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Compliance and Overpayments; Options and Strategies for  
Self-Disclosure and Repayments

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Agenda

- Why Disclose?
- When Is It Time to Disclose?
- Where To Disclose?
- How to Disclose and What to Expect?
- What Do the New CIAs require?



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Why Disclose?

- 60 Day Rule Obligation
  - Reverse False Claims Act
  - Civil Monetary Penalties Law
- Contractual Requirements
- Kindergarten Rule
- What is the government's expectation to disclose?



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When Is It Time to Disclose?

- Conduct an investigation to determine:
  - Is there an overpayment?
    - Pay attention to legal authority (statute, regulation, sub-regulatory guidance)
    - Condition of payment or participation? Material Compliance Deficiency?
  - Is there fraud liability exposure?
    - Legal and factual question



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When Is It Time to Disclose?

- 60 Day Rule Really is the 8 Month Rule
  - Statute:
    - Rule – Report and return identified overpayments
    - Identified – determined an overpayment received and quantified the amount
    - Therefore, the obligation to report and return is not triggered until identification completed
  - Regulation:
    - Reasonable diligence period = presume 6 months is sufficient to determine whether overpayment received, absent extraordinary circumstances
    - Add additional 60 days to report and return
  - Practically:
    - Conduct internal review diligently and be able to explain time needed to complete identification
    - Government generally wants providers to not unreasonably delay refund (*See Kane v. Continuum*)

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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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### Voluntary refund

- Simple process
- Minimizes legal fees
- Satisfies legal obligation to report and return overpayment
- No reduction from tainted claims
- No release
- Six-year lookback period under final rule
- Can help limit FCA exposure



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### CMS Self-Referral Disclosure Protocol (SRDP)

- Actual or potential violations of the physician self-referral law (commonly referred to as "Stark law") only
- Lookback period is 6 years
- Beginning June 1, 2017, mandatory use of OMB forms on CMS website
- Benefits:
  - Reduce the amount "due and owing"
  - Stop the 60-day clock after submission to CMS
  - No FCA release, but can help limit exposure
  - Eliminate/manage uncertain liability that may impede bond financing or acquisition

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### SRDP Results (last accessed September 5, 2017)

Calendar Year	Number of Disclosures Settled	Range of Amounts of Settlements	Aggregate Amount of Settlements
2011	3	\$60 - \$579,000	\$709,060
2012	14	\$1,600 - \$584,700	\$1,236,200
2013	24	\$760 - \$317,620	\$2,468,348
2014	41	\$3,322 - \$463,473	\$5,175,168
2015	49	\$5,081 - \$815,495	\$6,706,458
2016	102	\$65-\$1,166,763	\$6,913,968
<b>Totals</b>	<b>233</b>	<b>\$60 - \$1,196,763</b>	<b>\$23,209,222</b>

**Notes**  
As of December 31, 2016, an additional 92 disclosures to the SRDP were withdrawn, closed without settlement or settled by CMS' law enforcement partners.

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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)



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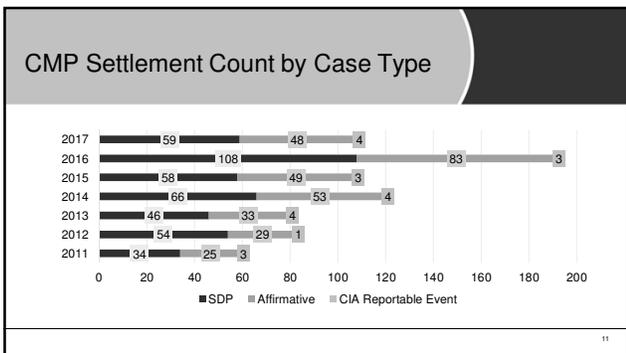
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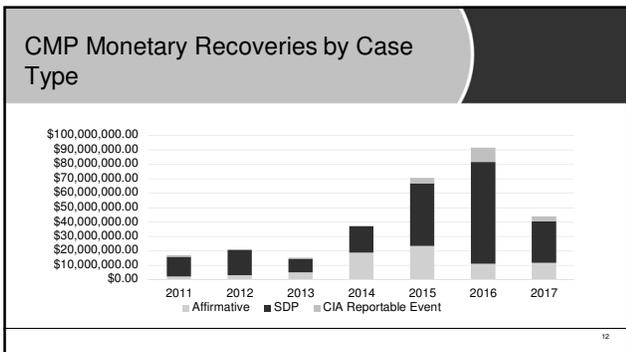
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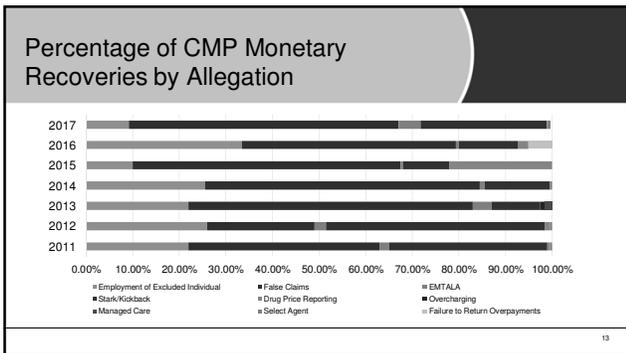
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- ### OIG SDP Resolutions
- Benchmark 1.5 multiplier
    - Claims Calculation
      - All claims or statistical sample of 100 claims minimum
      - Use point estimate (not lower bound)
    - Excluded persons – salary and benefits-based
    - AKS – remuneration-based
  - 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




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




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**Outcomes: Disclosure Pros and Cons**

<p><b>Pros</b></p> <ul style="list-style-type: none"> <li>▪ Legal duty if received overpayment</li> <li>▪ Start from positive place             <ul style="list-style-type: none"> <li>– Good corporate citizen</li> <li>– Effective compliance program</li> </ul> </li> <li>▪ Can be prepared</li> <li>▪ Less disruptive</li> <li>▪ Lower multiplier more likely</li> <li>▪ Presume no CIA/exclusion</li> <li>▪ Closure</li> <li>▪ Less reputational effect possible</li> </ul>	<p><b>Cons</b></p> <ul style="list-style-type: none"> <li>▪ Some pathways are less predictable than others</li> <li>▪ Payment usually necessary</li> <li>▪ Not place to get agency's opinion</li> <li>▪ Can be long process</li> <li>▪ Referrals among agencies possible</li> <li>▪ Follow on actions by private insurance or states</li> <li>▪ Some publicity still happens</li> </ul>
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**What do the new Integrity Agreements require?**

- Corporate Integrity Agreements (CIAs)/Integrity Agreements
  - Have own written obligations for reporting overpayments
  - Claims Review sample sizes vary between 30-100 (no longer Discovery Samples of 50 claims)
  - Overpayment rates calculated (no longer netting of over/under payments and the 5% threshold to determine the need for extrapolation)
  - Overpayments need to be refunded - CMS Overpayment Rule applies
  - Determination of extrapolation is often the responsibility of the provider

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**What do the new Integrity Agreements require?**

- Providers with CIAs and Integrity Agreements
  - Required to hire an Independent Review Organization (IRO)
    - Claims Review Provision
      - Random sample of 30-100 paid claims (typically Medicare, Medicaid, federal healthcare program claims)
      - Specified time frame (quarterly or annually)
      - **Certified professional coders** determine whether the claim was **correctly coded**, submitted and reimbursed
      - **Clinicians** with the relevant education, training and specialized expertise determine if items and services furnished were **medically necessary** and appropriately documented
      - If either medical coding or medical necessity are not supported by the medical record documentation = **overpayment**

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### What do the new Integrity Agreements require?

- Repayment of Identified Overpayments
  - As required by the CMS Overpayment Rule
    - Refund overpayments within 60 days of identification by the IRO
    - Provider determines if an extrapolated overpayment needs to be repaid
      - Consideration should be given to:
        - How long the billing problem has been going on?
        - Determining liability to the full scope of the overpayment and not just a limited period of time (sampling timeframe)
        - The government can go back 6 years to identify the universe of affected claims
    - If extrapolation is necessary, the provider will repay the amount at the mean point estimate calculated by the IRO

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### What do the new Integrity Agreements require?

- OIG's expectation
  - Providers will involve counsel and statisticians, when necessary and in good faith, to determine the need for extrapolation and refund accordingly
  - OIG Monitors will consider the need for extrapolation when reading IRO reports

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THANK YOU

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Appendix

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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.

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 CMPL 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].”

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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 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

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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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