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Hot off the Press! The OIG Revises its Self-Disclosure Protocol for the First Time in Several Years

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For the first time since 2013, on November 8, 2021, the Department of Health and Human Services Office of Inspector General (OIG) updated its Health Care Fraud Self-Disclosure Protocol (SDP). The updated SDP makes several important revisions and clarifications that directly impact providers and suppliers who seek to self-disclose potential violations of healthcare fraud statutes to the government.

Importantly, the OIG emphasized that the benefits of such self-disclosure remain intact:

- The OIG has instituted a presumption against requiring Corporate Integrity Agreements (CIAs) as part of its releasing the discloser from permissive exclusion.
- The likelihood that a self-discloser would be required to pay a damages multiplier greater than 1.5 times the single damages amount is low if the provider cooperates throughout the SDP process (although the OIG retains the right to impose a higher multiplier if warranted).
- CMS has agreed to suspend statutory obligations to report or return overpayments while the OIG

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negotiates a settlement with providers who are following the SDP.

- Engaging in the SDP usually results in a faster resolution of the matter and avoidance of the costs and disruptions of an investigation and litigation.

Here are the relevant changes and clarifications that CMS made regarding the use of the Self-Disclosure Protocol:

- CIA Participants: A provider that is currently under a Corporate Integrity Agreement can utilize the SDP as long as the provider includes its CIA status in the disclosure and copies its OIG CIA monitor on the self-disclosure. Such providers must still separately report Reportable Events to the OIG pursuant to the CIA.
- Grant Recipients and Contractors: The OIG clarified that disclosures regarding government grants or contractors should be disclosed pursuant to the OIG's Grant Self-Disclosure Program or Contractor Self-Disclosure Program, respectively.
- OIG's Website: The OIG now requires that providers submit all self-disclosures through its website: <https://oig.hhs.gov/compliance/self-disclosure-info/self-disclosure-protocol/>.
- Damages Calculation: When self-disclosers submit the required damages calculation through the SDP, they must include a calculation or estimate of damages to each separately impacted Federal healthcare program as well as a grand total of all damages.
- DOJ Involvement in SDP: The OIG clarified that the Department of Justice (DOJ) may elect to participate in SDP settlement discussions, particularly when the False Claims Act (FCA) is implicated. The DOJ settles such cases using its discretion consistent with FCA cases, although the OIG will advocate that self-disclosers receive

the benefits of the SDP. The OIG will refer any self-disclosure of criminal conduct to the DOJ.

- Minimum Settlement Amounts: The OIG updated the minimum amount required to settle an SDP matter to coincide with the new statutory amounts of penalties the OIG can impose. Consequently, going forward the OIG will require a minimum settlement of \$100,000 to resolve kickback matters and \$20,000 for all other matters.

The benefits of utilizing the OIG's Self-Disclosure protocol remain intact, but it is essential that providers and suppliers make educated decisions and know what to expect before initiating the SDP process. Akerman's healthcare attorneys are available to assist with SDP matters.

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