

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 estimate 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 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. Even though the DRG will become 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.

In determining the FY 2004 proposed 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 of 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.

We are proposing to maintain DRGs 526 and 527 for FY 2004, and to adopt the same methodology to establish the relative weights as we used for FY 2003. The FDA issued a decision on April 24, 2003 approving drug-eluting stents. For the final rule, we will use the best available data at that time to establish the FY 2004 relative weights for DRGs 526 and 527.

f. *Artificial Anal Sphincter*. The ICD-9-CM Coordination and Maintenance Committee created two new codes to describe procedures involving an artificial anal sphincter for use for discharges occurring on or after October 1, 2002. One code (49.75, Implantation or revision of artificial anal sphincter) is used to identify cases involving implantation or revision of an artificial anal sphincter. The second code (49.76, Removal of artificial anal sphincter) is used to identify cases involving the

removal of the device. In Table 6B of the August 1, 2002 IPPS final rule (67 FR 50242), we assigned both codes to one of four MDCs based on principal diagnosis, and to one of six DRGs within those MDCs as follows: MDC 6, DRG 157 (Anal and Stomal Procedures With CC) and DRG 158 (Anal and Stomal Procedures Without CC); MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast), DRG 267 (Perianal and Pilonidal Procedures); MDC 21 (Injuries, Poisonings, and Toxic Effect of Drugs), DRG 442 (Other O.R. Procedures for Injuries With CC) and DRG 443 (Other O.R. Procedures for Injuries Without CC); and MDC 24 (Multiple Significant Trauma), DRG 486 (Other O.R. Procedures for Multiple Significant Trauma).

We have received a request that we review these DRG assignments. According to the requester, the artificial anal sphincter procedures are expensive and the payment does not adequately cover a hospital's costs in the most likely occurring DRGs 157 and 158. The requester submitted data showing cases involving artificial anal sphincters with average charges of \$44,000, and suggested that we assign codes 49.75 and 49.76 in MDC 6 to DRG 170 (Other Digestive System O.R. Procedures With CC) and DRG 171 (Other Digestive System O.R. Procedures Without CC) because DRG 170 and DRG 171 are higher weighted than DRGs 157 and 158.

At this time, we are not proposing to assign these cases to DRGs 170 and 171. Although we recognize the data submitted by the commenter appear to show this procedure is associated with above average costs in the DRGs to which these cases are assigned, we believe the current assignment is the most clinically appropriate at this time. As noted above, the procedure codes to identify the implantation, revision, or removal of these devices were effective beginning on October 1, 2002. Therefore, we propose to monitor the costs of these cases using actual Medicare cases with these codes included from the FY 2003 MedPAR that will be used for the FY 2004 DRG relative weights.

C. Recalibration of DRG Weights

We are proposing to use the same basic methodology for the FY 2004 recalibration as we did for FY 2003 (August 1, 2002 IPPS final rule (67 FR 50008)). That is, we are proposing to recalibrate the DRG weights based on charge data for Medicare discharges using the most current charge information available (the FY 2002 MedPAR file).

The MedPAR file is based on fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. FY 2002 MedPAR data include discharges occurring between October 1, 2001 and September 30, 2002, based on bills received by CMS through December 31, 2002, from all hospitals subject to the IPPS and short-term acute care hospitals in Maryland (which is under a waiver from the IPPS under section 1814(b)(3) of the Act). The FY 2002 MedPAR file includes data for approximately 11,404,829 Medicare discharges. Discharges for Medicare beneficiaries enrolled in a Medicare+Choice managed care plan are excluded from this analysis. The data include hospitals that subsequently became CAHs, although no data are included for hospitals after the point they are certified as CAHs.

The proposed methodology used to calculate the DRG relative weights from the FY 2002 MedPAR file is as follows:

- To the extent possible, all the claims were regrouped using the DRG classification revisions discussed in section II.B. of this preamble.
- Charges were standardized to remove the effects of differences in area wage levels, indirect medical education and disproportionate share payments, and, for hospitals in Alaska and Hawaii, the applicable cost-of-living adjustment.
- The average standardized charge per DRG was calculated by summing the standardized charges for all cases in the DRG and dividing that amount by the number of cases classified in the DRG. A transfer case is counted as a fraction of a case based on the ratio of its transfer payment under the per diem payment methodology to the full DRG payment for nontransfer cases. That is, transfer cases paid under the transfer methodology equal to half of what the case would receive as a nontransfer would be counted as 0.5 of a total case.
- Statistical outliers were eliminated by removing all cases that are beyond 3.0 standard deviations from the mean of the log distribution of both the charges per case and the charges per day for each DRG.
- The average charge for each DRG was then recomputed (excluding the statistical outliers) and divided by the national average standardized charge per case to determine the relative weight.
- The transplant cases that were used to establish the relative weight for heart and heart-lung, liver, and lung transplants (DRGs 103, 480, and 495) were limited to those Medicare-approved transplant centers that have cases in the FY 2000 MedPAR file. (Medicare coverage for heart, heart-lung, liver, and lung transplants is limited to