

(40.1 days) are significantly higher than data on all other procedures in DRG 525 (average charges ranging from \$112,748 to \$190,672) and (average length of stay ranging from 10.9 to 16.7). According to the commenter, the implantable pulsatile technology represents a different class of device and procedure (long-term support) compared to the less resource intensive, short-term devices used in other procedures in DRG 525.

The commenters requested three possible alternatives for the reclassification of procedure code 37.66: (1) Create a unique DRG for this procedure; (2) add this procedure code to DRG 103 (Heart Transplant); or (3) add a new technology add-on payment for code 37.66 to DRG 525.

Response: In response to comments we received on the creation of new DRG 525 last year, we noted that these four codes represent the most expensive cases in MDC 5 (67 FR 49991). However, the specific point made by the commenters this year, that procedure code 37.66 is significantly different in terms of clinical procedures and resource utilization from the other procedures in DRG 525, was not raised prior to this year's proposed rule.

While we recognize the significant disparities referenced by the commenter warrant further consideration, the potential solutions suggested by the commenter are significant changes to the DRG system that warrant public comment. In particular, the reassignment of code 37.66 to DRG 103 would result in inclusion of nontransplant cases in this existing single-procedure DRG. Therefore, in light of the significant impacts of each of the commenters' suggestions on the structure of the DRGs involved and the need to submit any such significant impacts to public review and comment, we are not changing DRG 525 for FY 2004. We appreciate the commenter bringing this issue to our attention. We will evaluate whether to make further changes to DRG 525 in light of the information that there is significant disparity in the costs of the different procedures included in the DRG. We note that the outlier payment policy will help to offset extraordinarily expensive costs.

Furthermore, the volume and mix of cases in this DRG is likely to change over the next year. Currently, CMS has approved the use of LVADs in two instances. They can be used as either a bridge to heart transplant or for support of blood circulation postcardiotomy (the period following open-heart surgery). In these two applications, the LVAD is used as temporary mechanical circulatory support. CMS is currently

reviewing a request for expanded coverage for these devices as destination (or permanent) therapy for end-stage heart failure patients who are not candidates for heart transplantation. Destination therapy means that the patient will use the LVAD for the remainder of his or her life.

We believe it will be helpful to have data on the resources and volume associated with any potential destination therapy cases prior to revising DRG 525.

e. Drug-Eluting Stents

In the August 1, 2002 final rule, we created two new temporary DRGs to reflect cases involving the insertion of a drug-eluting coronary artery stent as signified by the presence of code 36.07 (Insertion of drug-eluting coronary artery stent): DRG 526 (Percutaneous Cardiovascular Procedure With Drug-Eluting Stent With AMI); and DRG 527 (Percutaneous Cardiovascular Procedure With Drug-Eluting Stent Without AMI). We expect that when claims data are available that reflect the use of these stents, we will combine drug-eluting stent cases with other cases in DRGs 516 and 517.

In the absence of MedPAR data reflecting the use of drug-eluting stents, it was necessary to undertake several calculations to establish the FY 2003 DRG relative weights for these two new DRGs. First, based on prices in countries where drug-eluting stents were already being used compared to the average price of nondrug-eluting stents in those countries, we calculated a price differential of approximately \$1,200. When we apply average overall hospital charge markups to this technology (based on weighted average cost-to-charge ratios), we estimated that the charge differential between nondrug-eluting and drug-eluting stents would be approximately \$2,664 per stent. However, we recognize that some cases involve more than one stent. Using an average of 1.5 stents per procedure, we estimated that the net incremental charge for cases that would receive drug-eluting stents is \$3,996.

In order to determine accurately the DRG relative weights for these two new DRGs relative to all other DRGs, we also must estimate the volume of drug-eluting stent cases likely to occur. We used the manufacturer's estimate that as many as 43 percent of current stent patients will receive drug-eluting stents during FY 2003 to calculate the FY 2003 DRG relative weights, although we prorated this percentage since the new

DRGs did not become active until April 1, 2003.⁴

In determining the FY 2004 DRG relative weights for DRGs 526 and 527, we assumed that 43 percent of coronary stent cases (those with code 36.06 (Insertion of nondrug-eluting coronary artery stent)) from DRGs 516 and 517 would be reassigned to new DRGs 526 and 527 (with code 36.07), and the charges for these cases would be increased \$3,996 per case, to approximate the higher charges associated with the drug-eluting stents in DRGs 526 and 527. The relative weights for DRGs 516 and 517 are calculated based on the charges of the cases estimated to remain in these two DRGs.

Comment: In response to our statement in the proposed rule that we would use the best available data to establish the FY 2004 relative weights for DRGs 526 and 527, one commenter (the manufacturer of the only FDA-approved drug-eluting stents at this time) commissioned an independent accounting firm to collect costs, charges, and utilization data from hospitals on drug-eluting and nondrug-eluting stents.

The data were collected from a randomized, statistically significant sample of United States hospitals with interventional cardiac catheterization laboratories. First, the firm identified those hospitals that performed coronary angioplasty on Medicare beneficiaries. The method used to identify these hospitals was first to review MedPAR data to isolate those hospitals with average volume in DRGs with a placement of coronary artery stent, ICD-9-CM procedure code (36.06). From this list of hospitals, it was necessary to eliminate those that appeared to have quality issues with the data. This resulted in a list of 1,033 hospitals for the "population" group from which the sample was drawn.

A sample size sufficient to achieve a confidence level of 95 percent that the results would be within 5 percent of the actual distribution (assuming a normal distribution) was then determined, and a randomized selection within each state identified 279 hospitals. An additional 30 hospitals from a preliminary phase of the study were added because these hospitals had already supplied nondrug-eluting stent data and had committed to supply drug-

⁴ Even though the DRG became active on April 1, 2003, we expect that hospitals did not use this technology before FDA approval. (We intend to identify and review any cases with the code 36.07 that occurred prior to FDA approval.) Therefore, no payments are expected to have been made under these DRGs for cases occurring before FDA approval.