

HHS OIG Releases an Updated Health Care Fraud Self-Disclosure Protocol

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On November 8, 2021, the U.S. Department of Health and Human Services Office of Inspector General (“OIG”) released a revised Provider Self-Disclosure Protocol, renamed Health Care Fraud Self-Disclosure Protocol (“SDP”). Prior to this update, the SDP had not been updated since 2013. While many of the revisions were procedural only, some of the revisions were notable, including an increase in the minimum amount required to settle fraud claims under the SDP.

Background. The SDP was established in 1998 as a mechanism for health care providers, suppliers and other persons subject to the OIG’s civil monetary penalty (“CMP”) authorities to voluntarily disclose self-discovered evidence of possible fraud implicating federal health care program funds. Benefits of the SDP include potentially minimizing costs and disruptions for the disclosing party by avoiding a government-initiated investigation and accompanying litigation, paying a lower multiplier on damages than would be required in a government-initiated investigation, and a release from the OIG’s permissive exclusion authorities without integrity agreement obligations. The OIG has a website related to the SDP with additional information, including a list of recently settled SDP submissions. The OIG reported in the revised SDP that, between 1998 and 2020, it resolved over 2,200 disclosures, resulting in recoveries of more than \$870 million to the federal health care programs. Certain conduct is not eligible for the SDP, such as disclosure of an arrangement that involves only liability under the federal physician self-referral law (or “Stark Law”) without also involving potential liability under the federal anti-kickback statute (“AKS”). The CMS Self-Referral Disclosure Protocol (“SRDP”) is available for conduct that involves only liability under the Stark Law.

Updates. The most important update in the revised SDP is that the OIG increased the minimum amount required to settle fraud claims under the SDP in conformity



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with 2018 changes to statutory minimum penalty amounts for CMPs. The new minimum settlement amounts are \$100,000 for kickback-related SDP submissions (up from \$50,000) and \$20,000 for all other SDP submissions (up from \$10,000).

In addition, all SDP submissions must now be made through OIG's website (rather than either by mail or through the website), an SDP submission must disclose whether the disclosing party is subject to a Corporate Integrity Agreement, Corporate Integrity Agreement reportable events can be disclosed through the SDP, and an SDP submission must separately list damages to each impacted federal healthcare program as well as total damages.

Next, the OIG clarified that the Department of Justice may participate in the settlement of a matter disclosed through the SDP and resolve it under the False Claims Act. The OIG also clarified that grant- or government contract-related disclosures should be done through the OIG's Grant Self-Disclosure Program or Contractor Self-Disclosure Program, respectively, not the Health Care Fraud SDP. Finally, the OIG made several miscellaneous changes to statistics, terminology, and background information.

Many of the core requirements for SDP submissions have not changed, however, such as timing and content requirements and damages calculation methodologies. In addition, the potential benefits of SDP submissions have not changed, including a potential exclusion release and lower multiplier for damages calculations.

If you have any questions about the SDP or a potential disclosure through the SDP, please contact the authors or your regular Dorsey attorney.