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The OIG's Updated Self-Disclosure Protocol: Greater Transparency, but Proceed With Caution

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On April 17, the Department of Health and Human Services Office of Inspector General published an updated Self-Disclosure Protocol (''SDP'').

Originally introduced in 1998, the SDP provides a mechanism through which health care organizations may voluntarily report to the OIG potential violations of criminal, civil, or administrative law governing federal health care programs for which exclusion or civil monetary penalties are authorized.

The 2013 updated SDP includes various new provisions, many previously found only in the OIG's open letters and internal policy, such as limitations on the SDP's scope with respect to its applicability to the Stark law, a statement from the OIG on what it views to be the minimum damages multiplier, settlement amounts, and guidelines for the content of SDP submissions.[1]

In the updated SDP, the OIG emphasizes what it sees as the benefits of voluntary disclosure and notes that ''good faith disclosure of potential fraud and cooperation with OIG's review and resolution process are typically indications of a robust and effective compliance program.''

The OIG reported that within the last 15 years, over 800 disclosures were resolved under the SDP, amounting to more than $280 million in recoveries for Federal health care programs.

Although the revised SDP largely preserves the general construct of voluntary disclosures under the prior SDP, it does introduce new criteria that affect the timing, content, and mechanics of a disclosure under the SDP. While the OIG provides greater clarity related to the self-disclosure process through the revised SDP, however, there are a number of areas in which uncertainty remains.

Health care organizations need to think strategically about how to self-report and what the appropriate venue to disclose potential violations of federal health care laws (*i.e.*, Department of Justice, Centers for Medicare & Medicaid Services, OIG, contractors, or some combination) may be.

Ultimately, what remains lacking is a single mechanism through which all potential violations of laws affecting federal health care programs could be disclosed and, therefore, resolved.

What Remains. . .

Significantly, the overall content and intent of the SDP remains substantially the same. The OIG continues to recognize the importance of the self-disclosure process and reaffirms the idea that those individuals or entities who utilize the process are likely to emphasize and value compliance.

As such, the OIG remains committed both to maintaining the self-disclosure process as well as facilitating timely resolution of self-disclosed matters. With respect to the content of self-disclosures, the crux of the submission, which encompasses both the internal investigation and damages calculation, is largely the same as under the previous SDP.

The SDP remains available to all health care organizations and is not limited to any specific industry, medical specialty or type of service. Nor is it limited to organizations that bill directly the federal health care programs, remaining open to all individuals and entities subject to the OIG's civil monetary penalty (CMP) authorities. Specifically named in the revised SDP as eligible for participation are pharmaceutical and device manufacturers.

[1] U.S. Department of Health & Human Services, Office of the Inspector General, *OIG's Provider Self-Disclosure Protocol* (April 17, 2013), available at: http://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf.

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This is a significant statement, since many self-disclosures result from items found during the ''due diligence'' process preceding a transaction, and the OIG's willingness to be a venue for the resolution of these findings is important for the health care industry.

The revised SDP also confirms prior guidance that suggests that disclosing parties which are already subject to a government inquiry are not necessarily precluded from using the SDP, but the SDP cannot be used as a means to avoid such inquiry. Additionally, parties that are already subject to a Corporate Integrity Agreement (''CIA''), which has its own reporting requirements, are also able to use the SDP process.

What's New and Issues to Consider

Eligible Conduct

With respect to the type of conduct that may be disclosed, the revised SDP confirms that it can be used for conduct that potentially violates Federal criminal, civil, or administrative laws for which CMPs are authorized. The OIG makes clear that a disclosing party must, ''explicitly identify the laws that were potentially violated'' and not refer broadly to federal health care laws in general.

While this requirement for explicitly identifying the laws, on its face, seems easy enough, matters still in the process of being investigated internally may not be at the point where a definitive statement in this regard can be made.

Health care organizations need to think strategically about how to describe the ''potential violations'' in such matters, since decisions at the outset could potentially affect the scope of release and perhaps even whether items being investigated by the government, but which may not yet be known by the disclosing party, are within the scope of the disclosure.

Citing to the fact that disclosing parties who fail to acknowledge potential violations are the ones likely to have unclear or incomplete submissions, the OIG noted that statements such as ''the Government may think there is a violation but we don't agree. . .'' may result in the disclosing party's removal from the SDP.

While this is not a new requirement in the SDP, going forward, the OIG makes clear that it will not accept a disclosure that fails to reflect that there may be a ''potential violation.''

This requirement can be a difficult pill to swallow for health care organizations considering a disclosure under the OIG's SDP. This is especially so for disclosures that are prompted by third parties, such as competitor allegations or those found during the due diligence process.

Where a competitor or potential buyer is challenging a business practice, the disclosing party truly may not believe that their facts and circumstances rise to the level of a ''potential violation,'' yet they have no choice but to disclose expeditiously, sometimes before they have completed their internal investigation to an extent sufficient to know whether there is a ''potential violation.''

In these types of circumstances especially, the use of the word ''violation'' tends to be daunting to many organizations considering entering the SDP, and may unnecessarily deter organizations from seeking the benefit of the SDP in favor of other disclosure venues.

Perhaps a better approach would be to use the standard found in the OIG's Advisory Opinion process, where the OIG may review conduct and says that the conduct ''could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present.'' Alternatively, the OIG could use the word ''implicate'' instead of ''violate'' with respect to the federal health care laws.

Either approach would help with the ''psychology'' of encouraging the health care industry to participate in self-disclosures, and neither approach would change the substance of what is being disclosed and resolved through the SDP.

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Significantly, the OIG reiterates its stance from the 2009 Open Letter, in which it says it will no longer handle Stark-only cases. In the revised SDP, the OIG makes clear that disclosing parties must analyze each arrangement to determine whether the conduct raises liability under the AKS, the Stark law, or both.

But frequently it is unclear whether something is a ''Stark-only'' violation until the internal investigation is complete, which only occurs after the SDP submission. Even then, because of the subjective nature inherent in analyzing intent, it is not always clear whether the relevant conduct is purely a Stark matter or may also be a kickback issue.

Intent must often be inferred from facts and circumstances. This is especially true when the entity does not have direct access to the former employees or other individuals who engaged in the conduct. Typically, like minds may disagree on whether improper intent under the AKS exists even after a thorough investigation.

Because of this, for the time being, health care organizations may be inclined to disclose through the DOJ, either main Justice or the local U.S. attorney's office, which brings with it the added benefit of obtaining False Claims Act releases but also might result in more significant exposure.

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Settlement Terms

The OIG acknowledges that use of the SDP is likely indicative of a robust and effective compliance program. As such, the OIG confirms what many within the health law community had already believed to be the case—that there is ''a presumption against requiring [corporate] integrity obligations in exchange for a release of OIG's permissive exclusion authorities in resolving an SDP matter.''

In fact, the OIG reports that of the 235 cases resolved since 2008, only one required integrity measures. This confirmation is good news for those who may recall the OIG's seesaw on this issue in the earlier days of the SDP—with the OIG sometimes requiring full blown corporate integrity agreements (CIAs), sometimes requiring a lesser corporate compliance agreement (CCA) or certification of compliance, and often changing its position on this issue during the pendency of a disclosure.

As consistency in OIG policy is absolutely critical for health care organizations considering a self-disclosure, the stated presumption of "no CIA" is a very significant development to be expressly included in the SDP.

This made it extraordinarily difficult for counsel to recommend use of the SDP, since there was no way to know whether the standard in effect when submitting the disclosure would be the standard used when the matter was settled several years later and, indeed, often it was not.

As consistency in OIG policy is absolutely critical for health care organizations considering a self-disclosure, the stated presumption of ''no CIA'' is a very significant development to be expressly included in the SDP.

The OIG confirms that individuals and entities that take advantage of the self-disclosure process should pay a lower multiplier for purposes of calculating damages than would normally be expected in resolving a government investigation, where double damages is generally the minimum multiplier for obtaining a release.

Although the precise multiplier may vary based on case-specific facts, the OIG states that they will generally require a minimum multiplier of 1.5. The OIG touts the lower multiplier and lack of integrity obligations as two of the benefits of self-disclosing.

The OIG maintains the minimum of $50,000 to resolve kickback-related disclosures and articulated a new a stated minimum of $10,000 to resolve any other matter. These minimums include Federal health care program damages and any relevant multiplier.

While these minimums do help to establish reasonable expectations across the health care industry regarding the likely outcome of self-disclosures, as well as a reasonable business decision on the part of the OIG as to what is worthy of governmental resources, they also may deter certain disclosures not believed (rightly or wrongly) to meet the minimums or suggest that conduct that implicates the statute but is below that amount would not be subject to liability.

For instance, it still is common for health care executives (even in organizations with robust compliance programs) to misperceive the consequences of inducements of small dollar amounts, believing erroneously that potential liability is calculated by the amount of the inducement, rather than the resulting referral revenue.

Also, there are circumstances in which there has been an inducement, but not much referral revenue. In such circumstances, it is not entirely clear where compliant organizations should go. Although small overpayments can be refunded to the contractor, small inducement revenue may not be readily disclosed elsewhere.

The revised SDP also addresses refunds made on disclosed items. If, prior to resolution of the disclosure, the disclosing party refunds an overpayment related to the same conduct, the OIG will credit the amount refunded toward the ultimate settlement amount. However, the OIG is not bound by any amount that is repaid outside of the SDP process. Therefore, where refunds are made, the OIG may question the methodology of the overpayment calculation.

Significantly, the OIG reminds that in its notice of proposed rulemaking, CMS had proposed to suspend the obligation to report and return overpayments within 60 days of identification (or when the next cost report is due) when OIG acknowledges receipt of a submission to the SDP, assuming it is timely made.

Thus, there is typically no need to make a refund separate from the self-disclosure in the SDP. Notably, the OIG's acknowledgment of receipt typically occurs soon after the initial submission to the SDP and does not require official acceptance into the SDP.

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As with other ability to pay cases, the disclosing party will need to provide, and certify to the truthfulness and completion of, extensive financial information, including audited financial statements, tax returns, and asset records. In addition to submitting the financial information, the disclosing party should include an assessment of how much they believe they can afford to pay (which, of course, may be difficult to determine where there are Stark-only disclosures pending at CMS.)

Timing

The SDP also contains guidance on the timing of disclosures and anticipated length of final resolution. Spe-

cifically, OIG states that it ''expects disclosing parties to disclose with good faith willingness to resolve all liability within the CMPL's six year statute of limitations.''

Accordingly, the disclosing party must agree, as a ''condition precedent'' to acceptance into the SDP, to waive and not plead statute of limitations, laches or any similar defense except to the extent such defenses would have been available to the disclosing party had an administrative action been filed on the date of submission.

Of particular importance, the OIG has attempted to streamline the internal process for disclosures ''to reduce the average time a case is pending with OIG to less than 12 months from acceptance into the SDP.'' However, to keep within this timeframe, the OIG is now requiring that internal investigations and damages calculations be submitted 90 days from the date of initial submission.

What is lacking from the revised SDP is an articulation of the time period in which the OIG will notify a disclosing party as to whether they have been accepted or rejected into the SDP.

This is a significant change from the previous version of the SDP, which required that internal investigations and damages calculations be complete 90 days from *acceptance* into the SDP.

Depending on the speed with which the OIG evaluates a submission to determine acceptance, the new timing may force disclosing parties to quantify damages without knowing whether they have availed themselves of the protection of acceptance into the SDP. What is lacking from the revised SDP is an articulation of the time period in which the OIG will notify a disclosing party as to whether they have been accepted or rejected into the SDP.

While resolution within a year is a welcome development, notification of acceptance into the SDP on a timely basis is even more important to the health care community. A health care organization making a disclosure faces the most uncertainty and vulnerability in the days after the disclosure and before acceptance into the protocol.

This tightened timeframe also may prove to be a challenge for the health care industry. Even the previous ''90 day from acceptance'' standard posed considerable challenges for health care organizations and will remain so especially for organizations in the midst of a transaction, in which the timing of the disclosure may be transaction-dependent (i.e., submission before signing or closing) rather than investigation-driven.

Of course, the OIG's timing standard is far preferable to the standard of CMS's physician self-referral protocol for Stark law matters, which requires full quantification before acceptance into that protocol. While OIG is committed to 12-month resolution, Stark-related items in the CMS self-referral protocol appear to be on a considerably longer time frame. As such, disclosures of Stark-related items are increasingly ending up at the U.S. attorneys' offices, having been eliminated from the OIG's SDP some time ago.

Calculating Damages

The revised SDP requires that reviews be conducted by ''qualified individuals,'' such as statisticians, accountants, auditors, consultants and medical reviewers and that the accompanying report include such individuals' qualifications. While it certainly stands to reason that the individual who performs such a review be qualified, the SDP's listing of statisticians, accountants, consultants, and auditors does suggest that the SDP demands a high level of expertise.

Over the past decade, health care organizations have created robust compliance departments and may have personnel with the necessary skills to conduct reviews, but it is not clear that the skill set typically maintained in-house is now sufficient for purposes of the SDP. For instance, can a provider undertake a ''do-it-yourself'' disclosure, even if it were to use the OIG's recommended RAT-STATS program to develop a statistically significant random sample using only trained internal personnel, but without a statistician?

The revised SDP also includes additional guidance related to sampling for purposes of calculating damages. As always, there is a choice between reviewing all of the claims affected by the potential violation or a sample of claims. In the revised SDP, where a sample is used, the OIG eliminates a minimum precision level for the sampling review in the SDP. The OIG states that eliminating precision levels will alleviate the burdens associated with the review and analysis of ''unreasonably large sample sizes.''

Instead of requiring a precision level, the SDP now requires the disclosing entity to review at least 100 claims to reach the estimate of the damages. This is largely good news since large sample sizes typically account for a long length of time in resolving disclosures, as well as great expense to health care organizations.

Nevertheless, if a provider has identified a potential violation involving fewer than 100 claims, or one for which a very high level of precision could be met with fewer than 100 claims, they are left having to review all the claims up to 100.

Unfortunately, even with the revised SDP, the OIG and other government enforcement and oversight agencies have not created a "one stop shop" for disclosures for certain physician financial relationships.

Moreover, elimination of a recommended precision level may have other unintended consequences. Statisticians typically design samples around a desired precision level, until now, frequently using the precision level previously set forth in the OIG's protocol for self-disclosures of all types, whether or not in the SDP.

The concept was that if a given precision level was sufficient for the OIG, it ought to be sufficient for all refund and disclosure purposes, and CMS contractors

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evaluating refunds typically accepted this rationale. Without a minimum precision level as an alternative, it will be difficult to point to an acceptable, objective standard when disclosing or refunding beyond the OIG.

Conclusion

Overall the revised SDP provides greater transparency and certainty with the self-disclosure process. Yet, there are still a number of factors that health care organizations should consider when deciding whether to participate in the OIG's self-disclosure SDP as opposed to other venues for disclosure and/or refund.

Unfortunately, even with the revised SDP, the OIG and other government enforcement and oversight agencies have not created a ''one stop shop'' for disclosures for certain physician financial relationships. Thus, health care organizations seeking global settlement and consideration for physician financial relationship issues also may find that they need to look beyond HHS for a satisfactory resolution.