The OIG's Revised and Expanded Self-Disclosure Protocol: Increased Transparency by the Government

SDP Protocol Publicly Acknowledges How the OIG Approaches Calculations

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On April 17, 2013, the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) released an updated self-disclosure protocol (SDP) that significantly overhauls the process for providers and others to voluntarily disclose and resolve instances of potential fraud involving federal health care programs such as Medicare and Medicaid.[1] The revised SDP adds substantial new guidance on assembling the content included in disclosures and provides greater transparency into the OIG's process for resolution of disclosed matters. Notably, the SDP for the first time publicly acknowledges how the OIG approaches damages calculations in particular situations and sets minimum settlement amounts for resolving particular disclosed matters.

History of the SDP

The updated SDP supersedes and replaces all previous guidance on the SDP, including the 1998 *Federal Register* publication establishing the SDP and the three open letters OIG issued in 2006, 2008, and 2009 to clarify its implementation and application in certain contexts.[2] The OIG created the SDP to provide guidance to health care providers on how to investigate and report instances of potential violations of federal criminal, civil, or administrative laws and resolve liability under the OIG's Civil Monetary Penalty Law provisions (CMP).[3]

The SDP was not intended to be the appropriate mechanism for disclosing matters that simply involve overpayments or errors that do not suggest violations of law.[4] In the 1998 *Federal Register* publication establishing the SDP,

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the OIG focused more on the mechanics of self-disclosure and, in particular, on the OIG's views on the appropriate elements of a disclosing party's investigation of and work plan to address potential instances of noncompliance.[5] For example, the protocol required that the disclosing party provide a report of its internal investigation detailing a laundry list of information about the nature and extent of the improper or illegal practice and the disclosing party's discovery and response to the issue.[6]

The OIG's open letters provided additional guidance regarding the type of matters appropriate for resolving in the SDP.[7] In the 2006 Open Letter, the OIG indicated that providers may use the SDP to resolve liability for potential violations of the physician self-referral law (Stark),[8] but just three years later modified its position, and in the 2009 Open Letter stated that the SDP was not an appropriate vehicle for resolving Stark-only violations. Instead, providers could use the SDP to disclose potential Stark violations only if the misconduct also gave rise to liability under the anti-kickback statute.[9] Notably, the 2009 Open Letter also adopted a minimum $50,000 settlement amount to resolve kickback-related disclosures.

The open letters also addressed whether disclosing parties would be subject to integrity measures as part of the resolution. Here again the OIG altered its position in a relatively short span of time. In the 2006 Open Letter, the OIG publicly announced that based on its experience in administering the SDP, it would require that, when appropriate, the resolution include a certification of compliance agreement (CCA) rather than the more onerous corporate integrity agreement (CIA).[10] Two short years later, the OIG took the position that the providers' self-disclosure, along with a "quick response to OIG's requests for further information, and performance of an accurate audit" are indications that the provider "has adopted effective compliance measures" obviating the need for either a CIA or CCA.[11]

The updated SDP reaffirms the principles established by this prior guidance but also provides increased transparency and insight into the OIG's processes and assumptions for analyzing the disclosed misconduct and designing the appropriate resolution. In particular, the SDP provides updated guidance and clarification on who may use the SDP, the content that must be included in an SDP disclosure, and the parameters for resolving potential CMP liability for the disclosed misconduct.

Eligibility for the SDP

Although the SDP was always "open to all health care providers, whether individuals or entities, and [was] not limited to any particular industry, medical specialty or type of service,"[12] the OIG for the first time explicitly states in the revised guidance that the SDP is open to anyone who may be facing CMP liability, including pharmaceutical or medical device manufacturers.[13] According to Tony Maida, Deputy Chief of the Administrative and Civil Remedies Branch of the Office of Counsel to the Inspector General and principal author of the SDP, to date, no manufacturer has availed itself of the SDP despite being subject to CMP liability in certain situations.[14] For example, manufacturers may face potential kickback liability based on the activity of their sales representative(s).

The updated SDP also clarifies that the SDP remains available to disclosing parties under a CIA or those already subject to a government investigation so long as the disclosure is made in good faith and is not an attempt to circumvent the government's investigation.[15] Moreover, the updated SDP provides that a party may disclose conduct of another entity for which the disclosing party may have successor liability through a merger or acquisition. Consistent with the limitations the OIG first announced in the 2009 Open Letter, the SDP remains unavailable for resolving Stark-only potential violations.[16] The SDP, however, continues to be available for resolution of Stark law

issues based on the same facts giving rise to potential violations of the anti-kickback statute or other violations of federal criminal, civil, or administrative law for which CMPs are authorized.

Required Content

The SDP establishes a method for electronically submitting disclosures through the OIG's Web site[17] and includes considerable new detail on the information disclosing parties must include in disclosure reports, including new content requirements specific to particular *types* of potential violations. The OIG advises disclosing parties to take care to identify clearly any portions of their submission that they believe are trade secrets or are commercial, financial, privileged, or confidential and appropriately designate such information or documents as potentially exempt from disclosure under the Freedom of Information Act (FOIA).[18]

Required Content for All Disclosures

The new protocol requires disclosing parties to submit certain basic information, including:

- basic demographic information about the disclosing party;
- organizational chart showing ownership or controlling interests of the disclosing entity;
- the identification of and contract information for the disclosing party's representative for purposes of the SPD;
- a "concise statement of all details relevant to the conduct disclosed" including the time period involved, the types of claims, and the names of any individuals implicated and their roles;
- a statement of the federal criminal, civil, or administrative law "potentially violated by the disclosed conduct;"
- the federal health care programs affected;
- a damages estimate for each federal health care program impacted;
- a description of the disclosing party's corrective action upon discovery of the misconduct;
- a statement about whether the disclosing party has any knowledge of an already pending government investigation (or a government contractor inquiry) into the conduct being disclosed as well as information about any other government investigations against the disclosing party relating to federal health care programs;
- the name of the individual who is authorized to settle the disclosed matter; and
- a certification as to the truthfulness of the disclosure.[19]

Required Content for False Billing Disclosures

The updated SDP adds specific content requirements for disclosures involving the submission of improper claims to federal health care programs. Specifically, disclosing parties must submit a report based on the disclosing party's internal investigation that estimates the damages, *i.e.*, the improper amount paid by the affected federal health care programs because of the disclosed conduct.[20] The damages may be determined either by a review of all of the claims affected by the disclosed matter or by a statistically valid random sample of claims that then is projected to the population of claims affected.[21] In a change from previous guidance, the updated SDP requires that the sample use at least 100 items, which according to Mr. Maida, is consistent with the practice of the OIG's Office of Audit Services.[22] Specifically, the report submitted to the OIG must include:

- the review objective;
- a description of the population of claims about which information is needed and the methodology used to develop the population;
- the sources of the data;
- information about the personnel who conducted the review and their qualifications; and
- the characteristics used for testing the item.[23]

If the damages review is based on a sample, the SDP requires the disclosing party to also include the sampling plan followed, including the sampling unit; sampling frame;

sample size; source of random numbers; the method of selecting sampling units; the sample design; missing sample items; and the estimation methodology used.[24]

Required Content for Disclosures Related to Excluded Persons

The updated SDP adds entirely new content requirements for disclosures related to individuals who have been excluded from participation in federal health care programs,[25] *i.e.*, who appear on the OIG's List of Excluded Individuals and Entities.[26] Disclosures related to excluded persons now must include the following information:

- the identity of the excluded individual and any provider identification number;
- the job duties performed by the individual;
- the dates of the individual's employment or contract;
- a description of any background checks the disclosing party completed before and/or during the individual's employment or contract;
- a description of the disclosing party's screening process and any flaw or breakdown in the process that led to the individual's hiring or contract;
- a description of how the conduct was discovered; and
- a description of any corrective action (including copies of revised policies or procedures) implemented to prevent future hiring of excluded persons.[27]

Notably, the updated SDP requires the disclosing party to screen all current employees and contractors against the OIG List of Excluded Individuals and Entities prior to making its disclosure. The SDP goes on to state that after conducting this follow-up screening, the disclosing party should disclose *all* excluded persons in one submission.[28] One interpretation of this new screening requirement is that once a party makes an SDP submission related to excluded persons, the OIG may respond poorly to any additional future disclosures regarding excluded persons. It remains an open question how a disclosing party filing a SDP disclosure because of successor liability should implement this screen requirement. For example, should the disclosing party screen all of its own employees and contractors in addition to the employees and contractors for the predecessor entity? Moreover, the six-year limitations period for CMP liability[29] could present a disclosing party with substantial practical hurdles in identifying the employees and contractors of its predecessor entity.

Finally, the updated SDP reveals the OIG's long-standing approach to resolving liability for excluded persons who provide items or services that are not directly and separately reimbursable or paid for by federal health care programs.[30] In such circumstances, the OIG will calculate damages based on the disclosing party's total costs of employing or contracting with that individual, including salary, benefits, insurance, and employer taxes, adjusted for the disclosing entity's federal health care program payor mix.[31] The OIG uses the resulting amount as the single damages to the federal health care programs resulting from the employment of or contracting with the excluded individual. Although the OIG indicates that it has used this methodology in the past, this is the first time the OIG has articulated it publicly.[32]

Required Content for Disclosures of Anti-Kickback and Stark Law Violations

The updated SDP, which continues to restrict Stark disclosures to cases in which there is also a colorable anti-kickback violation, emphasizes that parties disclosing potential violations of these laws must include greater detail about the potential violations. In particular, the disclosing party must explicitly describe why the disclosed conduct or arrangement may violate the anti-kickback statute (and Stark law).[33] Notably, the OIG states that it "will not accept any disclosing party into the SDP that fails to acknowledge clearly that the disclosed arrangement constitutes a potential violation of the [anti-kickback statute], and if

applicable, the Stark Law."[34] Merely stating that the OIG could view the disclosed conduct or arrangement as a potential violation is insufficient — the party must directly acknowledge the potential violation. To that end, the SDP requires that the disclosing party include a narrative statement of the relevant details of the disclosed conduct and an analysis of why the conduct or arrangement potentially violates the law. Specifically, this statement should include:

- the participants' identities;
- the participants' relationship to one another to the extent that the relationship affects potential liability (*e.g.*, hospital-physician);
- the payment arrangement; and
- the dates during which the arrangement occurred.[35]

The OIG also identifies specific examples of information it "finds helpful in assessing and resolving" conduct involving potential anti-kickback statute and Stark violations.[36] Among the examples provided are information about how fair market value was determined and why it is now in question or why the arrangement was arguably not commercially reasonable (*e.g.*, lacked a reasonable business purpose). Anti-kickback and Stark disclosures must describe the corrective action taken to remedy the suspect arrangement and safeguards to prevent the conduct from recurring.[37]

With respect to calculation of damages, anti-kickback and Stark disclosures also must include an estimate of the amount paid by federal health care programs associated with the potential violations, including the total amount of remuneration involved in each arrangement without regard to whether a portion of the total remuneration was for a lawful purpose.

Disclosing parties with matters that implicate potential violations of the anti-kickback statute and the Stark law should consider carefully whether to disclose the matter using the OIG's SDP or the Centers for Medicare & Medicaid Services (CMS) Self-Referral Disclosure Protocol (SRDP).[38] A disclosing party should not use both protocols to disclose the same potentially improper conduct or arrangement.[39] If the disclosing party selects to proceed under the OIG's SDP, the party should be aware that the OIG could not release Stark liability.

Resolution and Consequences of Self-Disclosure

Perhaps most significantly, the updated SDP articulates a formulaic approach to calculating the amount disclosing parties should expect to pay to resolve disclosed matters. The updated SDP establishes a $10,000 floor for the resolution of all non-kickback matters while maintaining the $50,000 minimum settlement amount for potential anti-kickback violations the OIG first established in the 2009 Open Letter. These minimum settlement amounts could be problematic for parties that wish to disclose isolated and small-scale violations (*e.g.*, a single consulting arrangement that potentially violates the anti-kickback statute or a handful of prescriptions by an excluded physician) as the OIG based these amounts on the *maximum* per-transaction CMP penalty available — thereby effectively converting a statutory ceiling into a settlement floor. In addition, the updated SDP reaffirms the OIG's practice of applying a minimum multiplier of 1.5 times the single damages amount for disclosed violations.

In an effort to streamline the SDP process, the SDP also shortens the period during which disclosing parties have to complete the required internal investigation following an initial submission. Disclosing parties now must submit findings from their investigation within 90 days of the initial submission rather than 90 days after acceptance into the SDP. Disclosing parties also must complete their damages calculation within this 90-day period after initial submission. Unless a disclosing party can negotiate an extension of this time period (the availability of which the updated SDP does not address), this shortened timeframe may force parties who learn of complex poten-

tial violations to delay availing themselves of the SDP during the internal investigation, thereby remaining vulnerable to government investigations and whistleblower actions likely to result in greater penalties.

The Benefits of Using the SDP

There are several benefits to using the SDP to disclose potential fraud. First, disclosing parties receive the benefit of a lower multiplier on single damages and a speedy resolution of liability — especially when compared to often multi-year government investigations or whistleblower actions. Second, providers using the SDP can continue to expect that the OIG will not, as a matter of course, impose integrity measures as a condition for its exclusion release in settling the disclosed matter. Third, using the SDP may mitigate potential liability under the Affordable Care Act's 60-day overpayment provision.[40]

The 60-day overpayment provision requires an individual or entity that has received an overpayment from Medicare or Medicaid to report and return the overpayment by the later of: 1) 60 days after the overpayment is identified; or 2) that day any corresponding cost report is due.[41] Overpayments that have not been reported and returned within the applicable time period give rise to liability under the CMP[42] and the False Claims Act.[43] Specifically, the SDP recognizes that the proposed rule issued by CMS in February 2012 proposed to suspend the obligation to report and return overpayments made by Medicare or Medicaid when OIG acknowledges receipt of a timely SDP submission.[44] The SDP states that the OIG will provide additional guidance on its Web site as necessary when CMS issues the final rule on the overpayment obligation.

Finally, in matters that may involve or require the involvement of the Department of Justice (DOJ) — for example, to release False Claims Act liability — the OIG has stated that it will advocate to DOJ "that the disclosing party receive a benefit from disclosure under the SDP."[45] Although the OIG is careful to point out that the DOJ has full discretion to resolve any cases in which it is involved, such advocacy from the OIG is likely to carry substantial weight.

Conclusion

Notably, the OIG has not addressed whether, and if so how, the principles articulated in the updated SDP will be applied to individuals and entities currently engaged in the SDP process. To the extent that the SDP reflects long-standing OIG practice, it is reasonable to expect that the individuals or entities currently in the SPD will be treated in accordance with such practice.[46] The new procedures discussed in the updated SDP (*e.g.*, the time period within the disclosing party must conclude its internal investigation) are likely to be applied only prospectively.

Endnotes:

1. Updated OIG's Provider Self-Disclosure Protocol *available at* oig.hhs.gov/compliance/self-disclosure-info/index.asp [*hereinafter* SDP].
2. SDP at 1. The prior self-disclosure guidance remains available as an "additional resource" on the OIG's Web site.
3. *See* Section 1128A of the Social Security Act, 42 U.S.C. § 1320a-7a.
4. 63 Fed. Reg. 58,399, 58,400 (Oct. 30, 1998).
5. *Id.*
6. *Id.* at 58,401-402.
7. The OIG's open letters are available on the OIG's Web site, *supra* at note 1.
8. 42 U.S.C. § 1395nn.
9. 42 U.S.C. § 1320a-7b(b).
10. For additional information about the difference between a CCA and a CIA, *see oig.hhs.gov/faqs/corporate-integrity-agreements-faq.asp.*
11. 2008 Open Letter at 2.
12. 63 Fed. Reg. at 58,400.
13. SDP at 3.
14. American Health Lawyers Association Fraud and Abuse Practice Group Roundtable Discussion: OIG's Updated Provider Self-Disclosure Protocol – What Does Revamp Mean to You? (May 22, 2013).
15. SDP at 3.
16. SDP at 4.
17. As of May 28, 2013, the online submission function was not yet operational. *See oig.hhs.gov/compliance/self-disclosure-info/index.asp.*
18. 5 U.S.C. § 552. *See* SDP at 15.
19. SPD at 5-6.

20. SDP at 7.
21. *Id.*
22. *See supra* note 14.
23. SDP at 8.
24. SDP at 8-9.
25. 42 U.S.C. § 1320a-7.
26. The OIG's List of Excluded Individuals and Entities is available online at oig.hhs.gov/exclusions/index.asp.
27. SDP at 9.
28. *Id.*
29. 42 U.S.C. § 1320a-7a(c)(1).
30. *See supra* note 14.
31. SDP at 10.
32. *Id.*
33. SDP at 11.
34. *Id.*
35. *Id.*
36. *Id.*
37. *Id.* at 12.
38. *See www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html.*
39. *Id.* at 13-14.
40. *See* Section 1128J(d) of the Social Security Act, 42 U.S.C. § 1320a-7k(d).
41. *Id.*
42. 42 U.S.C. § 1320a-7a(a)(10).
43. 31 U.S.C. § 3729(a)(1)(G).
44. 77 Fed. Reg. 9,179-9,187 (Feb. 16, 2012).
45. SDP at 13.
46. *See supra* note 14.

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