

Health Care Compliance Association
Annual Healthcare Enforcement Compliance Institute

OIG's Self-Disclosure Protocol

Dennis Pangindian, Office of Inspector General, U.S. Department of Health and Human Services

Tony Maida, Partner, McDermott Will & Emery, LLP

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Agenda

- Understanding the landscape:
 - 60 Day Overpayment Rule
 - The Civil Money Penalties Law (CMPL)
- Deciding whether to disclose and where to disclose
- Resolutions under OIG's Self-Disclosure Protocol

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60 Day Rule



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Overpayment Statute: ACA, Section 6402(a); SSA Section 1128J(d); 42 U.S.C. § 1320a-7k(d)

- **In general.** If a person has received an overpayment, the person shall –
 - report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and
 - notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.
- **What is an “Overpayment?”**
 - The term “**overpayment**” means any **funds** that a person receives or retains under subchapter XVIII or XIX of this chapter to which the person, after **applicable reconciliation**, is not entitled under such subchapter.

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Overpayments and False Claims

- **Deadline for reporting and returning overpayments.** The later of –
 - the date which is 60 days after the date on which the overpayment was identified; or
 - the date any corresponding cost report is due, if applicable
- **Enforcement:** If an overpayment is retained past the deadline, it may constitute an “obligation” under the False Claims Act.
 - False Claims Act: imposes liability for “knowingly concealing or knowingly and improperly avoiding or decreasing an obligation” to pay the United States. (31 USC 3729(a)(1)(G))
 - CMPL action for a penalty of up to \$20,000 per item or service and three times the amount claimed and exclusion for “Any person . . . that **knows** of an **overpayment** . . . and does not report and return the overpayment in accordance with [section 6402].”

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Final Rule, 81 FR 7954 (February 12, 2016)

- Regulatory provisions interpreting the Overpayment Statute (42 C.F.R. 401.301-5)
 - Lookback period
 - 6 years from the date the overpayment was received
 - How to report and return
 - Use the “most appropriate mechanism” based on the “nature of the overpayment”
 - Meaning of identified
 - When a provider or supplier “has determined, or should have determined through the exercise of reasonable diligence, that [it] received an overpayment and quantified the amount of the overpayment”
 - “Should have determined” means the provider or supplier failed to exercise reasonable diligence and in fact received an overpayment

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When does the 60 day clock start?

- CMS said providers have time to conduct the “reasonable diligence” before the 60 day clock starts to run
 - After receiving “credible information” the provider needs to undertake reasonable diligence
 - CMS articulated a 6 month “benchmark” for conducting reasonable diligence, except in “extraordinary circumstances” such as Stark issues, natural disasters, or states of emergency
 - The 60 day clock starts to run when either:
 - When the reasonable diligence is completed, or
 - On the day the credible information was received and the provider failed to conduct reasonable diligence (and an overpayment in fact was received)

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What does “reasonable diligence” mean?

- Reasonable diligence includes both:
 - Proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments; and
 - Investigations conducted in good faith and in a timely manner by qualified individuals in response to obtaining credible information of a potential overpayment
- CMS believes that “undertaking no or minimal compliance activities to monitor the accuracy and appropriateness of ... Medicare claims would expose a provider or supplier to liability under the identified standard articulated in this rule based on a failure to exercise reasonable diligence if the provider or supplier received an overpayment”

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What does “credible information” mean?

- Includes information that supports a reasonable belief that an overpayment may have been received
- Determining whether information is credible is a fact-specific inquiry
- Examples:
 - Government or contractor audit results
 - “Obligation to accept or appeal” – or disagree with findings but not appeal
 - Scope of duty to review is limited to the issue audited
 - However, providers may need to review claims beyond the audit time period to meet the 6 year lookback period
 - General government work, such as the OIG Work Plan or CMS transmittals, do not constitute “credible information” triggering the rule’s obligations. CMS encourages providers to use publically available sources to inform their compliance program planning
 - Hotline complaints
 - May qualify as credible information depending on facts
 - Preamble gives examples of single detailed complaint or multiple complaints about the same issue
 - Significant increases in Medicare revenue with no apparent reason

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The Civil Money Penalties Law (CMPL)

- Section 1128A of the Social Security Act
 - Codified at 42 U.S.C. § 1320a-7a
 - Regulations: 42 C.F.R Part 1003
- Intent standard: “knows or should know”
 - Deliberate ignorance
 - Reckless disregard
- Six-year statute of limitations
- Remedies
 - Civil money penalties, assessments, and exclusion

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Overpayment or Potential Fraud Liability?

- Legal Questions
 - Applicable coverage and payment statutes and regulations
 - Manual provisions
 - 60 Day Overpayment Rule
- Factual Questions
 - Who, what, when, where, why
 - Internal investigation/review process
- Optics Considerations
 - Comfort level of explaining the decision to the government or other external stakeholder (e.g. potential buyer) in the future

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Legal Question: Is There an Overpayment

- Primacy of legal authority
 - Statute
 - Regulation
 - Sub-regulatory guidance
 - National Coverage Decisions
 - Local Coverage Decisions
 - CMS Preambles
 - CMS Manuals
 - Contractor Guidance
 - Appeal experience
- Binding requirement or Guidance?
- Clear or ambiguous?
- Condition of Payment or Participation?
- Legal standard or audit standard?

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Gathering Facts

- Who should direct the investigation
 - Counsel
 - Inside or outside
 - Compliance
 - HR
 - Other
- Who should “conduct” the investigative steps
 - Counsel
 - Auditors
 - Compliance staff
 - HR staff
 - Managers
 - Outside consultants
- What are the investigative steps?
 - Allows you to ask better questions in interviews
 - Gives you important background
 - You may want to ask witnesses about particular documents
- Start with preserving and gathering documents
 - Can establish whether there is a problem
- Audits as a starting point?
 - Can establish whether there is a problem

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Deciding Where to Disclose

- If you decide there is an overpayment or potential liability, where to report and return:
 - Contractor Refund
 - CMS SRDP
 - OIG SDP
 - State Medicaid agencies
 - DOJ



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Self-Disclosure Options

Refund	SRDP	SDP	State Agency	U.S. Attorney
<ul style="list-style-type: none"> • Simple process/ minimizes legal fees • No reduction in amount • No release of any kind • Six-year lookback period 	<ul style="list-style-type: none"> • Track record suggests likelihood of reasonable settlement • Stark only • 1877(g)(1) release • Six-year lookback period 	<ul style="list-style-type: none"> • Benchmark 1.5 multiplier • Release of CMPL and exclusion • Potentially reduce FCA exposure • Six-year SOL 	<ul style="list-style-type: none"> • Release of State authorities only • Uncertainty on posture and penalty amount • Experience may vary widely • SOL varies 	<ul style="list-style-type: none"> • Broadest release • Uncertainty on posture and penalty amount • Experience may vary widely • Six-year SOL

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OIG Self-Disclosures: Resolution Data

FY 2017-2019

Total Settlements: \$51,551,470.90

Annual Averages FY 2017-2019

Total Settled Cases: 75

Months in SDP: 7.72

Average Settlement Size: \$681,588.59

Median Settlement: \$149,447.82

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OIG Self-Disclosure Protocol

- What is not eligible

- Errors or overpayments where no potential violation of CMPL
- Requests for opinion on whether there is a potential violation
- Stark-only conduct
- Minimum settlement amount: \$10,000 (\$50,000 for AKS)



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OIG's Grant Self Disclosure Program

- Mandatory Disclosures

- HHS grant recipients/ subrecipients must disclose evidence of potential violations of Federal criminal law involving fraud, bribery, or gratuity violations, potentially affecting the Federal award. Federal regulation, 45 C.F.R. § 75.113, mandates disclosures of criminal offenses that non-Federal entities must make with respect to HHS grants.

- Voluntary Disclosures

- Recipients of HHS awards may voluntarily disclose conduct creating liability under the Civil Monetary Penalty Law (CMPL), 42 U.S.C. § 1320a-7a, or any other conduct—such as conduct that might violate civil or administrative laws—that does not clearly fall within the scope of offenses described at 45 C.F.R. § 75.113.

- Self-Disclosure Guidance: <https://oig.hhs.gov/compliance/self-disclosure-info/grant.asp>

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OIG Grant Self Disclosure Program

- Disclosers should complete the OIG Grant Self-Disclosure Submission Form: <https://oig.hhs.gov/compliance/self-disclosure-info/files/Grant%20Self%20Disclosure%20Submission%20Form.pdf>
- Grant disclosures may be submitted to grantdisclosures@oig.hhs.gov

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OIG Grant Self Disclosure Program

- Submission Content (unique to the Grant Self Disclosure Program)
 - Grantee information (e.g., DUNS number, nature of the entity, etc.)
 - Award Information (e.g., HHS agency, type of award, purpose of grant)
 - Description of the conduct (including the types of conduct and the names/ roles of the persons involved)
 - Estimate of the financial impact to the Federal government and a description of the method for calculating the financial impact
 - List of all Federal agencies from whom the discloser is currently receiving awards

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OIG SDP Resolutions

- Benchmark 1.5 multiplier
 - Claims Calculation
 - All claims or statistical sample of 100 claims minimum
 - Use point estimate (not lower bound)
 - Excluded persons – salary and benefits-based
 - AKS – remuneration-based
 - Grants – based on financial impact to the Federal government
- Presumption of no CIA
- Six-year statute of limitations
- Tolling of the 60-day period after submission

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Common Mistakes Providers Make in the OIG Self-Disclosure Protocol

- States in the initial disclosure or at settlement that there is no fraud liability.
- Does not identify potential laws violated.
- Discloses the conduct too early.
- No plan to quantify damages.
- Conduct only violates the Stark law.
- Refuses to pay a multiplier.
- Lack of cooperation.
- Calculating damages in a manner contrary to the revised SDP.

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Outcomes: Disclosure Pros and Cons

Pros

- Legal duty if received overpayment
- Start from positive place
 - Good corporate citizen
 - Effective compliance program
- Can be prepared
- Less disruptive
- Lower multiplier more likely
- Presume no CIA/exclusion
- Closure
- Less reputational effect possible

Cons

- Some pathways are less predictable than others
- Payment usually necessary
- Not place to get agency's opinion
- Can be long process
- Referrals among agencies possible
- Follow on actions by private insurance or states
- Some publicity still happens

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Thank you!

Dennis Pangindian
 202-836-1058
dennis.pangindian@oig.hhs.gov

Tony Maida
 212-547-5492
tmaida@mwe.com

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