

add-on payments for FY 2003. For similar reasons, we did not consider data on the charges for multilevel fusions in our analysis of whether this technology meets the cost threshold for FY 2004.

In its application for add-on payments for FY 2004, the applicant used data from the CMS FY 2001 Standard Analytical File for physicians and hospitals. The analysis linked a 5-percent sample of hospital spinal fusions cases with the corresponding physician claims. Because there were no ICD-9-CM codes to identify multilevel fusions in 2001, multilevel fusions were identified using CPT codes on the physician claims. Average charges were taken from actual cases used in clinical trials.

After grouping these cases into one, two, and three or more levels fused in DRGs 497 and 498 (Spinal Fusion Except Cervical With and Without CC, respectively), the applicant then calculated average charges assuming the use of the InFUSE™ for these cases. For DRG 497, the estimated single-level fusion average charge was \$41,321; for DRG 498, the estimated single-level fusion average charge was \$37,200. Because these DRGs are not currently split for different numbers of fusion levels involved, Medtronic has calculated its own standard deviation of average charges to determine the threshold for these DRGs using the 5-percent sample data. For DRG 497, the threshold (calculated by Medtronic) was \$45,646, which is greater than the estimated average charge of \$41,321 for single-level fusions noted above. For DRG 498, the threshold (calculated by Medtronic) was \$36,935, which is less than the average charges for single-level fusions in this DRG as noted above.

However, we note the thresholds to qualify for the new technology add-on payments for FY 2003 published in Table 10 of the August 1, 2002 IPPS final rule for DRGs 497 and 498 were \$58,040 and \$41,923, respectively. These thresholds were computed based on all cases assigned to these DRGs, and do not differentiate between the number of spinal levels fused. Because we are not redefining these DRGs to differentiate cases on the basis of the number of levels of the spine fused in the manner suggested by the applicant's analysis, the thresholds published in last year's final rule are applicable for a new technology to qualify for add-on payments in these DRGs for FY 2004. Therefore, because the averages calculated by the applicant for single-level fusions do not exceed the published thresholds, as proposed, we

did not approve this technology on the basis of this analysis.

The applicant also submitted data from actual cases involving the InFUSE™ with single level fusions only. The data submitted included 31 claims from 4 hospitals (only one Medicare patient was included in the sample). All 31 cases were from DRG 498. The average standardized charge for these cases was \$47,172. Based on these data, the average standardized charge exceeds the threshold for DRG 498. However, we note that this limited sample excludes any cases from DRG 497.

For discharges occurring on or after October 1, 2002, ICD-9-CM codes 84.51 (Insertion of interbody spinal fusion device) and 84.52 (Insertion of recombinant bone morphogenetic protein) are effective to identify cases involving this technology. Therefore, in an effort to resolve the difficulties in obtaining sufficient data upon which to determine whether this technology exceeds the applicable threshold in the May 19, 2003 proposed rule, we stated our intention to review available MedPAR data for the first several months of FY 2003 to identify these cases and calculate their average standardized charges to compare with the thresholds. We noted that some of these cases would involve multilevel spinal fusions, and that it would be necessary to adjust for those cases in order to remove them from the calculation of the average charges.

We have analyzed data from the March update of FY 2003 MedPAR, containing claims data for the first 6 months of FY 2003. As discussed above, accounting for a lag time in claims processing, we are assuming that this data accounts for approximately 5 months of FY 2003 discharges. We identified InFUSE™ cases by the presence of the two new ICD-9-CM codes 84.51 and 84.52, used in combination with each other. We identified 117 and 88 cases in the March 2003 MedPAR data for DRGs 497 and 498, respectively.

We standardized the charges 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, and calculated an average standardized charge of \$64,931 for the 117 cases in DRG 497. For DRG 498, the average standardized charge was \$58,266 for the 88 cases in our data. The average standardized charge across both DRGs was \$62,752. As we noted in the proposed rule, we anticipate that some of these cases will involve multilevel

spinal fusions. Based on the applicant's analysis of FY 2001 Standard Analytical File data in which they were able to distinguish between one, two, and three or more levels fused by using CPT codes on the physician claims, we determined that the average charges of single level fusions were about 78 percent of the average charges across all spinal fusions in the analysis. (It was not possible to independently match records from the Standard Analytical File in the time available after we attained the March 2003 MedPAR data.) However, as noted above, these data are from FY 2001 and did not include any cases involving InFUSE™. Therefore, we anticipate more of the cases in our data will be single-fusion cases, consistent with the FDA approval, and that the total charges in our data for single-level fusion cases will be higher than 78 percent of the average for all InFUSE™ cases in our data. Given the relatively recent approval by the FDA of this product, we anticipate the majority of uses are in accordance with the FDA's approval criteria. Therefore, to estimate the average standardized charges of the single-level spinal fusion cases in our data, we estimated 90 percent of the average standardized charges of all the InFUSE™ cases in our data would approximate the charges for single-level cases.

Finally, because these were FY 2003 cases compared to FY 2002 thresholds (based on FY 2001 cases), we adjusted the average charges (by the market basket) to be consistent with the FY 2002 thresholds. The resulting average standardized charge for the cases from our FY 2003 MedPAR data for all InFUSE™ cases across both DRGs 497 and 498 was \$53,376.

We then calculated the case-weighted threshold amount across DRGs 497 and 498 based on the proportion of cases in our data in each DRG. Since 57 percent of the cases we identified in our database were in DRG 497, we applied this percentage to the threshold amount for DRG 497 of \$58,040. We then added this amount to 43 percent of the threshold amount for DRG 498, for a combined threshold amount of \$51,121. Because our data indicates that the average standardized charge for single-level InFUSE™ cases exceeds this threshold amount, this technology has met the cost criteria to qualify for new technology add-on payments.

Because the technology meets the cost threshold based on the MedPAR data, we evaluated whether it qualifies as a substantial clinical improvement. According to the applicant:

"InFUSE™ Bone Graft is more appropriate to use and has been proven