OIG Issues Updated Provider Self-Disclosure Protocol

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The protocol was originally published in October 1998 ((63 Fed. Reg. 58399) (Oct. 30, 1998)) for the purpose of providing a process by which health care providers could voluntarily report and resolve instances of potential fraud involving federal health care programs.

According to the OIG release, the agency has resolved more than 800 self-disclosures over the last 15 years, with recoveries exceeding $218 million.

In 2006, 2008, and 2009, the OIG issued open letters to health care providers regarding various aspects of the 1998 SDP; and, in June 2012, the OIG solicited public comments. This recent update is a result of the OIG’s consideration of those comments, and it completely supersedes the 1998 Self-Disclosure Protocol and the open letters.

Parties who take advantage of the self-disclosure process may avoid not only larger monetary losses but also the burdens that accompany compliance with numerous CIA requirements.

The updated Self-Disclosure Protocol (SDP) addresses the following areas: (1) the benefits of disclosure; (2) eligibility criteria and guidance; (3) requirements of provider submissions, including specific requirements for submissions involving false billing, excluded persons, the federal anti-kickback statute (AKS) and the Stark law; and (4) resolution.

Benefits of Disclosure

In this update, the OIG again emphasizes the importance of integrity when dealing with federal health care programs and it identifies certain specific benefits of disclosure.

First, the update recognizes the OIG’s belief that a good faith disclosure typically indicates an effective compliance plan. In furtherance of this recognition, the OIG acknowledges the presumption against the requirement of corporate integrity agreements (CIAs) in exchange for a release of the OIG’s permissive exclusion authority. According to the update, since 2008 when this presumption was first announced in an OIG Open Letter, only one of 235 SDP settlements resulted in imposition of an integrity measure.
Second, the update recognizes the OIG’s general practice of imposing a minimum multiplier of 1.5 times single damages to dispose of civil monetary penalty matters, rather than higher multipliers, which are normally used in resolving government-initiated investigations.

Third, use of the SDP may mitigate potential exposure for failure to return a Medicare or Medicaid overpayment within the later of (1) 60 days after the date on which the overpayment is identified, or (2) the date any corresponding cost report is due. Failure to report and return an overpayment within this timeframe may result in liability under the Civil Monetary Penalties Law and the False Claims Act.

In this regard, the update references CMS’s February 16, 2012 Notice of Proposed Rulemaking (77 Fed. Reg. 9179-9187) (Feb. 16, 2012)) in which CMS proposed to suspend the obligation to report overpayments to the time when the OIG acknowledges receipt of a SDP submission and to suspend the time for returning overpayments to when a settlement agreement is arrived at or when the party withdraws or is removed from the SDP. Additional guidance will be provided by OIG when the final rule is issued.

Fourth, the OIG commits to continue to reduce the time for its processing of SDP submissions which the update describes as an average of less than 12 months from the date of submission. In furtherance of this commitment, the OIG is reducing the time in which a provider must complete its internal investigation and damages calculation time from within 90 days of a provider’s acceptance into the SDP to within 90 days from the date of the provider’s initial submission.

Eligibility Criteria and Guidance

The update reiterates that the SDP should not be used to report mere overpayments and that it is intended to address only those matters potentially involving federal criminal, civil, or administrative laws for which civil monetary penalties are authorized. The update also restates that the SDP is not limited to any particular industry, service, or specialty but is available to all providers, suppliers, and other individuals and entities that are subject to the civil monetary penalties laws. For example, the update references pharmaceutical companies or medical device manufacturers that may want to report violations of the AKS and entities that may have successor liabilities resulting from mergers or acquisitions.

In addition, the update reiterates that the SDP is not available for conduct that violates only the Stark law, and that sole Stark law violations should, instead, be disclosed pursuant to CMS’s Self-Referral Disclosure Protocol. http://www.cms.gov/PhysicianSelfReferral.

As a corollary to CMS’s proposal that the 60-day time period for repayment of an identified overpayment be tolled, disclosing parties should disclose a good faith willingness to resolve liability within the six-year statute of limitations of the civil monetary penalty law.

Further, as a condition of acceptance into the SDP, parties must agree to waive and not plead the statute of limitations or similar defenses to any administrative action filed by the OIG that involves the disclosed conduct.

In addition, the update admonishes disclosing parties to ensure that the conduct has ended and corrective action has been taken prior to submission of the SDP.

With respect to improper kickback arrangements in particular, the provider should ensure that such arrangements are terminated prior to or no later than 90 days of submission.

Content of SDP Submissions

Under the revised SDP, parties who are unable to complete their internal investigations prior to submission must certify that they will complete it within 90 days of the date of initial submission. That is shorter than the time provided in the original SDP, which required completion within 90 days of acceptance by the OIG of the provider into the SDP program.

The updated protocol describes 11 specific areas that are required to be included in the provider’s submission. They include a concise statement of all details of relevant conduct and transactions, including identification of involved individuals and their roles; identification of the specific federal criminal, civil, and administrative laws that were potentially violated and the health care programs affected by the conduct; an estimate of damages or certification that an estimate will be submitted with 90 days of the initial submission; a description of any corrective action that was undertaken upon discovery of the conduct; a statement as to whether the particular matter is being investigated by any government agency or contractor; and a certification that the submission is truthful and has been submitted in a good faith effort to resolve potential liabilities and assist the OIG in its resolution.

The update also addresses certain specific areas such as false billing, excluded persons, kickbacks, and physician self-referrals. When improper claims are involved, the disclosing party is required to conduct a review and submit a report that estimates the improper amount that was paid by a federal health care program. The review must be of either all the claims affected or a statistically valid sample.

Among the changes to the sampling methodology is an increase of the minimum sample size for damage estimates from 30 units to at least 100 items. With respect to matters involving excluded persons, the update requires that the provider identify the excluded individual, the individual’s provider number, and the individual’s job duties. The provider also is required to summarize the background checks that had been completed during the period of employment, the provider’s screening process, and any corrective action.

In terms of calculating damages, where the items or services were separately billed, the amount paid by the federal health care program must be disclosed. Where the items or services in question were not separately billed, the OIG arrives at the single damages amount with reference to the total cost of employment or contracting of the excluded individual or entity, and the disclosing party’s federal health care program payer mix.

With respect to violations of the AKS, and where applicable, Stark law violations, the updated SDP provides a non-exclusive list of the types of information it is looking for, including how fair market value was determined; why payments that may have been required from referral sources were not made, such as lease or other contract payments; and whether payments were made for services not performed.

The update also requires that the disclosing party submit an estimate of the amount paid for services as-
associated with violations of the AKS and include the amount of total remuneration involved in each arrangement.

At the same time, the disclosing party may include an explanation as to why any portion of the total remuneration should not be included in the OIG’s determination of the settlement amount. The updated SDP reiterates that it is not available for violations that are solely of the Stark law, but is available for conduct that implicates both the AKS and the Stark law.

Resolution

The updated SDP stresses that cooperation from the reporting provider is critical to a speedy resolution and beneficial result. It encourages disclosing parties to address potential criminal conduct, and it advises that as in civil cases, the OIG will advocate for a disclosing party when the Department of Justice is considering whether to prosecute.

The updated SDP requires a minimum settlement amount of $50,000 for anti-kickback related matters and a minimum of $10,000 for all other matters. If the disclosing party maintains that it is financially unable to pay a settlement, the OIG will require the party to submit and certify to the truthfulness of extensive financial information, including audited financial statements and tax returns.

Advantages and Disadvantages of the Updated Protocol

As the government continues to significantly expand its fraud-fighting efforts, the SDP protocol becomes an increasingly important alternative to treble damages under the False Claims Act, penalties under the civil monetary penalties laws, and possibly criminal prosecution. The decision whether to disclose potential violations is a significant one that should be made only after careful analysis of all relevant facts and thorough assessment of all possible liabilities, both monetary and otherwise.

While the OIG’s self-disclosure protocol certainly offers many potential benefits, it is not without potential detriments. The update’s restatement of the presumption against integrity agreements is a significant benefit, as is the OIG’s recognition that it will generally settle SDP disclosures for 1.5 times single damages.

Government initiated investigations often settle for at least two times damages and frequently result in some type of integrity measure, including comprehensive CIAs. Parties who take advantage of the self-disclosure process may avoid not only larger monetary losses but also the burdens that accompany compliance with numerous CIA requirements.

In addition, parties who self-disclose may obtain relief from the 60-day overpayment reporting and return requirements with their attendant potential CMP and False Claims Act liabilities.

Moreover, a party that self-discloses has the opportunity to present the relevant facts and circumstances in the best light possible. This opportunity could be lost completely or, at a minimum, substantially compromised where investigators or qui tam relators provide information to government decision makers in the first instance.

One of the potential detriments created by the update is the shortening of the time period for completion of the disclosing party’s investigation from 90 days following acceptance into the program to 90 days following initial submission.

While likely well intentioned, this change can result in the expenditure of significant resources in a short period of time and the possibility of compromise to the thoroughness and accuracy of the investigation, particularly where a complex set of facts or a myriad of legal and regulatory issues exist.

Another detriment to self-disclosure is the potential availability of the disclosure to private litigants, including existing or potential qui tam relators. Conceivably, submissions to the government could be obtained through discovery or the Freedom of Information process. The update’s requirement that the implicated civil and criminal laws be identified with specificity creates the potential for an even more detailed road map for a disclosing party’s potential adversaries.

Finally, the update makes it clear that OIG will coordinate with the Department of Justice in the resolution of SDP matters and that if DOJ decides to participate in the settlement, it will be DOJ and not OIG who will determine the appropriate resolution.

While the OIG intends to communicate to DOJ its desire that the disclosing party benefit from self-disclosure, it is very likely that DOJ will undertake a more stringent assessment of potential liabilities and possibly require a larger settlement amount.