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
Complex Enforcement and Compliance Environment

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**

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Individual Accountability: Enforcement Examples

- Former Toumey CEO to personally pay $1 million to settle False Claims Act case

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Individual Accountability: Enforcement Examples (cont’d)

- Ex-CFO gets 17 years after taking $11M from grants

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**OIG’s Focus on Individual Accountability: CIA Developments**

**4. Management Certifications.**

The definition of individual accountability in the context of the CIA is crucial. It involves the principle that individuals are responsible for their actions and decisions, and they must be held accountable for them. This accountability extends to the decision-making process, including the assessment of risks and the implementation of appropriate controls. The development of management certifications is a key aspect of ensuring that individuals are accountable for their actions. These certifications serve as a formal acknowledgment that an individual has met the necessary standards and requirements for their role.

**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**

The risk assessment and internal review process is a critical component of ensuring compliance and mitigating risks. It involves the identification and prioritization of potential risks, the development of strategies to address these risks, and the monitoring of the effectiveness of these strategies. This process is essential for maintaining the integrity of the operations and ensuring that the CIA is operating in accordance with all applicable laws and regulations.
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.
  - 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.

The Affordable Care Act Law

- Section 6402(a)’s obligation to report and return overpayments applies to:
  - Providers
  - Suppliers
  - Medicaid Managed Care Organizations
  - Medicare Advantage Organizations
  - Prescription Drug Plan Sponsors
- CMS was charged with issuing implementing regulations. However, Section 6402(a) did not require implementing regulations to become effective.
Timeline of Significant Overpayment Developments

- **March 2010**
  - ACA requirement for reporting and refunding Medicare and Medicaid overpayments enacted

- **February 2012**
  - Medicare Parts C/D Proposed Rule

- **January 2014**
  - Medicare Parts C/D Final Rule

- **February 2016**
  - No Medicaid Proposed Rule to date

- **January 2017**
  - Four Months
  - Medicare Parts A/B Final Rule
  - Medicare Parts A/B Proposed Rule

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“Identification Defined: 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

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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)

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.
Parts A/B Overpayment Final Rule: Timeline

- Receipt of "Credible Information" of a Potential Overpayment
  - No More than 6 Months to Investigate and Quantify Potential Overpayments (absent "extraordinary circumstances")
  - 60 days to report and return the Overpayments

Triggers Duty to Investigate

Unless "Extraordinary Circumstances," No More Than 8 Months to Investigate and Report and Refund Medicare Parts A and B Overpayments

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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

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Operationalizing the 60-Day Rule:
Key Questions and Considerations
How to Effectively Implement the 60-Day Rule?

- High Stakes — Darling of Govt./Whistleblowers
- Complex Organization / Numerous Impacted Stakeholders
- Complex law and regulation — many gray areas
- 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
- Payments received in violation of AKS or Stark
- Medicare and Medicaid HMO payments
- EHR incentive payments
- Value-based program payments
- Accountable Care Organization shared savings

Note: This list is not exhaustive.

Credible Information – Application to Multi-Hospital Systems?

Hospital A
- Credible information of potential overpayment

Hospital B
- Credible information of potential overpayment

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?
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?

Additional Considerations (cont’d)
• 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?