

provided by a facility to a patient with CHF, chest pain, or asthma, minimum eight hours, maximum forty-eight hours) that also showed one or more of the ICD-9 (International Classification of Diseases, Ninth Edition) diagnosis codes required for payment of APC 339. We ignored other separately payable codes so that the claims with G0244 would not be excluded for having multiple major procedures on a single claim. We packaged the costs of allowable revenue centers and HCPCS codes with status indicator "N" into the cost of G0244, and trimmed as was done for the calculation of the median costs for other APCs.

To calculate the weights for APCs 649 (Prostate Brachytherapy with Palladium seeds) and 684 (Prostate Brachytherapy with Iodine seeds) into which the cost of brachytherapy seeds are packaged, we selected claims that contained HCPCS codes 77778 and 55859 where the lines containing codes 77778 and 55859 have the same date of service and the claim contained either HCPCS code C1720 (Palladium seeds) or C1718 (Iodine seeds) (which need not be the same date of service as 77778 and 55859). We ignored line items for services paid on the laboratory fee schedule and lines with separately payable HCPCS (even if multiple majors). We packaged all remaining costs from allowable revenue centers and packaged HCPCS into the claim (regardless of date of service). We separated the claims with Palladium seeds from claims with Iodine seeds. We then created a median cost for prostate brachytherapy with Palladium seeds (APC 0649; G0256) from the claims containing 77778, 55859, and C1720 (Palladium seeds), and we created a median cost for prostate brachytherapy with Iodine seeds (APC 0684; G0261) from claims containing 77778, 55859, and C1718 (Iodine seeds).

- Using the median APC costs, we calculated the relative payment weights for each APC. As in prior years, we scaled all the relative payment weights to APC 0601, Mid-level clinic visit, because it is one of the most frequently performed services in the hospital outpatient setting. We assigned APC 0601 a relative payment weight of 1.00 and divided the median cost for each APC by the median cost for APC 0601 to derive the relative payment weight for each APC. Using 2002 data, the median cost for APC 0601 is \$58.78.

Section 1833(t)(9)(B) of the Act requires that APC revisions, relative payment weight revisions, and wage index and other adjustments be made in a manner that ensures that estimated aggregate payments under the OPPTS for 2004 are neither greater than nor less

than the estimated aggregate payments that would have been made without the changes. To comply with this requirement concerning the APC changes, we compared aggregate payments using the CY 2003 relative weights to aggregate payments using the CY 2004 proposed weights. Based on this comparison, we are proposing to make an adjustment of 1.003107132 to the weights. The weights that we are proposing for CY 2004, which incorporate the recalibration adjustments explained in this section, are listed in Addendum A and Addendum B.

IV. Transitional Pass-Through and Related Payment Issues

A. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or "transitional pass-through payments" for certain medical devices, drugs, and biological agents. As originally enacted by the BBRA, this provision required the Secretary to make additional payments to hospitals for current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act, Public Law 107-186; current drugs, biological agents, and brachytherapy devices used for the treatment of cancer; and current drugs and biological products.

For those drugs, biological agents, and devices referred to as "current," the transitional pass-through payment began on the first date the hospital OPPTS was implemented (before enactment of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA), Public Law 106-554, enacted December 21, 2000).

Transitional pass-through payments are also required for certain "new" medical devices, drugs, and biological agents that were not being paid for as a hospital outpatient service as of December 31, 1996 and whose cost is "not insignificant" in relation to the OPPTS payment for the procedures or services associated with the new device, drug, or biological. Under the statute, transitional pass-through payments can be made for at least 2 years but not more than 3 years.

Section 1833(t)(6)(B)(i) of the Act required that we establish by April 1, 2001, initial categories to be used for purposes of determining which medical devices are eligible for transitional pass-through payments. Section 1833(t)(6)(B)(i)(II) of the Act explicitly authorized us to establish initial categories by program memorandum (PM). On March 22, 2001, we issued two PMs, Transmittals A-01-40 and A-01-

41 that established the initial categories. We posted them on our Web site at: <http://www.hcfa.gov/pubforms/transmit/A0140.pdf> and <http://www.hcfa.gov/pubforms/transmit/A0141.pdf>, respectively.

Transmittal A-01-41 includes a list of the initial device categories, a crosswalk of all the item-specific codes for individual devices that were approved for transitional pass-through payments, and the initial category code by which the cross-walked individual device was to be billed beginning April 1, 2001. Items eligible for transitional pass-through payments are generally coded using a Level II HCPCS code with an alpha prefix of "C." Pass-through device categories are identified by status indicator "H" and pass-through drugs and biological agents are identified by status indicator "G." Subsequently, we added a number of additional categories, retired 95 categories effective January 1, 2003, and made clarifications to some of the categories' long descriptors found in various program transmittals. A list of device category codes in effect as of July 1, 2003, can be found in Transmittal A-03-051, which was issued on June 13, 2003. This PM can be accessed on our Web site at <http://www.cms.gov>.

Section 1833(t)(6)(B)(ii) of the Act also requires us to establish, through rulemaking, criteria that will be used to create additional device categories. The criteria for new categories were the subject of a separate interim final rule with comment period published in the **Federal Register** on November 2, 2001 (66 FR 55850) and made final in the November 1, 2002 **Federal Register** (67 FR 66781) announcing the 2003 update to the OPPTS.

Transitional pass-through categories are for devices only; they do not apply to drugs or biological agents. The regulations at § 419.64 governing transitional pass-through payments for eligible drugs and biological agents are unaffected by the creation of categories.

The process to apply for transitional pass-through payment for eligible drugs and biological agents or for additional device categories can be found on respective pages on our Web site at <http://www.cms.gov>. If we revise the application instructions in any way, we will post the revisions on our Web site and submit the changes for approval by the Office of Management and Budget (OMB) as required under the Paperwork Reduction Act (PRA). Notification of new drug, biological, or device category application processes is generally posted on the OPPTS Web site at <http://www.cms.gov>.