CINDERELLA MAY NOT TURN INTO A PUMPKIN AFTER ALL: THE PROPOSED RELAXATION OF THE TWO-MIDNIGHT RULE

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Health Care Alert

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On July 8, 2015, the Centers for Medicare and Medicaid Services ("CMS") released a Proposed Rule regarding the 2016 Hospital Outpatient Prospective Payment System ("OPPS").[1] The Proposed Rule, in addition to proposing updates to Medicare payment policies and rates under the OPPS, includes proposed changes to the "Two-Midnight Rule" regarding short inpatient hospital stays for calendar year 2016. This *Client Alert* provides background on the Two-Midnight Rule, an overview of the proposed changes, and recommends how hospitals can best prepare for changes going forward.

IMPETUS FOR THE TWO-MIDNIGHT RULE

Advances in technology and improvements in medicine have reduced average inpatient length of stay and allowed many traditionally inpatient services to migrate to the outpatient setting, bringing increased focus to short inpatient stays by government officials. Historically, CMS provided little guidance to physicians and hospitals regarding when an inpatient stay is appropriate, deferring instead to providers' clinical judgment. Government contractors, however, aware of favorable reimbursement to hospitals for services provided in an inpatient setting, aggressively targeted overutilization of hospital admissions, particularly short inpatient stays. CMS and government enforcement officials have linked an uptick in observation stays to a response by providers to recovery audit contractor ("RAC") denials of inpatient admissions.[2] This trend, however, is not without its own financial consequences. For example, Medicare beneficiaries may face higher out-of-pocket costs, including higher co-pays for physician services and prescription drug costs that they otherwise would not be responsible for as an inpatient, and observation days do not qualify toward the three-day eligibility requirement for Medicare coverage for skilled nursing facility care subsequent to a hospital visit.[3] Providers, as a result, have requested numerous changes to address these issues, including changes to the RAC contingency fee structure.

THE TWO-MIDNIGHT RULE IMPOSES OBLIGATIONS ON HOSPITALS AND AUDITORS

To address these concerns, and in an effort to clarify criteria for establishing and documenting the medical necessity of inpatient admissions, CMS introduced the Two-Midnight Rule (the "Rule") in August of 2013 as part of its Inpatient Prospective Payment System ("IPPS") Final Rule. [4] The Rule established that an inpatient admission would be presumed reasonable and necessary if the admitting practitioner expects the patient to require a hospital stay that crosses two midnights and "clear and complete" medical record documentation supports that reasonable expectation (or the patient needs treatment specified on the "inpatient-only" list

published by CMS).[5] "Clear and complete" medical record documentation includes the presence of "complex medical factors," such as beneficiary medical history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event occurring during hospitalization. A hospital stay that actually spans two midnights, as well as stays that the physician *anticipates* will cross at least two midnights (as that expectation is assessed at the time of the patient's admission based on information then available to the physician), are reimbursable stays under the IPPS. Stays lasting less than two midnights, where a physician did not anticipate such stay would last two midnights, should be treated and billed as outpatient services under the OPPS (unless on the inpatient-only list or a national exception exists).[6]

In implementing the Rule, CMS intended to impose a control mechanism on hospitals to prevent inappropriate inpatient admissions by requiring adherence to length of stay considerations as well as adequate documentation regarding clinical decision-making, which it referred to as the "Two-Midnight Benchmark." At the same time, CMS intended to create a "Two-Midnight Presumption" such that inpatient stays that cross two midnights with valid inpatient orders would be presumed medically necessary and, in turn, would not be subject to RAC review.[7]

PROVIDER RESPONSE AND DELAYED ENFORCEMENT

that it imposed burdensome documentation requirements and undermined physician clinical decision-making as it relates to inpatient admission assessments.

The original implementation date for the Rule was October 1, 2013. However, CMS delayed enforcement of the Rule, and Congress recently extended the moratorium through September 30, 2015.[8] For claims with admission dates from the original implementation date of the Rule — October 1, 2013 — through the end of the moratorium period, RAC auditors were limited to prepayment reviews. Over the course of this two-year moratorium period, CMS implemented a "Probe and Educate" program, through which hospital inpatient claims were sampled and assessed for compliance with the inpatient admission criteria set forth in the Rule, and providers were, in turn, educated on the results as necessary regarding inappropriate admission coding and billing patterns.[9] Moreover, CMS advised physicians to apply the Rule's standards in their admission decisions, even though government contractors could not yet use the Rule to render medical necessity determinations.

In addition to advocating for an extension of the Rule's ongoing enforcement moratorium, hospitals have requested additional guidance regarding hospital short-stay reimbursement and suggested limits on the Recovery Audit Program to address problems related to claims submission. In response, in December of 2014, CMS announced a number of changes to the Recovery Audit Program. [10] Specifically, CMS will limit the "look-back period" for inpatient admission reviews from three years to six months from the date of service, require RACs to complete complex reviews within 30 days or risk losing their contingency fee (even where error is found), and impose a 30-day waiting period on RACs before sending an adjustment claim to the Medicare Administrative Contractor ("MAC") to allow for discussion between the provider and the RAC prior to any payment adjustments. These changes will be effective with the next round of Recovery Audit Program contract awards. [11]

PROPOSED MODIFICATIONS TO THE TWO-MIDNIGHT RULE

While CMS "continue[s] to believe that the 2-midnight benchmark provides, for payment purposes, clear guidance on when a hospital inpatient admission is appropriate for Medicare Part A payment, while respecting the role of

physician judgment," it also believes that the concerns raised by stakeholders "merit continued consideration."[12] This Proposed Rule is CMS' response to those concerns, based not only on CMS' experience gained through the "Probe and Educate" program, but also based on input solicited from hospitals, physicians, the Medicare Payment Advisory Commission, beneficiary advocates, and Congress.

In the Proposed Rule, CMS relaxes the requirements for hospital stays expected to last less than two midnights, provided documentation in the medical record supports the admitting physician's determination that the patient requires inpatient hospital care. In so doing, CMS lays out the following three-pronged approach to analyzing inpatient admissions:

- Less Than Two Midnights: If a physician expects the hospital stay to last less than two midnights, the appropriateness of an inpatient admission for reimbursement under the IPPS will be judged on a case-by-case basis, relying upon the judgment of the admitting physician that the patient requires a "reasonable and necessary admission to the hospital as an inpatient." In determining whether such an admission should be paid under the IPPS, CMS places emphasis on the following: the severity of signs and symptoms exhibited by the patient, the predictability of an adverse event occurring, and whether needed diagnostic tests are appropriately outpatient (thus not requiring the patient to stay at the hospital for 24 hours or more). These claims will be subject to medical review, which, as in the current Rule, will include a review of all submitted medical records and can include evidence-based guidelines or commercial utilization tools that may aid in determining whether an inpatient hospital admission is appropriate.
- No Midnights: CMS expects that, with most inpatient admissions where the stay is expected to last less than two midnights, the patient will remain inpatient at least one night. However, CMS acknowledges that a patient may be unexpectedly discharged or transferred to another facility. While the case-by-case approach described above is applicable, CMS makes clear that these cases will be prioritized for medical review. Moreover, CMS makes clear that, for minor surgical procedures or other hospital treatments where the patient is expected to be in the hospital for only a few hours, it would be "rare and unusual" for a beneficiary to require inpatient hospital admission. These, too, will be prioritized for medical review.
- Two Midnights: If a physician expects the hospital stay to last two midnights or longer, it is presumed that inpatient admission is appropriate. This is unchanged from the current Two-Midnight Presumption.

All inpatient admissions, regardless of the number of midnights the patient is expected to stay, require appropriate supporting documentation in the medical record, and IPPS payment is only appropriate based on the admitting physician's clinical judgment that an inpatient hospital admission is reasonable and necessary.[13]

The Proposed Rule does not affect the enforcement moratorium, which is currently scheduled to expire September 30, 2015.

PROPOSED MODIFICATIONS TO MEDICAL REVIEW OF INPATIENT ADMISSIONS

In an effort to create a more collaborative approach to the review of inpatient admissions, CMS announces in the Proposed Rule that it is changing the short inpatient stay medical review process, effective October 01, 2015. Specifically, Quality Improvement Organizations ("QIOs") will conduct the first line of medical reviews, with RACs only focusing on hospitals with "consistently high denial rates based on QIO patient status review outcomes."[14] As support for this change, CMS cited QIOs' existing role, which includes assuring coverage

determinations are in accord with Medicare standards, as well as case review work to improve the quality of health care for Medicare beneficiaries, including peer review, beneficiary complaints, and EMTALA violations. CMS also cited QIOs' history of collaboration and interaction between and among state survey agencies, MACs, RACs, and providers.[15]

Under this new medical review process, QIOs will review a sample of post-payment claims and make a determination of the medical appropriateness of inpatient admissions. QIOs will refer claim denials to the MACs for payment adjustments and will educate hospitals about denied claims. Further, QIOs will collaborate with hospitals in their development of quality improvement processes. Hospitals that exhibit a pattern of high denial rates and frequent inpatient hospital admissions for stays that do not span one midnight, or that fail to improve their performance after QIO educational intervention, will be referred to the RACs for further payment audit. [16] CMS will adopt this new medical review process, effective immediately, regardless of whether the Two-Midnight Rule stays the same or is modified. [17]

RECOMMENDATIONS

CMS's proposed modifications to the Rule reinforce the continued importance of ensuring that medical records contain the appropriate documentation to support an inpatient admission. While the Proposed Rule would relax the presumption against admission for patients expected to stay in the hospital less than two midnights, greater responsibility would be placed on the admitting physician to document the reasoning behind the admission decision for these patients. If the Proposed Rule is finalized in the same form, hospitals should revisit their inpatient admission processes to incorporate this new three-pronged approach, as well as educate and audit their physicians to ensure that sufficient documentation to support all inpatient admissions is included in the medical record.

We note that the changes discussed above are only proposed changes. Comments to CMS on the Proposed Rule must be submitted by August 31, 2015, and a Final Rule is expected to be published on or around November 1, 2015,[18] with a January 1, 2016 anticipated effective date. Because the moratorium on the current Rule is scheduled to expire September 30, 2015, it is possible that the current Two-Midnight Rule will go into affect at that time, absent another delay in its enforcement. Regardless of the outcome of a Final Rule, however, CMS will begin implementing the new QIO medical review strategy for short-stay inpatient claims effective immediately.[19]

Notes:

[1] See Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Program; Short Inpatient Hospital Stays, 80 Fed. Reg. 39200, 39348 (July 8, 2015), available at http://www.gpo.gov/fdsys/pkg/FR-2015-07-08/pdf/2015-16577.pdf.

[2] See generally, e.g., Centers for Medicare & Medicaid Services, Special Open Door Forum: CMS Rule 1599-F: Inpatient Hospital Admission and Medical Review Criteria (2-Midnight Provision) and Part B Inpatient Billing in Hospitals (August 15, 2013) available http://www.medpac.gov/documents/reports/chapter-7-hospital-short-stay-policy-issues-(june-2015-report).pdf?sfvrsn=0. For a summary of the provider viewpoint, see, e.g., http://www.aha.org/content/13/fs-twomidnight.pdf. For a discussion of the government viewpoint, see, e.g., the Department of Health and Human

Services, Office of Inspector General, *Memorandum Report: Hospitals' Use of Observation Stays and Short Inpatient Stays for Medicare Beneficiaries*, OEI-02-12-00040 (July 29, 2013), *available at* https://oig.hhs.gov/oei/reports/oei-02-12-00040.pdf.

- [3] See https://oig.hhs.gov/oei/reports/oei-02-12-00040.pdf.
- [4] 78 Fed. Reg. 50495 (August 19, 2013).
- [5] *Id.*
- [6] CMS explained in the FY 2014 IPPS Final Rule that it might identify additional "inpatient-only" procedures through subregulatory guidance. *Id.* at 50948. Subsequently, CMS accepted and considered suggestions regarding "rare and unusual" circumstances pursuant to which an inpatient admission that is expected to span less than two midnights would nonetheless be reimbursable under the IPPS. To date, only newly initiated mechanical ventilation (excluding anticipated intubations related to minor surgical procedures or other treatment) has been identified as such a "rare and unusual" national exception, though CMS has since invited further feedback on suggested national exceptions. *See* 79 Fed. Reg. 49853; *see also* 80 Fed. Reg. at 39349.
- [7] 78 Fed. Reg. at 50949.
- [8] The Protecting Access to Medicare Act of 2014 (Pub. L. 113-93) extended the Rule's enforcement delay through March 31, 2015. More recently, Congress extended the moratorium through the end of Fiscal Year 2015, through the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114-10). Accordingly, CMS will continue the Probe and Educate Process and will prohibit Recovery Auditor inpatient hospital patient status reviews for dates of admission between October 1, 2013 and September 30, 2015.
- [9] For an overview of the CMS "Probe and Educate" program, *see generally* Medicare Inpatient Hospital Probe and Educate Status Update (February 24, 2014), available at http://cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Downloads/UpdateOnProbeEducateProcessForPosting02242014.pdf.
- [10] See CMS.gov, Recovery Audit Program "Recent Updates," December 30, 2014, located at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Recent_Updates.html; see also 80 Fed. Reg. at 39350.
- [11] See supra n.10.
- [12] In fact, CMS asserts in the Proposed Rule that the Rule has been effective in combatting the growing trend of long outpatient hospital stays. Specifically, CMS cites a FY 2014 decrease by 11 percent in the proportion of outpatient long-stay encounters (defined as more than two days) involving observation services, as compared to FY 2013, which coincides with the adoption of the Rule on October 1, 2013. 80 Fed. Reg. at 39353.
- [13] Id. at 39350-51.
- [14] Center for Medicare & Medicaid Services, "Fact Sheet: Two-Midnight Rule" (July 1, 2015), *available at* http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-07-01-2.html; see also 80 Fed. Reg. at 39352–53.
- [15] 80 Fed. Reg. at 39352.
- [16] Id. at 39353.

[17] *Id*.

[18] See supra n.14.

[19] 80 Fed. Reg. at 39352–53.

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