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# OIG Offers Carrot For Self-Disclosure Protocol

*Thursday, Apr 24, 2008* --- On April 15, 2008, the Office of the Inspector General for the Department of Health and Human Services (OIG) released an Open Letter to Health Care Providers (Open Letter) addressing refinements and clarifications to the Office of Inspector General's Provider Self-Disclosure Protocol (Protocol).

As announced by the Open Letter, the OIG is adopting a presumption in favor of not requiring providers to enter into a Corporate Integrity Agreement (CIA) as part of the resolution of matters disclosed under the Protocol. This is a significant advantage to providers and suppliers who may have previously chosen to avoid the Protocol, and accepted the risks of nondisclosure, because of concerns over the costs and other burdens of a CIA.

The OIG also provided new information that providers and suppliers must include in their initial submission, in addition to the Basic Information already required by the Protocol.

*OIG Self-Disclosure Protocol – The Basics*

Since its release in 1998, the OIG's Protocol has provided an avenue for health care providers and suppliers to proactively and voluntarily report misconduct identified through a variety of means, including effective compliance programs and internal investigations.

As reported recently by the OIG's Office of Counsel, statistics on the Protocol from its origin in 1998 to date reflect 379 disclosures accepted into the Protocol; 165 were resolved with monetary settlements totaling $118 million. There were 53 disclosures submitted during calendar year 2007.

Examples of the types of issues disclosed under the Protocol include billing for medically unnecessary services, billing for services performed by excluded individuals, duplicative billing, alteration of records and anti-kickback and physician self-referral violations.

The OIG does not accept simple billing errors for the Protocol. Rather, the Protocol is intended to facilitate the resolution of matters that, in the provider's or supplier's reasonable assessment, are potentially violative of Federal criminal, civil or administrative laws. Among other factors it considers for acceptance into the Protocol, the OIG must be convinced that the provider or supplier is offering the disclosure in good faith, and generally, the OIG will not accept a matter for the Protocol that is already under investigation by the government.

The Protocol is available to all types of health care providers and sets out recommended investigative and audit measures.

It is important to note that the OIG is not constrained by any findings that a provider or supplier discloses, and the OIG may resolve the matter in any manner that the OIG determines appropriate. Therefore, any supplier or provider retains a measure of risk when utilizing the Protocol to address identified misconduct, and should discuss such risks with legal counsel before utilizing the Protocol.

Assuming the OIG accepts the written disclosure as sufficient to meet the requirements of the Protocol, the process allows resolution with the OIG, usually by means of a monetary settlement and often accompanied by a CIA.

Downsides of the Protocol have included concerns by providers and suppliers about the extent of information required to secure acceptance under the Protocol, the cautionary advice by the OIG that the matter may not end with the disclosure but may require referral to or involvement with the Department of Justice (DOJ), and an aversion by providers and suppliers to incurring the costs and other burdens associated with a CIA.

*The 2008 Open Letter*

Inspector General Daniel Levinson, like his predecessors, has clearly placed the Protocol at the center of the OIG's compliance and fraud enforcement activities. The Open Letter contains two significant changes in the OIG's policies toward self-disclosing providers.

– Presumption That A CIA Will Not Be Required For Those Accepted Into The Protocol. Most importantly, the OIG is adopting a presumption in favor of not requiring a CIA (or even the somewhat less burdensome Certification of Compliance Agreement, or CCA) as part of the resolution of matters disclosed under the Protocol.

There are, however, some prerequisite conditions that must not be overlooked: (1) submission of a "complete and informative disclosure;" (2) "quick" responses to the OIG's information requests; and (3) performance by the self-disclosing party of an "accurate" audit or self-assessment as required by the Protocol. These conditions are all indications, according to the OIG, of an effective compliance program.

The general purpose of a CIA, which represents a waiver of the OIG's discretionary authority to exclude a provider or supplier from future participation in Federal health care programs, is to reduce the risks to those programs of future misconduct by the provider or supplier.

By not requiring a CIA, the OIG has indicated its confidence that a self-disclosing provider or supplier is not likely to pose a future risk to the Federal health care programs (or at least no more of a risk than providers and suppliers who do not have a known history of misconduct).

 

It is not clear from the Open Letter whether providers and suppliers who disclose misconduct outside the Protocol (e.g., to the DOJ or a state Medicaid Fraud Control Unit) would be able to avail themselves of this presumption against a CIA, which may have the result of making the Protocol a more attractive option for achieving disclosure than other available options.

The 2008 Open Letter builds on the OIG's past policies of providing concessions on integrity obligations for self-disclosing providers, following earlier Open Letters addressing the Protocol issued in 2000, 2001, and 2006.

The 2000 Open Letter first suggested that the OIG might "be more flexible in considering the terms of a CIA" or "not even require a CIA" for self-disclosing providers. The 2001 Open Letter indicated that self-disclosure would be the first factor the OIG would consider in determining whether to release the OIG's administrative exclusion authorities without a CIA.

In 2006, Inspector General Levinson himself announced that CIAs had only been required in 27 of the 136 self-disclosures that had been settled to date, apparently seeking to lessen the fears in the health care community associated with use of the Protocol.

The OIG specifically examined the issue of CIAs for self-disclosing providers and suppliers when it issued a white paper in May 2001, Self-Disclosure of Provider Misconduct: Assessment of CIA Modifications. At that time, the OIG concluded that "significant and appropriate [CIA] modifications" resulted from self-disclosure submissions.

This paper described, through case vignettes, the types of concessions that had resulted from self-disclosure, including reducing CIA terms from the typical five-year time period to three years, and reducing (or eliminating) the role of the independent review organization (IRO) in performing compliance audits under CIAs. In addition, in some situations the OIG had conformed the requirements of the CIA to the providers' or suppliers' existing compliance programs, resulting in a lesser burden for those which self-disclose.

In short, self-disclosure results in significant advantages to the provider or supplier given the options available to the OIG, and self-disclosure results in significant advantages to the provider or supplier.

– Additional Information Required For Protocol Disclosures. The second major part of the Open Letter is the announcement of additional information that will be required in order to self-disclose under the Protocol.

In the past, the Protocol offered two avenues for self-disclosure.

First, a provider or supplier could disclose at the beginning of its own internal investigation by including only certain "Basic Information" in its submission. This Basic Information was limited to the name, address, identification number, and tax identification number(s) of the disclosing provider or

 

supplier; whether the provider was aware that the matter is already under government investigation; a description of the matter being disclosed; the type of provider or supplier; the Federal health care programs affected; the reasons why the provider or supplier believes that a violation of Federal law may have occurred; and a certification that the submission contains truthful information and is made in good faith.

Second, the provider or supplier also had the option of disclosing after it had completed its internal investigation and self-assessment by submitting more detailed information as part of its submission.

Under the 2008 Open Letter, the OIG will no longer permit providers or suppliers to submit bare-bones disclosures limited to the "Basic Information." All submissions will now need to include a complete description of the conduct providers or suppliers are disclosing; a description of the internal investigation or a commitment regarding when the investigation will be completed; an estimate of Federal health care program damages or a commitment regarding when that estimate will be completed; and a statement of the laws potentially violated.

The OIG will also require the completion of the internal investigation and self-assessment within three months after acceptance into the Protocol. This heightened requirement appears to be driven by the OIG's concerns about disclosures not being made in good faith or not containing enough information for the OIG to determine whether to admit a provider or supplier to the Protocol.

– Remaining Cautions For Disclosure Under The Protocol? Although the Protocol may offer significant comfort given possible alternatives, the decision whether to self-disclose (and where – to the OIG, the Medicare contractor, Medicaid, or the Department of Justice) has always been a decision that has required careful consideration, hopefully with input from legal counsel.

The primary concerns with the Protocol have been the lack of significant incentives to those self-disclosing, inconsistent or disparate treatment of self-disclosers, and the time it often took to resolve a self-disclosure with the OIG. Interested parties should also note that recent positions taken by the DOJ suggest that the Protocol may not be viewed as a "public disclosure" that would bar a qui tam recovery under the False Claims Act.

Although the 2008 Open Letter offers some favorable prospects to providers and suppliers to encourage use of the Protocol, providers and suppliers should still use caution (as well as legal counsel) with respect to all disclosures of misconduct to avoid prejudicing future options.

*Conclusion*

The OIG has offered a significant new incentive for the health care industry to consider in determining whether to use the Protocol by offering a

 

presumption that a CIA will not be required. The OIG has also renewed its promise to expedite resolution of Protocol matters. In exchange, the OIG has strengthened its requirements for Protocol submissions.

Only time and experience will reveal how successful these changes will be in encouraging disclosure. The OIG's Protocol, the White Paper on Self-Disclosure of Provider Misconduct: Assessment of CIA Modifications, and the 2008 Open Letter (as well as the prior Open Letters) are available on the OIG's Web site.

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