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CLIENT ALERT

NEW OIG SELF-DISCLOSURE PROTOCOL RELEASED

On April 17, 2013, the Office of Inspector General (“OIG”) released its “Updated OIG’s Provider [Self-Disclosure Protocol](#)” (“Updated SDP”), through which the OIG revised and updated its [1998 Self-Disclosure Protocol](#) (“1998 SDP”) on the same topic. The Updated SDP not only serves to incorporate the information contained in the OIG’s [2006](#), [2008](#), and [2009](#) Open Letters clarifying the self-disclosure protocol (the “Protocol” or “SDP”), but also organizes, streamlines, and adds substantial new information to the 1998 SDP and subsequent Open Letters which it explicitly supersedes. To assist with your understanding of the Updated SDP, we will discuss some important changes and considerations contained in the Protocol. (Note: the Protocol is not for disclosures that are “mere billing errors or overpayments,” which should be submitted to the Medicare Administrative Contractor through a separate form and process.)

Benefits of Disclosure

Although the 1998 SDP and the subsequent Open Letters encouraged health care providers to self-disclose potential violations to the OIG in return for certain benefits, these benefits were not discussed at length, aside from the 2008 Open Letter’s presumption against requiring Corporate Integrity Agreements (“CIAs”). In the Updated SDP, the OIG lists four benefits a provider can obtain through self-disclosure (although the OIG retains discretion over when not to provide such benefits):

1. A presumption against requiring CIAs in exchange for a release of the OIG’s permissive exclusion authority;
2. A lower multiplier on single damages than would normally be the case (i.e., a minimum of 1.5x);
3. A suspended obligation to report and return overpayments through the CMS regulations, although these suspended obligations are contingent on CMS’s finalization of its proposed regulations on the issue; and
4. A reduction in the time the case would be pending, through the OIG’s streamlined process (i.e., less than 12 months).

Eligibility Criteria and Guidance

The Updated SDP reiterates and clarifies which providers may use the Protocol, along with which potential violations are covered under the Protocol and which are not. First, it is important to note that providers may use the Protocol for its own conduct or potential successor liability, but cannot use it for the conduct of unrelated third parties. Second, providers may use the Protocol even if they are currently subject to a CIA or a government inquiry of some kind, so long as their self-disclosure is not intended to circumvent the CIA or inquiry. While the scope of the SDP remains fairly broad, encompassing potential violations of law for which CMPs are authorized, the OIG continues to assert that actions or arrangements violating only the physician's self-referral/Stark Law should not be reported through the SDP, and should be reported through the CMS Self-Referral Disclosure Protocol instead.

In addition, the Updated SDP requires providers to agree to toll the statute of limitations as of the date of self-disclosure and to waive statute of limitations or similar defenses to the OIG's actions relating to the self-disclosed conduct for any post-disclosure period. The provider must also have completed corrective action by the time of disclosure, or in the case of an improper kickback arrangement, within 90 days of disclosure.

Submission Content

Unlike the 1998 SDP, which provided one in-depth, comprehensive outline for all disclosing providers to follow when using the Protocol, the Updated SDP creates separate guidance for different types of disclosable violations, such as improper billing or excluded providers. To do so, the Updated SDP includes one section containing information that must be included for all disclosures, followed by three sections with violation-specific requirements. Important information in each section is discussed below:

1. Requirements for All Disclosures
 - a. SDP disclosures may now be submitted through the OIG's website (once it is active) or by mail. Email and fax submissions are still prohibited.
 - b. Most of these generally applicable requirements are unchanged or only slightly revised when compared to the 1998 SDP, but a few changes are important to note:
 - i. *Shortened Investigation Period*: Providers now have 90 days after their SDP submission to complete their internal investigations, whereas previous guidance gave providers 90 days after their acceptance into the SDP by the OIG. Note that providers are obligated to repay and return overpayments 60 days from the date the overpayment was identified (unless they are subject to the cost reporting deadline).
 - ii. *More Discretion Regarding Internal Investigations*: The extensive requirements in the 1998 SDP surrounding the provider's internal

investigation are absent, although the provider should still thoroughly undertake and document its investigation.

- c. Providers must acknowledge that the disclosed conduct is a potential violation of certain laws and explicitly identify which laws are involved, including the Anti-Kickback Statute and/or Stark Law
2. Requirements for Conduct Involving False Billing
 - a. This section has incorporated most of the sampling and self-assessment guidelines from the 1998 SDP in determining damages.
 - b. The primary difference between the 1998 SDP's sampling guidelines and those in the Updated SDP involve the sample size.
 - i. *Larger Sample Size and Looser Statistics*: Whereas the 1998 SDP required a sample size large enough to garner a 90% confidence level and 25% precision, with a minimum sample size requirement of 30 claims, the Updated SDP eliminates most of these strict requirements, opting instead for a minimum of 100 claims and the looser requirement of a statistically valid study.
3. Requirements for Conduct Involving Excluded Persons
 - a. This is a new special section in the Updated SDP, spelling out prior OIG practices that were not detailed in the 1998 SDP or subsequent Open Letters.
 - b. To calculate damages, a provider must follow the instructions contained in this section, which involve calculations with variables such as the provider's total costs of employment or contracting and the percentage of its federal health care program pay or mix.
 - c. Before self-disclosing information about an excluded person, a provider must screen all current employees and contractors and report all excluded persons in a single SDP submission.
 - i. Note that the OIG just released [new guidance](#) concerning provider screening for excluded persons on May 8, 2013
4. Requirements for Conduct Involving the Anti-Kickback Statute and Law
 - a. This section has no express precedent in the 1998 SDP.
 - b. A provider self-disclosing a prohibited arrangement under this section must report its damages as the total amount of remuneration involved in the arrangement, without regard to whether a portion constituted lawful remuneration. The provider may seek to explain why some portion of the arrangement was lawful and should not be considered in the damage calculation, but such a decision is ultimately up to the OIG.
 - c. As stated earlier, conduct or relationships that violate the Stark Law but not the Anti-Kickback Statute should not be reported through the SDP.

Claim Resolution

In its discussion of claim resolution under the Protocol, the Updated SDP reiterates previously addressed concepts such as the OIG's expectation of cooperation from a disclosing provider and the effect of the SDP on Department of Justice and/or CMS investigations. It also updates information regarding minimum settlement amounts: kickback-related SDP submissions cannot be settled for less than \$50,000, and other submissions cannot be settled for less than \$10,000. Finally, it adds three new provisions. First, providers claiming difficulty in paying a proposed settlement must provide extensive financial information supporting their claim. Second, the OIG will allow overpayment refunds relating to the disclosed conduct to serve as a credit toward the ultimate settlement amount; however, the OIG is not bound by such a refund, and the provider will still have to pay a multiplier on any damages. Third, the OIG advises providers to clearly identify trade secrets or other privileged information on their submissions so as to ensure such information's exemption from disclosure under the Freedom of Information Act.

Please contact Attorneys Anthony Cichello (ajc@kb-law.com); Robert Griffin (rgriffin@kb-law.com); Jennifer Gallop (jgallop@kb-law.com); or Anjali Waikar (awaikar@kb-law.com); if you have any questions about the Updated SDP.