

MAUREEN WEAVER  
203.498.4384  
mweaver@wiggin.com

JAMES GLASSER  
203.498.4313  
jglasser@wiggin.com

JOSEPH MARTINI  
203.363.7603  
jmartini@wiggin.com

JODY ERDFARB  
203.363.7608  
jerdfarb@wiggin.com

## Office of Inspector General Revamps Self-Disclosure Protocol

### UPDATED PROTOCOL FEATURES INCENTIVES FOR PROVIDERS: LOWER MULTIPLIERS AND PRESUMPTION AGAINST REQUIRING INTEGRITY AGREEMENTS

On April 17, 2013, the Department of Health and Human Services' Office of Inspector General ("OIG") released a substantially revised Self-Disclosure Protocol ("SDP") (<https://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf>). This updated SDP supersedes and replaces the OIG's original 1998 SDP, as well as three Open Letters to Providers that the Inspector General issued about the SDP in 2006, 2008 and 2009.

In the updated SDP, the OIG notes that over the last fifteen years it has resolved over 800 disclosures under the original SDP, resulting in recoveries totaling more than \$280 million. The OIG explains that the updated SDP is based on the OIG's experience in resolving these disclosures, as well as on public comments solicited in 2012.

According to the OIG, members of the health care industry have a "legal and ethical duty" to detect and prevent fraudulent and abusive practices and must be prepared to investigate, assess losses and make full disclosure of any such issues identified. The updated SDP highlights two "significant" benefits to self-disclosure:

- When individuals and entities use the SDP and cooperate with the OIG, the OIG will resolve the matter using a lower

multiplier on single damages than would normally be required in a government investigation – generally, a minimum multiplier of 1.5 times single damages.

- Because the OIG believes that a good faith disclosure and cooperation with the OIG's review process "are typically indications of a robust and effective compliance program," the OIG has established a presumption against requiring integrity agreement obligations in resolving an SDP matter.

All health care providers should review the updated SDP and incorporate its principles and guidelines into their compliance programs. A few highlights are worth special mention:

- The OIG emphasizes that the SDP is only available for matters that involve potential violations of federal criminal, civil, or administrative law for which civil monetary penalties are authorized. It is not available for a matter exclusively involving overpayments or errors, which should be disclosed to the appropriate CMS contractor or payor.
- The SDP is not available for disclosure of an arrangement that involves liability only under the Stark physician self-referral law. Those disclosures are appropriate for the CMS Self-Referral Disclosure Protocol ([http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self\\_Referral\\_Disclosure\\_Protocol.html](http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html)) and may only be disclosed under the SDP

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if they also involve potential violations of the Anti-Kickback Statute.

CMS Notice of Proposed Rulemaking, dated February 16, 2012.

- Like the original SDP, the updated SDP contains requirements and content guidelines for submission of a self-disclosure to the OIG. In addition, the updated SDP provides guidelines for three specific types of self-disclosures: conduct involving false billing, excluded persons, and potential violations relating to Anti-Kickback and Stark laws. These guidelines list specific information that must be discussed in the disclosure and include instructions on calculation of damages for each of these areas.
- According to the updated SDP, the OIG will not demand an admission of liability in settlement agreements but will expect payments above single damages, as noted based on a minimum multiplier of 1.5 times the single damages. The updated SDP also sets forth a minimum settlement requirement of \$50,000 for all kickback-related violations accepted into the SDP and a \$10,000 minimum settlement for all other accepted SDP matters.
- The OIG has "streamlined" its internal process to reduce the average time a case is pending with the OIG to less than 12 months from acceptance into the SDP.
- Conspicuously absent from the updated SDP is discussion or guidance on how far back providers should investigate in calculating damages, other than a comment that organizations making disclosures should be prepared to resolve as far back as six years, the statute of limitations for OIG civil monetary authority. There is no mention of the ten-year look back period discussed in the

Wiggin and Dana has represented many clients in self-disclosures under the OIG's SDP and the CMS SRDP and has advised clients on less formal disclosures and on overpayment refunds to federal and state authorities. While there is always a risk that a self-disclosure could lead to further inquiry and review (and some have, in our experience), in general we have found that most clients making voluntary self-disclosures have avoided integrity agreements, high damage amounts and harsher sanctions. Moreover, when clients that regularly audit, self-disclose and refund overpayments face federal and state audits or investigations, they are often able to negotiate a more favorable resolution of the matter by demonstrating a track record of voluntary disclosures and refunds. In the end, there is no substitute for an ability to demonstrate a robust and operative compliance program when interacting with regulators.

As the OIG recognizes in the updated SDP, organizations considering whether or not to make a disclosure to the OIG or other government authority face a "significant decision." Discussions about options for self-disclosure can be highly sensitive. In these situations, it is advisable to involve legal counsel to ensure that these discussions are conducted in a privileged manner and informed by a full assessment of legal risks and options.

Please feel free to contact any member of our Health Care Compliance team if you have questions about this advisory or need assistance on a matter.

*This publication is a summary of legal principles. Nothing in this article constitutes legal advice, which can only be obtained as a result of a personal consultation with an attorney. The information published here is believed accurate at the time of publication, but is subject to change and does not purport to be a complete statement of all relevant issues.*