Two Midnight Rule: Where are we now?

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Health Care Compliance Association Webinar

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Agenda

• Background
  — Brief overview of the Two Midnight Rule
  — Recent Updates

• Enforcement Update
  — Contractor reviews of patient status claims
  — Medicare appeals backlog
  — OIG scrutiny

• Practical Considerations
  — Importance of continued compliance efforts
  — Practical takeaways from contractor reviews
  — Analysis of potentially defective claims
  — Medicare Advantage considerations

Background
History of Two Midnight Rule

Quick Recap – 2013 through 2017

- **October 1, 2013** – Implementation of Two Midnight Rule
- **January 1, 2015** – Effective date for significant revisions to certification requirements
- **September 30, 2015** – End of Probe & Educate Period
- **October 1, 2015** – Quality Improvement Organizations (QIOs) KEPRO and Livanta assume responsibility for conducting patient status reviews
- **January 1, 2016** – Effective date of case-by-case “rare and unusual” exception expansion
Overview of Two Midnight Rule

- **General Rule:**
  - A hospital inpatient admission is generally considered reasonable and necessary if the physician (or other qualified practitioner) ordered the inpatient admission based on:
    - His/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.

42 C.F.R. § 412.3(e).

Patient Status: Pre-Two Midnight Rule

- **Former Medicare Benefit Policy Manual, Ch. 1, § 10**
  - Inpatient admission is a “complex medical judgment” that can only be made by physician after considering several factors, such as:
    - Patient medical needs and history
    - Severity of signs and symptoms
    - Likelihood of adverse event
    - 24 hour benchmark
  - Admit as inpatient if hospital care expected for 24 hours or more
Review Standards: Presumption vs. Benchmark

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<tr>
<th>Two Midnight Presumption</th>
<th>Two Midnight Benchmark</th>
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<tr>
<td><strong>Claims with two or more midnights after inpatient admission order</strong> CMS</td>
<td><strong>Claims with less than two midnights after inpatient admission order</strong> CMS contractors are to consider total amount of time patient received medically necessary hospital services (including time in outpatient settings) before the inpatient admission order to determine whether the medical record supports the physician’s two midnight stay expectation.</td>
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<td>contractors are to presume medical necessity of the inpatient admission.</td>
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**Two Midnight Rule “Exceptions”**

- "Exceptions" to Two Midnight Expectation
  - Payment under Part A may be appropriate even though there was not an expectation for a two midnight stay:
    - Inpatient-Only List Procedure
    - “Rare and Unusual” Exception
- Unforeseen Circumstances
  - Due to unforeseen circumstances (such as beneficiary death, transfer, discharge against medical advice) the stay is shorter than the physician’s initial expectation of a stay of at least two midnights.
- “Exception” to Inpatient Admission Order Requirement
  - Missing or defective order guidance
“Original” Rare and Unusual Exception

• Since adoption of the Two Midnight Rule, CMS has stated in guidance that there may be “rare and unusual” circumstances in which an inpatient admission for a service not on the inpatient only list may be reasonable and necessary in the absence of an expectation of a two midnight stay.

• However, prior to the CY 2015 OPPS Proposed Rule released in July 2015:
  • CMS had indicated that this exception applied categorically (as opposed to being determined on a case-by-case basis)
  • CMS only identified one example: newly initiated mechanical ventilation

“Expanded” Rare and Unusual Exception

• Effective January 1, 2016, CMS expanded the “rare and unusual” exception to permit additional “rare and unusual” exceptions to the Two Midnight Benchmark that are determined on a case-by-case basis by the physician responsible for the care of the beneficiary, subject to CMS medical review.
  • The inpatient admission must be supported by clear documentation in the patient’s medical record.

• Relevant Factors:
  — 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).
“Expanded” Rare and Unusual Exception

- Déjà vu to pre-Two Midnight Rule patient status standards
- Confusion regarding standard for expanded rare and unusual exception
  - Time based?
  - Severity of illness?
  - Level of care needed?
- CMS has not provided examples of cases that would fit expanded exception
- What about the challenges related to the pre-Two Midnight standard?
  - What weight will contractors grant physician judgment that inpatient admission was necessary despite expected stay less than two midnights?
- Significant resources required for providers to re-train and re-educate on new standard.

Documentation Requirements: Certifications

- CMS initially required a physician certification be completed for every inpatient admission prior to patient discharge.
- However, effective January 1, 2015, a physician certification is required only for long-stay cases (defined as 20 days or longer) or outlier cases.
**Documentation Requirements:**

**Inpatient Admission Orders**

- **42 C.F.R. § 412.3(a):** The physician order must be present in the medical record and be supported by the physician admission and progress notes, in order for the hospital to be paid for hospital inpatient services under Medicare Part A.
  
  — Prior to the Two Midnight Rule, there was no clear regulatory requirement for a inpatient admission order as a condition of payment.
  
- **Note:** Conditions of Participation for acute care hospitals include a requirement that all “patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital.” 42 CFR § 482.12(c)(2).

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**Ordering Practitioners**

- The order to admit must be furnished by a physician or other qualified practitioner who is:
  
  — a) licensed by the State to admit inpatients to hospitals,
  
  — b) granted privileges by the hospital to admit inpatients to that specific facility, and
  
  — c) knowledgeable about the patient’s hospital course, medical plan of care, and current condition at the time of admission
Missing or Defective Orders

- CMS sub-regulatory guidance states that in *extremely rare circumstances*, the order to admit may be missing or defective (that is, illegible, or incomplete, for example “inpatient” is not specified), yet the intent, decision, and recommendation of the ordering practitioner to admit the beneficiary as an inpatient can clearly be derived from the medical record.

- Contractors have been provided with discretion to determine that this information may constrictively satisfy the requirement that the hospital inpatient admission order be present in the medical record.
  - Initially included January 2014 guidance
  - Now included in manual guidance (Medicare Benefit Policy Manual, Ch. 1, §10.2)

Overview of Two Midnight Rule:
CMS Manual Guidance

- Although the Two Midnight Rule has been in effect for over 3 years, CMS only recently updated the Medicare Benefit Policy Manual to reflect this significant change in policy.

  - **January 2017** - CMS updated Chapter 1 of the Medicare Benefit Policy Manual to include brief *general references* to the Two Midnight Rule.

  - **March 2017** - CMS issued Change Request 9979, which also revises Chapter 1 of the Medicare Benefit Policy Manual to include additional information regarding inpatient admission orders and certification requirements.
    - Imports most of the language from the January 2014 Order and Certification Guidance to Chapter 1 of the Medicare Benefit Policy Manual and updates the content to reflect the current certification requirements now limited to outlier and long-stay cases.
    - Does not make any material substantive modifications to the language from the January 2014 Guidance or provide any new material guidance.
Patient Notice of Status Determinations

- Notice of Observation Treatment and Implication for Care Eligibility (NOTICE) ACT
  - Enacted August 6, 2015, effective August 6, 2016
  - Generally requires hospitals to provide individuals receiving outpatient observations services for more than 24 hours with a notification explaining their status as outpatient and implication
  - Standard Medicare Outpatient Observation Notice (MOON) form required as of March 8, 2017

Enforcement Update
Patient Status Review Strategy

• In recognition of some of the challenges associated with the Two Midnight Rule, CMS has employed a limited review strategy for patient status determinations:
  – **Oct. 2013 – Sept. 2015**: Probe & Educate Reviews conducted by MACs
    – Extended several times
  – **Oct. 2015 – Present**: Reviews conducted by Quality Improvement Organizations (QIOs)
    – Potential referrals to Recovery Audit Contractors (RACs)

QIO Review Challenges

• Unsurprisingly, there have been some challenges with the QIO patient status reviews.
  – **May 4, 2016**: CMS temporarily paused the QIO patient status reviews to promote consistent application of medical reviews and improve standardization in the review process
  – **June 6, 2016**: CMS announced that the QIOs would re-review all short stay patient status claims that were denied under the QIO medical review process
  – **July 28, 2016**: CMS announced that patient status claims impacted by the QIO temporary suspension will be subject to a 6 month look-back period
  – **September 12, 2016**: QIOs resumed initial patient status reviews with continued CMS oversight
  – **April 2017**: QIO record selection process changed
    – QIOs will sample the top 175 providers with a high or increasing number of Short Stay claims per area with a request for 25 cases, and all other providers previously identified as having “Major Concerns” in the prior round of review will have a request for 10 cases.
RAC Referrals

- Beginning in January 2016, RACs may conduct provider-specific patient status reviews for those providers that have been referred by the QIO as exhibiting persistent noncompliance with Medicare payment policies, including, but not limited to:
  - Consistently failing to adhere to the Two Midnight rule, or
  - Failing to improve their performance after QIO educational intervention.

- CMS awarded new Fee-for-Service RAC contracts on October 31, 2016.

OIG Scrutiny: 2016 Report

- On December 19, 2016, the Office of Inspector General (OIG) released a report titled “Vulnerabilities Remain Under Medicare’s 2-Midnight Hospital Policy”
  - OIG analyzed Medicare Part A and B claims data from FY 2013 and 2014, and determined that the number of inpatient stays decreased, and the number of outpatient stays increased since the implementation of the Two Midnight rule in October 2013.
  - OIG found that hospitals are billing for many short inpatient stays (defined as a stay that lasted less than two midnights) that are potentially inappropriate; for these stays, Medicare paid a total of almost $2.9 billion
  - OIG raised concerns about long outpatient stays and that an increased number of beneficiaries in outpatient stays pay more and have limited access to Skilled Nursing Facility (SNF) services than they would as inpatients.
OIG Scrutiny: 2016 Report

• OIG’s analysis was limited:
  — OIG only looked at FY 2013 and 2014
  — CMS has since implemented significant changes to the Two Midnight Rule (e.g., the expanded rare and unusual exception)
  — OIG’s review was limited to a claims review and did not include a medical record review

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OIG Scrutiny: 2016 Report

• OIG recommended that CMS, among other things:
  — Improve oversight of hospital billing under the Two Midnight policy and increase protections for beneficiaries
  — Conduct routine analysis of hospital billing and target for review the hospitals with high or increasing numbers of short inpatient stays that are potentially inappropriate under the Two Midnight policy
  — Closely oversee the case-by-case exception finalized in January 2016, as “this policy change has the potential for abuse and should be monitored closely”
  — Identify and target for review the short inpatient stays that are potentially inappropriate
Medical Appeals Backlog

• January 17, 2017: HHS Final Rule regarding changes to Medicare appeals process, aimed at addressing the significant appeals backlog.
  - Changes included:
    — Allowing attorney adjudicators to handle certain matters (such as deciding appeals when decisions can be issued without an Administrative Law Judge (ALJ) hearing, reviewing certain dismissals, and dismissing requests for hearings when the appellant withdraws)
    — Allowing the designation of certain Medicare Appeals Council decisions as precedential
  - Final Rule was effective March 20, 2017

Medicare Appeals Backlog – Second Settlement Program

• November 3, 2016: CMS announced second global hospital appeals settlement program for certain inpatient status claims under appeal.
  — 66% of net allowable amount
  — Resembled 2014 settlement program (68% net allowable amount)
  — Deadline to submit an Expression of Interest was January 31, 2017
Medicare Appeals Backlog

• AHA filed suit against HHS in 2014 seeking mandamus relief to compel HHS to meet its statutory deadline for administrative review of denial of claims for Medicare reimbursement.

• In December 2016, the District Court for the District of Columbia imposed deadlines for HHS to reduce the appeals backlog, including complete elimination of the backlog by December 31, 2020.

• In a March 2017 status report, HHS reported they will not be able to meet the court-imposed deadlines.
  — HHS reported a current backlog of 667,326 appeals at the ALJ level.
  — HHS projected the number of pending appeals to grow to 1,009,768 by September 30, 2021.

Practical Considerations
Importance of Continued Compliance

- Some providers may be experiencing Two Midnight Rule compliance fatigue due to changing rules and current lack of traditional enforcement activity.
- However, it is important for compliance personnel to emphasize the importance of continued compliance:
  - Good opportunity to work out any potential issues now
  - RACs (QIO referrals and resumption of RAC activity)
  - Obligations Under 60 Day Rule to refund overpayments
  - Providers may also be subject to patient status reviews in other contexts
    - Corporate Integrity Agreement reviews
    - Potential whistleblower lawsuits

Takeaways from Contractor Reviews

- Experiences with QIO patient status reviews have been mixed
  - Some providers have experiences where QIOs do not appear to fully understand the nuances of the Two Midnight Rule, including the applicable authority
  - Other providers have reported more positive experiences
  - Providers would be well advised to review QIO findings critically
- Many QIOs do not appear to be focusing on the underlying documentation and medical necessity of inpatient only claims
- Important to monitor QIO websites for issuances and informational provider calls
Considerations for Potentially Defective Inpatients Admission Claims

- Considerations for providers:
  - Policies & Procedures (patient status)
  - Utilization Review procedures
  - Process for evaluating potentially defective claims
    - Missing or defective order guidance language
      - Although this discretion is given to contractors, some providers have sought to rely on this guidance

60-Day Rule Considerations

- 60-Day Overpayment Rule:
  - Enacted as part of the Affordable Care Act
  - CMS released its final rule interpreting the Affordable Care Act requirements for Part A/B providers in February 2016
- Consider potential implications of patient status review findings, including from QIO contractors.
  - Excerpts from Final Rule Preamble:
    - “[C]ontractor overpayment determinations are always a credible source of information for other potential overpayments.”
    - “[I]n certain cases, the conduct that serves as the basis for the contractor identified overpayment may be nearly identical to conduct in some additional time period not covered by the contractor audit.”
Medicare Advantage Considerations

• No explicit requirement that Medicare Advantage organizations follow the Two Midnight Rule
  — Certain Medicare Advantage organizations have adopted policies consistent with the Two Midnight Rule; others rely on screening criteria or other approaches

• It is important for providers to confirm they understand each Medicare Advantage organization’s policy for patient status determinations

Where are we headed?

• In 2015, multiple organizations included the American Hospital Association and MedPAC evaluated alternative payment policy approaches.

• Currently, legislative efforts are focused on other healthcare priorities, such as Repeal & Replace.

• Providers would be well advised to continue to monitor possible future legislative activity or potential payment changes.
Questions?