

Comment: Many commenters argued that the proposed payment for drug-eluting stents is inadequate and asked that CMS consider the data it has received to date from hospital claims to determine whether the proposed FY 2004 payment rate for drug-eluting stents is adequate. Other commenters requested that CMS use the most current United States data available (as opposed to data from the United Kingdom) to establish the DRG weights for FY 2004.

Some commenters noted that current DRG weights account for 1.5 stents per case, but that the number of stents per case is expected to rise because the insertion of drug-eluting stents is more technically challenging in comparison to competitive products. The commenters also noted that because drug-eluting stents are able to treat smaller vessels, more diffuse disease in diabetics, and longer lesions, a rise is expected in the stent per patient ratio. The commenters asked that CMS adjust its ratio of 1.5 stents per case to an amount closer to 2 stents per case when recalibrating the DRG weights. Another commenter explained that, based on their analysis, an average of 1.7 drug-eluting stents is used per procedure and the average cost per drug-eluting stent is \$3,195. The commenter requested that these amounts be used to compute the relative weights for DRGs 526 and 527. The commenter also noted that the payment rates for FY 2003 are higher than the payment rates for FY 2004 due to the decline in the DRG relative weights.

One commenter suggested as an alternative to increasing the weights for drug-eluting stents that payment be contingent on the type and number of stents used per procedure. The commenter recommended that CMS set up revenue codes to indicate the type and number of stents used per case and make payment approximately \$1,000 above the cost per stent.

Another commenter also noted that the demand from hospitals for drug-eluting stents is much higher than the projected 43 percent of coronary artery stent cases. The commenter estimated that 85 to 90 percent of all stent cases should be reassigned from DRGs 516 and 517 to DRGs 526 and 527. Another commenter explained that drug-eluting stents, compared with nondrug-eluting stents, have already been shown to decrease angiographic restenosis in coronary arteries by more than half, which should reduce the need for repeat procedure rates from 20 percent of cases to less than 5 percent. As a result, demand for drug-eluting stents is expected to increase and the commenter estimated that 70 percent of all coronary

artery stent cases will involve the use of drug-eluting stents. Therefore, 70 percent of all stent cases should be moved to DRGs 526 and 527 to account for drug-eluting stents instead of the 43 percent proposed by CMS.

One commenter explained that there are many added costs of using drug-eluting stents, such as that the area of blockage to be treated is to be predilated with an angioplasty balloon before and after implanting the stent, the use of intravascular ultrasound to ensure proper positioning and deployment of stents in certain cases, and increased length of time a patient spends in the cardiac catheterization laboratory. The commenter also added that percutaneous transluminal coronary angioplasty volume is expected to increase due to obesity, smoking, sedentary lifestyle, and diabetes. Therefore, the commenter recommended that CMS ensure that drug-eluting stents are adequately paid.

Response: As described above, we used data submitted to us from a survey of U.S. hospitals to evaluate our proposed methodology. Our analysis indicates that the proposed charge differential and the number of stents per procedure in our methodology are appropriate. However, we have increased our assumed utilization rate of drug-eluting stents to 69 percent from 43 percent, based on these data.

With respect to the decline in the proposed FY 2004 DRG relative weights compared to FY 2003, every year we recalibrate the DRG weights comparing the average charge per DRG to all other DRGs. The weights of one DRG can change for numerous reasons (for example, increase or decrease in total cases or increase or decrease in charges) and cause weights from other DRGs to increase or decrease due to budget neutrality.

As we proposed, we are maintaining DRGs 526 and 527 for FY 2004, and adopting the same methodology to establish the relative weights as we used for FY 2003. We have used the best available data to establish the final FY 2004 relative weights for DRGs 526 and 527 included in this final rule. We will continue to evaluate the appropriate assignment of these cases in the future.

Comment: One commenter recommended that CMS move drug-eluting stents to DRGs 516 and 517 and adjust the weights, because CMS should not provide a financial incentive for hospitals to favor one therapy when other alternatives with equal or better outcomes are available. The commenter stated further that CMS should not create an incentive that promotes a more expensive treatment for which risks and

benefits are not yet completely known. Another commenter suggested that drug-eluting stents should receive add-on payments for new technology instead of receiving their own DRG payment.

Response: We explained our rationale for creating new DRGs 525 and 526 (instead of assigning these cases to DRGs 516 or 517 or approving a new technology add-on) in the August 1, 2002 IPPS final rule (67 FR 50005) and refer the commenters to that rule for our response. We appreciate the commenter's continual input and interest in these issues.

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 (Diseases and Disorders of the Digestive System), 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).

Prior to the publication of the proposed rule, we 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: DRG 157 and DRG 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