KING & SPALDING

Client Alert

Healthcare Practice Group

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CMS Proposes Significant Changes to the Two Midnight Rule in the 2016 OPPS Proposed Rule

On July 1, 2015, the Centers for Medicare & Medicaid Services (CMS) released the Calendar Year 2016 Outpatient Prospective Payment System (OPPS) Proposed Rule (CMS 1633 P). In response to stakeholder concern, CMS proposes to expand a current, but limited, exception to the controversial Two Midnight Rule. The scope of the expansion is unclear at this point, but as described below, the proposal allows for Part A coverage of one-day stays under standards similar to the pre-Two Midnight Rule standards for evaluating patient status. In addition, CMS announced significant changes regarding contractor review of patient status claims, as discussed in detail below.

Genesis of the Two Midnight Rule

Almost two years ago, on August 2, 2013, CMS issued final rule CMS-1599-F, containing the Fiscal Year (FY) 2014 Inpatient Prospective Payment System (IPPS), in which CMS implemented what is commonly known as the Two Midnight Rule. The Two Midnight Rule represented a significant and rapid departure from past practice. In many respects, CMS abandoned longstanding policies regarding the determination of patient status.

The pre-Two-Midnight inpatient admission standard relied on the physician's complex medical judgment and left substantial room for differences in opinion. As a result, contractor reviews in this area exploded as Recovery Audit Contractors (RACs) questioned the admitting physician's clinical judgment, which led to the well-publicized backlog of Medicare appeals and CMS's one-time offer to settle such appeals at 68 percent of the paid amount. In an attempt to provide clarity to its standard, CMS developed the Two Midnight Rule, which, as explained below, was originally a time-based inquiry designed to clarify inpatient admission standards.

Two Midnight Rule Overview

As originally promulgated, the Two Midnight Rule provides that a hospital inpatient admission was generally considered reasonable and necessary if the physician (or other qualified practitioner) ordered the admission based on his or her expectation that the patient would require at least two

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midnights of medically necessary hospital services, or if the beneficiary required a procedure on the CMS Inpatient Only list. Conversely, if the physician expected to keep the patient in the hospital for a period of time that did not span two midnights, the services would generally be appropriate only for outpatient payment.

In January 2014, CMS published additional guidance regarding the Two Midnight Rule, and in this guidance acknowledged that there may be "rare and unusual" exceptions to the Two Midnight Rule in which an inpatient admission may be appropriate and payable under Part A even though a physician ***does not expect*** the patient to require hospital services for at least two midnights but concludes that inpatient admission is necessary. CMS identified as one example patients who require newly initiated mechanical ventilation, but also stated that the "rare and unusual" exception does not apply to patients receiving telemetry or patients who are admitted to an Intensive Care Unit (ICU). CMS also invited the hospital industry to bring to the agency's attention other possible "rare and unusual" exceptions. Until now, CMS had not expanded upon the one "rare and unusual" exception identified above and had seemed to indicate that this exception applied categorically (as opposed to being determined on a case-by-case basis).

In the FY 2014 IPPS rule, CMS also announced two medical review standards in connection with the Two Midnight Rule. Under the Two Midnight Presumption, Medicare contractors are instructed to presume that inpatient hospital claims with lengths of stay greater than two midnights following a valid inpatient order are medically necessary and, therefore, appropriate for Medicare Part A payment. For cases spanning less than two midnights after an inpatient admission order, the Two Midnight Benchmark applies. Under the benchmark, such cases are not presumed to be medically necessary, but reviewers are instructed to consider the total amount of time the patient spent receiving medically necessary services in the hospital, including time in outpatient settings before inpatient admission. If the total amount of hospital time spans two midnights and supports the physician's expectation that the patient required two midnights of hospital services, then the claim is appropriately payable under Medicare Part A.

Proposed Changes to the Two Midnight Rule

In the Proposed Rule, CMS does not seek to modify the Two Midnight Presumption or the Two Midnight Benchmark. Instead, CMS states that its proposal is intended to expand upon the existing "rare and unusual" ***exception*** to the Two Midnight Rule in which CMS recognized that inpatient admission (and Part A payment) may be appropriate in some circumstances even though there is no expectation that the patient would require hospital services for a period of time spanning at least two midnights. Under the proposed expansion, inpatient admission, and Part A payment, would be appropriate on a case-by-case basis if documentation in the medical record supports the admitting physician's determination that the patient requires inpatient hospital care despite an expected length of stay that is less than two midnights. CMS proposes that the following factors (among others) would be relevant to determining whether a patient requires inpatient admission under the expanded policy:

- The severity of the signs and symptoms exhibited by the patient;
- The medical predictability of something adverse happening to the patient; and
- The need for diagnostic studies that appropriately are outpatient services (that is, their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more).

CMS reiterated that under its current policy, and proposed revised policy, Medicare review contractors are permitted to take into account evidence-based guidelines or commercial utilization tools to evaluate the inpatient admission decision. In response to industry suggestion that CMS adopt specific criteria for the review of short-stay inpatient

claims, CMS requests public comments on whether specific medical review criteria should be adopted for inpatient hospital admissions that are not expected to span at least two midnights and, if so, what those criteria should be.

Although CMS did not adopt a new short-stay payment policy (such as a short-stay DRG), CMS did acknowledge that several stakeholder groups have analyzed potential short-stay payment policies. However, CMS stated that there is no consensus on what a short-stay payment policy should be and that CMS will continue to consider potential payment changes.

Analysis of CMS's Proposal

The Two Midnight Rule is a standard that bases Medicare coverage and payment for inpatient stays on the length of time a beneficiary remains as an inpatient (the Two Midnight Presumption) or the length of time a physician expects the beneficiary to receive hospital services (the Two Midnight Benchmark), the relevant length of time being two midnights. When it finalized the Two Midnight Rule, CMS stated that factors such as the need for level of care or the need for a certain level of intensity of services were no longer relevant for determining Medicare inpatient coverage. *See* 78 Fed. Reg. 50947. By contrast, the "rare and unusual" exception articulated by CMS in January 2014, and now the proposed expansion of the "rare and unusual" exception proposed in the 2016 OPPS rule, base Medicare coverage not on the length of time services will be required, but rather on a physician's determination of the need for a higher level or more intense services—namely inpatient services—after evaluating a number of factors that have to do with the patient's clinical condition. It would appear, therefore, that if CMS were to adopt this proposal, inpatient stays that are less than two midnights may be appropriately defended as payable in the following two circumstances:

- Where the stay meets the Two Midnight Benchmark—that is, the beneficiary receives both outpatient and inpatient services for a period of time lasting more than two midnights; and

- Where it can be demonstrated in the medical record that a physician appropriately determined the patient required inpatient services although the stay was brief and did not meet the Two Midnight Benchmark.

What is not clear from CMS's proposal is how frequently this expanded exception would apply or how it differs from the admission standard that existed prior to the adoption of the Two-Midnight Rule. Prior to FY 2014, Medicare manuals described the inpatient admission decision as a "complex medical judgment" that could only be reached after a physician considered a number of factors, including the factors that CMS now proposes would be relevant for consideration under the proposed expansion (such as the severity of the signs and symptoms exhibited by the patient and likelihood of adverse consequences). *See* Medicare Benefit Policy Manual, Chapter 1, Section 10. While the expansion of coverage for short stays is welcome news to hospitals, the proposed standard is strikingly similar to the pre-Two Midnight standard which lacked clarity and enabled RACs to second-guess medical decision making.

Patient Status Review Changes

The Proposed Rule also includes significant changes to CMS's medical review strategy of patient status determinations. For the lifetime of the Two Midnight Rule, CMS limited patient status reviews to Medicare Administrative Contractors (MACs) performing "Probe & Educate" reviews. Under the Probe & Educate program, MACs have conducted pre-payment probe reviews of a sample of claims, depending on hospital size. The Probe & Educate period has been repeatedly extended and is currently set to expire on September 30, 2015.

In the Proposed Rule, CMS announces that, no later than October 1, 2015, Quality Improvement Organization contractors (QIOs) will begin to conduct reviews of short inpatient stays, thus transitioning this role away from

MACs. Importantly, CMS states this change will be implemented regardless of whether CMS ultimately implements the modifications to the Two Midnight Rule described above.

Under the new medical review short-stay inpatient review process, QIOs will review a sample of ***post***-payment claims and make a determination of the medical appropriateness of the admission as an inpatient. QIOs will also provide education to hospitals regarding claims denied under the Two Midnight Rule.

Hospitals that are found to exhibit continued issues (such as a consistently high denial rate) will be referred to the RACs for further payment audits. The number of claims a RAC will be allowed to review for patient status issues will be determined based on the hospital's claim volume and the denial rate identified by the QIO.

0.2% Rate Cut

CMS also included further discussion of the 0.2% payment reduction enacted as a result of the Two Midnight Rule. In FY 2014 IPPS, CMS announced the payment reduction and included what many considered an unsatisfactory explanation of its rationale for the reduction, indicating that its actuaries estimated that the Two Midnight Rule would lead to increased admissions and would increase IPPS expenditures by approximately $220 million in FY 2014. The rate cut has been controversial in the provider community has been challenged by several provider groups in court. *See Athens Reg. Med. Ctr. v. Sebelius*, Case No. 1-14-cv-503 (D.D.C.).

Conclusion

If finalized, the changes announced in the OPPS Proposed Rule will likely have a significant impact on hospital providers. Comments on the Proposed Rule are due on August 31, 2015. King & Spalding will continue to evaluate the Proposed Rule and intends to hold a Healthcare Roundtable on **July 14, 2015** to address these issues and their potential impact in greater detail.

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