

PUBLICATION

What You Need to Know About the Updated Health Care Fraud Self-Disclosure Protocol

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As part of the Department of Health and Human Services' (HHS) ongoing evaluation of its self-disclosure process, the Office of the Inspector General (OIG) recently issued an update to the newly renamed Healthcare Fraud Self-Disclosure Protocol (SPD). The SPD – which provides a process through which healthcare providers, suppliers, and other entities subject to civil monetary penalties can disclose instances of potential fraud related to participation in federal healthcare programs – revises the previously named Provider Self-Disclosure Protocol, last amended by the OIG in 2013 (2013 SPD). The revisions can be summarized as follows:

- **Increased Minimum Settlement Amounts**: The OIG now requires a minimum \$100,000 settlement (increased from \$50,000 under the 2013 SPD) to resolve kickback-related matters and \$20,000 (increased from \$10,000 under the 2013 SPD) to resolve matters involving other improper claims. These minimum acceptable settlement amounts were increased for consistency with new statutory minimum civil monetary penalties established under Section 50412 of the Bipartisan Budget Act of 2018.
- **DOJ May Participate in Settlements and Coordinates with OIG in Criminal Matters**: The SPD clarifies that the U.S. Department of Justice (DOJ) may choose to participate in the settlement of matters disclosed to the OIG under the SPD, including through resolution of such matters under the False Claims Act ([31 U.S.C. § 3729](#)). The OIG also coordinates with DOJ on disclosures involving criminal conduct. Notably, the OIG deleted a sentence from the 2013 SPD, which stated that in cases referred to the DOJ, "the OIG will advocate that the disclosing parties receive a benefit from disclosure under the SPD."
- **Both Individual and Aggregate Estimated Damages Required**: The SPD now requires that every disclosure identify the estimated damages to each federal health care program relevant to the disclosed conduct, including both (i) the total estimated damages amount for each affected federal health care program; and (ii) the sum of estimated damages for all affected federal health care programs in the aggregate.
- **Reportable Events Under a CIA Can Be Reported, With Specific Details Required**: The SPD clarifies that a party subject to a Corporate Integrity Agreement (CIA) may use the SPD to make disclosures, provided that the party discloses in its SPD submission that it is subject to a CIA and sends a copy of the disclosure to its OIG monitor. Disclosures that are Reportable Events as defined under the CIA must be disclosed as such, as set forth in the CIA.
- **Online Submissions Only**: Disclosures are now only accepted through the OIG's [online portal](#) and will no longer be accepted via mail.
- **No HHS Contractor or Grant-Related Disclosures**: The SPD clarifies that it is not appropriate to report grant-related conduct or HHS contractor-related conduct pursuant to the SPD. Parties

disclosing grant-related or HHS contractor-related conduct should refer to the OIG's Grant Self-Disclosure Program or its Contractor Self-Disclosure Program, respectively.

- **Updated Tip Line:** The hotline number to report potential misconduct of other parties is now listed in the SDP as 1-800-HHS-TIPS.

While these procedural updates to the disclosure process are not insignificant, disclosing parties familiar with the procedures of the 2013 SDP should note that none of the following have changed under the updated SDP: (i) the timelines or content requirements for disclosures; (ii) the methods for calculation of damages; and (iii) the benefits of a timely settlement with a lower multiplier and exclusion release.

The OIG's longstanding position is that all participants in the health care industry have a legal and ethical duty to detect and prevent improper activities that defraud the federal health care programs. A critical component of this duty is for all individuals and entities participating in the programs to implement specific processes and procedures to investigate and resolve circumstances involving potentially fraudulent activities, including voluntarily disclosing such activities pursuant to the SPD.

The benefits of such good-faith self-disclosure include:

demonstrating the existence of a robust and effective compliance program to the OIG, which can avoid the imposition of a mandatory CIA;

securing assessment of lower civil monetary penalties (CMPs) than in government-initiated investigations; and

mitigating exposure to False Claims Act liability related to the retention of overpayments received as a result of the potentially fraudulent activity.

Since first publishing the SDP in 1998 to establish a detailed process for health care providers, suppliers, or other entities subject to CMPs to self-disclose potentially fraudulent activities, the OIG has resolved over 2,200 disclosures, with recoveries of more than \$870 million. While the updates are mainly procedural in nature, reflecting recent legislative changes to minimum penalty amounts and clarifying prior language in the 2013 SDP, it is important to understand them to ensure any self-disclosures are executed correctly to avoid additional costs and potential penalties.

The SDP represents an important process by which disclosing parties can resolve matters of potential fraud with the OIG without the costly burdens of a CIA. As stated in the SDP, the OIG believes that good faith disclosure of potential fraud and cooperation with OIG's review and resolution process indicates a robust and effective compliance program, leading the OIG to institute a presumption against requiring CIAs for disclosing entities. It is therefore important for health care entities hoping to benefit from the SDP to understand the OIG's recent updates and comply with all procedural changes when making disclosures.

For more information or assistance with making disclosures under the SPD, please contact [Robert Wells](#), [Heather Alleva](#), or any member of Baker Donelson's [Health Care Fraud and Abuse Counseling Group](#).