

B. Discussion of Pro Rata Reduction

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for a given year to an "applicable percentage" of projected total Medicare and beneficiary payments under the hospital OPPS. For a year before 2004, the applicable percentage is 2.5 percent; for 2004 and subsequent years, we specify the applicable percentage up to 2.0 percent. We propose to set the percentage at 2.0 percent for the 2004 OPPS.

If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a prospective uniform reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We make an estimate of pass-through spending to determine not only whether payment exceeds the applicable percentage but also to determine the appropriate reduction to the conversion factor.

For devices, making an estimate of pass-through spending in 2004 entails estimating spending for two groups of items. The first group consists of those items for which we have claims data (that is, items that were eligible in 2002 and that will continue to be eligible in 2004). The second group consists of those items for which we have no direct claims data (that is, items that became, or will become, eligible in 2003 and will retain pass-through status and items that will be newly eligible beginning in 2004).

To estimate 2004 pass-through spending for device categories in the first group, we would use volume and hospital cost (derived from charges on claims using cost-to-charge ratios) information from 2002 claims data. This information would be projected forward to 2004 levels using appropriate inflation and utilization factors. For existing categories with no claims data in 2002 that are, or will be, active in 2004, we would follow the method described in the November 2, 2001 final rule (66 FR 55857). We would use price information from manufacturers and

volume estimates from claims related to procedures that use the devices in question. This information would be projected forward to 2004 using appropriate inflation and utilization factors to estimate 2004 pass-through spending for this group of categories. For categories that become eligible in 2004, we would use the same method as described for categories that were newly active in 2002. We anticipate that any new categories for January 1, 2004 will be announced after the publication of this proposed rule but before the publication of the final rule. Therefore, the estimate of pass-through spending would incorporate pass-through spending for categories made effective January 1, 2004.

To estimate 2004 pass-through spending for drugs and biological agents, we would make estimates of utilization, collect data on average wholesale price (AWP) and combine these with ratios used to represent hospital acquisition costs for these drugs. We would collect drug-specific information on Medicare use from the pharmaceutical manufacturer where possible and rely on other sources (such as peer-reviewed clinical studies) as needed. In the past, we relied upon the AWP published in the Redbook to establish the AWP of pass-through drugs payable under the OPPS. As described elsewhere in this preamble, we plan to adopt and apply the provisions outlined in the Payment Reform for Part B drugs. For the purpose of calculating payments for transitional pass-through items, we would determine 95 percent of the drug's average wholesale price based on the newly established AWP. We would use published ratios on hospital acquisition costs reported in our proposed rule of August 9, 2002 (67 FR 52129). For sole source drugs the ratio of acquisition cost to AWP equals 0.71; for multi-source drugs, the ratio is 0.68; and for multi-source drugs with generic competitors, the ratio equals 0.46.

For drugs and biological agents that may receive pass-through status effective January 1, 2004, we propose to use the same methodology as described for drugs and biological agents that received pass-through status in 2003. Any new pass-through drugs and

biological agents effective beginning in 2004 would be announced after the publication of this proposed rule but before the publication of the final rule. Therefore, the estimate of pass-through spending would incorporate pass-through spending for these drugs and biological agents made effective January 1, 2004.

After using the methodologies described above to determine projected 2004 pass-through spending for the groups of devices, drugs, and biological agents, we would calculate total projected 2004 pass-through spending as a percentage of the total projected payments (Medicare and beneficiary payments) under OPPS to determine if the pro rata reduction will be required.

Table 12 shows our current estimate of 2004 pass-through spending for known pass-through drugs, biologicals, and devices based on information available at the time this table was developed. We are uncertain whether estimated pass-through spending in 2004 will exceed \$456 million (2.0 percent of total estimated OPPS spending). We have not yet completed the estimate of pass-through spending for a number of drugs and devices. In particular, we do not have estimates for those drugs still under agency review for additional pass-through payments beginning October 2003 or the changes in pass-through spending that could result from quarterly rather than annual updates of AWP for pass-through drugs. Finally, we would incorporate an estimate of pass-through spending for items for which pass-through payment becomes effective later in 2004 (that is, April 1, 2004; July 1, 2004; and October 1, 2004) based on estimates of items that become eligible for pass-through payment on October 1, 2003 and January 1, 2004. Specifically, we would assume a proportionate amount of spending for items that become eligible later in the year while making an adjustment to account for the fact that items made eligible later in the year will not receive pass-through payments for the entire year. We invite comments on the methodology as described above and the estimates for utilization that appear in the table below.

TABLE 12.—ESTIMATES FOR 2004 TRANSITIONAL PASS-THROUGH SPENDING

New HCPC	APC	Drug biological	2004 pass-through payment portion	2004 estimated utilization	2004 anticipated pass-through payments
Existing Pass-through Drugs/Biologicals					
C9111	9111	Injection Bivalrudin, 250 mg per vial	\$100.50	21,007	2,111,200
C9112	9112	Perflutren lipid microsphere, per 2 ml	\$37.44	67,000	2,508,480