

We also proposed a separate payment policy for drugs, biologicals, and radiopharmaceuticals for which generic alternatives have been approved by the Food and Drug Administration (FDA) between October 2001 and December 2002.

We solicited comment on both our proposed methodology and payment rates for separately payable drugs and radiopharmaceuticals for 2004. We requested that commenters who disagree with the proposed rate for a drug or radiopharmaceutical submit verifiable information to support their opinions that the proposed rate is inaccurate and does not reflect the price that is widely available to the hospital market.

We received a number of comments on our payment methodology options for separately payable drugs, biologicals, and radiopharmaceuticals. Those comments are summarized below along with our responses.

Comment: We received a number of comments noting disagreement with the proposed payment rates for separately paid drugs, biologicals and radiopharmaceuticals overall. Many of these comments were included in the comments on our packaging proposal, summarized above, and expressed some of the same concerns, such as restrictions to patient access, particularly to cancer chemotherapy drugs. One hospital commenting on the proposed rates stated that, as with most hospitals, they continually attempt to leverage buying power to reduce the costs of drugs but, like most hospitals, have been unable to do so for certain drugs. Commenters asked that we critically review the data used to establish the payment rates including consideration of the charge compression issue. Commenters stated that the proposed payments would not cover the direct acquisition costs of certain items.

A number of commenters objecting to our proposed payment rates stated that the hospital data that we use to calculate those rates are flawed and that the methodology we employ to convert hospital claims data to relative weights is problematic. Commenters attributed these concerns to issues such as hospital billing practices that result in inaccurate reporting of units or charges, HCPCS coding changes, and the use of cost-to-charge ratios across all products regardless of whether an item is high or low cost.

We received numerous comments on alternatives to our proposed policies for separately payable drugs and radiopharmaceuticals. One commenter suggested that we pay the amount of the hospital's acquisition cost plus an

additional 25 percent to pay for costs of receiving, processing and storing the items. Other comments suggested that we limit the decreases for all separately paid drugs to a reduction of 10 percent in the payment rates, as we proposed for blood and blood products, instead of our proposed policy of limiting reductions in median costs for those separately paid items with median costs with reductions greater than 15 percent. Another suggestion was that we establish a payment rate floor for a product that could be raised if a manufacturer submitted information demonstrating that the rate should be higher than the floor.

Several commenters indicated that we should use only claims that have the appropriate administration or procedure code and the HCPCS code for a particular drug or radiopharmaceutical when determining the median cost for that drug or radiopharmaceutical. One commenter recommended that we pay for drugs and biologicals at 95% AWP to standardize payments for drugs and biologicals across different practice settings. Another commenter requested that we establish payment floors that are equal to those in the pending Congressional Medicare legislation (for example, certain sole source drugs would be paid at least 88 percent of AWP in 2004); whereas another drug manufacturer recommended that we use the Federal Supply Schedule price plus a certain percentage (for example, 12.5 percent) as an absolute minimum payment amount for drugs and radiopharmaceuticals.

In addition to the comments regarding our proposed payment rates for drugs, biologicals and radiopharmaceuticals overall, we received comments concerning the proposed rate for specific items. For a few of those items, we received external cost data that met the preferred criteria we set forth in our proposed rule (for example, non-proprietary data that demonstrates actual, market-based prices at which a broadly-based national sample of hospitals were able to procure the item). Several commenters suggested that we substitute external data on hospital acquisition cost for median costs calculated from our claims data when determining the payment rate for drugs and radiopharmaceuticals for which we have received such data. Others recommended that we use external data to benchmark payment for drugs and radiopharmaceuticals and make appropriate adjustments to the proposed 2004 payment levels. Even though most commenters supported the use of external data in place of hospital claims data, a national hospital association

expressed concern about the use of external data in OPPS. The commenter indicated that if external data is used for rate setting in 2004, then we may have to continue to collect data on acquisition cost for future years to be able to continue to adjust the weights. Instead, the commenter was supportive of using claims data to set payment rates without the use of external data and urged us to remain committed to the averaging process inherent in the prospective payment system.

Response: We have decided to adopt the general principle proposed in our August 12, 2003 proposed rule limiting the reduction in median costs to one-fourth of the difference between the value derived from our claims data and a 15 percent reduction. For example, a drug whose median cost decreased by 35 percent from the median cost used to establish the separate payment rate for 2003 would be 15 percent + (1/4 times 35–15) percent, or 20 percent. However, we will not apply this methodology to the medians of those drugs, biologicals and radiopharmaceuticals that are packaged in 2003 but for which we will allow separate payment in 2004. Payment for drugs, biologicals and radiopharmaceuticals that emerge from packaged status in 2004 because their median per day costs are greater than \$50 per day will be based on the unadjusted median cost derived from our April–December 2002 claims data. Since these items are packaged in 2003, we did not calculate any adjusted medians on which to base their payments on for 2003. Thus, we are unable to determine the extent to which their median costs fluctuate from 2003 to 2004.

As discussed in our proposed rule and elsewhere in this final rule, we used a more complete set of claims for the April–December 2002 claims period and the most recently submitted cost report data to calculate median costs for all currently separately paid drugs, biologicals and radiopharmaceuticals. Our analysis of the later and more complete data revealed that a number of these items continued to experience a decline of more than 15% in median cost. We again considered several options to address the fluctuations in medians, which for some items would result in wide fluctuations in payments to hospitals. One option was to do nothing to adjust for the fluctuations; another option was to apply a more modest give-back (for example, 50 percent instead of 75 percent, after allowing for the 15 percent reduction.) We also considered the comments we received on drug payments in general and for specific items.