

radiation therapy (CPT codes 77520 and 77522) should be placed in a different APC than codes for intermediary (CPT code 77523) and complex (CPT code 77525) radiation therapy. As we stated in the correction notice of February 10, 2003 (68 FR 6636), we also agree with commenters that it would be inappropriate to return codes for simple proton beam therapy to a new technology APC due to having sufficient claims data to integrate these codes into the OPPS. We continue to believe that the placement of these codes in APC 0664 is appropriate based on having used 98 percent of total claims for simple proton beam therapy to set the 2004 median for APC 0664. Therefore, CPT codes 77520 and 77522 will remain in APC 0664.

The placement of intermediate (CPT code 77523) and complex (CPT code 77525) proton beam therapies in APC 650 in the November 1, 2002 final rule (67 FR 66718) for the 2003 OPPS was an error that was corrected in the correction notice of February 10, 2003 (68 FR 6636). We clarified in the correction notice that these CPT codes were placed in new technology APC 0712 for CY 2003 because they lacked sufficient cost data to confidently move these codes out of a new technology APC. We continue to lack sufficient cost data to move these codes into a clinical APC; therefore, we will crosswalk CPT codes 77523 and 77525 from new technology APC 0712 to the corresponding new technology APC 1511 for CY 2004. Once sufficient data is available, we will be able to determine whether intermediate and complex proton beam therapies should be placed in the same APC.

FDG PET Procedures

Comment: Several commenters commended us for our proposed rates for FDG PET procedures. They were pleased that the proposed 2004 rates for the FDG PET procedure and the radiopharmaceutical when combined are nearly identical to the rates for the combined procedure and radiopharmaceutical for 2003. Commenters stated that the retention of FDG PET procedures in a new technology APC will allow providers an additional year to improve their reporting practices, while providing us with another year of more accurate claims data.

Response: We agree with commenters that the retention of FDG PET procedures in a new technology APC for an additional year will allow providers a reasonable amount of time to improve their reporting practices, while providing us with another year of claims

experience. Therefore, we will retain FDG PET procedures in new technology APC 1516.

Comment: One commenter expressed concern that HCPCS code G0296 did not appear in Addendum B of the August 12, 2003 proposed rule. The commenter urged us to place this new code in APC 1516 with other FDG PET procedures.

Response: We thank the commenter for bringing to our attention the absence of HCPCS code G0296 from addendum B of the proposed rule. We agree with the commenter's recommendation to place this code in the same APC as other FDG PET procedures. Therefore, we will place HCPCS code G0296 in new technology APC 1516.

Comment: One commenter recommended the establishment of a revenue code dedicated solely to PET procedures.

Response: Revenue codes exist for hospital accounting purposes and, in general we do not require that particular services be billed with particular revenue codes. We are not convinced that adding specific requirements for revenue coding or expanding the revenue codes to acquire more specific information will result in better data or that the end result would be cost effective in terms of its potential effect on hospital operations.

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, Pub. L. 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 OPPS was implemented (before enactment of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA), Pub. L. 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 OPPS 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 current device category codes can be found below, in Table 10.

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 for transitional pass-through payment. 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 OPPS.

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.