

Locke Lord QuickStudy: Modifications to OIG's Health Care Fraud Self-Disclosure Protocol Provides Additional Benefits for Reporting

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"Houston, we have a problem:" words no in-house counsel ever wants to hear, especially regarding potential compliance issues with federal fraud prevention statutes and regulations. Fortunately, the Office of the Inspector General's Health Care Fraud Self-Disclosure Protocol (SDP) provides a way for companies to soften the blow of potential violations by voluntarily disclosing fraudulent conduct. Amended November 8, 2021, the SDP provides several benefits for businesses to consider when evaluating whether to disclose potential fraud to the Office of the Inspector General (OIG).

OIG of the United States Department of Health and Human Services (HHS) created the SDP in 1998 to allow businesses to voluntarily identify, disclose, and resolve instances of potential fraud involving federal health care programs. The SDP provides businesses with guidance on how to investigate potential misconduct, quantify damages, and report the conduct to resolve liability under OIG's civil monetary penalty (CMP) authorities. Today, the SDP continues to serve as a safety net for potential violators who act promptly and in good faith to rectify misconduct.

Whether to disclose potential fraud to OIG is a significant decision, but the SDP provides significant benefits that provide additional incentives for doing so, which should be evaluated carefully, perhaps with the aid of outside counsel. Currently, there are four significant benefits to disclosure:

(1) A presumption *against* requiring integrity agreement obligations: A corporate integrity agreement (CIA) is a document that outlines the obligations to which an entity agrees as part of a civil settlement. An entity agrees to the CIA obligations in exchange for OIG's agreement that it will not seek to exclude the entity from participation in Medicare, Medicaid, or other Federal health care programs. Compliance procedures instituted under CIAs can be onerous, and CIAs can negatively impact stock valuation and shareholder confidence. OIG has resolved several hundred cases by settlement under the SDP since 2016, all of them without instituting any integrity measures.

(2) Lower multiplier on single damages: OIG's general practice in CMP settlements for businesses who voluntarily self-disclose is to require a minimum multiplier of 1.5 times single damages, which is a lower multiplier on single damages than would normally be required in resolving a Government-led investigation. Reporting under SDP, while not guaranteed, often is a route to lower penalties, which otherwise can be substantial.

(3) Mitigating potential exposure under other federal statutes and regulations. The Centers for Medicare & Medicaid Services (CMS) has agreed to suspend the obligation to report overpayments when OIG acknowledges receipt of a submission to the SDP so long as the submission is timely made. CMS also agreed to suspend the obligation to return overpayments until a settlement agreement is entered or the business withdraws or is removed from the SDP.

(4) Reduction of time to settlement: The goal of the SDP was to create a streamlined internal process to resolve potential violations. One of the most significant changes to the SDP announced by the November 8, 2021 update is a change in the timeframe to submit the findings of the completed internal investigation and damages calculation. In the past, the average time was 90 days from acceptance into the SDP. Now, however, OIG commits to releasing findings within 90 days from the date of the initial submission of the report.

The requirements for disclosure depend on whether the business is reporting potential violations of conduct involving false billing, violations involving excluded persons, or violations involving the anti-kickback statute (AKS) and physician self-referral law (Stark Law). In all cases, prior to disclosure, the disclosing party should ensure that the conduct has ended, or at least, in the case of improper kickback arrangements, that the corrective action will be taken and the improper arrangement will be terminated within 90 days of submission to the SDP.

If you have identified potential violations of federal health care law in your business, taking swift corrective action potentially can reduce your business's potential exposure. It should provide some comfort to know that OIG has created a safe haven for those who timely report and cooperate with government investigators through the SDP.

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