

Response: As stated above, we discussed our position on this issue in detail in the September 7, 2001 final rule (66 FR 46905). Our rationale for this policy has not changed since we discussed it in that final rule, and we did not propose changes to this policy in the May 19, 2003 proposed rule. Therefore, we are denying this application for add-on payments for FY 2004.

4. Review of the High-Cost Threshold

The current cost threshold for a new technology to qualify for add-on payments is that the average standardized charges of cases involving the new technology must be demonstrated to exceed 1 standard deviation beyond the geometric mean of the standardized charges of the DRG to which the new technology will be assigned. If the new technology is assigned to more than one DRG, the qualifying threshold is equal to the case-weighted (based on the proportion of cases involving the new technology estimated to be assigned to each DRG) average threshold across all relevant DRGs. When we established this threshold in the September 7, 2001 final rule, we expressed our belief that it is important to establish a threshold that recognizes the variability in costs per case within DRGs and maintains the fundamental financial incentives of the IPPS (66 FR 46917).

In commenting on this approach, MedPAC and some hospital associations supported the 1 standard deviation threshold. However, others, particularly representatives of the manufacturers of new technology, have argued this threshold is too high, and that virtually no new technology would qualify for the special payment provision.

We are concerned that establishing higher payments for a great number of new technologies may be inflationary because the add-on payments reduce the efficiency incentives hospitals face when new technologies must otherwise be financed out of current payments for similar cases. Traditionally, under the IPPS, new technologies were required to compete with existing treatment methods on clinical and cost criteria. Add-on payments are intended to give new technologies a competitive boost relative to existing treatment methods with the goal of encouraging faster and more widespread adoption of new technologies.

Much of the current variation around the mean within any particular DRG is due to the range of procedures contained within each DRG. Generally, some of these procedures will be more expensive than the mean and some will

be less expensive. The threshold should be set high enough to ensure that it identifies truly high-cost technologies. If the threshold were set too low (for example, at \$2,500, as some have suggested), additional technologies may qualify merely by association with a procedure only slightly more costly than the mean for the DRG.

For example, consider a DRG with five different procedures and mean charges of \$15,000. The mean charges for each procedure are distributed around \$15,000, as illustrated in the following table. A qualifying threshold of \$2,500 would result in any new technology that is only used for the fifth procedure automatically qualifying for new technology add-on payments (unless the new technology had the unlikely effect of lowering the mean cost for cases with this procedure by at least \$2,500). This is because the average charge of \$20,000 for cases in this procedure already exceeds the mean charges for the DRG plus \$2,500.

Procedure	Mean charge
1	\$10,000
2	12,000
3	15,000
4	17,000
5	20,000

At the same time, we recognize that the very limited number of applications that have been submitted the past 2 years (five for FY 2003; two for FY 2004) may indicate that only a very small number of the new technologies that come onto the market every year are costly enough even to apply for new technology add-on payments. Therefore, for FY 2005 and subsequent fiscal years, in the May 19, 2003 proposed rule, we proposed to reduce the threshold to 75 percent of 1 standard deviation beyond the geometric mean standardized charge for all cases in the DRG to which the new medical service or technology is assigned (§ 412.87(b)(3)).

Based on our analysis of the thresholds for FY 2004, this proposed change would reduce the average threshold across all DRGs to qualify for the add-on payments from approximately \$9,900 above the mean standardized charges for each DRG to approximately \$7,400. This reduction would maintain the averaging principles of the IPPS while easing the requirement somewhat to allow more technologies to qualify. Furthermore, the situation illustrated above, where a technology qualifies on the basis of its association with a high cost procedure, is much less likely to occur as a result

of this reduction than if the threshold were reduced dramatically.

Comment: Some commenters were concerned that the revised threshold of 75 percent of the standard deviation remains too high. The commenters noted that even with the revised cost threshold, few technologies would qualify for add-on payments.

On the assumption that the vast majority of technologies that would qualify for add-on payments would be identified by a new ICD-9-CM procedure code, one commenter identified a total of 26 ICD-9-CM procedure codes issued between the years of 1998 and 2001. The commenter then analyzed 2001 MedPAR data and found that only 2 of the 26 procedures will exceed either the current 1 standard deviation threshold, and 4 would exceed the a threshold at 75 percent of 1 standard deviation. The commenter also explained that the proposed reduction of the threshold is only an 8-percent reduction, and continues to block eligibility for add-on-payments for important new technologies, even where costs increase by 70 percent. The commenter recommended that CMS use a threshold based upon 75 percent of the standardized amount inflated to charges, plus the geometric mean charges for the DRG. The commenter identified 13 of the 26 procedures that would qualify using this threshold.

Another commenter asked that CMS consider adopting separate criteria for biologics and devices, because they have different price levels and pricing patterns relative to drugs and relative to DRG standardized amounts. Other commenters recommended a threshold where the cost of the technology must exceed the cost of existing technologies by at least 50 percent of the DRG standardized amount, multiplied by the DRG weight, but not to exceed \$7,500.

One commenter was concerned that, because of budget neutrality, any reduction to the threshold for new technologies would allow more technologies to qualify for add-on payments and would therefore reduce payments for all other hospital inpatient services. The commenter explained that shifting money within the IPPS leaves some hospitals without additional money they need to ensure beneficiaries have access to the newest medical tests and treatments. Therefore, the commenter recommended that add-on payments continue to be limited to new, cutting-edge, breakthrough technologies with significant cost implications.

Response: As stated in the August 1, 2002 final rule (67 FR 50011), it is our intention to implement this provision without fundamentally disrupting the