

IPPS. A substantial number of cases receiving extra cost-based payments (or substantial disaggregation of the DRGs into smaller units of payment) would undermine the efficiency incentives of the DRG payment system. Also, we continue to believe a threshold based on the standard deviation is appropriate for this purpose. (For further reading on this, see the September 7, 2001 final rule (66 FR 46917).)

The DRG system is an average-based system under which hospitals expect to finance costly cases through less costly cases. We believe the add-on policy envisioned by some commenter, that would reduce the maximum threshold across all DRGs to 75 percent of the standardized amount (approximately \$3,300) adjusted to charges, would significantly disrupt the averaging principles of the IPPS. By assuming only 26 new technologies over a 4-year span, the analysis presented by the commenter dramatically underestimates the annual volume of new technologies that would be likely to meet such a reduced threshold. Industry sources cite over 1,000 companies producing medical devices, diagnostic products, and medical information systems in the U.S., producing over \$70 billion worth of products annually. A very limited number of these products receive specific ICD-9-CM procedure codes, particularly in years prior to the establishment of the IPPS new technology add-on policy. A more accurate estimate of the number of technologies likely to be approved under this revised threshold could be attained by listing the technologies approved during that period with the average wholesale price.

As stated above, we recognize the limited number of applications for add-on payments that have been submitted in the past 2 years and, therefore, we are lowering the threshold. We believe this new threshold is a fair balance that maintains the averaging principles of the IPPS while easing the qualifying requirement. Therefore, for FY 2005 and subsequent fiscal years, we are reducing the threshold to 75 percent of 1 standard deviation (based on the logarithmic values of the charges) beyond the geometric mean standardized charges for all cases in the DRG to which the new medical service or technology is assigned, transformed back to charges.

We disagree with the commenter's suggestion that we establish separate thresholds for biologics and devices. We believe the IPPS is intended to pay hospitals for their costs to treat patients, and physicians select from a range of options based on the medical needs of the patients. The payment system

should be neutral with respect to those options. We are concerned that establishing separate thresholds for biologics and devices would indicate an inappropriate payment preference for one or the other option.

Comment: Other commenters representing hospitals approved of the threshold proposed by CMS. One commenter explained that a threshold that limits the number of new technologies is necessary, as the administrative burden for hospitals and the program is significant for each additional item qualifying. Given the finite pool of funds, an abundance of qualifying technologies could result in prorata reductions, such as those that were experienced under the outpatient prospective payment system. With that in mind, the commenter asked that CMS look at other approval mechanisms that would direct the funds to be focused on significantly expensive new technologies that also have significant volumes nationally. For example, national expenditures projected by CMS for each technology seeking approval should exceed \$30 million. Assuming national total expenditures of \$75 billion with a 1 percent set aside at \$750 million, and a marginal cost at 50 percent, 25 technologies could be approved by CMS.

As an alternative, the commenter recommended that CMS incorporate new technologies into the appropriate DRG without having to specifically code the new technology. The DRG weights would then be adjusted to reflect the increased costs associated with such new technologies rather than making a separate add-on payment. The commenter believed this would be a reasonable compromise between the need to incorporate new technologies into the DRGs, while avoiding an unduly burdensome coding and billing process.

Response: We believe the incremental costs to hospitals associated with this provision should be minimal. Specifically, the additional payments are triggered by the presence of an ICD-9-CM code on the bill, information already required to process the claim for normal DRG payments. Accordingly, there should be little need for training or other operational changes in response to the approval of a new technology for add-on payments.

Also, adding further criteria as suggested by the commenter would make it even more difficult for new technologies to qualify for add-on payments. In this final rule, it is our intention to lower the threshold in order to increase the number of applications we receive each year for add-on

payments. With respect to the commenter's suggestion to incorporate a new technology in a DRG and raise the weight of the DRG based on the increased cost of the new technology, we are concerned that this suggestion would have the potential to create possibly large imbalances in the DRG weights if the predicted volume of a particular technology turns out to be inaccurate. We believe an add-on payment is the most appropriate methodology to provide additional payments for qualifying high cost new technologies, while still maintaining the overall integrity of the DRG system.

5. Technical Changes

Subpart H of part 412 describes payments to hospitals under IPPS. We have become aware of references to the calculation of IPPS payments in this subpart that inadvertently omit references to new technology add-on payments. For example, § 412.112(c) describes the basis for per case payments. This section refers to outlier payments under subpart F, but was not revised to reflect the implementation of the new technology add-on payments. Therefore, in the May 19, 2003 proposed rule, we proposed to amend § 412.112(c) to add a new paragraph (d) to include a reference to additional payments for new medical services or technologies under subpart F.

We did not receive any comments on this proposal and, therefore, are adopting it as final.

Section 412.116(e) currently states that payments for outlier cases are not made on an interim basis. That is, for hospitals receiving payments under a biweekly, lump-sum payment methodology, outlier payments are not included in the calculation of the lump-sum payment amounts. Rather, outlier payments are calculated on a case-by-case basis. Similarly, due to the unique nature of the new technology add-on payments, in the May 19, 2003 proposed rule, we proposed that they would also be calculated on a case-by-case basis rather than included in the calculation of interim payment amounts. Therefore, we proposed to revise § 412.116(e) to include this policy.

We did not receive any comments on this proposal. Therefore, in this final rule, we are adopting the proposal as final without modification.

III. Changes to the Hospital Wage Index

A. Background

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary must adjust the