

categories are packaged into the existing APCs. For the categories existing as of publication of this proposed rule, we have determined that there are no close or identifiable costs associated with the devices in our data related to the respective APCs that are normally billed with those devices. Therefore, for these categories we are proposing to set the offset to \$0 for 2004.

If we create a new device category and determine that our data contain identifiable costs associated with the devices in any APC, we would apply an offset. We propose, if any offsets apply, for new categories, to announce the offsets in the program memorandum that announces the information regarding the new category.

VI. Payment for Drugs, Biologicals, Radiopharmaceutical Agents, Blood, and Blood Products

A. Pass-Through Drugs and Biologicals

Section 1833(t)(6)(D)(i) of the Act requires us to make transitional pass-through payment for new drugs equal to the amount by which 95 percent of the average wholesale price (AWP) of the drug exceeds the proposed payment rate. In the past, we have used the AWP published in the Red Book to determine payment amounts for pass-through drugs as we explain in the correction notice issued on February 10, 2003 (68 FR 6637). However, we are concerned about the extent to which Medicare pays more for drugs than other payers and more than the market-based price of drugs. To address this problem of how to pay appropriately for drugs that are priced using the AWP, we are developing regulations that would revise the current payment methodology for part B covered drugs paid under section 1842(o) of the Act. When the AWP regulations are made final, we propose to adopt and apply the provisions of the final AWP rule to establish the AWP of pass-through drugs payable under the OPSS. If implementation of the AWP final rule necessitates mid-year changes in the 2004 OPSS payment rates for pass-through drugs, we propose to make those changes on a prospective payment basis through our regular OPSS PM and PRICER quarterly updates. We further propose to issue instructions by program memorandum regarding implementation of the provisions of the AWP final rule to set payment rates for pass-through drugs under the OPSS.

An AWP final rule could be published before 2004. However, if the AWP final rule is not issued in time to permit us to apply its provisions to price pass-through drugs furnished on or after

January 1, 2004, we propose to use 95 percent of the AWP listed in the most recent quarterly update of the Single Drug Pricer (SDP). In the past, we have relied solely on the Red Book to determine the AWP for a pass-through drug, as we explain in the correction notice issued on February 10, 2003 (68 FR 6637). However, on January 1, 2003, we introduced for the first time a single pricing source for approximately 400 drugs and biologicals for which the Medicare payment allowance is based on 95 percent of their AWP. We established the SDP to address apparent discrepancies in drug pricing that were the unintended result of delegating calculation of AWP to multiple contractors, whose application of the pricing methodology established under 42 CFR 405.517 sometimes varied. The SDP continues to rely on published compilations such as the Red Book and First Data Bank to identify wholesale drug prices. However, using the SDP enables us to establish a uniform Medicare payment allowance for drugs whose payment is based on 95 percent of their AWP, which results in greater consistency in Medicare drug pricing nationally. If a drug with pass-through status is not included in the SDP, we propose to forward to the SDP contractor the AWP information submitted as part of the pass-through application.

Because the January SDP would not be available in time, we propose to announce the January 1, 2004 prices for pass-through drugs in our January 2004 OPSS implementing instructions to fiscal intermediaries and in the January 2004 OPSS PRICER rather than in the 2004 final rule, which is to be published in the **Federal Register** by November 1, 2003. We further propose to update the AWP for pass-through drugs paid under the OPSS on a quarterly basis in accordance with the quarterly updates of the SDP. The updated rates for pass-through drugs and biologicals would also be issued through our quarterly OPSS program memoranda and PRICER updates.

Additional information regarding the SDP can be found on the CMS Web site in Program Memorandum AB-02-174, issued December 3, 2002.

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

1. Background

Under the OPSS, 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 OPSS 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.

Packaging costs into a single aggregate payment for a service, procedure, or episode of care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. In general, packaging the costs of items and services into the payment for the primary procedure or service with which they are associated encourages hospital efficiencies and also enables hospitals to manage their resources with maximum flexibility. Notwithstanding our commitment to package as many costs as possible, we are aware that packaging payments for certain drugs and radiopharmaceuticals, especially those that are particularly expensive or rarely used, might result in insufficient payments to hospitals, which could adversely affect beneficiary access to medically necessary services.

As discussed in the November 1, 2002 final rule (67 FR 66774), we packaged payment for drugs and radiopharmaceuticals into the APCs with which they were billed if the median cost per line for the drug or radiopharmaceutical was less than \$150, and we established a separate APC payment for drugs and radiopharmaceuticals for which the median cost per line exceeded than \$150. This supported our general view that payment for drugs and radiopharmaceuticals should be made as part of the payment for the services in which they are used in order to encourage efficient purchase and use of drugs and radiopharmaceuticals provided in the hospital outpatient department.