

Morgan Lewis

# ***FAST BREAK:*** **SELF DISCLOSURES**

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# Agenda

- CMS Self-Referral Disclosure Protocol (“SRDP”)
- OIG Voluntary Self-Disclosure Protocol (“SDP”)
- Other Self-Disclosure Avenues
- To Self-Disclose or Not to Self-Disclose?

# CMS SRDP Basics

- Open to all persons who received an overpayment as a result of a violation of the Stark Law
  - Current government audit or investigation is not a bar to disclosure under SRDP
  - Disclosures must be in good faith
- Applicable only to physician self-referral violations
  - Does not supersede OIG SDP
  - Violations falling under both SRDP and SDP should be disclosed only to OIG
  - Comply with CIA disclosure obligations.

# CMS SRDP Basics

- Disclosing party should make submission to the SRDP with the intention of resolving overpayment liability as a result of noncompliant conduct
  - Separate from the CMS Advisory Opinion Process
  - New requirement included in revised SRDP protocol; disclosing party must certify to noncompliance
- Coordination with OIG and DOJ
  - CMS reserves right to refer matters to OIG or to DOJ
  - “CMS may use a disclosing party’s submission to prepare a recommendation to OIG or DOJ ....”
  - CMS admonition: decision to disclose a matter involving noncompliance with the Stark Law “should be made carefully.”

# CMS SRDP Basics

- Stay of ACA§6402 overpayment return requirement until settlement, withdrawal, or removal
  - Do not make interim payments to CMS
  - Submission to DOJ does not satisfy a provider's obligations under the 60 Day Rule

# SRDP Process

- Preparation of Materials by Disclosing Party
  - SRDP Form
  - Physician Information Form
  - Cover Letter
  - Financial Analysis Worksheet
  - Certification Statement
- Disclosure Submission
  - Must submit electronically for automatic stay email
  - Obligation to update (e.g., change of ownership, change of designated representative); must also submit electronically but include “update” in subject line
  - Certification statement must be sent through hard copy with original signature of the certifying official

# Resolutions Under the SRDP

- CMS is not bound by disclosing party's conclusions
- CMS is not obligated to resolve a disclosure in any particular manner
- No appeal rights for disclosed claims resolved through the SRDP
  - If removed/withdraw, disclosing party may appeal any subsequent overpayment demand
- Resolutions are only of CMS authorities
  - No CMP or FCA release via the SRDP

# Tips on Disclosure Submissions

- Even though providers are required to use CMS's SRDP form, can still provide information for CMS to consider when evaluating the disclosure (e.g., details/context to help CMS evaluate pervasiveness of noncompliance, provide mitigating information)
- May also be necessary if advocacy required related to potential referral to law enforcement
- But get to the point – a shorter disclosure could potentially expedite process



# Tips on Disclosure Submissions

- Which official will sign the certification (“to the best of my knowledge, the information provided contains truthful information”) – keep him/her informed
- Manage expectations – the process takes a long time
- May need to deal with financial auditors regarding establishing reserve amounts
- Can resolve overpayment liability by refunding overpayments to the contractor; don’t need to utilize the SRDP when amounts at issue are small

# By the Numbers

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 - \$815,405	\$6,706,458
2016	102	\$80 - \$1,195,763	\$6,913,988
2017	47	\$83 - \$575,680	\$3,876,588
<b>Totals</b>	<b>280</b>	<b>\$60 - \$1,195,763</b>	<b>\$27,085,810</b>

As of December 31, 2017, an additional 119 disclosures to the SRDP were withdrawn or settled by CMS' law enforcement partners.

# OIG SDP Basics

- First published in 1998 “to establish a process for health care providers to voluntarily identify, disclose and resolve instances of potential fraud involving the Federal health care programs”
  - Health Care Provider Self-Disclosures
  - HHS Contractor Self-Disclosures
  - HHS Grantee Self-Disclosures
- The OIG has had recoveries of more than \$280 million
- For reporting period April 1, 2017 – September 30, 2017 the OIG recovered over \$12.6 million

# OIG SDP Basics

- Conduct that potentially violates Federal criminal, civil or administrative laws for which CMPs are authorized
- Disclosing party “must acknowledge that the conduct is a potential violation” and must identify the specific laws that are implicated
  - Disclosing parties “should not refer broadly to, for example, ‘Federal laws, rules, and regulations’ or ‘the Social Security Act.’”
  - Statements such as “‘the Government may think there is a violation, but we disagree’ raise questions about whether the matter is appropriate for the SDP.”
- If conduct is Stark only, then must go to CMS
- Cannot request an opinion from OIG regarding whether a violation has occurred
- SDP is not available for a matter that does not involve potential violations of Federal criminal, civil, or administrative law for which CMPs are authorized

# Requirements for Specific Conduct – False Billing

- Must conduct a review to estimate the improper amount paid (“damages”), consisting of a review of either:
  - All the claims affected by the disclosed matter, or
  - A statistically valid random sample of the claims (at least 100 items) that can be projected to the population of claims affected by the matter
- Damages estimates may not include reductions
- OIG will verify the calculation of damages
- The report of findings must include, at a minimum:
  - Review objective
  - Population
  - Sources of data
  - Personnel qualifications
  - Characteristics measured

# Requirements for Specific Conduct – AKS/Stark

- Narrative must include a concise statement of all details directly relevant to the disclosed conduct and a specific analysis of why each disclosed arrangement potentially violates the AKS and Stark Laws, including:
  - Participant’s identities;
  - Their relationship to one another to the extent the relationship effects potential liability;
  - The payment arrangements; and
  - The dates during which each suspect arrangement occurred
- Types of information OIG finds helpful:
  - How FMV was determined and why now in question
  - Why required payments from referral sources, under leases or other contracts, were not timely made or collected or did not conform to the negotiated agreement and how long such lapses existed
  - Why the arrangement was arguably not commercially reasonable

# Resolutions Under the SDP

- Cooperation is essential
- OIG coordination with DOJ
  - Civil matters
  - Criminal matters
- OIG Coordination with SRDP
- Minimum settlement amounts
  - “For kick-back related submissions accepted into the SDP, OIG will require a minimum \$50,000 settlement amount to resolve the matter.”
- Financial inability to pay
- Overpayment reconciliation
- FOIA Implications of disclosure

# Tips for Preparing an OIG Self-Disclosure

- Start preparing at the right time
- Follow all of the requirements
- Include a complete description of the conduct and investigation
- Identify all the laws at issue
- Consider how to quantify the financial impact
- Disclose at the right time
- Document the process and correspondence
- Expect a settlement agreement with a multiplier of damages



# Disclosure to Other Parties

- Depending on the circumstances, disclosure to another party may also make sense
  - Medicare Advantage Plans and Medicaid MCOs
  - MACs
  - DOJ
  - Local AUSAs
- Note that these disclosures won't stop the 60-day clock and may not trigger the public disclosure bar under the FCA

# To Disclose or Not to Disclose



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# To Disclose or Not to Disclose

- Considerations
  - Scope
  - Isolated or systemic
  - Circumstances surrounding intent
  - Explanations and defenses
  - Dollars involved
  - Effectiveness of compliance program review
  - Trust for, and relationship with, local and national enforcement people vs. Medicare contractors
  - Benefits/risks of disclosing vs. not disclosing

# To Disclose or Not to Disclose

- Potential Benefits
  - Reduced repayment amount compared to repayment amount if government identifies the overpayment
  - Government unlikely to impose a CIA
  - Releases received from government as part of settlement agreement will protect against certain types of liability
  - Government is less likely to conduct its own, more intrusive investigation
  - Decreased exposure for individuals

# To Disclose or Not to Disclose

- Potential Risks
  - Tension between government's and provider's perspective of appropriate level of cooperation
    - Government looks for candor, flexibility, demonstrated attitude of compliance
  - Government follow-up investigation uncovering non-disclosed compliance
  - Repayment may not be enough—settlement with multiplier
  - Referral to DOJ
  - Government enforcement trends
    - Criminal liability
    - Individual liability
  - Self-disclosure to one agency may not resolve liability to another agency
  - Self-disclosure potentially not a public disclosure under FCA

# To Disclose or Not to Disclose

- Potential risks of self-disclosure
  - Self-disclosures may take a significant amount of time to resolve
    - OIG v. CMS
    - Is company okay with uncertainty/extended process?
  - Complexity of fraud and abuse laws resulting in unnecessary disclosures
    - What is company's risk tolerance?
  - FOIA implications

# Thanks!



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Jake Harper advises stakeholders across the healthcare industry, including hospitals, health systems, large physician group practices, practice management companies, hospices, chain pharmacies, manufacturers, and private equity clients, on an array of healthcare regulatory, transactional, and litigation matters. His practice focuses on compliance, fraud and abuse, and reimbursement matters, self-disclosures to and negotiations with OIG and CMS, internal investigations, provider mergers and acquisitions, and appeals before the PRRB, OMHA, and the Medicare Appeals Council.

# Join us next month!

Please join us for next month's webinar:

*"Fast Break: DOJ 'No-Poaching' Agreements in Healthcare"*

Featuring Ryan Kantor and Mark Krotoski

➤ Thursday July 26, 3:00 PM (EST)