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

1. Statutory Basis

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

Section 1833(t)(6)(C)(i) of the Act sets the additional payment amounts for the drugs and biologicals as the amount

by which the amount determined under section 1842(o) of the Act (95 percent of the average wholesale price (AWP)) exceeds the portion of the otherwise applicable hospital outpatient department fee schedule amount that the Secretary determines to be associated with the drug or biological. Section 1833(t)(6)(C)(ii) provides that the additional payment for medical devices be the amount by which the hospital's charges for the device, adjusted to cost, exceed the portion of the otherwise applicable hospital outpatient department fee schedule amount determined by the Secretary to be associated with the device. Under section 1833(t)(6)(D), the total amount of pass-through payments for a given year cannot be projected to exceed an "applicable percentage" of total payments. For a year (or a portion of a year) before 2004, the applicable percentage is 2.5 percent; for 2004 and subsequent years, the applicable percentage is 2.0 percent. If the Secretary estimates that total pass-through payments would exceed the caps, the statute requires the Secretary to reduce the additional payments uniformly to ensure the ceiling is not exceeded.

Section 201(c) of the BBRA amended section 1833(t)(2)(E) of the Act to require that these pass-

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

Implementation of this pass-through provision requires us to--

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

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

2. Identifying Eligible Pass-Through Items

a. Drugs and Biologicals

Section 1833(t)(6)(A) of the Act establishes definitions and examples of the drugs and biologicals that are candidates for pass-through payments. As indicated above, these drugs and biologicals are characterized as both current and new. Current refers to those drugs and biologicals for which payment is made on the first date the hospital outpatient PPS is implemented, that is, on July 1, 2000. They include the following:

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

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

stimulating factors, biological response modifiers, bisphosphonates, and a device of brachytherapy.

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

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

b. Medical Devices

Under section 201(b) of the BBRA 1999, for purposes of making pass-through payments, a new or innovative medical device is one for which payment as a hospital outpatient service was not being made as of December 31, 1996 and for which the cost of the device "is not insignificant" in relation to the hospital outpatient department fee schedule amount payable for the service involved. For the purpose of identifying "new medical devices" that may be eligible for pass-through payments, we are excluding equipment, instruments, apparatuses, implements or items that are generally used for diagnostic or therapeutic purposes, that are not implanted or incorporated into a body part, and that are used on more than one patient (that is, are reusable). This material is generally considered to be hospital overhead costs and the depreciation expenses associated with them are reflected in the APC payments. The unit of payment for the outpatient PPS is a service or procedure. Equipment or instrumentation is a method or means of delivering that service. We are not establishing separate APC payments for equipment, instruments, apparatuses, implements, or items because payment for these types of devices is packaged in

the APC payment for the service or item with which they are used. However, as we discuss above in section III.C.8, we have created new technology APCs to accommodate new technology services that may be performed using equipment or instrumentation that is capitalized and depreciated and used on more than one patient. An example of a new technology service is CPT code 53850, Transurethral destruction of prostate tissue; by microwave thermotherapy. We have assigned this procedure to new technology APC 0980. (See section III.C.8 of this preamble for further discussion of payment for new technology under the hospital outpatient PPS.)

Section 201(e) of the BBRA 1999 amends section 1833(t)(1)(B) of the Act to include as "covered OPD services" implantable items described in paragraphs (3), (6), or (8) of section 1861(s) of the Act. Paragraph (3) refers to diagnostic tests including diagnostic x-rays, mammographies, laboratory tests, and other diagnostic tests. Paragraph (6) refers to implantable durable medical equipment (DME), and paragraph (8) refers to prosthetic devices that replace all or part of an internal body organ (including colostomy bags and supplies directly related to

colostomy care). Implantables are not mentioned specifically in these paragraphs, but we consider a prosthetic device that replaces all or part of an internal body organ that is mentioned in section 1861(s)(8) to be an implantable. The BBRA 1999 Conference Report lists pacemakers, defibrillators, cardiac sensors, venous grafts, drug pumps, stents, neurostimulators, and orthopedic implants, as well as items that come in contact with human tissue during invasive procedures as examples of implantable items.

Implantable items covered under section 201(e) of the BBRA 1999 may be considered eligible for the transitional pass-through payments allowed under section 201(b) of the BBRA 1999 to the extent that these implantables meet the statutory requirements set forth in section 201(b) and the criteria established in this final rule for payment of these devices.

Although we are recognizing the implantable items identified in section 201(e) of the BBRA 1999 for possible pass-through payments, we are not applying the pass-through provision to any DME, orthotics, and prosthetic devices that are not covered under section 201(e) of the BBRA 1999.

Rather, we will pay for these items under the DMEPOS fee schedule when the hospital is acting as a supplier.

3. Criteria to Define New or Innovative Medical Devices Eligible for Pass-through Payments

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

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

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

c. They are determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as required by section 1862(a)(1)(A) of the Act. We recognize that some investigational devices are refinements of existing technologies or replications of existing technologies and may be considered reasonable and necessary. We will consider devices for coverage under the outpatient PPS if they have received an FDA investigational device

exemption (IDE) and are classified by the FDA as Category B devices. (See §§405.203 to 405.215.) However, in accordance with §405.209, payment for a nonexperimental investigational device "is based on, and may not exceed, the amount that would have been paid for a currently used device serving the same medical purpose that has been approved or cleared for marketing by the FDA."

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

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

f. They are not equipment, instruments, apparatuses, implements, or such items for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the

Medicare Provider Reimbursement Manual (HCFA Pub. 15-1). (As indicated above, these costs are considered overhead expenses that have been factored into the APC payment.)

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

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

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

Response: We will use the same criteria established in the June 16, 1999 final rule (64 FR 32198) titled "Medicare Program; Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers" to identify IOLs that may be considered new technology and eligible for pass-through payments. In accordance with that rule, IOLs must first be approved by the FDA before they can be considered as a new technology IOL. The rule establishes only one criterion for distinguishing new technology IOLs from other IOLs. Specifically, all claims of the IOL’s

clinical advantages and superiority over existing IOLs must have been approved by the FDA for labeling and advertising purposes. For further discussion on the reasons for relying on the FDA's determination, we refer the reader to the IOL proposed rule published on September 4, 1997 (62 FR 46700 through 46701). We recognize that this criterion has been developed to define the characteristics that distinguish a new technology IOL from other IOLs in order to comply with section 141(b) of the Social Security Act Amendments of 1994 (Pub. L. 103-432) that is specific to IOLs furnished in ASCs and not hospital outpatient departments. However, we believe that it is appropriate to rely on an established approach to assist us in distinguishing this new technology since more than 1 million IOLs are inserted annually during or subsequent to cataract surgery performed in the outpatient setting. Moreover, we believe that consistent application of the criterion in both the ASC and hospital outpatient prospective payment systems is less burdensome to those requesting recognition of new technology IOLs. Therefore, when IOLs that are recognized as "new technology IOLs" in accordance with the provisions of the June 16, 1999 final rule are furnished in a hospital outpatient setting,

we will pay for such new technology IOLs in accordance with the hospital outpatient PPS method for determining additional payments under the pass-through provision set forth in this final rule.

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

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

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

Section 1833(t)(6)(A)(iv)(II) of the Act, as added by section 201(b) of the BBRA 1999 provides that the transitional pass-throughs apply to new drugs, biologicals, and devices whose cost is not insignificant in relation to the hospital outpatient PPS payment amount. Section 1833(t)(6)(C) defines the additional payment as the difference between an amount specified by the law and the portion of the applicable fee schedule amount determined to be associated with the item. The objective of this section

is to prevent the hospital outpatient PPS from creating disincentives for the diffusion of valuable new technology by initially paying a rate significantly below the costs of these items. We believe that the "not insignificant" criterion was included in recognition that: (1) the costs of some new technologies would not be large enough relative to the fee schedule amount to provide disincentives for their use in the short run; and (2) that an excessive number of pass-through items could place a substantial burden on the claims processing systems of both HCFA and individual hospitals in a way that could hamper the rapid processing of pass-through payments for those items that would be significantly more costly than the applicable fee schedule amount. Therefore, in order to be consistent with the objectives of this section, we are establishing the following criteria for determining whether the costs of drugs, biologicals, and devices are "not insignificant" relative to the hospital outpatient department fee schedule amount:

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

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

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

The following illustrates the application of these three criteria.

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

1. (a) Multiply the fee schedule amount for APC 0001 by 25 percent

$100.00 X .25 = $25.00

(b) Compare the reasonable cost for ZZ to the product derived in Step 1

$32.00 > $25.00

Finding: The first criterion is met.

2. (a) Multiply the portion of the fee schedule amount for APC 0001 that is associated with a device by 25 percent

$25.00 X .25 = $6.25

(b) Subtract the portion of the fee schedule amount for APC 0001 attributable to a device from the reasonable cost for ZZ

$32.00 - $25.00 = $7.00

(c) Compare the remainder in Step 4 to the product in Step 2(a)

$7.00 > $6.25

Finding: The second criterion is met.

3. (a) Multiply the fee schedule amount for APC 0001 by 10 percent

$100.00 X .10 = $10.00

(b) Compare the remainder in Step 3 to the product derived in Step 3(a)

$7.00 < $10.00

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

5. Calculating the Additional Payment

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

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

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

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

determine if a revenue center-specific set of cost-to-charge ratios should be used for 2002 and beyond.

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

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

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

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

We have identified a large number of items subject to the transitional pass-through payment through our own data-gathering activities or through comments on the proposed

rule. Many of them already have HCPCS codes, and we are taking steps to establish temporary codes for the remaining items. We will make additional payments for these items when the hospital outpatient PPS system is implemented on July 1. A list of the items already known to us is set forth in Addendum K.

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

A manufacturer or other interested party who wishes to bring items that may be eligible for additional transitional pass-through payments to our attention should mail requests

for consideration of items to the following address ONLY: PPS New Tech/Pass-Throughs, Division of Practitioner and Ambulatory Care, Mailstop C4-03-06, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244-1850.

To be considered, requests **MUST** include the following information:

- Trade/brand name of item.
- A detailed description of the clinical application of the item, including HCPCS code(s) to identify the procedure(s) with which the item is used. If the item replaces or improves upon an existing item, identify the predecessor item by trade/brand name and HCPCS code.
- Current cost of the item to hospitals (i.e., actual cost paid by hospitals net of all discounts, rebates, and incentives in cash or in-kind). In other words, submit the best and latest information available that provides evidence of the hospital's actual cost for a specific item.
- Date of sale of first unit.
- For drugs, submit the most recent average wholesale price (AWP) of the drug and the date associated with the AWP quote.

- If the item requires FDA approval/clearance, submit information that confirms receipt of FDA approval/clearance and the date obtained.
- If the item already has an assigned HCPCS code, include the code and its descriptor in your submission plus a dated copy of the HCPCS code "recommendation application" previously submitted for this item.
- If the item does not have an assigned HCPCS code, follow the procedure discussed, below, for obtaining HCPCS codes and submit a copy of the application with your payment request.
- Name, address, and telephone number of the party making the request.
- Other information as HCFA may require to evaluate specific requests.

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

Considering the exigencies of implementing a new system, we intend to establish temporary codes in 2000 to

permit implementation of additional payments for other eligible items effective beginning October 1, 2000. The process for submitting information will be the same as for national codes.

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

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

As indicated in the instructions posted at our website address cited above, the deadline for submission of applications for a national HCPCS code for the CY 2001 cycle is April 1, 2000. The HCPCS process will proceed to assign national codes as warranted, and we expect these codes will be used in the hospital outpatient PPS starting January 1, 2001. Because the coding application will

contain information vital to determining a specific item or product’s eligibility for pass-through payments, we are requesting that a copy of the application be sent concurrently to ATTN: PPS New Tech/Pass-Throughs at the address shown above.

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

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

How quickly additional payment for a new item can be implemented will depend on processing and systems constraints; it will in general require at least 6 months

and may require as many as 9 or more months. Thus, a submission that we receive in May (which is too late for October implementation) might be assigned a temporary code to be used for implementing additional payments starting the following January.

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

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

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

possible within the constraints imposed by our system requirements.