteria set forth in the April 7, 2000 final rule with comment period for defining a new medical device that would be eligible for transitional pass-through payments and amended § 419.43 by adding new paragraph (e)(4) to include all eight criteria;
- Clarified the assignment of “C” codes to eligible pass-through items;
- Corrected a trigger date for grandfathering of provider-based FQHCs; and
- Clarified our intent regarding prior notice of beneficiary cost-sharing liability in emergency situations.

#### 1. Transitional Pass-Through Provisions a. “Not Insignificant” Cost Criteria

Section 1833(t)(6) of the Act, as added by section 201(b) of the BBRA 1999, requires the Secretary to make transitional pass-through payments for post-1996 new drugs, biologicals, and devices for at least 2 but no more than 3 years when the cost of the item is “not insignificant” in relation to the hospital outpatient prospective payment system payment amount. In the April 7, 2000 final rule with comment period, we established three criteria that a new device, drug, or biological must meet to determine whether its costs are not insignificant relative to the APC payment with which the item is associated (65 FR 18480–81). We stated that all of the following cost criteria must be satisfied in order for a new device, drug, or biological to be eligible for transitional pass-through payments:

- Its expected reasonable cost exceeds the applicable fee schedule amount determined to be associated with the drug, biological, or device by 25 percent.
- The expected reasonable cost of the new drug, biological, or device exceeds the portion of the fee schedule amount determined to be associated with the drug, biological, or device by 25 percent.
- 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 exceeds 10 percent of the applicable hospital outpatient fee schedule amount.

After we published the April 7, 2000 final rule with comment period, we gained considerable experience from reviewing applications for transitional pass-through payments. Based on that experience, we concluded that the 25-percent limitation was too restrictive and could result in limiting Medicare beneficiaries’ access to new products. Therefore, in the August 3, 2000 interim final rule with comment period, we changed that criterion to ensure that Medicare beneficiaries would continue to have access to the latest technologies. We now require that the expected reasonable cost of a new drug, biological, or device must exceed 10 percent of the applicable fee schedule amount for the associated service. In addition, we also postponed the effective date of the other two criteria applying to a new device, biologicals, or drugs for which a transitional pass-through payment is first made to on or after January 1, 2003. As stated in the August 3, 2000 interim final rule with

comment period, the delay in the effective date for these two criteria is necessary so that we will have sufficient time to gather and analyze data needed to determine the current portion of the fee schedule amounts associated with a device, drug, or biological, which is an essential factor in applying these criteria.

*Comment:* Several commenters commended us for revising the one “not insignificant” criterion and postponing the other two criteria until after December 31, 2002. However, some argued that we created an uneven playing field by changing our policies after we published our April 7, 2000 final rule and announced pass-through application deadlines. They claimed that our untimely lowering of the cost threshold from 25 percent to 10 percent unfairly disadvantaged companies that did not submit pass-through applications by the deadline for our August 1, 2000 payments because they believed that their products would not qualify for payment. One commenter recommended that we rapidly process applications submitted for our January 1, 2001 update and change the effective date of that update to November 1, 2000. Another commenter advocated that we apply the 10-percent cost threshold retroactively to all device pass-through applications to ensure equitable treatment for all manufacturers.

*Response:* Based on our review of transitional pass-through applications, we believe that we have not applied our policy change inconsistently to applications that we received. The change to the lower cost threshold is effective for services furnished on or after August 1, 2000. If an applicant’s product was denied pass-through status because its cost was considered to be “not insignificant” and that applicant can show that our decision was not based on the 10-percent criterion, the applicant may request that we reevaluate the application. In addition, we encourage other interested parties who withheld applications because they believed that their products would not qualify for pass-through status to submit them. Further, we cannot update the pass-through payments effective November 1, 2000 as requested. Adding new pass-through items to our outpatient prospective payment system requires changes to our complex Medicare computerized claims processing systems that we can make only at the beginning of a calendar quarter.

*Comment:* One commenter believed that reducing the cost threshold to 10 percent for new devices may be too low. The commenter stated that the lower



cost threshold would expose hospitals to financial risk created by the use of new and expensive technology furnished in providing patient care. The commenter advocated that we consider as an option “establishing \* \* \* a floor—or a variable percentage that is higher for low-cost cases and lower for high-cost cases.”

*Response:* We believe that this option will require time to evaluate its merits, assess its impact on our systems and determine systems changes that would be required to implement it. Therefore, we will consider this request for possible inclusion in our future proposed rule for outpatient prospective payment system updating that we expect to publish in the spring of 2001.

*Comment:* One commenter urged that we grant the public another opportunity to evaluate and comment on all three “not insignificant” cost criteria before implementing them.

*Response:* Before we implement all three of these criteria, we plan to provide notice and opportunity for public comment. Since we do not expect to implement two of these criteria before January 1, 2003, we would not expect to publish a proposed rulemaking until the spring of 2002.

*Comment:* One commenter asked how we would apply the three “not insignificant” cost criteria in instances when multiple units of a new device are used in performing a procedure. The commenter recommended that we use the “weighted average cost of the product, based on the average number of unit used in a procedure.”

*Response:* We plan to fully describe our approach to implementing these three criteria in a future proposed rule. As previously stated, we will not implement two of these criteria before January 1, 2003. Therefore, we do not expect to publish a proposed rulemaking until the spring of 2002.

*Comment:* One commenter asked that we clarify how transitional pass-through payments will be incorporated into the APC payments at the end of the 2- to 3-year transitional period for a given device. The commenter also asked how we would prevent the cost for the pass-through items from being diluted significantly by the median cost of other procedures grouped in the same APC.

*Response:* We plan to use a methodology similar to that currently used to construct the APC groups to incorporate payment for pass-through items into the APC payments once their pass-through status expires. That is, we have assigned a unique HCPCS code to each eligible pass-through item that will allow us to track its payments and utilization over the 2 to 3 years that it

is eligible for pass-through status. The codes will allow us to match the pass-through items to the specific procedures or medical visits with which they are used. After we gain appropriate information about the actual costs a hospital incurs to provide a pass-through item, we will package the cost for the pass-through with that for the relevant procedure or medical visit with which it is used and assign the packaged service to a clinically related APC group with comparable resources. We will limit the cost variation within each group as required by section 1833(t)(2) of the Act, as amended by section 201(g) of the BBRA 1999. In accordance with this provision, the items and services within a group cannot be considered comparable with respect to the use of resources if the highest median cost item or service within a group is more than two times greater than the lowest median cost item or service within the same group. By law, the Secretary is allowed certain exceptions to this requirement, that is, for low volume items and services.

*Comment:* One commenter asked if we would provide adequate recognition for multiple devices used in a procedure “if multiple procedure discounting is allowed to cut the pass-through generated recognition of these costs in half.”

*Response:* Under the hospital outpatient prospective payment system, devices eligible for pass-through payments are paid separately and not subject to the multiple procedure discounting policy. This policy applies only to the actual surgical procedure that is performed to implant the pass-through device. These procedures are denoted by a status indicator “T” and listed in Addendum B of this rule.

*Comment:* One commenter urged us to correct erroneous APC groupings more frequently than during our scheduled quarterly or annual update cycles until we stabilize the hospital outpatient prospective payment system.

*Response:* We understand the importance of paying appropriately for services billed under our new outpatient system and are committed to resolving problems that would preclude us from making appropriate payments in a timely manner. However, because of the complexity of our system we cannot commit to making changes other than during the scheduled updating cycles.

#### b. Definition of Medical Device

In the April 7, 2000 final rule with comment period, we established eight specific criteria that new or innovative medical devices must meet to be considered eligible for pass-through

payments under section 1833(t)(6) of the Act. We stated in that rule that new or innovative medical devices must meet all of the following criteria to be considered eligible for transitional pass-through payments:

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

(2) They have been approved or cleared for use by the FDA.

(3) 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. Therefore, we indicated that we will consider devices for coverage under the hospital outpatient prospective payment system if they have received an FDA investigational device exemption (IDE) and are classified by the FDA as Category B devices. However, in accordance with regulations at § 405.209, payment for a nonexperimental investigation 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.

(4) 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.

(5) The associated cost is not insignificant in relation to the APC payment for the service in which the innovative medical equipment is packaged.

(6) They are not equipment, instruments, apparatuses, implements, or 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).

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

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

In the August 3, 2000 rule, we revised criteria (3), (4), and (7) and amended § 419.43(e)(4) to include all eight criteria. We stated in that rule that our change in policies reflects experience

gained in reviewing and processing transitional pass-through applications for devices since publishing our April 7, 2000 final rule with comment period. With regard to criteria (3), we revised it by removing the cost limitation provision for IDE Category B devices that qualify for transitional pass-through payments. We explained in the August 3, 2000 interim final rule that on review of our policy for such new devices, we believed that it would be more appropriate to remove the cost limitation because they are subjected to the same eligibility requirements as any other device applying for pass-through status and because pass-through payments for a specific device are temporary.

For criteria (4), we modified our interpretation of which devices are eligible for transition pass-through payments to include new medical devices that are used for one patient only, are single use, come in contact with human tissue, and are surgically implanted or inserted in a patient during a procedure but may also be removed during that procedure so that the patient leaves the hospital without the device. Our revised interpretation also includes clips that are used as radiological site or tissue markers.

As explained in the August 3, 2000 interim final rule, it became apparent, based on experience gained in processing a large number of applications for new medical device pass-through status, that our attempt to distinguish implantable devices using the criteria we had outlined in our April 7, 2000 final rule with comment period had some practical limitations. We also explained that, in some instances, the new medical device is implanted temporarily rather than permanently as indicated in our original policy published in the April 7, 2000 final rule with comment period. However, we did not intend for our policy to exclude new medical devices that are implanted or inserted during a procedure but also may be removed during that procedure so that the patient leaves the hospital without the device. Rather, we believed that these devices should be considered for pass-through payments because they also are implantables. We further stated in the August 3, 2000 interim final rule with comment period that it had become apparent that some implantable clips are expensive and function other than as tools or supplies necessary for a surgeon to perform a surgical procedure. We did not intend to exclude such clips from consideration for pass-through payments. Therefore, we revised our interpretation of which devices are eligible for transitional pass-

through status to include also new single use medical devices that may be temporarily implanted or inserted in a patient.

Finally, in criterion (7), we became aware of the need, based on our review of pass-through applications, to clarify that supplies include pharmacological imaging and stressing agents, including contrast media but excluding radiopharmaceuticals (for which payment under the transitional pass-through provision is established by section 1833(t)(6)(A) of the Act).

*Comment:* One commenter urged that we issue detailed guidelines that clarify whether an IDE Category B device with pass-through status will be assigned only one "C-code" for both its clinical investigation and commercialization.

*Response:* Our general policy is to assign only one code to an eligible pass-through item.

*Comment:* One commenter asked how we would reconcile differences in pass-through payment differences (over 2 to 3 years) that are made for an eligible IDE Category B device during its clinical investigation phase versus those paid once the device is commercialized.

*Response:* Policy decisions regarding the analytical treatment of costs associated with specific items that will be included in our database for constructing APCs will be made in the context of the methodology that we use to derive updated APC weights and payments. This methodology will be fully described in a subsequent proposed rule prior to incorporating the cost for pass-through devices such as eligible IDE Category B devices into our APC payments.

*Comment:* One commenter asked that we clarify when the definition of a device includes or excludes all of a device's components. The commenter also asked whether we assigned separate codes for the device's components.

*Response:* If a device can be separated into distinct components and such components are considered integral to the functioning of that device, we evaluate the device and all its component parts to determine whether any or all would qualify for transitional pass-through payment. For example, we have approved several implantable neurostimulator systems for pass-through payment. These systems usually include at least two or three separate components such as a generator, leads, and receiver/transmitter. In this case, we have assigned separate HCPCS codes to each of the eligible components. However, if an eligible pass-through item is considered a component of a non-eligible item, such as a piece of capital

equipment, only the eligible item will receive a HCPCS code to bill for pass-through payments.

*Comment:* One commenter warned us about medical devices that we have approved for pass-through payments such as electrophysiology catheters that the commenter alleges are not single use items. The commenter stated that hospitals use them more than once. The commenter advocated that we advise hospitals not to request additional payments for any approved pass-through item if they reprocess or reuse them.

*Response:* In the August 3, 2000 interim final rule with comment period, we revised criterion "d" of the eight medical device eligibility criteria to explicitly preclude pass-through payments for new medical devices other than those that are single use. Therefore, additional payments will not be made for devices that are reprocessed or reused. Hospitals that bill these devices might be considered to be engaging in fraudulent billing practices.

*Comment:* A number of the commenters urged that we abandon the use of an individual or brand-specific approach to approving devices for transitional pass-through payments and adopt an approach that distinguishes devices based on categories. The commenters argued that a category approach is more appropriate and more efficient to implement than an individual, item-specific approach. They alleged that the latter approach creates winners and losers and delays timely approval of new technologies.

*Response:* As previously stated, we adopted a trade-name specific approach for several reasons. First, such an approach provides better information. Codes that are largely item-specific allow us to track what procedures the items are used with and costs of the items. When the pass-through payments for an item ends, we would expect to have good information for assigning it to relevant APCs and ensuring appropriate payment for these APCs. Adopting a scheme with a significant degree of categorization would require use of averages in making assignments and setting payment rates. Decisions based on these more limited data would likely lead to intensified concerns about the appropriateness of APC assignment and payment.

Second, this approach permits finer discrimination in eligibility decisions. An item-by-item approach allows us to be sure individual items in fact meet the criteria for eligibility. Of major concern in this instance is whether a device is "new" using the standard of the statute. Section 1833(t)(6)(A) of the Act limits

transitional pass-through payment to those devices for which “\* \* \* payment for the device \* \* \* as an outpatient hospital service under this part was not being made as of December 31, 1996.” Adopting categories would in some cases mix “old” and “new” devices. In these instances, either some old devices would get special treatment that they would not be eligible for if they were examined on an item-specific basis, or an entire category could be considered old, thus depriving some new devices from special treatment they would be eligible for if they were examined on an item-specific basis.

Third, an item-specific scheme avoids issues associated with the design of categories needed for purposes of transitional pass-through payments. It largely avoids concerns about what items should be in what category or whether new categories should be created to accommodate items that may appear to be little different from those in existing categories.

Fourth, an item-specific approach allows us to assure that a newly arriving device can obtain the full period of pass-through status it is arguably eligible for under the statute. A categorization approach would likely lead to latecomers being eligible for pass-through payments only for a shorter period. Insofar as revision to APC payment rates reflected the costs of items in the category by the time the category was terminated, the shorter period would be of little consequence. However, if the costs of the late-coming item were significantly higher, this procedure could appear objectionable. A solution in this case would be to create a new code, which could be specific to that item, thus departing from a categorization approach.

We recognize that a category approach would lessen concerns about competitive disadvantages that may have been inadvertently created by an item specific approach and about access to specific items by hospitals and their patients. However, we found no satisfactory way of establishing categories that would not run into difficulty regarding the test of whether a device is “new” as described above. Consequently, we are making no change in our approach in response to comments.

## 2. Revision to Grandfather Provision for Certain FQHCs and “Look-Alikes”

In the April 7, 2000 final rule with comment period, which discussed the provider-based status criteria and requirements, we grandfathered FQHCs or “look-alikes” that were designated as such before 1995 in order to assure the

continuity of care and access to care for patients of some of these facilities. To meet our original policy intent of helping to ensure that the new criteria do not disrupt the delivery of services to patients of these facilities, in the August 3, 2000 interim final rule with comment period (65 FR 47674), we corrected § 413.65(m) to state that 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 considered as a department of a provider, without regard to compliance with the provider-based criteria, if the facility—

(1) Received a grant on or before April 7, 2000 under section 330 of the Public Health Service Act and continues to receive funding under such a grant, or is receiving funding from a grant made on or before April 7, 2000 under section 330 of the Public Health Service Act under a contract with recipient of such a grant, and continues to meet 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 on or before April 7, 2000 to meet the requirements for receiving a grant under section 330 of the Public Health Service Act, and continues to meet such requirements. We made this change to clarify that grandfathering under § 413.65 is based on continued status as a section 330 of the Public Health Service Act grantee or a “look-alike” facility. We received no comments on this change.

## 3. Clarification of Notice of Beneficiary Cost-Sharing Liability

In the August 3, 2000 interim final rule with comment, we also addressed whether hospitals could reasonably be expected to furnish an exact statement of the patient’s financial liability, since the exact scope of services needed may not be known at the time notice must be given. Specifically, we stated that when the extent of care needed is not known before the patient is admitted, the hospital may furnish a written notice to the patient that explains the general fact that the beneficiary will incur a coinsurance liability to the hospital that he or she would not incur if the facility were not provider based. Furthermore, we clarified that the estimate of “potential financial liability” in this written notice may be based on typical or average charges for visits to the facility or organization, while stating that the patient’s actual liability will depend upon the actual services furnished by the hospital.

*Comment:* One commenter stated that our clarification regarding the notice of beneficiary cost sharing liability was helpful, but recommended that we amend or modify the regulations at § 413.65(g)(7) to reflect such clarification since the wording of the existing regulations states twice that the notice must be given “prior to the delivery of services” without an exclusion for emergency medical conditions. In addition, the regulation states that the hospital has an obligation to notify the beneficiary of the “potential financial liability” not just to provide the beneficiary with “an estimate based upon typical or average charges” in the event that the exact type and extent of care is not known.

The commenter also recommended that we require hospitals to only notify the beneficiary of the fact that the beneficiary will incur a coinsurance liability for hospital outpatient services without giving a dollar amount of beneficiary copayment. Such a notice could include a statement that the copayment liability will be determined by us and the beneficiary will be notified of the exact amount once the hospital is notified of the amount determined by us. The commenter believes that an estimate based on charges would “miss the point” of this provision since beneficiary copayment amounts are now determined by HCFA using an APC grouper, not charges.

*Response:* We appreciate the commenter’s concerns and agree that a change in the regulations is needed to reflect the clarification provided in the August 3, 2000 interim final rule with comment period in a future proposed rule. As we stated in the August 3, 2000 interim final rule with comment period (65 FR 47675), we are developing a proposed rule that will further revise and clarify the notice requirements. We are doing this to allow the public a full opportunity to comment on the changes and to ensure that we have the benefit of all relevant comments.

We disagree with the commenter’s statement that an estimate based on charges would “miss the point” of this provision since such a notice is required only to give the beneficiary an idea or an example of their “potential financial liability”. As stated in the August 3, 2000 interim final rule with comment period (65 FR 47675), the estimate should state that the beneficiary’s “actual liability will depend upon actual services furnished by the hospital.” Also, with the delay in the effective date of the provider-based status regulations until January 10, 2001, hospitals will have at least five months of experience with APC

payments under outpatient prospective payment system and should be able to develop an appropriate estimate of a copayment amount based on APCs rather than charges.

#### 4. Clarification of Protocols for Off-Campus Departments

In the April 7, 2000 final rule, under new § 489.24(i)(2) we require hospitals to establish protocols for handling individuals with potential emergency conditions who arrive at hospital off-campus departments. Section 489.24(i)(2)(ii) further requires that if the off-campus department is a physical therapy, radiology, or other facility not routinely staffed with physicians, RNs, or LPNs, the department personnel must be given protocols that direct them to contact emergency personnel at the main hospital campus.

In the August 3, 2000 interim final rule with comment period, we clarified that § 489.24(i)(2) does not require a delay of an appropriate transfer when the main hospital campus does not have the specialized capability or facilities required by the individual or when the individual's condition is deteriorating so rapidly that the time needed to move the individual to the main hospital campus would significantly jeopardize the individual's life or health. We also stated that the contact with emergency personnel at the main hospital campus should be made either after, or concurrently with, the actions needed to arrange an appropriate transfer under § 489.24(i)(3)(iii), if doing otherwise would significantly jeopardize the individual's life or health. We noted that this clarification does not relieve the off-site department of the responsibility for making this contact, but only clarifies that the contact may be delayed in specific cases when doing otherwise would endanger a patient subject to EMTALA protection. We received no comments on this clarification.

#### 5. Typographical Errors in the Provider-Based Regulations

*Comment:* One commenter questioned whether the provider-based regulations in §§ 413.65 and 489.24, as they appeared in the April 7, 2000 final rule with comment period (65 FR 18538), contained typographical errors.

*Response:* We are aware of typographical errors in the provider-based regulations as published in the April 7, 2000 final rule with comment period (65 FR 18538) and will be publishing a correction notice (HCFA-1005-CN) to make these corrections.

### III. Provisions of This Interim Final Rule With Comment Period

#### A. Changes Relating to the BBRA 1999 Public Comments

Except for the changes discussed in the preamble, we are adopting the BBRA 1999 provisions implemented in the April 7, 2000 final rule with comment period and the August 3, 2000 interim final rule with comment period, described in section II of this preamble, as final without modification. We are making the following changes to the regulation text as a result of the public comments received:

We are revising § 419.41(c)(4)(i) to provide that, effective January 1, 2001, when multiple APCs for a single drug or biological are furnished to a beneficiary on the same day, the inpatient hospital deductible limitation on coinsurance will be applied to the aggregate coinsurance for the drug or biological. The section is further revised to provide that, effective July 1, 2001, the coinsurance amount for the procedure or service that resulted in the administration of the drug or biological will be aggregated with the coinsurance for the drug or biological in applying the limit.

We are revising § 419.70(f)(2)(ii) to remove the phrase "without applying the cost reductions under section 1861(v)(1)(S) of the Act". We recognize that the phrase may have inadvertently caused confusion to the extent it is redundant, as pointed out by a commenter.

#### B. Annual Updates to Components of the Hospital Outpatient Prospective Payment System

In this interim final rule with comment period, for calendar year 2001, we are updating the wage index and the conversion factor adjustment for covered hospital outpatient services furnished beginning January 1, 2001. We also are updating the existing APC groups to reflect new codes that have been assigned. In accordance with section 1833(t)(9)(A) of the Act and section 201(h)(2) of the BBRA 1999, we will undertake a complete system update in 2001 for hospital outpatient prospective payments. That update will take effect on January 1, 2002. We will consult with an expert outside advisory panel composed of appropriate representatives of providers. This panel will review and advise us concerning the clinical integrity of the APC groups and relative weights. The panel will be allowed to use data other than those we have collected or developed during our review of the APC groups and relative weights.

#### 1. APC Groups

We are updating the existing APC groups effective January 1, 2001 to reflect the addition of new CPT and alpha-numeric codes, the deletion of invalid codes, changes to the list of procedures we pay for only in an inpatient setting (the "inpatient list"), the creation of a new status indicator, newly covered procedures, reconfigurations due to the inclusion of device costs, and revisions to correct errors and provide consistency in the placement of codes.

##### a. New Codes

There are 936 new codes, 645 of which are "C" codes. "New" in this context means new since the April 7, 2000 final rule with comment period was published. Many of the "C" codes were published in program memoranda over the intervening months. New codes are shown in Addendum B with an asterisk in the column preceding the code.

##### b. Deleted Codes

With the exception of "C" codes, codes deleted effective January 1 of each year are given a 3-month grace period in which they will still be recognized. "C" codes are temporary codes used exclusively to bill pass-through items and new technology services and items paid under the hospital prospective payment system. We will retire these codes prospectively at the start of a new calendar quarter based on specific service dates and are not extending the same 3-month grace period to them. We will drop all non "C" codes from APCs effective April 1. Deleted codes are shown in Addendum B. They are followed by the letter D. The AMA's CPT books also list deleted codes.

##### c. Revisions to Correct Errors or Inconsistencies

We are revising the APCs in order to correct errors and to provide greater consistency in the placement of codes. For example, we had assigned various types of cardiovascular diagnostic tests to four APCs, with rates based on data that, on subsequent review, appeared limited. We are recategorizing these APCs. This recategorization results in three APCs with greater clinical coherence.

Medicare covers influenza, pneumococcal, and hepatitis B immunizations routinely, with no copayment or deductible due for flu and pneumonia vaccines or their administration. Other vaccines may be covered in certain circumstances, but are, in fact, given so infrequently that our cost data are limited. We are

rearranging the preventive vaccines and assigning the less frequently furnished vaccines based on their reported costs, but within a smaller range. We expect very few immunizations other than influenza and pneumonia to be billed, but if they are billed, we will update our data.

We also are changing the APCs to which bone density studies are assigned. The codes used in 1996 captured both central and peripheral bone density studies. Coding changes since that time have separated the two types of studies, but this distinction was not reflected in the 1996 data. In order to better reflect these differences, we are separating the various codes and assigning central dual energy x-ray absorptiometry (DEXA) bone density studies to a new technology APC.

We did not include the codes for transfusion laboratory services (for example, typing and crossmatching) in APCs in the April 7, 2000 final rule with comment period. We are now creating three APCs to capture these codes, and an additional APC to capture fertility procedures.

#### d. Device-Related Codes

As described in the April 7, 2000 final rule with comment period, revenue centers 274, 275, and 278 were not included for purposes of calculating the APC rates because prior to the BBRA 1999, we anticipated paying for durable medical equipment and prosthetics (including implantable devices) outside of the outpatient prospective payment system and it was unfeasible to revise our database to reflect the revenue centers in time to publish a final rule and implement the prospective payment system by July 1, 2000. To reflect the inclusion of implantable devices as required under the BBRA 1999, we have recalculated APC rates with these

revenue centers included. As a result, the median cost for certain procedures such as inserting pacemakers, replacing leads, and providing neurostimulators increased significantly.

In order to recognize these cost increases, which are attributable to the devices, and to aid in the assignment of devices to APCs at the end of the pass-through period, we are reconfiguring certain APCs. That is, we are creating APC groups for the insertion of pacemakers, the replacement of pacemaker electrodes, the implantation of a pacemaker and electrodes, and the removal of a pacemaker. These changes reflect our basic criteria that procedures within an APC group be clinically similar and comparable in terms of resources, with the highest cost item or service within a group being no more than 2 times greater than the lowest cost item or service within the same group.

#### e. Inpatient Codes Moved to the Outpatient Setting

In response to numerous requests, we reviewed the composition of the inpatient list. While we continue to believe that we have the majority of the codes assigned properly, for the reasons discussed in section III.B.2. we are persuaded to move a number of codes to the outpatient setting. We are able to place most codes into closely related APCs.

#### f. "Two-times" Rule

The BBRA 1999 required us to ensure that no APC contains codes such that the highest median cost in the APC exceed twice the lowest median cost. We undertook an analysis of APCs in relation to this requirement as part of the 2001 update. (Note that the law provides for exceptions based on low volume and other reasons. We consider a code that captures fewer than 2

percent of the services within an APC to be low volume, and we disregard codes for unlisted services or procedures, since we do not know what service or procedure was billed.) For example, moving a radical mastectomy code from the inpatient list to a breast procedure APC caused the group to fail the two-times test. In another instance, as described above, we packaged costs associated with implantable devices into the relevant procedure codes. This change would also cause device-related APCs to fail the two-times test. For these situations and others that failed the two-times test, we are reconfiguring the APCs appropriately.

#### g. Inpatient Codes Moved to Outpatient and Affected by Device

Seven codes related to vascular and neurological procedures were moved from the inpatient list into APCs, that were then split according to device use, in response to comments.

#### h. Newly Covered Codes

The updated APCs reflect recent HCFA decisions to provide Medicare coverage for an electrical bioimpedance procedure and three magnetic resonance angiography services. The codes for these newly covered services are M0302 and 71555, 73725, and 74185, respectively.

#### i. Pass-Through Requests for Drugs

Since publication of the April 7, 2000 final rule with comment period, we have received additional requests for pass-through status for a number of drugs. The codes for the additional eligible pass-through drugs are shown in Addendum B.

The following table contains a listing of the changes in the APC groups discussed above.

### SUMMARY OF CHANGES TO APCs

New Codes	Changes to APC Placement of Existing Codes						
	Revisions or corrections of errors	Device-related codes	Inpatient moved to outpatient	"Two-times" rule	Inpatient codes moved to outpatient and affected by device	Newly covered codes	Pass-through requests for drugs
936 codes added, 645 of which are "C".	111 codes changed.	87 codes changed.	56 codes changed (12 as of 8/1/2000).	25 codes changed.	7 codes changed.	4 codes changed.	4 codes changed

SUMMARY OF CHANGES TO APCs—Continued

New Codes	Changes to APC Placement of Existing Codes						
	Revisions or corrections of errors	Device-related codes	Inpatient moved to outpatient	“Two-times” rule	Inpatient codes moved to outpatient and affected by device	Newly covered codes	Pass-through requests for drugs
Denoted by asterisk in Addendum B.	APCs—0004, 0087, 0099, 0100, 0102, 0123, 0282, 0340, 0342, 0346, 0347, 0348, 0349, 0354, 0356, 0602, 0761, 0970, 0971, 0974, 0976, 1044, 1401, 1402, 1403, 1404, 1405, 1406, 1407, and 1409.	APCs—0082, 0083, 0089, 0091, 0093, 0103, 0104, 0105, 0106, 0107, 0108, 0109, 0115, 0119, 0124, 0185, 0224, 0225, 0226, 0227, 0228, 0229, 0256, and 1002.	APCs—0005, 0020, 0021, 0029, 0046, 0050, 0081, 0114, 0115, 0120, 0121, 0162, 0165, 0194, 0195, 0198, 0216, 0254, 0256, 0263, 0264, 0279, 0280, 0970, 0974, and 0981..	APCs—0028 and 0029.	HCPCS— 37620, 35011, 36834, 61880, 61888, 33284, 63741.	HCPCS— 71555, 73725, 74185, M0302.	HCPCS— J1650, J2770, J1810, J7315

Addenda A and B reflect changes to the APC groups, effective January 1, 2001. Addendum C, entitled “Hospital Outpatient Department (HOPD) Payment for Procedures by APC, Calendar Year 2001,” is not published in this interim final rule with comment period, but will be posted on our website at <http://www.hcfa.gov/medlearn/refopps.htm>. Addendum C will display data similar to those contained in Addenda A and B, but sorted by APCs with each procedure code listed that is assigned to the APC.

2. Inpatient Procedures List Update

In the preamble to the April 7, 2000 final rule with comment period, we indicated that, as part of our annual update process, we would update the procedures on the inpatient list. The first annual revision of this list is effective on January 1, 2001. We are removing 44 procedures from the list and placing them in APCs. (Several procedures that were inadvertently left on the inpatient list in the April 7, 2000 final rule with comment period were removed from the list and placed in APCs in August 2000.) The revised list is included in Addendum E.

We have attempted to limit the inpatient only list to those procedures that, in current medical practice as understood by our clinical staff, require inpatient care, such as those that are highly invasive, result in major blood loss or temporary deficits of organ systems (such as neurological impairment or respiratory insufficiency), or otherwise require intensive or extensive postoperative care. Insofar as advances in medical

practice mitigate concerns about these procedures being performed on an outpatient basis, we will be prepared to remove them from the inpatient list and provide for payment under the hospital outpatient prospective payment system. Since the April 7, 2000 final rule with comment period was published, we have received requests to move a number of procedures from the inpatient list because, based on medical evidence, the procedures can be performed safely in a hospital outpatient setting. These included breast and other cancer procedures, repairs of facial trauma, many orthopedic procedures, several vascular procedures, and some genito-urinary procedures.

Among the procedures we are removing from the inpatient list and placing in APCs as a result of these requests are excision of chest wall tumors, several orthopedic repairs, vascular procedures, and ureteral endoscopies. We are moving overnight pulse oximetry from the inpatient list to packaged status. We also are moving several comparable procedures, for example, related ureteral endoscopies.

At this time, we are not removing from the inpatient list various spinal procedures, including osteotomies and laminectomies. We also are not removing several open abdominal and retroperitoneal procedures from the inpatient list because many of these procedures involve prolonged invasion of the thoracic cavity, the peritoneum, or the retroperitoneal space. Patients undergoing these procedures typically require prolonged postoperative monitoring. Moreover, the information

provided to us by requesters did not provide convincing evidence that these procedures are currently being performed or can be safely performed in an outpatient setting. However, we are aware that, with advances in technology and surgical techniques, many of these procedures may eventually be performed safely in a hospital outpatient setting. We will continue to review all the procedures on the inpatient list and will consider additional requests to move specific procedures to the outpatient setting. We ask that these requests contain detailed rationale along with medical evidence that the procedure may be performed safely in an outpatient setting.

We note that, in some instances, requests for removing a particular procedure from the inpatient list may have resulted from a misunderstanding about appropriate coding. Less invasive versions of the procedure on the inpatient list may be in an APC. The presence of certain thorascopies on the inpatient list, for example, does not mean that no thorascopy will be paid under the outpatient prospective payment system.

We also were asked to move several procedures from APCs to the inpatient list. Because of the rapid advance in technology and surgical techniques mentioned above, we believe that if procedures have been assigned APCs, we should not reverse that status unless it becomes obvious that we have made an error. Thus, we are moving to the inpatient setting only one of the codes for which we received a request (open treatment of a knee dislocation, which requires more than outpatient

postoperative monitoring), and two other codes (for nephrectomy with total ureterectomy and for escharotomy) that had been assigned APCs in error.

Beginning in April 2001, we will, if warranted, revise the inpatient list at least quarterly to better reflect changes in medical practice that permit procedures that were previously performed only in an inpatient setting to be safely and effectively performed in an outpatient setting. In the April 7, 2000 final rule with comment period, we discussed our intent to revise the list as part of the annual update of APCs and asked that interested parties advise us of procedures that can be performed in an outpatient setting. Since we will be making quarterly updates to the outpatient prospective payment system for other purposes, we will also change the inpatient list quarterly, if warranted. Generally, because of systems limitations, 3 months or more are required after a decision is made before we can implement a change.

The inpatient list was not a result of a provision of the BBRA 1999; it was included in the September 1998 proposed rule and we responded to comments and made the provision final in the April 7, 2000 final rule with comment. Accordingly, we did not request comments on our policy on the establishment of the inpatient list at that time. Nonetheless, we received a number of comments concerning the existence of this list, the provisions for updating it, and its implications for other Medicare payment systems. We will consider these comments and expect to discuss the matter further in the proposed rule updating the hospital outpatient prospective payment system for 2002, which we will publish in the spring of 2001.

### 3. Wage Index Adjustment

Under section 1833(t)(2)(D) of the Act, we are 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 under the hospital outpatient prospective payment system.

In the April 7, 2000 final rule with comment period, we specified, in regulations at § 419.43(c), that each year we use the hospital inpatient prospective payment system wage index established in accordance with 42 CFR Part 412 to make a wage adjustment for relative differences in labor and labor-related costs across geographic areas under the hospital outpatient prospective payment system. We note

that, by statute, we implement the annual update of the hospital inpatient prospective payment system on a fiscal year basis. However, we update the hospital outpatient prospective payment system on a calendar year basis. Therefore, the hospital inpatient prospective payment system wage index values established for urban and rural areas and for reclassified hospitals published in the **Federal Register** on August 1, 2000 (65 FR 47149 through 47157) are being applied for wage adjustments under the hospital outpatient prospective payment system, effective January 1, 2001. The fiscal year 2001 hospital inpatient wage index reflects the effects of hospitals redesignated under section 1886(d)(8)(B) of the Act and hospital reclassifications under section 1886(d)(10) of the Act. After publication of the hospital inpatient wage index values for fiscal year 2001 on August 1, 2000, we discovered several errors in the values for several geographic areas. The correct wage index values for all areas are republished in Addenda F, G, and H of this interim final rule with comment period.

In this interim final rule with comment period, we are establishing the methodology that we will use in making adjustments for area wage differences for services furnished in the Virgin Islands. We note that a hospital inpatient prospective payment system wage index value is not calculated for the Virgin Islands because there are no hospitals located in that area that are paid under the inpatient hospital prospective payment system. Because the wage index that we adopted in our April 7, 2000 final rule with comment period does not include a value for adjusting wage differences for the Virgin Islands, we will use the wage index for the Virgin Islands as calculated for the skilled nursing facilities prospective payment system to make this adjustment. The skilled nursing facilities prospective payment system uses the inpatient hospital wage index data to adjust its prospective payment rates for the same fiscal year (that is effective October 1, 2000) as covered by the hospital inpatient prospective payment system wage index values. As stated in the July 31, 2000 skilled nursing facilities prospective payment system final rule (65 FR 46770), "The computation of the wage index \* \* \* incorporate[s] the latest data and methodology used to construct the hospital wage index. For these reasons, the wage index adjustment that we will apply to the Virgin Islands for services

furnished on or after January 1, 2001 is 0.6306.

Although the wage index for skilled nursing facilities is based on a fiscal year beginning October 1, we will apply the wage index factor for the Virgin Islands that goes into effect on October 1 of each year to the hospital outpatient prospective payment system services furnished during the following calendar year. This is consistent with how we apply the hospital inpatient prospective payment system wage index values to the hospital outpatient prospective payment system services.

Consistent with the methodology applicable for services furnished in 2000 (on or after August 1, 2000), in making adjustments for area wage differences for services furnished in 2001, we will recognize 60 percent of the hospital's costs as labor-related costs that are standardized for geographic wage differences.

### 4. Conversion Factor Update

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. Thus, the update to the outpatient hospital prospective payment system conversion factor for 2001 is 2.4 percent (3.4 percent minus 1 percent).

In accordance with section 1833(t)(9)(B) of the Act, the conversion factor for 2001 also has been adjusted to ensure that the revisions we made to update the wage index are made on a budget-neutral basis. A budget neutrality factor of .9989 was calculated for wage index changes by comparing total payments from our simulation model using the wage index values that will be effective January 1, 2001.

The market basket increase of 2.4 percent for 2001 and the required budget neutrality adjustment calculated to be .9989 result in a conversion factor for 2001 of \$49.596.

### IV. Waiver of Notice of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comments 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. For the reasons set forth below, we find that the circumstances surrounding this interim final rule with comment period make it either unnecessary or impracticable to pursue a notice-and-comment procedure before the provisions of this interim final rule with comment period take effect.

As discussed earlier in this interim final rule with comment period, we implemented the hospital outpatient prospective payment system on August 1, 2000 in accordance with the methodology that we set forth in the April 7, 2000 final rule with comment period (65 FR 18434). In section III.I. of the April 7, 2000 final rule with comment period (65 FR 18501), we discuss how we will update the outpatient prospective payment system on an annual basis. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the conversion factor used to determine the APC payment rates. Under the regulations, 42 CFR 419.43, the wage adjustment under outpatient prospective payment system is based on the hospital inpatient wage index, and we updated the hospital inpatient wage index after the publication of the April 7, 2000 final rule with comment period. Accordingly, in this interim final rule with comment period, we are updating the conversion factor and the wage index adjustment for covered hospital outpatient services furnished beginning January 1, 2001, using the methodology published in the April 7, 2000 final rule with comment period, for which we had previously received comments. We also are updating the existing APC groups to reflect new and deleted CPT codes for 2001 and reconfiguring certain APC groups using more recent data to ensure clinical integrity and consideration of resource use as required by section 1833(t)(8)(A) of the Act and as described in the April 7, 2000 final rule with comment period (65 FR 18456 and 18501). Because these various adjustments are being made in accordance with existing methodology as set forth in the April 7, 2000 final rule with comment period, we believe it is unnecessary to address them further through the notice-and-comment procedure.

In addition, we find good cause to waive prior notice-and-comment procedures with respect to the Virgin Islands wage index methodology

because it would have been impracticable to undertake and complete notice-and-comment procedures on this issue in time for the Virgin Islands outpatient prospective payment system wage index value to be effective at the same time as the updated outpatient prospective payment system wage index values for all other areas.

Accordingly, we find good cause to waive the notice-and-comment procedure with respect to the annual update of the wage index values, conversion factor, and the APC groups. However, we are providing for a 60-day comment period as specified in the "Dates" section of this preamble.

## II. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

## VI. Regulatory Impact

### A. General

We have examined the impacts of this interim final rule with comment period 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, if 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).

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any one 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.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations and government agencies. For purposes of the RFA, we consider all hospitals to be small entities. Individuals and States are not

included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This 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 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 (Public Law 98-21) designated hospitals in certain New England counties as belonging to the adjacent NECMA. Thus, for purposes of the hospital outpatient prospective payment system, we classify these hospitals as urban hospitals.

### B. Analysis for Changes in this Interim Final Rule with Comment Period

We implemented the outpatient prospective payment system on August 1, 2000 in accordance with the methodology published in the April 7, 2000 final rule with comment period. In section III.I. of the April 7, 2000 final rule with comment period (65 FR 18501), we discuss how we will update the outpatient prospective payment system on an annual basis. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the conversion factor used to determine the APC payment rates. We are required under section 1833(t)(8)(A) of the Act to revise not less often than annually the wage and other adjustments. Accordingly, in this interim final rule with comment period, we are updating the conversion factor and the wage index adjustment for covered hospital outpatient services furnished beginning January 1, 2001, using the methodology published in the April 7, 2000 final rule with comment period, for which we had previously received comments.

In section IX.B. of the preamble of the April 7, 2000 final rule with comment period, we gave our Office of the Actuary's projection of the additional benefit expenditures from the Medicare Part B Trust Fund resulting from implementation of the hospital outpatient prospective payment system and the hospital outpatient provisions enacted by the BBRA 1999. The impact of implementing the hospital outpatient prospective payment system on the Medicare program is reflected in the table below, which is republished from the April 7, 2000 final rule with



comment period (65 FR 18530). The calendar year 2001 increase in total payments to hospitals, which results primarily from the updated conversion factor, is already included as part of HCFA's current law baseline expenditures for hospital outpatient services under the outpatient prospective payment system.

Fiscal year	Impact (in millions)
2001 .....	\$3,030
2002 .....	3,520
2003 .....	4,230
2004 .....	4,670

We also are updating the existing APC groups to reflect new and deleted CPT codes for 2001 and adjusting the groups to reflect more recent data as we described in the April 7, 2000 final rule with comment period. The provisions of this interim final rule with comment period do not measurably alter the effect of the outpatient prospective payment system on the groups of hospitals or geographic areas as projected in Table 2 of the April 7, 2000 final rule with comment period (65 FR 18533-18534).

**C. Federalism**

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

**D. Executive Order 12866 and 5 U.S.C. 804(2)**

The statutory effects of the provisions that are being implemented by this interim final rule with comment period result in expenditures exceeding \$100 million per year. Therefore, this interim final rule with comment period is an economically significant rule under Executive Order 12866, and a major rule under 5 U.S.C. 804(2).

In accordance with the provisions of Executive Order 12866, this interim final rule with comment period was reviewed by the Office of Management and Budget.

**List of Subjects in 42 CFR Part 419**

Health facilities, Hospitals, Medicare.

For the reasons set forth in the preamble, 42 CFR Part 419 is amended as set forth below:

**PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES**

1. The authority citation for Part 419 continues to read as follows:

**Authority:** Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395l(t), and 1395hh).

2. Section 419.41 is amended by revising paragraph (c)(4)(i) to read as follows:

**§ 419.41 Calculation of national beneficiary coinsurance amounts and national Medicare program payment amounts.**

\* \* \* \* \*

(c) \* \* \*

(4) \* \* \*

(i) The coinsurance amount for an APC cannot exceed the amount of the inpatient hospital deductible, established in accordance with § 409.82 of this chapter, for that year. For purposes of this paragraph (c)—

(A) Effective for drugs and biologicals furnished on or after January 1, 2001, the coinsurance amount for multiple APCs for a single drug or biological furnished on the same day will be aggregated and treated as the coinsurance amount for one APC.

(B) Effective for drugs and biologicals furnished on or after July 1, 2001, the coinsurance amount for the APC or APCs for a drug or biological furnished on the same day will be aggregated with the coinsurance amount for the APC that reflects the administration of the drug or biological furnished on that day and treated as the coinsurance amount for one APC.

\* \* \* \* \*

3. Section 419.70 is amended by revising paragraph (f)(2)(ii) to read as follows:

**§ 419.70 Transitional adjustment to limit decline in payment.**

\* \* \* \* \*

(f) \* \* \*

(2) \* \* \*

(ii) The reasonable cost of these services for this period.

\* \* \* \* \*

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare/Supplementary Medical Insurance Program)

Dated: November 1, 2000.

**Michael M. Hash,**

*Acting Administrator, Health Care Financing Administration.*

Approved: November 1, 2000.

**Donna E. Shalala,**

*Secretary.*

**Note to the Addenda:** The following Addenda A through H will not appear in the Code of Federal Regulations.

Addenda A through H provide various data pertaining to the Medicare hospital outpatient prospective payment system. Addendum A contains the APCs with title, status indicators, relative weight, payment

rate, national unadjusted coinsurance, and minimum unadjusted coinsurance. Addendum B differs from Addendum A in that the APC titles are not listed and both HCPCS codes and descriptions appear. Addendum C, entitled "Hospital Outpatient Department (HOPD) Payment for Procedures by APC, Calendar Year 2001," is not published in this interim final rule with comment period, but will be posted on our website at (<http://www.hcfa.gov/medlearn/refopps.htm>). Addendum C will display data similar to those contained in Addenda A and B, but sorted by APCs with each procedure code listed that is assigned to the APC. Addendum D lists the status indicators for how various services are treated under the hospital outpatient prospective payment system. Addendum E lists the procedures that we pay for only in an inpatient setting. Addendum F lists the wage index for urban areas, Addendum G lists the wage index for rural areas, and Addendum H lists the wage index for hospitals that are reclassified.

**Addendum A.—List of Hospital Outpatient Ambulatory Payment Classification Groups with Status Indicators, Relative Weights, Payment Rates, and Coinsurance Amounts**

The payment rate (once wage adjusted) is the total payment to the hospital. The coinsurance amount is part of the total payment rate.

Those APCs with status indicators "G" or "J" denote the inclusion of drugs that are eligible for pass-through payments. The relative weight column for these drug APCs is empty since payment for pass-through drugs/biologicals is calculated using the average wholesale price for the drug/biological rather than the relative weight. Note also that the only coinsurance column that has been filled is the minimum unadjusted coinsurance column. The coinsurance is applied to the nonpass-through portion of the payment rate for the drug/biological.

Those APCs with status indicator "H" denote the inclusion of devices that are eligible for pass-through payments. The relative weight, payment rate, and coinsurance columns are not filled for these APCs. The relative weight and payment rate columns are empty because payment for pass-through devices is determined based on the hospital's submitted charges adjusted to cost using the hospital's cost-to-charge ratio. This calculation is done in the PRICER. The coinsurance columns for these APCs are not filled since the coinsurance is applied to the APC that contains the procedure with which the pass-through device is used rather than to the device APC.

**Addendum B.—Hospital Outpatient Department (HOPD) Payment Status by HCPCS Code and Related Information**

The codes listed in this addendum include the 2001 CPT codes as published in CPT 2001 by the American Medical Association. Also listed are the codes that have been deleted for 2001. These codes are denoted in the CPT column with the subscript letter "D". These codes are billable through March 31, 2001 for services occurring before January 1, 2001. Deleted codes billed after March 31,

2001 will be rejected. CPT codes appearing for the first time in 2001 are denoted in the CPT column with bolded print. These codes are new for 2001 and are billable effective January 1, 2001.

All CPT codes that are paid only as inpatient procedures are denoted by the status indicator "C". A number of procedures that appeared on the inpatient list in the April 7, 2000 final rule with comment period

are now payable under the hospital outpatient prospective payment system. The status indicators for these codes have been updated to reflect their current payment status.

ADDENDUM A.—LIST OF HOSPITAL OUTPATIENT AMBULATORY PAYMENT CLASSIFICATIONS WITH STATUS INDICATORS, RELATIVE WEIGHTS, PAYMENT RATES, AND COINSURANCE AMOUNTS, CALENDAR YEAR 2001

APC	Group title	Status indicator	Relative weight	Payment rate	National unadjusted coinsurance	Minimum unadjusted coinsurance
0001	Photochemotherapy .....	S	0.47	\$23.31	\$8.49	\$4.66
0002	Fine needle Biopsy/Aspiration .....	T	0.62	\$30.75	\$17.66	\$6.15
0003	Bone Marrow Biopsy/Aspiration .....	T	0.98	\$48.61	\$27.99	\$9.72
0004	Level I Needle Biopsy/ Aspiration Except Bone Marrow .....	T	1.84	\$91.26	\$32.57	\$18.25
0005	Level II Needle Biopsy /Aspiration Except Bone Marrow .....	T	5.41	\$268.32	\$119.75	\$53.66
0006	Level I Incision & Drainage .....	T	2.00	\$99.19	\$33.95	\$19.84
0007	Level II Incision & Drainage .....	T	3.68	\$182.51	\$72.03	\$36.50
0008	Level III Incision & Drainage .....	T	6.15	\$305.02	\$113.67	\$61.00
0009	Nail Procedures .....	T	0.74	\$36.70	\$9.63	\$7.34
0010	Level I Destruction of Lesion .....	T	0.55	\$27.28	\$9.86	\$5.46
0011	Level II Destruction of Lesion .....	T	2.72	\$134.90	\$50.01	\$26.98
0012	Level I Debridement & Destruction .....	T	0.53	\$26.29	\$9.18	\$5.26
0013	Level II Debridement & Destruction .....	T	0.91	\$45.13	\$17.66	\$9.03
0014	Level III Debridement & Destruction .....	T	1.50	\$74.39	\$24.55	\$14.88
0015	Level IV Debridement & Destruction .....	T	1.77	\$87.78	\$31.20	\$17.56
0016	Level V Debridement & Destruction .....	T	3.53	\$175.07	\$74.67	\$35.01
0017	Level VI Debridement & Destruction .....	T	12.45	\$617.47	\$289.16	\$123.49
0018	Biopsy Skin, Subcutaneous Tissue or Mucous Membrane .....	T	0.94	\$46.62	\$17.66	\$9.32
0019	Level I Excision/ Biopsy .....	T	4.00	\$198.39	\$78.91	\$39.68
0020	Level II Excision/ Biopsy .....	T	6.51	\$322.87	\$130.53	\$64.57
0021	Level III Excision/ Biopsy .....	T	10.49	\$520.26	\$236.51	\$104.05
0022	Level IV Excision/ Biopsy .....	T	12.49	\$619.45	\$292.94	\$123.89
0023	Exploration Penetrating Wound .....	T	1.98	\$98.20	\$40.37	\$19.64
0024	Level I Skin Repair .....	T	2.43	\$120.51	\$44.50	\$24.10
0025	Level II Skin Repair .....	T	3.74	\$185.49	\$70.66	\$37.10
0026	Level III Skin Repair .....	T	12.11	\$600.61	\$277.92	\$120.12
0027	Level IV Skin Repair .....	T	15.80	\$783.62	\$383.10	\$156.72
0028	Level I Incision/Excision Breast .....	T	12.37	\$613.52	\$303.74	\$122.70
0029	Level II Incision/Excision Breast .....	T	31.39	\$1,557.05	\$820.79	\$311.41
0030	Breast Reconstruction .....	T	31.11	\$1,543.16	\$763.55	\$308.63
0032	Placement Transvenous Catheters/Arterial Cutdown .....	T	5.40	\$267.82	\$119.52	\$53.56
0033	Partial Hospitalization .....	P	4.17	\$206.82	\$48.17	\$41.36
0040	Arthrocentesis & Ligament/Tendon Injection .....	T	2.11	\$104.65	\$40.60	\$20.93
0041	Arthroscopy .....	T	24.57	\$1,218.58	\$592.08	\$243.72
0042	Arthroscopically-Aided Procedures .....	T	29.22	\$1,449.19	\$804.74	\$289.84
0043	Closed Treatment Fracture Finger/Toe/Trunk .....	T	1.64	\$81.34	\$25.46	\$16.27
0044	Closed Treatment Fracture/Dislocation Except Finger/Toe/Trunk .....	T	2.17	\$107.63	\$38.08	\$21.53
0045	Bone/Joint Manipulation Under Anesthesia .....	T	11.02	\$546.55	\$277.12	\$109.31
0046	Open/Percutaneous Treatment Fracture or Dislocation .....	T	22.29	\$1,105.50	\$535.76	\$221.10
0047	Arthroplasty without Prosthesis .....	T	22.09	\$1,095.58	\$537.03	\$219.12
0048	Arthroplasty with Prosthesis .....	T	29.06	\$1,441.26	\$725.94	\$288.25
0049	Level I Musculoskeletal Procedures Except Hand and Foot .....	T	15.04	\$745.93	\$356.95	\$149.19
0050	Level II Musculoskeletal Procedures Except Hand and Foot .....	T	21.13	\$1,047.96	\$513.86	\$209.59
0051	Level III Musculoskeletal Procedures Except Hand and Foot .....	T	27.76	\$1,376.79	\$675.24	\$275.36
0052	Level IV Musculoskeletal Procedures Except Hand and Foot .....	T	36.16	\$1,793.39	\$930.91	\$358.68
0053	Level I Hand Musculoskeletal Procedures .....	T	11.32	\$561.42	\$253.49	\$112.28
0054	Level II Hand Musculoskeletal Procedures .....	T	19.66	\$975.06	\$472.33	\$195.01
0055	Level I Foot Musculoskeletal Procedures .....	T	15.47	\$767.26	\$355.34	\$153.45
0056	Level II Foot Musculoskeletal Procedures .....	T	17.30	\$858.02	\$405.81	\$171.60
0057	Bunion Procedures .....	T	21.00	\$1,041.52	\$496.65	\$208.30
0058	Level I Strapping and Cast Application .....	S	1.09	\$54.06	\$19.27	\$10.81
0059	Level II Strapping and Cast Application .....	S	1.74	\$86.30	\$29.59	\$17.26
0060	Manipulation Therapy .....	S	0.77	\$38.19	\$7.80	\$7.64
0070	Thoracentesis/Lavage Procedures .....	T	3.64	\$180.53	\$79.60	\$36.11
0071	Level I Endoscopy Upper Airway .....	T	0.55	\$27.28	\$14.22	\$5.46
0072	Level II Endoscopy Upper Airway .....	T	1.26	\$62.49	\$41.52	\$12.50
0073	Level III Endoscopy Upper Airway .....	T	4.11	\$203.84	\$91.07	\$40.77
0074	Level IV Endoscopy Upper Airway .....	T	13.61	\$675.00	\$347.54	\$135.00
0075	Level V Endoscopy Upper Airway .....	T	18.55	\$920.01	\$467.29	\$184.00
0076	Endoscopy Lower Airway .....	T	8.06	\$399.75	\$197.05	\$79.95
0077	Level I Pulmonary Treatment .....	S	0.43	\$21.33	\$12.62	\$4.27
0078	Level II Pulmonary Treatment .....	S	1.34	\$66.46	\$29.13	\$13.29
0079	Ventilation Initiation and Management .....	S	3.18	\$157.72	\$107.70	\$31.54
0080	Diagnostic Cardiac Catheterization .....	T	31.55	\$1,564.75	\$838.92	\$312.95
0081	Non-Coronary Angioplasty or Atherectomy .....	T	28.81	\$1,428.86	\$710.91	\$285.77
0082	Coronary Atherectomy .....	T	51.01	\$2,529.89	\$1,351.74	\$505.98
0083	Coronary Angioplasty .....	T	29.70	\$1,473.00	\$794.30	\$294.60
0084	Level I Electrophysiologic Evaluation .....	S	10.70	\$530.68	\$177.79	\$106.14
0085	Level II Electrophysiologic Evaluation .....	S	27.06	\$1,342.07	\$654.48	\$268.41
0086	Ablate Heart Dysrhythm Focus .....	S	47.62	\$2,361.76	\$1,265.37	\$472.35
0087	Cardiac Electrophysiologic Recording/Mapping .....	S	9.53	\$472.65	\$214.72	\$94.53
0088	Thrombectomy .....	T	26.49	\$1,313.80	\$678.68	\$262.76

## ADDENDUM A.—LIST OF HOSPITAL OUTPATIENT AMBULATORY PAYMENT CLASSIFICATIONS WITH STATUS INDICATORS, RELATIVE WEIGHTS, PAYMENT RATES, AND COINSURANCE AMOUNTS, CALENDAR YEAR 2001—Continued

APC	Group title	Status indicator	Relative weight	Payment rate	National unadjusted coinsurance	Minimum unadjusted coinsurance
0089	Insertion/Replacement of Permanent Pacemaker and Electrodes .....	T	78.45	\$3,890.81	\$2,275.19	\$778.16
0090	Insertion/Replacement of Pacemaker Pulse Generator .....	T	78.28	\$3,882.37	\$2,133.88	\$776.47
0091	Level I Vascular Ligation .....	T	14.79	\$733.52	\$348.23	\$146.70
0092	Level II Vascular Ligation .....	T	20.21	\$1,002.34	\$505.37	\$200.47
0093	Vascular Repair/Fistula Construction .....	T	12.82	\$635.82	\$277.34	\$127.16
0094	Resuscitation and Cardioversion .....	S	4.51	\$223.68	\$105.29	\$44.74
0095	Cardiac Rehabilitation .....	S	0.64	\$31.74	\$16.98	\$6.35
0096	Non-Invasive Vascular Studies .....	S	2.06	\$102.16	\$61.48	\$20.43
0097	Cardiac Monitoring for 30 days .....	X	1.62	\$80.35	\$62.40	\$16.07
0098	Injection of Sclerosing Solution .....	T	1.19	\$59.02	\$20.88	\$11.80
0099	Electrocardiograms .....	S	0.38	\$18.85	\$14.68	\$3.77
0100	Stress Tests and Continuous ECG .....	X	1.70	\$84.32	\$71.57	\$16.86
0101	Tilt Table Evaluation .....	S	4.47	\$221.70	\$128.84	\$44.34
0102	Electronic Analysis of Pacemakers/other Devices .....	S	0.45	\$22.32	\$12.62	\$4.46
0103	Miscellaneous Vascular Procedures .....	T	13.09	\$649.21	\$295.70	\$129.84
0104	Transcatheter Placement of Intracoronary Stents .....	T	14.94	\$740.96	\$339.51	\$148.19
0105	Revision/Removal of Pacemakers, AICD, or Vascular Device .....	T	15.06	\$746.92	\$372.32	\$149.38
0106	Insertion/Replacement/Repair of Pacemaker Electrodes .....	T	18.96	\$940.34	\$503.07	\$188.07
0107	Insertion of Cardioverter-Defibrillator .....	T	147.51	\$7,315.91	\$5,086.37	\$1,463.18
0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads .....	T	210.84	\$10,456.84	\$5,484.72	\$2,091.37
0109	Removal of Implanted Devices .....	T	6.53	\$323.86	\$133.51	\$64.77
0110	Transfusion .....	S	5.83	\$289.15	\$122.73	\$57.83
0111	Blood Product Exchange .....	S	14.17	\$702.77	\$300.74	\$140.55
0112	Extracorporeal Photopheresis .....	S	39.60	\$1,964.01	\$663.65	\$392.80
0113	Excision Lymphatic System .....	T	13.89	\$688.89	\$326.55	\$137.78
0114	Thyroid/Lymphadenectomy Procedures .....	T	19.56	\$970.10	\$493.78	\$194.02
0115	Cannula/Access Device Procedures .....	T	19.34	\$959.19	\$506.74	\$191.84
0116	Chemotherapy Administration by Other Technique Except Infusion .....	S	2.34	\$116.06	\$23.21	\$23.21
0117	Chemotherapy Administration by Infusion Only .....	S	1.84	\$91.26	\$71.80	\$18.25
0118	Chemotherapy Administration by Both Infusion and Other Technique .....	S	2.90	\$143.83	\$72.03	\$28.77
0119	Implantation of Devices .....	T	9.87	\$489.59	\$161.50	\$97.92
0120	Infusion Therapy Except Chemotherapy .....	T	1.66	\$82.33	\$42.67	\$16.47
0121	Level I Tube changes and Repositioning .....	T	2.36	\$117.05	\$52.53	\$23.41
0122	Level II Tube changes and Repositioning .....	T	5.04	\$249.96	\$114.93	\$49.99
0123	Bone Marrow Harvesting and Bone Marrow/Stem Cell Transplant .....	S	4.13	\$204.83	\$40.97	\$40.97
0124	Revision of Implanted Infusion Pump .....	T	2.55	\$126.64	\$81.36	\$25.33
0130	Level I Laparoscopy .....	T	25.36	\$1,257.75	\$659.53	\$251.55
0131	Level II Laparoscopy .....	T	41.81	\$2,073.61	\$1,089.88	\$414.72
0132	Level III Laparoscopy .....	T	48.91	\$2,425.74	\$1,239.22	\$485.15
0140	Esophageal Dilatation without Endoscopy .....	T	4.74	\$235.09	\$107.24	\$47.02
0141	Upper GI Procedures .....	T	7.15	\$354.61	\$184.67	\$70.92
0142	Small Intestine Endoscopy .....	T	7.45	\$369.49	\$162.42	\$73.90
0143	Lower GI Endoscopy .....	T	7.98	\$395.78	\$199.12	\$79.16
0144	Diagnostic Anoscopy .....	T	2.23	\$110.60	\$49.32	\$22.12
0145	Therapeutic Anoscopy .....	T	7.46	\$369.98	\$179.39	\$74.00
0146	Level I Sigmoidoscopy .....	T	2.83	\$140.36	\$65.15	\$28.07
0147	Level II Sigmoidoscopy .....	T	6.26	\$310.47	\$149.11	\$62.09
0148	Level I Anal/Rectal Procedure .....	T	2.34	\$116.06	\$43.59	\$23.21
0149	Level II Anal/Rectal Procedure .....	T	12.86	\$637.80	\$293.06	\$127.56
0150	Level III Anal/Rectal Procedure .....	T	17.68	\$876.86	\$437.12	\$175.37
0151	Endoscopic Retrograde Cholangio-Pancreatography (ERCP) .....	T	10.53	\$522.25	\$245.46	\$104.45
0152	Percutaneous Biliary Endoscopic Procedures .....	T	8.22	\$407.68	\$207.38	\$81.54
0153	Peritoneal and Abdominal Procedures .....	T	19.62	\$973.08	\$496.31	\$194.62
0154	Hernia/Hydrocele Procedures .....	T	22.43	\$1,112.45	\$556.98	\$222.49
0157	Colorectal Cancer Screening: Barium Enema .....	S	1.79	\$88.78	.....	\$22.19
0158	Colorectal Cancer Screening: Colonoscopy .....	S	7.98	\$395.78	.....	\$98.94
0159	Colorectal Cancer Screening: Flexible Sigmoidoscopy .....	S	2.83	\$140.36	.....	\$35.09
0160	Level I Cystourethroscopy and other Genitourinary Procedures .....	T	5.43	\$269.30	\$110.11	\$53.86
0161	Level II Cystourethroscopy and other Genitourinary Procedures .....	T	10.94	\$542.58	\$249.36	\$108.52
0162	Level III Cystourethroscopy and other Genitourinary Procedures .....	T	17.49	\$867.44	\$427.49	\$173.49
0163	Level IV Cystourethroscopy and other Genitourinary Procedures .....	T	28.98	\$1,437.30	\$792.58	\$287.46
0164	Level I Urinary and Anal Procedures .....	T	2.17	\$107.64	\$33.03	\$21.53
0165	Level II Urinary and Anal Procedures .....	T	3.89	\$192.92	\$91.76	\$38.58
0166	Level I Urethral Procedures .....	T	10.17	\$504.39	\$218.73	\$100.88
0167	Level II Urethral Procedures .....	T	21.06	\$1,044.50	\$555.84	\$208.90
0168	Level III Urethral Procedures .....	T	24.94	\$1,236.93	\$536.11	\$247.39
0169	Lithotripsy .....	T	46.72	\$2,317.13	\$1,384.20	\$463.43
0170	Dialysis for Other Than ESRD Patients .....	S	6.68	\$331.30	\$72.26	\$66.26
0180	Circumcision .....	T	13.62	\$675.49	\$304.87	\$135.10
0181	Penile Procedures .....	T	32.37	\$1,605.43	\$906.36	\$321.09
0182	Insertion of Penile Prosthesis .....	T	52.11	\$2,584.45	\$1,525.05	\$516.89
0183	Testes/Epididymis Procedures .....	T	18.26	\$905.62	\$448.94	\$181.12
0184	Prostate Biopsy .....	T	4.94	\$245.01	\$122.96	\$49.00
0185	Removal or Repair of Penile Prosthesis .....	T	32.37	\$1,605.43	\$906.36	\$321.09
0190	Surgical Hysteroscopy .....	T	17.85	\$885.29	\$443.89	\$177.06
0191	Level I Female Reproductive Procedures .....	T	1.19	\$59.02	\$17.43	\$11.80
0192	Level II Female Reproductive Procedures .....	T	2.38	\$118.04	\$35.33	\$23.61
0193	Level III Female Reproductive Procedures .....	T	8.93	\$442.89	\$171.13	\$88.58

ADDENDUM A.—LIST OF HOSPITAL OUTPATIENT AMBULATORY PAYMENT CLASSIFICATIONS WITH STATUS INDICATORS, RELATIVE WEIGHTS, PAYMENT RATES, AND COINSURANCE AMOUNTS, CALENDAR YEAR 2001—Continued

APC	Group title	Status indicator	Relative weight	Payment rate	National unadjusted coinsurance	Minimum unadjusted coinsurance
0194	Level IV Female Reproductive Procedures .....	T	16.21	\$803.96	\$395.94	\$160.79
0195	Level V Female Reproductive Procedures .....	T	18.68	\$926.46	\$483.80	\$185.29
0196	Dilatation & Curettage .....	T	14.47	\$717.66	\$357.98	\$143.53
0197	Infertility Procedures .....	T	2.40	\$119.03	\$49.55	\$23.81
0198	Pregnancy and Neonatal Care Procedures .....	T	1.34	\$66.46	\$33.03	\$13.29
0199	Vaginal Delivery .....	T	11.20	\$555.48	\$157.83	\$111.10
0200	Therapeutic Abortion .....	T	13.89	\$688.89	\$373.23	\$137.78
0201	Spontaneous Abortion .....	T	13.00	\$644.75	\$329.65	\$128.95
0210	Spinal Tap .....	T	3.00	\$148.79	\$62.40	\$29.76
0211	Level I Nervous System Injections .....	T	3.32	\$164.66	\$74.78	\$32.93
0212	Level II Nervous System Injections .....	T	3.64	\$180.53	\$88.78	\$36.11
0213	Extended EEG Studies and Sleep Studies .....	S	11.15	\$553.00	\$290.42	\$110.60
0214	Electroencephalogram .....	S	2.32	\$115.06	\$58.50	\$23.01
0215	Level I Nerve and Muscle Tests .....	S	1.15	\$57.04	\$30.05	\$11.41
0216	Level II Nerve and Muscle Tests .....	S	2.87	\$142.34	\$64.69	\$28.47
0217	Level III Nerve and Muscle Tests .....	S	5.87	\$291.13	\$156.68	\$58.23
0220	Level I Nerve Procedures .....	T	13.96	\$692.36	\$326.21	\$138.47
0221	Level II Nerve Procedures .....	T	18.36	\$910.58	\$463.62	\$182.12
0222	Implantation of Neurological Device .....	T	124.43	\$6,171.23	\$2,955.13	\$1,234.25
0223	Implantation of Pain Management Device .....	T	7.05	\$349.65	\$154.27	\$69.93
0224	Implantation of Reservoir/Pump/Shunt .....	T	17.89	\$887.27	\$453.41	\$177.45
0225	Implantation of Neurostimulator Electrodes .....	T	17.72	\$878.84	\$408.33	\$175.77
0226	Implantation of Drug Infusion Reservoir .....	T	5.62	\$278.73	\$109.42	\$55.75
0227	Implantation of Drug Infusion Device .....	T	11.17	\$553.99	\$330.11	\$110.80
0228	Creation of Lumbar Subarachnoid Shunt .....	T	25.06	\$1,242.88	\$696.46	\$248.58
0229	Transcatheter Placement of Intravascular Shunts .....	T	34.81	\$1,726.44	\$1,030.12	\$345.29
0230	Level I Eye Tests .....	S	0.98	\$48.61	\$22.48	\$9.72
0231	Level II Eye Tests .....	S	2.64	\$130.94	\$59.87	\$26.19
0232	Level I Anterior Segment Eye .....	T	6.04	\$299.56	\$134.66	\$59.91
0233	Level II Anterior Segment Eye .....	T	13.79	\$683.93	\$331.60	\$136.79
0234	Level III Anterior Segment Eye Procedures .....	T	20.64	\$1,023.66	\$502.16	\$204.73
0235	Level I Posterior Segment Eye Procedures .....	T	2.94	\$145.81	\$78.91	\$29.16
0236	Level II Posterior Segment Eye Procedures .....	T	6.70	\$332.29	\$147.96	\$66.46
0237	Level III Posterior Segment Eye Procedures .....	T	33.96	\$1,684.28	\$852.68	\$336.86
0238	Level I Repair and Plastic Eye Procedures .....	T	2.80	\$138.87	\$58.96	\$27.77
0239	Level II Repair and Plastic Eye Procedures .....	T	6.26	\$310.47	\$123.42	\$62.09
0240	Level III Repair and Plastic Eye Procedures .....	T	13.47	\$668.06	\$315.31	\$133.61
0241	Level IV Repair and Plastic Eye Procedures .....	T	16.60	\$823.30	\$384.47	\$164.66
0242	Level V Repair and Plastic Eye Procedures .....	T	23.70	\$1,175.42	\$597.36	\$235.08
0243	Strabismus/Muscle Procedures .....	T	17.99	\$892.23	\$431.39	\$178.45
0244	Corneal Transplant .....	T	32.88	\$1,630.72	\$851.42	\$326.14
0245	Cataract Procedures without IOL Insert .....	T	26.55	\$1,316.77	\$623.85	\$263.35
0246	Cataract Procedures with IOL Insert .....	T	26.55	\$1,316.77	\$623.85	\$263.35
0247	Laser Eye Procedures Except Retinal .....	T	4.89	\$242.52	\$112.86	\$48.50
0248	Laser Retinal Procedures .....	T	4.19	\$207.81	\$94.05	\$41.56
0250	Nasal Cauterization/Packing .....	T	2.21	\$109.61	\$38.54	\$21.92
0251	Level I ENT Procedures .....	T	1.68	\$83.32	\$27.99	\$16.66
0252	Level II ENT Procedures .....	T	5.18	\$256.90	\$114.24	\$51.38
0253	Level III ENT Procedures .....	T	12.02	\$596.14	\$284.00	\$119.23
0254	Level IV ENT Procedures .....	T	12.45	\$617.47	\$272.41	\$123.49
0256	Level V ENT Procedures .....	T	25.40	\$1,259.74	\$623.05	\$251.95
0258	Tonsil and Adenoid Procedures .....	T	18.62	\$923.48	\$462.81	\$184.70
0260	Level I Plain Film Except Teeth .....	X	0.79	\$39.18	\$22.02	\$7.84
0261	Level II Plain Film Except Teeth Including Bone Density Measurement .....	X	1.38	\$68.44	\$38.77	\$13.69
0262	Plain Film of Teeth .....	X	0.40	\$19.83	\$10.90	\$3.97
0263	Level I Miscellaneous Radiology Procedures .....	X	1.68	\$83.32	\$45.88	\$16.66
0264	Level II Miscellaneous Radiology Procedures .....	X	3.83	\$189.96	\$108.97	\$37.99
0265	Level I Diagnostic Ultrasound Except Vascular .....	S	1.17	\$58.03	\$38.08	\$11.61
0266	Level II Diagnostic Ultrasound Except Vascular .....	S	1.79	\$88.78	\$57.35	\$17.76
0267	Vascular Ultrasound .....	S	2.72	\$134.90	\$80.06	\$26.98
0268	Guidance Under Ultrasound .....	X	2.23	\$110.60	\$69.51	\$22.12
0269	Echocardiogram Except Transesophageal .....	S	4.40	\$218.22	\$114.01	\$43.64
0270	Transesophageal Echocardiogram .....	S	5.55	\$275.25	\$150.26	\$55.05
0271	Mammography .....	S	0.70	\$34.72	\$19.50	\$6.94
0272	Level I Fluoroscopy .....	X	1.40	\$69.43	\$39.00	\$13.89
0273	Level II Fluoroscopy .....	X	2.49	\$123.49	\$61.02	\$24.70
0274	Myelography .....	S	4.83	\$239.55	\$128.12	\$47.91
0275	Arthrography .....	S	2.74	\$135.89	\$72.26	\$27.18
0276	Level I Digestive Radiology .....	S	1.79	\$88.78	\$49.78	\$17.76
0277	Level II Digestive Radiology .....	S	2.47	\$122.50	\$69.28	\$24.50
0278	Diagnostic Urography .....	S	2.85	\$141.35	\$81.67	\$28.27
0279	Level I Angiography and Venography except Extremity .....	S	6.30	\$312.46	\$174.57	\$62.49
0280	Level II Angiography and Venography except Extremity .....	S	14.98	\$742.95	\$380.12	\$148.59
0281	Venography of Extremity .....	S	4.40	\$218.22	\$115.16	\$43.64
0282	Level I Computerized Axial Tomography .....	S	2.38	\$118.04	\$94.51	\$23.61
0283	Level II Computerized Axial Tomography .....	S	4.89	\$242.52	\$179.39	\$48.50
0284	Magnetic Resonance Imaging .....	S	8.02	\$397.76	\$257.39	\$79.55
0285	Positron Emission Tomography (PET) .....	S	15.06	\$746.92	\$415.21	\$149.38

## ADDENDUM A.—LIST OF HOSPITAL OUTPATIENT AMBULATORY PAYMENT CLASSIFICATIONS WITH STATUS INDICATORS, RELATIVE WEIGHTS, PAYMENT RATES, AND COINSURANCE AMOUNTS, CALENDAR YEAR 2001—Continued

APC	Group title	Status indicator	Relative weight	Payment rate	National unadjusted coinsurance	Minimum unadjusted coinsurance
0286	Myocardial Scans .....	S	7.28	\$361.06	\$200.04	\$72.21
0290	Standard Non-Imaging Nuclear Medicine .....	S	1.94	\$96.21	\$55.51	\$19.24
0291	Level I Diagnostic Nuclear Medicine Excluding Myocardial Scans .....	S	3.15	\$156.22	\$93.14	\$31.24
0292	Level II Diagnostic Nuclear Medicine Excluding Myocardial Scans .....	S	4.36	\$216.24	\$126.63	\$43.25
0294	Level I Therapeutic Nuclear Medicine .....	S	5.13	\$254.43	\$144.06	\$50.89
0295	Level II Therapeutic Nuclear Medicine .....	S	19.85	\$984.48	\$609.17	\$196.90
0296	Level I Therapeutic Radiologic Procedures .....	S	3.57	\$177.06	\$100.25	\$35.41
0297	Level II Therapeutic Radiologic Procedures .....	S	6.13	\$304.03	\$172.51	\$60.81
0300	Level I Radiation Therapy .....	S	1.98	\$98.20	\$47.72	\$19.64
0301	Level II Radiation Therapy .....	S	2.21	\$109.61	\$52.53	\$21.92
0302	Level III Radiation Therapy .....	S	8.21	\$407.18	\$216.55	\$81.44
0303	Treatment Device Construction .....	X	2.83	\$140.36	\$69.28	\$28.07
0304	Level I Therapeutic Radiation Treatment Preparation .....	X	1.49	\$73.90	\$41.52	\$14.78
0305	Level II Therapeutic Radiation Treatment Preparation .....	X	4.06	\$201.36	\$97.50	\$40.27
0310	Level III Therapeutic Radiation Treatment Preparation .....	X	13.98	\$693.35	\$339.05	\$138.67
0311	Radiation Physics Services .....	X	1.32	\$65.46	\$31.66	\$13.09
0312	Radioelement Applications .....	S	4.09	\$202.85	\$109.65	\$40.57
0313	Brachytherapy .....	S	7.89	\$391.31	\$164.02	\$78.26
0314	Hyperthermic Therapies .....	S	5.88	\$291.62	\$150.95	\$58.32
0320	Electroconvulsive Therapy .....	S	3.68	\$182.51	\$80.06	\$36.50
0321	Biofeedback and Other Training .....	S	1.26	\$62.49	\$29.25	\$12.50
0322	Brief Individual Psychotherapy .....	S	1.32	\$65.46	\$14.22	\$13.09
0323	Extended Individual Psychotherapy .....	S	1.85	\$91.75	\$22.48	\$18.35
0324	Family Psychotherapy .....	S	1.87	\$92.74	\$20.19	\$18.55
0325	Group Psychotherapy .....	S	1.55	\$76.88	\$19.96	\$15.38
0330	Dental Procedures .....	S	1.51	\$74.89	\$14.98	\$14.98
0340	Minor Ancillary Procedures .....	X	1.04	\$51.58	\$12.85	\$10.32
0341	Immunology Tests .....	X	0.13	\$6.44	\$3.67	\$1.29
0342	Level I Pathology .....	X	0.26	\$12.90	\$8.03	\$2.58
0343	Level II Pathology .....	X	0.45	\$22.32	\$12.16	\$4.46
0344	Level III Pathology .....	X	0.79	\$39.18	\$23.63	\$7.84
0345	Transfusion Laboratory Procedures Level I .....	X	0.22	\$10.92	\$5.37	\$2.18
0346	Transfusion Laboratory Procedures Level II .....	X	0.51	\$25.49	\$12.03	\$5.10
0347	Transfusion Laboratory Procedures Level III .....	X	0.84	\$41.90	\$20.13	\$8.38
0348	Fertility Laboratory Procedures .....	X	0.52	\$25.57	\$5.11	\$5.11
0349	Miscellaneous Laboratory Procedures .....	X	0.48	\$23.65	\$4.73	\$4.73
0354	Administration of Influenza/Pneumonia Vaccine .....	K	0.13	\$6.33	.....	.....
0355	Level I Immunizations .....	K	0.19	\$9.42	\$5.05	\$1.88
0356	Level II Immunizations .....	K	0.36	\$17.86	\$4.82	\$3.57
0359	Injections .....	X	0.96	\$47.61	\$9.52	\$9.52
0360	Level I Alimentary Tests .....	X	1.38	\$68.44	\$34.75	\$13.69
0361	Level II Alimentary Tests .....	X	3.53	\$175.07	\$88.09	\$35.01
0362	Fitting of Vision Aids .....	X	0.51	\$25.30	\$9.63	\$5.06
0363	Otorhinolaryngologic Function Tests .....	X	2.83	\$140.36	\$53.22	\$28.07
0364	Level I Audiometry .....	X	0.68	\$33.72	\$13.31	\$6.74
0365	Level II Audiometry .....	X	1.47	\$72.91	\$22.48	\$14.58
0367	Level I Pulmonary Test .....	X	0.83	\$41.16	\$20.65	\$8.23
0368	Level II Pulmonary Tests .....	X	1.66	\$82.33	\$42.44	\$16.47
0369	Level III Pulmonary Tests .....	X	2.34	\$116.06	\$58.50	\$23.21
0370	Allergy Tests .....	X	0.57	\$28.27	\$11.81	\$5.65
0371	Allergy Injections .....	X	0.32	\$15.87	\$3.67	\$3.17
0372	Therapeutic Phlebotomy .....	X	0.43	\$21.33	\$10.09	\$4.27
0373	Neuropsychological Testing .....	X	3.21	\$159.20	\$44.96	\$31.84
0374	Monitoring Psychiatric Drugs .....	X	1.17	\$58.03	\$13.08	\$11.61
0600	Low Level Clinic Visits .....	V	0.98	\$48.61	\$9.72	\$9.72
0601	Mid Level Clinic Visits .....	V	1.00	\$49.60	\$9.92	\$9.92
0602	High Level Clinic Visits .....	V	1.66	\$82.33	\$16.47	\$16.47
0610	Low Level Emergency Visits .....	V	1.34	\$66.46	\$20.65	\$13.29
0611	Mid Level Emergency Visits .....	V	2.11	\$104.65	\$36.47	\$20.93
0612	High Level Emergency Visits .....	V	3.19	\$158.21	\$54.14	\$31.64
0620	Critical Care .....	S	8.60	\$426.53	\$152.78	\$85.31
0701	SR 89 chloride, per mCi .....	G	.....	\$783.75	.....	\$95.62
0702	SM 153 lexidronam, 50 mCi .....	G	.....	\$942.09	.....	\$134.87
0704	IN 111 Satumomab pendetide per dose .....	G	.....	\$712.50	.....	\$86.93
0705	TC 99M tetrofosmin, per dose .....	G	.....	\$136.80	.....	\$16.69
0725	Leucovorin calcium inj, 50 mg .....	G	.....	\$49.73	.....	\$6.66
0726	Dexrazoxane hcl injection, 250 mg .....	G	.....	\$161.11	.....	\$21.59
0727	Etidronate disodium inj 300 mg .....	G	.....	\$63.65	.....	\$8.53
0728	Filgrastim 300 mcg injection .....	G	.....	\$171.38	.....	\$22.96
0730	Pamidronate disodium, 30 mg .....	G	.....	\$232.51	.....	\$31.16
0731	Sargramostim injection 50 mcg .....	G	.....	\$27.42	.....	\$3.67
0732	Mesna injection 200 mg .....	G	.....	\$36.51	.....	\$4.89
0733	Non esrd epoetin alpha inj, 1000 u .....	G	.....	\$11.40	.....	\$1.53
0750	Dolasetron mesylate, 10 mg .....	G	.....	\$14.81	.....	\$1.98
0754	Metoclopramide hcl injection up to 10 mg .....	G	.....	\$2.00	.....	\$0.27
0755	Thiethylperazine maleate inj up to 10 mg .....	G	.....	\$5.02	.....	\$0.67
0761	Unspecified oral anti-emetic .....	G	.....	\$0.60	.....	\$0.08
0762	Dronabinol 2.5mg oral .....	G	.....	\$3.20	.....	\$0.48

ADDENDUM A.—LIST OF HOSPITAL OUTPATIENT AMBULATORY PAYMENT CLASSIFICATIONS WITH STATUS INDICATORS, RELATIVE WEIGHTS, PAYMENT RATES, AND COINSURANCE AMOUNTS, CALENDAR YEAR 2001—Continued

APC	Group title	Status indicator	Relative weight	Payment rate	National unadjusted coinsurance	Minimum unadjusted coinsurance
0763	Dolasetron mesylate oral, 100 mg .....	G	.....	\$65.21	.....	\$8.74
0764	Granisetron hcl injection 100 mcg .....	G	.....	\$1.85	.....	\$0.25
0765	Granisetron hcl 1 mg oral .....	G	.....	\$44.70	.....	\$5.99
0768	Ondansetron hcl injection 1 mg .....	G	.....	\$6.09	.....	\$0.82
0769	Ondansetron hcl 8mg oral .....	G	.....	\$25.15	.....	\$3.37
0800	Leuprolide acetate, 3.75 mg .....	G	.....	\$492.71	.....	\$63.27
0801	Cyclophosphamide oral 25 mg .....	G	.....	\$2.12	.....	\$0.28
0802	Etoposide oral 50 mg .....	G	.....	\$45.95	.....	\$6.16
0803	Melphalan oral 2 mg .....	G	.....	\$2.07	.....	\$0.28
0807	Aldesleukin/single use vial .....	G	.....	\$569.76	.....	\$76.35
0809	Bcg live intravesical vac .....	G	.....	\$159.39	.....	\$19.45
0810	Goserelin acetate implant 3.6 mg .....	G	.....	\$446.49	.....	\$59.83
0811	Carboplatin injection 50 mg .....	G	.....	\$98.90	.....	\$13.25
0812	Carbus bischl nitro inj 100 mg .....	G	.....	\$103.27	.....	\$13.84
0813	Cisplatin 10 mg injection .....	G	.....	\$42.18	.....	\$5.65
0814	Asparaginase injection 10,000 u .....	G	.....	\$57.41	.....	\$7.69
0815	Cyclophosphamide 100 mg inj .....	G	.....	\$6.13	.....	\$0.82
0816	Cyclophosphamide lyophilized 100 mg .....	G	.....	\$6.13	.....	\$0.82
0817	Cytarabine hcl 100 mg inj .....	G	.....	\$5.94	.....	\$0.80
0818	Dactinomycin 0.5 mg .....	G	.....	\$12.73	.....	\$1.71
0819	Dacarbazine 10 mg inj .....	G	.....	\$1.13	.....	\$0.15
0820	Daunorubicin 10 mg .....	G	.....	\$80.04	.....	\$10.73
0821	Daunorubicin citrate liposom 10 mg .....	G	.....	\$64.60	.....	\$8.66
0822	Diethylstilbestrol injection 250 mg .....	G	.....	\$4.20	.....	\$0.56
0823	Docetaxel, 20 mg .....	G	.....	\$283.65	.....	\$38.01
0824	Etoposide 10 mg inj .....	G	.....	\$4.06	.....	\$0.54
0826	Methotrexate Oral 2.5 mg .....	G	.....	\$2.92	.....	\$0.39
0827	Floxuridine injection 500 mg .....	G	.....	\$129.56	.....	\$17.36
0828	Gemcitabine HCL 200 mg .....	G	.....	\$88.46	.....	\$11.85
0830	Irinotecan injection 20 mg .....	G	.....	\$117.81	.....	\$15.79
0831	Ifosfomide injection 1 gm .....	G	.....	\$141.50	.....	\$18.96
0832	Idarubicin hcl injection 5 mg .....	G	.....	\$341.38	.....	\$45.75
0833	Interferon alfacon-1, 1 mcg .....	G	.....	\$3.91	.....	\$0.52
0834	Interferon alfa-2a inj recombinant 3 million u .....	G	.....	\$33.22	.....	\$4.45
0836	Interferon alfa-2b inj recombinant, 1 million .....	G	.....	\$11.28	.....	\$1.51
0838	Interferon gamma 1-b inj, 3 million u .....	G	.....	\$199.50	.....	\$26.73
0839	Mechlorethamine hcl inj 10 mg .....	G	.....	\$11.01	.....	\$1.48
0840	Melphalan hydrochl 50 mg .....	G	.....	\$363.48	.....	\$48.71
0841	Methotrexate sodium inj 5 mg .....	G	.....	\$0.45	.....	\$0.06
0842	Fludarabine phosphate inj 50 mg .....	G	.....	\$237.03	.....	\$31.76
0843	Pegaspargase, singl dose vial .....	G	.....	\$1,321.65	.....	\$177.10
0844	Pentostatin injection, 10 mg .....	G	.....	\$1,562.75	.....	\$209.41
0847	Doxorubicin hcl 10 mg vl chemo .....	G	.....	\$15.79	.....	\$2.12
0849	Rituximab, 100 mg .....	G	.....	\$420.29	.....	\$56.32
0850	Streptozocin injection, 1 gm .....	G	.....	\$65.79	.....	\$8.82
0851	Thiotepa injection, 15 mg .....	G	.....	\$100.30	.....	\$13.44
0852	Topotecan, 4 mg .....	G	.....	\$573.75	.....	\$76.88
0853	Vinblastine sulfate inj, 1 mg .....	G	.....	\$4.11	.....	\$0.55
0854	Vincristine sulfate 1 mg inj .....	G	.....	\$30.16	.....	\$4.04
0855	Vinorelbine tartrate, 10 mg .....	G	.....	\$75.51	.....	\$10.12
0856	Porfimer sodium, 75 mg .....	G	.....	\$2,603.67	.....	\$348.89
0857	Bleomycin sulfate injection 15 u .....	G	.....	\$294.48	.....	\$39.46
0858	Cladribine, 1mg .....	G	.....	\$53.47	.....	\$7.16
0859	Fluorouracil injection 500 mg .....	G	.....	\$2.75	.....	\$0.37
0860	Pllicamycin (mithramycin) inj 2.5 mg .....	G	.....	\$93.80	.....	\$12.57
0861	Leuprolide acetate injection 1 mg .....	G	.....	\$22.90	.....	\$3.07
0862	Mitomycin 5 mg inj .....	G	.....	\$121.65	.....	\$16.30
0863	Paclitaxel injection, 30 mg .....	G	.....	\$173.50	.....	\$23.25
0864	Mitoxantrone hcl, 5 mg .....	G	.....	\$223.02	.....	\$29.88
0865	Interferon alfa-n3 inj, human leukocyte derived, 250,000 iu .....	G	.....	\$7.86	.....	\$1.05
0884	Rho d immune globulin inj, 1 dose pkg .....	G	.....	\$35.91	.....	\$4.38
0886	Azathioprine oral 50mg .....	G	.....	\$1.24	.....	\$0.17
0887	Azathioprine parenteral 100 mg .....	G	.....	\$67.88	.....	\$9.10
0888	Cyclosporine oral 100 mg .....	G	.....	\$5.80	.....	\$0.78
0889	Cyclosporin parenteral 250mg .....	G	.....	\$15.81	.....	\$2.12
0890	Lymphocyte immune globulin 250 mg .....	G	.....	\$249.13	.....	\$30.39
0891	Tacrolimus oral per 1 mg .....	G	.....	\$2.66	.....	\$0.36
0900	Alglucerase injection, per 10 u .....	G	.....	\$37.53	.....	\$5.03
0901	Alpha 1 proteinase inhibitor, 10 mg .....	G	.....	\$2.09	.....	\$0.28
0902	Botulinum toxin a, per unit .....	G	.....	\$4.39	.....	\$0.59
0903	Cytomegalovirus imm IV, vial .....	G	.....	\$370.50	.....	\$49.65
0905	Immune globulin 500 mg .....	G	.....	\$27.28	.....	\$3.33
0906	RSV-ivig, 50 mg .....	G	.....	\$427.73	.....	\$57.32
0907	Ganciclovir Sodium 500 mg injection .....	K	0.45	\$22.26	.....	\$4.45
0908	Tetanus immune globulin inj up to 250 u .....	G	.....	\$102.60	.....	\$13.75
0909	Interferon beta-1a, 33 mcg .....	G	.....	\$204.73	.....	\$27.43
0910	Interferon beta-1b, .25 mg .....	G	.....	\$57.00	.....	\$7.64
0911	Streptokinase per 250,000 iu .....	K	1.76	\$87.25	.....	\$17.45

## ADDENDUM A.—LIST OF HOSPITAL OUTPATIENT AMBULATORY PAYMENT CLASSIFICATIONS WITH STATUS INDICATORS, RELATIVE WEIGHTS, PAYMENT RATES, AND COINSURANCE AMOUNTS, CALENDAR YEAR 2001—Continued

APC	Group title	Status indicator	Relative weight	Payment rate	National unadjusted coinsurance	Minimum unadjusted coinsurance
0913	Ganciclovir long act implant 4.5 mg .....	G	.....	\$4,750.00	.....	\$636.50
0914	Reteplase, per 37.6mg .....	G	.....	\$2,612.50	.....	\$350.08
0915	Alteplase inj rec, per 10 mg .....	K	3.80	\$188.46	.....	\$37.69
0916	Imiglucerase, unit .....	G	.....	\$3.75	.....	\$0.50
0917	Pharmacologic stressors .....	K	0.36	\$17.86	.....	\$3.57
0918	Brachytherapy Seeds, Any type, Each .....	H	.....	.....	.....	.....
0925	Factor viii per iu .....	G	.....	\$0.88	.....	\$0.12
0926	Factor VIII (porcine) per iu .....	G	.....	\$2.09	.....	\$0.28
0927	Factor viii recombinant per iu .....	G	.....	\$1.17	.....	\$0.16
0928	Factor ix complex per iu .....	G	.....	\$.71	.....	\$0.10
0929	Anti-inhibitor per iu .....	G	.....	\$1.43	.....	\$0.19
0930	Antithrombin iii injection per iu .....	G	.....	\$.82	.....	\$0.11
0931	Factor IX non-recombinant, per iu .....	G	.....	\$0.72	.....	\$0.10
0932	Factor IX recombinant, per iu .....	G	.....	\$1.12	.....	\$0.10
0949	Plasma, Pooled Multiple Donor, Solvent/Detergent Treated, Frozen .....	K	2.94	\$145.76	.....	\$29.15
0950	Blood (Whole) For Transfusion .....	K	2.08	\$103.33	.....	\$20.67
0952	Cryoprecipitate .....	K	0.70	\$34.70	.....	\$6.94
0953	Fibrinogen Unit .....	K	0.48	\$23.80	.....	\$4.76
0954	RBC Leukocytes Reduced .....	K	2.83	\$140.35	.....	\$28.07
0955	Plasma, Fresh Frozen .....	K	2.26	\$111.85	.....	\$22.37
0956	Plasma Protein Fraction .....	K	1.26	\$62.49	.....	\$12.50
0957	Platelet Concentrate .....	K	0.98	\$48.55	.....	\$9.71
0958	Platelet Rich Plasma .....	K	1.16	\$57.54	.....	\$11.51
0959	Red Blood Cells .....	K	2.04	\$101.31	.....	\$20.26
0960	Washed Red Blood Cells .....	K	3.81	\$188.75	.....	\$37.75
0961	Infusion, Albumin (Human) 5%, 500 ml .....	K	2.77	\$137.38	.....	\$27.48
0962	Infusion, Albumin (Human) 25%, 50 ml .....	K	1.38	\$68.44	.....	\$13.69
0970	New Technology— I (\$0-\$50) .....	T	0.52	\$25.79	.....	\$5.16
0971	New Technology— II (\$50-\$100) .....	S	1.55	\$76.88	.....	\$15.38
0972	New Technology— III (\$100-\$200) .....	T	3.09	\$153.26	.....	\$30.65
0973	New Technology— IV (\$200-\$300) .....	T	5.16	\$255.91	.....	\$51.18
0974	New Technology— V (\$300-\$500) .....	S	8.25	\$409.17	.....	\$81.83
0975	New Technology— VI (\$500-\$750) .....	T	12.90	\$639.79	.....	\$127.96
0976	New Technology— VII (\$750-\$1000) .....	S	18.05	\$895.21	.....	\$179.04
0977	New Technology— VIII (\$1000-\$1250) .....	T	23.20	\$1,150.63	.....	\$230.13
0978	New Technology— IX (\$1250-\$1500) .....	T	28.36	\$1,406.54	.....	\$281.31
0979	New Technology— X (\$1500-\$1750) .....	T	33.51	\$1,661.96	.....	\$332.39
0980	New Technology— XI (\$1750-\$2000) .....	T	38.67	\$1,917.89	.....	\$383.58
0981	New Technology— XII (\$2000-\$2500) .....	S	46.40	\$2,301.26	.....	\$460.25
0982	New Technology— XIII (\$2500-\$3500) .....	T	61.87	\$3,068.50	.....	\$613.70
0983	New Technology— XIV (\$3500-\$5000) .....	T	87.65	\$4,347.09	.....	\$869.42
0984	New Technology— XV (\$5000-\$6000) .....	T	113.43	\$5,625.67	.....	\$1,125.13
0987	New Device Technology— I (\$0-\$250) .....	X	.....	\$127.86	.....	\$25.57
0988	New Device Technology— II (\$250-\$500) .....	X	.....	\$383.58	.....	\$76.72
0989	New Device Technology— III (\$500-\$750) .....	X	.....	\$639.30	.....	\$127.86
0990	New Device Technology— IV (\$750-\$1000) .....	X	.....	\$895.01	.....	\$179.00
0991	New Device Technology— V (\$1000-\$1500) .....	X	.....	\$1,278.59	.....	\$255.72
0992	New Device Technology— VI (\$1500-\$2000) .....	X	.....	\$1,790.03	.....	\$358.01
0993	New Device Technology— VII (\$2000-\$3000) .....	X	.....	\$2,557.18	.....	\$511.44
0994	New Device Technology— VIII (\$3000-\$4000) .....	X	.....	\$3,580.05	.....	\$716.01
0995	New Device Technology— IX (\$4000-\$5000) .....	X	.....	\$4,602.92	.....	\$920.58
0996	New Device Technology— X (\$5000-\$7000) .....	X	.....	\$6,137.23	.....	\$1,227.45
0997	New Device Technology— XI (\$7000-\$9000) .....	X	.....	\$8,182.98	.....	\$1,636.60
1000	Perclose Closer Prostar Arterial Vascular Closure .....	H	.....	.....	.....	.....
1001	AcuNav-diagnostic ultrasound .....	H	.....	.....	.....	.....
1002	Cochlear Implant System .....	H	.....	.....	.....	.....
1003	Cath, ablation, Livewire TC .....	H	.....	.....	.....	.....
1004	Fast-Cath, Swartz, SAFL, CSTA .....	H	.....	.....	.....	.....
1006	ARRAY post chamber IOL .....	H	.....	.....	.....	.....
1007	Ams 700 penile prosthesis .....	H	.....	.....	.....	.....
1008	Urolume-implant urethral stent .....	H	.....	.....	.....	.....
1009	Plasma, cryoprecipitate-reduced, unit .....	K	0.86	\$42.76	.....	\$8.55
1010	Blood, L/R, CMV-neg .....	K	2.88	\$142.84	.....	\$28.57
1011	Platelets, L/R, CMV-neg, unit .....	K	11.86	\$588.15	.....	\$117.63
1012	Platelet concentrate, L/R, irradiated, unit .....	K	1.92	\$95.23	.....	\$19.05
1013	Platelet concentrate, L/R, unit .....	K	1.18	\$58.30	.....	\$11.66
1014	Platelets, aph/pher, L/R, unit .....	K	8.93	\$443.11	.....	\$88.62
1016	Blood, L/R, froz/deglycerol/washed .....	K	7.15	\$354.68	.....	\$70.94
1017	Platelets, aph/pher, L/R, CMV-neg, unit .....	K	9.33	\$462.54	.....	\$92.51
1018	Blood, L/R, irradiated .....	K	3.13	\$155.48	.....	\$31.10
1019	Platelets, aph/pher, L/R, irradiated, unit .....	K	9.64	\$478.09	.....	\$95.62
1024	Quinupristin 150 mg/dalfopristin 350 mg .....	J	.....	\$102.05	.....	\$13.67
1025	Marinr CS catheter .....	H	.....	.....	.....	.....
1026	RF Perfrmr cath 5F RF Marinr .....	H	.....	.....	.....	.....
1027	Magic x/short, Radius14mm .....	H	.....	.....	.....	.....
1028	Prcis Twst trnsvg anch sys .....	H	.....	.....	.....	.....
1029	CRE guided balloon dil cath .....	H	.....	.....	.....	.....
1030	Cthtr:Mrshal,Blu Max Utr Dmnd .....	H	.....	.....	.....	.....

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APC	Group title	Status indicator	Relative weight	Payment rate	National unadjusted coinsurance	Minimum unadjusted coinsurance
1033	Sonicath mdl 37-410 .....	H	.....	.....	.....	.....
1034	SURPASS, Long30 SURPASS-cath .....	H	.....	.....	.....	.....
1035	Cath, Ultra ICE .....	H	.....	.....	.....	.....
1036	R port/reservoir impl dev .....	H	.....	.....	.....	.....
1037	Vaxcelchronic dialysis cath .....	H	.....	.....	.....	.....
1038	UltraCross Imaging Cath .....	H	.....	.....	.....	.....
1039	Wallstent/RP: Trach .....	H	.....	.....	.....	.....
1040	Wallstent/RP TIPS—20/40/60 .....	H	.....	.....	.....	.....
1042	Wallstent, UltraFlex: Bil .....	H	.....	.....	.....	.....
1043	Atherectomy sys, coronary .....	H	.....	.....	.....	.....
1045	I-131 MIBG (iobem-sulfate) O.5mCi .....	G	.....	\$1,140.00	.....	\$139.08
1047	Navi-Star, Noga-Star cath .....	H	.....	.....	.....	.....
1048	NeuroCyberneticPros: gen .....	H	.....	.....	.....	.....
1051	Oasis Thrombectomy Cath .....	H	.....	.....	.....	.....
1053	EnSite 3000 catheter .....	H	.....	.....	.....	.....
1054	Hydrolyser Thromb Cath 6/7F .....	H	.....	.....	.....	.....
1055	Transesoph 210, 210-S Cath .....	H	.....	.....	.....	.....
1056	Thermachoice II Cath .....	H	.....	.....	.....	.....
1057	Micromark Tissue Marker .....	H	.....	.....	.....	.....
1059	Carticel, auto cult-chnr cyte .....	G	.....	\$14,250.00	.....	\$2,010.00
1060	ACS multi-link tristor stent .....	H	.....	.....	.....	.....
1061	ACS Viking Guiding cath .....	H	.....	.....	.....	.....
1063	EndoTak Endurance EZ, RX leads .....	H	.....	.....	.....	.....
1067	Megalink biliary stent .....	H	.....	.....	.....	.....
1068	Pulsar DDD pmkr .....	H	.....	.....	.....	.....
1069	Discovery DR, pmaker .....	H	.....	.....	.....	.....
1071	Pulsar Max, Pulsar SR pmkr .....	H	.....	.....	.....	.....
1072	Guidant: bln dil cath .....	H	.....	.....	.....	.....
1073	Gynecare Morcellator .....	H	.....	.....	.....	.....
1074	RX/OTW Viatrac-peri dil cath .....	H	.....	.....	.....	.....
1075	Guidant: lead .....	H	.....	.....	.....	.....
1076	Ventak mini sc defib .....	H	.....	.....	.....	.....
1077	Ventak VR Prizm VR, sc defib .....	H	.....	.....	.....	.....
1078	Ventak: Prizm, AVIIIDR defib .....	H	.....	.....	.....	.....
1079	CO 57/58 0.5 mCi .....	G	.....	\$264.10	.....	\$32.22
1084	Denileukin difitox, 300 mcg .....	G	.....	\$942.88	.....	\$126.35
1086	Temozolomide, 5 mg .....	G	.....	\$5.70	.....	\$0.76
1087	I-123 per uCi capsule .....	G	.....	\$0.84	.....	\$0.10
1089	CO 57, 0.5 mCi .....	G	.....	\$91.20	.....	\$11.13
1090	IN 111 Chloride, per mCi .....	G	.....	\$152.00	.....	\$18.54
1091	IN 111 Oxyquinoline, per 5 mCi .....	G	.....	\$508.25	.....	\$62.01
1092	IN 111 Pentetate, per 1.5 mCi .....	G	.....	\$769.50	.....	\$93.88
1094	TC 99M Albumin aggr, per vial .....	J	.....	\$34.20	.....	\$4.17
1095	TC 99M Depreotide, per vial .....	G	.....	\$760.00	.....	\$101.84
1096	TC 99M Exametazime, per dose .....	G	.....	\$445.31	.....	\$63.75
1097	TC 99M Mebrofenin, per vial .....	G	.....	\$46.76	.....	\$5.71
1098	TC 99M Pentetate, per vial .....	G	.....	\$22.80	.....	\$2.78
1099	TC 99M Pyrophosphate, per vial .....	J	.....	\$42.75	.....	\$5.22
1100	Medtronic AVE GT1 guidewire .....	H	.....	.....	.....	.....
1101	Medtronic AVE, AVE Z2 cath .....	H	.....	.....	.....	.....
1102	Synergy Neurostim Genrtr .....	H	.....	.....	.....	.....
1103	Micro Jewel Defibrillator .....	H	.....	.....	.....	.....
1104	RF Conductor Ablative Cath .....	H	.....	.....	.....	.....
1105	Sigma 300VDD pacmkr .....	H	.....	.....	.....	.....
1106	SynergyEZ Pt Progrmr .....	H	.....	.....	.....	.....
1107	Torqr, Solist cath .....	H	.....	.....	.....	.....
1108	Reveal Cardiac Recorder .....	H	.....	.....	.....	.....
1109	Implantable anchor: Ethicon .....	H	.....	.....	.....	.....
1110	Stable Mapper, cath electrd .....	H	.....	.....	.....	.....
1111	AneuRx Aort-Uni-llcstnt&cath .....	H	.....	.....	.....	.....
1112	AneuRx Stent graft/del.cath .....	H	.....	.....	.....	.....
1113	Tlnt Endo Sprng Stnt Grft Sys .....	H	.....	.....	.....	.....
1114	TalntSprgStnt+Graf endo pros .....	H	.....	.....	.....	.....
1115	5038S,5038,5038L pace lead .....	H	.....	.....	.....	.....
1116	CapSureSP pacing Lead .....	H	.....	.....	.....	.....
1117	Ancure Endograft Del Sys .....	H	.....	.....	.....	.....
1118	Sigma300DR LegIIDR.pacemkr .....	H	.....	.....	.....	.....
1119	Sprint6932,6943 defib lead .....	H	.....	.....	.....	.....
1120	Sprint6942,6945 defib lead .....	H	.....	.....	.....	.....
1121	Gem defibrillator .....	H	.....	.....	.....	.....
1122	TC 99M arcitumomab per dose .....	G	.....	\$926.25	.....	\$124.12
1123	Gem II VR defibrillator .....	H	.....	.....	.....	.....
1124	InterStim Test Stim Kit .....	H	.....	.....	.....	.....
1125	Kappa 400SR, Ttopaz II SR pmkr .....	H	.....	.....	.....	.....
1126	Kappa 700 DR pacemakr .....	H	.....	.....	.....	.....
1127	Kappa 700SR.pmkr sgl chamber .....	H	.....	.....	.....	.....
1128	Kappa 700D,Ruby IID pmkr .....	H	.....	.....	.....	.....
1129	Kappa 700VDD.pacmkr .....	H	.....	.....	.....	.....



## ADDENDUM A.—LIST OF HOSPITAL OUTPATIENT AMBULATORY PAYMENT CLASSIFICATIONS WITH STATUS INDICATORS, RELATIVE WEIGHTS, PAYMENT RATES, AND COINSURANCE AMOUNTS, CALENDAR YEAR 2001—Continued

APC	Group title	Status indicator	Relative weight	Payment rate	National unadjusted coinsurance	Minimum unadjusted coinsurance
1130	Sigma 200D,LGCY IID sc pmkr	H				
1131	Sigma 200DR, pmkr	H				
1132	Sigma 200SR Leg II:sc pac	H				
1133	Sigma SR, Vita SR, pmaker	H				
1134	Sigma 300D pmkr	H				
1135	Entity DR 5326L/R, DC, pmkr	H				
1136	Affinity DR 5330L/R, DC, pmkr	H				
1137	CardioSEAL implant syst	H				
1143	AddVent mod 2060BL,VDD	H				
1144	Afnty SP 5130,Integrity SR,pmkr	H				
1145	Angio-Seal 6fr, 8fr	H				
1147	AV Plus DX 1368: lead	H				
1148	Contour MD sc defib	H				
1149	Entity DC 5226R-pmkr	H				
1151	Passiveplus DX lead, 10mdls	H				
1152	LifeSite Access System	H				
1153	Regency SC+ 2402L pmkr	H				
1154	SPL:SPOI,02,04 – defib lead	H				
1155	Repliform 8 sq cm	H				
1156	Tr 1102TrSR+ 2260L,2264L,5131	H				
1157	Trilogy DCT 23/8L pmkr	H				
1158	TVL lead SV01,SV02,SV04	H				
1159	TVL RV02,RV06,RV07: lead	H				
1160	TVL-ADX 1559: lead	H				
1161	Tendril DX, 1388 pacing lead	H				
1162	TempoDr, TrilogyDR+DC pmkr	H				
1163	Tendril SDX, 1488T pacing lead	H				
1164	Iodine-125 brachytx seed	H				
1166	Cytarabine liposomal, 10 mg	G		\$371.45		\$49.77
1167	Epirubicin hcl, 2 mg	J		\$24.94		\$3.34
1171	Autosuture site marker stple	H				
1172	Spacemaker dissect ballon	H				
1173	Cor stntS540,S670,o-wire stn	H				
1174	Bard brachytx needle	H				
1178	Busulfan IV, 6 mg	G		\$26.48		\$3.55
1180	Vigor SR, SC, pmkr	H				
1181	Meridian SSI, SC, pmkr	H				
1182	Pulsar SSI, SC, pmkr	H				
1183	Jade IIS, Sigma 300S,SC, pmkr	H				
1184	Sigma 200S, SC, pmkr	H				
1188	I 131, per mCi	G		\$5.86		\$0.75
1200	TC 99M Sodium Glucoheptonate, per vial	G		\$113.05		\$13.79
1201	TC 99M succimer, per vial	G		\$135.66		\$16.55
1202	TC 99M Sulfur Colloid, per dose	G		\$38.00		\$4.64
1203	Verteporfin for Injection	G		\$1,458.25		\$195.41
1205	TC 99M Disofenin, per vial	G		\$427.50		\$57.29
1207	Octreotide acetate depot 1mg	G		\$135.10		\$16.48
1302	SQ01: lead	H				
1303	CapSure Fix 6940/4068-110, lead	H				
1304	Sonicath mdl 37-416,-418	H				
1305	Apligraf	G		\$1,157.81		\$163.31
1306	NeuroCyberneticPros: lead	H				
1311	Trilogy DR+/DAO pmkr	H				
1312	Magic WALLSTENT stent-Mini	H				
1313	Magic medium, Radius 31mm	H				
1314	Magic WALLSTENT stent-Long	H				
1315	Vigor DR, Meridian DR pmkr	H				
1316	Meridian DDD pmkr	H				
1317	Discovery SR, pmkr	H				
1318	Meridian SR pmkr	H				
1319	Wallstent/RP Enteral-60mm	H				
1320	Wallstent/RP Iliac Del Sys	H				
1325	Pallidium – 103 seed	H				
1326	Angio-jet rheolytic thromb cath	H				
1328	ANS Renew NS trnsmt	H				
1333	PALMZA Corinthian bill stent	H				
1334	Crown,Mini-crown,CrossLC	H				
1335	Mesh, Prolene	H				
1336	Constant Flow Imp Pump	H				
1337	IsoMed 8472-20/35/60	H				
1348	I 131 per mCi solution	G		\$146.57		\$17.88
1350	Prosta/Oncoseed, RAPID strand, I-125	H				
1351	CapSure(Fix)pacing lead	H				
1352	Gem II defib	H				
1353	Itrel Interstm neurostim+ext	H				
1354	Kappa 400DR,Diamond II 820DR	H				
1355	Kappa 600DR, Vita DR	H				
1356	Profile MD V-186HV3 sc defib	H				

ADDENDUM A.—LIST OF HOSPITAL OUTPATIENT AMBULATORY PAYMENT CLASSIFICATIONS WITH STATUS INDICATORS, RELATIVE WEIGHTS, PAYMENT RATES, AND COINSURANCE AMOUNTS, CALENDAR YEAR 2001—Continued

APC	Group title	Status indicator	Relative weight	Payment rate	National unadjusted coinsurance	Minimum unadjusted coinsurance
1357	Angstrom MD V-190HV3 sc defib .....	H	.....	.....	.....	.....
1358	Affinity DC 5230R-Pacemaker .....	H	.....	.....	.....	.....
1359	Pulsar,Pulsar Max DR,pmkr .....	H	.....	.....	.....	.....
1363	Gem DR, DC, defib .....	H	.....	.....	.....	.....
1364	Photon DR V-230HV3 DC defib .....	H	.....	.....	.....	.....
1365	Guidewire, Hi-Torque14/18/35 .....	H	.....	.....	.....	.....
1366	Guidewire,PTCA, Hi-Torque .....	H	.....	.....	.....	.....
1367	Guidewire, Hi-Torque CrossIt .....	H	.....	.....	.....	.....
1369	ANS Renew Stim Sys recvr .....	H	.....	.....	.....	.....
1370	Tension-Free Vaginal Tape .....	H	.....	.....	.....	.....
1371	Symp Nitinol Transhep Bil Sys .....	H	.....	.....	.....	.....
1372	Cordis Nitinol bil stent .....	H	.....	.....	.....	.....
1375	Stent, coronary, NIR .....	H	.....	.....	.....	.....
1376	ANS Renew Stim Sys lead .....	H	.....	.....	.....	.....
1377	Specify 3988 neuro lead .....	H	.....	.....	.....	.....
1378	InterStim Tx 3080/3886 lead .....	H	.....	.....	.....	.....
1379	Pisces-Quad 3887 lead .....	H	.....	.....	.....	.....
1400	Diphenhydramine hcl 50mg .....	G	.....	\$1.18	.....	\$.16
1401	Prochlorperazine maleate 5mg .....	G	.....	\$1.31	.....	\$.18
1402	Promethazine hcl 12.5mg oral .....	G	.....	\$.03	.....	\$.00
1403	Chlorpromazine hcl 10mg oral .....	G	.....	\$.55	.....	\$.07
1404	Trimethobenzamide hcl 250mg .....	G	.....	\$.36	.....	\$.05
1405	Thiethylperazine maleate10mg .....	G	.....	\$.69	.....	\$.09
1406	Perphenazine 4mg oral .....	G	.....	\$.71	.....	\$.10
1407	Hydroxyzine pamoate 25mg .....	G	.....	\$.20	.....	\$.03
1409	Factor viia recombinant, per 1.2 mg .....	G	.....	\$1,596.00	.....	\$213.86
1410	ProSORBA column .....	H	.....	.....	.....	.....
1411	Herculink,OTW SDS bil stent .....	H	.....	.....	.....	.....
1420	StapleTac2 Bone w/Dermis .....	H	.....	.....	.....	.....
1421	StapleTac2 Bone wo Dermis .....	H	.....	.....	.....	.....
1450	Orthosphere Arthroplasty .....	H	.....	.....	.....	.....
1451	Orthosphere Arthroplasty Kit .....	H	.....	.....	.....	.....
1500	Atherectomy sys, peripheral .....	H	.....	.....	.....	.....
1600	TC 99M sestamibi, per syringe .....	G	.....	\$109.25	.....	\$13.33
1601	TC 99M medronate, per dose .....	G	.....	\$38.38	.....	\$4.68
1602	TC 99M apcitide, per vial .....	G	.....	\$47.50	.....	\$5.80
1603	TL 201, mCi .....	G	.....	\$28.50	.....	\$3.48
1604	IN 111 capromab pendetide, per dose .....	G	.....	\$1,008.90	.....	\$135.19
1605	Abciximab injection, 10 mg .....	G	.....	\$513.02	.....	\$68.74
1606	Anistreplase, 30 u .....	G	.....	\$2,693.80	.....	\$360.97
1607	Eptifibatide injection, 5 mg .....	G	.....	\$12.57	.....	\$1.68
1608	Etanercept injection, 25 mg .....	G	.....	\$134.42	.....	\$18.01
1609	Rho(D) immune globulin h, sd, 100 iu .....	G	.....	\$20.55	.....	\$2.51
1611	Hylan G-F 20 injection, 16 mg .....	G	.....	\$204.87	.....	\$27.45
1612	Daclizumab, parenteral, 25 mg .....	G	.....	\$397.29	.....	\$53.24
1613	Trastuzumab, 10 mg .....	G	.....	\$48.85	.....	\$6.55
1614	Valrubicin, 200 mg .....	G	.....	\$423.23	.....	\$56.71
1615	Basiliximab, 20 mg .....	G	.....	\$1,250.01	.....	\$167.50
1616	Histrelin Acetate, 0.5 mg .....	G	.....	\$14.91	.....	\$2.00
1617	Lepirdin, 50 mg .....	G	.....	\$124.49	.....	\$16.68
1618	Von Willebrand factor, per iu .....	G	.....	\$.95	.....	\$.13
1619	Ga 67, per mCi .....	G	.....	\$25.97	.....	\$3.17
1620	TC 99M Biscisate, per vial .....	G	.....	\$417.53	.....	\$55.95
1621	Xe 133, per mCi .....	G	.....	\$28.50	.....	\$3.66
1622	TC 99M Mertiatide, per vial .....	G	.....	\$185.82	.....	\$24.90
1623	TC 99M Gluceptate .....	G	.....	\$22.61	.....	\$2.76
1624	P32 sodium, per mCi .....	G	.....	\$74.10	.....	\$9.04
1625	IN 111 Pentetreotide, per mCi .....	G	.....	\$283.42	.....	\$37.98
1626	TC 99M Oxidronate, per vial .....	G	.....	\$38.38	.....	\$4.68
1627	TC-99 labeled red blood cell, per test .....	G	.....	\$38.95	.....	\$4.75
1628	P32 phosphate chromic, per mCi .....	G	.....	\$137.12	.....	\$16.73
1700	Authen Mick TP brachy needle .....	H	.....	.....	.....	.....
1701	Medtec MT-BT-5201-25 ndl .....	H	.....	.....	.....	.....
1702	WWMT brachytx needle .....	H	.....	.....	.....	.....
1703	Mentor Prostate Brachy .....	H	.....	.....	.....	.....
1704	MT-BT-5001-25/5051-25 .....	H	.....	.....	.....	.....
1705	Best Flexi Brachy Needle .....	H	.....	.....	.....	.....
1706	Indigo Prostate Seeding Ndl .....	H	.....	.....	.....	.....
1707	Varisource Implt Ndl .....	H	.....	.....	.....	.....
1708	UroMed Prostate Seed Ndl .....	H	.....	.....	.....	.....
1709	Remington Brachytx Needle .....	H	.....	.....	.....	.....
1710	US Biopsy Prostate Needle .....	H	.....	.....	.....	.....
1711	MD Tech brachytx needle .....	H	.....	.....	.....	.....
1712	Imagyn brachytx needle .....	H	.....	.....	.....	.....
1790	Iridium 192 HDR .....	H	.....	.....	.....	.....
1791	OncoSeed, Rapid Strand I-125 .....	H	.....	.....	.....	.....
1792	UroMed I-125 Brachy seed .....	H	.....	.....	.....	.....
1793	Bard InterSource P-103 seed .....	H	.....	.....	.....	.....

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APC	Group title	Status indicator	Relative weight	Payment rate	National unadjusted coinsurance	Minimum unadjusted coinsurance
1794	Bard IsoSeed P-103 seed .....	H	.....	.....	.....	.....
1795	Bard BrachySource I-125 .....	H	.....	.....	.....	.....
1796	SourceTech Med I-125 .....	H	.....	.....	.....	.....
1797	Draximage I-125 seed .....	H	.....	.....	.....	.....
1798	Syncor I-125 PharmaSeed .....	H	.....	.....	.....	.....
1799	I-Plant I-125 Brachytx seed .....	H	.....	.....	.....	.....
1800	Pd-103 brachytx seed .....	H	.....	.....	.....	.....
1801	IoGold I-125 brachytx seed .....	H	.....	.....	.....	.....
1802	Iridium 192 brachytx seeds .....	H	.....	.....	.....	.....
1803	Best Iodine 125 brachytx sds .....	H	.....	.....	.....	.....
1804	Best Palladium 103 seeds .....	H	.....	.....	.....	.....
1805	IsoStar Iodine-125 seeds .....	H	.....	.....	.....	.....
1806	Gold 198 .....	H	.....	.....	.....	.....
1810	D114S Dilatation Cath .....	H	.....	.....	.....	.....
1811	Surgical Dynamics Anchors .....	H	.....	.....	.....	.....
1812	OBL Anchors .....	H	.....	.....	.....	.....
1850	Repliform 14/21 sq cm .....	H	.....	.....	.....	.....
1851	Repliform 24/28 sq cm .....	H	.....	.....	.....	.....
1852	TransCyte, per 247 sq cm .....	H	.....	.....	.....	.....
1853	Suspend, per 8/14 sq cm .....	H	.....	.....	.....	.....
1854	Suspend, per 24/28 sq cm .....	H	.....	.....	.....	.....
1855	Suspend, per 36 sq cm .....	H	.....	.....	.....	.....
1856	Suspend, per 48 sq cm .....	H	.....	.....	.....	.....
1857	Suspend, per 84 sq cm .....	H	.....	.....	.....	.....
1858	DuraDerm, per 8/14 sq cm .....	H	.....	.....	.....	.....
1859	DuraDerm, per 21/24/28 sq cm .....	H	.....	.....	.....	.....
1860	DuraDerm, per 48 sq cm .....	H	.....	.....	.....	.....
1861	DuraDerm, per 36 sq cm .....	H	.....	.....	.....	.....
1862	DuraDerm, per 72 sq cm .....	H	.....	.....	.....	.....
1863	DuraDerm, per 84 sq cm .....	H	.....	.....	.....	.....
1864	SpermaTex, per 13.44 sq cm .....	H	.....	.....	.....	.....
1865	FasLata, per 8/14 sq cm .....	H	.....	.....	.....	.....
1866	FasLata, per 24/28 sq cm .....	H	.....	.....	.....	.....
1867	FasLata, per 36/48 sq cm .....	H	.....	.....	.....	.....
1868	FasLata, per 96 sq cm .....	H	.....	.....	.....	.....
1869	Gore Thyroplasty Dev .....	H	.....	.....	.....	.....
1870	DermMatrix, per 16 sq cm .....	H	.....	.....	.....	.....
1871	DermMatrix, 32 or 64 sq cm .....	H	.....	.....	.....	.....
1872	Dermagraft, per 37.5 sq cm .....	H	.....	.....	.....	.....
1873	Bard 3DMax Mesh .....	H	.....	.....	.....	.....
1929	Maverick PTCA Cath .....	H	.....	.....	.....	.....
1930	Coyote Dil Cath, 20/30/40mm .....	H	.....	.....	.....	.....
1931	Talon Dil Cath .....	H	.....	.....	.....	.....
1932	Scimed Remedy Dil Cath .....	H	.....	.....	.....	.....
1933	Opti-Plast XL/Centurion Cath .....	H	.....	.....	.....	.....
1934	Ultraverse 3.5F Bal Dil Cath .....	H	.....	.....	.....	.....
1935	Workhorse PTA Bal Cath .....	H	.....	.....	.....	.....
1936	Uromax Ultra Bal Dil Cath .....	H	.....	.....	.....	.....
1937	Synergy Balloon Dil Cath .....	H	.....	.....	.....	.....
1938	UroForce Bal Dil Cath .....	H	.....	.....	.....	.....
1939	Raptur, Ninja PTCA Dil Cath .....	H	.....	.....	.....	.....
1940	PowerFlex,OPTA 5/LP Bal Cath .....	H	.....	.....	.....	.....
1941	Jupiter PTA Dil Cath .....	H	.....	.....	.....	.....
1942	Cordis Maxi LD PTA Bal Cath .....	H	.....	.....	.....	.....
1943	RXCrossSail OTW OpenSail .....	H	.....	.....	.....	.....
1944	Rapid Exchange Bil Dil Cath .....	H	.....	.....	.....	.....
1945	Savvy PTA Dil Cath .....	H	.....	.....	.....	.....
1946	R1s Rapid Dil Cath .....	H	.....	.....	.....	.....
1947	Gazelle Bal Dil Cath .....	H	.....	.....	.....	.....
1948	Pursuit Balloon Cath .....	H	.....	.....	.....	.....
1949	Oracle Megasonics Cath .....	H	.....	.....	.....	.....
1979	Visions PV/Avanar US Cath .....	H	.....	.....	.....	.....
1980	Atlantis SR Coronary Cath .....	H	.....	.....	.....	.....
1981	PTCA Catheters .....	H	.....	.....	.....	.....
2000	Orbiter ST Steerable Cath .....	H	.....	.....	.....	.....
2001	Constellation Diag Cath .....	H	.....	.....	.....	.....
2002	Irvine 5F Inquiry Diag EP Cath .....	H	.....	.....	.....	.....
2003	Irvine 6F Inquiry Diag EP Cath .....	H	.....	.....	.....	.....
2004	Biosense EP Cath—Octapolar .....	H	.....	.....	.....	.....
2005	Biosense EP Cath—Hexapolar .....	H	.....	.....	.....	.....
2006	Biosense EP Cath—Decapolar .....	H	.....	.....	.....	.....
2007	Irvine 6F Luma-Cath EP Cath .....	H	.....	.....	.....	.....
2008	7F Luma-Cath EP Cath 81910-15 .....	H	.....	.....	.....	.....
2009	Irvine 7F Luma-Cath EP Cath .....	H	.....	.....	.....	.....
2010	Fixed Curve EP Cath .....	H	.....	.....	.....	.....
2011	Deflectable Tip Cath—Quad .....	H	.....	.....	.....	.....
2012	Celsius Abln Cath .....	H	.....	.....	.....	.....
2013	Celsius Large Abln Cath .....	H	.....	.....	.....	.....

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APC	Group title	Status indicator	Relative weight	Payment rate	National unadjusted coinsurance	Minimum unadjusted coinsurance
2014	Celsius II Asym Abln Cath .....	H	.....	.....	.....	.....
2015	Celsius II Sym Abln Cath .....	H	.....	.....	.....	.....
2016	Navi-Star DS, Navi-Star Ther .....	H	.....	.....	.....	.....
2017	Navi-Star Abln Cath .....	H	.....	.....	.....	.....
2018	Polaris T Ablation Cath .....	H	.....	.....	.....	.....
2019	EP Deflectable Cath .....	H	.....	.....	.....	.....
2020	Blazer II XP Abln Cath .....	H	.....	.....	.....	.....
2021	SilverFlex EP Cath .....	H	.....	.....	.....	.....
2022	CP Chillii Cooled Abln Cath .....	H	.....	.....	.....	.....
2023	Chillii Cld AblnCath-std, Ig .....	H	.....	.....	.....	.....
2100	CP CS Reference Cath .....	H	.....	.....	.....	.....
2101	CP RV Reference Cath .....	H	.....	.....	.....	.....
2102	CP Radian 7F EP Cath .....	H	.....	.....	.....	.....
2103	CP Radian 7F EP Cath w/Track .....	H	.....	.....	.....	.....
2104	Lasso Deflectable Cath .....	H	.....	.....	.....	.....
2151	Veripath Guiding Cath .....	H	.....	.....	.....	.....
2152	Cordis Vista Brite Tip Cath .....	H	.....	.....	.....	.....
2153	Bard Viking Cath .....	H	.....	.....	.....	.....
2200	Arrow-Trerotola PTD Cath .....	H	.....	.....	.....	.....
2300	Varisource Stnd Catheters .....	H	.....	.....	.....	.....
2597	CliniCath/kit 16/18 sgl/dbl .....	H	.....	.....	.....	.....
2598	CliniCath 18/20/24G-single .....	H	.....	.....	.....	.....
2599	CliniCath 16/18G-double .....	H	.....	.....	.....	.....
2601	Bard DL Ureteral Cath .....	H	.....	.....	.....	.....
2602	Vitesse Laser Cath 1.4/1.7mm .....	H	.....	.....	.....	.....
2603	Vitesse Laser Cath 2.0mm .....	H	.....	.....	.....	.....
2604	Vitesse E Laser Cath 2.0mm .....	H	.....	.....	.....	.....
2605	Extreme Laser Catheter .....	H	.....	.....	.....	.....
2606	SpineCath XL Catheter .....	H	.....	.....	.....	.....
2607	SpineCath Intradiscal Cath .....	H	.....	.....	.....	.....
2608	Scimed 6F Wiseguide Cath .....	H	.....	.....	.....	.....
2609	Flexima Bil Drainage Cath .....	H	.....	.....	.....	.....
2610	FlexTipPlus Intraspinal Cath .....	H	.....	.....	.....	.....
2611	AlgoLine Intraspinal Cath .....	H	.....	.....	.....	.....
2612	InDura Catheter .....	H	.....	.....	.....	.....
2700	MycroPhylax Plus SC defib .....	H	.....	.....	.....	.....
2701	Phylax XM SC defib .....	H	.....	.....	.....	.....
2702	Ventak Prizm 2 VR Defib .....	H	.....	.....	.....	.....
2703	Ventak Prizm VR HE Defib .....	H	.....	.....	.....	.....
2704	Ventak Mini IV+ Defib .....	H	.....	.....	.....	.....
2801	Defender IV DR 612 DC defib .....	H	.....	.....	.....	.....
2802	Phylax AV DC defib .....	H	.....	.....	.....	.....
2803	Ventak Prizm DR HE Defib .....	H	.....	.....	.....	.....
2804	Ventak Prizm 2 DR Defib .....	H	.....	.....	.....	.....
2805	Jewel AF 7250 Defib .....	H	.....	.....	.....	.....
2806	GEM VR 7227 Defib .....	H	.....	.....	.....	.....
2807	Contak CD 1823 .....	H	.....	.....	.....	.....
2808	Contak TR 1241 .....	H	.....	.....	.....	.....
3002	EasyTrak Defib Lead .....	H	.....	.....	.....	.....
3001	Kainox SL/RV defib lead .....	H	.....	.....	.....	.....
3003	Endotak SQ Array XP lead .....	H	.....	.....	.....	.....
3004	Intervene Defib Lead .....	H	.....	.....	.....	.....
3400	Siltex Spectrum, Contour Prof .....	H	.....	.....	.....	.....
3401	Saline-Filled Spectrum .....	H	.....	.....	.....	.....
3500	Mentor Alpha I Inf Penile Pros .....	H	.....	.....	.....	.....
3510	AMS 800 Urinary Pros .....	H	.....	.....	.....	.....
3551	Choice/PT Graphix/Luge/Trooper .....	H	.....	.....	.....	.....
3552	Hi-Torque Whisper .....	H	.....	.....	.....	.....
3553	Cordis guidewires .....	H	.....	.....	.....	.....
3554	Jindo guidewire .....	H	.....	.....	.....	.....
3555	Wholey Hi-Torque Plus GW .....	H	.....	.....	.....	.....
3556	Wave/FlowWire Guidewire .....	H	.....	.....	.....	.....
3557	HyTek guidewire .....	H	.....	.....	.....	.....
3800	SynchroMed EL infusion pump .....	H	.....	.....	.....	.....
3801	Arrow/MicroJect PCA Sys .....	H	.....	.....	.....	.....
3851	Elastic UV IOL AA-4203T/TF/TL .....	H	.....	.....	.....	.....
4000	Opus G 4621, 4624 SC pmkr .....	H	.....	.....	.....	.....
4001	Opus S 4121/4124 SC pmkr .....	H	.....	.....	.....	.....
4002	Talent 113 SC pmkr .....	H	.....	.....	.....	.....
4003	Kairos SR SC pmkr .....	H	.....	.....	.....	.....
4004	Actros SR, Actros SLR SC pmkr .....	H	.....	.....	.....	.....
4005	Philos SR/SR-B SC pmkr .....	H	.....	.....	.....	.....
4006	Pulsar Max II SR pmkr .....	H	.....	.....	.....	.....
4007	Marathon SR pmkr .....	H	.....	.....	.....	.....
4008	Discovery II SSI pmkr .....	H	.....	.....	.....	.....
4009	Discovery II SR pmkr .....	H	.....	.....	.....	.....
4300	Integrity AFx DR 5342 pmkr .....	H	.....	.....	.....	.....
4301	Integrity AFx DR 5346 pmkr .....	H	.....	.....	.....	.....

## ADDENDUM A.—LIST OF HOSPITAL OUTPATIENT AMBULATORY PAYMENT CLASSIFICATIONS WITH STATUS INDICATORS, RELATIVE WEIGHTS, PAYMENT RATES, AND COINSURANCE AMOUNTS, CALENDAR YEAR 2001—Continued

APC	Group title	Status indicator	Relative weight	Payment rate	National unadjusted coinsurance	Minimum unadjusted coinsurance
4302	Affinity VDR 5430 pmkr .....	H	.....	.....	.....	.....
4303	Brio 112 DC pmkr .....	H	.....	.....	.....	.....
4304	Brio 212, Talent 213/223 DC pmkr .....	H	.....	.....	.....	.....
4305	Brio 222 DC pmkr .....	H	.....	.....	.....	.....
4306	Brio 220 DC pmkr .....	H	.....	.....	.....	.....
4307	Kairos DR DC pmkr .....	H	.....	.....	.....	.....
4308	Inos2, Inos2+ DC pmkr .....	H	.....	.....	.....	.....
4309	Actros DR,D,DR-A,SLR DC pmkr .....	H	.....	.....	.....	.....
4310	Actros DR-B DC pmkr .....	H	.....	.....	.....	.....
4311	Philos DR/DR-B/SLR DC pmkr .....	H	.....	.....	.....	.....
4312	Pulsar Max II DR pmkr .....	H	.....	.....	.....	.....
4313	Marathon DR pmkr .....	H	.....	.....	.....	.....
4314	Momentum DR pmkr .....	H	.....	.....	.....	.....
4315	Selection AFm pmkr .....	H	.....	.....	.....	.....
4316	Discovery II DR .....	H	.....	.....	.....	.....
4317	Discovery II DDD .....	H	.....	.....	.....	.....
4600	Snynox,Polyrox,Elox,Retrox .....	H	.....	.....	.....	.....
4602	Tendril SDX, 1488K pmkr lead .....	H	.....	.....	.....	.....
4603	Oscor/Flexion pmkr lead .....	H	.....	.....	.....	.....
4604	CrystallineActFix,CapsureFix .....	H	.....	.....	.....	.....
4605	CapSure Epi pmkr lead .....	H	.....	.....	.....	.....
4606	Flexend pmkr lead .....	H	.....	.....	.....	.....
4607	Finelinell/EZ, Thinlinell/EZ .....	H	.....	.....	.....	.....
5000	BX Velocity w/Hepacoat .....	H	.....	.....	.....	.....
5001	Memotharm Bil Stent, sm, med .....	H	.....	.....	.....	.....
5002	Memotharm Bil Stent, large .....	H	.....	.....	.....	.....
5003	Memotharm Bil Stent, x-large .....	H	.....	.....	.....	.....
5004	PalmazCorinthian IQ Bil Stent .....	H	.....	.....	.....	.....
5005	PalmazCorinthian IQ Trans/Bil .....	H	.....	.....	.....	.....
5006	PalmazTrans Bil Stent Sys-Med .....	H	.....	.....	.....	.....
5007	PalmazTrans XL Bil Stent--40mm .....	H	.....	.....	.....	.....
5008	PalmazTrans XL Bil Stent--50mm .....	H	.....	.....	.....	.....
5009	VistaFlex Biliary Stent .....	H	.....	.....	.....	.....
5010	Rapid Exchange Bil Stent Sys .....	H	.....	.....	.....	.....
5011	IntraStent, IntraStent LP .....	H	.....	.....	.....	.....
5012	IntraStent DoubleStrut LD .....	H	.....	.....	.....	.....
5013	IntraStent DoubleStrut, XS .....	H	.....	.....	.....	.....
5014	AVE Bridge Stent Sys-10/17/28 .....	H	.....	.....	.....	.....
5015	AVE/X3 Bridge Sys, 40-100 .....	H	.....	.....	.....	.....
5016	Biliary stent single use cov .....	H	.....	.....	.....	.....
5017	WallstentRP Bil--20/40/60/68mm .....	H	.....	.....	.....	.....
5018	WallstentRP Bil--80/94mm .....	H	.....	.....	.....	.....
5019	Flexima Bil Stent Sys .....	H	.....	.....	.....	.....
5020	Smart Nitinol Stent--20mm .....	H	.....	.....	.....	.....
5021	Smart Nitinol Stent--40/60mm .....	H	.....	.....	.....	.....
5022	Smart Nitinol Stent--80mm .....	H	.....	.....	.....	.....
5023	BX Velocity Stent--8/13mm .....	H	.....	.....	.....	.....
5024	BX Velocity Stent--18mm .....	H	.....	.....	.....	.....
5025	BX Velocity Stent--23mm .....	H	.....	.....	.....	.....
5026	BX Velocity Stent--28/33mm .....	H	.....	.....	.....	.....
5027	BX Velocity w/Hep--8/13mm .....	H	.....	.....	.....	.....
5028	BX Velocity w/Hep--18mm .....	H	.....	.....	.....	.....
5029	BX Velocity w/Hep--23mm .....	H	.....	.....	.....	.....
5030	Stent, coronary, S660 9/12mm .....	H	.....	.....	.....	.....
5031	Stent,coronary, S660 15/18mm .....	H	.....	.....	.....	.....
5032	Stent,coronary, S660 24/30mm .....	H	.....	.....	.....	.....
5033	Niroyal Stent Sys, 9mm .....	H	.....	.....	.....	.....
5034	Niroyal Stent Sys, 12/15mm .....	H	.....	.....	.....	.....
5035	Niroyal Stent Sys, 18mm .....	H	.....	.....	.....	.....
5036	Niroyal Stent Sys, 25mm .....	H	.....	.....	.....	.....
5037	Niroyal Stent Sys, 31mm .....	H	.....	.....	.....	.....
5038	BX Velocity Stent w/Raptor .....	H	.....	.....	.....	.....
5039	IntraCoil Periph Stent--40mm .....	H	.....	.....	.....	.....
5040	IntraCoil Periph Stent--60mm .....	H	.....	.....	.....	.....
5041	BeStent Over-the-Wire 24/30mm .....	H	.....	.....	.....	.....
5042	BeStent Over-the-Wire 18mm .....	H	.....	.....	.....	.....
5043	BeStent Over-the-Wire 15mm .....	H	.....	.....	.....	.....
5044	BeStent Over-the-Wire 9/12mm .....	H	.....	.....	.....	.....
5045	Multilink Tetra Cor Stent Sys .....	H	.....	.....	.....	.....
5046	Radius 20mm cor stent .....	H	.....	.....	.....	.....
5047	Niroyal Elite Cor Stent Sys .....	H	.....	.....	.....	.....
5048	GR II Coronary Stent .....	H	.....	.....	.....	.....
5130	Wilson-Cook Colonic Z-Stent .....	H	.....	.....	.....	.....
5131	Bard Colorectal Stent-60mm .....	H	.....	.....	.....	.....
5132	Bard Colorectal Stent-80mm .....	H	.....	.....	.....	.....
5133	Bard Colorectal Stent-100mm .....	H	.....	.....	.....	.....
5134	Enteral Wallstent--90mm .....	H	.....	.....	.....	.....
5279	Contour/Pericufflex Stent .....	H	.....	.....	.....	.....

ADDENDUM A.—LIST OF HOSPITAL OUTPATIENT AMBULATORY PAYMENT CLASSIFICATIONS WITH STATUS INDICATORS, RELATIVE WEIGHTS, PAYMENT RATES, AND COINSURANCE AMOUNTS, CALENDAR YEAR 2001—Continued

APC	Group title	Status indicator	Relative weight	Payment rate	National unadjusted coinsurance	Minimum unadjusted coinsurance
5280	Inlay Dbl Ureteral Stent .....	H	.....	.....	.....	.....
5281	Wallgraft Trach Sys 70mm .....	H	.....	.....	.....	.....
5282	Wallgraft Trach Sys 20/30/50 .....	H	.....	.....	.....	.....
5283	Wallstent/RP TIPS—80mm .....	H	.....	.....	.....	.....
5284	Wallstent TrachUltraFlex .....	H	.....	.....	.....	.....
5600	Closure dev, VasoSeal ES .....	H	.....	.....	.....	.....
5601	VasoSeal Model 1000 .....	H	.....	.....	.....	.....
6001	Composix Mesh 8/21 in .....	H	.....	.....	.....	.....
6002	Composix Mesh 32 in .....	H	.....	.....	.....	.....
6003	Composix Mesh 48 in .....	H	.....	.....	.....	.....
6004	Composix Mesh 80 in .....	H	.....	.....	.....	.....
6005	Composix Mesh 140 in .....	H	.....	.....	.....	.....
6006	Composix Mesh 144 in .....	H	.....	.....	.....	.....
6012	Pelvicol Collagen 8/14 sq cm .....	H	.....	.....	.....	.....
6013	Pelvicol Collagen 21/24/28 sq cm .....	H	.....	.....	.....	.....
6014	Pelvicol Collagen 36 sq cm .....	H	.....	.....	.....	.....
6015	Pelvicol Collagen 48 sq cm .....	H	.....	.....	.....	.....
6016	Pelvicol Collagen 96 sq cm .....	H	.....	.....	.....	.....
6017	Gore-Tex DualMesh 75/96 sq cm .....	H	.....	.....	.....	.....
6018	Gore-Tex DualMesh 150 sq cm .....	H	.....	.....	.....	.....
6019	Gore-Tex DualMesh 285 sq cm .....	H	.....	.....	.....	.....
6020	Gore-Tex DualMesh 432 sq cm .....	H	.....	.....	.....	.....
6021	Gore-Tex DualMesh 600 sq cm .....	H	.....	.....	.....	.....
6022	Gore-Tex DualMesh 884 sq cm .....	H	.....	.....	.....	.....
6023	Gore-TexPlus 1mm, 75/96sq cm .....	H	.....	.....	.....	.....
6024	Gore-TexPlus 1mm, 150sq cm .....	H	.....	.....	.....	.....
6025	Gore-TexPlus 1mm, 285sq cm .....	H	.....	.....	.....	.....
6026	Gore-TexPlus 1mm, 432sq cm .....	H	.....	.....	.....	.....
6027	Gore-TexPlus 1mm, 600sq cm .....	H	.....	.....	.....	.....
6028	Gore-TexPlus 1mm, 884 sq cm .....	H	.....	.....	.....	.....
6029	Gore-TexPlus 2mm, 150 sq cm .....	H	.....	.....	.....	.....
6030	Gore-TexPlus 2mm, 285 sq cm .....	H	.....	.....	.....	.....
6031	Gore-TexPlus 2mm, 432 sq cm .....	H	.....	.....	.....	.....
6032	Gore-TexPlus 2mm, 600 sq cm .....	H	.....	.....	.....	.....
6033	Gore-TexPlus 2mm, 884 sq cm .....	H	.....	.....	.....	.....
6034	Bard ePTFE: 150 sq cm—2mm .....	H	.....	.....	.....	.....
6035	Bard ePTFE 150 sqcm-1mm,75-2mm .....	H	.....	.....	.....	.....
6036	Bard ePTFE: 50/75 sqcm-1,2mm .....	H	.....	.....	.....	.....
6037	Bard ePTFE: 300 sq cm-1,2mm .....	H	.....	.....	.....	.....
6038	Bard ePTFE: 600 sq cm-1mm .....	H	.....	.....	.....	.....
6039	Bard ePTFE: 884 sq cm-1mm .....	H	.....	.....	.....	.....
6040	Bard ePTFE: 600 sq cm-2mm .....	H	.....	.....	.....	.....
6041	Bard ePTFE: 884 sq cm-2mm .....	H	.....	.....	.....	.....
6050	Female Sling Sys w/wo Matrl .....	H	.....	.....	.....	.....
6051	Stratasis Sling, 20/40 cm .....	H	.....	.....	.....	.....
6052	Stratasis Sling, 60 cm .....	H	.....	.....	.....	.....
6053	Surgisis Soft Graft .....	H	.....	.....	.....	.....
6054	Surgisis Enhanced Graft .....	H	.....	.....	.....	.....
6055	Surgisis Enhanced Tissue .....	H	.....	.....	.....	.....
6056	Surgisis Soft Tissue Graft .....	H	.....	.....	.....	.....
6057	Surgisis Hernia Graft .....	H	.....	.....	.....	.....
6058	SurgiPro Hernia Plug, med/lg .....	H	.....	.....	.....	.....
6080	Male Sling Sys w/wo Matrl .....	H	.....	.....	.....	.....
6200	Exxcel Sft ePTFE vas graft .....	H	.....	.....	.....	.....
6201	Impra Venaflö—10/20cm .....	H	.....	.....	.....	.....
6202	Impra Venaflö-30/40cm .....	H	.....	.....	.....	.....
6203	Impra Venaflö-50cm,vt45 .....	H	.....	.....	.....	.....
6204	Impra Venaflö-stepped .....	H	.....	.....	.....	.....
6205	Impra Carboflö—10cm .....	H	.....	.....	.....	.....
6206	Impra Carboflö—20cm .....	H	.....	.....	.....	.....
6207	Impra Carboflö—30/35/40cm .....	H	.....	.....	.....	.....
6208	Impra Carboflö—40/50cm .....	H	.....	.....	.....	.....
6209	Impra Carboflö—ctrflex .....	H	.....	.....	.....	.....
6210	Exxcel ePTFE vas graft .....	H	.....	.....	.....	.....
6300	Vanguard III Endovas Graft .....	H	.....	.....	.....	.....
6500	Preface Guiding Sheath .....	H	.....	.....	.....	.....
6501	Soft Tip Sheaths .....	H	.....	.....	.....	.....
6502	Perry Exchange Dilator .....	H	.....	.....	.....	.....
6525	Spectranetics Laser Sheath .....	H	.....	.....	.....	.....
6600	Micro Litho Flex Probes .....	H	.....	.....	.....	.....
6650	Fast-Cath Guiding Introducer .....	H	.....	.....	.....	.....
6651	Seal-AwayGuiding Introducer .....	H	.....	.....	.....	.....
6652	Bard Excalibur Introducer .....	H	.....	.....	.....	.....
6700	Focal Seal-L .....	H	.....	.....	.....	.....
7000	Amifostine, 500 mg .....	G	.....	\$350.31	.....	\$46.94
7001	Amphotericin B lipid complex, 50 mg .....	G	.....	\$95.00	.....	\$12.73
7003	Epoprostenol injection 0.5 mg .....	G	.....	\$16.53	.....	\$2.22
7004	Immune globulin 5 gms .....	G	.....	\$272.80	.....	\$33.28

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APC	Group title	Status indicator	Relative weight	Payment rate	National unadjusted coinsurance	Minimum unadjusted coinsurance
7005	Gonadorelin hydroch, 100 mcg .....	G		\$14.80		\$1.98
7007	Milrinone lactate, per 5 ml, inj .....	K	0.47	\$23.31		\$4.66
7010	Morphine sulfate (preservative free) 10 mg .....	G		\$7.41		\$ .99
7011	Oprelvekin injection, 5 mg .....	G		\$236.31		\$31.67
7014	Fentanyl citrate inj up 2 ml .....	G		\$0.98		\$0.13
7015	Busulfan, oral, 2 mg .....	G		\$1.73		\$0.23
7019	Aprotinin, 10,000 kiu .....	G		\$196.35		\$26.31
7022	Elliot's B solution, per ml .....	G		\$14.25		\$1.91
7023	Treatment for bladder calculi, per 500 ml .....	G		\$23.54		\$3.15
7024	Corticotrelin ovine triflutate, per 0.1 mg .....	G		\$353.88		\$45.77
7025	Digoxin immune FAB (Ovine), 40 mg vial .....	G		\$530.44		\$64.71
7026	Ethanolamine oleate, 100 mg .....	G		\$27.21		\$3.65
7027	Fomepizole, 1.5 mg .....	G		\$728.33		\$97.60
7028	Fosphenytoin, 50 mg .....	G		\$8.55		\$1.15
7029	Glatiramer acetate, 20 mg .....	G		\$27.40		\$3.67
7030	Hemin, 1 mg .....	G		\$0.90		\$0.12
7031	Octreotide acetate injection 1mg .....	G		\$115.34		\$15.46
7032	Sermorelin acetate, 0.5 mg .....	G		\$15.78		\$2.11
7033	Somatrem, 5 mg .....	G		\$199.50		\$26.73
7034	Somatropin, 1 mg (any derivation) .....	G		\$39.90		\$5.35
7035	Teniposide, 50 mg .....	G		\$195.28		\$26.17
7036	Urokinase, inj, IV, 250,000 I.U. ....	K	6.78	\$336.29		\$67.26
7037	Urofollitropin, 75 I.U. ....	G		\$69.73		\$9.34
7038	Muromonab-CD3, 5 mg .....	G		\$741.00		\$99.29
7039	Pegademase bovine inj 25 I.U. ....	G		\$139.33		\$18.67
7040	Pentastarch 10% inj, 100 ml .....	G		\$15.11		\$2.04
7041	Tirofiban hydrochloride 12.5 mg .....	G		\$399.00		\$53.47
7042	Capecitabine, oral, 150 mg .....	G		\$1.94		\$0.26
7043	Infliximab injection 10 mg .....	G		\$58.08		\$7.78
7045	Trimetrexate glucuronate 25 mg .....	G		\$69.83		\$9.36
7046	Doxorubicin hcl liposome inj 10 mg .....	G		\$311.72		\$41.77
7047	Droperidol/fentanyl inj .....	G		\$7.02		\$0.90
7048	Alteplase, 1 mg .....	K	0.38	\$18.70		\$3.74
7049	Filgrastim 480 mcg injection .....	G		\$273.03		\$35.06
7315	Sodium hyaluronate, 20 mg .....	G		\$125.59		\$16.83
8099	Spectranetics Lead Lock Dev .....	H				
8100	Adhesion barrier, ADCON-L .....	H				
8102	SurgiVision Esoph Coil .....	H				
9000	Na chromate Cr51, per 0.25mCi .....	G		\$259.36		\$34.75
9001	Linezolid inj, 200mg .....	J		\$34.14		\$4.57
9002	Tenecteplase, 50mg/vial .....	J		\$2,612.50		\$350.08
9003	Palivizumab, per 50mg .....	J		\$664.49		\$89.04
9004	Gemtuzumab ozogamicin inj,5mg .....	J		\$1,929.69		\$258.58
9005	Retepase inj, half-kit, 18.8 mg/vial .....	G		\$1,306.25		\$175.04
9006	Tacrolimus inj, per 5mg (1 amp) .....	J		\$109.83		\$14.72
9007	Baclofen Intrathecal kit-1amp .....	G		\$79.80		\$10.69
9008	Baclofen Refill Kit—500mcg .....	G		\$222.30		\$29.79
9009	Baclofen Refill Kit—2000mcg .....	G		\$467.40		\$62.63
9010	Baclofen Refill Kit—4000mcg .....	G		\$820.80		\$109.99
9011	Caffeine Citrate, inj, 1ml .....	G		\$12.22		\$1.57
9100	Iodinated I-131 Albumin .....	G		\$246.05		\$30.02
9102	51 Na chromate, 50mCi .....	G		\$216.60		\$26.43
9103	Na lothalamate I-125, 10uCi .....	G		\$12.27		\$1.50
9104	Anti-thymocyte globulin,25mg .....	G		\$251.75		\$33.73
9105	Hep B imm glob, per 1 ml .....	G		\$152.00		\$20.37
9106	Sirolimus 1mg/ml .....	J		\$6.51		\$.87
9107	Tinzaparin sodium, 2ml vial .....	J		\$159.60		\$20.50
9108	Thyrotropin Alfa,1.1 mg .....	G		\$494.00		\$70.72
9109	Tirofiban hydrochloride 6.25 mg .....	G		\$199.50		\$28.56
9217	Leuprolide acetate for depot suspension, 7.5 mg .....	G		\$592.60		\$79.40
9500	Platelets, irradi, ea unit .....	K	1.77	\$87.97		\$17.59
9501	Platelets, pheresis, ea unit .....	K	9.69	\$480.75		\$96.15
9502	Platelets, pher/irradi, ea unit .....	K	10.52	\$521.66		\$104.33
9503	Fresh frozen plasma, ea unit .....	K	1.65	\$81.83		\$16.37
9504	RBC, deglycerolized, ea unit .....	K	4.35	\$215.83		\$43.17

ADDENDUM A.—LIST OF HOSPITAL OUTPATIENT AMBULATORY PAYMENT CLASSIFICATIONS WITH STATUS INDICATORS, RELATIVE WEIGHTS, PAYMENT RATES, AND COINSURANCE AMOUNTS, CALENDAR YEAR 2001—Continued

APC	Group title	Status indicator	Relative weight	Payment rate	National unadjusted coinsurance	Minimum unadjusted coinsurance
9505	RBC, irradiated, ea unit .....	K	2.58	\$127.86	.....	\$25.57
9998	Enoxaparin .....	G	.....	\$5.53	.....	\$0.79

ADDENDUM B.—HOSPITAL OUTPATIENT DEPARTMENT (HOPD) PAYMENT STATUS BY HCPCS CODE AND RELATED INFORMATION

CPT/HCPCS	HOPD Status Indicator	Description	APC	Relative Weight	Payment Rate	National Unadjusted Coinsurance	Minimum Unadjusted Coinsurance
00100	N	Anesth, salivary gland .....	.....	.....	.....	.....	.....
00102	N	Anesth, repair of cleft lip .....	.....	.....	.....	.....	.....
00103	N	Anesth, blepharoplasty .....	.....	.....	.....	.....	.....
00104	N	Anesth, electroshock .....	.....	.....	.....	.....	.....
00120	N	Anesth, ear surgery .....	.....	.....	.....	.....	.....
00124	N	Anesth, ear exam .....	.....	.....	.....	.....	.....
00126	N	Anesth, tympanotomy .....	.....	.....	.....	.....	.....
00140	N	Anesth, procedures on eye .....	.....	.....	.....	.....	.....
00142	N	Anesth, lens surgery .....	.....	.....	.....	.....	.....
00144	N	Anesth, corneal transplant .....	.....	.....	.....	.....	.....
00145	N	Anesth, vitrectomy .....	.....	.....	.....	.....	.....
00147	N	Anesth, iridectomy .....	.....	.....	.....	.....	.....
00148	N	Anesth, eye exam .....	.....	.....	.....	.....	.....
00160	N	Anesth, nose/sinus surgery .....	.....	.....	.....	.....	.....
00162	N	Anesth, nose/sinus surgery .....	.....	.....	.....	.....	.....
00164	N	Anesth, biopsy of nose .....	.....	.....	.....	.....	.....
00170	N	Anesth, procedure on mouth .....	.....	.....	.....	.....	.....
00172	N	Anesth, cleft palate repair .....	.....	.....	.....	.....	.....
00174	N	Anesth, pharyngeal surgery .....	.....	.....	.....	.....	.....
00176	N	Anesth, pharyngeal surgery .....	.....	.....	.....	.....	.....
00190	N	Anesth, facial bone surgery .....	.....	.....	.....	.....	.....
00192	N	Anesth, facial bone surgery .....	.....	.....	.....	.....	.....
00210	N	Anesth, open head surgery .....	.....	.....	.....	.....	.....
00212	N	Anesth, skull drainage .....	.....	.....	.....	.....	.....
00214	N	Anesth, skull drainage .....	.....	.....	.....	.....	.....
00215	N	Anesth, skull fracture .....	.....	.....	.....	.....	.....
00216	N	Anesth, head vessel surgery .....	.....	.....	.....	.....	.....
00218	N	Anesth, special head surgery .....	.....	.....	.....	.....	.....
00220	N	Anesth, spinal fluid shunt .....	.....	.....	.....	.....	.....
00222	N	Anesth, head nerve surgery .....	.....	.....	.....	.....	.....
00300	N	Anesth, head/neck/trunk .....	.....	.....	.....	.....	.....
00320	N	Anesth, neck organ surgery .....	.....	.....	.....	.....	.....
00322	N	Anesth, biopsy of thyroid .....	.....	.....	.....	.....	.....
00350	N	Anesth, neck vessel surgery .....	.....	.....	.....	.....	.....
00352	N	Anesth, neck vessel surgery .....	.....	.....	.....	.....	.....
00400	N	Anesth, skin, ext/per/atruunk .....	.....	.....	.....	.....	.....
00402	N	Anesth, surgery of breast .....	.....	.....	.....	.....	.....
00404	N	Anesth, surgery of breast .....	.....	.....	.....	.....	.....
00406	N	Anesth, surgery of breast .....	.....	.....	.....	.....	.....
00410	N	Anesth, correct heart rhythm .....	.....	.....	.....	.....	.....
00420	N	Anesth, skin surgery, back .....	.....	.....	.....	.....	.....
00450	N	Anesth, surgery of shoulder .....	.....	.....	.....	.....	.....
00452	N	Anesth, surgery of shoulder .....	.....	.....	.....	.....	.....
00454	N	Anesth, collar bone biopsy .....	.....	.....	.....	.....	.....
00470	N	Anesth, removal of rib .....	.....	.....	.....	.....	.....
00472	N	Anesth, chest wall repair .....	.....	.....	.....	.....	.....
00474	N	Anesth, surgery of rib(s) .....	.....	.....	.....	.....	.....
00500	N	Anesth, esophageal surgery .....	.....	.....	.....	.....	.....
00520	N	Anesth, chest procedure .....	.....	.....	.....	.....	.....
00522	N	Anesth, chest lining biopsy .....	.....	.....	.....	.....	.....
00524	N	Anesth, chest drainage .....	.....	.....	.....	.....	.....
00528	N	Anesth, chest partition view .....	.....	.....	.....	.....	.....
00530	N	Anesth, pacemaker insertion .....	.....	.....	.....	.....	.....
00532	N	Anesth, vascular access .....	.....	.....	.....	.....	.....
00534	N	Anesth, cardioverter/defibr .....	.....	.....	.....	.....	.....
*00537	N	Anesth, cardiac electrophys .....	.....	.....	.....	.....	.....
00540	N	Anesth, chest surgery .....	.....	.....	.....	.....	.....
00542	N	Anesth, release of lung .....	.....	.....	.....	.....	.....
00544	N	Anesth, chest lining removal .....	.....	.....	.....	.....	.....
00546	N	Anesth, lung, chest wall surg .....	.....	.....	.....	.....	.....
00548	N	Anesth, trachea, bronchi surg .....	.....	.....	.....	.....	.....
*00550	N	Anesth, sternal debridement .....	.....	.....	.....	.....	.....
00560	N	Anesth, open heart surgery .....	.....	.....	.....	.....	.....
00562	N	Anesth, open heart surgery .....	.....	.....	.....	.....	.....

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ADDENDUM B.—HOSPITAL OUTPATIENT DEPARTMENT (HOPD) PAYMENT STATUS BY HCPCS CODE AND RELATED INFORMATION—  
Continued

CPT/ HCPCS	HOPD Status Indicator	Description	APC	Relative Weight	Payment Rate	National Unadjusted Coinsurance	Minimum Unadjusted Coinsurance
*00563	N	Anesth, openproc w/pump .....					
*00566	N	Anesth CABG w/o pump .....					
00580	N	Anesth heart/lung transplant .....					
00600	N	Anesth, spine, cord surgery .....					
00604	N	Anesth, surgery of vertebra .....					
00620	N	Anesth, spine, cord surgery .....					
00622	N	Anesth, removal of nerves .....					
00630	N	Anesth, spine, cord surgery .....					
00632	N	Anesth, removal of nerves .....					
00634	N	Anesth for chemonucleolysis .....					
*00635	N	Anesth, lumbar puncture .....					
00670	N	Anesth, spine, cord surgery .....					
00700	N	Anesth, abdominal wall surg .....					
00702	N	Anesth, for liver biopsy .....					
00730	N	Anesth, abdominal wall surg .....					
00740	N	Anesth, upper gi visualize .....					
00750	N	Anesth, repair of hernia .....					
00752	N	Anesth, repair of hernia .....					
00754	N	Anesth, repair of hernia .....					
00756	N	Anesth, repair of hernia .....					
00770	N	Anesth, blood vessel repair .....					
00790	N	Anesth, surg upper abdomen .....					
00792	N	Anesth, part liver removal .....					
00794	N	Anesth, pancreas removal .....					
00796	N	Anesth, for liver transplant .....					
00800	N	Anesth, abdominal wall surg .....					
00802	N	Anesth, fat layer removal .....					
00810	N	Anesth, low intestine scope .....					
00820	N	Anesth, abdominal wall surg .....					
00830	N	Anesth, repair of hernia .....					
00832	N	Anesth, repair of hernia .....					
00840	N	Anesth, surg lower abdomen .....					
00842	N	Anesth, amniocentesis .....					
00844	N	Anesth, pelvis surgery .....					
00846	N	Anesth, hysterectomy .....					
00848	N	Anesth, pelvic organ surg .....					
00850	N	Anesth, cesarean section .....					
00855	N	Anesth, hysterectomy .....					
00857	N	Analgesia, labor & c-section .....					
00860	N	Anesth, surgery of abdomen .....					
00862	N	Anesth, kidney/ureter surg .....					
00864	N	Anesth, removal of bladder .....					
00865	N	Anesth, removal of prostate .....					
00866	N	Anesth, removal of adrenal .....					
00868	N	Anesth, kidney transplant .....					
00870	N	Anesth, bladder stone surg .....					
00872	N	Anesth kidney stone destruct .....					
00873	N	Anesth kidney stone destruct .....					
00880	N	Anesth, abdomen vessel surg .....					
00882	N	Anesth, major vein ligation .....					
00884	N	Anesth, major vein revision .....					
00900D	N	Anesth, perineal procedure .....					
00902	N	Anesth, anorectal surgery .....					
00904	N	Anesth, perineal surgery .....					
00906	N	Anesth, removal of vulva .....					
00908	N	Anesth, removal of prostate .....					
00910	N	Anesth, bladder surgery .....					
00912	N	Anesth, bladder tumor surg .....					
00914	N	Anesth, removal of prostate .....					
00916	N	Anesth, bleeding control .....					
00918	N	Anesth, stone removal .....					
00920	N	Anesth, genitalia surgery .....					
00922	N	Anesth, sperm duct surgery .....					
27280	C	Fusion of sacroiliac joint .....					
27282	C	Fusion of pubic bones .....					
27284	C	Fusion of hip joint .....					
27286	C	Fusion of hip joint .....					
27290	C	Amputation of leg at hip .....					
27295	C	Amputation of leg at hip .....					
27299	T	Pelvis/hip joint surgery .....	0043	1.64	\$81.34	\$25.46	\$16.27
27301	T	Drain thigh/knee lesion .....	0008	6.15	\$305.02	\$113.67	\$61.00
27303	C	Drainage of bone lesion .....					
27305	T	Incise thigh tendon & fascia .....	0049	15.04	\$745.93	\$356.95	\$149.19
27306	T	Incision of thigh tendon .....	0049	15.04	\$745.93	\$356.95	\$149.19

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ADDENDUM B.—HOSPITAL OUTPATIENT DEPARTMENT (HOPD) PAYMENT STATUS BY HCPCS CODE AND RELATED INFORMATION—  
Continued

CPT/ HCPCS	HOPD Status Indicator	Description	APC	Relative Weight	Payment Rate	National Unadjusted Coinsurance	Minimum Unadjusted Coinsurance
27307	T	Incision of thigh tendons .....	0049	15.04	\$745.93	\$356.95	\$149.19
27310	T	Exploration of knee joint .....	0050	21.13	\$1,047.96	\$513.86	\$209.59
27315	T	Partial removal, thigh nerve .....	0220	13.96	\$692.36	\$326.21	\$138.47
27320	T	Partial removal, thigh nerve .....	0220	13.96	\$692.36	\$326.21	\$138.47
27323	T	Biopsy, thigh soft tissues .....	0021	10.49	\$520.26	\$236.51	\$104.05
27324	T	Biopsy, thigh soft tissues .....	0022	12.49	\$619.45	\$292.94	\$123.89
27327	T	Removal of thigh lesion .....	0022	12.49	\$619.45	\$292.94	\$123.89
27328	T	Removal of thigh lesion .....	0022	12.49	\$619.45	\$292.94	\$123.89
27329	T	Remove tumor, thigh/knee .....	0022	12.49	\$619.45	\$292.94	\$123.89
27330	T	Biopsy, knee joint lining .....	0050	21.13	\$1,047.96	\$513.86	\$209.59
27331	T	Explore/treat knee joint .....	0050	21.13	\$1,047.96	\$513.86	\$209.59
27332	T	Removal of knee cartilage .....	0050	21.13	\$1,047.96	\$513.86	\$209.59
27333	T	Removal of knee cartilage .....	0050	21.13	\$1,047.96	\$513.86	\$209.59
27334	T	Remove knee joint lining .....	0050	21.13	\$1,047.96	\$513.86	\$209.59
27335	T	Remove knee joint lining .....	0050	21.13	\$1,047.96	\$513.86	\$209.59
27340	T	Removal of kneecap bursa .....	0049	15.04	\$745.93	\$356.95	\$149.19
27345	T	Removal of knee cyst .....	0049	15.04	\$745.93	\$356.95	\$149.19
27347	T	Remove knee cyst .....	0049	15.04	\$745.93	\$356.95	\$149.19
27350	T	Removal of kneecap .....	0050	21.13	\$1,047.96	\$513.86	\$209.59
27355	T	Remove femur lesion .....	0050	21.13	\$1,047.96	\$513.86	\$209.59
27356	T	Remove femur lesion/graft .....	0050	21.13	\$1,047.96	\$513.86	\$209.59
27357	T	Remove femur lesion/graft .....	0050	21.13	\$1,047.96	\$513.86	\$209.59
27358	T	Remove femur lesion/fixation .....	0050	21.13	\$1,047.96	\$513.86	\$209.59
27360	T	Partial removal, leg bone(s) .....	0050	21.13	\$1,047.96	\$513.86	\$209.59
27365	C	Extensive leg surgery .....	.....	.....	.....	.....	.....
27370	N	Injection for knee x-ray .....	.....	.....	.....	.....	.....
27372	T	Removal of foreign body .....	0022	12.49	\$619.45	\$292.94	\$123.89
27380	T	Repair of kneecap tendon .....	0049	15.04	\$745.93	\$356.95	\$149.19
27381	T	Repair/graft kneecap tendon .....	0049	15.04	\$745.93	\$356.95	\$149.19
27385	T	Repair of thigh muscle .....	0049	15.04	\$745.93	\$356.95	\$149.19
27386	T	Repair/graft of thigh muscle .....	0049	15.04	\$745.93	\$356.95	\$149.19
27390	T	Incision of thigh tendon .....	0049	15.04	\$745.93	\$356.95	\$149.19
27391	T	Incision of thigh tendons .....	0049	15.04	\$745.93	\$356.95	\$149.19
27392	T	Incision of thigh tendons .....	0049	15.04	\$745.93	\$356.95	\$149.19
27393	T	Lengthening of thigh tendon .....	0050	21.13	\$1,047.96	\$513.86	\$209.59
27394	T	Lengthening of thigh tendons .....	0050	21.13	\$1,047.96	\$513.86	\$209.59
27395	T	Lengthening of thigh tendons .....	0051	27.76	\$1,376.79	\$675.24	\$275.36
27396	T	Transplant of thigh tendon .....	0050	21.13	\$1,047.96	\$513.86	\$209.59
27397	T	Transplants of thigh tendons .....	0051	27.76	\$1,376.79	\$675.24	\$275.36
27400	T	Revise thigh muscles/tendons .....	0051	27.76	\$1,376.79	\$675.24	\$275.36
27403	T	Repair of knee cartilage .....	0050	21.13	\$1,047.96	\$513.86	\$209.59
27405	T	Repair of knee ligament .....	0051	27.76	\$1,376.79	\$675.24	\$275.36
27407	T	Repair of knee ligament .....	0051	27.76	\$1,376.79	\$675.24	\$275.36
27409	T	Repair of knee ligaments .....	0051	27.76	\$1,376.79	\$675.24	\$275.36
27418	T	Repair degenerated kneecap .....	0051	27.76	\$1,376.79	\$675.24	\$275.36
27420	T	Revision of unstable kneecap .....	0051	27.76	\$1,376.79	\$675.24	\$275.36
27422	T	Revision of unstable kneecap .....	0051	27.76	\$1,376.79	\$675.24	\$275.36
27424	T	Revision/removal of kneecap .....	0051	27.76	\$1,376.79	\$675.24	\$275.36
27425	T	Lateral retinacular release .....	0050	21.13	\$1,047.96	\$513.86	\$209.59
27427	T	Reconstruction, knee .....	0052	36.16	\$1,793.39	\$930.91	\$358.68
27428	T	Reconstruction, knee .....	0052	36.16	\$1,793.39	\$930.91	\$358.68
27429	T	Reconstruction, knee .....	0052	36.16	\$1,793.39	\$930.91	\$358.68
27430	T	Revision of thigh muscles .....	0051	27.76	\$1,376.79	\$675.24	\$275.36
27435	T	Incision of knee joint .....	0051	27.76	\$1,376.79	\$675.24	\$275.36
27437	T	Revise kneecap .....	0047	22.09	\$1,095.58	\$537.03	\$219.12
27438	T	Revise kneecap with implant .....	0048	29.06	\$1,441.26	\$725.94	\$288.25
27440	T	Revision of knee joint .....	0047	22.09	\$1,095.58	\$537.03	\$219.12
27441	T	Revision of knee joint .....	0047	22.09	\$1,095.58	\$537.03	\$219.12
27442	T	Revision of knee joint .....	0047	22.09	\$1,095.58	\$537.03	\$219.12
27443	T	Revision of knee joint .....	0047	22.09	\$1,095.58	\$537.03	\$219.12
27445	C	Revision of knee joint .....	.....	.....	.....	.....	.....
27446	C	Revision of knee joint .....	.....	.....	.....	.....	.....
27447	C	Total knee replacement .....	.....	.....	.....	.....	.....
27448	C	Incision of thigh .....	.....	.....	.....	.....	.....
27450	C	Incision of thigh .....	.....	.....	.....	.....	.....
27454	C	Realignment of thigh bone .....	.....	.....	.....	.....	.....
27455	C	Realignment of knee .....	.....	.....	.....	.....	.....
27457	C	Realignment of knee .....	.....	.....	.....	.....	.....
27465	C	Shortening of thigh bone .....	.....	.....	.....	.....	.....
27466	C	Lengthening of thigh bone .....	.....	.....	.....	.....	.....
27468	C	Shorten/lengthen thighs .....	.....	.....	.....	.....	.....
27470	C	Repair of thigh .....	.....	.....	.....	.....	.....
27472	C	Repair/graft of thigh .....	.....	.....	.....	.....	.....
27475	C	Surgery to stop leg growth .....	.....	.....	.....	.....	.....

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