

the procedure and for the lead.” Insert the following sentence in its place: “The APC payment accounts for the cost of the procedure and cost of the left ventricular lead is billed under the appropriate device category “C” code.”

On page 66741, in column 1, we failed to acknowledge and address a comment that objected to removing CPT code 92986 from the inpatient only list. Remove the response in this column and replace it with the following: “*Response:* We agree with the commenters and with the APC Panel’s recommendations that CPT code 47001 be payable under the OPPS beginning in 2003. Because this is an add-on code, payment will be packaged with the payment for the surgical procedure with which it is billed. We are making final our proposal to remove this code from the inpatient list but we will consider presenting this concern to the APC panel.

“The comment that urged that CPT code 92986, Percutaneous balloon valvuloplasty; aortic valve, not be assigned to APC 0083 did not contain an explanation for the allegation that it cannot be performed safely in an outpatient setting. In the absence of such justification and in the absence of other comments disagreeing with our proposal to pay under the OPPS for the 41 CPT codes listed in Table 6 of the August 2002 proposed rule (67 FR 52115), we are making these proposed changes final.”

On page 66745, in Table 6, we included an incorrect APC assignment for an APC. Remove 693A and insert 648. APC 693 was split into two APCs to enable us to establish a weight for the services that require devices based on the claims on which the devices were billed. The APC with devices is APC 648, Breast Reconstruction with Prosthesis. It was properly shown in Addendum A of the November 1, 2002, final rule.

On page 66756, in column 2, at the end of the first complete paragraph, replace the comma after “misuse” with a period, and remove the following words “or received marketing approval based on the use of surrogate outcomes.” We never intended to perform reasonable and necessary determinations on new technology solely because FDA marketing approval was based on surrogate outcomes.

On page 66760, in Table 9, in the section titled “Pass-through Devices Effective January 2003,” we reversed the HCPCS codes for two items in the table (HCPCS codes C2614 and C2632). Remove HCPCS code C2614 and APC 2614 and replace them with HCPCS code C2632 and APC 2632. In the same

location, remove HCPCS code C2632 and APC 2632 and replace them with HCPCS code C2614 and APC 2614.

On page 66768, in column 1, first comment at the top of the column, we incorrectly printed an exact replica of the immediately preceding comment. Remove the duplicate comment.

On page 66772, we failed to include a drug that meets our criteria as an orphan drug. HCPCS code J1785, Injection imiglucerase/unit meets the criteria for an orphan drug as specified in the November 1, 2001, final rule on page 66772. Remove the first full response in column 3 and replace it with the following: “*Response:* After reviewing the comments and reexamining whether there were other orphan drugs than the three we proposed to pay separately, we have decided to remove four orphan drugs that do not have any other non-orphan indications from the OPPS system and will pay them on a reasonable cost basis. In addition to the three drugs we proposed to treat as orphan drugs in the August 9, 2002, proposed rule, we have determined that J1785, Injection imiglucerase/unit, meets the criteria of having no indication other than an orphan indication and therefore meets our definition of an orphan drug and will be paid on a reasonable cost basis. Other drugs that have orphan status according to the FDA will be partly protected by the dampening options described in section III.B. of this final rule.” On page 66820, remove all Addendum A entries for APC 0916. On page 66983, under CPT/HCPCS code J1785, remove status indicator K and insert status indicator F. Remove the APC number, relative weight, payment amount, and minimum unadjusted copayment. See these changes in Tables 1 and 2.

On page 66778, in the first response in column 1, we erroneously said that APC 312 is the lowest paying brachytherapy APC. Remove the response to the first comment under “Brachytherapy” and replace it with the following: “*Response:* The time frame of the claims used to set payment rates in the final rule differed from the time frame used in the proposed rule. According to the claims data used for the proposed rule, APC 312 was the lowest paying brachytherapy APC. However, according to the claims data used for the final rule, APC 0313 is the lowest paying brachytherapy APC. Therefore, CPT 77799 will remain in APC 313. This is consistent with our policy of assigning unspecified codes to the lowest paying similar APC because we do not know what procedures are being performed. Moreover, we do not

apply the two times rule to unspecified codes like 77799 for the same reason. In 2003, CPT code 77799 is assigned to APC 0313.”

On pages 66779, 66780, and 66781, our discussions of the use of the Red Book in the setting of payment rates for pass-through drugs may have been misleading because we had misunderstandings regarding Red Book publications. The Red Book issues one comprehensive annual printed version, and it was our intent to convey that we relied on the most recent comprehensive annual printed version of the Red Book to set the pass-through payments for drugs for the 2003 OPPS. Our discussions of the Red Book in the November 1, 2002, **Federal Register** erroneously suggested that we rely on updates other than the comprehensive annual printed version. The corrections below clarify that we rely on the comprehensive annual printed version of the Redbook (which is printed once a year) to set the payment rates for pass-through drugs and that we intend to continue to do so in the future.

On page 66779, in column 3, in the last paragraph, delete the second sentence and insert the following: “We update the APC rates for drugs that are eligible for pass through payments in 2003 using the comprehensive annual printed version of the Red Book.”

On page 66780, remove the following beginning on the first line of column 1 of page 66780: “* * * when we would again * * * update the AWP’s for any pass-through drugs based on the latest quarterly version of the Red Book.” Insert a period.

On page 66781, remove the first paragraph of the response beginning at the bottom of column 1 of page 66781 and insert: “*Response:* Upon considering the commenters suggestions that we use the October 2002 Red Book to set the pass-through rates for drugs and biologicals, we decided to continue using the comprehensive annual printed version of the Red Book since it is most consistent with our publication schedule. In the future, for all of our final rules that must be published by November, we intend to use the comprehensive annual printed version of the Red Book.”

On page 66781, column 2, last response, remove the response and insert: “*Response:* As stated elsewhere in this final rule, we update the payment rates for pass-through drugs and biologicals only on an annual basis using the information published in the annual comprehensive printed version of the Red Book. We rely upon the Red Book to accurately reflect information supplied by manufacturers.”