OIG Revises Health Care Fraud Self-Disclosure Protocol

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On November 8, 2021, the US Department of Health and Human Services (HHS) Office of Inspector General (OIG) issued an update to the <u>Health Care Fraud Self-Disclosure Protocol</u> (SDP). This update revises and renames the Provider Self-Disclosure Protocol last updated by OIG in 2013. The changes are mostly procedural in nature and update the SDP based on legislative adjustments to penalty amounts.

IN-DEPTH

OIG recently posted revisions to the SDP, which was first published in the 1998 *Federal Register* as a process through which healthcare providers, suppliers and other entities subject to civil monetary penalties can voluntarily self-disclose matters involving potential fraud stemming from participation in federal healthcare programs. Pursuant to the SDP, examples of what can be appropriately disclosed include, but are not limited to, submissions of improper claims to federal healthcare programs, potential violations of the federal Anti-Kickback Statute and the physician self-referral law (otherwise known as the Stark law), and employment or contracting with excluded individuals on OIG's List of Excluded Individuals and Entities.

The SDP's goal is to facilitate compliance with federal healthcare program requirements by offering entities subject to civil monetary penalties the opportunity to make good faith disclosures of potential fraud and avoid the costs and disruptions associated with government-directed investigations and civil or administrative litigation.

The timelines, content requirements and methods used to calculate damages are consistent between the 2013 and 2021 versions of the SDP. The 2021 SDP changes are as follows:

 OIG increased the minimum amounts required to settle under the SDP to match new statutory minimum penalty amounts as set forth under the amendments to Section 50412 of the Bipartisan Budget Act of 2018, which increased maximum civil monetary penalties in section 1128A(a) of the Social Security Act (42 USC 1320a-7a) for false claims from \$10,000 to \$20,000, and for Anti-Kickback Statute-related conduct from \$50,000 to \$100,000.

- OIG now requires SDP submissions to be made through the <u>OIG's web page</u> and online portal, rather than by sending a letter to OIG.
- OIG clarified that the SDP is not the appropriate mechanism to report grant- or governmentcontract-related conduct. In 2019, OIG created the <u>Grant Self-Disclosure Program</u> for grant recipients to use for grant-related issues. In 2014, OIG issued guidance to HHS contractors to disclose compliance issues using the <u>Contractor Self-Disclosure Program</u>.
- OIG clarified that a reporting party must indicate in its disclosure whether it is subject to a corporate integrity agreement. OIG also clarifies that reportable events (as defined by the corporate integrity agreement) can be disclosed under the SDP.
- OIG made clarifying revisions to the existing language that confirmed that in some instances, the US Department of Justice may choose to participate in the settlement of SDP cases and resolve the matter under the False Claims Act.
- OIG clarified that a party disclosing under the SDP must include damages to each affected federal healthcare program separately and the sum of all damages to all affected federal healthcare programs.

The latest revisions to the SDP are part of OIG's ongoing evaluation of the disclosure process. OIG previously issued Open Letters to Health Care Providers in 2006, 2008 and 2009 and solicited public comment prior to the 2013 version of the SDP, which amended and replaced the 1998 *Federal Register* Notice and Open Letters.

The SDP has been active since its inception. OIG stated that it has resolved more than 2,200 disclosures between 1998 and 2020, resulting in recoveries of more than \$870 million to the federal healthcare programs. Between 2016 and 2020, OIG resolved more than 330 settlements through the SDP. According to <u>OIG's web page</u>, OIG has entered into more than 600 settlements since 2013 with organizations that self-disclosed conduct through the SDP, with settlements as high as \$20.9 million.

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