Avoiding False Claims Liability, Enhancing CMS Compliance and Addressing Issues Around Patient Status Determinations: *Two Midnight Rule Challenges*

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Both Civil and Criminal Enforcement of Medical Necessity Requirements

- Traditionally, the False Claims Act was applied to expressly false certifications; cases where worthless services were provided or grossly inadequate services were provided.

- Today, the False Claims Act is being used as a tool to seek civil damages and criminal charges against individuals and institutions for failure to adhere to standards of care.
OIG/DOJ Recoveries

- Total health care fraud recoveries since January 2009 through fiscal year 2015 = $16.5 BILLION

- $1.9 Billion in FY 2015

Source: 12/3/2015 DOJ Press Release – Justice Department Recovers Over $3.5 Billion from False Claims Act Cases in Fiscal Year 2015
## OIG/DOJ Activity

<table>
<thead>
<tr>
<th></th>
<th>DOJ</th>
<th>2015</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>New criminal health care fraud investigations</td>
<td>983</td>
<td>924</td>
<td></td>
</tr>
<tr>
<td>New civil health care fraud investigations</td>
<td>808</td>
<td>782</td>
<td></td>
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<tr>
<td>OIG</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New criminal actions</td>
<td>800</td>
<td>867</td>
<td></td>
</tr>
<tr>
<td>New civil actions</td>
<td>667</td>
<td>529</td>
<td></td>
</tr>
<tr>
<td>Exclusions from Medicare, Medicaid and other federal health care programs</td>
<td>4,112</td>
<td>4,017</td>
<td></td>
</tr>
</tbody>
</table>

Source: Annual Report of the Departments of Health and Human Services and Justice (FYs 2014 and 2015)
Fraud and Abuse Enforcement Casts a Wide Net

- Liability exists for tainted services (services provided in violation of Stark, anti-kickback and other laws).
- Liability exists for billing errors not timely corrected.
- Liability exists for services billed but not provided.
- Liability exists for billing for services which are not medically necessary.
  - Patient status errors are generally denied under the general category of billing for services which are not medically necessary.
DOJ Healthcare Recoveries

- DaVita Healthcare Partners, Inc.
  - Paid $450 million to resolve allegations that they knowingly billed government for unnecessary waste
  - Paid $350 million to resolve claims that it violated False Claims act by paying kickbacks to physicians to induce patient referrals to its clinics
DOJ Healthcare Recoveries

- Hospitals involved in nearly $330 million in settlements and judgments
  - $250 million in 2015 related to hospitals allegedly implanting cardiac devices in Medicare payments contrary to CMS criteria
    - 70 settlements involving 457 hospitals in 43 states
OIG/DOJ Activity

- Physician employment agreements
  - **Example: Tuomey Healthcare System**
    - $237 Million jury verdict
    - Government position – NOT commercially reasonable to employ physicians at net loss on professional services.
    - Settled while on appeal for $72.4 million (10/16/15)
  - **Example: Halifax Hospital Medical Center**
    - $85 million settlement of Stark portion
    - Government position – NOT commercially reasonable to employ physicians at a loss.
OIG/DOJ Activity

- Hospitals and Health Systems - **Short Stays**
  - Kyphoplasty Settlements
    - In December 2015 - 32 hospitals located in 15 states agreed to pay $28 million
    - Brings total to 130+ hospitals totaling $105 million
OIG/DOJ Activity

- Hospitals and Health Systems - **Short Stays**
  - Medical Center of Central Georgia
    - Allegations of medically unnecessary inpatient admissions
      - Zero-day stays
      - One-day stays
      - Cardiac stays with a procedure
      - Cardiac stays without a procedure
    - Settlement: $20 million
Status Determinations as an Area of Liability

- All patients in a hospital receiving services are in either an inpatient status or an outpatient status.
  - Observation is a service of Outpatient Status and must be ordered
  - Patient status dramatically affects reimbursement

- Conflicting guidance about what constitutes an appropriate inpatient admission created a regulatory and enforcement quagmire that was devastating to hospitals.

Many Cases + Much Confusion = Recoupments, Denials and Appeals

EdiPhy Advisors
“The **expectation** of the physician should be based on such complex medical factors as patient **history** and **comorbidities**, the **severity** of signs and symptoms, current **medical needs**, and the **risk** of an adverse event.”

“The factors that lead to a particular clinical expectation must be documented in the medical record in order to be granted consideration.”
Medicare Regulations Define the Medical Necessity of Inpatient Admission

- 42 CFR 412.3(e) “…Surgical procedures, diagnostic tests and other treatment are generally appropriate for inpatient admission and inpatient hospital payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights.”

- Or, admit[s] for a surgical procedure on the “inpatient only list.”

- Or, the patient meets the Mechanical Ventilation exception

- Or the new January 1, 2016 inpatient determination.
Additional exception to inpatient necessity rule @ 42 CFR § 412.3(d)(1)

- Complex Medical Judgment despite a stay expected to be less than 2 midnights.
- “rare and unusual exception”
- Case by case
  - Severity
  - Risk of adverse outcome
  - MBPM old criteria
  - Not IP only surgery

42 CFR § 412.3(d)(1)

- “when the admitting physician expects a hospital patient to require hospital care for only a limited period of time that does not cross 2 midnights, the services may be appropriate for payment under Medicare Part A if the physician determines and documents in the patient’s medical record that the patient requires a reasonable and necessary admission to the hospital as an inpatient”

- No change to 2 MN “presumption”
### Compare the Language

<table>
<thead>
<tr>
<th><strong>EXPECTATION OF TWO MIDNIGHTS:</strong></th>
<th><strong>NO EXPECTATION OF TWO MIDNIGHTS:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>The expectation of the physician should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. The factors that lead to a particular clinical expectation must be documented in the medical record in order to be granted consideration. <a href="https://www.gpo.gov/fdsys/pkg/FR-2021-07-29/pdf/2021-16685.pdf">CMS-1633-FC, §412.3 (d)(1)(i)</a></td>
<td>The physician’s decision should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. In these cases, the factors that lead to the decision to admit the patient as an inpatient must be supported by the medical record in order to be granted consideration.” <a href="https://www.gpo.gov/fdsys/pkg/FR-2021-07-29/pdf/2021-16685.pdf">CMS-1633-FC, §412.3 (d)(3)</a></td>
</tr>
</tbody>
</table>
Does Intensity of Services (Level of Care) Matter?

According to CMS....nope...never did!

Contrary to the commenters’ suggestion, we do not refer to “level of care” in guidance regarding hospital inpatient admission decisions. Rather, we have consistently provided physicians with the aforementioned time-based admission framework to effectuate appropriate inpatient hospital admission decisions. This is supported by recent findings by the Office of Inspector General (OIG).
How to Show a Valid Expectation

- Risk of Adverse Event
- History & comorbidities
- Current Medical Needs
- Severity

Expectation

Must Be Documented in Chart “to be granted consideration”
How NOT to Validate the Expectation

- Custodial Care
- MD Unsupported predictions or statements
- Patient or Hospital Convenience (delays)
Medical Necessity - Building Blocks

- **WHO**: Severity of illness, acute threat
- **WHAT**: What services are required to address threat or reduce the acute risk
- **WHEN**: Timing is everything. When did services begin. How long is the patient expected to require services in the hospital
- **WHERE**: Are services required in a hospital setting for the anticipated length of time
- **WHY**: Why is this patient expected to require services in the hospital setting for the anticipated time
Medicaid agencies

- Typically Medicaid agencies remain tied to a “24 hour” or “overnight” standard.
- Temporal analysis remains important.
- Intensity of service likewise remains important.
- Typically “outpatient” procedures are unlikely to be paid on an inpatient basis.
Commercial payers

- Health plans typically utilize evidence based criteria as screening criteria.
- Important to stress medical necessity of hospital setting and intensity of service as well as temporal analysis.
- Medicare Advantage plans must provide Medicare “inpatient services.”
CMS changed medical review strategy for short hospital stays so that QIO contractors conduct reviews of short inpatient stays.
CMS 1633 F (on medical review)

- The medical reviewer’s clinical judgment would involve the synthesis of all submitted medical record information (for example, progress notes, diagnostic findings, medications, nursing notes, and other supporting documentation).

- Medicare review contractors must abide by CMS policies in conducting payment determinations, but are permitted to take into account evidence-based guidelines or commercial utilization tools that may aid such a decision.

- Did not formally adopt commercial screening tools at this time.

- All of these rules and policies went into effect January 1, 2016.
Hospitals that are found to exhibit a pattern of practices, including, but not limited to: having high denial rates and consistently failing to adhere to the 2-midnight rule (including having frequent inpatient hospital admissions for stays that do not span one midnight), or failing to improve their performance after QIO educational intervention, will be referred to the Recovery Auditors for further medical review.

In addition to the formal QIO medical review process mentioned above, we intend to continuously monitor ... applicable claims data... looking for trends and gaming.

The number of claims that a Recovery Auditor will be allowed to review for patient status will be based on the claim volume of the hospital and the denial rate identified by the QIO (between 10 and 25 admissions).
Case Example
Excerpt from Medical Record

CC: Diarrhea; nausea and vomiting

HPI:
[Name] is a 77 y.o. male with h/o HTN, Vascular dementia, NIDDM, of medications and reported Vit B12 deficiency who presents 4 day history of diarrhea and cough. Patient has end-stage dementia and unable to give history. History given by wife at bedside who is patient's primary care-giver. Per patient's wife, 4 days ago, patient had acute onset cough, mostly Non-productive then started having some non-bloody and non-bilious diarrhea. Patient unable to tell if he has been having fevers or chills. Patient has not had any nausea or vomiting but reports that he has not been hungry in the last 3 days and has not been eating anything. Wife also noted decreased urine output. No dysuria or hematuria reported. Patient in bed, appears not to be in any distress and remains pleasant. Patient is mostly bed bound and waxes and wanes in his mental status at baseline. Patient's wife says patient currently at his baseline mental status

PmHx:
Past Medical History
Diagnosis
• Hypertension
• Bronchitis
• Diabetes mellitus
• Vitamin B12 deficiency
• Arthritis

Home medications:
No current facility-administered medications on file prior to encounter.

Current Outpatient Prescriptions on File Prior to Encounter
Medication Sig Dispense Refill
This 77 year old male presented to the Emergency Department on 5/28/16 at approximately 18:56 with complaints of non-bloody diarrhea, no oral intake and decreased urine output for three (3) days prior to presentation to the hospital. His family noted that he was increasingly confused beyond his baseline dementia and that he was unable to ambulate.

On examination, he was noted to answer questions inappropriately. His laboratory abnormalities included BUN/creatinine 27/1.8 (baseline creatinine 1.6) consistent with dehydration. His potassium level was 3.2. A urinalysis was remarkable for greater than 50 WBC and leukocyte esterase.

The patient's relevant medical history included diabetes mellitus, dementia and hypertension.

His treatment plan included intravenous fluids and antibiotics, a clostridium difficile toxin, and serial assessments.
Inpatient status is recommended.

He was admitted as an inpatient on 5/28/16 at 21:45. He received intravenous fluids and intravenous antibiotics (Ciprofloxacin/Flagyl) and attempts were made to obtain stool testing for culture and clostridium difficile. On hospital Day 2 (5/29/16), the progress note stated that although he was improved the plan was to change his antibiotics to oral dosing and ascertain whether he would be able to tolerate oral medications and nutrition for an additional midnight prior to discharge.

Inpatient admission for this patient was appropriate because of his risk for worsening dehydration and renal failure from volume losses caused by acute gastroenteritis. Moreover, he required antibiotic therapy for his urinary tract infection and gastroenteritis, pending culture results. In both instances, intravenous therapy was required including fluids and antibiotics until he could tolerate orally.

In this case, the patient is expected to receive his medically necessary hospital care through the second midnight.
August 2015 CMS Announcement

Recovery Auditors essentially barred from inpatient status reviews through December 31, 2015
## Summary of Inpatient Status Auditors Over Time

<table>
<thead>
<tr>
<th>Period</th>
<th>Contractor Type(s)</th>
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<tbody>
<tr>
<td>Through September 30, 2015</td>
<td>MACs conducting probe and educate.</td>
</tr>
<tr>
<td>October 1, 2015 through December 31, 2015</td>
<td>BFCC QIOs begin conducting reviews. MACs completing some remaining provider education.</td>
</tr>
<tr>
<td>January 1, 2016 and beyond</td>
<td>QIOs continue conducting initial reviews. RAs conduct further reviews upon referral by QIOs.</td>
</tr>
<tr>
<td>May 4, 2016</td>
<td>Temporary pause in QIOs conducting initial patient status reviews of hospital short stays</td>
</tr>
</tbody>
</table>
On August 1, 2014, the QIO program separated medical case review from its quality improvement activities in each State under two types of regional contracts.

Source: http://www.qioprogram.org/contact-zones
CMS 1633 F - QIOs and Audit Rules

- Beneficiary and Family Centered Care (BFCC) = QIO that conducts medical review
- Appeals process unchanged: section 1869 of the Act and procedures in 42 CFR Part 405
- Claims to review are selected using the 2 midnight “presumption.”
- QIOs have begun to conduct post-payment reviews of claims and refer findings to the MACs for payment adjustments
On May 4, 2016, CMS placed a temporary pause on BFCC QIOs performance of initial patient status reviews as a result of inconsistencies in the application of the two midnight policy for short hospital stays.

- CMS is requiring the BFCC-QIOs to re-review all claims they denied since October 2015
- CMS expects reviews to resume in 60-90 days and will notify stakeholders when the pause is lifted
- QIO reviews are anticipated to resume in July
BFCC QIO 2 Midnight Claim Review Guideline

1. Did the inpatient stay from the point of a valid inpatient admission order to discharge last "2 Midnights,"
   - Yes
   - No

2. Did the patient need hospital care
   - Yes
   - No

3. Did the provider render a medically necessary service on the Inpatient Only List?
   - Yes
   - No

4. Was it reasonable for the admitting physician to expect the patient to require medically necessary hospital services, or did the patient receive medically necessary hospital services, for 2 Midnights or longer, including all out-patient/observation and inpatient care time?
   - Yes
   - No

   Claim is NOT Payable Under Part A

   * NOTE – If any of the following “Unforeseen Circumstances” resulted in a shorter stay the stay is payable Under Part A
     - Death
     - Transfer
     - Departures against medical advice
     - Clinical improvement
     - Election of hospice

5. Does the claim fit within one of the "rare and unusual" exceptions identified by CMS (Currently Mechanical Ventilation)?
   - Yes
   - No

6. For claims with a Date of Admission on or after January 1, 2016
   Does the medical record support the admitting physician's determination that the patient required inpatient care despite not meeting the two midnight benchmark, based on complex medical factors such as:
     - Patient history and comorbidities and current medical needs
     - Severity of signs and symptoms
     - Risk of an adverse event
   - Yes
   - No

   Claim is Payable Under Part A
   (Assuming all other requirements are met)

   Claim is NOT Payable Under Part A
Cases Selected for Review

- CMS will provide the BFCC-QIO with a monthly sample of eligible paid provider claims with lengths of stay of less than 2 midnights.

Excluded from this sample will be:

- Medicare Advantage claims
- If discharge status code is:
  - beneficiary death
  - transfer to another inpatient hospital facility
  - departure against medical advice
  - inpatient-only list

Source: Livanta QIO website
CMS Guidance to QIOs Reviewing Short Stay Hospital Claims for Patient Status: Admissions On or After January 1, 2016 (Last Updated: 12/30/2015)

- “We will address the technical medical review questions posed by commenters in sub-regulatory guidance. We expect to release this information on the CMS Web no later than December 31, 2015”
  - As of yet, there is no such website. Link is nonfunctional.

- QIOs will conduct patient status reviews on a sample of inpatient hospital Part A claims for appropriateness of inpatient admission under the 2 midnight rule for acute care inpatient hospitals, long-term care hospitals, and inpatient psychiatric facilities impacted by CMS-1599-F.
  - QIOs will NOT audit admissions at Inpatient Rehabilitation Facilities (IRFs) and Critical Access Hospitals (CAHs)

- Twice a calendar year, the QIOs will conduct patient status reviews using a provider sample from claims paid within the previous 6 months. (sample 10-25 admissions every 6 months)

- QIOs will review the technical sufficiency of the Inpatient admission order.
CMS Guidance to QIOs Reviewing Short Stay Hospital Claims for Patient Status: Admissions On or After January 1, 2016
(Last Updated: 12/30/2015)

- QIOs will request a minimum of 10 records in a 30-45-day time period from hospitals. The maximum number of record requests per 30 days will be 30 records.
- QIOs shall rate and stratify providers for education and corrective action based upon the results of the completed initial patient status claim review.
- One on one provider education available claim by claim.
- At the direction of CMS, the QIO will refer providers with inpatient status claims identified as having ‘Major Concerns’ to the Recovery Audit Contractor (RACs) to implement provider specific audits.
- The substance of the review and instructions are the same as in prior publications (CMS1599F and 1633F).
Additional Documentation Requests (ADR) rules Revised & Effective January 1, 2016

- Recovery Auditor can still request charts every 45 days.
- A Baseline Annual limit is set equal to 0.5% of the provider’s total number of paid Medicare claims from prior year.
- The ADR 45 day Cycle Limit is calculated as the ADR Annual limit divided by 8.
- ADR limits will be diversified across all claim types based on the Type of Bills (TOB) paid in the previous year.

Source: Medicare Fee-For-Service Recovery Audit Program – Last updated 5/3/2016
Adjusted ADR limit look-back period is 6-months (based on the claim paid date.)

0.5% Baseline Annual ADR limit look-back period is 3-years.

Patient status reviews-limited to a 6-month look-back period if claim filed within 3 months of Date of Service.

CMS will adjust provider ADR limits based on compliance with Medicare rules. Providers with low denial rates will have ADR limits decreased while providers with high denial rates will have their ADR limits increased.
Risk-Based, Adjusted ADR Limits

After three (3) 45-day cycles, CMS will calculate (or recalculate) a provider’s Denial Rate, which reflects compliance with Medicare rules. The Denial Rate will then be used to identify the provider’s corresponding “Adjusted” ADR Limit, based on Table 1, below. The Adjusted ADR Limit will be used for the next three 45-day ADR cycles.

<table>
<thead>
<tr>
<th>Denial Rate (Range)</th>
<th>Adjusted ADR Limit (% of Total Claims)</th>
</tr>
</thead>
<tbody>
<tr>
<td>91-100%</td>
<td>5.0%</td>
</tr>
<tr>
<td>71-90%</td>
<td>4.0%</td>
</tr>
<tr>
<td>51-70%</td>
<td>3.0%</td>
</tr>
<tr>
<td>36-50%</td>
<td>1.5%</td>
</tr>
<tr>
<td>21-35%</td>
<td>1.0%</td>
</tr>
<tr>
<td>10-20%</td>
<td>0.5%</td>
</tr>
<tr>
<td>4-9%</td>
<td>0.25%</td>
</tr>
<tr>
<td>0-3%</td>
<td>No reviews for 3 (45 day) review cycles</td>
</tr>
</tbody>
</table>

Source: Medicare Fee-For-Service Recovery Audit Program – Last updated 5/3/2016
Extrapolation

- CMS will consider allowing Recovery Auditors to use Extrapolation to estimate overpayment amounts for:
  - Providers who maintain a high denial rate for an extended time period
  - Providers who have excessively high denial rates for a shorter time period
  - Providers with a moderate denial rate, whose improper payments equal a significantly high overpayment dollar amount

Source: Medicare Fee-For-Service Recovery Audit Program – Last updated 5/3/2016
Coming Soon – MOON

Medicare Outpatient Observation Notice (MOON)

Patient Name: Patient ID: Physician:

Date: Time: ??

On <date> at <time>, you began receiving observation services at <hospital name>. You’re a hospital outpatient receiving observation services, also called an observation stay. You are not an inpatient.

Observation services:
- Are given to help your doctor decide if you need to be admitted as an inpatient or discharged;
- Are given in the emergency department or another area of the hospital; and
- Usually last 48 hours or less.

How being an outpatient affects what you may have to pay: Being a hospital outpatient affects the amount you may have to pay for your time in the hospital and may affect coverage of services after you leave the hospital.

Medicare Part B covers outpatient hospital services, including observation services when they are medically necessary. Generally, if you have Medicare Part B, you may pay:
- A copayment for each individual outpatient hospital service that you get; and
- 20 percent of Medicare-approved amount for most doctor services, after the Part B deductible.
PROPOSED Discharge Planning Rule

- Impacts:
  - Hospitals (including IRFs, LTACHs, CAH)
  - Home Health Agencies

- Applies to all inpatients and certain outpatients (patients receiving observation services, undergoing surgery or other same-day procedures where anesthesia or moderate sedation used and emergency department patients who have been identified by a practitioner as needing a discharge plan.)
**PROPOSED Discharge Planning Rule**

- Required to develop a discharge plan within 24 hours of admission or registration
- Complete the plan before patient is discharged or transferred to a different facility
PROPOSED Discharge Planning Rule

- Provide discharge instructions to patients who are discharged home
- Have a medication reconciliation process with the goal of improving patient safety by enhancing medication management
- For patients transferred to another facility, send specific medical information to receiving facility
- Establish a post-discharge follow-up process
PROPOSED Discharge Planning Rule

- Increased patient participation in the discharge planning process
- Hospitals and CAHs would be required to consider factors in evaluating a patient’s discharge needs, including,
  - The availability of non-health care services and community-based provided that may be available to patients post discharge
- Providers impacted would be required to use and share data on quality and resource use measures.
Questions?

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