feature focus

OIG's Open Letter on the Self-Disclosure Protocol

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On April 15, 2008, the Office of Inspector General (OIG) of the US Department of Health and Human Services issued "An Open Letter to Health Care Providers" (Open Letter), which details certain "refinements and clarifications" to its Self-Disclosure Protocol (SDP).[1] The SDP, which the OIG originally unveiled in 1998, is a program in which providers who uncover potentially fraudulent activities in their organizations may disclose such activities to the OIG. The potential benefits of such disclosure generally have been a reduction in damages, the avoidance of a government investigation, and a greater likelihood that the provider will not be excluded from Federal health care programs for its misconduct. In the Open Letter, the OIG creates another significant benefit to disclosure—the potential avoidance of a Corporate Integrity Agreement (CIA) or Certification of Compliance Agreement (CCA).

Refinements and clarifications to the SDP

Although providers do take advantage of the SDP (according to the OIG, providers have disclosed approximately $120 million under the SDP) the OIG determined that improvements could be made to the SDP to facilitate increased disclosures by providers. These improvements are designed to make the SDP process more efficient and beneficial to providers.

The Open Letter aims to increase the efficiency of the SDP by requiring providers to make a more complete initial submission, including commitments regarding when the provider's internal investigation and damages estimate will be completed (to the extent not completed at the time of the initial disclosure). The following information must now be provided: (1) a complete description of the conduct being disclosed; (2) a description of the provider's internal investigation or a commitment regarding when it will be completed; (3) an estimate of the damages to the federal health care programs and the methodology used to calculate that figure or a commitment of when the provider will complete such estimate; and (4) a statement of the laws potentially violated by the conduct. The information required in the initial disclosure is in addition to the "basic information" currently required to be disclosed under the SDP, which includes certain information about the provider (e.g., name, address, provider and tax identification numbers, etc.), whether the provider is currently under investigation by a government agency or contractor, a full description of the nature of the matter being disclosed, the type of health care provider implicated and any provider billing numbers associated with the matter being disclosed, the reasons why the provider believes that a violation of law may have occurred, and a certification regarding the truthfulness of the submission.[2]

To ensure that providers conduct a timely internal investigation of the potential misconduct, the Open Letter states that the provider must be able to complete its investigation and damages assessment within three months of acceptance into the SDP. Under the SDP, providers are expected to submit a detailed report to the OIG demonstrating that the potentially fraudulent conduct has been thoroughly reviewed, including a discussion of the nature and extent of the improper or illegal practice (e.g., the potential causes of the incident or practice, the period in which the incident or practice occurred, and the corporate officials and departments involved in the matter) and the organization's discovery and response to the matter (e.g., how the incident or practice was identified, the steps used by the entity to investigate the

matter, and any disciplinary action taken against corporate officials, employees, and agents as a result of the investigation). The provider is also expected to conduct an internal financial review of the problematic incident or practice in order to calculate its impact on federal health care programs. Because all of this must be completed within three months of the initial disclosure, providers should have completed their internal investigations and financial reviews at the time of the disclosure or be prepared to dedicate sufficient resources to these efforts to ensure that they are completed within three months of the disclosure.

The OIG has streamlined its internal process for reviewing and resolving the SDP submissions, which presumably means that providers who comply with the Open Letter should expect to have their disclosures resolved more quickly than in the past. This should make the SDP more appealing to providers who are looking for a quick resolution to their disclosure.

The Open Letter also adds a potential benefit to a self-disclosure: the avoidance of a CIA or CCA. In order to receive this benefit, providers must make a complete and informative disclosure, quickly respond to OIG requests for further information, and conduct an accurate audit. The OIG interprets compliance with the foregoing as evidence that the provider has implemented effective compliance measures, thus rendering a CIA or CCA unnecessary.

Although the OIG does not generally impose CIAs on providers who make self-disclosures,[3] the Open Letter provides an additional assurance to providers that good-faith disclosures will not result in CIAs. CIAs typically last five years and require providers to implement a comprehensive compliance program, submit various reports to the OIG, retain (at significant expense to the organization) an independent review organization to audit and review the provider's claims, and agree to certain stipulated penalties for violations of the CIA. CCAs are less onerous, but still require providers to certify that they will operate their compliance programs for a period of years and provide for stipulated penalties. Knowing that disclosures will generally not result in CIAs or CCAs should make the SDP a more appealing option for providers and may encourage more internal auditing and monitoring as a result.

Certain practical considerations

The Open Letter's revisions and clarifications to the SDP make it a more attractive mechanism for disclosing potential wrongdoings; however, potential issues regarding the SDP still persist. The Open Letter emphasizes that the OIG expects "full cooperation" from providers and that providers must "timely respond to OIG's request for additional information." One practical issue is whether the OIG will require the provider to waive the attorney-client privilege in connection with the SDP. In the original 1998 SDP publication,[4] the OIG observed that it "must have access to all audit work papers and other supporting documents without the assertion of privileges or limitations on the information produced." However, the OIG also stated that "[i]n the normal course of verification, the OIG will not request production of written communications subject to the attorney-client privilege." It is unclear whether there is an expectation under the Open Letter that providers will be more willing to waive the attorney-client privilege. In any event, compliance officers and legal counsel who conduct internal investigations should be mindful that portions of the investigation may ultimately be provided to the OIG if the provider makes a self-disclosure. The 1998 SDP publication noted that the OIG will discuss with the provider's counsel ways to obtain access to information without the need for the provider to waive the attorney-client privilege, and counsel for the provider may want to consider contacting the OIG in this regard.[5]

The Open Letter also emphasizes that only potentially fraudulent conduct involving federal health care programs should be disclosed through the SDP. Billing errors and overpayments should be submitted directly to the claims processing entity. Sometimes the line between simple billing mistakes and potential fraud is a blurry one, particularly when one considers that the Federal False Claims Act contains a "reckless disregard" standard.[6] As a result, providers should consider consulting their compliance departments and/or inside or outside legal counsel when potential billing issues arise, to help evaluate whether fraud could potentially be involved in the billing error. Matters that are considered by the provider to be simple billing mistakes and disclosed to the claims processing entity as such may ultimately be referred to the OIG (outside of the SDP process) by the claims-processing entity if it believes that potential misconduct occurred.

In connection with a disclosure, providers should be aware that a disclosure regarding one particular aspect of an arrangement or a transaction may lead to the OIG investigating other issues that involve the same arrangement or transaction. For example, a provider that discloses a below-fair-market-value physician lease arrangement should ensure, as part of its internal investigation of the arrangement, that other aspects of the arrangement and other arrangements with the physician comply with applicable law. The OIG will not necessarily limit its review to the specific issue disclosed by the provider, which the OIG acknowledged in the 1998 SDP publication: "Matters uncovered during the verification process, which are outside of the scope

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of the matter disclosed to the OIG, may be treated as new matters outside of the Provider Self-Disclosure Protocol."[7]

Finally, it is important for providers to remember that disclosures to the OIG under the SDP do not prevent the OIG from referring the matter to the Department of Justice or other enforcement bodies for additional investigation and potential penalties and/or prosecution. However, a provider's use of the SDP and cooperation with the OIG would potentially be a mitigating factor in the OIG's recommendations to other enforcement bodies.

Conclusion

A well-designed compliance program may, from time to time, uncover compliance problems that potentially require disclosure to the government. When potentially fraudulent conduct is identified, compliance officers should consult with inside or outside counsel to determine whether the organization should take advantage of the SDP. Providers that make a good faith effort to conduct a thorough internal investigation of the potentially fraudulent conduct and quantify the financial impact to federal health care programs will likely have their disclosures resolved more quickly by the OIG and without the imposition of a CIA or CCA. ■

1 The April 15, 2008 Open Letter may be found on the OIG's website at http://oig.hhs.gov/fraud/docs/openletters/OpenLetter4-15-08.pdf. Inspector General Daniel R. Levinson announced the issuance of the Open Letter at the HCCA conference in New Orleans on April 15, 2008.
2 63 Fed. Reg. 58,399, 58,401 (Oct. 30, 1998).
3 An "Open Letter to Health Care Providers" issued by the OIG on April 24, 2006 indicated that CIAs had only been required in 27 of 136 self-disclosures that were resolved with monetary settlements as of that date. Department of Health & Human Services, Office of Inspector General, An Open Letter to Health Care Providers (April 24, 2006).
4 63 Fed. Reg. 58,399 (Oct. 30, 1998).
5 63 Fed. Reg. 58,399, 58,403 (Oct. 30, 1998).
6 31 U.S.C. §§ 3729-3733.
7 63 Fed. Reg. 58,399, 58,403 (Oct. 30, 1998).