

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 OPPS Web site at <http://www.cms.gov>.

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 proposed 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.

In the August 12, 2003 proposed rule, we described in the detail the methodology we used to make an estimate of pass-through spending in 2004 (68 FR 47992). In general, we specified that after using the respective methodologies described in the proposed rule, 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 would be required.

Table 9 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 specified in the proposed rule that we were uncertain whether estimated pass-through spending in 2004 would exceed

\$456 million (2.0 percent of total estimated OPPS spending) because we had not yet completed the estimate of pass-through spending for a number of drugs and devices. In particular, we did 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 invited comments on the methodology we proposed and the estimates for utilization that appeared in Table 12 of the August 12, 2003 proposed rule. We received several comments on this proposal, which are summarized below along with our responses.

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

HCPC	APC	Drug biological	2004 pass-through payment portion	2004 estimated utilization	2004 anticipated pass-through payments
Existing Pass-through Drugs/biologicals					
J0583	9111	Injectin Bivalrudin, per 1 mg	\$0.40	\$5,278,000	\$2,111,200
C9112	9112	Injection, Perflutren lipid microsphere, per 2 ml	37.44	67,000	2,508,480
C9113	9113	Injection, Pantoprazole sodium, per vial	6.34	20,000	126,800
J1335	9116	Injection, Ertapenum sodium, per 500 mg	6.00	14,400	86,400
J2505	9119	Injection, Pegfilgrastim, per 6 mg single dose vial	708.00	110,344	78,123,329
J9395	9120	Injection, Flukevstrant, per 25 mg	22.13	274,156	6,067,072
C9121	9121	Injection, Argatroban, per 5 mg	4.13	50,000	206,500
C9200	9200	Orcel, per 36 cm2	286.80	1,000	286,800
C9123	9123	Transcyte, per 247 sq cm	194.76	100	19,476
C9203	9203	Injection Perflexane lipid microspheres, per 10 ml vial	36.00	82,400	2,966,400
J2324	9114	Injection, Nesiritide, per 0.5 mg vial	38.30	60,000	2,298,000
J3315	9122	Injection, Triptorelin pamoate, per 3.75 mg	100.70	307,440	30,959,208
J3487	9115	Injection, Zoledronic acid, per 1 mg	54.93	539,000	29,607,270
J3486	9204	Injectionm Ziprasidone mesylate, per 10 mg	5.25	234,286	1,230,000
C9205	9205	Injection, Oxaliplatin, per 5 mg	23.86	280,756	6,698,845
C9208	9208	Injection, IV, Agalsidase beta, per 1 mg	31.27	194,533	6,083,040
C9201	9201	Dermagraft, per 37.5 square centimeters	145.92	9,264	1,351,803
C9209	9209	Injection, IV, Laronidase, per 2.9 mg	162.72	2,612	425,092
Pass-through Drugs/Biologicals Effective January 2004					
C9207	9207	Injection, IV, Bortezomib, per 3.5 mg	262.66	102,680	26,970,000
C9210	9210	Injection, IV, Palonosetron HCl, per 0.25 mg (250 micrograms) ...	77.76	37,500	2,916,000
C9211	9211	Injection, alefacept, for intravenous use, per 7.5 mg	168.00	13,775	2,314,200
C9212	9212	Injection, alefacept, for intramuscular use, per 7.5 mg	119.40	27,550	3,289,470
Existing Pass-through Devices					
C1783	1783	Ocular implant, aqueous drainage assist device		324	160,250
C1814	1814	Retinal tamponade device, silicone oil		35,173	13,675,262
C1884	1884	Embolization Protective System		25,000	38,601,544
C1888	1888	Catheter, ablation, non-cardiac, endovascular (implantable)		215	129,731