60-Day Repayment Rule: Discussion of Examples, Sampling Methods, and Strategies

HCCA 2020 Compliance Institute
March 29th – April 1st, 2020
Nashville, TN

Breakout Session (#707)
March 31st, 2:00 – 3:00 pm

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Agenda

• Brief Review of 60 Day Rule
• Important Legal Developments - Allina
• The Audit Letter/ Demand
  • Is it an audit?
  • Whether and How To Respond
  • Appeal Strategies
Potential Overpayment Analysis: The 60 Day Rule

- Medicare Parts A and B providers/suppliers are to report and return overpayments within 60 days after the overpayment identified
  - Legal DUTY to investigate CREDIBLE allegations of potential overpayments
  - Six-year lookback period
  - Failure to comply could result in improper retention of an overpayment and violation of the False Claims Act

Potential Overpayment Analysis: The 60 Day Rule

- Government Audit Findings
  - 60 Day Rule: Credible Allegation of an Overpayment is An Adverse Government Audit Finding
  - Legally, DUTY TO INVESTIGATE

When defendant submits claims for payment to Medicare, there is "implied certification" that conditions for payment satisfied

To be liable under False Claims Act, the "error" or false representation must be material to payment

Potential Overpayment Analysis: The Legal Issues


- When defendant submits claims for payment to Medicare, there is "implied certification" that conditions for payment satisfied
- To be liable under False Claims Act, the "error" or false representation must be material to payment
Potential Overpayment Analysis

The Legal Issues

• Escobar: Materiality standard
  • Not all violations of standards are "False Claims"
  • Violation may not be "material"
  • Example: Government knew of issue and paid
    • Ambulance services
    • D'Agostino v. ev3, Inc., 845 F.3d 1 (1st Cir. 2016)

• Note: Evolving Case Law!

Potential Overpayment Analysis

The Legal Issues

• Claims Processing
  • Use of "dummy prescriber IDs" not support False Claims Act when needed for claims processing
  • Evidence government new of problem and “routinely paid”
    • United States ex rel. Spay v. CVS Caremark, 875 F.3d 746 (3rd Cir. 2017)
Potential Overpayment Analysis

The Legal Issues

- **Home Health Plan of Care**
  - *United States v. Dynamic Visions, Inc.*, 216 F. Supp. 3d 1 (D.C.C. 2016) (materiality satisfied where defendant home health agency's plans of care were clearly deficient or non-existent.
  - *United States ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, 892 F.3d 822 (6th Cir. 2018), *petition for cert. filed*, No. 18.699 (U.S. Nov. 28, 2018) reversing district court’s dismissal of FCA allegations based on home health care provider's alleged failure to obtain timely plans of care certifications. Timing was material as express condition of payment and government guidance.

Potential Overpayment Analysis

The “Problem”

- **Government Audit Findings**
  - Local Coverage Determination (LCD)
    - Was this LCD applicable?

- See *Caring Hearts Personal Care Home Services, Inc. v. Burwell*, 824 F.3d 968 (10th Cir. 2016)
CMS Audits

Important Cases

- Claim Denial based on failure to follow Local Coverage Determination (LCD)
  - An LCD is not a law – despite what a contractor may say
  - LCD cannot change the scope of benefits to which patient is entitled
    - US v. AseraCare, Inc. 938 F.3d 1278 (11th Cir. 2019)

- Azar v. Allina Health Services, 139 S.Ct. 1804 (2019)

  - HHS must engage in notice and comment rulemaking before publishing methods that impact reimbursement amounts owed to providers

  - In other words...you can’t make up new rules on websites, in letters, etc. to deny payments to providers
CMS Audits

Executive Order

• Executive Order 13891 (October 9, 2019)

  • "Americans are subject to only those binding rules imposed through duly enacted statutes or through regulations lawfully promulgated under them...."

  • What is "subregulatory guidance" then??

CMS Audits

Allina Impact

• October 31, 2019 DHHS Memo:
  • Impact of Allina on Medicare Payment Rules
    • ...Congress has imposed more stringent procedural requirements for certain Medicare rules...the payment rules that you develop often form the basis for enforcement actions... (includes overpayment collections based on audit)
    • The critical question is whether the enforcement action could be brought absent the guidance document
**CMS Audits/ Demands**

*The Alphabet Soup*

- When An Audit Isn't An Audit
  - The MAC's "Special Demands"
- Targeted Probe and Educate (TPE)
- Unified Program Integrity Contractors (UPIC)
  - Not just Medicare anymore!
- Recovery Audits
  - Prepayment review...then postpay review?

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**CMS Demands**

*Refund*

- Medicare "Overpayments"
  - Provider Billed/ Reimbursed by FFS
  - Cahaba erred by not telling provider to bill Medicare Advantage plan instead
  - Palmetto Sends "DEMAND LETTER" in 2018 from claims from 2014
    - Includes language that **YOU** have to go back and refund "overpayments" dating to 2012
CMS Demands

Refund

- Medicare Advantage "Overpayments"
- Take a second (third, fourth or fifth!) look
  - Who was overpaid?
    - The PLANS!
  - What is Palmetto telling you they will do?
  - What claims are impacted?
    - Any "60-Day Rule" Implications?

CMS Demands

Refund 60 Day Rule

- Medicare Advantage Demand
- Letters sent with some information about claims
  - No Audit Performed
  - Not clear any paid in error
    - No data available to confirm beneficiary eligibility status
    - Is there a credible allegation of an overpayment?
**CMS Demands**

*Other Audits*

- Targeted Probe and Educate
  - The New Medical Director Concludes He's Right!
  - The provider has had multiple UPIC, RA audits with no findings!
- Strategy for Provider?
  - Contact CMS
  - Appeal
  - 60-Day Rule
  - Federal Court!

**MAC Audits**

*Observation Hours*

- National Government Services (NGS) Audits in 2020
- Removal of Observation Hours from Hospital Claims
  - Hospital allegedly failed to provider Medicare Outpatient Observation Notice (MOON) to patient in timely manner
  - Financial impact: removal of observation hours
  - Reported: CMS agreed that MOON compliance is condition of participation – not payment
- Impact of Allina?
Update on UPIC Audits

- Unified Program Integrity Contractor
  - Audits Medicare
  - Audits Medicaid

- What are coverage standards for Medicare versus Medicaid?
  - Prior Authorization?

Recovery Audits

- Recovery Auditors
  - Audits Medicare
  - Audits Medicaid
    - Post-pay audits of claims subject to prepayment review
      - Did you have appeal rights after prepay approved?
      - How many times should a claim be reviewed?
CMS Audits
Allina Impact

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State Law Initiatives
Proposed Rules for Statistics

• Basis is to prevent FRAUD OR ABUSE
  • Kentucky as example
  • No requirement to perform extrapolations on "routine" audits
  • Keep your eyes out --- to prevent significant denials on low error rates, bad math…..

  • If statistics used - ensure
    • Replication
    • Validity
If “systemic error”

- Probe Audits
  - No “magic number”
  - 30-50 claims?
  - Start with current/most recent and work BACKWARDS as needed
  - Knowing when to stop is hardest part.....
  - What if you find 5 out of 30 claims could be erroneous....

Statistics in Compliance

- Representative is NOT the same as RANDOM

- Statistically VALID does not the same as statistically RANDOM
Statistics in Compliance

Precision – How "tight" the data points are:

→ versus ←

Statistics in Compliance

Accuracy – How "close" / reliable is the data point to the actual overpayment

← versus →
### Variable Sample Size Output Using Estimated Error Rate

#### Confidence Level

<table>
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<tr>
<th>Sample Precision</th>
<th>80%</th>
<th>90%</th>
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<tr>
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<tr>
<td>15%</td>
<td>174</td>
<td>286</td>
<td>404</td>
<td>691</td>
</tr>
</tbody>
</table>

#### Universe Size

- **30,000**

#### Estimated Error Rate

- **40%**

#### Difference Values

- Estimated Mean: **66.67**
- Estimated Std. Deviation: **103.28**

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### Variable Sample Size Using Estimated Error Rate

#### Universe Size

- **30,000**

#### Anticipated Error Rate

- **40%**

#### Reported Amounts

- Total Amount: **5,000,000.00**
- Standard Deviation: **100.00**

#### CONFIDENCE LEVEL

- 80%
- 95%
- 99%
- All

#### OUTPUT TO

- Test File and Screen
- Printer and Screen
- Test File, Printer, and Screen
- Screen Only
**Statistics in Compliance**

*RAT - STATs*

- Merely using RAT STATS does NOT mean outcome is
  - Reliable
  - Representative
  - Appropriate

... or satisfies DUE PROCESS

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**Statistics**

*CMS Standards in PIM*

Medicare Program Integrity Manual – Chapter 8

- UPDATES Effective January 1, 2019
  - What is sustained/high error rate?
    - 50% from previous pre- post- payment review
      - How calculate 50%?
    - Must use statistical experts, written approval for methodology for *every* sampling
      - Qualifications for experts include specific degrees, years of relevant experience
    - Clear specification for dates used...
      - HINT: This has caused issues for reviewers in past
Statistics in Compliance

Government Audits

• Corporate Integrity Agreements from HHS-OIG = 5%

• CMS Medicare Managed Care Manual, Chapter 7, § 120.2, 5
  • CMS requires accurate data
  • If plan submits 5% or greater duplicates (errors), not accurate

Questions?

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