**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Parts 416, 419, 476, 478, 480, and 495**

**[CMS-1589-FC]**

**RIN 0938-AR10**

**Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Revision to Quality Improvement Organization Regulations**

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

**ACTION:** Final rule with comment period.

**SUMMARY:** This final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2013 to implement applicable statutory requirements and changes arising from our continuing experience with these systems. In this final rule with comment period, we describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. In addition, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the ASC Quality Reporting (ASCQR) Program, and the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program. We are continuing the electronic reporting pilot for the Electronic Health Record (EHR) Incentive Program, and revising the various regulations governing Quality Improvement Organizations (QIOs),

- *Outpatient Status:* We are concerned about recent increases in the length of time that Medicare beneficiaries spend as outpatients receiving observation services. In addition, hospitals continue to express concern about Medicare Part A to Part B rebilling policies when a hospital inpatient claim is denied because the inpatient admission was not medically necessary. In the CY 2013 OPPS/ASC proposed rule (77 FR 45155 through 45157), we provided an update on the Part A to Part B Rebilling Demonstration that is in effect for CY 2012 through CY 2014, which was designed to assist us in evaluating these issues. We also solicited public comments on potential clarifications or changes to our policies regarding patient status that may be appropriate, which we discuss in this final rule with comment period.

- *Ambulatory Surgical Center Payment Update:* For CY 2013, we are increasing payment rates under the ASC payment system by 0.6 percent. This increase is based on a projected CPI-U update of 1.4 percent minus a multifactor productivity adjustment required by the Affordable Care Act that is projected to be 0.8 percent. Based on this update, we estimate that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix), for CY 2013 will be approximately $4.074 billion, an increase of approximately $310 million compared to estimated CY 2012 payments.

- *New Technology Intraocular Lenses:* We are revising the regulations governing payments for new technology intraocular lenses (NTIOLs) to require that the IOL's labeling, which must be approved by the FDA, contain a claim of a specific clinical benefit based on a new lens characteristic in comparison to currently available

## XI. Outpatient Status: Solicitation of Public Comments in the CY 2013 OPPS/ASC Proposed Rule

A. Background

Under section 402(a)(1)(A) of the Social Security Amendments of 1967 (Pub. L. 90-248), the Secretary is permitted to engage in demonstration projects to determine whether changes in the methods of payment for health care and services under the Medicare program would increase the efficiency and economy of those services through the creation of incentives to those ends without adversely affecting the quality of such services. Under this statutory authority, CMS has implemented the Medicare Part A to Part B Rebilling (AB Rebilling) Demonstration, which allows participating hospitals to receive 90 percent of the allowable Part B payment for Part A short-stay claims that are denied on the basis that the inpatient admission was not reasonable and necessary. Participating hospitals can rebill these denied Part A claims under Part B and be paid for additional Part B services than would usually be payable when an inpatient admission is deemed not reasonable and necessary. This demonstration is slated to last for 3 years, from CY 2012 through CY 2014.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45155 through 45157), we provided an update of the status of the demonstration. In addition, we solicited public comments on a related issue: potential policy changes we could make to improve clarity and consensus among providers, Medicare, and other stakeholders regarding the relationship between admission decisions and appropriate Medicare payment, such as

when a Medicare beneficiary is appropriately admitted to the hospital as an inpatient and the cost to hospitals associated with making this decision.

In the proposed rule, we discussed that when a Medicare beneficiary arrives at a hospital in need of medical or surgical care, the physician or other qualified practitioner must decide whether to admit the beneficiary for inpatient care or treat him or her as an outpatient. In some cases, when the physician admits the beneficiary and the hospital provides inpatient care, a Medicare claims review contractor, such as the Medicare Administrative Contractor (MAC), the Recovery Audit Contractor (RAC), or the Comprehensive Error Rate Testing (CERT) Contractor, determines that inpatient care was not reasonable and necessary under section 1862(a)(1)(A) of the Act and denies the hospital inpatient claim for payment. In these cases, under Medicare's longstanding policy, hospitals may rebill a separate inpatient claim for only a limited set of Part B services, referred to as "Inpatient Part B" or "Part B Only" services (Section 10, Chapter 6 of the Medicare Benefit Policy Manual (Pub. 100-02)). The hospital also may bill Medicare Part B for any outpatient services that were provided in the 3-day payment window prior to the admission (Section 10.12, Chapter 4 of the Medicare Claims Processing Manual (Pub. 100-04)). These claims are subject to the timely filing restrictions.

Once a Medicare beneficiary is discharged from the hospital, the hospital cannot change the beneficiary's patient status from inpatient to outpatient and then submit an outpatient claim because of the potentially significant impact on beneficiary liability. As we discuss below, hospital inpatients have significantly different Medicare benefits and

liabilities than hospital outpatients, notably coverage of self-administered drugs and, for patients who are admitted to the hospital as inpatients for 3 or more consecutive calendar days, Medicare coverage of postacute SNF care (to the extent all other SNF coverage requirements are met). To enable beneficiaries to make informed financial and other decisions prior to hospital discharge, Medicare allows the hospital to change a beneficiary's inpatient status to outpatient (using condition code 44 on an outpatient claim) and bill all medically necessary services that it provided to Part B as outpatient services, but only if the change in patient status is made prior to discharge, the hospital has not submitted a Medicare claim for the admission, and both the practitioner responsible for the care of the patient and the utilization review committee concur with the decision (Section 50.3, Chapter 1 of the Medicare Claims Processing Manual (Pub. 100-04); MLN Matters article SE0622, Clarification of Medicare Payment Policy When Inpatient Admission Is Determined Not To Be Medically Necessary, Including the Use of Condition Code 44: "Inpatient Admission Changed to Outpatient," September 2004). Medicare beneficiaries are provided with similar protections, which are outlined in the Hospital Conditions of Participation (CoPs). For example, in accordance with 42 CFR 482.13(b), Medicare beneficiaries have the right to participate in the development and implementation of their plan of care and treatment, to make informed decisions, and to accept or refuse treatment. Informed discharge planning between the patient and the physician is important for patient autonomy and for achieving efficient outcomes.

In the proposed rule, we stated that while the limited scope of allowed rebilling for "Inpatient Part B" services protects Medicare beneficiaries and provides disincentives for hospitals to admit patients inappropriately, hospitals have expressed concern that this policy provides inadequate payment for resources that they have expended to take care of the beneficiary in need of medically necessary hospital care, although not necessarily at the level of inpatient care. A significant proportion of the Medicare CERT error rate consists of short (1- or 2-day) stays where the beneficiary received medically necessary services that the CERT contractor determined should have been provided as outpatient services and not as inpatient services. Hospitals have indicated that often they do not have the necessary staff (for example, utilization review (UR) staff or case managers) on hand after normal business hours to confirm the physician's decision to admit the beneficiary. Thus, for a short-stay admission, the hospital may be unable to timely review and change a beneficiary's patient status from inpatient to outpatient prior to discharge in accordance with the condition code 44 requirements.

In the proposed rule, we indicated that we have heard from various stakeholders that hospitals appear to be responding to the financial risk of admitting Medicare beneficiaries for inpatient stays that may later be denied upon contractor review by electing to treat beneficiaries as outpatients receiving observation services, often for longer periods of time, rather than admitting them as inpatients. In recent years, the number of cases of Medicare beneficiaries receiving observation services for more than 48 hours, while still small, has increased from approximately 3 percent in 2006 to approximately 7.5 percent in 2010. This trend is concerning because of its effect on

Medicare beneficiaries. There could be significant financial implications for Medicare beneficiaries of being treated as outpatients rather than being admitted as inpatients, of which CMS has informed beneficiaries.[1] For instance, if a beneficiary is admitted as an inpatient, the beneficiary pays a one-time deductible for all hospital services provided during the first 60 days in the hospital. As a hospital inpatient, the beneficiary would not pay for self-administered drugs or have any copayments for the first 60 days; whereas if the beneficiary is treated as an outpatient, the beneficiary has a copayment for each individual outpatient hospital service received. While the Medicare copayment for a single outpatient hospital service cannot be more than the inpatient hospital deductible, the beneficiary's total copayment for all outpatient services received may be more than the inpatient hospital deductible. In addition, usually self-administered drugs provided in an outpatient setting are not covered by Medicare Part B and hospitals may charge the beneficiary for them. Also, the time spent in the hospital as an outpatient is not counted towards the 3-day qualifying inpatient stay that section 1861(i) of the Act requires for Medicare Part A coverage of postacute care in a SNF.

As a result of these concerns related to the impact of extended time as an outpatient on Medicare beneficiaries, the CERT error rate, and the impact on hospitals of a later inpatient denial, CMS initiated the AB Rebilling Demonstration for a 3-year period for hospitals. This demonstration is voluntary and allows participating hospitals to rebill outside of the usual timely filing requirements for services relating to all inpatient short-stay claims that are denied for lack of medical necessity because the inpatient

[1] CMS Pamphlets: "Are You a Hospital Inpatient or Outpatient? If You Have Medicare - Ask!", CMS Product No. 11435, Revised, February 2011; "How Medicare Covers Self-Administered Drugs Given in Hospital Outpatient Settings," CMS Product No. 11333, Revised, February 2011.

admission was not medically necessary. Under the demonstration, hospitals may receive 90 percent of the Medicare allowable payment for all Part B services that would have been medically necessary had the beneficiaries originally been treated as outpatients and not admitted as inpatients. We note that hospitals cannot rebill for observation services, which, by definition, must be ordered prospectively to determine whether an inpatient admission is necessary (Chapter 1, Section 50.3.2 of the Medicare Claims Processing Manual (Pub. 100-04); FAQ 2723, available on the CMS Web site at https://questions.cms.gov/faq.php?id=5005&faqId=2723). Hospitals that participate in the AB Rebilling Demonstration will waive any appeal rights associated with the denied inpatient claims eligible for rebilling. Under the demonstration, Medicare beneficiaries are protected from any adverse impacts of expanded rebilling. For example, hospitals cannot bill beneficiaries for self-administered drugs or additional cost-sharing that would be required under Medicare Part B. The demonstration will inform us on the impact that expanded rebilling may have on the Medicare Trust Funds, beneficiaries, hospitals, and the CERT error rate. The demonstration is designed to evaluate potential impacts of expanded rebilling on admission and utilization patterns, including whether expanded rebilling would reduce hospitals' incentive to make appropriate initial admission decisions.

Hospitals expressed significant interest in the AB Rebilling Demonstration, which began on January 1, 2012. The demonstration was approved to accept up to 380 hospitals. In order to participate in the demonstration, a hospital must not be receiving periodic interim payments from CMS, and must be a Medicare-participating hospital as

defined by section 1886(d) of the Act, a category that includes all hospitals paid under the Medicare IPPS, but excludes hospitals paid under the IPF PPS, the IRF PPS, and the LTCH PPS, and cancer hospitals, CAHs, and children's hospitals.

The hospitals that volunteered to participate and were accepted in the demonstration began rebilling in early spring of 2012. More information about the demonstration is available on the CMS Web site at: http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/CERT/Part_A_to_Part_B_Rebilling_Demonstration.html. We stated in the proposed rule that we plan to conduct an evaluation of the demonstration during and after its completion.

B. Summary of Public Comments Received

While we are implementing the AB Rebilling Demonstration, we also solicited public comments in the CY 2013 OPPS/ASC proposed rule on other actions that we could potentially undertake to address stakeholders' concerns. In the proposed rule, we stated that there may be several ways of approaching the multifaceted issues that have been raised in recent months around a beneficiary's patient status and Medicare hospital payment. Given the complexity of this topic, we sought public perspectives on potential options the agency might adopt to provide more clarity and consensus regarding patient status for purposes of Medicare payment. We invited commenters to draw on their knowledge of these issues to offer any suggestions that they believe would be most helpful to them in addressing the current challenges, while keeping in mind the various impacts in terms of recently observed increases in the length of time for which patients

receive observation services, beneficiary liability, Medicare spending, and the feasibility of implementation of any suggested changes for both the Medicare program and hospitals.

We received approximately 350 public comments in response to our solicitation in the CY 2013 OPPS/ASC proposed rule from hospitals and hospital associations, physician associations, rehabilitative and long-term care facilities, beneficiaries, beneficiary advocacy organizations, Quality Improvement Organizations (QIOs), organizations specializing in medical necessity review, and other interested parties. The commenters provided significant input, and the majority requested that CMS not implement a comprehensive solution or set of solutions regarding patient status in the CY 2013 OPPS/ASC final rule with comment period. Instead, many commenters recommended that CMS develop an informed course of action in the upcoming months through a formal, ongoing dialogue with all interested stakeholders (for example, through open door forums or a task force). A few commenters recommended a more immediate course of action to limit beneficiary liability for SNF care and for the difference in beneficiary cost-sharing between hospital inpatient and outpatient services.

In this section, we summarize the feedback we received in response to our solicitation of public comments in the CY 2013 OPPS/ASC proposed rule. We are not providing responses to the public comments we received because in the proposed rule we strictly solicited public comments, and did not propose any changes in policy. We will consider the feedback we received from the public as we move forward. We structured our summary of the public comments around key suggestions that we have heard from

stakeholders in the following areas: (1) Part A to Part B Rebilling; (2) Clarifying Current Admission Instructions or Establishing Specified Clinical Criteria; (3) Hospital Utilization Review; (4) Prior Authorization; (5) Time-Based Criteria for Inpatient Admission; (6) Payment Alignment; and (7) Public Comments on Other Topics (including Rules for External Review of Inpatient Claims, Improving Beneficiary Protections, and Revising the Qualifying Criteria for SNF Coverage). We summarize the public comments below in the context of each of these suggestions.

1. Part A to Part B Rebilling

Some stakeholders have suggested that, when a Part A inpatient claim is denied because an inpatient level of care was not reasonable and necessary although some medical care was necessary, CMS allow hospitals to rebill Medicare and receive payment for all Part B services that would have been payable had the patient originally been treated as an outpatient rather than an inpatient. As we describe above, the AB Rebilling Demonstration allows participating providers to receive 90 percent of the allowable payment amount for such services (except observation services) as Part B Inpatient services. Because establishing such a policy on a national basis could result in increases in Medicare expenditures and could affect beneficiary liability for hospital care, CMS implemented the demonstration to assess Medicare spending and other outcomes while protecting beneficiaries from any increase in liability.

Comments: Commenters expressed some support for the AB Rebilling Demonstration as an important step in determining what types of policy clarifications are needed. The commenters noted that the beneficiary protections against changes in

liability are a key benefit of the demonstration. While some commenters expressed appreciation for the opportunity for increased Part B payment to hospitals, they disagreed with the demonstration's requirement to forego appeals of the denied inpatient claims eligible for rebilling. One commenter requested that CMS provide interim reports to stakeholders describing the demonstration's evaluation criteria and its progress towards meeting its goals.

Some commenters recommended that CMS establish a national policy allowing the rebilling of all Part B services that would have been payable if the patient had been treated as an outpatient rather than admitted as an inpatient because, according to the commenters, outpatient and inpatient services are sometimes indistinguishable. The commenters believed that the Medicare statute does not preclude such a policy and that, due to the recent focus on claims audit and review, hospitals would have no incentive to admit beneficiaries inappropriately in response to a more generous rebilling policy. However, other commenters expressed concern that there would be such an incentive. They indicated that allowing expanded rebilling with a change in bill type from a Part A claim to a Part B claim would remove the incentive to bill accurately, as hospitals would file more inpatient claims under Part A in order to receive the (typically higher) Diagnosis-Related Group (DRG) payment under the IPPS, knowing that, in the event of the inpatient claim being denied, they could rebill under Part B and receive the same (typically lower) OPPS payment they would have received if they had billed an outpatient claim initially.

Several commenters suggested that allowing full Part B rebilling would negate and undermine the designs of the OPPS and the IPPS. The commenters stated that OPPS payments are established to compensate hospitals for the care provided in the outpatient setting, and that they act as a natural complement to the IPPS. They indicated that making the two payment systems retroactively interchangeable would result in the payment rates calculated under each system being miscalibrated and failing to adjust appropriately over time to migration of services from the inpatient to the outpatient setting. In addition, according to the commenters, a national policy allowing full Part B rebilling would provide an unfair market advantage to providers who make inappropriate inpatient admission determinations over those who do not. The commenters reasoned that Medicare's current policies are well-founded, longstanding, widely known and largely followed, and that the current challenges do not warrant the extensive resources that full rebilling and other policy changes would entail.

Some commenters indicated that a national policy allowing full Part B rebilling following the denial of an inpatient claim would have limited utility because typically the timely filing period has lapsed by the time the inpatient claim is denied, providers could not appeal the inpatient claim, and providers would not receive the Part A payment that they seek. In addition, according to the commenters, the manual process of recoding the inpatient claim as an outpatient claim is costly. A few commenters suggested that CMS allow rebilling of all Part B services but apply a penalty by limiting payment to a discounted amount. Other commenters were concerned about the significant financial

burden of Part B rebilling for beneficiaries who have Part A coverage but do not have coverage for Part B services.

Some commenters also suggested that CMS allow hospitals to change a beneficiary's inpatient status to outpatient after discharge in order to submit a Part B outpatient claim either prior to or after submitting an inpatient claim. Other commenters recommended that CMS extend the timely filing deadline to 1 year from the date of service or 6 months to 1 year from the date of the inpatient claim denial, whichever is later. Some commenters suggested that CMS extend the timely filing deadline only for claims that are denied after a significant amount of time has passed since the date of service.

Commenters suggested mechanisms to protect beneficiaries from increases in their liability associated with any of these policy changes. For example, several commenters believed that hospitals could waive any increases in beneficiary cost-sharing or that CMS could provide coverage for self-administered drugs in the outpatient department, cap the sum of outpatient services at the inpatient deductible, or establish annual maximum out-of-pocket costs. Many commenters also recommended the modernization and reform of the SNF qualification criteria (we describe these comments further below).

2. Clarifying Current Admission Instructions or Establishing Specified Clinical Criteria

In recent months, we have heard from some stakeholders who suggested a need for us to clarify our current instructions regarding the circumstances under which Medicare will pay for an admission in order to improve hospitals' ability to make

appropriate admission decisions. Stakeholders have suggested the establishment of more specific clinical criteria for admission and payment such as adopting specific clinical measures because, according to the commenters, the current criteria are not clear-cut. We have issued longstanding instructions that the need for admission is a complex medical judgment that depends upon multiple factors, including an expectation that the beneficiary will require an overnight stay in the hospital or need more than 24 hours of care, the patient's medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital's policies, the relative appropriateness of outpatient and inpatient treatment, and other factors (Section 10, Chapter 1 of the Medicare Benefit Policy Manual (Pub. 100-02)). We stated in the CY 2013 OPPS/ASC proposed rule that we are interested in receiving public comments and suggestions regarding whether and how we might improve our current instructions and clarify the application of Medicare payment policies for both hospitals and physicians, keeping in mind the challenges of implementing national standards that are broad enough to contemplate the range of clinical scenarios but prescriptive enough to provide greater clarity.

Comments: The public comments reflected a widespread understanding and agreement with CMS' guidance that the inpatient admission decision is ultimately a complex medical judgment that involves the consideration of many factors. Many commenters indicated that if Medicare adopted more specific guidelines or criteria, the clinical judgment of the treating physician should have primacy. A recurrent comment was that this judgment would always be necessary in certain cases, and should take

precedence over other criteria that may be used. Many commenters were concerned that decision-making tools (such as Interqual Clinical Decision Support or the Milliman Care Guidelines, alternatively described by commenters as commercial or proprietary screening tools), which are designed for use as guidelines rather than prescriptive tools, do not take into account patient "risk" and may undermine the physician's judgment.

In addition, many commenters believed that any selected criteria must apply equally to Medicare contractors, hospitals, and others and should match the audit review criteria. Many commenters expressed concern that Medicare's claims review contractors inappropriately disregard the physician's judgment, and do not employ a physician in making their determinations. (We describe the comments on external review criteria in further detail below). One commenter indicated that commercial screening tools do not always comport with Medicare rules. The commenter provided as an example that one popular tool fails to distinguish scheduled replacement pacemaker procedures from the placement of a new pacemaker on an emergency basis. Some of the public comments received from physicians identified what they characterized as significant problems with the accuracy, validity, and transparency of proprietary screening tools, including use of appropriateness standards that are not accepted by the relevant physician specialties and failure to follow Medicare payment policy.

Nevertheless, many commenters expressed support for various types of national criteria. These criteria included evidence-based guidelines such as the Agency for Healthcare Research and Quality's National Clearinghouse Guidelines or other rules developed in consultation with physician societies. Some commenters supported the use

of specific proprietary screening tools such as Interqual Clinical Decision Support or the Milliman Care Guidelines. Other commenters favored more transparent criteria similar to the Correct Coding Initiative (CCI) that are adapted for Medicare and are developed using physician input. One commenter indicated that the CCI edits have proven more cost-effective than proprietary tools. A few commenters suggested that use of the Program for Evaluating Payment Patterns Electronic Report (PEPPER) reports, which provide hospital-specific Medicare data statistics for discharges that are vulnerable to improper payments, would allow for continuous improvement in utilization and coding. One commenter noted that it would be useful to choose the set of criteria that are used by Medicaid and other payers, in order to facilitate uniform documentation that supports the specific criteria required by the various screening tools.

Some commenters pointed out process improvements that hospitals and physicians should make, regardless of whether CMS adopts specific clinical criteria or issues more specific admission instructions. Several commenters stated that physicians should improve their documentation in support of the patient status that they order, and that sometimes it is not clear whether the physician ordered inpatient admission or outpatient observation services. The commenters suggested that physicians document the need for admission in a standardized field on electronic health records or elsewhere. Other commenters emphasized the importance of the role of the hospital in selecting patient status for purposes of billing because they believed that the physician is focused on ordering the necessary care and, for good reason according to the commenters, is not occupied with the nuances of patient status designation for payment purposes.

3. Hospital Utilization Review

In the proposed rule, we asked commenters to consider the responsibility of hospitals to utilize all of the tools necessary to make appropriate initial admission decisions. We stated that we believe this is important because some hospitals have indicated that simply having case management and UR staff available to assist in decision-making outside of regular business hours may improve the accuracy of admission decisions.

Comments: Several commenters stated that some hospitals do not have UR staff on hand outside normal business hours or on weekends to assist with patient status determinations, and that this is especially problematic for patients with short inpatient stays. The commenters expressed varying opinions on hospital UR. Some commenters recognized that Medicare's regulations require the collaboration of the treating physician and the hospital's UR staff in making the appropriate patient status determination, and believed that neither party is dispensable. Several commenters indicated that 24-hour, 7 days a week availability of hospital UR and/or case management staff should be a hospital best practice, as it assists in making appropriate admission determinations for short-stay cases where the need for admission is unclear. Several commenters opined that Medicare should require the availability of hospital UR on a 24-hour/7 days a week basis. One commenter stated that CMS should develop a certification process of "deeming" acceptable individual hospital UR processes, using a standard of 24-hour/7 days a week availability, confirmation by an external physician, and adherence to the hospital CoPs. Another commenter recommended the use of a condition code on claims

to track whether UR confirmation of appropriate patient status is associated with fewer claim denials. Some commenters preferred reinforcement of hospital UR over the institution of external guidelines for admission.

However, several commenters indicated that Medicare's current UR requirements in the CoPs should be eliminated because of the administrative cost to the hospital, or because they do not result in more accurate admission determinations that are commensurate with their associated cost. One association believed that hospital UR will have limited utility as long as admission criteria are unclear. Yet another physician professional association stated that hospitals should be required to submit their claims based on the admitting physician's judgment rather than the opinion of another physician in the hospital.

4. Prior Authorization

In our proposed rule, we also invited public comments on the potential use of prior authorization for payment of a hospital inpatient admission.

Comments: Many commenters believed that the concept of using prior authorization on a targeted basis was promising and worthy of consideration. To facilitate administrative feasibility, many commenters suggested that it be used selectively for elective procedures, specific services that are not designated as inpatient-only services under the OPPS, or conditions that are at high-risk for inappropriate inpatient admission. The commenters were concerned that mandatory prior authorization could become a barrier to the provision of urgent care, and some recommended that CMS exclude patients in the emergency department or those receiving critical care.

Alternatively, the commenters suggested that prior authorization be used as an adjunct method for cases not meeting the admission criteria of commercial screening tools.

Several commenters believed that prior authorization is feasible because hospitals already have an infrastructure for obtaining prior authorization for commercial insurers. The commenters suggested that CMS could similarly redirect current resources towards a prior authorization program. Several commenters suggested an online tool for prior authorization.

A few commenters opposed prior authorization altogether based on administrative burden, and many commenters believed that it would need to result in guaranteed payment in order to be useful. One commenter observed that retrospective review is still required in many cases when prior authorizations are obtained from commercial insurers, due to incomplete or inaccurate prior authorization information and changes in what was planned or expected when the initial clinical information was submitted. The commenter stated that for this reason, commercial insurers reserve the right to perform, and often do perform, retrospective audits based on the completed medical record. In addition, the commenter stated that the CERT error rate evidences that the vast majority of providers understand and follow the current Medicare statutes and rules. Thus, according to the commenter, requiring prior authorization will add significant cost to the program without eliminating the inpatient error rate, at a time when the Medicare Trust Fund is at risk.

5. Time-Based Criteria for Inpatient Admission

In the proposed rule, we stated that some stakeholders have suggested that CMS has authority to define whether a patient is an inpatient or an outpatient. They believed

that it may be permissible and appropriate for us to redefine "inpatient" using parameters in addition to medical necessity and a physician order that we currently use, such as length of stay (LOS) or other variables. For example, currently a beneficiary's anticipated LOS at the hospital may be a factor in determining whether the beneficiary should be admitted to the hospital, but is not the only factor. We have issued instructions that state that, typically, the decision to admit should be made within 24 to 48 hours, and that expectation of an overnight stay may be a factor in the admission decision (Section 20.6, Chapter 6 and Section 10, Chapter 1 of the Medicare Benefit Policy Manual (Pub. 100-02)). However, we stated in the proposed rule that we are interested in hearing from stakeholders regarding whether it may be appropriate and useful to establish a point in time after which the encounter becomes an inpatient stay if the beneficiary is still receiving medically necessary care to treat or evaluate his or her condition. We indicated that such a policy could potentially limit the amount of time that a beneficiary is treated as an outpatient receiving observation services before the hospital encounter becomes inpatient, provided the additional time in the hospital is medically necessary. Currently, we do not specify a limit on the time a beneficiary may be an outpatient receiving observation services, although, in the past, we have limited payment of observation services to a specific timeframe, such as 24 or 48 hours. Some in the hospital community have indicated that it may be helpful for the agency to establish more specific criteria for patient status in terms of how many hours the beneficiary is in the hospital, or to provide a limit on how long a beneficiary receives observation services as an outpatient. We invited public comments regarding whether there would be more clarity regarding patient

status under such alternative approaches to defining inpatient status. We also noted that it is important for CMS to maintain its ability to audit and otherwise carry out its statutory obligation to ensure that the Medicare program pays only for reasonable and necessary care. We asked that commenters consider opportunities for inappropriately taking advantage of the Medicare system that time-based and other changes in criteria for patient status may create.

Comments: Some commenters expressed interest and support for criteria that are strictly time-based, based largely on a primary goal of eliminating extended observation cases. These commenters supported defining a patient as an inpatient after 24, 48, or 72 hours, and noted that such a policy could improve the problem of beneficiaries not qualifying for needed SNF care due to their outpatient status. One commenter believed that a 48-hour benchmark made sense because it is consistent with the activities that are required under the CoPs within the first 48 hours of a hospital stay. Another commenter suggested establishing a second decision point during the observation period, when the physician must reevaluate whether the patient needs to be admitted as an inpatient. However, the commenter noted that this may increase administrative complexity without commensurate benefit.

Some commenters representing the hospital community believed that patients who have been actively monitored for more than 24 to 48 hours as outpatients under observation and cannot be safely discharged are likely sufficiently complex cases that would benefit from being admitted as an inpatient, regardless of whether they technically meet inpatient admission criteria. The commenters posited that observation services are

more comparable to inpatient care than they are to other outpatient services, and that this fact would be more accurately reflected by a time-based admission policy. A few commenters suggested that CMS limit observation care to 24 hours, with exceptions for physician discretion. Several commenters suggested that CMS clarify the definition and parameters of outpatient observation services to help stakeholders determine when it is appropriate to furnish observation services and for how long. Another commenter suggested that CMS limit a patient's time in observation by requiring additional assessments and increased documentation of involvement by the physician.

In contrast, many commenters expressed reservations about a time-based approach. Some commenters posited that inpatient and outpatient services are different in nature. One physician association stated that the primary difference between the inpatient and outpatient setting is the availability of nurses (and related staff) and advanced technology in the inpatient setting, which accounts for the added cost of inpatient care. The commenter recommended structuring an inpatient DRG payment around short-stay admissions where the physician believes that these added components of care are necessary. Other commenters were concerned that under a time-based policy, the level of service would no longer be taken into account in hospital payment and that such a policy would inappropriately negate the need for medical necessity review. Some commenters stated that the medical review would simply shift to assessing the necessity of the patient's LOS as an outpatient or whether the patient needed continuing hospital care at the time they became an inpatient. Some commenters believed that a time-based policy would result in additional short inpatient stays than under current Medicare

guidance. Therefore, these commenters believed that hospitals would continue to be subject to audit risk and that short-stay audits would simply increase.

Another commenter expressed concern that hospitals may be substituting outpatient observation services for inpatient admissions in order to maximize their outpatient drug revenues under the Federal 340B Drug Pricing Program. The commenter recommended that CMS modify the definitions of "outpatient" and "inpatient" to explicitly clarify that a patient's status determination should be based solely on appropriate clinical judgment, and should not be influenced by financial motives under programs such as the 340B Drug Pricing Program.

Some commenters opposed time-based rules because, according to the commenters, it would undermine the judgment of the treating physician. Other commenters noted that the absence of objective clinical criteria for choosing a timeframe would render time-based criteria for admission arbitrary. Several commenters opposed limiting observation services to 24 hours because hospitals often need more time (particularly up to 48 hours) to evaluate diagnostic testing and develop the right treatment plan. They noted that practice patterns vary widely nationally and among facilities in the same region. Other commenters were concerned that a policy of never counting certain days as inpatient days could actually reduce beneficiary access to SNF care. Other commenters believed that a time-based policy would need refinement around issues like requirement of a physician order for inpatient admission.

Several commenters opposed time-based criteria because such criteria may conflict with the provision of inpatient surgical care for patients who require only short

admissions. The commenters pointed out that such a policy could conflict with Medicare's inpatient only list, and that as the standard of practice evolves to enable longer inpatient services to be furnished during short (1- or 2-day) inpatient stays, those services would no longer qualify as inpatient services. One commenter stated that there are some procedures that are so inherently complex that they may be performed only on an inpatient basis, regardless of how long (or short) the time was that the patient spent in the hospital. The commenter stated that establishing a bright-line time rule could create a situation whereby these services could be denied solely on the basis of the time spent in the hospital while ignoring the level of service required for subjecting a patient to an inherently risky procedure. The commenter expressed concern that CMS might require that all patients, regardless of clinical presentation, first undergo a period of 48 hours of observation before being admitted as inpatients to the hospital, despite the fact that their medical condition and treatment plan may be wholly consistent with an inpatient admission upon presentation to the hospital.

Several commenters recommended that rather than limiting the timeframe for observation services, observation care should be furnished in dedicated observation units in emergency departments rather than on floor units. They cited studies showing that the dedicated units save costs compared to inpatient care and demonstrate shorter timeframes than the floor units for diagnosing or discharging.

6. Payment Alignment

In the proposed rule, we asked commenters to consider how aligning payment rates more closely with the resources expended by a hospital when providing outpatient

care versus inpatient care of short duration might reduce payment disparities and influence financial incentives and disincentives to admit.

Comments: Commenters expressed significant interest in various means of improving the alignment of payment for what they termed equivalent outpatient and short inpatient hospital stays. Most of the commenters who supported payment alignment suggested developing a DRG for short inpatient stays, although several commenters recommended an expanded outpatient APC payment in addition to or in lieu of a short-stay DRG. Some commenters suggested basing the payment for short-stay inpatient admissions on a percentage of the related DRG by mean LOS. For example, if the mean LOS for a given DRG is 3 days, then the hospital would be paid one-third of that DRG for an inpatient admission with a 1-day stay. Several commenters suggested a short-stay outlier policy similar to the LTCH PPS, or a policy similar to the IPPS transfer policy. Other commenters more broadly suggested developing a resource-based payment structure specifically for short-stay, lower acuity admissions.

Some commenters noted, however, that aligning payment rates would reduce but not eliminate the financial risk of claim denial. According to the commenters, a payment alignment approach would not eliminate the potential for continued use of observation care over inpatient admission. One commenter asserted that the resources expended by a hospital for inpatient and outpatient care are already aligned when the care is billed appropriately.

7. Public Comments on Other Topics

We received a number of public comments on other related issues.

a. Rules for the External Review of Inpatient Claims

Comments: Many commenters expressed concerns about the criteria that are used by Medicare's contractors to determine the medical necessity of hospital inpatient admissions. The commenters were concerned that the review criteria being utilized by contractors do not match the admission criteria set forth in Medicare's guidance. In particular, according to the commenters, contractors are not employing physicians in making their medical necessity determinations, even though Medicare instructs that the admission decision is a complex medical judgment that involves forecasting a potential (not definite) need for an overnight stay or more than 24 hours of hospital care, or the risk of harm to the patient if not admitted (predictability of an adverse event). The commenters asserted that, as a result, claims reviewers inappropriately base their judgment on information that was not predictable or available to the physician at the time of admission.

Many commenters recommended that CMS increase its oversight of the Agency's medical review contractors, and ensure that its review rules are being followed. Commenters asked that CMS require all review contractors to use the same criteria to determine medical necessity that physicians and hospitals are required to use in making the inpatient admission decision; to use a physician reviewer in accordance with the QIO claim review standard, or to consult with the treating physician or a physician in the same specialty as the admitting physician; and to provide justification to the treating physician in support of a claim denial. According to the commenters, the review criteria that are used should apply uniformly to Medicare contractors, hospitals, and others.

Several commenters indicated that physician payment for professional services should be denied whenever inpatient hospital payment is denied, due to the role of the physician in the admission decision. In contrast, some physician commenters were concerned that they already are often inappropriately at risk for denial of their Part B claim when a hospital inpatient claim is denied, or when a hospital changes a patient's status to outpatient without their knowledge such that the place of service on the physician claim does not match that claimed by the hospital. They stated that, in some cases, the hospital does not bill Medicare, so there is no companion claim at all. Similarly, some physicians expressed concern that hospitals use "black box" proprietary tools to identify allegedly inappropriate admissions and change the patient's status to outpatient without the knowledge of the patient or the physician. These commenters also expressed concern for any adverse impact on beneficiary liability.

b. Improving Beneficiary Protections

Comments: Many commenters suggested means of improving beneficiary protections against unforeseen changes in his or her liability. These included providing Medicare coverage for self-administered drugs in the hospital outpatient department, waiving beneficiary coinsurance, capping the sum of outpatient services at the inpatient deductible, or establishing annual maximum out-of-pocket costs. Some commenters suggested that Medicare clarify and strengthen beneficiary notification and appeal rights regarding changes in patient status and the receipt of observation care. For example, according to the commenters, Medicare should require a straightforward explanation to beneficiaries of the cost-sharing implications of being an outpatient receiving observation

services compared to being an inpatient. One QIO noted that as part of their case review activities, QIOs review beneficiary appeals of inpatient hospital discharges to assure that patients are medically ready to move to the next level of care. The QIO believed that if a beneficiary receives only outpatient observation services and is not an inpatient, he or she has no right to appeal his or her discharge from the hospital to the QIO. The QIO stated that it often receives complaints from beneficiaries who believe they are being discharged prematurely, only to find out that the QIO cannot review that care because the hospital classified the stay as observation rather than inpatient.

Some commenters suggested means of penalizing hospitals for inappropriate admission patterns. They provided examples such as developing quality measures with payment penalties to identify instances of inappropriate use of observation care for patients meeting inpatient admission criteria, or counting time spent receiving observation services as inpatient time for the purposes of hospital readmission penalties. Other commenters recommended improving physician education regarding the beneficiary liabilities that are associated with patient status to facilitate patient status determinations that take beneficiary cost-sharing into account.

c. Revising the Qualifying Criteria for Skilled Nursing Facility (SNF) Coverage

Comments: Many commenters recommended that Congress and/or CMS modernize and revise the SNF qualification rules. Many beneficiaries, beneficiary representatives, SNFs, and others requested that CMS count the time a beneficiary spends as an outpatient receiving observation services towards the 3-day hospital inpatient stay that is required for coverage of SNF care. Many commenters indicated that the statutory

time-based rule that requires a beneficiary to have a 3-day inpatient hospital stay in order to qualify for SNF care is obsolete, given the advances in medical care, the trend towards reduced LOS, and the migration of services from inpatient to outpatient over the course of the Medicare program's history. These commenters recommended that this rule be replaced with clinically meaningful criteria that are not time-based or based on patient status.

A few commenters asserted that CMS could use its statutory authority under section 1812(f) of the Act (as enacted by section 123 of the Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97-248) to waive the 3-day qualification rule. Some commenters asserted that the criteria for using this authority would be met, namely that there would be no increase in associated costs to the Medicare program and that the acute nature of the SNF benefit would be maintained. The Act provides that the Secretary shall provide for coverage of extended care services which are not post-hospital extended care services at such time and for so long as the Secretary determines that the inclusion of such services will not result in any increase in the total payments made under Title XVIII, and will not alter the acute care nature of the SNF benefit. Other commenters believed that new statutory authority would be required to change the SNF criteria, and they expressed their support for bills they stated have been introduced in the Congress to count time in observation as inpatient time for purposes of SNF qualification. Some commenters recommended waiving the 3-day rule for certain diagnoses that benefit from short inpatient stays and speedy access to postacute rehabilitative services. They indicated that some beneficiaries require only a brief hospital assessment, rather than a

lengthy stay in acute care, prior to long-term skilled care, and that it is not uncommon for patients with hospital stays of less than 3 days to require follow up care in a SNF.

C. Summary

We appreciate all of the public comments that we received on this multi-faceted topic. We will take all of the public comments that we received into consideration as we consider future actions that we could potentially undertake to provide more clarity and consensus regarding patient status for purposes of Medicare payment.