Self-Disclosure Déjà Vu?

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The Voluntary Self-Referral Disclosure Protocol (SRDP) recently released by the Centers for Medicare and Medicaid Services (CMS) looks remarkably familiar. The new SRDP permits hospitals and other providers who believe that they are or might be providing services in violation of the federal Stark physician self-referral law (42 U.S.C. § 1395nn) to disclose such actual or potential violation to CMS in the hopes of resolving the matter as favorably as possible. Required by the health care reform law, the SRDP is specifically limited to reports of actual or potential violations of the Stark self-referral law, so-called Stark-only violations. In contrast, the Self Disclosure Protocol used by the Office of Inspector General (OIG) of Health and Human Services should be used to disclose potential violations that are based, at least in part, on the anti-kickback statute, False Claims Act, or civil monetary penalties.

The table in this article shows the comparison between the Self-Referral Disclosure Protocol and the Self Disclosure Protocol.

Comparison Between the Self-Referral Disclosure Protocol and the Self-Disclosure Protocol

Similarities in Both	Differences in SRDP
Full Disclosure: Disclosure of all information relevant to the alleged violation.	Method of Filing: Electronic filing via email, along with a mailed original and file copy. CMS's email acknowledgement of the filing tolls the 60-day repayment period for the duration of the investigation as to disclosed violations.
Governmental Inquiry: Notification of any known ongoing governmental inquiry or investigation (and	Complete Legal and Financial Analyses: The disclosure must include a detailed description of the violation and applicability of

Similarities in Both	Differences in SRDP
description of such notice).	the Stark law to the matter and a detailed financial analysis with the initial disclosure for the period of noncompliance, including a final amount, itemization by year, and methodology.
Agreement Not to Appeal: Agreement not to appeal any overpayment assessed as part of the settlement agreement.	Past Conduct: The disclosing party must disclose past similar conduct and any prior enforcement actions (civil, criminal, regulatory, or payment suspensions).
Mitigating Factors: Mitigation factors may reduce penalties depending on the facts and circumstances of the violation, but the government is not bound to resolve a disclosed violation or reduce the penalties associated with the same under the SRDP.	No Claims of Privilege or Limits on Documents Disclosed: Cooperation means no limits on supporting documentation.
Additional Violations: Treatment of discovered additional violations as outside the scope of the disclosure.	Separate from Advisory Opinion Process: Disclosing party is limited to one or the other, but not both simultaneously.
Full Cooperation: Expectation of full cooperation of the disclosing party in the process.	Required Use for Parties under Corporate Integrity Agreements: The SRDP must be used by parties with CIAs or certification

Similarities in Both	Differences in SRDP
	of compliance agreement to report Stark-only violations, with a copy of the disclosure sent by the disclosing party to the OIG.
Restrictions on Repayment: Repayment may only be made with CMS' permission after CMS verifies the amount to be repaid.	

Considerations Before Self-Disclosure

The decision of whether to disclose an actual or potential violation of any federal law is one that should be made in consultation with qualified legal counsel after a full internal investigation of the facts and circumstances giving rise to a disclosure. A few points to consider before disclosing a matter are:

- Will the disclosure resolve all the potential fraud and abuse violations involving the disclosing party? If not, what other laws and regulations are implicated and how can these violations be resolved? Disclosure may give other agencies a heads-up that they ought to take a closer look at you and your business partners.
- Have you thoroughly investigated your business's compliance with applicable laws and regulations to ferret out all potential issues and implemented corrective action with ongoing monitoring for any areas of noncompliance?
- Disclosing actual or potential violations means facing substantial civil penalties and fines, even if the final settlement amount is reduced from treble damages (to some other agreed-upon amount), and you have invited the government into your home to have a look around.
- Voluntary disclosures may adversely affect relations with business partners or health plans, as well as potentially result in termination from the state Medicaid program and/or termination of business agreements.
- Voluntarily providing otherwise privileged or confidential information undermines the protection of this information, making it discoverable by others.
- Substantial expenses are involved in the disclosure process and post-disclosure monitoring, separate and apart from any fines and penalties.

- A provider must consider whether the provider has (or can obtain) the financial and other records (going back six years or as far as required) to do the analysis necessary to determine the extent of violations and damages (or penalties) owed.
- Further complexities are added to the decision when clinical staff has changed, as disclosure implicates a privilege waiver and has other serious considerations. Disclosure may potentially impact former and new staff members in a number of ways.

Conclusion

The determination that a disclosure is or is not in the best interest of you and your business requires careful and deliberate analysis of the benefits and the risks involved. Disclosure is a process that, once begun, cannot be undone and requires a detailed legal and financial picture of your business.

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