

eluting stent data. Therefore, the total sample size for the survey instrument was 309 hospitals.

At the time of the survey, 83 of the selected hospitals had not yet received shipments of the drug-eluting stents and, hence, were not able to complete the survey because they had no cost or charge data for drug-eluting stents. The final number of completed surveys was 119 (or 53 percent of the sample).

The survey was designed to collect data regarding costs, charges, and utilization for drug-eluting stents at three different points in time: currently; October 1, 2003; and at full-maturity (defined as that point in time in which the hospital has achieved a stable and consistent usage of the drug-eluting stent). The data were submitted (including a sample of invoices) under a request for confidential treatment under the Freedom of Information Act.

Based on the data collected, the commenter recommended that CMS increase the large differential between nondrug-eluting and drug-eluting stents to create a payment differential of \$3,024. This represents the cost per case differential between nondrug-eluting stent and drug-eluting stent cases anticipated by surveyed hospitals on October 1, 2003. The current cost differential reported by the sample of hospitals was \$2,721. The commenter estimated that our proposed methodology results in a payment differential of \$1,451 and \$1,495 between DRGs 516 and 526, and DRGs 517 and 527, respectively. The surveyed hospitals reported average current and anticipated stents used per case of 1.4 and 1.5, respectively. Average projected utilization of drug-eluting stents relative to all stents was reported in the survey to currently be 33 percent, and by October 1, 2003, utilization is projected to be 69 percent.

Another commenter noted that the actual cost per stents is 59 percent higher than our projection of \$1,200. The commenter also noted that most cases use 2 stents instead of the projected 1.5 stents, and, therefore, the net incremental charge difference should be \$5,554 instead of the \$3,996 projected by CMS.

**Response:** The data submitted was extensively detailed and helped us better understand the costs, charges, and utilization for all types of stents. As noted above, we stated in the proposed rule that we would use the best available data at the time of the final rule to establish the FY 2004 relative weights for DRGs 526 and 527, and these data are much more detailed and current than any other sources available to us at this time. These data are

extremely useful to assess the appropriateness of our proposed methodology to determine the relative weights for DRGs 526 and 527.

The commenter recommended that CMS establish a payment differential between DRGs for nondrug-eluting stents and drug-eluting stents of \$3,024 to account for the estimated cost difference between the two types of stents. However, the DRG relative weights are established using the average charges per case of each DRG relative to the national average. Therefore, we examined the charge per case data from the sample.

The commenter referred to a mean charge differential per case of \$5,721, based on anticipated costs per drug-eluting stent on October 1, 2003. However, we do not believe it is appropriate to use anticipated October 1, 2003 charges for several reasons. First, these data cannot be substantiated. As noted above, we received a sampling of current invoices that allowed us to verify the current costs per drug-eluting stent. These invoices cannot verify the \$300 average per stent cost increase that reportedly will occur between the time the survey was conducted and October 1, 2003. Second, for all other DRGs, we are using charge data reflective of FY 2002 charges. Although we are establishing the FY 2004 relative weights in this final rule, using anticipated FY 2004 charge data would result in 2-year later charge data being used to establish the DRG 526 and 527 relative weights, while FY 2002 charge data are used to establish all other relative weights. Therefore, we believe the current data more closely approximate the data used to determine the FY 2004 relative weights for the remainder of the DRGs. Finally, hospitals must rely upon the manufacturer of the only currently available drug-eluting stents for information on future pricing. We believe this raises questions as to the validity of the data due to the lack of independently verifiable pricing data for the future.

Therefore, we are basing our evaluation of our proposed methodology on the sample data from the current period. The commenter reported a mean differential in charges per case of \$4,859 for the current period. However, we are concerned that the mean differential in charges per case is unduly influenced by extraordinarily high charge markups reported on the part of some hospitals. For example, one hospital reported charging \$28,000 per drug-eluting stent, while its costs per stent were only \$3,023. This same hospital reported charges of \$9,500 for nondrug-eluting

stents, with costs per stent of \$1,010. To control the distorting impact such a hospital would have on the mean charge differential, we examined the geometric mean charge differential based on current charges per case.

The survey data showed that, for seven hospitals, the charge per case was higher for nondrug-eluting stent cases. In order to calculate the geometric mean differential charge per case, it was necessary to remove these seven negative differentials. The result was a current geometric mean differential charge per case of \$4,186. As an alternative to removing these seven negative numbers, we set them to a \$1 differential, and calculated a geometric mean differential charge per case of \$2,291. Based on the range of these results, we believe our proposed charge differential of \$3,996 represents a reasonable approximation of the differential in charges per case, and we are proceeding to establish the DRG relative weights for DRGs 526 and 527 for FY 2004 using this amount.

We note that there is a difference between CMS and the commenter on the current cost difference between drug-eluting stents and nondrug-eluting stents (our estimate began with a \$1,200 per stent differential, while the survey found a \$2,721 current differential). It appears that the reason our charges per case for drug-eluting stents and nondrug-eluting stents are not substantially different from the charges in the survey data, despite the discrepancy in the cost differential, is due to the fact that hospitals are not marking up drug-eluting stents by the same proportion as nondrug-eluting stents. From the data submitted by the commenter, we found the average charge increase for nondrug-eluting stents is 183 percent. The average charge increase for drug-eluting stents is 124 percent. This lower markup reduces the differential in charges relative to the actual costs hospitals may incur.

Based on data submitted to us last year by the commenter, we proposed that 43 percent of stent cases from DRGs 516 and 517 would be reassigned to DRGs 526 and 527. However, based on the survey data, for FY 2004 we are changing our estimate to assume that 69 percent of coronary stent cases will be reassigned from DRGs 516 and 517 to DRGs 526 and 527, respectively. We note that, although this percentage is based on anticipated utilization on October 1, 2003, it is not based on data that is only available from the manufacturer. We are continuing to assume a utilization rate of 1.5 stents per case.