

Health Care Compliance Association
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Self-Disclosure: Obligations, Options, Outcomes

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Agenda

- Obligations: What are the rules
- Options: How to decide whether to disclose and where to disclose
- Outcomes: What to expect in resolving the disclosure under each option

2


Obligations

- Is there an overpayment?
 - Pay attention to legal authority (statute, regulation, sub-regulatory guidance)
 - Condition of payment or participation?
- Is there fraud liability exposure?
 - Legal and factual question
- 60 Day Rule
 - How does U.S. ex rel. Kane v. Continuum impact the analysis?
- Contractual Requirements
- Kindergarten Rule
- What is the government's expectation to disclose?

3

Options: 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



4


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 • <i>De facto</i> six-year lookback period 	<ul style="list-style-type: none"> • Benchmark 1.5 multiplier • Release of CMPL and exclusion • Potentially reduce FCA exposure • Updated guidelines • 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

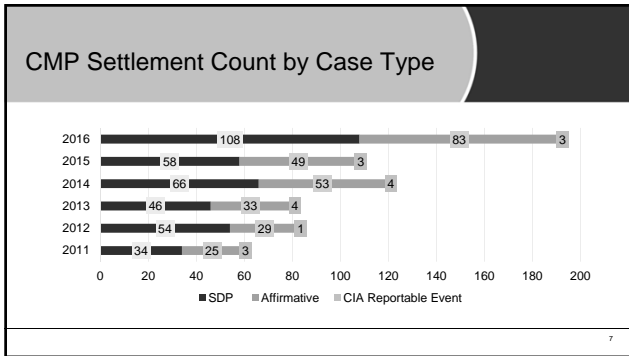
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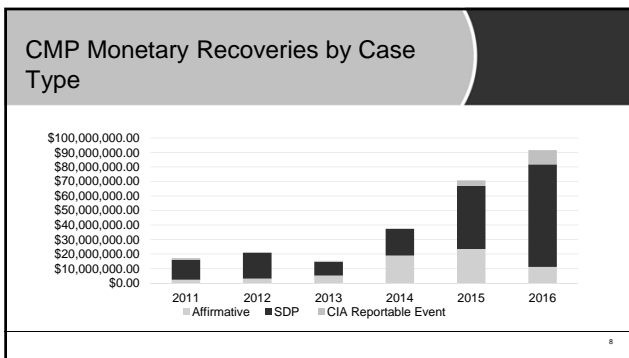
OIG Self-Disclosure Protocol

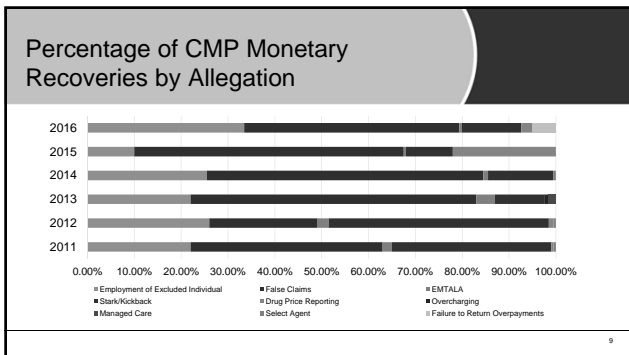
- What not eligible
 - Errors or overpayments where no potential violation of CMPL
 - Requests for opinion on whether there is a potential violation
 - Stark-only conduct
 - Settlement less than \$10,000 (\$50,000 for AKS)



6







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
- Presumption of no CIA
- Six-year statute of limitations
- Tolling of the 60-day period after submission
- Does not secure FCA release, but can help limit exposure, including 60-day issues
- More predictable process, but DOJ may become involved

10

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.
- Argues damages should be calculated in a manner contrary to the revised SDP.

11

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

12

Appendix

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.

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))
 - ACA also created new CMLP action for a penalty of up to \$10,000 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].”

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 identified
 - 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

16

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)

17

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"

18

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

19

Thank you!

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20
