

amounts using market applications by drug manufacturers and acquisition data solicited from the hospital industry through group purchasing organizations and individual hospitals and systems. The same commenter encouraged us to delay changes in pass-through payments pending an assessment of the impact of the AWP rule on physician practices.

Response: We wish to clarify how our use of the SDP to price pass-through drugs will affect the OPPS in 2004. The payment rates for pass-through drugs and biologicals that are shown in Addendum B are based on the April 1, 2003 SDP, which was the update that was available when we recalibrated the relative payment weights for this final rule. We also used these payment rates as the basis for estimating pass-through spending in 2004, which is discussed in section IV of this preamble.

We have carefully considered the commenter's concern about the confusion that could result if we were to revise the payment amounts for pass-through drugs and biologicals by installing prices from the January 2004 update of the SDP in the OPPS PRICER for implementation beginning January 1, 2004. We agree with the commenter that, because of the timing, this proposal could create operational problems both for providers and for our claims processing systems. Therefore, we will retain the payment amounts published in this final rule as the payment amounts for pass-through drugs effective January 1, 2004.

Further, to keep quarterly changes to a minimum, we have decided not to implement at this time our proposal to update the AWP for pass-through drugs paid under the OPPS on a quarterly basis in accordance with quarterly SDP updates.

At this time, we are not implementing the AWP rule. Therefore, we are not making final the OPPS changes we proposed that would have resulted from the AWP rule.

Comment: Several commenters were concerned about the delay in processing pass-through applications and assigning c-codes for new drugs and biologicals. Commenters believed that the lack of immediate payment under OPPS for new FDA-approved drugs and biologicals may drive hospitals to discontinue providing innovative life-saving therapies to Medicare beneficiaries until pass-through payments are established. Another commenter suggested that CMS create and regularly update a central on-line listing of all current codes for pass-through drugs, biologicals, and devices. The Web site should also list all pass-through drug and device applications

under review, and their status in the review process.

Response: We understand the concerns expressed by commenters about the impact of the time gap from FDA approval to our c-code assignment and payment for new pass-through items; however, our position on this issue remains the same as that described in the November 1, 2002 final rule (67 FR 66780–81).

B. Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status

1. Background

Under the OPPS, we currently pay for radiopharmaceuticals, drugs, and biologicals including blood, and blood products, which do not have pass-through status, in one of three ways: packaged payment, separate payment (individual APCs), and reasonable cost. As we explained in the April 7, 2000 final rule (65 FR 18450), we generally package the cost of drugs and radiopharmaceuticals into the APC payment rate for the procedure or treatment with which the products are usually furnished. Hospitals do not receive separate payment from Medicare for packaged items and supplies, and hospitals may not bill beneficiaries separately for any such packaged items and supplies whose costs are recognized and paid for within the national OPPS payment rate for the associated procedure or service. (Transmittal A–01–133, a Program Memorandum issued to Intermediaries on November 20, 2001, explains in greater detail the rules regarding separate payment for packaged services). As we explained in the November 1, 2002 final rule (67 FR 66757), we do not classify diagnostic and therapeutic radiopharmaceutical agents as drugs or biologicals as described in section 1861(t) of the Act.

Comment: Several trade associations and manufacturers urged CMS to revise its policy that radiopharmaceuticals are not drugs. They emphasized that radiopharmaceuticals go through the same FDA approval process as drugs, are approved for inclusion in the United States Pharmacopoeia Drug Indication, and have historically been considered drugs under OPPS. They indicated that Congress is considering a legislative clarification that under OPPS radiopharmaceuticals will continue to be treated and paid as drugs.

Response: We appreciate the comments on this issue. We do not intend, by our designation of radiopharmaceuticals for purposes of determining which items are eligible for pass-through status, to imply that

radiopharmaceuticals are not considered drugs under the Food, Drug, and Cosmetic Act or that they are not subject to the same FDA approval process as those items that we have designated as drugs. However, we will continue to consider radiopharmaceuticals as neither a drug nor biological. Our reasons were set forth in the November 1, 2002 final rule (67 FR 66757). In that rule, we stated that a careful reading of the statutory language in section 1861(t)(1) convinces us that inclusion of an item in, for example, the USPDI, does not necessarily mean that the item is a drug or biological. Inclusion in such a reference (or approval by a hospital committee) is a necessary condition for us to call a product a drug or biological, but it is not enough. CMS must make its own determination that a product is a drug or biological for OPPS purposes under its governing statutes, and this determination is different from and does not affect FDA's determination that a product is a drug or biological under the Food, Drug, and Cosmetic Act.

While we have determined that radiopharmaceuticals are not drugs under the OPPS, we have chosen to establish separate payment for radiopharmaceuticals under the same packaging threshold policy that we apply to drugs and biologicals. We have also determined that we will apply the same adjustments to the median costs for radiopharmaceuticals that will apply to non-pass-through, separately paid drugs and biologicals.

Payment for New Radionuclide Therapy for Certain Forms of Non-Hodgkins Lymphoma

Currently, payment for the radiopharmaceutical Zevalin (Ibritumomab Tiuxetan) is packaged into the payment for HCPCS codes G0273 (Pretx planning, non-Hodgkins) and G0274 (Radiopharm tx, non-Hodgkins). To ensure consistency with our payment policy for other radiopharmaceuticals (that is, making separate payment for radiopharmaceuticals whose costs are greater than \$150 per episode of care), we proposed to make payment for Zevalin (ibritumomab tiuxetan) separately from payment for the procedures with which Zevalin (ibritumomab tiuxetan) is used.

We proposed to use HCPCS A9522 (Indium 111 ibritumomab tiuxetan) to report the use of In-111 Zevalin (In-111 Ibritumomab Tiuxetan) and HCPCS A9523 (Yttrium 90 ibritumomab tiuxetan) to report the use of Y90 Zevalin (Y90 Ibritumomab Tiuxetan). We proposed to place HCPCS A9522 in