OIG Updates Its Provider Self-Disclosure Protocol: Available to Manufacturers for Narrow Group of Issues

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Abstract: *OIG has explicitly advised that pharmaceutical and device manufacturers are eligible for participation in the "Provider" Self Disclosure Protocol, notwithstanding its title. Medical device and pharmaceutical manufacturers should consider self-disclosure to OIG of potential kickback and excluded employee matters. A successful disclosure will serve as evidence that a manufacturer is committed to a corporate culture of compliance and maintains an effective compliance program, and will in all likelihood avoid imposition of a corporate integrity agreement (CIA).*

Background

On April 17, 2013, the HHS Office of Inspector General (OIG) posted its updated Provider Self-Disclosure Protocol (SDP), incorporating its previous Open Letter guidance into a "one stop" source and superseding its 1998 SDP.[1] In the new SDP, OIG emphasizes the benefits of self disclosure; specifically: (1) permissive exclusion releases without integrity agreement obligations (all but one of the 235 SDP cases were resolved without

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imposing integrity (e.g., CIA) obligations; (2) lower multipliers (typically 1.5 times actual damages); and (3) minimum settlements of $50,000 for anti-kickback statute related disclosures.

Within the last 15 years, over 800 disclosures have been resolved under the original SDP, amounting to more than $280 million in recoveries for Federal health care programs. For the most part, settlements under the Protocol have averaged under $120,000. Historically, non-providers such as medical device manufacturers rarely used the SDP, perhaps because it was originally envisioned (and written) for health care service providers. To debunk any concern that its SDP was limited to providers, OIG noted in its update that "a pharmaceutical or medical device manufacturer may use the SDP to disclose potential violations of the Federal anti-kickback statute (AKS) ... because such violations trigger CMP [Civil Monetary Penalties] liability...."

Under the new SDP, disclosing parties already subject to government oversight activities such as investigations or audits are not automatically precluded from using the SDP, provided that the disclosure is made in good faith and not an attempt to circumvent any ongoing inquiry. Manufacturers under CIAs may also use the SDP in addition to normal CIA reporting obligations.

Typical Manufacturer Conduct Eligible for the SDP

The SDP is available to facilitate the resolution of matters that potentially violate Federal criminal, civil, or administrative laws for which CMPs are authorized. In making a disclosure, a disclosing party should acknowledge that the conduct is a potential violation, and identify with specificity the laws that were potentially violated. Per OIG, "disclosing parties who avoid acknowledging that there is a potential violation are more likely to have unclear or incomplete submissions or unrealistic expectations about resolutions .... [S]tatements such as 'the Government may think there is a violation, but we disagree' raise questions about whether the matter is appropriate for the SDP." These admonitions were added to the Updated SDP because many prior self-disclosures were non-committal on potential legal violations, often resulting in longer timeframes for resolution or settlement.

In the context of device or pharmaceutical manufacturers, the SDP will be most relevant for purposes of disclosing Anti-Kickback Statute (AKS) violations and the employment of excluded individuals. Certain manufacturers with physician ownership may also consider disclosing Stark Law violations in addition to AKS violations[2] (e.g., physician ownership).[3]

Anti-Kickback Disclosures

The updated SDP provides more extensive details on what it expects to see in AKS related self-disclosures. Manufacturers who determine that self disclosure of an improper arrangement is appropriate should expect to provide specific details on the underlying arrangements, more context, and more legal analysis. OIG stresses that AKS compliance is a condition of payment of the federal healthcare programs (a legal conclusion that was hotly disputed until the Social Security Act was amended in 2010 by section 6404 of the Affordable Care Act), and requires a clear acknowledgment from disclosing parties that in their "reasonable assessment of the information available at the time of the disclosure, the subject arrangement(s) constitute potential violations of the AKS and, if applicable, the Stark Law." Given that the AKS is a criminal, intent-based statute, such disclosures can be challenging.

OIG also acknowledges that "[g]iven the various legal authorities at issue, OIG has broad discretion in determining an appropriate resolution in these cases," noting that it "generally" settles for an amount "based upon" a multiplier of the remuneration (and not federal health care program payments) conferred to the source of referrals. This can be a significant compromise inasmuch as the amount of alleged "kickback" is usually not nearly as significant as the "tainted claims" amount that the government often alleges serves as damages in False Claims Act matters.

Disclosure of Employment of an Excluded Individual

Historically, OIG has resolved many SDP submissions related to employing or contracting with individuals who appear on OIG's List of Excluded Individuals and Entities (LEIE).[4] If a manufacturer arranges or contracts (by employment or otherwise) with a person that it knows or should know is excluded by OIG, the manufacturer may be subject to CMP liability *if* the excluded person provides services payable, directly or indirectly, by a Federal health care program. This last factor is by no means a foregone conclusion for medical device manufacturers that generally are several relationships removed from the reimbursement of its devices from any federal health care program.

The SDP provides guidance to help outline information necessary for a complete excluded-person related disclosure. OIG expects disclosing entities to provide: (1) the identity of the excluded individual; (2) the job duties performed by that individual; (3) the dates of the individual's employment or contractual relationship; (4) a description of any background checks that the disclosing party completed before and/or during the individual's employment or

contract; (5) a description of the disclosing party's screening process and any flaw or breakdown in that process that led to the hiring or contracting with the excluded individual; (6) a description of how the conduct was discovered; and (7) a description of any corrective action (including a copy of any revised policy or procedure) implemented to prevent future hiring of excluded individuals. Note that "before disclosing the employment of an excluded individual, a disclosing party must screen all current employees and contractors against the LEIE. Once this has been done, the disclosing party should disclose all excluded persons in one submission." Put another way, a manufacturer should complete its internal investigation of any excluded persons with whom it may contract prior to self-disclosing under the SDP.

Calculation of damages in the employment of excluded individuals often proves difficult, especially for individuals who do not directly furnish healthcare services for which they directly bill Medicare or Medicaid. OIG advises that for purposes of resolving SDP matters not involving separately billable items or services (such as those furnished by administrative personnel), OIG will use " the disclosing party's total costs of employment or contracting[5] during the exclusion to estimate the value of the items and services provided by that excluded individual." This total amount will be multiplied by the disclosing party's revenue-based Federal health care program payor mix for the relevant time period. Under these circumstances, OIG admits, "the damages amounts can be difficult to quantify."

For a manufacturer, the amount that a Federal health care program has been damaged by that manufacturer's employment of, *e.g.*, an excluded sales representative, will be difficult to calculate because a manufacturer's "revenue-based Federal health care program payor mix for the relevant time period" may not be a workable proxy for actual damage to the Federal health care programs. Moreover, it is not at all clear that Federal health care programs cover or reimburse for marketing or other related services in connection with the manufacturing or distribution of medical devices. OIG tends to view such coverage and indirect payment broadly, however.

Manufacturers should also be mindful that on May 9, 2013 OIG published an Updated Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs (SAB) providing new guidance to the health care industry on how to handle individuals who have been excluded from federal health care programs.[6] The updated SAB replaces the OIG's original 1999 bulletin, and provides new guidance on best practices for screening employees and contractors against OIG's LEIE, as well as guidance on civil monetary penalty liability for entities that employ an excluded individual. Consistent with the SDP's inclusiveness, the term "provider" as used throughout the SAB includes "providers, suppliers, *pharmaceutical and device manufacturers*, and any other individual or entity, including a drug plan sponsor or managed care entity, that directly or indirectly furnishes, arranges, or pays for items or services" (emphasis supplied).

Implications

A manufacturer should carefully weigh the significant risks and benefits of a self-disclosure to OIG before engaging in the process. Unlike providers that may be subject to mandatory reporting and refund obligations for identified Medicare and Medicaid overpayments, medical device and pharmaceutical manufacturers have no such obligations. If the potential benefits of self-disclosing outweigh the risks, the SDP may provide a company with a helpful means to demonstrate to the OIG its effective compliance program. It may also provide companies a means to limit whistleblower complaints, with a greater measure of control over any subsequent government investigation and settlement. For example, a disclosing entity will have the opportunity to describe proactively the effectiveness of its compliance program, its culture of compliance, and the manner and means by which it discovered the problem and took immediate corrective action. Of course, self-disclosures do involve some element of risk that an investigation could expand. A thorough internal investigation prior to self-disclosure is prudent.

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. A related OIG podcast explaining the SDP is available at: https://oig.hhs.gov/newsroom/video/2011/heat_modules.asp#self-disclosure.
2. The SDP is not available for disclosure of an arrangement that involves *only* liability under the physician self-referral law (the Stark Law), without accompanying potential liability under the AKS for the same arrangement. Disclosing parties must analyze each arrangement involving a physician to determine whether it raises potential liability under the AKS, the Stark Law, or both laws. Stark-only conduct should be disclosed to CMS through its Self-Referral Disclosure Protocol, found at: http://www.cms.gov/PhysicianSelfReferral.
3. It is unlikely that a manufacturer would self disclose submission of improper claims to Federal health care programs. Nonetheless, manufacturers with provider or supplier subsidiaries may determine that the subsidiary engaged in unlawful billing practices.

4. Available online at https://exclusions.oig.hhs.gov.
5. The costs of employment or contracting include, but are not limited to, all salary and benefits and other money or items of value, health insurance, life insurance, disability insurance, and employer taxes paid related to employment of the individual (*e.g.*, employer's share of FICA and Medicare taxes).
6. 6 U.S. Department of Health & Human Services, Office of the Inspector General, Updated Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs (May 9, 2013), *available at* http://oig.hhs.gov/exclusions/files/sab-05092013.pdf.