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HHS OIG Self-Disclosure Protocol: Potential Redesign After 14 Years

BY HOWARD YOUNG AND ARIANNE CALLENDER

On June 18, the Department of Health and Human Services Office of Inspector General (OIG) announced that it is considering revising its voluntary Provider Self-Disclosure Protocol (SDP or Protocol) and is soliciting suggestions from the public on potential revisions.[1] The notice did not specify any anticipated changes or areas of particular interest to OIG. Instead, OIG announced that it is seeking suggestions on ''how best to revise the Protocol to address relevant issues and to provide useful guidance to the health care industry.''[2] The comment period closes on August 17, 2012.[3] The announcement did not indicate an anticipated release date for the revised Protocol.

[1] *See* 77 FR 36281, 36281–36282, available at https://federalregister.gov/a/2012-14585 (last visited June 18, 2012).

[2] See id.

[3] Incidentally this date corresponds to the height of the summer vacation schedules for many in the industry. Given that the SDP is not a regulation and this notice was voluntarily published in the *Federal Register* by OIG to obtain wide distribution, query whether any comments submitted after the deadline would be considered by OIG.

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Background

Since OIG originally published the SDP[4] 14 years ago, in 1998, modeled on the Department of Defense's self-disclosure protocol, the SDP has offered health care providers the opportunity to self-report potential fraud involving federal health care programs to OIG. The protocol was published at the same time as Health Insurance Portability and Accountability Act (HIPAA) health care fraud enforcement, False Claims Act (FCA) investigations, and so-called ''national enforcement projects'' were getting under way. It also coincided with the start of OIG's development and publication of its voluntary compliance program guidances for various industry sectors.

The OIG is seeking industry comment on self-disclosure protocol to address issues and provide guidance to the health care industry.

By the late 1990s, Stark Law compliance also emerged as a front-burner issue, particularly for hospitals, even though the Centers for Medicare & Medicaid Services (CMS) had not yet finalized its Stark Law regulations or issued a self-disclosure protocol for Stark Law issues.

Usage Trends and Participant's Views on the Protocol

The SDP was intended to be a ''win-win'' for the industry and OIG. On one hand, it provided a formal mechanism for providers to disclose identified noncompliance related to OIG's legal authorities in exchange for more lenient treatment than if the misconduct had been identified as part of a government investigation or qui tam lawsuit.

On the other hand, it promised OIG with a steady stream of disclosures of potential health care fraud mat-

[4] OIG Self-Disclosure Protocol documents available at http://www.oig.hhs.gov/compliance/self-disclosure-info/index.asp (last visited June 18, 2012).

ters through a process that shifted the lion share of the investigative burden to disclosing providers.

Many in the industry have found the results mixed after 14 years. While an expedited resolution of matters was one of the benefits many hoped for, due to a variety of factors, including limited OIG resources and perhaps a failure to prioritize the resolution of such matters over affirmative government investigations, many of which had court deadlines, the Protocol's self-disclosures often took well over a year (and sometimes two) to resolve.

In a sign that it is trying to expedite and re-prioritize on self-disclosures, OIG has reportedly brought down the time it takes to resolve such matters to under a year. Partly as a result of this, and a very formalistic approach inherent in the Protocol (which can make merely preparing a submission to OIG quite expensive), providers have often pursued other self-disclosure alternatives, such as reporting to contractors, states, U.S. attorneys' offices, or the Department of Justice.

Further, with the advent of the CMS Self-Referral Disclosure Protocol (SRDP) in 2010, providers also have the option of self-disclosing potential Stark Law violations to CMS, although this mechanism is still relatively new and has resulted in very few settlements with hospitals and physician practices thus far.[5]

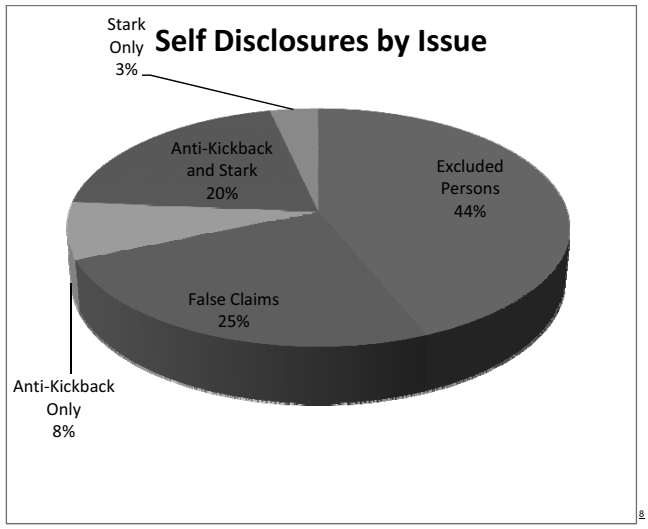
In many cases, industry lawyers felt that self-disclosures of potential health care fraud issues to those other government agencies resulted in a more expeditious and appropriate resolution than if they had disclosed through the Protocol. A 2008 survey of health lawyers by the American Health Lawyers Association related to the Protocol observed that two major criticisms of the voluntary disclosures made to the OIG were that the government often took too long to resolve self-disclosures and that providers often did not realize the upside or benefits of making a voluntary disclosure.[6]

Survey respondents shared their rationale for selection of the government agency to which they disclosed. Some participants preferred the formality of the SDP, and others opted to use the SDP when they believed that the damages amount would lead the contractor to make a referral for enforcement. Several of those surveyed reported to local U.S.attorney's offices due to their working relationships with the offices and the expectation that these offices would have greater sensitivity to local concerns. Participants also noted that they were more likely to disclose billing or cost report issues to contractors as opposed to OIG. Also, some preferred contractors because they were viewed as less likely to pursue enforcement.

Settlements of self-disclosures, many of which are summarized by OIG on its website, indicate that most providers have used the SDP to disclose billing for services of excluded persons, evaluation and management coding irregularities or duplicate billings, anti-kickback and self-referral (Stark Law) issues.[7]

Since 2001, OIG has posted information on approximately 170 self-disclosures on its website. Of these, the breakdown by issues is as follows:

- Billing for Services of Excluded Persons: 44 percent
- Anti-Kickback/Stark: 31percent
- False or Fraudulent Claims: 25 percent[8]



To date, according to statistics published by OIG, participating providers have resolved more than 800 matters with OIG through the Protocol, with settlements totaling $280 million.[9]

The largest self-disclosure settlement under the protocol was approximately $9.5 million in connection with billing improprieties and documentation lapses related to home health, hospice and durable medical equipment claims in 2004.

For the most part, settlements under the Protocol have been under $120,000 and many have not resulted in the imposition of a corporate integrity agreement (CIA). Nonproviders, such as pharmaceutical and medical device companies, have rarely used the Protocol, perhaps because the SDP was originally envisioned (and written) for licensed providers of health care services.

Open Letters Clarify Protocol

Since 2006, reflecting shifting sands in the Stark Law and OIG resource environment, OIG has issued three open letters clarifying aspects of the Protocol.[10] (OIG's forthcoming revision would be the first update to the Protocol itself.)

In 2006, on the heels of increased Stark Law enforcement, OIG announced an initiative to encourage providers to disclose conduct involving OIG self-referral and

[5] CMS publishes a summary of its SRDP settlements on its website, available at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self-Referral-Disclosure-Protocol-Settlements.html (last visited June 18, 2012).

[6] Howard Young, American Health Lawyers Association Voluntary Disclosure Survey, June 17, 2008.

[7] *See* http://www.oig.hhs.gov/fraud/enforcement/cmp/self_disclosure.asp (last visited June 18, 2012).

[8] Source, Office of Inspector General, http://www.oig.hhs.gov/fraud/enforcement/cmp/false_claims.asp, http://www.oig.hhs.gov/fraud/enforcement/cmp/kickback.asp (last visited July 19, 2012).

[9] *See* 77 FR 36281, 36281–36282, available at https://federalregister.gov/a/2012-14585 (last visited June 18, 2012).

[10] OIG Open Letters available at http://www.oig.hhs.gov/compliance/self-disclosure-info/index.asp (last visited June 18, 2012).

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anti-kickback authorities, stating that the office would calculate damages based on a multiplier of the value of the excess benefit that the provider conferred upon physicians as opposed to the total amount of ''tainted'' Medicare claims involved—a welcome concession and one that suggested a proportional approach to such resolutions given that the tainted claim approach to damages often resulted in very large and potentially highly punitive amounts.

Subsequently, in 2008, OIG clarified requirements for initial submissions to the Protocol and announced that it would not require compliance agreements (e.g., CIAs) in most SDP disclosures. OIG explained that initial submissions should (1) describe the conduct being disclosed; (2) provide the details of the internal investigation and proposed completion date; (3) estimate damages to the Federal health care programs; and (4) identify laws potentially violated by the conduct. OIG also indicated that it expects participants to complete their internal within three months of acceptance into the Protocol.

Finally, just a year later in 2009, perhaps because of limited OIG resources and the growth of program integrity resources at Centers for Medicare and Medicaid Services (CMS) to handle Stark Law matters, OIG backed away from its earlier solicitation of Stark Law self-disclosures, declaring that it would no longer accept disclosure of matters involving physician self-referral violations in the absence of a ''colorable anti-kickback violation,'' a term which the open letter did not define.

In that 2009 open letter, OIG also announced a minimum settlement amount of $50,000 for disclosures of anti-kickback issues, perhaps in recognition of OIG's limited resources.

OIG Has Yet to Weigh in on Expectations Regarding Reporting and Return of Overpayments

A significant development since the issuance of the Protocol and subsequent Open Letters is the new requirement under Section 6402 of the Patient Protection Affordable Care Act (ACA) that providers report and refund identified overpayments to CMS or its designated contractor within 60 days (the 60-day rule). On February 16, 2012, CMS published proposed regulations to implement this requirement as applied to Medicare Part A and B overpayments.[11] The proposed rules would suspend the obligation to report and return overpayments based on OIG's acknowledgement of a SDP submission. In contrast, submissions to the CMS Self Referral Disclosure Protocol (SRDP) would merely suspend the obligation to return overpayments, and providers would still be obligated to report the overpayment through a CMS or a designated contractor.

CMS has posted a Frequently Asked Question (FAQ) regarding the status of the 60-day rule for purposes of the SRDP, but did not directly address the proposed suspension of overpayment return and reporting obligations. OIG has not issued guidance since CMS released its proposed regulations implementing the 60-day rule.

Until the reporting and refund rules are finalized, or further guidance is issued, organizations may continue to face the prospect of making duplicate submissions to both the contractor and the SDP or SRDP as appropriate.[12]

Potential Suggestions, Areas for Comment

OIG's notice soliciting industry input on changes to the Protocol gives providers and other industry sectors (e.g., manufacturers) a valuable opportunity to provide OIG with feedback and suggestions to improve the Protocol and some of its key features.

Further, improvements to the Protocol could enhance its value as a tool for managing risk associated with potential FCA and Civil Monetary Penalty Law risks as well as those arising from the employment of excluded persons. This is an important consideration for private equity investors active in the health care sector firms and other buyers of health care businesses as they often unearth legal and compliance issues during acquisition due diligence and wish to resolve potential liability through self-disclosures.

Since OIG has issued an open call for suggestions, providers, their legal counsel and compliance professionals may also wish to submit general comments on their views related to the Protocol.

For life sciences companies, one area ripe for discussion relates to the Protocol's requirement that participants estimate Medicare or Medicaid ''damages,'' or paid claims. This requirement limits manufacturers' reasonable use of the Protocol since they are not providers that submit reimbursement claims and thus often are unable to comply with this provision.

Some other areas for potential industry comments include the following:

- The need to define the ''colorable anti-kickback violation'' requirement for disclosures involving self-referral issues and the Protocol's interplay with the CMS SRDP.
- Establishing a reasonable time frame for OIG's assessment of completed submissions under the Protocol insofar as some level of certainty will help disclosing entities formulate reasonable plans for resolution, which in turn may drive greater use of the Protocol.
- Clarity on whether OIG will once again consider Certification of Compliance Agreements (CCAs) for resolutions under the Protocol. OIG has not agreed to a CCA in several years and the reference in the 2008 Open Letter may be out of date or offer false hope. (Note: CCAs are less burdensome than CIAs but OIG has clearly continued to embrace the concept of certifications of compliance in its CIAs.)
- Guidance on whether, and in what circumstances, OIG would impose CIA obligations on self-disclosing individuals or entities.
- Potential for a more streamlined disclosure and proportional settlement approach for matters involving employment of excluded persons. OIG has

[11] 77 FR 9179. CMS stated that it would issue proposed regulations related to Medicare Parts C and D overpayments at a later date.

[12] Centers for Medicare & Medicaid Services Voluntary Self-Referral Disclosure Protocol Frequently Asked Questions, May 17, 2012, available at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/FAQsPhySelfRef.pdf (last viewed July 25, 2012).

substantial enforcement discretion in resolving these matters under its authorities, and as it showed in its 2009 Open Letter when it announced it would look to the amount of purported kickback paid to resolve Anti-Kickback Law related matters instead of the ''tainted claim'' damage measurement, OIG has shown a willingness to resolve matters using alternative methods that result in a more proportional and, many would assert, equitable settlement.

- Standards for applying the range of damages multipliers that OIG will apply to matters self-disclosed under the Protocol.
- Clarity on OIG's process for coordinating with DOJ and CMS to resolve FCA liability issues involved in Protocol submissions.

In this heated enforcement environment peppered with public official rhetoric in an attempt, understandably, to tout their focus on the continued problems associated with health care fraud and to serve a sentinel effect to reduce other misconduct or potential noncompliance, internal compliance systems are maturing, and organizations are increasingly considering voluntary disclosure as an efficient approach to reduce risk when faced with a potential fraud and abuse issue.

The OIG's decision to solicit public input is a welcome sign that it is open to enhance the voluntary self-disclosure experience. The health care industry and its advisors should take advantage of this opportunity and submit comments to OIG with the hope that such industry input will have a meaningful impact on SDP 2.0.

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