

HCCA 2016 Orange County Regional Area Compliance Conference

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Regulatory and Enforcement Update

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Goals of Session

- Explore Recent Enforcement and Regulatory Developments
- Analyze Provisions of Medicare Parts A and B final overpayment rulemaking
- Discuss strategies for addressing these fundamental changes, including investigation changes, governance considerations, and internal controls
- Questions

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Important Developments

Landscape Continues to Intensify

- Several recent enforcement and regulatory developments have impacted the healthcare industry, including:
 - Enhanced OIG compliance program expectations and increased focus on individual accountability
 - Updated OIG Permissive Exclusion Criteria
 - DOJ Compliance Counsel
 - Yates Memo
 - Aggressive Relator Strategies

OIG's Mounting Compliance Program Expectations

- **Corporate Integrity Agreements (CIAs)**
 - Agreement with HHS-OIG in connection with civil healthcare fraud settlement
 - Requires entity or individual to implement (or continue) certain integrity obligations for a period of years

Importance of CIA Trends to Non-CIA Obligated Providers

- **OIG uses CIAs to communicate prudent approaches to compliance program design and compliance-related initiatives.**
- **Emerging trends in CIAs reflect OIG's escalating compliance expectations for entities participating in federal healthcare programs.**
- **Why monitor and address emerging compliance trends?**
 - Fortify compliance infrastructure
 - A company's proactive efforts to monitor and address such emerging compliance trends often benefits the company when reviewed by Government enforcement agencies

Emerging CIA Trends

- Enhanced Board oversight
- Management’s responsibility for compliance
- Compliance Expert
- Active risk assessment and mitigation

Board Resolutions

3. *Board of Directors Compliance Obligations.* The Board of Directors (or a committee of the Board) of [REDACTED] (Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA. The Board (or a committee of the Board) must include independent (i.e., non-executive) members.

The Board (or a committee of the Board) shall, at a minimum, the following:

- meeting at least quarterly to review the [REDACTED] Compliance Program, including the performance of the Compliance Officer and the Compliance Committee;
- submitting to the OIG a description of the [REDACTED] Compliance Program, including other materials it reviewed, as well as the steps taken, in its oversight of the program, to support making the resolution better informed; and
- for each Reporting Period of the CIA, signed by each member of the Board (or a committee of the Board) summarizing its review and compliance with Federal health care program requirements and the obligations of this CIA.

At 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 [REDACTED] 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, [REDACTED] has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA.”

If the Board (or a committee of the Board) is unable to provide such a conclusion in the resolution, the Board (or a committee of the Board) shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at [REDACTED].

Corporate Incentive Agreement
[REDACTED]
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At 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 [REDACTED] 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, [REDACTED] has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA.”

Enhanced Management Certifications

Example of Management Certification Provision

[REDACTED] shall report to OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

4. **Management Certifications.** In addition to the responsibilities set forth in this CIA for all Covered Persons, certain [REDACTED] employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable [REDACTED] department is in compliance with applicable Federal health care program requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Chief Executive Officer, Chief Financial Officer, Chief Clinical Officer, Chief Nursing Officer, Executive Vice President, Physician Strategy and Alignment, Vice President, Programs of Excellence, Vice President, Post Acute Services and Regional Development, and Chief Administrative Officer. For each Reporting Period, each Certifying Employee shall sign a certification that states:

"I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of department] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and [REDACTED] policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the [insert name of department] of [REDACTED] is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States."

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above.

Within 120 days after the Effective Date, [REDACTED] shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Employee making the required certification).

Corporate Integrity Agreement
[REDACTED]

4. Management Certifications.

"I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of department] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and [REDACTED] policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the [insert name of department] of [REDACTED] is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States."

Retention of a Compliance Expert

Example of Compliance Expert Provision

3. **Board of Directors Compliance Obligations.** The Board of Directors (or a committee of the Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA. The Board must include independent (i.e., non-executive) members.

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

- a. meeting at least quarterly to review and oversee the [REDACTED] compliance program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. submitting to the OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period;
- c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board summarizing its review and oversight of [REDACTED] compliance with Federal health care program requirements and the obligations of this CIA; and
- d. for the second and fourth Reporting Periods of the CIA, the Board shall retain an individual or entity with expertise in compliance with Federal health care program requirements (Compliance Expert) to perform a review of the effectiveness of [REDACTED] Compliance Program (Compliance Program Review). The Compliance Expert shall create a work plan for the Compliance Program Review and prepare a written report about the Compliance Program Review. The written report (Compliance Program Review Report) shall include a description of the Compliance Program Review and any recommendations with respect to [REDACTED] compliance program. The Board shall review the Compliance Program Review Report as part of its review and oversight of [REDACTED] 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 [REDACTED]. In addition, copies of any materials provided to the

[REDACTED]
Corporate Integrity Agreement

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DOJ's Assessment of Compliance Effectiveness

- Accordingly to recent remarks from Leslie Caldwell, DOJ will assess the effective of compliance programs by asking question such as:
 - Does the institution ensure that its directors and senior managers provide strong, explicit and visible support for its corporate compliance policies?
 - Do the people who are responsible for compliance have stature within the company?
 - Do compliance teams get adequate funding and access to necessary resources?
 - Are the institution's compliance policies clear and in writing? Are they easily understood by employees?
 - Does the institution ensure that its compliance policies are effectively communicated to all employees? Are its written policies easy for employees to find?

DOJ's Assessment of Compliance Effectiveness (Cont'd)

- Do employees have repeated training, which should include direction regarding what to do or with whom to consult when issues arise?
- Does the institution review its policies and practices to keep them up to date with evolving risks and circumstances?
- Are there mechanisms to enforce compliance policies? Those include both incentivizing good compliance and disciplining violations. Is discipline even handed?
- The department does not look favorably on situations in which low-level employees who may have engaged in misconduct are terminated, but the more senior people who either directed or deliberately turned a blind eye to the conduct suffer no consequences.
- Does the institution sensitize third parties like vendors, agents or consultants to the company's expectation that its partners are also serious about compliance?

Yates Memorandum

- 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, “particularly in the aftermath of the financial crisis.”

Yates Memorandum

- In order to qualify for any cooperation credit, corporations must provide DOJ *all relevant facts relating the individuals responsible for the misconduct*.
 - Consider impact on internal investigations.
 - Potential revisions to Upjohn warning.
 - May dampen individuals’ willingness to be transparent with counsel.

Yates Memorandum

- Absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for any individuals.
- Decision to bring suit against individuals should be based on considerations beyond the individual's ability to pay.

UPHS Settlement

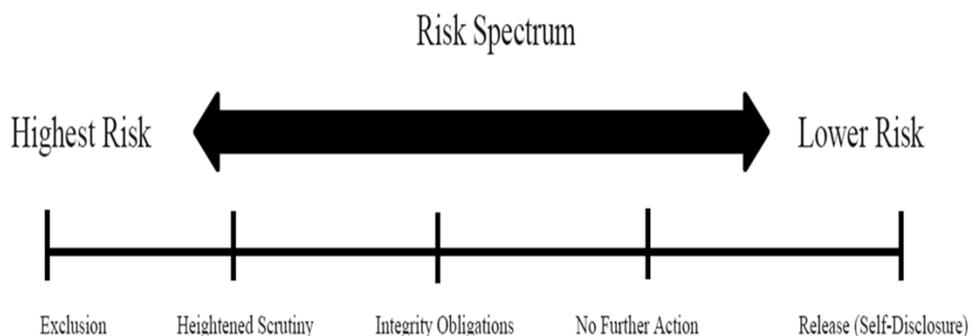
- The University of Pennsylvania Health System (UPHS) settled false claims allegations that UPHS billed Medicare for home health services that were not reasonable or necessary.
- Pursuant to the settlement agreement, UPHS agreed to pay approximately \$75,000 and also agreed to ongoing compliance monitoring by the United States Attorneys' Office (USAO) through 2019.
- As part of the ongoing monitoring, UPHS will be required to conduct semi-annual audits of home health claims and report the results to the USAO.
- USPHS is required to annually submit certified compliance reports to the USAO.
 - These reports must contain attestations by the USPHS billing compliance officer and the chief counsel. UPHS must also notify the USAO of any home health overpayments that are refunded.

Aggressive Relator Strategies

- Whistleblower cases continue to increase
- New relators, new relator's counsel
 - Not just the disgruntled employee relator anymore
- Defense counsel must be prepared to defend litigation, not merely investigation
- Even if government declines to intervene, relator's counsel continues case

OIG Permissive Exclusion Authority

- 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).



OIG Permissive Exclusion Authority

- **Examples of Key Aspects of the Revised Policy**

- **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.

OIG Permissive Exclusion Authority

- **Examples of Key Aspects of the Revised Policy (cont'd)**

- **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.

Significant Concepts from Medicare Parts A/B Overpayment Final Rule

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Recent Remarks from OIG Inspector General At HCCA Compliance Institute

- **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.

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The Affordable Care Act

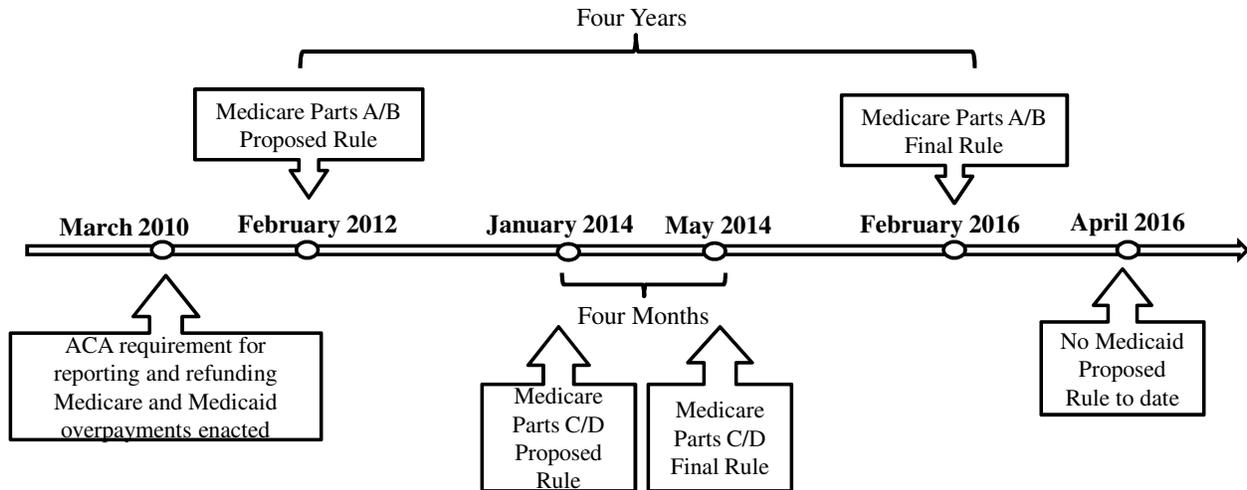
- March 23, 2010: Enactment of the Affordable Care Act (ACA)
- Section 6402(a) of the ACA (now codified at 42 U.S.C. § 1320a-7k(d)):
 - A person who has received an overpayment must report and return the overpayment within either 60 days after the date on which the overpayment was **identified** or on 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.

The Affordable Care Act

- 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.

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.

Timeline of Significant Overpayment Developments



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“Identification”, Defined

- Medicare Parts A/B: 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.**”
 - Guards against the “ostrich defense.”
- 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.*
- **Important Observations:**
 - A provider does not have to deplete its 60 days with efforts to quantify Medicare Parts A/B overpayments.
 - CMS also suspends the 60-day deadline for OIG Self-Disclosure Protocol or CMS Voluntary Self-Referral Disclosure Protocol submissions, at least until those submissions are resolved through settlement, withdrawal or removal.



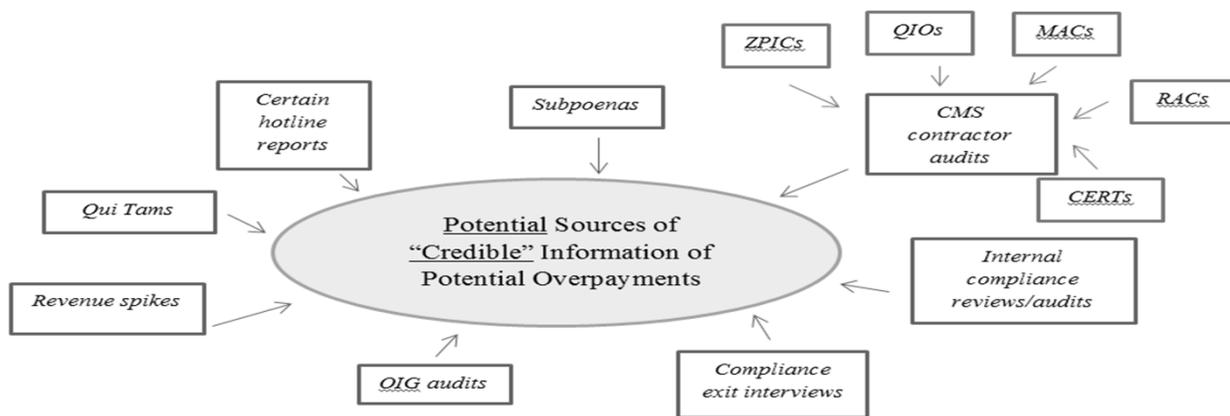
Credible Information of Potential Overpayments

- 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.*”
 - Merriam-Webster definition of credible: “offering reasonable grounds for being believed.”
 - Merriam-Webster definition of information: “knowledge that you get about someone or something: facts or details about a subject.”

Credible Information of Potential Overpayments

- CMS stated that it believes that “contractor overpayment determinations are *always* a credible source of information for other potential overpayments” and that “in 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.”

Potential Sources of “Credible” Information



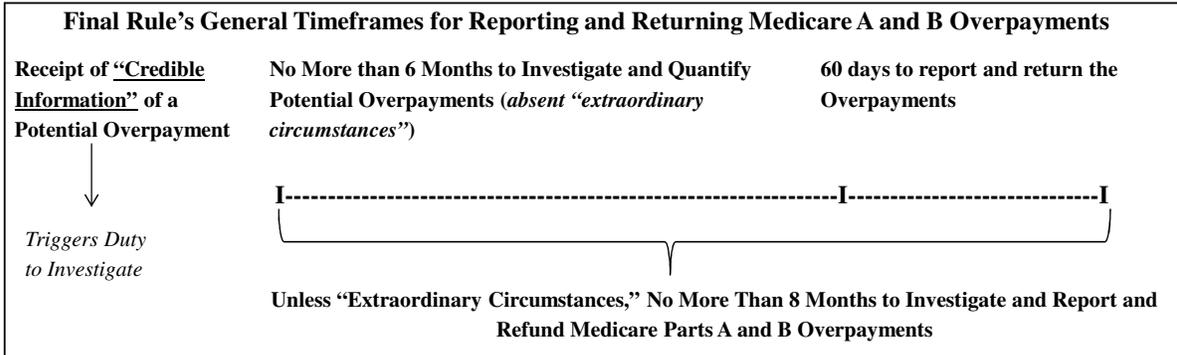
Exercise of Reasonable Diligence

- In the Medicare Parts A/B final rule, CMS states that absent “extraordinary circumstances,” a timely, good faith investigation of credible information will last *at most six months* from the receipt of the credible information.
- In Final A/B Rule, CMS stated that reasonable diligence includes both **proactive** compliance activities and **reactive** investigative activities.
- Important Considerations:
 - Size and scope of compliance programs will vary, but having no compliance activities may expose providers to liability.
 - “Gray” area fact patterns – potential that even providers acting in good faith based on a reasonable interpretation of CMS’s requirements may become subject to second-guessing by an aggressive whistleblower or enforcement entity.

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 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



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

Practical Tips for Internal Investigative and Remediation Strategies

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Practical Tips

- **Assessment of Key Policies, Procedures and Protocols**
 - Overpayment policy
 - Internal investigations policy
 - Audit protocols
 - Self-disclosure processes
 - Others

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Practical Tips (Cont'd)

• Examples of Key Policy Considerations

- **Credible Information of Potential Overpayments:** Credible Information is information that supports a reasonable belief that an Overpayment may have been received and triggers several important deadlines.
 - Who is authorized to determine whether information is “credible”?
 - Who is designated to answer questions regarding credible information of potential overpayments?
- **Lookback Period:** The CMS Final Rule includes a maximum lookback period of 6 years.
 - How will the organization approach the determination of an appropriate lookback period when assessing potential overpayments?
 - For example, will there a designated point person to help determine the appropriate lookback period when the organization is pursuing internal reviews?

Practical Tips (Cont'd)

• Examples of Key Policy Considerations

- **Internal Review Deadlines:** Once Credible Information of potential overpayments has been received, a good faith investigation of such Credible Information should be pursued promptly and *absent extraordinary circumstances*, should be completed within *six months* from receipt of the Credible Information.
 - How will the organization maintain a record of its review timelines to ensure that it does not exceeded the maximum six month period?
 - Who is authorized to determine whether *extraordinary circumstances* exist, thereby extending the six month internal review period.
- **Threshold for Immediate Notification of Compliance, Legal and Others:** Does the policy include triggers that allow for immediate reporting obligations to Compliance, Legal and other appropriate stakeholders?

Practical Tips (Cont'd)

- **Reasonable Diligence**

- Consider thoroughly 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.
- Consider implementing specific overpayment workflows to ensure that the appropriate stakeholders (such as legal or compliance) are involved in certain key aspects of the identification, investigation, reporting, and returning of overpayments.

Practical Tips (Cont'd)

- **Compliance Program Considerations**

- Can you demonstrate the effectiveness of your compliance program?
- How does your compliance program compare to evolving CIA requirements?
- Do you have an active risk assessment program?
- Do you have sufficient resources?

Practical Tips (Cont'd)

- **Investigation Strategies**
 - Preparing employees for government investigations and inquiries
 - *Upjohn* warnings
 - Potential need for individual counsel
 - Pressure to hold an individual accountable for the conduct
 - Insurance considerations

Practical Tips (Cont'd)

- **Don't forget your governing body**
 - Updates on significant industry developments
 - Expectations for active oversight and involvement
 - Resources needed by the entity to meet government expectations

Q&A

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