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Client Alert

Healthcare Practice Group

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CMS Finalizes Significant Changes to the Two Midnight Rule in the 2016 OPPS Final Rule

On October 30, 2015, the Centers for Medicare & Medicaid Services (CMS) released the Calendar Year 2016 Outpatient Prospective Payment System Final Rule (2016 OPPS Final Rule). In the 2016 OPPS Final Rule, CMS finalizes significant changes to the Two Midnight Rule that were first **proposed** this summer.

Beginning **January 1, 2016**, CMS will allow Part A coverage of one-day stays in certain limited circumstances under standards similar to the pre-Two Midnight Rule standards for evaluating patient status. Although the scope of this exception is unclear at this point, CMS notes that it would "continue to expect that stays under 24 hours would rarely qualify for an exception" to the Two Midnight Benchmark.

In the 2016 OPPS Final Rule, CMS also discusses the recent transition of patient status reviews to Quality Improvement Organizations (QIOs). However, the 2016 OPPS Final Rule does not provide much detail on how such reviews will be conducted.

In this Client Alert, we begin by providing a general background on the history of the Two Midnight Rule. Following this overview, we discuss the changes finalized in the 2016 OPPS Final Rule and the potential significance of such changes to the provider community.

Genesis of the Two Midnight Rule

Over two years ago, on August 2, 2013, CMS issued final rule CMS-1599-F, containing the Fiscal Year 2014 Inpatient Prospective Payment System (2014 IPPS Final Rule), 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 Auditors (RACs) routinely questioned the admitting physician's clinical judgment, which led to the well-publicized backlog of

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Medicare appeals and CMS's one-time Global Settlement Officer (GSO) to resolve 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 designed as a standard focused on a time-based inquiry.

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 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 the 2014 IPPS Final Rule, CMS also announced two medical review standards in connection with the Two Midnight Rule. Under the Two Midnight Presumption, CMS 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 CMS 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.

The Two Midnight Rule as originally promulgated also contained significant technical documentation requirements. Specifically, inpatient admission orders and physician certifications were required for all inpatient admissions. However, effective January 1, 2015, CMS walked back the certification requirement in response to provider concern regarding the utility of the certification requirement in light of the administrative burden imposed on providers. Accordingly, a physician certification is currently only required for long-stay cases -- defined as 20 days or longer -- or outlier cases.

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 nevertheless 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 the 2016 OPPS Final Rule, CMS had not expanded upon the one "rare and unusual" exception identified above and had seemed to indicate that the "rare and unusual" exception applied categorically (as opposed to being determined on a case-by-case basis).

Over the past two years, CMS has issued sub-regulatory guidance on the Two Midnight Rule at least 42 times, in forms such as Frequently Asked Question (FAQ) documents and provider Open Door Forums. Importantly, however, CMS has yet to issue manual guidance for the provider community.

2016 OPPS Final Rule - Changes to the Two Midnight Rule

The changes finalized in the 2016 OPPS Final Rule track the changes first proposed in July 2015 in the FY 2016 OPPS proposed rule (2016 OPPS Proposed Rule). For patient stays satisfying the Two Midnight Benchmark, CMS's policy remains unchanged. However, effective January 1, 2016, CMS will allow exceptions to the Two-Midnight Benchmark to be determined on a ***case-by-case basis*** by the physician responsible for the care of the beneficiary, subject to medical review. Said differently, Part A payment may be appropriate in some circumstances even though there is no expectation by the physician (or qualified ordering practitioner) of a two-midnight stay and one of the two pre-existing categorical exceptions (CMS "inpatient only" list and newly initiated mechanical ventilation) does not apply. CMS has indicated that this change to the Two Midnight Rule is in response to stakeholder concern and CMS's continued efforts to develop the most appropriate standard for determining Medicare Part A payment.

CMS frames the modification as an expansion of the pre-existing "rare and unusual" exception to the Two Midnight Rule. However, as noted above, that exception was previously limited to categorical announcements by CMS and, to date, CMS has only identified one such category (newly initiated mechanical ventilation). In the 2016 OPPS Final Rule, CMS declined to provide any specific clinical examples of cases that would be appropriate for Part A payment under its new case-by-case exception. Moreover, CMS does not define "rare and unusual" so it remains unclear how frequently CMS expects the case-by-case exception to be applied.

Although the new case-by-case exception appears to be inherently subjective to a certain extent, CMS states 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 also notes that an inpatient admission (and Part A payment) should be "rare and unusual" for minor surgical procedures or other treatment that is expected to keep the patient in the hospital "for only a few hours" or for a period of time that "does not span at least overnight" (thus, a subset of stays not meeting the Two Midnight Benchmark). CMS indicates that such cases will be prioritized for medical review.

Importantly, despite provider concern regarding the technical inpatient admission order authentication requirements, CMS did not specifically comment on the inpatient order requirements in the 2016 OPPS Final Rule. CMS also indicated that its actuaries estimate that these changes will not significantly impact overall IPPS expenditures. Accordingly, CMS is not changing the -0.2% payment adjustment that the agency enacted when the Two Midnight Rule first went into effect.

CMS again acknowledged that several commenters, including the Medicare Payment Advisory Commission (MedPAC) and the American Medical Association (AMA), recommend that CMS rescind the Two Midnight Rule. CMS also acknowledged that it is continuing to evaluate short-stay payment policy proposals but, given that there is no consensus among commenters, is not making any such changes at this time.

Analysis of Two Midnight Changes

The Two Midnight Rule is a standard that bases Medicare coverage and Part A 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 the agency originally 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 initially articulated by CMS in January 2014, and now the expansion of the "rare and unusual" exception in the 2016 OPPS Final 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 involving the patient's clinical condition. In the 2016 OPPS Final Rule, CMS maintains that it has consistently provided time-based guidelines but acknowledges that there are inherent differences between observation and inpatient services. However, the 2016 OPPS Final Rule does not provide clarity regarding how the time-based analysis under the Two Midnight Rule and the proposed level of care analysis under the case-by-case exception would be applied in practice when a physician is evaluating a patient to make a status determination.

Under the new rule, 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.

While the modifications finalized in the 2016 OPPS Final Rule appear strikingly similar to the pre-Two Midnight Rule standard, CMS maintains that the modifications are "not a return to the policy prior to the adoption of [the Two Midnight Rule]." Many providers may struggle with the lack of clarity regarding the new case-by-case exception when attempting to implement the change.

In response to commenters suggestions that this "case-by-case" analysis could lead to a return of the second-guessing of physician judgment that led to the appeals backlog, CMS attempted to ease provider fears by pointing to the new medical review strategy (detailed below) and the changes to the RAC program announced in December 2014.[1] CMS indicates that the case-by-case exception "continues" CMS's policy of recognizing "the important role of physician judgment and individual patient needs."

Patient Status Review Changes

The 2016 OPPS Final Rule also summarizes CMS's recent changes to its medical review strategy for patient status determinations. On October 1, 2015, QIOs assumed responsibility for conducting reviews of short inpatient stays, thus transitioning this role away from Medicare Administrative Contractors (MACs).[2] Under the new medical review short-stay inpatient review process, QIOs are reviewing a sample of post-payment claims to 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. Interestingly, CMS implemented this change although, in the 2016 OPPS Final Rule, it lauds the "Probe & Educate" reviews conducted by the MACs as bringing about "positive effects and improved provider understanding." Accordingly, some may question the value in transitioning patient status reviews to the QIOs in light of the significant cost and effort to do so and their alleged efficacy. Given the complexity

of the Two Midnight Rule, it is likely that the QIOs will encounter the same steep learning curve experienced by the MACs.

Hospitals that the QIOs find to have exhibited a "pattern of practices" (such as having high denial rates, consistently failing to adhere to the Two Midnight Rule, or failing to improve their performance after QIO educational interventions) will be referred to the RACs for further medical reviews.

CMS did not elaborate on the details of the QIO reviews (such as sample sizes, claim look-back periods, Additional Document Request limits, and error rates triggering referrals to RACs). Instead, CMS indicated that it will address such technical medical reviews questions in sub-regulatory guidance issued no later than December 31, 2015.

Conclusion

As described above, CMS has now finalized its previously proposed revisions to the Two Midnight Rule. These changes will go into effect on **January 1, 2016** and will allow for "case-by-case" determinations of whether short-stay cases may be appropriate for Part A payment based on the intensity of care and physician judgment.

Importantly, there is no guarantee that the Two Midnight Rule is finally settled. CMS explicitly notes that it will continue to assess the Two Midnight Rule payment policy in future rules and, as with all payment policies, may make future payment modifications. Providers may wish to carefully consider how to incorporate the case-by-case exception into their education efforts and/or appeal strategies considering the lack of clarity surrounding its application, the significant potential for confusion, and the potential for future additional changes.

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[1] In the 2016 OPPS Final Rule, CMS also indicated that it will be implementing the changes to the RAC program not just for new RAC contracts but also for existing contracts.
[2] From October 1, 2013 (the effective date of the Two Midnight Rule) to October 1, 2015, CMS limited patient status reviews to MACs performing "Probe & Educate" reviews.