

OIG Issues Revised Self-Disclosure Protocol

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On April 17, 2013, the Department of Health and Human Services Office of Inspector General released a revised provider self-disclosure protocol (SDP) that supersedes and replaces the 1998 Federal Register Notice and the Open Letters to Health Care Providers issued in 2006, 2008, and 2009. The SDP reaffirms the obligation on all members of the health care industry to take measures to detect and prevent fraudulent and abusive activities, and establishes new reporting requirements and guidance on calculating penalty multipliers.

Importance of Voluntary Self-Disclosure

The new SDP reaffirms the importance of self-disclosure, including OIG's position that individual and entities that use the SDP and cooperate with OIG during the SDP process deserve to pay a lower multiplier on single damages than would normally be required. For the first time, the SDP states OIG's general practice of requiring a minimum multiplier of 1.5 times the single damages, although the specific multiplier accepted may vary depending on the facts of each case.

CMS 60-Day Report and Repay Rule

The new protocol addresses CMS's proposed 60-day "report and repay" rule. The Affordable Care Act generally requires that providers report and return Medicare or Medicaid overpayments within 60 days of the date the overpayment is first identified. Failure to report and repay within 60 days may create liability under the Civil Monetary Penalties Law (CMPL) and False Claims Act. CMS issued its proposed rule implementing the 60-day repayment obligation in February 2012. (77 FR 9179). The proposed rule would suspend the obligation to report overpayments when OIG acknowledges receipt of a submission on the SDP, provided the submission is timely made. In return for suspending the 60-day requirement, the new SDP states that OIG expects disclosing parties to disclose with a good-faith willingness to resolve all liability within the CMPL's six-year statute of limitations. OIG has indicated it will provide additional guidance regarding the 60-day obligation and SDP process after CMS releases a final rule.

Eligibility Criteria and Guidance

The SDP provides greater guidance on how to investigate potentially fraudulent conduct, quantify damages, and report the conduct to OIG. According to the SDP, over the past 15 years, it has resolved over 800 disclosures, resulting in recoveries of more than \$280 million to Federal health care programs. The SDP states that all health care providers,

suppliers, or other individuals or entities that are subject to OIG's civil monetary penalty authority are eligible to use the SDP. Accordingly, the SDP is not limited to any particular industry, medical specialty, or type of service. By way of example, the SDP states that a pharmaceutical or medical device manufacturer may use the SDP to disclose potential violations of the Federal anti-kickback statute (AKS) because such violations trigger CMP liability.

In addition, the new protocol delineates conduct that is not eligible for the SDP, including (1) matters that do not involve potential violations of Federal criminal, civil, or administrative law for which civil monetary penalties are authorized, such as one exclusively involving overpayments or errors, (2) requests for opinions from OIG regarding whether an actual or potential violation has occurred, and (3) disclosure of an arrangement that involves only liability under the physician self-referral law (Stark) without accompanying potential liability under the AKS for the same arrangement. Conduct that only involves Stark violations should be disclosed to CMS through CMS's Self-Referral Disclosure Protocol.

Among other requirements, the SDP requires that the disclosing parties explicitly identify the laws that were potentially violated, and not just refer broadly to federal laws, rules and regulations. The SDP provides details for the content of all submissions as well as the specific requirements for conduct involving false billing, excluded persons, and the anti-kickback statute and physician self referral law.

The revised SDP is available [here](#).

For questions regarding this update, please contact
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