

TABLE 9.—ESTIMATE OF PASS-THROUGH SPENDING IN 2004—Continued

HCPC	APC	Drug biological	2004 pass-through payment portion	2004 estimated utilization	2004 anticipated pass-through payments
C1900	1900	Lead, left ventricular coronary venous system		2,095	2,819,912
C2614	2614	Probe, percutaneous lumbar discectomy		901	1,752,445
C2632	2632	Brachytherapy solution, iodine—125, per mCi		225	1,890,000
C1818	1818	Integrated keratoprosthesis		4	27,800
Pass-through Devices Effective January 2004					
C1819	1819	Tissue localization-excision dev		9,858	1,823,730
Other Items Expected To Be Determined Eligible for 2004					
Spending for future approved drugs					22,466,959
Spending for future approved devices					12,791,197
Total Spending for Pass-through Drugs/biologicals, and devices 2004.					302,784,216

Comment: Several commenters objected to the methods used to project pass-through drug spending, especially those techniques used to estimate future products that are first eligible for pass-through payments beginning in April 2004 or later in the year. They are concerned that pass-through expenditures in 2004 will exceed the statutory cap and cause us to impose a pro rata reduction. Several hospital associations propose that we limit the funds allocated for the pass-through pool to one percent and use the remaining 1.0 percent to fund all other APCs. They suggest that we over-estimate pass-through spending, which results in the reduction of payment rates for other critical care services.

Response: Section 1833(t)(6)(E)(i) of the Act requires that the Secretary estimate the total pass-through payments to be made for the forthcoming year (which allows us to determine the amount of the conversion factor for the forthcoming year) and to the extent the estimate exceeds the statutory limit, reduce the amount of each pass-through payment. For 2004, the statutory limit is 2.0 percent of total estimated program payments. In the August 12, 2003 proposed rule, we provided our best estimate at that time of pass-through payments for the drugs and devices for which we expected to make pass-through payments in 2004, and we explained our methodology for determining the estimate for the final rule. We provided a list of the devices and drugs we either knew would be paid under pass-through next year or which we believed may be paid as pass-through items in 2004.

We finalized our estimate of 2004 pass-through spending and, for the reasons discussed below, we have determined that no pro rata reduction will be required in 2004. As discussed below the estimate falls under the statutory limit of 2.0 percent. Therefore,

the conversion factor has been increased correspondingly from the proposed rule by 0.7 percent.

Pass-Through Devices Effective January 2004

Comment: One commenter recommended that we not impose a pro rata reduction on pass-through devices if the estimated pass-through expenditures increase appreciably. A device manufacturers' association was concerned that new drugs will take an increasing share of the pass-through pool. They suggested that the shift to more pass-through spending on drugs will increase under the easier qualifications for drug pass-through payments and encouraged us to reconsider the issue to determine how to ensure that devices maintain an "adequate" share of the pass-through pool.

Response: Section 1833(t)(6)(E)(iii) of the Act requires a prospective uniform reduction (pro rata) of the amount of each of the transitional pass-through payments made in that year, if it is expected that pass-through payments will exceed the cap set for OPPS pass-through expenditures. Therefore, if any pro rata reduction applies, we are required to apply it to pass-through devices as well as drugs and biological agents. For 2004, we do not expect the total payments for pass-through drugs and devices to exceed the statutory limit. Therefore, as discussed elsewhere, we will not impose a pro rata adjustment on any pass-through items in 2004.

V. Payment for Devices

A. Pass-Through Devices

Section 1833(t)(6)(B)(iii) of the Act requires that a category of devices be eligible for transitional pass-through payments for at least 2, but not more than 3, years. This period begins with the first date on which a transitional

pass-through payment is made for any medical device that is described by the category. We proposed that two device categories currently in effect would expire effective January 1, 2004. Our proposed payment methodology for devices that have been paid by means of pass-through categories, and for which pass-through status would expire effective January 1, 2004, is discussed in the section below.

Although the device category codes became effective April 1, 2001, most of the item-specific "C" codes for pass-through devices that were crosswalked to the new category codes were approved for pass-through payment in CY 2000 and as of January 1, 2001. (The crosswalk for item-specific "C" codes to category codes was issued in Transmittals A-01-41 and A-01-97). We based the expiration dates for the category codes listed in Table 10, on when a category was first created, or when the item-specific devices that are described by, and included in, the initial categories were first paid as pass-through devices, before the implementation of device categories. The device category expiration dates are listed in Table 10. We proposed to base the expiration date for a device category on the earliest effective date of pass-through payment status of the devices that populate that category. There are two categories for devices that will have been eligible for pass-through payments for more than 2½ years as of December 31, 2003, and we proposed that they would not be eligible for pass-through payments effective January 1, 2004. The two categories we proposed for expiration are C1765 and C2618, as indicated in Table 10. Each category includes devices for which pass-through payment was first made under OPPS in 2000 or 2001.

A comprehensive list of all currently effective pass-through device categories is displayed in Table 10. Also displayed