

with the proposals for drug administration discussed elsewhere in this final rule. For many of these commenters, the issues of packaging, drug payment rates and our discussion of drug administration in the proposed rule were intertwined. Some commenters that disagreed with our \$150 packaging threshold asserted that most visits involve delivery of drugs that had been designated as packaged and that overpayment for visits with no packaged drugs is small compared to the overall underpayment of both packaged and separately payable drugs. Particular concern was expressed about the packaging of cancer chemotherapy drugs. One commenter stated that the dosages may vary significantly, and where given in high doses the cost for a single drug alone may exceed the total packaged payment. Also, commenters stated that several packaged drugs are often administered during a single infusion, and where the cost of a single packaged drug may be less than \$150 the cost of multiple packaged drugs is often greater than \$150.

Several commenters indicated that the methodology and cost data we used to calculate the median cost per day for drugs and radiopharmaceuticals were based on incorrectly coded claims where the wrong number of units were reported and a very limited number of single claims were captured which failed to portray the hospitals' charges appropriately. Therefore, certain high cost items fell below the \$150 threshold.

Commenters expressed concern about patient access to effective but lower cost drugs and the disincentive we may create by paying separately for those over \$150 per day. One organization stated that cancer centers have reported that they have taken or are considering steps to restrict patient access to those drugs that we have packaged. One hospital estimated that it would lose approximately \$490 per visit for a patient receiving chemotherapy due to the \$150 packaging rule and the proposed reductions in payments for certain drugs. While some commenters expressed general concerns about packaging the costs of any drugs, biologicals or radiopharmaceuticals, other commenters recommended that we apply a \$50 threshold in lieu of the proposed \$150 threshold in determining which items to pay for separately. Some of the commenters recommending a \$50 threshold cited statutory changes under consideration by Congress that would mandate a \$50 threshold.

*Response:* For 2004, we have established a \$50 median cost per day threshold in determining whether drugs, biologicals and radiopharmaceuticals

will be packaged. Those items that fall below the threshold will be packaged into the costs of the service or procedure with which they are billed; those items with median costs above the threshold will be paid for separately in 2004.

We analyzed our data in determining our final drug administration coding and payment policy, as discussed elsewhere in this final rule, and reviewed the median costs of all APCs under both a \$150 and a \$50 packaging rule. We concluded that there was not a sufficient difference in the median costs under those two scenarios, resulting in inadequate payment when drugs, biologicals and radiopharmaceuticals costing between \$50 and \$150 would be used by the hospital. Therefore, we agree with the majority of commenters that, for 2004, the appropriate threshold should be \$50.

We also recognize, as several commenters did, that packaging creates incentives for hospital efficiencies and will continue to apply that concept to devices, most supplies and equipment associated with a procedural APC, and low cost drugs. However, we are convinced that under our current methodology for establishing relative weights, that packaging drugs, biologicals and radiopharmaceuticals costing in excess of the \$50 threshold per patient per day would not provide adequate payment in 2004 and could adversely affect beneficiary access to important therapies. Nevertheless, our final decision for 2004 does not mean that a change in our methodology for establishing relative weights in the future could not cause us to revisit our packaging policy in the future. Since we have lowered the packaging threshold from \$150 to \$50, we will not adopt the proposal to provide an exception to the packaging rule for drugs and radiopharmaceuticals whose payment status would change from 2003 to 2004 as a result of using newer 2002 data.

However, we note several exceptions to our policy of packaging drugs, biologicals and radiopharmaceuticals for which the median per day cost is less than the \$50 threshold. As discussed elsewhere in this final rule, we will allow separate payment under the OPPS for all blood and blood products and for single indication orphan drugs. We will also allow separate payment for hepatitis B vaccine under the OPPS. While the median per day costs for several hepatitis B vaccine codes fell below the \$50 threshold using the final rule data, we believe that continued separate payment for these codes is warranted given the special, separate benefit category established by

Congress. Separate payment for influenza and pneumococcal vaccines will continue to be made outside of the OPPS on a reasonable cost basis.

### 3. Payment for Drugs, Biologicals, and Radiopharmaceuticals That Are Not Packaged

In order to establish payment rates for separately payable drugs and radiopharmaceuticals for the 2004 OPPS, we first determined median cost for each drug and radiopharmaceutical per unit. When we compared the median cost per unit used for determining the 2003 payment rate (for example, the true or dampened median cost) for separately payable drugs and radiopharmaceuticals with their 2004 median cost per unit, we found fluctuations in costs from 2003 to 2004.

We solicited comments concerning the reasons for the fluctuations in median costs from 2003 to 2004. We stated our interest in determining whether these fluctuations reflect changes in the market prices of these drugs and radiopharmaceuticals or problems in the hospital claims data (for example, inaccurate coding, improper charges) that we use for setting payment rates.

In the proposed rule, we discussed in detail several options we considered to address the fluctuations in median costs for separately payable drugs and radiopharmaceuticals (68 FR 47997–47998). The option that we proposed for 2004 was a variation of the methodology used for the 2003 OPPS. For separately payable drugs and radiopharmaceuticals whose 2004 median costs decreased by more than 15 percent from the applicable 2003 median cost, we proposed to limit the reduction in median costs to one fourth of the difference between the value derived from claims data and a 15 percent reduction (for example, for a drug whose cost decreased by 35 percent from the applicable 2003 median cost, the allowed reduction from 2003 to 2004 would be 15 percent +  $(\frac{1}{4} \text{ times } 35 - 15) \text{ percent} = 20 \text{ percent}$ ). For separately payable drugs and radiopharmaceuticals whose median costs decreased by less than 15 percent from 2003 to 2004, we proposed to establish their payment rates using the median costs derived from the 2002 claims data. We stated that, based on more complete claims data we expected to have for the final rule and on the comments from the public, we would re-evaluate the appropriateness of adjusting median costs for drugs for which median costs would decline in 2004.