

claim of 50 units with a cost of \$50 would be given 50 line items each with a cost of \$1.

- The unit records with cost per unit greater or less than 3 standard deviations from the geometric mean were then trimmed.

- The remaining unit observations were arrayed and the median cost per unit of the drug or radiopharmaceutical was established.

- Next, the total number of units billed on all claims for the drug or radiopharmaceutical was divided by the total number of unique per-day records for the drug or radiopharmaceutical to arrive at an average number of units per day.

- The average number of units per day for each drug or radiopharmaceutical was then multiplied by the median cost per unit to arrive at its "median cost" per day.

- We then arrayed the median cost per day for all drugs and radiopharmaceuticals in ascending order and examined the distribution.

Many commenters have alleged that hospitals do not accurately bill the number of units for drugs and radiopharmaceuticals. Because this methodology assumes that hospitals bill the number of units accurately, we compared the median cost per day obtained by the above methodology with the median cost per day derived as follows: We aggregated line items as above and created records for each drug and radiopharmaceutical based on date of service. However, instead of calculating costs on a per-unit basis, we simply reduced total charges to total costs for each record and determined the median. This methodology assumes that hospitals record charges more accurately than units. We believed that calculating median costs using the second methodology would address the concerns of commenters and would help us determine whether our median cost per unit calculation accurately reflected the costs of drugs and radiopharmaceuticals.

In most cases, the median costs determined by the two methodologies were similar. Based on this comparison, we believe that calculating median costs per unit accurately reflects the actual cost of the drug or radiopharmaceutical. Furthermore, given the wide variability of doses used for many drugs, we believe that it is important to pay on a "per unit" basis for separately payable drugs and radiopharmaceuticals. For example, many chemotherapy agents are dosed based on both body area and frequency of administration. Thus, a patient with a body area of 2 m squared could receive 600 mg of a drug every 3

weeks, 400 mg every 2 weeks, or 200 mg every week depending on the chemotherapy regimen.

Based on our analyses, we believe that it is reasonable to continue our current policy of packaging drugs and radiopharmaceuticals with a median cost of less than \$150 per day. This means that approximately 52 percent of the drugs and radiopharmaceuticals will be packaged and 48 percent of the drugs and radiopharmaceuticals will be paid separately.

We noticed that several drugs and radiopharmaceuticals with median cost per line that were under \$150 for the 2003 OPPS have median costs per day that are equal to or greater than \$150 based on the data used for the 2004 OPPS. For some other drugs and radiopharmaceuticals, we saw that their median costs per line were equal to or greater than \$150 for 2003 OPPS; however, using the 2002 data, their median costs per day fell below \$150. These shifts from 2003 to 2004 would affect packaging decisions for a number of drugs.

Given that these variations exist, we propose to provide an exception in 2004 to the packaging rule for drugs and radiopharmaceuticals whose payment status would change as a result of using newer data and a different methodology. As we explain elsewhere in this proposed rule, we expect to use additional 2002 claims data for the establishment of our final policies for CY 2004. Based on this additional data and comments from the public, we intend to re-evaluate whether to package or pay separately for drugs for which the per-day median cost would cross the threshold from 2003 to 2004. For 2004, we propose that:

- Currently packaged drugs and radiopharmaceuticals with median costs per day that are at or above \$150 would receive separate payment in 2004.

- Currently separately payable drugs and radiopharmaceuticals with median costs per day that are under \$150 would continue to receive separate payment in CY 2004.

- Drugs whose pass-through status would expire on December 31, 2003, and whose median costs per day are under \$150 would receive separate payment in 2004.

- Currently packaged drugs and radiopharmaceuticals with median costs per day below \$150 would remain packaged in 2004.

We request comments on the methodology we used to determine the median cost per day, on the threshold we propose to use for packaging drugs and radiopharmaceuticals, and on the proposal to pay separately for drugs and

radiopharmaceuticals whose payment status would change based on use of recent claims data and our proposed methodology.

Although in the future we expect to expand packaging the costs of drugs and radiopharmaceuticals into the APCs for the services with which they are billed, we request comments on alternatives to packaging.

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

For the 2003 OPPS, the APC payment rate for separately payable drugs and radiopharmaceuticals with status indicator "K" is based on a relative weight calculated in the same way that the relative weights for procedural APCs are calculated. As with procedural APCs, we observed a decrease in the proposed payment rates for many separately payable drugs and radiopharmaceuticals; therefore, we dampened the payment reduction for APCs whose median costs decreased by more than 15 percent from 2002 to 2003.

In order to establish payment rates for separately payable drugs and radiopharmaceuticals for the 2004 OPPS, we first determined each drug's and radiopharmaceutical's median cost as described above. 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.

CY 2004 median costs decreased more than 15 percent from the corresponding 2003 median cost for many of the separately payable drugs and radiopharmaceuticals. Many of these decreases affected low-volume drugs and radiopharmaceuticals and may be the result of inaccurate coding. Similarly, the 2004 median costs increased by more than 15 percent from the corresponding 2003 median cost for approximately 12 (mostly low volume) drugs and radiopharmaceuticals. For many of the high-volume, separately payable drugs and radiopharmaceuticals, the 2004 median costs increased or decreased by less than 15 percent as compared to the corresponding 2003 median cost. We solicit comments concerning the reasons for the fluctuations in median costs from 2003 to 2004. We are interested 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