Navigating the OIG's Self-Disclosure Protocol

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SDP History

- Voluntary self-disclosure had been previously embraced by the OIG (e.g., Operation Restore Trust).
- Modeled after the DOD's self-disclosure protocol.
- Created at the same time that HIPAA, False Claims investigations and other enforcement projects were gaining momentum.
- Clarified by way of three open letters from the OIG (April 24, 2006, April 15, 2008, March 24, 2009).
- Currently being revised.
PURPOSES OF THE SDP

- The OIG believes that health care providers “must be willing to police themselves, correct underlying problems and work with the Government to resolve these matters.”
- To encourage providers to make voluntary self-disclosures.
- To provide guidance to providers that self-disclose.
- To help providers initiate a dialogue directed at resolving potential liabilities.
- To facilitate the resolution of matters that are potentially in violation of Federal criminal, civil or administrative laws.
- To create a procedure that results in a “win-win” situation for both the Government and providers.

GOOD FAITH REQUIREMENTS

- According to the 1998 publication, the Protocol does not have “rigid” requirements, but does lay out general reporting guidelines.
- However, the OIG admonishes that “Failure to conform to each element of the Protocol is not necessarily fatal to the provider’s disclosure, but will likely delay resolution of the matter.”
- Further, disclosures must be made in good faith and the OIG will not work with a provider that attempts to circumvent an inquiry or fails to fully cooperate.
- In addition, the OIG reserves the right to refer any matter to the DOJ or U.S. Attorney’s Office for consideration of the imposition of civil and/or criminal penalties.
All of this will be supersedes by the revised SDP, which is on track to be published in mid April. I am not sure we should spend the time on this language--the message is similar but the language will be different.

Susan Gillin, 3/22/2013

I replaced "regulation" with "publication." OIG has never issued a regulation about the SDP.

Susan Gillin, 3/22/2013
CONTENT OF DISCLOSURE SUBMISSION

- Information regarding the provider.
- The reasons why the provider believes that a violation of criminal, civil, or administrative law occurred.
- A full description of the nature of the matter being disclosed, including the names of the entities and individuals involved and an explanation of their roles in the matter – and identifies the corporate officials or employees who knew of, encourage, or participated in the incident AND those who should have known of, but failed to detect, the incident or practice based on their job responsibilities. (RCO Doctrine?)
- Statement regarding the impact or risks to health, safety, and quality of care posed by the incident.
- An estimate of the monetary impact of the incident.
- Certification of truthfulness.

OPEN LETTER – APRIL 2006

- OIG announces an initiative to promote voluntary disclosure of improper arrangements under the physician self-referral law (Stark). If a provider can demonstrate “the requisite level of trustworthiness and that also have in place, or are willing to develop, an effective compliance program, OIG will waive its exclusion authority concurrent with resolution of monetary liability under the False Claims Act and the CMP Law.”
- Advises that self-disclosure is an important factor regarding whether the OIG will require a Certification of Compliance Agreement (provider promises to continue to use their existing compliance program for a specified period) rather than a more burdensome CIA.
- Advises that participation in SDP is contingent upon “full cooperation and complete disclosure of the facts and circumstances surrounding the violation."

3/26/2013
Again, this list will be outdated by the time we are doing the speech. I will send you both the revised when I can, but it is still being cleared (in pretty much final form). Sorry about that!

Susan Gillin, 3/22/2013
OPEN LETTER – APRIL 2008

- Addresses “refinements” to the program intended to promote efficiency.
- Describes information that must be included in the provider’s initial submission.
- Advises that SDP is not intended to pertain to overpayments.
- OIG won’t require a CIA, CCA, or IA in exchange for a CMPL and exclusion release, if disclosing providers cooperate in good faith.

OPEN LETTER – MARCH 2009

- Addresses refinements to focus OIG resources on kickback violations.
- Advises that OIG will no longer accept disclosures that concerns violation of physician self-referral law unless there is a “colorable” violation of the anti-kickback statute.
- Sets a minimum penalty for kickback violations of $50,000.
I added this bullet.

Susan Gillin, 3/22/2013
Statistics

- Since 1998, over 800 disclosures have been resolved
- Over $280 million has been collected
- 2013 – New and Improved SDP

So, you think you have a compliance issue...

- What next?
  - Should I hire counsel, or can my compliance officer handle this?
  - Investigate the issue and conduct an audit, if appropriate
  - Quantify the problem
Now that I know the extent of the problem, should I disclose it?

- **Pros:**
  - Settle with a lower multiplier
  - Settle without a CIA
  - Toll the 60-day rule for overpayments
  - Avoid a lengthy and uncomfortable investigation!
  - Protect yourself from qui tam relators?

- **Cons:**
  - Potential for increasing likelihood of qui tam in the short term
  - Lack of complete predictability

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What are alternative options?

- **Alternative self-disclosure options:**
  - CMS Self-Referral Disclosure Protocol (Stark only)
  - DOJ/USAO

- **Alternatives to self-disclosure**
  - Report and repay to contractor
  - Do nothing and risk liability under FCA, CMPs
What should I expect in SDP?

- Will OIG conduct its own investigation?
  - The initial submission will be reviewed
    - Open investigations
    - Incomplete submissions
  - An OIG attorney and agent will review the submission and verify the damages calculation
- Cooperation is essential
- Average time pending is 12 months

What else should I expect?

- If you’re under a CIA, you can use SDP, but you also must comply with your CIA reporting obligations
- Be willing to enter into a tolling agreement for the disclosed conduct
- Expect to pay a penalty
What should I disclose?

- Matters that potentially violate civil, criminal, or administrative laws for which civil monetary penalties are authorized.
- Potential fraud requires an admission that you “knew or should have known” that the conduct was illegal.
- This means that in order to resolve the matter, you will pay a penalty.

Employment of Excluded Individuals

- Strict liability?
  - No, you knew or should have known the person was excluded.
    The LEIE has been available since 1999.
  - Sometimes there are mitigating circumstances.

- What are the damages?
  - Separately billable items or services
  - Non-separately billable items or services (costs to you)
Anti-Kickback and Stark

- Include a description and analysis of why the arrangements violate AKS and Stark
  - Not by reference to supporting documents
- OIG accepts arrangements that potentially violate Stark only if they also potentially violate AKS
- Stark only?
  - OIG will refer individual arrangements to CMS if there’s no potential AKS violation

Anti-Kickback and Stark Damages

- Compliance with AKS is a condition of payment
  - You must disclose the claims-based damages
- In the SDP, OIG settles on a multiplier of illegal remuneration, but this is not indicative of the government’s position in affirmative litigation
- Under the FCA, damages are not be based on remuneration
Stark only?

- Arrangements must also potentially violate the AKS
- This means the submission must indicate evidence of intent by the parties
- Technical Stark violations with no intent to induce referrals will be rejected

Who does OIG coordinate with?

- DOJ
  - When you request a FCA release (Civil Fraud Section)
  - When OIG believes DOJ has an interest
  - When criminal investigation is warranted
  - OIG advocates for DOJ to give you the benefit of self disclosing
- CMS
  - OIG does not participate in SRDP settlements
  - You should determine which protocol to go to
Penalties

- The purpose of the SDP is to resolve fraud matters
- Generally you will pay a minimum of 1.5 times single damages
- Damages methodologies described in the revised Protocol are not negotiable
- If you cooperate, OIG won’t impose integrity obligations

Finalizing the Settlement

- What will the settlement agreement look like?
- How negotiable are the terms of the settlement agreement?
- Can the settlement agreement be kept confidential?
- Will OIG issue a press release announcing the settlement?
Carrot and the Stick?