

determined that LTC-DRG 90 (Simple Pneumonia and Pleurisy Age >17 Without CC) would display similar clinical and resource use characteristics and have a similar length of stay to LTC-DRG 91. There were over 25 cases in LTC-DRG 90. Therefore, it would not be assigned to a low volume quintile for the purpose of determining the LTC-DRG relative weights. However, under our established methodology, LTC-DRG 91, with no LTCH cases, would need to be grouped to a low volume quintile. We identified that the low volume quintile with the closest weight to LTC-DRG 90 (0.7318; see Table 11 in the Addendum to this final rule) would be low volume quintile 2 (0.7372; see Table 11 in the Addendum to this final rule). Therefore, we assign LTC-DRG 91 a relative weight of 0.7372 for FY 2004.

Furthermore, we are providing LTC-DRG relative weights of 0.0000 for heart, kidney, liver, lung, pancreas, and simultaneous pancreas/kidney transplants (LTC-DRGs 103, 302, 480, 495, 512, and 513, respectively) for FY 2004 because Medicare will only cover these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified.

Based on our research, we found that most LTCHs only perform minor surgeries, such as minor small and large bowel procedures, to the extent any surgeries are performed at all. Given the extensive criteria that must be met to become certified as a transplant center for Medicare, we believe it is unlikely that any LTCHs would become certified as a transplant center. In fact, in the nearly 20 years since the implementation of the IPPS, there has never been a LTCH that even expressed an interest in becoming a transplant center.

However, if in the future a LTCH applies for certification as a Medicare-approved transplant center, we believe that the application and approval procedure would allow sufficient time for us to determine appropriate weights for the LTC-DRGs affected. At the present time, we are only including these six transplant LTC-DRGs in the GROUPE program for administrative purposes. Since we use the same GROUPE program for LTCHs as is used under the IPPS, removing these LTC-DRGs would be administratively burdensome.

Again, we note that as this system is dynamic, it is entirely possible that the number of LTC-DRGs with a zero volume of LTCH cases based on the system will vary in the future. We used the best most recent available claims data in the MedPAR file to identify zero

volume LTC-DRGs and to determine the relative weights in this final rule.

Table 11 in the Addendum to this final rule lists the LTC-DRGs and their respective relative weights, geometric mean length of stay, and five-sixths of the geometric mean length of stay (to assist in the determination of short-stay outlier payments under § 412.529) for FY 2004.

E. Add-On Payments for New Services and Technologies

1. Background

Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies under the IPPS. Section 1886(d)(5)(K)(ii)(I) of 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. As discussed below, for applicants for new technology add-on payments for FY 2005, we are establishing the criteria that will be applied to assess whether technologies would be inadequately paid under the DRGs 75 percent of 1 standard deviation (based on the logarithmic values of the charges and transformed back to charges) 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 final rule lists the qualifying criteria by DRG, based on the discharge data that we used to calculate the FY 2004 DRG weights. The

thresholds that are published in this 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 FY 2004 DRG weights in this final 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, 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. Applicants must submit a complete database 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