

OIG's Updated Provider Self-Disclosure Protocol

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John W. O'Brien
Senior Counsel
Office of Counsel to the Inspector General
U.S. Department of Health and Human Services
john.obrien@oig.hhs.gov

Self-Disclosure Protocol History

- October 1998: OIG publishes Provider SDP
 - Open to all providers
 - Geared to resolve potential violations of Federal criminal, civil, or administrative laws
 - Overpayments and billing errors to be reported to Medicare or Medicaid contractor

Self-Disclosure Protocol History

- Three OIG "Open Letters to Health Care Providers"
 - April 2006:
 - Self-disclosure likely to warrant Certificate of Compliance Agreement (CCA), not a Corporate Integrity Agreement (CIA)
 - Anti-Kickback Statute (AKS) and Stark Law liability
 - Resolution on "lower end of damages continuum" – multiple of benefit conferred, not claims/collections
 - April 2008: Generally no CIA or CCA required to get OIG permissive exclusion release for cooperative disclosing providers
 - March 2009: Stark-only violations not eligible for OIG SDP – should now be disclosed through CMS SDP

2013 OIG SDP Update Goals

- More transparency
- Set clear guidelines and expectations
- Simplify process by addressing common issues
- Consolidate previous guidance

4

Why Disclosure is Important

- Legal and ethical duty to deal with Federal health care programs with integrity
- Sign of an effective compliance program
- Risk further liability if do not self-disclose

5

SDP Benefits

- Lower multiplier (generally a 1.5 multiplier on damages)
- Presumption against requiring a CIA
- More timely resolution
- Avoid Government-initiated investigation

6

Procedures

- Provider must complete its investigation within 90 days from its initial submission to OIG of its self-disclosure
- Agree to tolling of Statute of Limitations
- Ensure corrective action in place
- Either written or electronic submission
<https://forms.oig.hhs.gov/forms/Self-Disc-Form-Protocol.aspx>

7

Who and What is Eligible

- Who = All health care providers, suppliers, or other individuals or entities subject to OIG's Civil Monetary Penalty (CMP) authorities at 42 CFR Part 1003
- What = potential violations of federal criminal, civil, or administrative law for which CMPs are authorized
 - Not admitting liability
 - Acknowledge potential liability that the provider wants to resolve through a settlement and payment of money
 - Examples: possible false or fraudulent claims; employment of or contracting with excluded persons or entities; and kickbacks

8

What is Not Eligible

- Errors or overpayments where no potential violation of Civil Monetary Penalties Law, False Claims Act, or Anti-Kickback Statute
- Requests for opinion on whether there is a potential violation - consider using OIG Advisory Opinion process
- Stark-only conduct self-disclosure should be made to CMS Self-Referral Disclosure Protocol (SRDP)

9

Submission Content

- Report of internal investigation's findings
- One main submission, with one supplement
- Simplified contents
- Must include information as required by Section III of the OIG's SDP

10

Claims Calculation

- Based on all claims reviewed or statistically valid random sample of claims reviewed
- Use point estimate
- Simplified audit protocol

11

Employing Excluded Persons

- Include Specific Information
- Check all employees and contractors when find one
- Damages Proxy where it is difficult to link claims directly to items or services provided by excluded employee or contractor

12

AKS and Stark

- Arrangement-by-arrangement analysis
- AKS or AKS and Stark = OIG SDP
- Stark only = CMS SRDP
- Explain why potential violation
- See common issues list in Section III.D of OIG SDP
- Include amount of remuneration and amount of claim-based damages

13

Resolution

- Cooperation essential
- Coordination with DOJ
- Minimum settlement amounts
- Inability to pay - raise this early in the process

14
