DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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Medicare Program; Payments for New Medical Services and New Technologies Under the Acute Care Hospital Inpatient Prospective Payment System

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule establishes a mechanism for increased Medicare payments for new medical services and technologies furnished to Medicare beneficiaries under the acute care hospital inpatient prospective payment system. The rule implements section 533 of the Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000; and finalizes related regulatory provisions that were addressed in a proposed rule published in the **Federal Register** on May 4, 2001 (66 FR 22646).

EFFECTIVE DATE: This final rule is effective October 9, 2001.

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SUPPLEMENTARY INFORMATION:

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I. Background

Section 1886(d) of the Social Security Act (the Act) sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Under the prospective payment system, we pay for inpatient hospital services on a rate per discharge basis that varies according to the diagnosis-related group (DRG) to which a Medicare beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG relative to the average resources used to treat cases in all DRGS.

On December 21, 2000, Congress passed the Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554). Section 533 of Public Law 106–554 requires the Secretary to establish a mechanism to recognize the costs of new medical services and technologies under the hospital inpatient prospective payment system by October 1, 2001, and to report to Congress on ways to more expeditiously incorporate new services and technologies into the DRG system under the hospital inpatient prospective payment system.

II. Issuance of Proposed Rule

On May 4, 2001 (66 FR 22646), as part of the annual hospital inpatient prospective payment system proposed rule, we proposed a mechanism to recognize the costs of new medical services and technologies and qualifying criteria for payments for these services and technologies. We received 61 public comments (which are addressed throughout this preamble) on our proposed criteria to qualify for this special payment and on the proposed mechanism to pay for qualifying new technologies. Due to this large number of public comments, we decided not to finalize the proposed mechanism and qualifying criteria in the FY 2002 hospital inpatient prospective payment system final rule (August 1, 2001, 66 FR 39828), but to publish a separate final rule.

In the August 1, 2001 hospital inpatient prospective payment system final rule, we indicated that although we intend to establish the mechanism by October 2001, we will not make additional payments under the mechanism for cases involving new technology during Federal fiscal year (FY) 2002 because it is not feasible. This is due to the timing of the enactment of Public Law 106–554 on December 21, 2000, the requirement that we establish the mechanism through notice and an opportunity for public comment, and the requirement that the payments be implemented in a budget neutral manner. That is, it was not feasible to establish the criteria by which new technologies would qualify through a proposed rule with opportunity for public comment as part of the May 4, 2001 proposed rule, finalize those criteria in response to public comments, allow technologies to qualify under those criteria, and implement payments for any qualified technologies in a budget neutral manner. Making the special payments in a budget neutral manner requires an adjustment to the standardized amounts (which must be published in final by August 1 each year) that we use to pay acute care hospitals under the prospective payment system.

III. Incorporating New Medical Services and Technologies in the Hospital Inpatient Prospective Payment System

Much attention recently has focused on how well Medicare incorporates the cost of new medical services and technologies into its payment systems. Of particular concern is the adequacy of Medicare's payment systems in facilitating access to new technologies for Medicare beneficiaries. Thus, section 533 of Public Law 106–554 was enacted. The discussion that follows addresses the requirements of section 533 of Public Law 106–554 for establishing a mechanism for recognizing the costs of new medical services and technologies, and for reporting to Congress on the ways to more expeditiously incorporate new services.

A. Overview

Medicare payment for an inpatient hospital discharge under the inpatient

prospective payment system is determined by multiplying the relative weight associated with a particular DRG by the national average standardized amount (adjusted for other hospital characteristics such as a geographic wage index, teaching status, and treating a high percentage of low-income patients). Cases are classified into DRGs for payment under the prospective payment system based on the principal diagnosis, up to eight additional diagnoses, and up to six procedures performed during the stay, as well as age, sex, and discharge status of the patient. The diagnosis and procedure information is reported by the hospital using codes from the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM). The DRG relative weights are recalculated each year to reflect the average resources expended across all hospitals to treat patients within a particular DRG.

In general, the inpatient prospective payment system makes payments for new medical services and technologies as soon as these items are payable. New items or services generally fit within existing DRGs, and hospitals using these items and services will be paid at established payment rates for the applicable DRGs. Payment rates subsequently may be adjusted through the annual process of evaluating the assignment of cases within DRGs and recalculating the relative weights associated with each DRG based on average charges. These annual adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources.

Since the prospective payment system was first implemented in October 1983, the pace of innovation in medical technology has been rapid. Generally speaking, the system appears to have accommodated these innovations without occasioning significant concerns regarding access to new technologies. In its March 2001 report to the Congress, the Medicare Payment Advisory Commission stated ''the design of the inpatient PPS [prospective payment system] makes it easier to ensure an appropriate distribution of payments while accommodating technological advances'' (page 44).

B. Current Practice—Coding and Payment

A number of issues arise relating to present methods of incorporation of new technologies in the inpatient hospital prospective payment system. One issue is the appropriate ICD–9–CM code to be assigned to the new technology. This issue is discussed in detail below. Assuming the new technology is or can be covered by Medicare, a determination must be made concerning to which DRG should the new technology be assigned. The DRG (and the value of the relative weight associated with that DRG) to which the new technology is assigned determines the payment rate for the new technology. Under the DRG system, the condition of the patient is the primary consideration in the decision to assign a new technology to a DRG. Therefore, a new technology generally will be assigned to the same DRG as the DRG's predecessor technologies and treatment modalities. In this way, hospitals can receive payment for new technology under the inpatient hospital prospective payment system quickly. As use of the new technology diffuses among hospitals, we have gradually and largely automatically recalibrated DRG payment rates based on hospital claims data to reflect increasing or decreasing costs of cases assigned to the DRG. Generally, it takes 2 years for claims data to be reflected in recalibrated DRG weights. Considering the actual costs as reflected in the claims data, we may also reassign new technologies to different DRGs. However, because a new technology is often more costly initially than the predecessor technologies, the adequacy of the initial payment rate occasionally becomes an issue.

At present, if payment is to be made other than by routine assignment of the new technology to an existing DRG, it is necessary to establish a new ICD–9–CM code. The lag between application for a new code and its being made effective for payment is at least a year. Because we use actual charge data from hospitals, additional costs or savings from the new technology are not reflected in the DRG weight for 2 years after a new code is effective. For example, the costs or savings attributable to any new technologies that were assigned new ICD–9–CM codes effective October 1, 1999, will be reflected in the DRG relative weights effective for discharges on or after October 1, 2001.

The lag before new technology affected payment has been viewed by some observers as a useful check on payment changes, helping to ensure that these changes reflect the benefit of a new technology. Hospitals would adopt and utilize the new technology, it was reasoned, with a speed and to a degree commensurate with its medical advantages. Any differences in the resource requirements between the new and existing technologies would then be reflected over time in claims data and in changes in the DRG weights. To the extent particular new technologies may have been initially given relatively low payment, the design of the system provided incentives to compensate by achieving efficiencies elsewhere. Conversely, if a particular new technology reduced costs compared to existing technologies, hospitals would reap the payment benefits until such time as the DRG weights began to reflect the lower costs.

C. Current Practice—Data

Recently, we provided an explicit avenue to permit more rapid payment adjustment through use of additional data. The Conference Report that accompanied the Balanced Budget Act of 1997 (Pub. L. 105–33) stated that ''in order to ensure that Medicare beneficiaries have access to innovative new drug therapies, the conferees believe that HCFA [now CMS] should consider, to the extent feasible, reliable, validated data other than Medicare Provider Analysis and Review (MedPAR) data in annually recalibrating and reclassifying the DRGs'' (H.R. Conf. Rep. No. 105–217, 105th Cong., 1st Sess., at 734 (1997)). The MedPAR data contains records for all Medicare hospital discharges and is the source data used for DRG recalibration. Although we had never precluded the use of non-MedPAR data, we established an explicit process for the submission of such data in a manner consistent with the annual recalibration of the DRG weights. We stated in the July 30, 1999 **Federal Register** that, in the case of external data, a significant sample of the data should be submitted by August 1, approximately 8 months prior to the publication of the proposed rule. This would allow us to verify and test the data and make a preliminary assessment as to the feasibility of the data's use (64 FR 41499). Subsequently, a complete database must be submitted no later than December 1, approximately 4 months prior to the publication of the proposed rule. On the issue of the use of sample data, we stated in the **Federal Register** that we were not establishing specific criteria regarding sample sizes or data collection methodologies prior to gaining experience that would enable us to realistically reflect the availability of external data based on actual experience. We also encouraged anyone interested in submitting such data in the future to contact us to discuss the specific data they wish to submit and whether the data may be adequate.

D. New Legislation

Section 533 of Public Law 106–554 addresses the issue of how new technologies are introduced into the DRGs, and how DRG payment rates must be adapted to accommodate them. Specifically, the provision requires that the Secretary:

- Not later than April 1, 2001, submit a report to Congress on methods of expeditiously incorporating new medical services and technologies into the clinical coding system.
- Not later than October 1, 2001, implement the preferred methods described in the report.
- Effective October 1, 2001, establish a mechanism to recognize the costs of new medical services and technologies after notice and opportunity for public comment.
- Establish criteria to identify new medical services or technologies after notice and an opportunity for public comment.

E. DRG Assignment Issues

As background for discussion of how the DRGs should be changed to better accommodate new technology, this section will discuss the rationale for basing the initial DRG assignment on patient condition. The underlying assumption of the prospective payment system is that because hospitals are responsible for the delivery of care they can respond to the incentives to control costs inherent in the system. The success of any payment system that is predicated on providing incentives for cost control is almost totally dependent on the effectiveness with which the incentives are communicated. The DRGs were designed to be a management tool that is used also as the basis for prospective payments. The key distinction between a management tool and payment method is the ability of the hospital to use the information to take action in response to the incentives in the system. Thus, a management tool communicates information in a form and at a level of detail that can lead to specific actions. The effectiveness of any incentive-based payment system is enhanced if the payment method is simultaneously a management tool.

Because the DRGs were developed to group clinically similar patients, an extremely important means of communication between the clinical and financial aspects of care was created. DRGs provided administrators and physicians with a meaningful basis for evaluating both the process of providing care and the associated financial impacts. Development of care pathways by DRG and profit-and-loss reports by DRG product lines became commonplace. With the adoption of these new management methods, length of stay and the use of ancillary services dropped dramatically.

The DRGs not only provided a communications tool for hospital management, but they also provided an effective means for hospitals and Medicare to communicate. Instead of accountants and lawyers arguing the fine points of cost accounting, the focus of payment deliberations became the determination of a fair payment rate for patients with specific clinical problems. The vast majority of modifications to the DRGs since the inception of the Medicare inpatient hospital prospective payment system have resulted from recommendations from hospitals. The recommendations have almost always been the result of clinicians identifying specific types of patients with unique needs. A recent example of such a clinical dialogue relates to the DRGs for burns. The FY 1999 update to the DRGs included a major restructuring of the burn DRGs. This restructuring was the direct result of detailed and specific clinical recommendations provided to CMS by burn specialists.

Central to the success of the Medicare inpatient hospital prospective payment system is that DRGs have remained a clinical description of why the patient required hospitalization. We believe it would be undesirable to transform DRGs into detailed descriptions of the technology and processes used by the hospital to treat the patient. If such a transformation were to happen, the DRGs would become largely a repackaging of fee-for-service without the management and communication benefits. A fundamental assumption underlying DRGs is that the hospital has the responsibility for deciding what technology and process to employ in treating a particular type of patient. As hospitals in the aggregate make treatment decisions, these decisions are reflected in the DRG payment weights. The separation of the clinical and payment weight methodologies allows a stable clinical methodology to be maintained while the payment weights evolve in response to changing practice patterns. The packaging of all services associated with the care of a particular type of patient into a single payment amount provides the incentive for efficiency inherent in a DRG-based prospective payment system. Substantial disaggregation of the DRGs into smaller units of payment, or a substantial number of cases receiving extra payments, would undermine the incentives and communication value in the DRG system.

F. Coding Issues

To permit us to identify use of a new technology on hospital claims and hence to make different payments than would otherwise be applicable, we would require a code that can be used to specify when that technology is used.

1. Process for Establishing New Codes

The ICD–9–CM Coordination and Maintenance Committee is responsible for discussing potential changes to ICD–9–CM. This is a Federal interdepartmental committee, co-chaired by the National Center for Health Statistics (NCHS) and CMS. The NCHS has lead responsibility for the ICD–9–CM diagnosis codes, while CMS has lead responsibility for the ICD–9–CM procedure codes. The Committee holds meetings twice a year, usually in May and November. Agendas for the discussions about procedure codes are published on CMS' Internet website a month before the meeting. A **Federal Register** notice is also published listing topics to be discussed. The meetings are open to the public and are held usually in Baltimore, Maryland. Shortly afterwards, an extensive summary of the meeting is published on CMS' website and the public is given an additional opportunity to comment. Final comments are due by early January. A complete, current timeline is included in the Summary Report of the Committee at: *www.hcfa.gov/medicare/icd9cm.htm.*

For a topic to be discussed at one of the two yearly meetings of the Committee, the Committee must receive a request 2 months prior to the meeting. This timeframe allows CMS to publish the agendas in the **Federal Register** notices and allows individuals and organizations to review the agenda and to determine if they wish to attend the public meetings. The timeframe is also necessary to allow the Committee to research the topic and prepare a draft solution in time for the meeting. During the meetings, the Committee provides a brief description of the topic (such as a new technology that may not be adequately identified by the current code) and then describes the technology or procedure through a formal presentation. Frequently, medical experts who perform the procedure make a presentation to describe the procedure and how it might be different from other procedures in the current code. Proposals are made to either continue capturing the procedure in the existing code, revise existing codes, or create a new code. The public then discusses the merits of the proposals and offers any alternate suggestions.

The ICD–9–CM is updated once a year, effective October 1. This date coincides with the annual updates to the DRGs within the inpatient hospital prospective payment system. Each spring we publish a proposed rule that includes proposed changes to the inpatient hospital prospective payment system. This notice also includes final decisions on changes to ICD–9–CM codes. By August 1, we publish the new codes in the Addendum to ICD–9–CM, which is a technical presentation of actual changes to be made in both the index and tabular sections of the ICD–9–CM coding books. The Addendum is available on CMS' website and is also sent to organizations such as the American Hospital Association (AHA) and the American Health Information Management Association (AHIMA) to distribute to their members. By October 1 of each year, the Department of Health and Human Services also produces a CD–ROM version of the ICD–9–CM, which may be purchased through the Government Printing Office. Since the ICD–9–CM is not a copyrighted system, many publishers and organizations distribute and sell books or other publications that include the changes to ICD–9–CM.

Although the Committee's process for discussing proposed changes to the ICD–9–CM fully involves and informs the public, the deliberative nature of the process does require some time. Topics discussed at the May and November 2000 meetings of the Committee are for changes to ICD–9–CM in October 2001. Therefore, depending on whether a request is considered at the May or November meeting, resulting changes may not be effective for approximately a year to a year-and-a-half later.

2. Options To Expedite the Implementation of Coding Changes

Several constraints upon the system would complicate implementing extensive changes. One significant complication is the interaction between the DRG system and the ICD–9–CM diagnosis and procedure codes (in the case of new services and technologies, the discussion focuses on procedure rather than diagnosis codes). When a new procedure code is created, a decision must be made as to whether the new code affects DRG assignment (for example, resulting in a case being assigned to a surgical rather than a medical DRG). Currently, new technology is generally assigned to the same DRG as its predecessor codes. Even if new codes do not affect DRG assignment, the GROUPER software (used to assign cases to DRGs) must be reprogrammed to recognize and classify all the new codes. This is necessary to allow Medicare's claims processing systems to process the claim.

In addition to the changes to the GROUPER software, implementing changes to ICD–9–CM codes is a detailed and far-reaching process involving modifications to code books and software coding systems, as well as changes to hospitals' claims processing systems. As described above, the current process is organized around the annual publication of coding changes in the **Federal Register** as part of the updates and changes to the inpatient hospital prospective payment system. The changes are made available during the summer, and communicated via multiple channels to hospitals. This process allows for the necessary processing changes to be thoroughly tested prior to implementation, both by CMS and by the hospitals. This testing procedure is essential given the volume (generally 11 million claims annually) and dollar impact (approximately $76 billion during FY 2002) of Medicare inpatient discharges.

Another important issue when considering expediting the process of making coding changes is that the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected (section 1886(d)(4)(C)(iii) of the Act). If ICD–9–CM changes were made at multiple times during the year, the budget neutrality requirement would mean the standardized amounts, and potentially the cost outlier thresholds, would change as well. These changes would compromise the prospective nature of the payment system, whereby hospitals are able to project their revenues for the year and plan accordingly. Because we do not believe the requirement in section 533 of Public Law 106–554 to explore ways to expedite coding changes was intended to disrupt the prospective nature of the payment system, we did not consider options that would require revising the DRG weights and the standardized amounts more than once a year.

With these considerations in mind, in the May 4, 2001 proposed rule, we explored the potential for shortening the current process.

First, we proposed to move the November meeting of the Coordination and Maintenance Committee to December. To move it further would disrupt the process for production of the annual inpatient prospective payment system regulation. This step would shorten the code assignment process by a month and permit coding changes resulting in payment changes to be implemented within a year.

Second, we proposed to expedite the process by issuing new coding decisions resulting from the spring meeting of the Committee (currently in May) that would be effective the following October 1. We also stated it may be necessary to move the May meeting to April to accommodate this change. Because the timing of this process would not allow the coding changes to be incorporated into the proposed rule published in the spring, cases with the new codes would have to be assigned to the same DRG to which they would have been assigned without the new code and no other payment adjustments would be possible. These coding changes would thus not affect the DRG weights or the budget neutrality calculations. However, more rapid introduction of new codes would permit reflection of the codes in claims data more quickly, and thus would permit eventual adjustment of payment rates sooner than otherwise possible. This capability could be of particular use where otherwise available data were not sufficient to support an immediate payment change, because hospital claims data permitting identification of use of the new technology would be available more quickly.

This proposed change would reduce the time between discussion of a proposed code and its implementation from a minimum of 11 months to 6 months. It would allow for the collection of MedPAR data a full year earlier than under the current process, providing the possibility that DRG revisions based on new codes could be expedited by up to 1 year.

As noted in the May 4, 2001 proposed rule, there would be significant challenges to making this proposed process work. Because the changes would not be included in the proposed rule published in the spring, the public would be given less opportunity to consider the merits of the proposals, and it would have to either attend the spring meeting of the Committee or respond to the summary report within a few weeks. The decisions from the spring meeting must be finalized by the middle of June in order for us to include the changes in the Addendum to ICD–9–CM and in order to make changes in the GROUPER software to be effective October 1; it may be necessary to schedule the spring meeting earlier to meet this deadline. The opportunity to solicit additional input from industry groups and experts would be curtailed because of the short time lines. There would be an increased risk of errors related to revisions in the procedure

code index (a manual process performed by CMS), as there would be less time available to review and revise the procedure index to ensure that all changes are accurately reflected.

For example, in the final rule published on August 1, 2001 (66 FR 40065), we created a new procedure code to capture percutaneous gastrojejunostomy (code 44.32). All coding instructions (indexing, inclusion terms, and exclusion terms) must be verified so that the procedure is appropriately indexed. If one of the many index entries for gastrojejunostomy is not correctly updated, percutaneous gastrojejunostomy would be assigned to another gastroenterostomy (code 44.39), which is an operating room procedure. This can have a significant impact on national health care data. Coders at different hospitals may follow different entries and arrive at different codes. To limit the potential for confusion in the hospital and coding communities resulting from two separate schedules for implementing code changes, we proposed to limit these changes to those that meet our definition of new technology eligible for special treatment as described below. Under the proposal, it would not be necessary, however, to demonstrate that the cases involving the new technology would be inadequately paid, since there would be no payment impacts of these changes.

The changes would be included in the Addendum to ICD–9–CM for the inpatient hospital prospective payment system, and placed on the website for use by the industry in updating books and software systems. They also would be published in the final rule, and included in the CD–ROM version of ICD–9–CM that is distributed by the Government Printing Office.

Comment: Comenters generally supported changing the ICD–9–CM Coordination and Maintenance Committee meetings from May and November to April and December each year. They believed this would provide a greater opportunity to have topics considered in a timely fashion. The commenters also supported implementing codes discussed at the April meeting the following October. Commenters recommended that all topics discussed at the April meeting be implemented the following October, and disagreed that these more rapid changes should be limited to new technologies. One commenter wrote that it would be confusing to implement procedural coding decisions from a single Coordination and Maintenance Committee meeting in two different years.

One commenter expressed concern regarding the scheduling of Committee meetings in December and April. The commenter was concerned that, by implementing code changes from the April meeting as part of the October updates, the proposed DRG assignments would not be included in the proposed rule usually published in the spring for the fiscal year that begins October 1. The commenter stated that this would be a major concern to the hospital industry because hospitals need time to comment on all proposed changes to the DRGs, analyze the changes for budgeting, train staff on coding changes, and implement software changes.

Response: We appreciate the support of the majority of the commenters that Committee meetings should be held in April and December of each year to expedite the revision of ICD–9–CM codes and are adopting the proposed change in the schedules as final. We will begin this revised schedule in calendar year 2002. The meeting scheduled for November 1 and 2, 2001, will be held as scheduled because many organizations have already planned their travel schedule around these days. The spring 2002 meeting is currently scheduled for April 18 and 19, 2002.

We also agree, based on the comments, that attempts should be made to include all proposals discussed and approved at the April meeting as part of code revisions the following October. This may not always be possible if additional issues are raised that require analysis and further research. Therefore, with the extremely short timelines from the April meeting to publication of the final addendum in June, we encourage those seeking new codes to submit complete documentation for consideration prior to the April meeting. We note that we are retaining the requirement that requestors must notify the Committee 2 months prior to the meeting in order to have an issue addressed.

We acknowledge the commenter's concern that, by implementing code changes discussed at the April meeting by the following October, there will not be the opportunity to propose DRG reclassifications associated with these new codes in the annual proposed rule published in the spring. Therefore, as stated above, these new codes will be assigned to (and paid according to) the same DRG as their predecessor technology. The DRG classifications of these new codes will be discussed in the annual final rule.

There will also be less time to communicate and prepare for the changes. Nevertheless, we believe the requirement to expeditiously incorporate new technology into the ICD–9–CM coding system necessarily entails tradeoffs.

Comment: One commenter questioned why new codes approved by the Committee at its April meeting could not be published in the proposed rule. The commenter noted that the proposed rule has not been published until May the last several years.

Response: The preparation of the proposed rule and the calculations associated with the proposed payment rates begin in January and February. In particular, if a code is being proposed for reassignment to another DRG, it is necessary to perform calculations of the payment effects of such a change to ensure budget neutrality. Therefore, even though the actual publication of the proposed rule may occur after the Committee's meeting has been held, it would not be possible to incorporate coding changes approved at the April meeting in time for publication in the proposed rule.

Comment: Commenters argued that a 23-month delay could still exist after new codes for new technologies are approved by the Committee before actual payment is available to hospitals for these new technologies. For example, if a new technology is introduced after the October deadline for consideration at the December ICD–9–CM Coordination and Maintenance Committee meeting, the earliest such a technology could qualify for special new technology payments under section 533 of Public Law 106–554 would be almost 2 years later, when a new ICD–9–CM code would become effective.

Response: The commenter is incorrect that payment would not be available to hospitals for a new technology until a new code is effective. After the Committee approves a new technology for an ICD–9–CM code, coders would assign the new technology to an appropriate existing code until such time as a new code, if necessary, could be established. Payment would be made in accordance with the DRG to which that existing code was assigned.

We believe that product sponsors will anticipate when their new products will come to market and begin the process of attaining a new code (if necessary) to coincide with the introduction of the product into the marketplace. That is, it is unlikely that a new product coming onto the market in November could not have been anticipated in time for consideration at the December Committee meeting (requests must be submitted by October for consideration at the December meeting). Therefore, we believe the actual time between the marketing of a new product and the

effective date of a new ICD–9–CM code to capture the associated procedure would generally be substantially less than 23 months.

Comment: Several commenters representing hospital groups strongly urged us to continue with annual updates to ICD–9–CM. They stated that more frequent code changes would be burdensome to hospitals. They further stated that ICD–9–CM changes require coding personnel to become familiar with the new codes and their systems, clinical data abstraction systems, laboratory systems, order-entry systems, as well as decision-support systems.

Commenters pointed out that some hospitals, especially small and rural hospitals, do not have automated encoding systems and coding personnel do not have access to the Internet. These hospitals utilize books to assign codes. They added that keeping up with a quarterly change in ICD–9–CM codes would be quite a challenge unless code book publishers adopted a quarterly update publication schedule. Several commenters stated that hospitals had great difficulty with the quarterly coding changes introduced with the outpatient hospital prospective payment system. Another commenter stated that the complexity associated with quarterly updates and billing requirements should be of utmost concern and must be avoided.

Other commenters representing medical technology manufacturers supported more frequent changes to ICD–9–CM. One commenter suggested that codes be changed twice a year, after each ICD–9–CM Coordination and Maintenance Committee meeting. The commenter believed that vendors that provide new technologies and the providers that use them would be motivated to accurately report any new codes as soon as possible. The commenter pointed out that the only constraint to issuing codes twice a year would be the need to update software programs such as the Clinical Data Editor which lists current ICD–9–CM codes. The commenter believed that because many software companies update their software quarterly, this should not be a problem.

Several commenters recommended that codes be updated quarterly. They believed this would lead to more rapid data gathering on new technologies. One commenter suggested that because DRGs are updated once a year, the new codes created on a quarterly basis be assigned to existing DRGs. Another commenter recommended updating the DRGs on a quarterly basis along with quarterly updates of ICD–9–CM codes.

Finally, a commenter emphasized the need to decouple the introduction of new codes from payment determinations. The commenter believed this will allow the expedited introduction of new codes without disrupting the prospectivity of the payment system.

Response: We agree that it is important to update ICD–9–CM in an organized and timely fashion. As some of the commenters suggested, coding changes have a great impact on other activities such as software development and coding book updates. When the codes are changed, all software using these codes must be updated. Code books would also have to be updated, at an expense to hospitals.

We understand the desire for more expeditious introduction of new codes from the perspective of tracking the data associated with new technology. However, we also understand the concerns expressed in the comments submitted by the hospital community with introducing new ICD–9–CM codes on a more frequent basis than annually. We believe the change to the ICD–9–CM Coordination and Maintenance Committee meetings discussed above appropriately balances these concerns. We will continue to pursue ways to further expedite the introduction of new codes.

Comment: Several commenters disagreed that the introduction of new codes and the assignment of those codes to DRGs at multiple times during the year would compromise the prospective nature of the payment system.

Response: Our statement in the proposed rule that changes to the ICD–9–CM codes at multiple times during the year would compromise the prospective nature of the payment system assumed these changes would affect the DRG assignment and, therefore, the payments for affected cases. We agree that, if the coding changes had no impact on payment, the principles of certainty and predictability that underlie the prospective payment system would not be compromised. However, as reflected in the previous comment and response, implementing new ICD–9–CM codes at multiple times during the year would be a labor-intensive, and thereby costly, undertaking for hospitals.

Comment: Some commenters recommended that the Committee hold three meetings a year. Other commenters that addressed this issue supported plans to hold two meetings a year.

Response: To date, the Committee has been able to sufficiently address requests by lengthening the time allotted for meetings as opposed to adding additional meetings. This has worked well in the past. Should the need arise, we will consider scheduling a third meeting. For now, we plan to hold only two meetings a year.

Comment: Several commenters supported the open process involved with the ICD–9–CM Coordination and Maintenance Committee. They also supported the continuance of this process.

Response: We agree that the open process involved with the Committee has worked well. These open meetings allow the public to fully evaluate proposed changes to ICD–9–CM. Those participating in the meetings have brought expertise in coding, medicine, data systems, as well as code book preparation to the discussions. This has consistently led to useful changes to the coding system. Frequently, these discussions lead to alternate suggestions on how to resolve coding problems. We will continue this open process for updating ICD–9–CM.

Comment: One commenter suggested that procedures associated with a new technology for which the Food and Drug Administration (FDA) has issued an ''approvable letter'' should be provided an ICD–9–CM procedure code. According to the commenter, the FDA may issue an approvable letter setting forth the actions that must be taken before final approval.

Response: One of the questions asked by participants at the Committee meetings is whether or not the procedure is investigational. The public participants tend to oppose the creation of new codes for relatively new, unproven procedures. They usually recommend waiting to see how widespread the technology will become. Because of space limitations in the code book, the public participants tend to recommend waiting to see if the device or procedure is approved by the FDA. We will continue to discuss new procedures at the Committee meetings. On occasion, we may discuss procedures or devices that are under FDA investigation. As is currently the case, public participants at the meetings will be given the opportunity to discuss whether or not the code is needed.

3. Limitations of ICD–9–CM

While the updating process currently in use may not lend itself to expeditiously incorporating new medical services and technologies into the ICD–9–CM coding system, another important factor is the dated and limited structure of the ICD–9–CM system. The ICD–9–CM system was developed in the 1970s and implemented in 1979.

Dramatic advances have occurred in medicine since that time. Although the ICD–9–CM Coordination and Maintenance Committee has attempted to make coding modifications to capture new technology, it has sometimes been difficult to achieve a reasonable result.

The ICD–9–CM procedure codes are made up of four digits: two numerical characters followed by a decimal, and then two additional numerical characters. The first two digits indicate a category, such as 36—Operations on the vessels of the heart. The third digit provides additional breakdown, such as 36.0—Removal of coronary artery obstruction and insertion of stents. When the fourth digit is added, the code is fully described. There are only 10 codes available within each category (fourth digits 0–9). Once a category is full, we must either combine types of similar procedures under one code, or find a place in another section of the code book for a new code. The benefit of such a system is that we can collapse the codes into categories when analyzing claims data to capture a wide range of similar procedures. However, if similar codes are placed in separate sections of the code book, coders may not easily find them. Errors may occur when trying to identify particular types of cases when codes are not carefully placed within a system such as the current ICD–9–CM.

ICD–9–CM is 22 years old and the premises on which the coding system was established are dated. A number of approaches and techniques used for procedures such as lasers and the use of scopes were not anticipated when the structure of ICD–9–CM was developed. Consequently, the basic categories were established on technology that is now outdated. Making needed coding changes each year has been quite difficult and involves making compromises that effect the precision of the coding.

4. Short-Term Solutions Within the ICD–9–CM Structure

To consider how we might better respond to requests for new codes in the short term, we examined ICD–9–CM to attempt to identify an open series of codes that could be used for new procedures and technologies. There are currently 16 categories of procedure codes. However, codes 17.00 through 17.99 are not in use. These codes are found between category 3, ''Operations on the Eye,'' and category 4, ''Operations on the Ear.'' This series of 100 codes could be used to provide codes for new procedures and technology. To fully utilize this new series of codes, we would assign new procedures to the next available code.

A limitation of this approach would be that this category would capture a diverse group of procedures potentially affecting all body systems. Assigning diverse procedure codes to this category would undoubtedly create considerable confusion for coders. Currently, procedures are grouped by body system, and similar procedures are placed in categories. This arrangement assists the coder in choosing the most appropriate code because he or she can quickly review closely related codes that are together. Using category 17 for new technology codes, on the other hand, would mean that closely related codes would be widely separated.

Use of category 17 would also require a major revision of coding rules since coders are taught to identify codes within a group of similar procedures. They are not accustomed to looking for a list of unrelated procedures in a separate section of the coding book.

To supplement the category 17 codes, the Coordination and Maintenance Committee may be able to assign vacant codes in other categories. However, large numbers of sequences are already fully or nearly fully occupied, and this strategy would only provide limited availability of new codes.

Comment: Several commenters supported the need to develop short-term solutions to the limitations of ICD–9–CM. They generally supported creating a new series of codes in category 17 of ICD–9–CM for new technologies. However, some commenters stressed the need to assign new codes to the appropriate place in the body of ICD–9–CM as the first priority. They believed this will maintain the structure of ICD–9–CM and reduce confusion. They recommended that only when unused codes within the appropriate section of ICD–9–CM are not available should category 17 codes be used.

One commenter pointed out another series of unused procedure codes: the codes in category 0 (codes 00.00 through 00.99). The commenter suggested using these codes when slots are not available in the appropriate section of ICD–9–CM. The commenter further recommended that we use codes from category 0 prior to using the codes in category 17.

Response: We agree with the commenters that new codes should be created in the appropriate section of ICD–9–CM as a first priority. Only when there are no available slots in other chapters should codes be created in category 17. We also agree that using codes 00.00 through 00.99 is an excellent idea. Using these two empty categories would create 200 available slots for new codes. We will discuss this issue as part of the ICD–9–CM Coordination and Maintenance Committee meetings.

Comment: One commenter supported the use of category 17 of ICD–9–CM for new procedures, but pointed out that ICD–9–CM was designed to report the procedure performed, not the device or other specific technology used. The commenter went on to state that ICD–9–CM was never intended to report information on a single procedure reflecting a single technology or a single manufacturer's technology. The commenter also suggested that if new codes were created for individual devices instead of groups of similar procedures, the available empty codes would be quickly used up.

Response: We agree with the commenter that ICD–9–CM should continue to develop new codes for new types of procedures. We do not believe it should be converted to a system which tries to identify all new devices created by individual manufacturers. We believe the ICD–9–CM Coordination and Maintenance Committee should continue to evaluate the merits for requests for new codes and consider them in the context of the structure and limitations of ICD–9–CM.

5. Alternative Short-Term Approaches

Some observers have expressed concern that the additional codes available within the ICD–9–CM code set may not be adequate to accommodate both routine changes in coding and the new technologies under consideration, particularly if a long-term change, such as adoption of ICD–10—Procedure Coding System (ICD–10–PCS), is significantly delayed. We have examined several alternative short-term options in the event the additional available codes are used before a long-term solution is reached. In evaluating these alternatives, we must consider the changes each entails to hospitals' and CMS' coding and claims processing systems, and the time necessary to implement such changes (balanced against the timeframe for adopting a long-term coding solution).

Expanding ICD–9–CM procedure codes by making them alphanumeric or adding a fifth digit would make available a substantial number of new codes for new technology but would require substantial system changes and create standards issues. This approach was extensively discussed in meetings of the ICD–9–CM Coordination and Maintenance Committee prior to the development of ICD–10–PCS. Input from the public indicated that such a

significant modification to a limited and dated system would only make the system worse. The time it would take to make this system work well would be longer than that required to build a new system and the resources needed for system changes would be significant. Such a modification of the ICD–9–CM standard code set would require the formal standards modification and adoption process prescribed by the regulations implementing the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191.

Using the V-code section of ICD–9–CM diagnosis codes to report new technology would not require any systems changes or create any standards issues and would create a moderate number of codes for new technology. We have discussed this recommendation with NCHS. NCHS opposed this option as an inappropriate use of diagnosis codes. While ''V'' codes are used for the classification of factors influencing health status and contact with health services, they are not a substitute for procedure coding. By adding procedure coding concepts to the diagnosis coding system, confusion could easily lead to increased errors. Furthermore, the V-code section has only a limited number of available spots.

We also considered using HCFA (the Health Care Financing Administration was recently renamed the Centers for Medicare & Medicaid Services (CMS)) Common Procedure Coding System (HCPCS) codes to report use of new technology for inpatient cases. However, using HCPCS would require a moderate amount of systems change and would require the formal standards modification and adoption process prescribed by Public Law 104–191, since the HCPCS code set is not the standard code set prescribed for inpatient services. However, it would make a substantial number of codes available for new technology. Alphanumeric HCPCS codes are currently used in outpatient departments and physician offices for reporting services, and they are used on a limited basis by hospitals in reporting the use of hemophilia clotting factors used during an inpatient stay.

Use of HCPCS codes would require that a new service or technology either be assigned a code through otherwise applicable processes for HCPCS coding or that CMS assign a specific, temporary code for use in connection with new technology payments for inpatient hospital services. Specifically assigned codes could be assigned relatively quickly. However, use of such codes would run the risk of confusion if other codes were assigned to the same service or items when used in other settings. More generally, HCPCS coding would duplicate information found in the ICD–9–CM procedure codes. Careful attention to integration of coding across the two systems would be necessary, and dissemination of information about correct coding to hospital coders would present challenges. Even with excellent integration and dissemination, the risk of confusion by hospital coders would be high.

The use of HCPCS codes would also raise questions on how the accuracy of claims data will be assessed. CMS contracts with Peer Review Organizations to validate the accuracy of coded data. Consideration would need to be given to how the accuracy of these data could be verified. If two separate coding systems with overlapping information are used, considerable variations in reporting practices might arise.

Similar to the option of using alphanumeric ICD–9–CM procedure codes, changes in systems and in hospital coding procedures that would be associated with this approach would take time and resources to implement for hospitals, CMS, and potentially other payers such as Medicare secondary insurers.

In recognition of these considerations, we proposed not to proceed with use of HCPCS codes for this purpose at the present. We believed this possibility should be revisited later if the ICD–9–CM codes in fact prove inadequate and if a longer term solution is not yet available. However, we solicited public comments on the concept of using HCPCS codes to identify specific new technologies on inpatient hospital claims.

Comment: One commenter suggested that V codes be used in combination with existing procedure codes to act as a flag and differentiate the new technology procedures from the old procedures. The commenter suggested that the following new V codes be created to identify new technology:

V00 Admission/Encounter for New Technology Procedures

The following categories would be used to identify new technology:

V00.0 New Technology—Drugs
V00.1 New Technology—Musculoskeletal/Integumentary
V00.2 New Technology—Respiratory, Nose, Throat
V00.3 New Technology—Cardiovascular
V00.4 New Technology—Digestive System
V00.5 New Technology—Urinary
V00.6 New Technology—Genital System/Male and Female
V00.7 New Technology—Nervous System
V00.8 New Technology—Eye, Ear
V00.9 New Technology—NEC/NOS

The commenter suggested that we use these codes beginning October 1, 2001. If this were not possible, the commenter suggested that we implement the codes after discussion at the next meeting of the ICD–9–CM Coordination and Maintenance Committee.

Another commenter opposed the use of V codes as a way of supplementing the procedure codes. The commenter believed that this was an inappropriate use of diagnosis codes. The commenter stated that the ICD–9–CM diagnosis codes have space constraints as well. The commenter suggested that it is possible that there might not be sufficient available codes to meet the need for new procedure codes, but using available V codes for procedures would seriously restrict the ability to create new diagnosis codes when necessary.

Response: The use of V codes for new technology is on the agenda to be discussed at the November 1, 2001 meeting of the ICD–9–CM Coordination and Maintenance Committee. The NCHS is responsible for the diagnosis part of the meeting. However, it should be mentioned that previous discussions at the meeting have not been supportive of proposals such as this. This use of diagnosis codes to help identify procedures or technologies is contrary to the usual structure and content of ICD–9–CM diagnosis codes.

Moreover, it would not be possible to implement the use of V codes as recommended by the commenter on October 1, 2001. The addendum to ICD–9–CM, which lists code revisions, has already been distributed. Software vendors and publishers have already begun preparing their coding products. We believe the Committee should continue its open process of discussion of code revisions in this regard. To implement a code change without providing the public an opportunity to comment would not be consistent with that process.

Comment: One commenter opposed expanding ICD–9–CM procedure codes by making them alphanumeric or adding an additional digit. The commenter believed that this approach would be difficult and costly to implement. The commenter also stated that it would essentially convert ICD–9–CM into a new coding system, and thus the system would not be a ''short-term'' approach, as it would have to undergo

the formal standards modification and adoption process of Public Law 104–191. In addition, the commenter stated that, if a new procedure coding system is going to be formally adopted through the standards modification and adoption process, it should be ICD–10–PCS, which is a significant improvement over ICD–9–CM.

Response: We agree with the commenter's explanation for why it would be unwise to initiate a process of modifying ICD–9–CM procedure codes involving the use of alphanumeric characters or the addition of digits, as this effort would utilize extensive resources and offer few overall improvements.

Comment: Several commenters supported our proposal not to use HCPCS codes for inpatient claims. The commenters stated that hospitals have had great difficulty with the quarterly coding changes introduced with the outpatient prospective payment system. One commenter stated that some hospitals have not been able to keep their systems current with the onslaught of HCPCS coding changes, especially the device pass-through C-codes. The commenter also stated that many hospitals have separate coding staffs for inpatient records and for outpatient records. The commenter further stated that introducing HCPCS coding into the inpatient Medicare reporting system would create significant burdens and training issues and that there would also need to be information system changes to activate the HCPCS codes.

Another commenter opposed the use of both HCPCS codes and CPT codes on inpatient claims. The commenter stated that the use of another procedure coding system in addition to ICD–9–CM for inpatient claims increases the complexity and destroys clinical analysis capability of the DRG system.

Several commenters supported using HCPCS codes as procedure codes in the inpatient hospital setting. One commenter urged CMS to adopt the same process it uses for the outpatient hospital prospective payment system, in order to expedite the assignment of temporary new technology codes that qualify for additional payment under the inpatient hospital prospective payment system.

One commenter supported the use of level two of HCPCS codes for new technology, but not for all medical services and technology. The commenter stated that the best approach would be to use a combination of HCPCS and ICD–9–CM procedure codes to report new medical services and new technologies. The commenter supported the continued use of ICD–9–CM procedure codes for any new service or technology that represents a new procedure. However, if the new service or technology represents an item, drug, or device, as opposed to a procedure, then a HCPCS code should be assigned. This commenter did not support the use of temporary HCPCS codes (for example, G codes) in connection with new technology payments for inpatient hospital services, as this could result in duplicative or overlapping codes among different coding systems. The commenter recommended that new items, drugs, or devices meeting the definition of new technology should be assigned a HCPCS code through the usual HCPCS process. Consideration should also be given to the feasibility of implementing new HCPCS codes more frequently than once a year. The commenter also stated that a number of payers already report HCPCS codes in Form Locator 44 on the billing form (UB–92). The commenter recommended that CMS approach the National Uniform Billing Committee to explore this option.

Response: We agree that introducing HCPCS coding into the inpatient system as a solution to limitations with ICD–9–CM would be burdensome to hospitals and increase the complexity and confuse the logic of the inpatient hospital coding scheme. In addition, HCPCS codes could not be used for reporting diagnosis and treatment of hospital inpatients unless and until the HCPCS code set was formally adopted under the modifications and adoption procedures required for national standards under Public Law 104–191. As noted above, using categories 0 and 17 of ICD–9–CM appears to offer workable short-term solutions. As discussed below, a longer term solution is the adoption of a more flexible coding system such as ICD–10. Therefore, we are not introducing the use of HCPCS codes for inpatient use at this time.

Comment: One commenter recommended that we require the use of Universal Product Numbers (UPNs) as a means of reporting all new medical devices qualifying as new technologies. The commenter mentioned that there are currently two industry standards with different formats for UPN codes. The commenter recommended that both of these formats be accepted, and added that the UPNs would facilitate the use of a bar code that would assist in ordering, tracking, and validating inventory. The commenter also stated that the use of UPNs would substantially reduce administrative costs. The commenter recommended that UPN codes be incorporated into the existing ICD–9–CM coding system—the ICD–9–CM procedure code descriptor would identify the procedure and the UPN code would then make clear which products qualify as new technologies.

Response: We have been exploring the use of UPN codes for ambulatory bills. Since this coding system is not currently in widespread use, it was not selected as one of the national standards for medical coding under Public Law 104–191. If UPN codes were to be implemented, they would first have to be evaluated under the standards modification and adoption procedures for designating national standards under Public Law 104–191. Designating any new coding system as a national standard is a lengthy process that involves public discussions as well as proposed and final rulemaking. We will continue our process of evaluating UPN codes as a future national coding standard.

6. Development of ICD–10–PCS; A Possible Long-Term Solution

While acknowledging the limitations of the ICD–9–CM coding system, the Secretary designated the ICD–9–CM coding system as the national standard for reporting, among other things, diagnosis and treatment of hospital inpatients, in a final rule published in the **Federal Register** on August 17, 2000 (65 FR 50311), following notice and comment rulemaking in accordance with Public Law 104–191. In that same final rule, the public was advised that ICD–10–PCS has great promise as a future replacement of ICD–9–CM. However, it was also noted that ICD–10–PCS, at that time, required additional testing and revision prior to a decision on whether to use it as a national standard. At that time, work was proceeding on an updated variant of the ICD system, ICD–10, that could replace ICD–9–CM, but this system was not yet completed. The World Health Organization developed ICD–10 as an international diagnosis coding system. NCHS has been modifying ICD–10 to replace the diagnosis section of ICD–9–CM. This system is being referred to as ICD–10–CM. At the same time, CMS has been developing the ICD–10–PCS as a possible replacement for the ICD–9–CM procedure codes.

Criteria for the development of a new procedure coding system were established in 1993 by the National Committee on Vital and Health Statistics (NCVHS) in a report concerning recommendations for a single procedure classification system. The criteria included the following:

- Completeness—all substantially different procedures have a unique code.

• Expandability—the structure of the system allows incorporation of new procedures and technologies as unique codes.

• Standardized terminology—the coding system includes definitions of the terminology used. While the meaning of the specific words can vary in common usage, the coding scheme does not include multiple meanings for the same term. Each term is assigned a specific meaning.

• Multiaxial—the system has a multiaxial structure with each code character having the same meaning within the specific procedure section and across procedure sections to the extent possible.

• Diagnostic information is not included in the procedure description.

Using these criteria, CMS developed the ICD–10–PCS through a contract with 3M Health Information Systems. The ICD–10–PCS system provides much greater code capacity because all substantially different procedures have a unique code. While the ICD–9–CM procedure coding system is limited to a maximum of 10,000 codes, the current draft of ICD–10–PCS contains 197,769 codes and the number could be expanded further.

7. Public Meeting on Implementing ICD–10–PCS

The Department of Health and Human Services is starting the process of soliciting public comments on whether it should proceed to adopt ICD–10–PCS as the national standard for coding inpatient hospital services to replace the ICD–9–CM procedures code set. A public meeting on this issue was held May 17, 2001, in the CMS Auditorium in Baltimore, Maryland. The complete report summarizing the results of that meeting, including the presenters' position papers, can be found at: *http://www.hcfa.gov/medicare/icd9cm.htm*. The public was encouraged to attend and participate in the discussion on whether ICD–10–PCS should become a national standard. Organizations and groups were given the opportunity to make a brief presentation on their members' behalf.

Comment: Several commenters supported the ICD–10–PCS as a long-term solution for replacing the ICD–9–CM. One commenter noted the number of interested parties during the May 17, 2001 ICD–9–CM Coordination and Maintenance Committee meeting who endorsed ICD–10–PCS. Other commenters suggested that we coordinate the implementation of ICD–10–PCS at the same time as the ICD–10–CM diagnosis code set. One commenter objected to the potential adoption of ICD–10–PCS.

Response: We agree that ICD–10–PCS is the best long-term solution to replace ICD–9–CM. As mentioned earlier, organizations were given the opportunity to submit a position paper and make a presentation on this issue. Several organizations requested the opportunity to present on this issue. The position papers developed are posted as part of the Summary Report of the ICD–9–CM Coordination and Maintenance Committee. The presenters' remarks summarized these position papers. The following are excerpts from the position papers.

''ICD–10–PCS represents a significant improvement over ICD–9–CM and substantially meets the characteristics of a procedural coding system outlined by the NCVHS as described above. ICD–10–PCS also meets all of the HIPAA requirements outlined earlier * * * Replacement with a new procedural coding system for inpatient services is absolutely necessary and ICD–10–PCS meets the criteria for such a replacement system.''

American Health Information Management Association

''AHA has worked closely with institutional members in the field-testing of ICD–10–PCS. The field-testing results are very positive. Results indicate that ICD–10–PCS can easily accommodate the expansion of new procedure codes. Coders working with ICD–10–PCS also found the new system to be efficient, logical, and easy to understand and learn * * * Based on the testing, the new procedure classification system holds a great deal of promise and should be considered for future use * * * Therefore, the AHA supports the HIS industry in requesting that ICD–10–PCS implementation be carried out in tandem with the migration to ICD–10–CM.''

American Hospital Association

''Our position is that ICD–9–CM is not adequate for long-term future use and that providers, payers, and Medicare beneficiaries would be well served by a conversion to ICD–10–PCS.''

Federation of American Hospitals

''Based on AMA's support for the elimination of complex regulatory burdens mandated by the Medicare program, the AMA does not support the adoption of ICD–10–PCS. The AMA believes that the implementation of ICD–10–PCS will only add to the regulatory burden faced by physicians and other health care providers. ICD–10–PCS is a substantial departure from ICD–9 and from all existing health care code sets. As a result, it would require significant resources to implement and problems inherent in the system suggest that it may not be worth the cost.''

American Medical Association

''ASHA appreciates having had the opportunity to provide input on the development of this system and is pleased to see that many of our recommendations have been incorporated into the final version of the ICD–10–PCS * * *. Again, ASHA supports the implementation of the ICD–10–PCS as a replacement for Volume 3 of the ICD–9–CM.''

American Speech-Language Hearing Association

''AdvaMed supports the rapid adoption of the International Classification of Disease, Procedural Coding System, 10th Edition (ICD–10–PCS), for use in hospital inpatient billing* * *It is a system that has been developed over the past decade with substantial input from the clinical community and offers tremendous versatility in describing the differences in the use and characteristics of medical technologies.''

AdvaMed

''The transition from ICD–9–CM to ICD–10–PCS will help enhance the quality of care available for Medicare beneficiaries and provide better management tools for healthcare professionals * * * ICD–10–PCS should be implemented to bring our coding system up to the standards of the rest of the world, to improve our ability to understand the impact on procedure and technology selection on patient outcomes, and to provide better options for paying hospitals appropriately for the care they provide.''

Medical Technology Partners

''Importantly, ICD–10–PCS has the capacity to grow as medical science grows * * * ICD–10–PCS may have the flexibility and durability to span this century—a statement that cannot be made about any other medical coding system currently proposed or in use. A coding system that could be updated decade after decade would provide an unprecedented continuity of medical data.''

Ingenix Syndicated Content Group

''We believe that the ICD–10–PCS fulfills these criteria, and we urge the Health Care Financing Administration to implement the ICD–10–PCS as a national standard for coding inpatient procedures as quickly as possible.''

Princeton Reimbursement Group

The only organization presenting at the meeting that did not support the adoption of ICD–10–PCS as the national standard for inpatient procedure coding was the American Medical Association.

While it is widely acknowledged that the ICD–9–CM diagnoses and procedures coding system is dated, we are not yet ready to begin the final decisionmaking process as to which coding system will become the next national standard. The NCHS has not yet completed the final draft of ICD–10–CM diagnosis code set. While CMS has completed ICD–10–PCS and held public meetings on its possible implementation, we are not yet ready to proceed with making final recommendations. CMS believes that further action on naming new coding systems should not begin until NCHS has completed ICD–10–CM. Most

organizations commenting on this topic want decisionmaking action deferred until both systems are complete. At that time, the formal standards modification and adoption process will begin, to determine if both ICD–10–CM and ICD–10–PCS should be implemented as new standards and whether they should be implemented at the same time.

The May 4, 2001 proposed rule stated that implementation of ICD–10–CM and ICD–10–PCS could not occur before October 2003. Linking the ICD–10–PCS implementation date to ICD–10–CM could postpone such implementation well beyond 2003. To date, there has not been any public evaluation of or testimony on ICD–10–CM. In addition, ICD–10–PCS and ICD–10–CM could not be used for reporting diagnosis and treatment of inpatients until those code sets were formally adopted under the national standards modification and adoption process of Public Law 104–191. Those procedures are very involved and the process can be very lengthy.

8. Methods of Expeditiously Incorporating New Medical Services and Technologies Into the Coding System

In summary, we are developing a two-part strategy for expeditiously incorporating new medical services and technologies into the clinical coding system used with respect to payment for inpatient hospital services. First, we are shortening the timeframe for implementing new codes by processing changes without first publishing them in the proposed rule in the spring. This means new codes approved at the spring meeting of the ICD–9–CM Coordination and Maintenance Committee could be implemented by October of the same year, although the DRG assignment for these new codes would initially be the same as the predecessor technologies. We also are moving the November meeting to December (and the May meeting to April, to allow more time to implement decisions from the spring meeting by October). These changes will reduce the time it currently takes to implement new codes, as well as reduce the time required to collect data through the MedPAR by up to a year in many cases.

Second, to make more codes available to identify new technology, we will begin immediately to work with the public to use categories 0 and 17 of ICD–9–CM procedures. This will provide room for 200 additional procedure codes. We also will continue the current process of adding and revising codes within the current categories as room and structure allow. Our long-range strategy is to consider the implementation of the ICD–10–PCS and ICD–10–CM code sets as replacement systems for ICD–9–CM. However, because such a change would require proceeding in accordance with the standards modification and adoption process under Public Law 104–191, in addition to the need to revise both our payment systems and those of hospitals, this would be a lengthy process.

IV. New Requirements Relative to New Services and Technologies

Section 533(b) of Public Law 106–554 amended section 1886(d)(5) of the Act to add new subparagraphs (K) and (L) to address a process of identifying and ensuring adequate payment for new medical services and technologies under Medicare. Under new section 1886(d)(5)(K)(i) of the Act, effective for discharges beginning on or after October 1, 2001, the Secretary is required to establish (after notice and opportunity for public comment) a mechanism to recognize the costs of new services and technologies under the inpatient hospital prospective payment system. New section 1886(d)(5)(K)(ii)(I) of the Act specifies that the mechanism 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 * * * is inadequate.'' New 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).

New sections 1886(d)(5)(K)(ii) through (vi) of the Act further provide—

- For an additional payment for new medical services and technology in an amount beyond the DRG prospective payment system payment rate that adequately reflects the estimated average cost of the service or technology.
- That the requirement for an additional payment for a new service or technology may be satisfied by means of a new-technology group (described in new section 1886(d)(5)(L) of the Act), an add-on payment, a payment adjustment, or any other similar mechanism for increasing the amount otherwise payable with respect to a discharge.
- For the collection of data relating to the cost of new medical services or technology for not less than 2 years and no more than 3 years after an appropriate inpatient hospital services code is issued. The statute further provides that discharges involving new services or technology that occur after the collection of these data will be classified within a new or existing DRG group with a weighting factor derived from cost data collected for discharges occurring during such period.

In the May 4, 2001 proposed rule, we included a discussion of how we proposed to implement the provisions of section 533(b) of Public Law 106–554 (66 FR 22693). This final rule establishes a mechanism to implement those provisions.

A. Criteria for Identifying New Medical Services and Technology

New 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). (For convenience, hereafter we refer to ''new medical services and technology'' as ''new technology.'') In the May 4, 2001 proposed rule, we proposed that a new technology would be an appropriate candidate for an additional payment when, in the judgment of the Secretary, it represents an advance in medical technology that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries (proposed § 412.87(b)(1)). This proposed criterion was intended to ensure that new technology can be demonstrated to provide a substantial clinical improvement based on verifiable evidence. In the May 4, 2001 proposed rule, we proposed to make determinations regarding which new technologies meet this criterion using a panel of Federal clinical and other experts, supplemented as appropriate with outside expertise. As explained below, we also proposed that new technologies meeting this clinical definition must also be demonstrated to be inadequately paid otherwise under the DRG system to receive special payment treatment (proposed § 412.87(b)(3)). New technologies that do not meet these proposed standards would be paid through other applicable DRG payments. These payments would be recalibrated over time to reflect the actual use of the new technologies.

In addition to the clinical and cost criteria, we proposed that, in order to qualify for the special payment treatment provided under new section 1886(d)(5)(K)(ii)(I) of the Act, a specific technology must be new (proposed § 412.87(b)(2)). We believe the new provision contemplates 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 (generally 2 years). Specifically, new section 1886(d)(5)(K)(ii)(II) of the Act states that the Secretary must ''provide for the collection of data with respect to the costs of a new medical service or technology * * * for a period of not less than two years and not more than three years beginning on the date on which an inpatient hospital code is issued with respect to the service or technology.'' In addition, new section 1886(d)(5)(K)(ii)(III) states that the Secretary must ''provide for additional payment to be made * * * with respect to discharges involving a new medical service or technology described in subclause (I) that occur during the period described in subclause (II) in an amount that adequately reflects the estimated average costs of such service or technology.''

We also proposed in the May 4 proposed rule that the results of all determinations would be announced in the **Federal Register** as part of the annual updates and changes to the inpatient hospital prospective payment system (proposed § 412.87(b)(1)). In addition, we noted that this determination is separate and distinct from the coverage decision process.

We solicited comments on these proposals. In particular, given that this process is the result of new legislation with possibly major implications for the hospital inpatient prospective payment system, we invited public comment on: Our definition of new medical services and technologies; the use of Federal clinical and other experts to make determinations regarding which criteria meet our definition of a new service or technology; the information necessary to determine whether payment would be inadequate; and our payment mechanism (see the following discussions for these latter two issues).

Comment: Commenters argued that our proposed rule did not establish a clear means whereby new technologies may qualify for additional payments to be effective for discharges occurring on or after October 1, 2001. These commenters believed that section 533 of Public Law 106–554 requires new technologies to be identified and special payments to be made at that point.

Several commenters argued that particular new technologies should be recognized for special payment under this provision beginning October 1, 2001. On the other hand, a commenter representing hospitals encouraged us to proceed carefully and deliberately.

Response: Although we are establishing the methodology by which new technologies may become eligible for special payments in this final rule, we will not make additional payments under the methodology during FY 2002. This is due to the timing of the enactment of Public Law 106–554 on December 21, 2000, the requirement that we establish the mechanism through notice and an opportunity for public comment, and the requirement that the payments be implemented in a budget neutral manner. That is, it was not feasible to establish the criteria by which new technologies would qualify through a proposed rule with opportunity for public comment as part of the May 4, 2001 proposed rule, finalize those criteria in response to public comments, allow technologies to qualify under those criteria, and implement payments for any qualified technologies in a budget neutral manner. Making the special payments in a budget neutral manner requires an adjustment to the standardized amounts (which must be published in final by August 1 each year) that we use to pay acute care hospitals under the prospective payment system.

It was not possible to establish a process through proposed and final rulemaking, whereby new technologies could qualify for this special payment provision, prior to publishing a proposed rule for FY 2002. As noted previously, Public Law 106–554 was enacted on December 21, 2000. We are required to publish our proposed rule updating the standardized amounts and including other changes to the hospital inpatient prospective payment system by April 1 of each year, and to publish a final rule by August 1 of each year.

We did, however, carefully evaluate all technologies of which we were aware, including those submitted for consideration during the public comment period on the May 4, 2001 proposed rule, that might seek designation as ''new'' under this provision. All of those that were submitted during the public comment period were previously existing technologies with data already available in the MedPAR file. Therefore, they would not be eligible under our criterion to be considered new. Of new technologies that we considered prior to publication of the proposed rule, none submitted data we believe were sufficient to document that the technology would be inadequately paid under existing DRGs. However, one new technology, intravascular brachytherapy, was assigned to a higher weighted DRG based on the clinical characteristics of the procedure.

Comment: A number of comments addressed our proposed eligibility requirements for a medical service or technology to qualify as ''new technology''. Several commenters were concerned that the criteria were too vague and subjective to be implemented. Specifically, commenters took issue with the ''substantial improvement'' requirement, stating that the statute does not require such a stringent test and that the term is too subjective and cumbersome to administer properly.

The Medicare Payment Advisory Commission (MedPAC), which stated it was in general agreement with the criteria overall, commented that it would be difficult to operationalize the ''substantial improvement'' criterion, which makes judgements about the extent to which a given technology improves diagnosis or treatment. Another commenter suggested rewording the criterion to say ''substantial differences'' and stated that these differences should be measured based on diagnostic or therapeutic effects.

Other commenters, representing national associations of hospitals, supported our proposed criteria for identifying new technology, although one commenter also expressed reservations about the ambiguity of the ''substantial improvement'' criterion.

Response: As stated previously, we proposed the ''substantial improvement'' criterion to limit these special payments for those technologies that afford clear improvements over the use of previously available technologies. We believe the special payments for new technology established by this final rule should be limited to those new technologies that have been demonstrated to represent a substantial improvement in caring for Medicare beneficiaries, such that there is a clear advantage to creating a payment incentive for physicians and hospitals to utilize the new technology. Where such an improvement is not demonstrated, we continue to believe the incentives of the DRG system provide a useful balance to the introduction of new technologies.

In that regard, we would point out that various new technologies introduced over the years have been demonstrated to have been less effective than initially thought, or in some cases even potentially harmful. We believe it is in the best interest of Medicare beneficiaries to proceed very carefully with respect to the incentives created to quickly adopt new technology.

Therefore, we are adopting our proposed requirement that a new technology must represent a substantial improvement, and are clarifying the way it will be applied. We will evaluate a request for special payment for a new

technology against the following criteria in order to determine if the new technology meets the substantial improvement requirement:

• The device offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.

• The device offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that use of the device to make a diagnosis affects the management of the patient.

• Use of the device significantly improves clinical outcomes for a patient population as compared to currently available treatments. Some examples of outcomes that are frequently evaluated in studies of medical devices are the following:

◆ Reduced mortality rate with use of the device.

◆ Reduced rate of device-related complications.

◆ Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).

◆ Decreased number of future hospitalizations or physician visits.

◆ More rapid beneficial resolution of the disease process treatment because of the use of the device.

◆ Decreased pain, bleeding, or other quantifiable symptom.

◆ Reduced recovery time.

We will require the requester to submit evidence that the technology meets one or more of these criteria. We note that these criteria are not intended for use in making coverage decisions under section 1862(a)(1)(A) of the Act.

Comment: Several commenters requested that we clarify the time period in which a technology would be considered new for purposes of qualifying for this special add-on payment. The commenters noted that proposed § 412.87(b)(2) states that '' [a] medical service or technology may be considered new within 2 or 3 years after it becomes available on the market * * *.'' The commenters argued that this requirement should be clarified to state that the 2-year to 3-year period begins with the assignment of an appropriate tracking code, not the point at which the technology becomes available on the market. Several commenters indicated that this would enable previously existing technologies to qualify if they receive a new code that better enables tracking of their data.

Response: The 2-year to 3-year period referenced in section 1886(d)(5)(K)(ii)(II) of the Act is the time that is required for discharge data associated with a new technology to be reflected in the DRG weights. Therefore, the most appropriate point to begin the period during which a technology may be considered new is the point at which the technology becomes available on the market and the ICD–9–CM code issued by the ICD–9–CM Coordination and Maintenance Committee becomes effective. The 2-year to 3-year time period provided under the Act recognizes the lag between market approval and a new ICD–9–CM code becoming effective.

Technology will no longer be considered new after the point at which data begin to become available reflecting the code assigned to the technology by the Committee. We do not believe it would be appropriate to consider technologies that have been on the market for more than 2 or 3 years for approval under this provision on the basis that the Committee subsequently issues a more precise procedural code. Data reflecting the costs of these technologies are already available in the MedPAR data. We would, however, continue our past practice of evaluating whether existing procedures are appropriately classified to a DRG. To the extent the introduction of a new code for existing technology helps to better identify higher costs associated with a procedure, we would work to expedite the appropriate assignment of that code (for example, using more recent MedPAR data).

Comment: Several commenters objected to our proposal to consult a Federal panel of experts in evaluating new technology under the ''substantial improvement'' criterion. One commenter referred to the panel as an unnecessary layer of bureaucracy that should be eliminated. The commenter believed the panel would be unnecessary and that CMS should automatically deem drugs and biologicals approved by FDA through its ''fast-track'' processes as new technology.

A number of commenters requested further details regarding the composition of the panel and its review process. They requested that CMS establish clear timelines on when the panel will review applications for new technologies and publish these timelines on the CMS website. The commenters further stated that meetings of the panel should be open to the public and the meeting date and agenda announced in advance, with technology sponsors allowed to present their request at the meetings. The commenters also requested that a reconsideration process be established.

Response: The role of the Federal panel will be to evaluate whether a new technology represents a substantial improvement in the diagnosis or treatment of Medicare beneficiaries. Because there is not another body currently making such determinations, it is necessary to establish the panel. The panel will be comprised of CMS clinical staff, supplemented with coding and claims processing experts on staff at CMS. The panel may be supplemented with outside expertise as appropriate.

The panel will consider all relevant information (including FDA ''fast-track'' approval) in making its determinations. However, we do not envision an automatic approval process under this provision.

The panel will consider applications on an ongoing, ad hoc basis. As described below, the initial data submission must be no later than early October, approximately 6 months prior to the publication of the proposed annual update rule, and a complete dataset must be submitted no later than mid-December. Similarly, initial clinical data (peer-reviewed articles, study results, etc.) to demonstrate the substantial improvement associated with the new technology must be submitted by early October. This will permit the panel to request further documentation if necessary prior to reaching a decision. It will also allow time to consider whether outside expertise is needed, and, if so, to convene appropriate experts. It is anticipated that consultations with the sponsors of technologies will be utilized as necessary.

Decisions of the panel will be published in the annual proposed rule announcing updates to the inpatient prospective payment system, along with summaries of the documentation considered. This will permit the sponsors of the technology to request a reconsideration of a negative decision, as well as allow the public to evaluate the decisions and request reconsideration.

Comment: Commenters requested we clarify how subsequent versions of an approved new technology will be treated under this provision. The commenters suggested that the special payment provision should be available to any new technology that is introduced while the first eligible version of the technology is still eligible for special payment. The commenters further suggested that if the subsequent variations of the new technology are substantially similar, they should be automatically eligible for the special

payment provision. If the subsequent versions are different or broader than the initial technology, there should be an abbreviated application process available.

Response: We agree with the commenters that subsequent new technologies that are substantially similar to a currently approved (for special payment) technology should be eligible for special payment as well. Otherwise, our payment policy would bestow an advantage to the first applicant representing a particular new technology to receive approval.

Applicants would still be required to submit data showing they would be inadequately paid and that the subsequent technology meets the criterion that it be new (case data are not currently available in the MedPAR data). Once data become available to incorporate the costs of the new technology into the DRG recalibration process, subsequent versions must demonstrate they meet the substantial improvement criterion (with the previously new technology included in the comparative baseline) in order to qualify for special treatment.

For example, Company A and Company B are simultaneously developing a new technology. Company A applies and is approved for additional payments under this provision for FY 2003. Company B then submits an application to demonstrate its product is substantially similar to Company A's product, and is approved for additional payments for FY 2004. In FY 2005, data are available on Company A's product to be used for DRG recalibration. Therefore, no additional payments are made for Company A's product during FY 2005, and, because Company B's product is substantially similar to Company A's product, no additional payments will be made for Company B's product during FY 2005. Similarly, if Company A developed a variation of the new technology in FY 2005, this variation must meet all three criteria in order to be eligible (substantial clinical improvement, inadequately paid otherwise, and data unavailable for DRG recalibration).

Presumably, a substantially similar technology would be assigned the same ICD–9–CM code as the initial new technology. Because the approval of additional new technologies would affect the budget neutrality calculations and the requirement for the public to have the opportunity to review and comment on decisions that would impact on hospital payments, we will implement subsequently approved technologies through the annual notice of proposed and final rulemaking.

Comment: One commenter requested clarification whether a new use of an existing technology would qualify as new under our criteria.

Response: If the new use of the existing technology was for treating patients not expected to be assigned to the same DRG as the patients receiving the existing technology, it may be considered for approval, but it must also meet the substantial improvement and inadequacy of payment criteria in order to qualify for special payment.

Comment: One commenter requested that, when a procedure is approved as a new technology under the proposed criteria outlined in section IV.F. of the May 4, 2001 proposed rule (66 FR 22693), it automatically be issued a new ICD–9–CM code without the requestor having to contact the ICD–9–CM Coordination and Maintenance Committee.

Response: Before any procedure can be uniquely classified either within the regular DRGs or under the new technology process, it first must be identified. A procedure is identified through an ICD–9–CM code. This code may be a general code, such as for a bronchial dilation. It also may be more precise, such as for the implantation of an external, pulsatile heart-assist system. Participants at the public meetings of the ICD–9–CM Coordination and Maintenance Committee carefully evaluate the need for a new, unique ICD–9–CM code. They consider factors such as: whether or not there is an existing code that adequately identifies the procedure; whether the procedure is so unique that it warrants a unique code; whether there is room within ICD–9–CM for a new code; whether the structure of ICD–9–CM allows for the capture of the needed data; and whether documentation in the medical record will allow for the identification of the procedure to the extent specified by the proposed code.

These are very different considerations than those suggested by the criteria to qualify for special payment under this provision. Therefore, it would not be appropriate to allow technologies to bypass the Committee review process.

B. Determining Adequacy of Current Payments for New Services and Technology

Because the inpatient hospital prospective payment system includes costs associated with all aspects of a patient's stay in the hospital, it is not enough to simply identify a technology as ''new'' and pay an additional amount. A single DRG may encompass many different treatment approaches for a particular illness, with an array of costs associated with those approaches. Clinicians are expected to select the appropriate approach based on the needs of the patient, with the payments averaging out over time to approximate the level of resources needed to treat the average patient in the DRG.

Section 1886(d)(5)(K)(ii) of the Act, as added by section 533(b) of Public Law 106–554, requires that the Secretary make a determination whether the payment otherwise applicable under the existing DRG is inadequate compared to the estimated costs incurred with respect to new technology (as defined earlier in this final rule). We believe that, in order to evaluate whether the DRG payment inadequately reflects the costs of new technology, we must be able to assess the costs of cases involving the new technology against other cases in the DRG. In other words, the criteria for identifying new technology that will receive special payment treatment should reflect whether the new technology is so expensive that hospitals are unlikely to offset the higher costs with other less costly cases within the DRG. In the May 4 proposed rule, we proposed that this threshold be set at one standard deviation beyond the mean standardized charge for all cases in the DRG 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) (proposed § 412.87(b)(3)). (Standardization adjusts the actual charges of a case by the payment factors such as the wage index, the indirect medical education adjustment factor, and the disproportionate share adjustment factor.)

We proposed to make this comparison preferably using Medicare cases identifiable in our MedPAR database, although data from a clinical trial (including FDA clinical trials) where no bills were submitted for payment may be considered. To the extent possible, CMS proposed to rely on existing information in making these determinations. In most instances, the information would include the Medicare provider number of the hospital where each case was treated, the beneficiary identification numbers of the Medicare patients, the dates of admission and discharge, the charges associated with each case, and all relevant ICD–9–CM codes associated with each case (individual patient information is needed to permit matching of the hospital data with the Medicare payment file on the patient). We proposed to assess the charges of identified cases involving the new

technology, accounting for the additional costs of the new technology that might not be included in the charges if the new technology is being provided by the manufacturer as part of a clinical trial. If the costs of the new technology are not included in the total charges, we proposed to require the requestor to submit adequate documentation upon which to formulate an estimate of the likely costs to hospitals of the new technology.

We proposed that a significant sample of the data must be submitted no later than early October, approximately 6 months prior to the publication of the proposed rule. Subsequently, a complete database must be submitted no later than mid-December. This proposed timetable was necessary to allow CMS adequate time to assess and verify the data, as well as to work with the submitters to deal with any unique situations with respect to data availability. It was also necessary to allow us to accurately incorporate the data into the annual proposed rule, which we begin preparing in January. We solicited public comments on this process.

To illustrate the proposed use of the standard deviation thresholds, the proposed rule considered DRG 8 (Peripheral and Cranial Nerve and Other Nervous System Procedures Without CC). The average standardized charge of cases assigned to this DRG based on discharges during FY 2000 was $13,212, and the standard deviation was $8,978. Therefore, under our proposal, if a requestor were to seek assignment of a new technology that would otherwise be assigned to DRG 8 to a different DRG, the requestor would be expected to provide data indicating that the average standardized charge of cases receiving this new technology will exceed $22,190. We proposed that these data must be of a sufficient sample size to demonstrate a significant likelihood that the true mean across all cases likely to receive the new technology will exceed the mean for the cases in DRG 8 by one standard deviation.

We explained in the proposed rule that using standard deviation as the threshold takes into account the distribution of charges associated with different treatment modalities around the mean charge for a particular DRG, and the extent to which lower cost cases in the DRG should be expected to offset higher cost cases. Using this method, new technology in a DRG with very little variation in charges would be more likely to meet the criteria. This would be appropriate because there are fewer opportunities within such a DRG to recover the costs of very high cost cases from excess payments for very low cost cases.

In the proposed rule, we noted that, we will continue to evaluate the appropriateness of all DRG assignments. This applies not only to new technology but existing technologies as well.

Comment: Some commenters disagreed with our proposed timetable for submitting data. One commenter recommended that, if MedPAR data are available for review, the timeline for applying for consideration for this special provision should be February 1, for inclusion in the proposed rule scheduled to be published April 1 each year. If only manufacturer (non-MedPAR) data are available, the commenter recommended a deadline of December 1 for submitting data for consideration. Another commenter recommend a two-step process for submitting data, where CMS would accept the manufacturer's ''good faith estimate'' of the hospitals' acquisition costs, then validate that initial estimate based upon actual claims experience.

Response: The proposed timetable originated from the one established in the July 30, 1999 final rule (64 FR 41500). We have attempted to balance the mandate to expedite incorporation of new technology into the clinical coding system for the hospital inpatient prospective payment system with the integrity and incentives of the inpatient hospital prospective payment system. In particular, because the payments under this provision are to be budget neutral, meaning overall payments are reduced to pay for higher payments for new technology cases, it is imperative to provide adequate opportunity to validate the data submitted. If we did not validate the data, then technologies that do not warrant special payment might qualify, which means other payments might be reduced more than is appropriate under the budget neutrality adjustment.

The December 1 deadline for submitting data not currently in the MedPAR database would not allow sufficient time to process, verify, and analyze the data prior to reaching a decision by mid-January for inclusion in the proposed rule, particularly if there is a large volume of requests submitted.

In particular, because these data are not currently in the MedPAR database, it will be necessary to independently verify the data submitted, especially the costs of the technology and the DRGs where the new technology will likely be assigned.

Although the availability of data in the MedPAR database will facilitate our analyses, a February 1 deadline would be unworkable due to the lead time needed to prepare the proposed rule (DRG reclassification decisions must be completely programmed during February to complete the calculation of the proposed standardized amounts). In addition, it is unclear what data will be available in the MedPAR database. New technology under this provision is defined by the fact that data are otherwise not available to reflect the costs of the new technology in the DRG weights through recalibration. Therefore, even if some MedPAR data were available, it is presumed additional data not available in MedPAR on the costs of the new technology will be needed in all instances.

For these reasons, we believe the timetable we set forth in the proposed rule is appropriate, and we are implementing it effective for applications to be eligible for special new technology payments during FY 2003.

With regard to the two-step process suggested by the commenter, our process does accommodate the fact that actual hospital acquisition costs may not be available at the time a request is being considered. However, we require manufacturers to provide sufficient information to allow their pricing estimate to be substantiated at the time the request is being considered.

Comment: Several commenters suggested we delete the proposed requirement that a ''significant sample'' of the data be submitted no later than early October. The commenters suggested that instead we should rely on data that can be reasonably provided by the manufacturer at the time of introduction of the new technology. Furthermore, the commenters believed that any economic data required should be reasonably derived from the clinical trials conducted in conjunction with submissions to FDA for marketing approval or for an investigational device exemption. These data may include economic models that reflect manufacturer list price and other variables, as well as published data to estimate likely volume of use in Medicare patients.

Another commenter requested that we clarify that, where the charges of a new technology are not included in the charges of trial participants because the technology is provided at no cost, we will adjust the standardized charges of cases involving the new technology to reflect that fact.

Response: We agree with the commenters' characterization of the types of data that are likely to be available to demonstrate a technology would be inadequately paid. As stated

in the proposed rule and above, the timetable we established is designed to allow adequate time to assess and verify the data, as well as to work with the submitters to deal with any unique situations with respect to data availability.

Commenters may have misunderstood our reference to a ''significant sample'' of data by early October. Apart from any statistical implications of that term, we intended to convey that requestors would need to submit a sample of sufficient size to enable us to undertake an initial validation and analysis of the data. Any problems we encountered in our review of this sample of data could then potentially be addressed prior to the December deadline to submit all of the data for analysis.

Finally, in cases where charges related to a new technology are not reflected in the total billed charges for a case, we intend to rely on verifiable pricing information supplied by the manufacturer. The estimated charges of the new technology will be added to the standardized charges for determining whether the average standardized charges of a new technology meets the one standard deviation threshold.

Comment: Several commenters expressed concern that our proposed requirement that the data submitted include Medicare beneficiary patient identifiers would lead to burdensome compliance issues with respect to patient confidentiality.

Response: We appreciate the concern that our data submission requirement not place requesters in the position of potential patient privacy violations. These concerns are significant because the final rules on privacy of individually identifiable health data became effective on April 14, 2001. Health plans, including Medicare, and providers that conduct certain transactions electronically, including the hospitals that will receive payment under this final rule, will be required to come into compliance with the final privacy rules no later than April 14, 2003. The privacy rules, however, permit providers to share with health plans information needed to ensure correct payment if they have obtained consent from the patient to use that patient's data for treatment, payment, or health care operations. (See 45 CFR 164.502 and 164.506.) Since the information to be provided here is needed to ensure correct payment, no additional consents will be required. However, we will continue to evaluate the need for this information as we acquire more experience analyzing requests.

Comment: Many commenters objected to using a threshold of one standard deviation above the mean charges of other cases in the DRG for determining that a new technology would be inadequately paid. Commenters stated that, using this threshold, virtually no new technology in recent years would qualify for the special payment provision.

To illustrate the impact of the standard deviation threshold, commenters included analysis of the standard deviation for each DRG in MDC 5 (Diseases and Disorders of the Circulatory System) as a percentage of the average charges for the DRG. Across all DRGs in MDC 5, the analysis found that the standard deviation was 69 percent of the average DRG charges. Some commenters suggested alternative criteria, such as the lower of 120 percent of the base DRG payment amount, or $2,500 in average increased costs.

One commenter suggested that high-cost outlier cases should be removed from the calculation of the mean and standard deviation because these cases have a disproportionate effect on those statistics. Alternatively, the commenter suggested the threshold should be set based on the distribution of the charges using a logarithmic transformation of the arithmetic charge values. The commenter believed this would produce a more normal distribution and result in mean and standard deviation values that are less effected by outliers.

On the other hand, several commenters believed that the standard deviation threshold was appropriate. MedPAC stated that this approach maintains the case-based payment inherent in the system, and appropriately recognizes the variability in costs per case. Hospital associations also generally approved of the criteria, although at least one expressed reservations that this may result in a threshold that is too high for some DRGs. Another national hospital association, however, expressed concern that the threshold may be too low for some DRGs. This commenter suggested the threshold be set at the greater of one standard deviation or $10,000.

Response: The suggestions from the commenters reflect the divergent opinions within the healthcare community about how far this policy should go to provide special payment for new technologies. We do not believe a set minimum dollar threshold, such as $2,500 is appropriate. For many DRGs this would represent a relatively small percentage of the costs of a case. Similar to MedPAC, we believe it is important to establish thresholds that recognize the variability in costs per case within DRGs and maintain the fundamental financial incentives of the prospective payment system as much as possible. We continue to believe a threshold based on the standard deviation is appropriate for that purpose.

We did explore whether a logarithmic specification to estimate the standard deviation would be a more appropriate method in light of the concern expressed by the commenters that our proposed threshold was unduly influenced by outlier cases. We first converted the charges of all cases in each DRG to their logarithmic values, and then calculated the mean and standard deviations of those logarithmic values. Next, we added together the mean and standard deviations, and then transformed that number back to charges.

Using this methodology, the average standard deviation as a percentage of the mean charges for the DRG declines from 75 percent using the proposed methodology to 50 percent using the logarithmic transformation. The average amount by which a new technology would have to exceed the DRG charges declines as well, from $11,794 in the proposed rule, to $7,799.

We believe the standard deviation based on a logarithmic transformation of the charges is an appropriate methodology to use to establish the threshold. Charge data for most DRGs tend to be skewed toward high cost cases, and a few extremely costly cases can have a disproportionate effect on the calculation of the standard deviation. Therefore, in order to qualify for the special payment provision, a new technology must result in average charges above the DRG mean charges plus one standard deviation of charges based on the logarithmic distribution.

Comment: Several commenters pointed out that the proposed language of § 412.87(b)(3) indicated we would compare the costs of the cases involving a new medical service or technology with the average charges for all cases in the DRG. Because hospital charges are much greater than costs, this criterion further disadvantages new technologies.

Response: We agree that it would be inappropriate to require new technologies to exhibit costs in excess of one standard deviation of average charges. In this final rule, we are revising the proposed language of § 412.87(b)(3) to refer to the charges of cases involving new technologies rather than costs.

Comment: Some commenters objected to our proposal to use the case-weighted average standard deviation of all relevant DRGs for a particular new technology, rather than determining

eligibility separately for each DRG involved. The commenters believed it would be more appropriate to apply thresholds separately.

Another commenter supported our proposed approach. Several commenters requested clarification of how we would calculate the standard deviation when a new technology involves more than one DRG.

Response: We believe a single threshold should apply to each new technology as proposed. We would expect hospitals will evaluate whether to adopt a new technology on the basis of all cases where it is applicable, rather than assessing the technology on a DRG-by-DRG basis. As described above, a fundamental premise of a prospective payment system is that hospitals will receive payments in excess of costs for some cases, and vice versa. The same is likely to occur for a specific technology across several DRGs. Therefore, for purposes of determining whether the technology should qualify for special payment treatment, it is most appropriate to evaluate the adequacy of payments across all DRGs.

To clarify this calculation, we would determine a case-weighted mean standardized charge and standard deviation for all of the DRGs to which a technology is likely to be assigned (based on the number of cases estimated to be assigned to each relevant DRG). The resulting mean standardized charge and standard deviation would then be the threshold amount that the new technology would have to exceed in order to qualify. That is, in order to qualify, a new technology that would be applicable across multiple DRGs would need to demonstrate that the mean standardized charge and the standard deviation for all cases likely to receive the new technology, across all DRGs, must exceed the case-weighted mean standardized charge and standard deviation for all cases currently in the DRGs to which the new technology would be assigned.

Comment: Commenters requested that we include either in this final rule or on our Internet website a listing of qualifying thresholds for each DRG.

Response: We have included this information in Table 1 of this final rule. The data are based on the discharge data used to calculate the DRG relative weights for FY 2002, as published in the August 1, 2001 final rule (66 FR 40054).

C. Developing a Payment Mechanism

Section 1886(d)(5)(K)(v) of the Act, as added by section 533(b) of Public Law 106–554, provides flexibility to the Secretary in terms of deciding exactly how the requirement for an additional payment will be satisfied: a new-technology group, an add-on payment, a payment adjustment, or any other similar mechanism for increasing the amount otherwise payable. In the May 4 proposed rule, we stated that we believe the approach most consistent with the design and incentives of the inpatient hospital prospective payment system would be to assign new technology to the most appropriate DRG based on the condition of the patient as described above, and adjust payments for individual cases that involve the new technology when the costs of those cases exceed a threshold amount. That is, we proposed to pay an additional amount not for every case involving the new technology, but only where the costs of the entire case exceed the DRG payment amount. This proposal reflected our concern that the establishment of new DRGs specifically for the purpose of recognizing costly new technology could potentially disrupt the DRG classification structure. In particular, some new technologies may involve large numbers of cases across multiple DRGs. If we were to create new DRGs specifically for new technology, this could pull cases out of existing DRGs, possibly leading to distortions in the relative weights and inadequate payments for cases remaining in the existing DRGs.

In the May 4, 2001 proposed rule, we proposed that Medicare provide higher payments for cases with higher costs involving identified new technologies, while preserving some of the incentives under the average-based payments for all treatment modalities for a particular patient category. The payment mechanism we proposed would be based on the cost to hospitals for the new technology. We proposed under § 412.88 that Medicare would pay a marginal cost factor of 50 percent for the costs of the new technology in excess of the full DRG payment. This would be calculated before any outlier payments under section 1886(d)(5)(A) of the Act, if applicable. Similarly, cases involving new technology would be eligible for outlier payments, with the additional amounts paid for the new technology included in the base payment amount. Costs would be determined by applying the cost-to-charge ratio in a manner identical to that currently used for outlier payments. Under the proposal, if the costs of a new technology case exceed the DRG payment by more than the estimated costs of the new technology, Medicare payment would be limited to the DRG payment plus 50 percent of the estimated costs of the new technology, except if the case qualified for outlier payments. (We proposed a conforming change to § 412.80 by adding a new paragraph (a)(3) to provide that outlier qualifying thresholds and payments would be in addition to standard DRG payments and additional payments for new medical services and technology (effective October 2001).)

In the proposed rule, we gave the following example: consider a new technology estimated to cost $3,000, in a DRG that pays $20,000. A hospital submits three claims for cases involving this new technology. After applying the hospital's cost-to-charge ratio, it is determined the costs of these three cases are $19,000, $22,000, and $25,000. Under the proposed approach, Medicare would pay $20,000 (the DRG payment) for the first claim. For the second claim, Medicare would pay one half of the amount by which the costs of the case exceed the DRG payment, up to the estimated cost of the new technology, or $21,000 ($20,000 plus one half of $2,000). For the third claim, Medicare would pay $21,500 ($20,000 plus one half of the total estimated costs of the new technology).

In the May 4 proposed rule we stated that we believe it is appropriate to limit the additional payment to 50 percent of the additional cost to appropriately balance the incentives. We stated that this proposed limit would provide hospitals an incentive for continued cost-effective behavior in relation to the overall costs of the case. In addition, we believe hospitals would face an incentive to balance the desirability of using the new technology versus the old; otherwise, there would be a large and perhaps inappropriate incentive to use the new technology. For example, in the late 1980s, we considered whether to establish a special payment adjustment for tissue plasminogen activator (TPA), a thrombolytic agent used in treating blockages of coronary arteries, reflecting the high costs of the drug. We did not establish such an adjustment because we believed that the updates to the standardized amounts, combined with the potential for continuing improvements in hospital productivity, would be adequate to finance appropriate care of Medicare patients. In fact, the costs of the drug were offset by shorter hospital stays and an overall reduction in costs per case. As clinical experience with TPA accumulated, furthermore, it appeared that the drug was not as widely beneficial as its original proponents expected. Establishing an add-on payment for this drug might have actually led to more extensive use of this drug for patients who would not

have benefited, and might have even been harmed, by its blood-thinning characteristics.

Comment: Several commenters representing hospital associations suggested that we prospectively adjust the DRG weights to account for the expected additional costs of new technology. They further stated that this would incorporate the additional costs into the DRG weights, rather than providing a separate add-on amount on a case-by-case basis. The commenters argued that the add-on payment methodology increases the complexity of the system.

One commenter suggested our proposed payment mechanism violates section 1886(d)(5)(K)(v) of the Act, which prohibits the Secretary from establishing a separate fee schedule for payments for new technologies under this provision. The commenter believed that the proposed methodology amounts to a fee schedule, with the vast majority of new technologies being paid at the marginal cost of such technologies.

Response: We considered all options, including the one suggested here, prior to proposing an add-on payment. However, as noted above, we believe the proposed payment mechanism appropriately balances the incentives for cost-effective behavior with the incentives created to utilize eligible new technologies due to the increased payments.

It should be noted that CMS had discretion prior to Public Law 106–554 to use data other than MedPAR as part of the recalibration process. In the July 30, 1999 **Federal Register**, we described the process whereby we would consider non-MedPAR data in the DRG reclassification and recalibration. This was in response to the Conference Report that accompanied Public Law 105–33, which stated ''in order to ensure that Medicare beneficiaries have access to innovative new drug therapies, the conferees believe that CMS should consider, to the extent feasible, reliable, validated data other than Medicare Provider Analysis and Review (MedPAR) data in annually recalibrating and reclassifying the DRGs'' (H.R. Conf. Rep. No. 105–217 at 734 (1997)).

We are concerned, however, that the approach suggested by the commenters may not adequately fulfill Congress' intent in enacting section 533 of Public Law 106–554. Specifically, Congress already recognized that the Secretary could use non-MedPAR data to adjust the DRG weights, as evidenced by the Conference Report reference just quoted. Therefore, if incorporating new technology in the DRG weights sooner would be sufficient to fulfill Congress' intent in section 533, there would have been no need to enact section 533.

We disagree with the commenter who suggested our proposed methodology equates to a fee schedule. The additional payments made under this provision recognize the additional costs incurred by hospitals above the normal DRG payment. They are not fees paid for the use of a new technology irrespective of the amount otherwise paid under the existing prospective payment system. Therefore, they are an add-on payment, consistent with the language of section 533.

Comment: Other commenters representing medical technology manufacturers recommended that, rather than our proposed add-on payment methodology, we should create a limited number of new technology DRGs. They stated that the proposed methodology is flawed because it relies on charges, and charges for medical technology typically do not receive the same mark-up as other components of care.

Response: We are concerned about creating specific new technology DRGs for two reasons. In particular, we anticipate the number of technologies eligible for special payment during any given year will be relatively few. Establishing specific new technology DRGs would result in most, if not all, of these new technology DRGs being comprised of one or two procedures, with the DRG weights based entirely on the projected average charges associated with those very limited and specific procedures. As a result, payment for the new technology could be significantly higher than the payment for predecessor technologies in existing DRGs. This approach would forfeit the incentives to balance the clinical benefits of new technology with the higher costs. In addition, section 1886(d)(5)(L)(ii)(I) of the Act prohibits establishing new technology groups based on the costs associated with a specific new medical service or technology.

We are also concerned about the potential that a future technology may be so prevalent across so many DRGs that a disproportionate number of cases would be assigned to a new technology DRG rather than existing DRGs, resulting in distortions in DRG recalibration.

Comment: We received a mixed response to our proposal to pay 50 percent of excess costs up to a limit of 50 percent of the estimated average cost of the new technology. Several commenters objected to the proposal, arguing that the methodology does not comply with the statutory requirement to pay an amount that ''adequately reflects the estimated average costs'' of new technology. Generally, these commenters recommended that the add-on payment should be 100 percent of the costs of the new technology. Other commenters, including MedPAC, supported the payment mechanism as a way of maintaining the integrity of the DRG system and maintaining an incentive for hospitals and physicians to carefully weigh the clinical benefits of new technology against their costs.

Response: For several reasons, we do not believe it would be appropriate to pay 100 percent of the costs of new technology through the add-on payment. First, as stated above, the prospective payment system is an average-based system, allowing hospitals to recover the ''excess'' costs of high cost cases through ''excess'' payments for low cost cases. In deciding which treatment is most appropriate for any particular patient, physicians are expected to balance the clinical needs of patients with the efficacy and costliness of particular treatments. Paying an add-on amount equal to 100 percent of the costs of new technology would remove consideration of the costs of new technology from treatment decisions. We agree with MedPAC that it is important to maintain some incentive to weigh the costs of new technology in making clinical decisions.

Second, we do not believe it is appropriate to pay an add-on amount equal to 100 percent of the costs of new technology because there is no similar methodology to reduce payments for cost-saving technology. For example, as new technologies permit the development of less-invasive surgical procedures, the total costs per case may begin to decline as patients recover and leave the hospital sooner. However, Medicare will continue to pay the full DRG payment for those cases, without benefit of the reduced costs being reflected in the DRG weights for 2 to 3 years (as described above).

Third, we are concerned that, because these payments are linked to charges submitted by hospitals, there is the potential that hospitals may adapt their charge structure to maximize payments for DRGs that include eligible new technologies. The higher the marginal cost factor, the greater the incentive hospitals face in this regard.

In light of these concerns, we believe that an additional payment based on a 50-percent marginal cost factor is appropriate. In addition, we note that this final rule includes a target limit on total payments under this provision (see section III.D. of this preamble for a complete discussion of this issue). If, based on our projections of special

payments for the upcoming year, we estimate that the limit established by this target would be exceeded, we would prospectively revise downward the marginal cost factor so that the target is not exceeded, in order to limit the extent of the adjustment to the standardized amounts for budget neutrality.

D. Budget Neutrality

The report language accompanying section 533 of Public Law 106–554 indicates Congressional intent that the Secretary implement the new mechanism on a budget neutral basis (H.R. Conf. Rep. No. 106–1033, 106th Cong., 2d 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 proposed to simulate projected payments under this provision for new technology 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 factored into the budget neutrality factor, which is applied to the standardized amounts.

Because, under our proposal, any additional payments directed toward new technology under this provision would be offset to ensure budget neutrality, it would be important to carefully consider the extent of this provision and ensure that only technologies representing substantial advances are recognized for additional payments. In that regard, we proposed to discuss in the annual proposed and final regulations implementing changes to the inpatient hospital prospective payment system those technologies that were considered under this provision; our determination as to whether a particular new technology meets our criteria for a ''substantial improvement'' and for a new technology; 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.

The payments made under our proposed approach to implement this provision would be redistributed from all other payments made under the inpatient prospective payment system. Our projections of the aggregate payments for new technology would involve not only estimates of the effect of the new technology on the entire cost per case but also estimates of the volume of cases expected to involve the new technology during the upcoming year.

Comment: Two commenters representing hospitals expressed concerns regarding the amount of potential payments under this provision, and argued that the amount of the offset to the prospective payment system standardized amount should be set a prescribed limit. Specifically, the commenters were concerned that this provision would be financed by reducing payments for cases that do not involve new technology to pay for additional payments for cases that do involve new technology.

These commenters suggested that we establish a target limit on the payments for new technology under this special provision. Estimated total payments under this provision would be limited to a predetermined target percentage of total payments, thereby limiting the size of the standardized amount offset to no greater than the target limit. One commenter recommended that the limit be set at 0.5 percent of prospective payment system payments, based on the commenter's assessment of the new technology components in the hospital inpatient market basket.

Response: Because Congress intended section 533(b) to be implemented in a budget neutral manner (the Congressional Budget Office scored the budgetary impact of section 533 at zero dollars), requiring that special payments under this provision be financed by reducing payments for other cases, there is great potential for this provision to adversely impact certain hospitals. Although we believe that the criteria for qualifying new technology we proposed would appropriately limit the new technologies eligible for special payments to those with exceptionally high costs relative to their anticipated DRG payment, we are concerned that this provision should not result in inappropriately large redistributions of payments from hospitals that do not employ new technology to those that do. Therefore, after careful consideration of the comments received on this provision, we are establishing a target limit on the percentage of total payments under this provision.

The report language accompanying section 533 of Public Law 106–544 states that ''[t]he total amount of projected additional payments under the mechanism would be limited to an amount not greater that the Secretary's annual estimation of the costs attributable to the introduction of new technology in the hospital sector as a whole (as estimated for purposes of the annual hospital update calculation.'' (H.R. Conf. Rep. No. 106–1033, 106th Cong., 2d Sess. at 897 (2000).) Although the Secretary has not historically prepared such an estimate, MedPAC has historically prepared such an estimate.

As part of its annual recommendation to Congress on the update to the standardized amounts, over the past several years, MedPAC has recommended an allowance for scientific and technological advances of 0.5 and 1.0 percent (June 2000 Report to Congress, page 126; and March 2001 Report to Congress, page 76). To appropriately balance 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 are setting the target limit for special payments for new technology under the provisions of section 533(b) of Public Law 106–554 at 1.0 percent of total operating prospective payments.

The target limit will be enforced based on an estimate of the total amount of payments projected to be made under this provision during the upcoming fiscal year, compared with total operating prospective payment system payments projected to be made during the same period (including adjustments for indirect medical education, disproportionate share of low-income patients, and outlier cases). Should the projected amount of new technology payments exceed the 1.0 percent target limit, we would make a prospective adjustment to lower the marginal payments for new technology cases (below the 50-percent level) so that the target is not exceeded.

We considered alternative approaches to enforcing the target limit. For example, one could establish a priority ranking of the approved technologies, and work down the list paying for as many new technologies as possible until the limit is reached. Such a ranking could be based on the clinical merits of the technology, or the cost implications of the technology. However, we were concerned that such an approach would exclude some otherwise approved technologies from receiving extra payments.

Another approach, the one we have selected, is to 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 reduced amount. Because, by definition, payments made under this provision would need to be at relatively high levels in order for the limit to come into play, and because new technology tends to be concentrated in particular categories of hospitals (for example, academic medical centers), we believe this is the most appropriate mechanism to enforce the target limit because substantial payment redistributions will have already likely occurred to these hospitals by the time the limit is reached. Although the marginal payment rate for individual technologies will be reduced, this should be offset by large overall payments for new technologies under this provision.

V. Provisions of the Final Rule

We are adopting the provisions of the May 4, 2001 proposed rule as final with the modifications that are discussed throughout this preamble. Specifically, this final rule specifies that a target for new technology payments under section 1886(d)(5)(K) of the Act will be set at 1.0 percent of total operating payments. Cases in which new technologies are used will qualify for payment under the new technology provision if their charges exceed one standard deviation from the mean charge (based on a logarithmic distribution) for all cases in that DRG. Payment will be limited to 50 percent of the amount by which the cost of the case exceeds the DRG payment for the case, up to 50 percent of the cost of the new technology. Should projected payments for the technology exceed the target amount in a given year, the marginal payment factor will be reduced prospectively from 50 percent as necessary to meet the target. This provision must be implemented in a budget neutral manner.

VI. Effective Date of the Final Rule

This final rule has been determined not to be a major rule as defined in Title 5, United State Code, section 804(2); that is, due to the budget neutrality aspect of the implemented provisions of section 533 of Public Law 106–554, the anticipated annual effect on the economy will not exceed $100 million or more. Therefore, 5 U.S.C. 801, as added by section 251 of Public Law 104–121, which provides that a major rule shall take effect 60 days after the later of (1) the date a report on the rule is submitted to Congress or (2) the date the rule is published in the **Federal Register**, does not apply.

VII. Regulatory Impact Analysis

A. General

We have examined the impacts of this rule as required by Executive Order 12866. We have examined the impacts of this rule under the criteria of the Regulatory Flexibility Act (RFA) Public Law 96–354, section 1102(b) of the Act, and the Unfunded Mandate Reform Act of 1995 (UMRA) Public Law 104–4. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for rules that constitute significant regulatory action, including rules that have an economic effect of $100 million or more annually (major rules). We have determined that this final rule is not a major rule within the meaning of Executive Order 12866.

The RFA requires agencies to analyze options for regulatory relief of small businesses in issuing a proposed rule and a final rule that has been preceded by a proposed rule. For purposes of the RFA, small entities include small businesses, nonprofit organizations and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $25 million or less annually. Based on 1997 Census Bureau data, there are 4,700 general short-term acute care hospitals (tax exempt; government or nonprofit). Of the 792 proprietary hospitals, 658 are proprietary hospitals with greater than $10 million in annual receipts. Individuals and States are not included in the definition of a small entity.

Also, section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital with fewer than 100 beds that is located outside of a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA). Section 601(g) of the Social Security Amendments of 1983 (Public Law 98–21) designated hospitals in certain New England counties as belonging to the adjacent NECMA. Thus, for purposes of the hospital inpatient prospective payment systems, we classify these hospitals as urban hospitals.

Because we are not making payments under this provision for FY 2002, there are no estimated impacts. Future impacts of this provision on hospitals, which may include small entities and would not include unfunded mandates, will be discussed in the annual proposed and final rules implementing the updates and other changes to the inpatient prospective payment system.

B. Anticipated Effects

As noted above, there is no impact on payments to hospitals during FY 2002. Future impacts of this provision will be included as part of the annual proposed and final rules updating the acute care hospital inpatient prospective payment system.

C. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that the final rule will not have any negative impact on the rights, roles, and responsibilities of State, local, or tribal governments.

D. Unfunded Mandate

Section 202 of the Unfunded Mandate Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any final rule that has been preceded by a final rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This final rule would not mandate any requirements for State, local, or tribal governments.

E. Executive Order 12866

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

VIII. Information Collection Requirements

This document does not contain any new information collection requirements that are subject to review and approval by the Office of Management and Budget (OMB) as provided for under the Paperwork Reduction Act of 1995. In particular, the requirements referenced in these

regulations are conducted on an individual case-by-case basis, and, therefore, are exempt for the PRA, as stipulated under 5 CFR 1320.3(h)(6).

TABLE 1.—MEAN AND STANDARD DEVIATIONS, BY DRG [1]

DRG	Cases	Mean	Standard deviation
1	33,680	$34,221	$17,102
2	6,750	$35,700	$17,893
3	2	$114,502	$11,624
4	6,003	$25,072	$13,170
5	92,462	$14,018	$6,792
6	364	$7,554	$3,946
7	12,412	$28,146	$14,441
8	4,137	$14,771	$8,602
9	1,600	$13,968	$7,449
10	17,473	$13,211	$6,878
11	3,108	$8,957	$4,907
12	46,381	$9,146	$4,608
13	6,376	$8,376	$4,319
14	317,412	$12,074	$6,357
15	144,440	$7,682	$3,797
16	11,084	$12,117	$5,995
17	3,496	$7,027	$3,563
18	25,812	$10,098	$5,247
19	8,590	$7,117	$3,829
20	5,603	$29,649	$16,261
21	1,305	$15,564	$8,129
22	2,527	$10,617	$5,666
23	9,396	$8,291	$4,353
24	52,442	$10,390	$5,414
25	25,247	$6,251	$3,342
26	31	$6,266	$3,909
27	3,425	$13,687	$7,317
28	11,272	$14,148	$7,368
29	4,469	$7,332	$3,923
31	3,467	$9,138	$4,690
32	1,729	$5,439	$2,885
34	20,124	$10,318	$5,334
35	5,686	$6,178	$3,226
36	3,154	$6,906	$3,026
37	1,441	$11,546	$5,753
38	101	$5,070	$3,040
39	906	$6,068	$3,462
40	1,524	$8,638	$4,331
42	2,199	$6,530	$3,535
43	85	$4,899	$2,913
44	1,230	$6,604	$3,577
45	2,418	$7,040	$3,578
46	3,036	$8,286	$4,388
47	1,278	$5,328	$3,073
49	2,223	$18,135	$8,896
50	2,461	$8,531	$4,134
51	201	$8,198	$4,422
52	217	$7,601	$3,828
53	2,459	$12,031	$6,317
54	2	$6,447	$1,733
55	1,491	$8,455	$4,508
56	494	$8,644	$4,304
57	703	$10,954	$6,215
59	105	$7,209	$3,911
60	2	$7,221	$2,545
61	229	$13,913	$6,554
62	3	$4,633	$2,084
63	2,989	$14,388	$7,788
64	3,021	$12,715	$6,891
65	34,317	$5,607	$2,930
66	6,940	$5,657	$3,089
67	494	$8,111	$4,574
68	16,632	$6,949	$3,454
69	5,406	$5,236	$2,545

TABLE 1.—MEAN AND STANDARD DEVIATIONS, BY DRG [1]—Continued

DRG	Cases	Mean	Standard deviation
70	24	$4,884	$3,203
71	82	$7,197	$3,640
72	877	$6,982	$3,692
73	6,591	$8,215	$4,366
75	38,768	$33,224	$15,468
76	38,787	$30,628	$14,878
77	2,333	$12,849	$6,282
78	31,837	$14,053	$6,514
79	169,072	$18,018	$9,147
80	8,971	$9,880	$4,948
81	4	$25,053	$14,517
82	61,618	$15,155	$8,215
83	6,419	$10,237	$5,258
84	1,500	$5,708	$2,978
85	20,492	$13,187	$6,844
86	2,109	$7,046	$3,797
87	59,825	$15,002	$7,866
88	387,633	$9,555	$4,709
89	523,306	$11,160	$5,497
90	53,588	$6,744	$3,159
91	54	$8,727	$5,111
92	13,717	$12,968	$6,607
93	1,663	$7,679	$3,878
94	11,989	$12,637	$6,571
95	1,588	$6,204	$3,082
96	61,673	$8,021	$3,937
97	31,319	$6,004	$2,955
98	18	$7,582	$4,869
99	18,898	$7,292	$3,873
100	7,580	$5,486	$2,971
101	19,910	$8,974	$4,681
102	5,122	$5,531	$2,994
103	471	$201,472	$88,012
104	19,527	$81,506	$33,051
105	25,736	$58,962	$24,215
106	3,385	$79,188	$31,820
107	87,178	$55,413	$21,398
108	5,998	$58,620	$26,620
109	59,671	$40,351	$16,091
110	52,195	$43,587	$20,444
111	8,459	$24,521	$11,025
113	42,092	$27,689	$14,908
114	8,659	$17,115	$8,391
115	14,139	$35,743	$14,537
116	90,458	$23,428	$9,246
117	3,694	$13,386	$7,342
118	7,529	$15,361	$7,697
119	1,298	$13,855	$7,253
120	37,300	$24,039	$11,815
121	161,319	$16,520	$8,201
122	78,646	$10,933	$5,624
123	40,546	$16,620	$9,332
124	131,648	$14,598	$6,634
125	79,518	$11,040	$5,161
126	5,130	$28,436	$14,368
127	675,000	$10,417	$5,270
128	9,362	$7,652	$3,640
129	4,121	$10,564	$6,345
130	85,502	$9,755	$4,906
131	28,033	$6,094	$2,922
132	146,801	$6,749	$3,415
133	8,243	$5,761	$3,153
134	35,952	$6,081	$3,270
135	7,207	$9,244	$4,732
136	1,214	$5,991	$3,354
138	193,004	$8,485	$4,419
139	82,257	$5,256	$2,783
140	69,373	$5,641	$2,826
141	89,931	$7,531	$3,850
142	45,586	$5,698	$2,972

TABLE 1.—MEAN AND STANDARD DEVIATIONS, BY DRG [1]—Continued

DRG	Cases	Mean	Standard deviation
143	203,055	$5,496	$2,840
144	81,220	$12,430	$6,670
145	7,183	$6,234	$3,543
146	10,602	$28,843	$13,084
147	2,604	$17,162	$7,124
148	128,536	$36,602	$17,385
149	18,314	$15,988	$6,363
150	19,681	$30,856	$14,557
151	4,781	$14,262	$6,152
152	4,345	$20,114	$9,492
153	2,070	$12,419	$5,334
154	28,558	$45,582	$22,620
155	6,534	$13,951	$6,030
156	4	$24,515	$15,028
157	7,848	$12,849	$6,386
158	4,593	$6,554	$3,240
159	16,163	$13,919	$6,659
160	11,549	$8,172	$3,745
161	11,021	$11,565	$5,625
162	7,131	$6,561	$3,189
163	5	$9,247	$5,009
164	4,797	$25,031	$11,606
165	2,053	$13,954	$5,974
166	3,503	$15,270	$6,996
167	3,248	$9,334	$3,949
168	1,318	$13,342	$6,733
169	830	$7,320	$3,923
170	10,920	$31,661	$15,545
171	1,274	$12,356	$5,789
172	30,262	$14,527	$7,677
173	2,666	$7,411	$4,273
174	238,934	$10,265	$5,186
175	32,223	$5,742	$2,920
176	14,986	$11,102	$5,506
177	9,143	$9,368	$4,574
178	3,584	$6,861	$3,386
179	12,227	$11,171	$5,759
180	85,143	$9,809	$5,057
181	26,209	$5,548	$2,829
182	242,227	$8,187	$4,273
183	83,676	$5,926	$3,122
184	79	$4,419	$2,409
185	4,742	$9,056	$4,830
186	3	$18,405	$20,674
187	641	$8,336	$4,371
188	75,191	$11,554	$6,075
189	11,923	$6,099	$3,389
190	49	$12,761	$5,926
191	8,818	$47,924	$23,462
192	1,088	$19,337	$9,024
193	5,231	$36,682	$17,597
194	713	$18,351	$8,617
195	4,292	$31,452	$13,969
196	1,157	$17,300	$7,001
197	18,613	$26,434	$12,496
198	5,707	$12,973	$5,941
199	1,699	$26,123	$13,033
200	1,058	$33,952	$16,409
201	1,424	$40,293	$19,691
202	25,853	$13,752	$7,269
203	28,853	$14,338	$7,733
204	56,928	$12,186	$6,210
205	22,786	$12,582	$6,592
206	1,934	$7,756	$4,175
207	30,650	$11,634	$6,092
208	10,017	$6,824	$3,696
209	339,625	$20,928	$7,567
210	119,568	$17,986	$7,417
211	31,401	$13,043	$4,799
212	6	$57,573	$33,539

TABLE 1.—MEAN AND STANDARD DEVIATIONS, BY DRG [1]—Continued

DRG	Cases	Mean	Standard deviation
213	9,090	$19,794	$9,448
216	5,917	$24,182	$11,536
217	16,277	$33,068	$16,354
218	21,104	$15,896	$7,086
219	19,357	$10,596	$4,412
220	6	$13,926	$6,350
223	13,119	$10,043	$4,772
224	10,983	$8,270	$3,609
225	5,688	$11,467	$5,400
226	5,114	$16,123	$7,698
227	4,647	$8,329	$3,762
228	2,319	$11,244	$5,538
229	1,089	$7,551	$3,649
230	2,346	$13,595	$6,666
231	11,253	$14,623	$7,174
232	797	$9,873	$4,737
233	5,030	$21,696	$10,843
234	3,144	$12,956	$7,125
235	4,996	$7,557	$3,909
236	38,004	$7,028	$3,697
237	1,675	$5,509	$2,682
238	7,875	$14,517	$7,359
239	48,837	$10,383	$5,292
240	11,259	$13,777	$7,033
241	3,157	$6,653	$3,599
242	2,429	$11,575	$6,019
243	86,835	$7,582	$3,847
244	12,079	$7,371	$3,781
245	5,101	$4,922	$2,658
246	1,377	$5,950	$3,193
247	16,745	$5,841	$3,056
248	10,464	$8,369	$4,331
249	11,271	$6,910	$3,691
250	3,438	$7,061	$3,603
251	2,395	$4,839	$2,541
253	19,553	$7,575	$3,837
254	10,395	$4,527	$2,252
256	6,026	$8,410	$4,480
257	16,174	$9,112	$4,025
258	15,852	$7,402	$3,036
259	3,731	$8,869	$4,250
260	4,849	$6,909	$2,982
261	1,826	$9,722	$4,969
262	606	$8,773	$4,213
263	18,078	$22,473	$12,380
264	3,592	$12,368	$6,593
265	3,654	$17,016	$8,218
266	2,683	$8,939	$4,427
267	233	$10,099	$5,245
268	868	$12,455	$6,679
269	7,352	$18,569	$9,303
270	2,601	$8,408	$4,226
271	9,563	$11,955	$6,102
272	5,424	$10,430	$5,406
273	1,279	$5,949	$3,210
274	2,321	$12,576	$6,967
275	246	$7,068	$4,484
276	1,172	$7,242	$3,830
277	84,730	$8,937	$4,492
278	33,239	$5,927	$2,921
279	3	$2,550	$1,458
280	15,468	$7,111	$3,566
281	7,089	$4,838	$2,486
282	3	$2,776	$646
283	5,596	$7,337	$3,849
284	1,861	$4,435	$2,410
285	6,167	$22,178	$10,857
286	2,048	$22,448	$10,632
287	5,653	$20,363	$10,040
288	2,609	$21,408	$9,984

TABLE 1.—MEAN AND STANDARD DEVIATIONS, BY DRG [1]—Continued

DRG	Cases	Mean	Standard deviation
289	4,711	$9,475	$4,696
290	8,639	$8,890	$4,252
291	64	$6,421	$2,912
292	4,632	$28,760	$14,261
293	619	$13,457	$6,625
294	87,396	$7,796	$4,126
295	3,263	$7,665	$4,171
296	233,776	$8,887	$4,580
297	43,365	$5,313	$2,709
298	86	$4,227	$2,343
299	1,173	$9,354	$5,053
300	15,908	$11,597	$6,055
301	3,186	$6,404	$3,554
302	7,642	$33,433	$15,262
303	19,313	$25,451	$11,944
304	11,690	$25,200	$12,299
305	2,962	$12,174	$5,779
306	7,274	$13,464	$6,515
307	2,065	$6,404	$2,638
308	7,413	$17,032	$8,420
309	4,070	$9,562	$4,995
310	23,711	$11,599	$5,752
311	7,918	$6,344	$3,030
312	1,479	$10,838	$5,460
313	586	$6,918	$3,749
315	29,885	$21,700	$10,594
316	104,168	$14,316	$7,562
317	1,504	$6,355	$4,181
318	5,549	$12,235	$6,592
319	422	$6,344	$4,153
320	185,584	$8,903	$4,369
321	30,258	$5,887	$2,803
322	61	$5,610	$2,749
323	17,186	$8,429	$4,735
324	7,460	$4,756	$2,640
325	8,134	$6,626	$3,620
326	2,666	$4,301	$2,463
327	11	$4,011	$2,006
328	658	$7,522	$4,114
329	76	$4,760	$2,733
331	45,848	$11,037	$5,883
332	4,907	$6,392	$3,626
333	280	$8,311	$4,255
334	8,579	$15,279	$6,397
335	10,649	$11,836	$4,640
336	9,465	$9,208	$4,241
337	3,012	$6,171	$2,467
338	1,216	$12,580	$6,334
339	1,337	$12,595	$6,238
341	2,704	$13,097	$7,597
342	297	$8,432	$4,109
344	3,468	$12,517	$7,111
345	408	$12,158	$5,737
346	4,425	$10,873	$5,923
347	365	$6,111	$4,094
350	6,229	$7,381	$3,762
352	749	$6,828	$3,920
353	2,511	$18,468	$8,772
354	7,480	$15,397	$6,967
355	5,456	$9,559	$3,707
356	24,916	$7,864	$3,397
357	5,517	$25,319	$12,074
358	20,083	$12,100	$5,313
359	29,672	$8,726	$3,458
360	15,788	$8,826	$3,997
361	374	$11,030	$5,326
363	2,838	$8,262	$4,621
364	1,630	$8,158	$4,241
365	1,712	$20,830	$10,330
366	4,393	$13,272	$7,187

TABLE 1.—MEAN AND STANDARD DEVIATIONS, BY DRG [1]—Continued

DRG	Cases	Mean	Standard deviation
367	581	$5,804	$3,619
368	3,097	$11,964	$6,156
369	3,121	$5,836	$3,537
370	1,078	$9,721	$4,374
371	1,296	$7,095	$2,780
372	917	$5,484	$2,633
373	3,703	$3,956	$1,708
374	118	$7,009	$3,183
375	10	$6,519	$2,880
376	247	$5,310	$3,009
377	48	$17,649	$8,033
378	153	$8,352	$4,083
379	337	$4,826	$2,768
380	58	$4,498	$2,471
381	149	$6,220	$3,465
382	44	$1,723	$967
383	1,700	$4,987	$2,853
384	114	$3,658	$2,099
389	15	$22,357	$13,168
390	14	$12,153	$9,490
392	2,311	$34,949	$17,050
394	1,859	$18,654	$8,770
395	86,456	$8,418	$4,521
396	15	$11,234	$7,337
397	17,475	$13,060	$7,124
398	17,426	$13,436	$6,962
399	1,715	$7,119	$3,892
400	6,418	$30,559	$15,016
401	5,550	$30,943	$15,124
402	1,490	$12,369	$6,278
403	31,624	$19,437	$10,245
404	4,625	$9,221	$5,463
406	2,497	$30,406	$14,779
407	711	$13,029	$5,948
408	2,168	$23,053	$11,140
409	2,799	$11,704	$6,368
410	33,080	$10,149	$5,353
411	13	$4,717	$2,623
412	29	$6,510	$3,640
413	6,392	$14,553	$7,717
414	765	$7,832	$4,651
415	38,554	$40,839	$20,733
416	182,689	$16,737	$8,522
417	16	$9,109	$5,531
418	22,714	$10,799	$5,728
419	15,220	$8,970	$4,675
420	3,098	$6,391	$3,306
421	11,387	$6,726	$3,463
422	79	$4,491	$2,525
423	7,417	$18,731	$9,501
424	1,264	$24,550	$12,072
425	15,626	$7,073	$3,762
426	4,423	$5,455	$2,947
427	1,624	$5,506	$3,008
428	831	$7,318	$3,753
429	25,769	$8,557	$4,250
430	58,439	$8,037	$4,037
431	312	$6,586	$3,306
432	465	$7,118	$3,892
433	5,404	$2,945	$1,677
439	1,331	$19,257	$8,994
440	5,095	$20,402	$9,799
441	595	$9,392	$5,040
442	15,277	$25,949	$12,950
443	3,705	$10,482	$5,464
444	5,156	$7,489	$3,871
445	2,414	$4,946	$2,580
447	5,419	$4,874	$2,761
449	27,866	$8,337	$4,444
450	6,827	$4,359	$2,287

TABLE 1.—MEAN AND STANDARD DEVIATIONS, BY DRG [1]—Continued

DRG	Cases	Mean	Standard deviation
451	3	$3,661	$1,689
452	22,558	$10,348	$5,628
453	5,047	$5,217	$3,083
454	3,908	$8,634	$4,546
455	926	$4,771	$2,719
461	3,461	$12,229	$6,684
462	12,886	$12,794	$6,412
463	21,658	$7,038	$3,634
464	6,394	$5,002	$2,798
465	154	$6,501	$3,829
466	1,460	$6,123	$3,744
467	524	$6,207	$3,956
468	56,634	$40,436	$20,195
470	91,129	$8,750	$4,248
471	11,452	$31,327	$10,631
473	7,597	$41,853	$21,410
475	106,641	$41,657	$21,697
476	4,110	$24,265	$11,524
477	24,655	$20,084	$9,803
478	106,268	$25,438	$12,600
479	24,705	$14,976	$6,929
480	536	$106,339	$47,738
481	371	$84,770	$38,759
482	5,661	$39,848	$19,532
483	41,640	$163,741	$91,302
484	310	$53,719	$25,103
485	2,865	$32,195	$15,089
486	1,849	$54,905	$28,043
487	3,333	$20,448	$10,772
488	769	$55,206	$27,898
489	13,936	$19,397	$9,910
490	5,360	$10,850	$5,902
491	12,053	$17,259	$6,454
492	2,669	$52,027	$29,545
493	54,438	$19,103	$8,585
494	29,646	$10,474	$4,767
495	152	$91,522	$43,233
496	1,462	$60,541	$27,811
497	17,089	$33,800	$15,718
498	12,653	$24,583	$11,561
499	30,042	$14,842	$6,792
500	43,667	$9,947	$4,368
501	2,165	$28,367	$13,126
502	580	$16,063	$6,974
503	5,499	$12,650	$6,099
504	112	$136,018	$72,135
505	145	$15,964	$9,765
506	914	$52,706	$27,278
507	289	$18,465	$9,271
508	654	$13,178	$6,914
509	175	$7,521	$4,121
510	1,613	$13,629	$6,439
511	598	$7,074	$3,875
512	322	$62,401	$26,643
513	111	$64,167	$22,861
514	16,717	$68,327	$25,311
515	3,705	$53,939	$21,310
516	74,959	$28,839	$11,990
517	168,815	$22,998	$10,791
518	47,230	$17,756	$8,980
519	5,385	$23,034	$10,757
520	10,402	$16,420	$7,565
521	22,607	$7,527	$4,035
522	11,542	$7,088	$3,155
523	14,748	$4,154	$2,098

[1] Cases are taken from the FY 2000 MedPAR file; DRGs are from GROUPER V.19.

List of Subjects in 42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR part 412 is amended as set forth below:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

1. The authority citation for part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 412.2, the introductory text of paragraph (f) is republished, and a new paragraph (f)(9) is added to read as follows:

§ 412.2 Basis of payment.

* * * * *

(f) *Additional payments to hospitals.* In addition to payments based on the prospective payment system rates for inpatient operating and inpatient capital-related costs, hospitals receive payments for the following:

* * * * *

(9) Special additional payment for certain new technology as specified in §§ 412.87 and 412.88 of Subpart F.

3. The title of Subpart F is revised to read as follows:

Subpart F—Payment for Outlier Cases and Special Treatment Payment for New Technology

4. A new undesignated center heading is added after the Subpart F heading and before § 412.80; the section heading of § 412.80 is revised; and a new paragraph (a)(3) is added to read as follows:

Payment for Outlier Cases

§ 412.80 Outlier cases: General provisions.

(a) *Basic rule.*

* * * * *

(3) *Discharges occurring on or after October 1, 2001.* For discharges occurring on or after October 1, 2001, except as provided in paragraph (b) of this section concerning transfers, CMS provides for additional payment, beyond standard DRG payments and beyond additional payments for new medical services or technology specified in §§ 412.87 and 412.88, to a hospital for covered inpatient hospital services furnished to a Medicare beneficiary if the hospital's charges for covered services, adjusted to operating costs and capital costs by applying cost-to-charge ratios as described in § 412.84(h), exceed the DRG payment for the case (plus payments for indirect costs of graduate medical education (§ 412.105), payments for serving a disproportionate share of low-income patients (§ 412.106), and additional payments for new medical services or technologies) plus a fixed dollar amount (adjusted for geographic variation in costs) as specified by CMS.

* * * * *

5. A new undesignated center heading and §§ 412.87 and 412.88 are added immediately following § 412.86, to read as follows:

Additional Special Payment for Certain New Technology

§ 412.87 Additional payment for new medical services and technologies: General provisions.

(a) *Basis.* Sections 412.87 and 412.88 implement sections 1886(d)(5)(K) and 1886(d)(5)(L) of the Act, which authorize the Secretary to establish a mechanism to recognize the costs of new medical services and technologies under the hospital inpatient prospective payment system.

(b) *Eligibility criteria.* For discharges occurring on or after October 1, 2001, CMS provides for additional payments (as specified in § 412.88) beyond the standard DRG payments and outlier payments to a hospital for discharges involving covered inpatient hospital services that are new medical services and technologies, if the following conditions are met:

(1) A new medical service or technology represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. CMS will determine whether a new medical service or technology meets this requirement and announce the results of its determinations in the **Federal Register** as a part of its annual updates and changes to the hospital inpatient prospective payment system.

(2) A medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD–9–CM code assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration). After CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered ''new'' under the criterion of this section.

(3) The DRG prospective payment rate otherwise applicable to discharges

involving the medical service or technology is determined to be inadequate, based on application of a threshold amount to estimated charges incurred with respect to such discharges. To determine whether the payment would be adequate, CMS will determine whether the charges of the cases involving a new medical service or technology will exceed a threshold amount set at one standard deviation beyond the geometric mean standardized charge for all cases in the DRG to which the new medical service or technology is assigned (or the case-weighted average of all relevant DRGs if the new medical service or technology occurs in many different DRGs). Standardized charges reflect the actual charges of a case adjusted by the prospective payment system payment factors applicable to an individual hospital, such as the wage index, the indirect medical education adjustment factor, and the disproportionate share adjustment factor.

§ 412.88 Additional payment for new medical service or technology.

(a) For discharges involving new medical services or technologies that meet the criteria specified in § 412.87, Medicare payment will be:

(1) The full DRG payment (including adjustments for indirect medical education and disproportionate share but excluding outlier payments); plus

(2) If the costs of the discharge (determined by applying cost-to-charge ratios as described in § 412.84(h)) exceed the full DRG payment, an additional amount equal to the lesser of—

(i) 50 percent of the costs of the new medical service or technology; or

(ii) 50 percent of the amount by which the costs of the case exceed the standard DRG payment.

(b) Unless a discharge case qualifies for outlier payment under § 412.84, Medicare will not pay any additional amount beyond the DRG payment plus 50 percent of the estimated costs of the new medical service or technology.

(c) If CMS estimates before the beginning of a Federal fiscal year that the additional payments under this section would exceed 1.0 percent of total operating payments under the hospital inpatient prospective payment system, the additional payment amounts under paragraph (a) of this section will be reduced prospectively to a percentage estimated to result in payments not to exceed 1.0 percent of total operating payments under the hospital inpatient prospective payment system.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance)

Dated: August 17, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: August 28, 2001.

Tommy G. Thompson,

Secretary.

[FR Doc. 01–22475 Filed 9–4–01; 11:03 am]

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