Health Care Compliance Association

Finally—It’s Final: CMS’s 60-Day Rule for Part A and B Providers

January 20, 2017
Sara Kay Wheeler

Goals of Session

• Overview of Enforcement and Compliance Environment
• Mechanics of the 60-Day Medicare A/B Overpayment Rule
• Operationalizing the 60-Day Rule: Key Questions and Considerations
• Questions
Enforcement and Compliance Environment

Complex Enforcement and Compliance Environment

- Expanding Universe of “Examiners”
- Powerful Weapons, Investigative and Auditing Techniques, and Innovative Theories of Recovery
- Enhanced Focus on Criminal and Civil Enforcement Against Responsible Individuals
- Enhanced Expectations for Effective Risk Mitigation and Compliance Program Expectations
Enforcement Environment

• Increased Qui Tam cases.
• Increased FCA penalties.
  – The minimum per claim penalty increased to $10,781, and the maximum per claim penalty increased to $21,563.
• New breed of whistleblower.
• Universal Health Services, Inc. v. United States ex rel. Escobar.
• Enhanced Medicaid enforcement.

FCA Enforcement of 60-Day Rule

  – Healthcare provider allegedly erroneously submitted claims to Medicaid for payment due to a software error. The provider failed to fully investigate and identify all overpayments until two years later.
  – The court interpreted “identification” to include situations where “a person is put on notice that a certain claim may have been overpaid.”
• Parties settled for $2.95 million on August 23, 2016
FCA Enforcement of 60-Day Rule

• August 2015: Pediatric Services of America Settlement
  — $6.88 million settlement to resolve allegations that provider, among other things, failed to investigate credit balances on its book to determine whether the credit balances resulted from overpayments made by federal healthcare programs.
  — DOJ described the settlement as “the first of its kind” and “precedent-setting.”

OIG Audit – NY Pres. (August 2016)

• OIG released audit findings for New York Presbyterian Hospital.
• Published by OIG in August 2016 but audit period covered calendar years 2011 and 2012.
• Sample of 285 claims resulted in findings of an alleged overpayment of over $800K.
  — On the basis of that sample, OIG extrapolated to a universe of 3,884 claims, resulting in a total alleged overpayment of over $14 million.
OIG Audit – NY Pres. (Cont’d)

- OIG recommended that the hospital “exercise reasonable diligence to investigate the potential overpayments outside of the Medicare reopening and recovery periods and work with the Medicare contractor to return any identified overpayments . . . in accordance with the 60-day repayment rule.”

- Hospital’s response:
  - All claims reviewed were subject to statutory and administrative finality limitations;
  - Time-barred claims are not Overpayments; and
  - Claims for which the hospital disagreed with OIG’s findings were not “identified” overpayments under the 60-day rule.

Individual Accountability: More than 1 Year Post Yates Memo

- **Yates Memo Overview**
  - On September 9, 2015, Deputy Attorney General, Sally Quillian Yates, issued a memorandum (the Yates Memo) regarding individual accountability for corporate wrongdoing.
  - Provides guidance for both civil and criminal investigations.
  - Emphasizes the need to hold individuals who perpetrated corporate wrongdoing accountable.

- **Discuss Impact of Yates Memo**
**Individual Accountability: Enforcement Examples**

**Former Tuomey CEO to personally pay $1 million to settle False Claims Act case**

Legal & Regulatory Issues

Ex-hospital CFO, physicians guilty in $580M kickback scheme

Written by Emily Wilson, Reporter | November 25, 2015 | Print | Email

The ex-CFO of the now-defunct Pacific Hospital in Long Beach, Calif., was among those who recently reached a plea agreement with prosecutors for his involvement in a fraud scheme that generated $505 million in false billings, according to the Department of Justice. Others involved in the scheme, including two orthopedic surgeons, have agreed to plead guilty in coming weeks.

The 15-year-long fraud scheme involved Pacific Hospital’s former CEO and others submitting bills to workers’ compensation insurers and the U.S. Department of Labor for spinal surgeries. The surgeries were performed on patients who had been referred by dozens of physicians.

**Individual Accountability: Enforcement Examples (cont’d)**

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Ex-Clinic CFO Gets 17 Years After Taking $11M From Grants

By Emily Wilson

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Terri McGuire Holka, 50, has pleaded guilty to participating in a scheme involving siphoning federal grant money given to Birmingham Health Care and Central Alabama Comprehensive Health to provide services to private entities and then to private individuals, including herself. Chief U.S. District Judge Karen O. Bowdler sentenced Holka to 17 years in prison for the scheme, in which prosecutors say she personally profited about $1.7 million.

**Chairman of the Board and Senior Vice President of Reimbursement Analysis to Pay an Additional $1.5 Million**

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North American Health Care Inc. (NAHC), its chairman of the board, John Stroesicke, and its senior vice president of Reimbursement Analysis, Margaret Oenkosky, have agreed to pay a total of $60 million to resolve allegations that they violated the False Claims Act by causing the submission of false claims to government health care programs for medically unnecessary rehabilitation therapy services, according to the Department of Justice.

North American Health Care Inc.’s (NAHC) Reimbursement Analysis Division, which performed audits for clients, submitted claims for therapy services to government health care programs, including Medicare, that were not medically necessary or provided. NAHC’s clients included home health agencies, nursing facilities and subacute centers.

Head of the Justice Department’s Civil Division, “Health care providers will be held accountable if they fail to ensure that their services are necessary and performed by qualified professionals.”

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OIG’s Focus on Individual Accountability: CIA Developments

Escalating Compliance Program Expectations

- Mandatory Compliance Programs (ACA § 6401(a)(8))
- DOJ Compliance Counsel
- CIA Trends
  - Enhanced Board Oversight
  - Compliance Expert
  - Active Risk Assessment and Mitigation
CIAs: Risk Assessments

Example of Risk Assessment and Internal Review Process

CIA 15 and 16 concluded that the risk assessment and internal review processes were as follows:

1. Risk Assessment and Internal Review Process

Within 120 days after the Effective Date, the Office of Compliance shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries. The risk assessment and internal review process shall be reviewed and updated at least annually to ensure the risk assessment and internal review process are appropriate and reasonable. The risk assessment and internal review process shall be developed annually and maintained in the Office of Compliance to ensure the completeness and accuracy of the risk assessment and internal review process. The risk assessment and internal review process shall be made available to all appropriate staff.

2. Disclosures

The Office of Compliance shall be responsible for ensuring that a Disclosures Program that includes the release of material that may be material to the Office of Compliance and the Office of Compliance's employees is developed and maintained. The Disclosures Program shall be reviewed and updated at least annually to ensure the completeness and accuracy of the Disclosures Program. The Office of Compliance shall be responsible for ensuring that the Disclosures Program is reviewed and updated at least annually to ensure the completeness and accuracy of the Disclosures Program.

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CIAs: Board Resolutions

3. Board of Directors' Comprehensive Objectives

The Board of Directors shall be responsible for the review and approval of the Board of Directors' Comprehensive Objectives. The Board of Directors shall review and approve the Board of Directors' Comprehensive Objectives at least annually.

At a minimum, the resolution shall include the following language:

"The Board of Directors (or name of applicable committee of the Board) has made a reasonable inquiry into the operations of the Compliance Program, including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board (or a committee of the Board) has concluded that, to the best of its knowledge, the Board (or a committee of the Board) has implemented an effective Compliance Program to meet Federal Health Care program requirements and the obligations of the CIA."
CIAs: Retention of a Compliance Expert

Example of Compliance Expert Provision

3. Board of Directors Compliance Obligations. The Board of Directors of the Compliance Committee in its review and oversight functions, shall be responsible with Federal health care program requirements and the obligations of the CIA. The Board shall include individuals with requisite, non-executive members.

The Board shall, at minimum, be responsible for the following:

a. meeting at least quarterly to review and approve each compliance program, including but not limited to the performance of the Compliance Program and Compliance Committee;

b. submitting to the OIG a summary of the documents and other materials it reviews, as well as any additional steps taken, such as the receipt of an independent advice or other third party services, in its oversight of the compliance program and in connection with resolving matters under this section;

c. for each Planning Period of the CIA, adopting, amending, ratifying, and certifying of the Board governing its review and evaluation of compliance with Federal health care program requirements under this section;

d. for the second and fourth Reporting Periods of the CIA, the Board shall create an individual or entity with expertise in compliance with Federal health care program requirements under this section, to review and evaluate the Compliance Program Review Report and prepare a written report about the Compliance Program Review. The written report shall include a description of the Compliance Program Review and any recommendations with respect to PSA’s compliance program. The Board shall review the Compliance Program Review Report as part of its review and oversight of PSA’s compliance program. A copy of the Compliance Program Review Report shall be provided to OIG in the Annual Report submitted for the second and fourth Reporting Periods by PSA. In addition, copies of any materials provided to the Board by the Compliance Expert, along with minutes of any meetings between the Compliance Expert and the Board, shall be made available to the OIG upon request.

Focus on Voluntary Self-Disclosures

• Recent Remarks from OIG Inspector General at HCCA Compliance Institute (April 2016)

  — **Self-disclosure** is now the mark of an effective compliance program.

  — **Self-correction** was specifically emphasized by Daniel Levinson as a pillar in the pursuit of the establishment of a strong healthcare institution.

• At its core, the 60-day overpayment rule is a combination of self-disclosure and self-correction.
Updated OIG Permissive Exclusion Authority

- Confluence of industry developments reflected in updated OIG permissive exclusion guidance.
- On April 18, 2016, OIG issued a revised policy statement containing the new criteria that OIG intends to use in implementing its permissive exclusion authority under 42 U.S.C.A. § 1320a-7(b)(7) (Revised Policy).

Examples of Key Aspects of the Revised Policy

- **Individual Accountability**
  - In the case of an individual, if the individual organized, led, or planned the unlawful conduct, this indicates higher risk.
  - In the case of an entity, if individuals with managerial or operational control at or on behalf of the entity organized, led, or planned the unlawful activity, this indicates higher risk.
  - If the person’s cooperation resulted in criminal, civil, or administrative action or resolution with or against other individuals or entities, this further indicates lower risk.

- **Internal Investigations**
  - If the person initiated an internal investigation before becoming aware of the Government’s investigation to determine who was responsible for the conduct, and shared the results of the internal investigation with the government, this indicates lower risk.
  - If the person self-disclosed the conduct cooperatively and in good faith as a result of the internal investigation, prior to becoming aware of the Government’s investigation, this indicates lower risk.
Updated OIG Permissive Exclusion Authority (cont’d)

Examples of Key Aspects of the Revised Policy (cont’d)

— Compliance Program
  — The existence of a compliance program that incorporates the seven elements of an effective compliance program does not affect the risk assessment.
  — The absence of a compliance program that incorporates the seven elements of an effective compliance program indicates higher risk.
  — If the entity has devoted significantly more resources to the compliance function, this indicates lower risk.

— History of Self Disclosures
  — If the person has a history, prior to becoming aware of the investigation, of significant self-disclosures made appropriately and in good faith to OIG, CMS (for Stark law disclosures), or CMS contractors (for non-fraud overpayments), this indicates lower risk.

Mechanics of the 60-Day Medicare A/B Overpayment Rule
**The Affordable Care Act Law**

- **March 23, 2010:** Enactment of the Affordable Care Act (ACA)

- **Section 6402(a) of the ACA** (now codified at 42 U.S.C. § 1320a-7k(d)):
  
  - A person who has received an overpayment must report and return the overpayment within either 60 days after the date on which the overpayment was **identified** or on the date any corresponding cost report is due, whichever is later.

  - The term “overpayment” means any Medicare or Medicaid funds that a person receives or retains to which the person, after **applicable reconciliation**, is not entitled.

**Failure to report and return an overpayment can result in False Claims Act (FCA) and Civil Monetary Penalties (CMP) liability, as well as exclusion from participation in federal health care programs.**

- **CMS** was charged with issuing implementing regulations. However, Section 6402(a) did not require implementing regulations to become effective.
“Identification” Defined: A/B Final Rule

- **Medicare Parts A/B Final Rule**: New regulatory definition in 42 C.F.R. § 401.305(a)(2)
  - An overpayment is identified “when the person **has, or should have** through the **exercise of reasonable diligence**, determined that the person has received an overpayment and **quantified** the amount of the overpayment.”

- This definition includes two key concepts:
  1. Concept of reasonable diligence
  2. Quantification
Concept of Reasonable Diligence

- The finalized definition of “identification” incorporates concept of “reasonable diligence.”

- In the Final Rule, CMS stated that reasonable diligence includes both proactive compliance activities and reactive investigative activities.
  - Size and scope of compliance programs will vary, but having no compliance activities may expose the provider to liability.

- When does the 60-day clock begin to tick?
  1. When the exercise of reasonable diligence is completed, or
  2. If there is a failure to exercise reasonable diligence, on the day when the person received credible information of a potential overpayment.

Credible Information of Potential Overpayments

- Keyword—Potential Overpayments.

- Receipt of “credible information” triggers a duty to investigate.
  - “Credible information” is not specifically defined, but includes information that “supports a reasonable belief that an overpayment may have been received.”
  - CMS specifically rejected an evidentiary standard—instead adopted a credible “information” standard.
Potential Sources of “Credible” Information (Not Exhaustive)

- Certain hotline reports
- Subpoenas
- ZPICs
- QIOs
- MACs
- RACs
- CAMS contractor audits
- CERTs
- Internal compliance reviews/audits
- Compliance exit interviews
- OIG audits
- Revenue spikes
- Ineligible persons
- Qui Tams

Quantifying a Potential Overpayment

- For Medicare Parts A/B, an overpayment is not “identified” until quantified (although there are time constraints for quantifying).
  - Prior to the issuance of the final Medicare Parts A/B rule, there was significant discussion in the industry regarding the quantification issue.
  - Quantifying an overpayment can present numerous complexities and can involve significant effort.
    - Can use “statistical sampling, extrapolation methodologies and other methodologies as appropriate to determine the amount of the overpayment, rather than identifying every claim.”
    - Must explain in an overpayment report how the amount of the overpayment was calculated if statistical and extrapolation methods are used.
## Medicare Parts A/B Overpayment Final Rule: Timeline

The final rule’s general timeframes for reporting and returning Medicare A and B overpayments are as follows:

<table>
<thead>
<tr>
<th>Event</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receipt of “Credible Information” of a</td>
<td>No More than 6 Months to</td>
</tr>
<tr>
<td>Potential Overpayment</td>
<td>Investigate and Quantify</td>
</tr>
<tr>
<td>This triggers duty to investigate</td>
<td>60 days to report and return the overpayments</td>
</tr>
</tbody>
</table>

Unless “Extraordinary Circumstances,” no more than 8 months to investigate and report and refund Medicare Parts A and B overpayments.

## Lookback Period

- Pursuant to the Medicare Parts A/B Final Rule, Medicare Parts A/B overpayments must be reported and returned “only if a person identifies the overpayment within six years of the date the overpayment was received.”
- **Maximum Threshold**: Providers should not be foreclosed from using a more limited lookback period if justified by the relevant circumstances (coverage change or EHR system conversion).
- Practical challenges of lookback period:
  - Recordkeeping difficulties
  - Evolving regulatory standards
  - Audit resources
  - Potential need for statistical sampling resources
Operationalizing the 60-Day Rule: Key Questions and Considerations

How to Effectively Implement the 60-Day Rule?

- High Stakes -- Darling of Govt./Whistleblowers
- Complex law and regulation -- many gray areas
- Complex Organization / Numerous Impacted Stakeholders
- How to prioritize limited resources
Who is charged with development and deployment?

- Compliance
- Partnership
- Legal

Input from Key Stakeholders

- Information Technology
- Finance
- Internal Audit
- Revenue Integrity
- Others

What is Considered an Overpayment under the 60-Day Rule?

- Overpayment is defined to include “any funds that a person receives or retains under sub-chapter XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such subchapter.” 42 U.S.C. § 13201-7.

- Consider potential scenarios involving funds that arguably could be received outside of sub-chapter XVIII or XIX

- CMS explicit that cause of overpayment does not impact the provider’s obligations to report and return.
  - Overpayments must be returned even if provider not at fault.
What Falls Under the 60-Day Rule Overpayment Umbrella?

- Payments for non-covered services
- Duplicate payments
- Medicare payments when another party responsible for payment
- Inappropriate coding or upcoding

Note: This list is not exhaustive.

Credible Information – Application to Multi-Hospital Systems?

Hospital A

Credible information of potential overpayment

Hospital B

Hospital C

Credible information of potential overpayment
Who determines what is “credible information” of a potential overpayment?

• Who at your organization has the authority to determine what is “credible information” of a potential overpayment?
• Who is responsible for documenting all important decisions regarding the investigation of potential overpayments, including whether (and when) certain information was ultimately determined to be a “credible” source of information?

How are potential sources of “credible information” analyzed?

• What standards are used?
• How is this analysis documented?
Who keeps an eye on the 60-day timelines?

- Who determines when the timeline for the 60-day analysis is triggered?
- Who is responsible for tracking the 60-day and 6-month investigation timeframes?
- What tools are used to keep track of these deadlines?

Timeline Considerations: What is Subject to the Initial 6-Month Investigative Deadline?

- Credible Information determined for Issue 1
- Credible Information determined for Issue 2

Issue 1 investigation/refund timeline

Issue 2 investigation/refund timeline
Policies, Procedures and Protocols

• Assessment of Key Policies
  — Overpayment policy
    — All payors?
    — Separate policy for Federal payors?
  — Internal investigations policy
    — Important in light of 6 month investigation timeline articulated in Final Rule
    — Lookback period considerations – who determines audit lookback period?

• Assessment of Key Procedures and Protocols
  — Audit protocols
  — Self-disclosure processes
  — Others

• Who at your organization is responsible for leading assessment of policies, procedures and protocols?
Additional Considerations

- Appeals/Contractor Denials.
  - CMS stated that it believes that “contractor overpayment determinations are always a credible source of information for other potential overpayments.”
  - Given this commentary, consider evaluating who within the organization reviews appeal decisions and makes determinations regarding whether to appeal particular decisions.

Additional Considerations (cont’d)

- Consider industry recognized error rates
  - For example, QIO patient status reviews
  - Government and qui tam relators may attempt to use error rates as a sword:
Additional Considerations (cont’d)

- Refunding Logistics/Documentation
  - Consider overpayment refund strategies with relevant payors
    - How much information regarding efforts to comply with the 60 day rule will be provided?

- Providers may face challenges in ensuring contractors process voluntary refunds.
  - Consider potential need for follow-up.
  - Consider advantages of providing certain voluntary refunds through checks, rather than electronic processing.
  - How are refunds documented?