

After reviewing the comments, and our final claims data for 2004, we decided that we would not adjust the medians for procedural APCs but that we would adjust medians for certain APCs for which we were given external data that could be made public because we were convinced that the medians from our claims data resulted in median costs that were grossly variant. We adjusted the medians for the following APCs using external data: APC 0107 (insertion of cardioverter-defibrillator), APC 0108 (Insertion/replacement/repair of cardioverter defibrillator leads and insertion of pulse generator), APC 0222 (implantation of neurostimulator), APC 0039 (which was broken out of APC 0222) and APC 0674 (prostate cryoablation). For each of these APCs we calculated an adjusted device portion of the median by taking one part of the device cost from our data and one part of the device cost supplied by external data. We added the adjusted device median to the nondevice median from our data to acquire the adjusted median. In the case of APC 0108, we used the external device cost data that was used to set the median for the 2003 OPPS because we received no outside data for the 2004 OPPS for this APC and because the proposed median of \$28,685.30 set forth in the proposed rule was considerably higher than the final rule data median of \$23,944.80, which resulted when additional claims were used to calculate the median cost. In other cases, we found that corrections in the APC assignment or splitting an APC into two APCs resulted in more accurate median costs.

For 2004, we will adjust median costs for drugs, biologicals and radiopharmaceuticals as proposed for reasons discussed in section VI.B.3. We will freeze payments for blood and blood products at the 2003 rates for reasons discussed in section VI.B.8. We will pay single indication orphan drugs at 88 percent AWP for reasons discussed in section VI.B.6.

Comparison of Procedural APC Medians for the 2004 OPPS to Adjusted Medians for 2003 OPPS

Using the data available to us at the time we developed the proposed rule, we identified APCs that showed decreases in median cost of more than 10 percent compared to the adjusted medians on which their payments were based for 2003. We discussed specific APC medians to the extent that we understood the reason for the decreases or were particularly puzzled by the change. We requested comments on the medians and provided a set of criteria for external data that could be used to

supplement the median costs derived from our claims data. The criteria we provided regarding the use of external data included a stipulation that the data must not be confidential because any data we use must be available to the public. We also provided a list of preferred (but not required) criteria that addressed our preferences for characteristics of the data. We indicated that to be of optimal use, the external data should represent a divergent group of hospitals by location and type, identify the number of devices billed to Medicare as well as rebates or reductions for bulk purchases, identify the HCPCS codes with which the devices would be used, identify the source of the data and include both charges and costs for each hospital by quarter for the last 3 quarters of 2002 (68 FR 47987). We did not propose to adjust the medians for procedural APCs in the manner that they were adjusted for the 2003 OPPS. For 2004 we did not apply a systematic adjustment to all medians that declined more than a specified percentage in comparison with the medians for 2003. Instead, as discussed previously, we adjusted the medians of 5 APCs based on external data where we thought it was necessary and we have split some APCs where we thought doing so would result in more accurate relative weights.

Use of External Data

Comment: Some commenters opposed the use of external data on the basis that they believe that they will result in unfair imbalances in payment. They recognized that the application of cost-to-charge ratios will not result in amounts that are equal to full acquisition costs but they believe that as long as the same standard methodology is used across all services, the relative payments will be correct. They indicated that in a system of averaging, it is not necessary or even expected that each item and service will be paid at acquisition cost. They encouraged us to remain faithful to the averaging process inherent in a prospective payment system and not to rely on external data. Some commenters opposed use of external data and supported the requirement that they be publicly disclosable. Other commenters stated that we should use our claims data to set weights because they accurately reflect the relative hospital costs of providing outpatient services. However, these commenters were concerned with how different rates for some services in the 2004 proposed rule are from the rates for the same services in 2003.

Some commenters said that we should use external data that are

proprietary and maintain the confidentiality of such data. Several commenters indicated that the prices for medical devices are often covered by agreements that preclude the parties from disclosing the price of the device and that we should use the data to set prices, notwithstanding that they cannot be made available for inspection by the parties whose payments may be reduced by their use. Several commenters stated that we used external data that were proprietary for setting of 2002 weights, and for some 2003 weights and that we should do so again because data from manufacturer price lists and invoices more accurately reflect the costs attained by applying the cost-to-charge ratios for hospital departments to the charges for the devices to get costs to package into the APC medians. These commenters stated that external data should be used more widely than data based on the criteria that were used for the 2003 OPPS for the use of external data (that is, that the device-cost portion of the APC exceeded 80 percent of the total APC cost for external data to be used). These commenters stated that external data should be used for all APCs that show significant reductions since the 2002 OPPS. In particular, they cited the APC Panel recommendation that outside data be used to set the median cost for APC 107.

Some commenters had specific comments on the criteria we provided for use of external data. One commenter stated that its members did not have and could not easily acquire the data that would ensure that the data represent a diverse group of hospitals by location and type nor could they identify specific hospitals that used their devices. The commenter also stated that its members could not provide the information on discounts and rebates against their price lists that we requested. The commenter indicated that its members did not want to provide the HCPCS codes in which their products were used but instead, wanted us to require the typical applications that they feel are most appropriate. The commenters agreed that they could provide the source of the data. The commenters stated that its members could not provide data that corresponded with the same period of time being used to set the relative weights for all APCs.

Response: In the proposed rule, we indicated that external data should cover services furnished during the last 3 quarters of 2002 (68 FR 47987). We appreciate that manufacturers and wholesalers would not want to disclose negotiated prices for 2003 or 2004 for competitive reasons. However, we fail to