

the Act specifies that the process must apply to a new medical service or technology if, "based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate." Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered "new" if it meets criteria established by the Secretary after notice and opportunity for public comment.

Section 412.87(b)(1) of our existing regulations provides that a new technology will be an appropriate candidate for an additional payment when it represents an advance in medical technology that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries (see the September 7, 2001 final rule (66 FR 46902)). Section 412.87(b)(3) provides that, to receive special payment treatment, new technologies meeting this clinical definition must be demonstrated to be inadequately paid otherwise under the DRG system. To assess whether technologies would be inadequately paid under the DRGs, we established this threshold at one standard deviation beyond the geometric mean standardized charge for all cases in the DRGs to which the new technology is assigned (or the case-weighted average of all relevant DRGs, if the new technology occurs in many different DRGs). Table 10 in the Addendum to this proposed rule lists the proposed qualifying criteria by DRG, based on the discharge data that we are using to calculate the proposed FY 2004 DRG weights. The thresholds that will be published in the final rule for FY 2004 will be used to evaluate applicants for new technology add-on payments during FY 2005.

In addition to the clinical and cost criteria, we established that, in order to qualify for the new technology add-on payments, a specific technology must be "new" under the requirements of § 412.87(b)(2) of our regulations. The statutory provision contemplated the special payment treatment for new technologies until such time as data are available to reflect the cost of the technology in the DRG weights through recalibration (no less than 2 years and no more than 3 years). There is a lag of 2 to 3 years from the point a new technology is first introduced on the market and when data reflecting the use of the technology are used to calculate the DRG weights. For example, data from discharges occurring during FY 2002 are used to calculate the proposed

FY 2004 DRG weights in this proposed rule.

Technology may be considered "new" for purposes of this provision within 2 or 3 years after the point at which data begin to become available reflecting the costs of the technology. After we have recalibrated the DRGs to reflect the costs of an otherwise new technology, the special add-on payment for new technology will cease (§ 412.87(b)(2)). For example, an approved new technology that received FDA approval in October 2002 would be eligible to receive add-on payments as a new technology at least until FY 2005 (discharges occurring before October 1, 2004), when data reflecting the costs of the technology would be used to recalibrate the DRG weights. Because the FY 2005 DRG weights will be calculated using FY 2003 MedPAR data, the costs of such a new technology would likely be reflected in the FY 2005 DRG weights.

Similar to the timetable for applying for new technology add-on payments during FY 2004, we are proposing that applicants for FY 2005 must submit a formal request, including a full description of the clinical applications of the technology and the results of any clinical evaluations demonstrating that the new technology represents a substantial clinical improvement, along with a significant sample of data to demonstrate the technology meets the high-cost threshold, no later than early October 2003. We are proposing that a complete database must be submitted no later than mid-December 2003. Complete application information is available at our Web site at: <http://www.cms.hhs.gov/providers/hipps/default.asp>. To allow interested parties to identify the technologies under review before the publication of the annual proposed rule, the Web site also lists the tracking forms completed by each applicant.

The new technology add-on payment policy provides additional payments for cases with high costs involving eligible new technologies while preserving some of the incentives under the average-based payment system. The payment mechanism is based on the cost to hospitals for the new technology. Under § 412.88, Medicare pays a marginal cost factor of 50 percent for the costs of the new technology in excess of the full DRG payment. If the actual costs of a new technology case exceed the DRG payment by more than the estimated costs of the new technology, Medicare payment is limited to the DRG payment plus 50 percent of the estimated costs of the new technology.

The report language accompanying section 533 of Public Law 106-554 indicated Congressional intent that the Secretary implement the new mechanism on a budget neutral basis (H.R. Conf. Rep. No. 106-1033, 106th Cong., 2nd Sess. at 897 (2000)). Section 1886(d)(4)(C)(iii) of the Act requires that the adjustments to annual DRG classifications and relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. Therefore, we account for projected payments under the new technology provision during the upcoming fiscal year at the same time we estimate the payment effect of changes to the DRG classifications and recalibration. The impact of additional payments under this provision would then be included in the budget neutrality factor, which is applied to the standardized amounts and the hospital-specific amounts.

Because any additional payments directed toward new technology under this provision must be offset to ensure budget neutrality, it is important to consider carefully the extent of this provision and ensure that only technologies representing substantial advances are recognized for additional payments. In that regard, we indicated that we would discuss in the annual proposed and final rules those technologies that were considered under this provision; our determination as to whether a particular technology meets our criteria to be considered new; whether it is determined further that cases involving the new technology would be inadequately paid under the existing DRG payment; and any assumptions that went into the budget neutrality calculations related to additional payments for that new technology, including the expected number, distribution, and costs of these cases.

To balance appropriately the Congress' intent to increase Medicare's payments for eligible new technologies with concern that the total size of those payments not result in significantly reduced payments for other cases, we set a target limit for estimated add-on payments for new technology under the provisions of sections 1886(d)(5)(K) and (L) of the Act at 1.0 percent of estimated total operating prospective payments.

If the target limit is exceeded, we would reduce the level of payments for approved technologies across the board, to ensure estimated payments do not exceed the limit. Using this approach, all cases involving approved new technologies that would otherwise receive additional payments would still receive special payments, albeit at a