

are the dates the devices described by the category were populated and their respective expiration dates. For devices continuing on pass-through status after 2003, expiration dates were set forth in the August 12, proposed rule and are finalized here. Newly added code C1819

is first announced in this final rule and is given a December 31, 2005 expiration date.

The methodology used to base expiration of a device category is the same as that used to determine the 95 initial categories that expired as of

January 1, 2003. A list including those 95 categories that expired as of January 1, 2003 (as well as 5 categories that continued to be paid in 2003) is found in the November 1, 2002 final rule (67 FR 66761 through 66763).

TABLE 10.—LIST OF CURRENT PASS—THROUGH DEVICE CATEGORIES WITH EXPIRATION DATES

HCPSC codes	Category long descriptor	Date(s) populated	Expiration date
C1765	Adhesion Barrier	10/1/00–3/31/01; 7/1/01.	12/31/03
C2618	Probe, cryoblation	4/1/01	12/31/03
C1888	Catheter, ablation, non-cardiac, endovascular (implantable)	7/1/02	12/31/04
C1900	Lead, left ventricular coronary venous system	7/1/02	12/31/04
C1783	Ocular implant, aqueous drainage assist device	7/1/02	12/31/04
C1884	Embolization protective system	1/1/03	12/31/04
C2614	Probe, percutaneous lumbar discectomy	1/1/03	12/31/04
C2632	Brachytherapy solution, iodine-125, per mCi	1/1/03	12/31/04
C1814	Retinal tamponade device, silicone oil	4/1/03	12/31/05
C1818	Integrated keratoprosthesis	7/1/03	12/31/05
C1819	Tissue localization excision device	1/1/04	12/31/05

We received several comments on this proposal, which are summarized below along with our responses.

Comment: A few parties provided comments on our criteria for eligibility for a new device category for pass-through payment as published in the November 1, 2002 **Federal Register** (67 FR 66781).

Response: We made no proposal to modify our criteria for establishment of a new category for transitional pass-through payment, so the criteria were not subject to comment in this rulemaking period. However, we will take note of these comments as considerations in our ongoing evaluation of the new device category process.

New Technology Treatment for New Devices for Brachytherapy Catheters and Needles

Comment: A commenter asked that we consider pass-through payment or new technology payment for new devices of brachytherapy catheters and needles when they are approved by FDA for new indications and treatment protocols.

Response: We have a process for applying for pass-through new technology APC status. See <http://www.cms.hhs.gov> for instructions. If a provider or other party believes that an item or service meets the criteria for pass-through or new technology status, the interested party should submit an application, and we will then make a judgement based on the individual circumstances described in the application.

B. Expiration of Transitional Pass-Through Payments in CY 2004

In the November 1, 2002 final rule, we established a policy for payment of devices included in pass-through categories that are due to expire (67 FR 66763). We stated that we would package the costs of the devices no longer eligible for pass-through payments in 2003 into the costs of the clinical APCs with which the devices were billed in 2001. There were very few exceptions to the policy (for example, brachytherapy sources for other than prostate brachytherapy), and we proposed to make no changes. Therefore, we proposed that payment for the devices that populate C1765 and C2618, which we proposed would cease to be eligible for pass-through payment on January 1, 2004, would be made as part of the payment for the APCs with which they are billed.

The methodology that we proposed to use to package expiring pass-through device costs is consistent with the packaging methodology that we describe in section II.B.5. For the codes in APCs displayed in Table 10 of the proposed rule, we proposed to use only those claims on which the hospital included the “C” code and to discard the claims on which no “C” code is billed. We proposed to limit our analysis to the claims with “C” codes because we are not confident that the claims for the relevant APCs include the charges for the devices unless the “C” codes are specifically billed.

To calculate the total cost for a service on a per-service basis, we included all charges billed with the service in a revenue center in addition to packaged

HCPSC codes with status indicator “N.” We also packaged the costs of devices that we proposed would no longer be eligible for pass-through payment in 2004 into the HCPSC codes with which the devices were billed.

We received several comments on this proposal, which are summarized below along with our responses.

Comment: A commenter supported packaging the cost of expiring pass-through codes C2618 and CC1765 into the payment for the procedure in which they are used because they believe that packaging minimizes payment incentive to use these devices over other appropriate devices. The commenter urged CMS to release the crosswalk it will use to assign pass-through device costs to specific APCs so that they can confirm the appropriateness of the assignment.

Response: There is no such crosswalk. Devices and packaged drugs (that is, those with a per day median cost of \$50 or less) are packaged into the HCPSC code on the single procedure claim (natural single or pseudo single) with which they are billed. The packaging is controlled solely by what the hospital bills on the claim. To determine what drugs and devices were packaged into an APC, one would need to undertake an extensive analysis of all single and pseudo single claims used in weight setting. The only time that judgment was used to attribute a device to an APC was not for purposes of packaging charges into APCs but rather was in the setting of median costs for 5 APCs in which external data on acquisition costs was used in a one to one proportion