

OIG Issues Open Letter To Health Care Providers Updating The 1998 Protocol For Voluntarily Self-Disclosing Fraudulent Conduct

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On April 15, 2008, the Office of Inspector General ("OIG") of the Department of Health and Human Services issued an "Open Letter to Health Care Providers" refining the OIG's Provider Self-Disclosure Protocol ("SDP"). The OIG promulgated the SDP in 1998 "to help ensure the integrity of the Federal health care programs" by giving health care providers a detailed set of guidelines for voluntarily self-reporting fraudulent behavior affecting such programs. See 63 Fed. Reg. 58339 (1998). Specifically, the SDP "offers health care providers specific steps, including a detailed audit methodology, that may be undertaken if they wish to work openly and cooperatively with the OIG."

In its April 15, 2008 Open Letter, the OIG refined the 1998 SDP to clarify the submission requirements "to provide an opportunity for providers to work with [the] OIG to more efficiently and fairly resolve

matters appropriately disclosed under the SDP." Under the original 1998 SDP guidelines, if a provider discovers fraudulent or illegal behavior affecting federal programs and chooses to self-disclose, it must provide a written submission to the OIG. The written submission must include basic information such as a description of the matter being disclosed, whether the matter is currently being investigated by a government agency, and the reasons why the provider believes that a violation has occurred. The written submission is also expected to include a detailed report of the provider's internal investigation and damages assessment conducted according to specific guidelines. Notably, the OIG will generally agree (for a reasonable period) to forgo initiating its own investigation if the provider conducts its review in accordance with the SDP's guidelines. After making its report, the provider is expected to fully

cooperate with the OIG to resolve the matter, including providing essential information upon request and without requiring "compulsory methods." The OIG also expects the provider to waive privileges if the documents are "critical to resolving the disclosure," but the OIG is willing to work with the provider's counsel to avoid this outcome.

Finally, the 1998 SDP addresses two possible outcomes for failing to comply with the SDP upon self-disclosure: (1) failure to work in good faith with the OIG will be considered an "aggravating factor when the OIG assesses the appropriate resolution of the matter;" and (2) the intentional submission of false or inaccurate information will be referred to prosecuting agencies and may independently result in sanctions and/or exclusion. The 1998 SDP does not, however, specifically address the consequences of failing to make an initial self-disclosure.

The new 2008 Open Letter now provides greater clarification as to what is expected in an initial disclosure:

- “[A] complete description of the conduct being disclosed;”
- “[A] description of the provider’s internal investigation or a commitment regarding when it will be completed;”
- “[A]n estimate of the damages to the Federal health care programs and the methodology used to calculate that figure or a commitment regarding when the provider will complete such estimate;”
- “[A] statement of the laws potentially violated by the conduct;” and
- A verification that the provider can “complete the investigation and damages assessment within 3 months after acceptance into the SDP.”

In addition to these requirements, the OIG has also revised its position on the use of Corporate Integrity Agreements (“CIA”). As set forth in the 1998 SDP guidelines and subsequent Open Letters from the

OIG, providers could benefit from self-reporting if the overall resolution of the problem included entering into an OIG-imposed CIA. In its 2008 Open Letter, however, the OIG has now determined that “[a] provider’s submission of a complete and informative disclosure, quick response to [the] OIG’s requests for further information, and performance of an accurate audit are indications that the provider has adopted effective compliance measures.” Accordingly, when negotiating a monetary settlement, the OIG will “generally not require the provider to enter into a Corporate Integrity Agreement or Certification of Compliance Agreement.” The OIG’s new position is intended to reward “the provider’s commitment to integrity” while advancing the OIG’s goal of resolving self-disclosures in a timely manner.

Finally, the Open Letter does not change the OIG’s position that (1) the decision to self-disclose fraudulent behavior rests solely with the provider; and (2) that the SDP is not intended to resolve billing or overpayment issues. Although the OIG has previously encouraged the self-disclosure of Stark violations, such as arrangements under which a physician pays a hospital below fair

market value for office space, like the 1998 SDP, the Open Letter does not provide specific examples of conduct that favors self-disclosure. Instead, the 2008 Open Letter states only that “[t]he SDP is intended to facilitate resolution of matters that potentially violate Federal criminal law, civil law, or administrative laws for which exclusion or civil monetary penalties are authorized.” Like the 1998 SDP, the Open Letter also does not identify specific consequences flowing from a failure to self-disclose or from a disclosure that does not conform to the SDP’s procedures.

Jenner & Block LLP provides information on recent developments and general topics of interest in the field of health care law. The information presented here is not intended to be legal advice. Please address any questions or comments to:

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