**Considerations for Self-Disclosure: Who, What, and When? Guidelines for Compliance Professionals**
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 Voluntary self-disclosure of a potential overpayment matter or other noncompliant activity may be mandated by law under certain circumstances and/or potentially be appropriate (if not mandated by law) and offer protections too significant to pass up under the circumstances. Self-disclosures can be a useful option for not only overpayment matters, but a wide array of noncompliant activity, including misconduct and substantial violations of law. However, in considering the options for self-disclosure a provider or supplier should carefully evaluate the relevant pros and cons of each situation, as well as the most appropriate agency entry point for the self-disclosure. Careful consideration may lead to the conclusion that self-disclosure may not even be warranted, but this determination should be made after a careful and thorough analysis, taking into consideration the facts and applicable legal considerations, best practices, the risk of non-disclosure and ultimately the advice of experienced counsel for these matters.

A self-disclosure can be made to the Office of Inspector General of the Department of Health and Human Services (“OIG”); the Centers for Medicare & Medicaid Services (CMS); or the Department of Justice, U.S. Attorney's Office (DOJ), or even the Attorney General of the state of location. There are no hard and fast rules, and the specific and precise factual and legal circumstances of each potential disclosure matter will dictate whether, and when, to self-disclose, and which agency will be the best choice to receive an initial self-disclosure. Regardless of which agency receives the disclosure, all the relevant agencies coordinate with each other, to some extent, to assess the warranted criminal and civil liability of the specific matter disclosed.

**Deciding Whether to Make a Voluntary Self-Disclosure**In deciding whether and how to make a voluntary self-disclosure, health care organizations should generally engage in the following process:

* Investigate and evaluate the report of overpayment and/or noncompliant activity and/or potential misconduct.
	+ At first identification of possible noncompliant activity, consider the necessity of preserving and collecting all potentially relevant documents, both hard and electronic copy, and issuing a "hold notification" within the organization so no relevant hard copy or electronic information is dissipated. 18 U.S.C. §1519.
	+ Consider having persons unconnected to the potential noncompliant event conduct an internal investigation of the matter including review of relevant documents and other information (i.e., representatives of the organization's compliance department and/or independent consultants directed by counsel). *See* OIG Open Letter to Health Care Providers (4/15/08). See also OIG-SDP; OIG Provider Self-Disclosure Protocol, (update April 17, 2013) available at https://oig.hhs.gov/compliance/self-disclosure-info/files/provider-self-disclosure-protocol.pdf (hereinafter “OIG-SDP”).
	+ An individual or entity that becomes aware that it is retaining federal or state funds to which it is not entitled is obligated to return those funds, even if receiving the funds was a result of a simple mistake or error. *See* 42 U.S.C. §1320a-7b(a)(3).

**Comment:** The general process of making a voluntary self-disclosure consists of identifying the problematic conduct through investigation, fixing the conduct to prevent it from recurring, quantifying any damages associated with the past noncompliant activity, and making a timely, complete, and transparent disclosure.

* Consider with counsel the benefits and risks of making the voluntary self-disclosure.
	+ Evaluate the potential advantages including: creating good will with the government that may foster agency leniency towards the organization; limiting the possibility and disruption of a government-directed investigation; expediting the time it takes to formally resolve the matter; avoiding severe criminal liability; minimizing civil exposure; neutralizing whistleblower suits; reducing overall penalties; and reducing treble damages to double if the False Claims Act disclosure provision applies. 31 U.S.C. §3729(a)(7)(A)–(C).
	+ Evaluate the potential disadvantages including: financial losses associated with repayments and pre-disclosure internal investigations; potential increased government scrutiny of the self-disclosed matter to verify facts; no immunity against liability and damages and penalties; and resulting penalties for conduct that may have remained undiscovered.

 **Comment:** The reality for health care organizations may be that disclosure is not all that "voluntary," but may be a legal obligation and/or essential in today's enforcement and litigation environment in order to avoid greater criminal, civil and/or administrative liability. See 31 U.S.C. 3729(b)(3): See also 81 Fed. Reg. No. 29, Pgs. 7654-7684, (Feb. 12, 2016); 42 C.F.R. Part 401-405 (Medicare Program; Reporting and Returning Overpayments).

**If Self-Disclosure Is Elected**

* If after considering the advantages and disadvantages of self-disclosure the provider or supplier decides to voluntarily self-disclose, consider to which entity or agency voluntary self-disclosure should be made: OIG, CMS and/or DOJ.

**Submitting the self-disclosure through the HHS OIG-SDP**

* Providers and suppliers should recognize that participation in the OIG-SDP is contingent upon full cooperation throughout the process and complete disclosure of the facts and circumstances surrounding the violation. The OIG promotes provider self-evaluation and self-disclosure, encouraging openness and cooperation through use of its SDP. The April 17, 2013 OIG Self-Disclosure Protocol supersedes the earlier October 30, 1998 Provider Self-Disclosure Protocol at 63 Fed. Reg. 58399
	+ A unique feature of the OIG-SDP is its prior commitment under ordinary circumstances to resolve the self-disclosed liability with a release from program exclusion liability without imposing corporate integrity obligations and the availability, in most situations, of a multiplier of 1.5 of the single damages. See OIG-SDP.
	+ Make a good faith determination that the conduct in question potentially violates Federal, criminal, civil, or administrative laws aimed at health care programs. However, OIG will not accept disclosure of a matter that involves only liability under the physician self-referral ("Stark") law in the absence of a colorable anti-kickback statute violation. *See* OIG Open Letter to Health Care Providers (3/24/09) and OIG-SDP.
		- Determine whether the matter has a "colorable" anti-kickback violation.
		- **Comment:** The anti-kickback statute makes it a felony for a person to knowingly and willfully offer, pay, solicit, or receive anything of value in return for a referral, or to induce generation of business reimbursable under a federal health care program. 42 U.S.C. §1320a-7b(b). Furthermore, the person does not need actual knowledge or specific intent to commit a violation of the anti-kickback statute in order to violate the law. Affordable Care Act §6402(f). Thus, a violation occurs when the person meets the mental state and knowingly engages in the prohibited conduct, not necessarily if and when the person knows he/she is violating the anti-kickback statutory provisions. Is it ever prudent to concede or admit that individuals and/or the organization had the "intent" to violate the anti-kickback statute?
* If the matter at issue violates the anti-kickback statute, determine whether any statutory exceptions apply, 42 U.S.C. §1320a-7b(b)(3), or whether the matter fits an applicable safe harbor, 42 C.F.R. §1001.952.
* Ascertain whether the matter disclosed carries the minimum settlement amount of $50,000 necessary to resolve the matter through the OIG SDP. *See*  OIG Open Letter to Health Care Providers (3/24/09) and OIG-SDP; *see* also 42 U.S.C. §1320a-7a(a)(7).

**Comment:** The provider should disclose mere billing errors and overpayments not suggestive of fraudulent activity to the entity that processes the claims and issues payment on behalf of the government agency responsible for that particular Federal health care program (e.g., Medicare fiscal agent or Medicare Administrative Contractor – “MAC”). See OIG-SDP.

* A provider that uncovers misconduct or an ongoing fraud scheme within its organization should consider a more immediate preliminary disclosure to the appropriate government law enforcement agency, i.e., OIG-HHS and/or Department of Justice. See OIG-SDP.

 **Comment:** Failure to return a known overpayment within sixty (60) days from the date of identification is actionable by whistleblowers under the False Claims Act. *See* U.S.C. 3729(b)(3) and Medicare Program: Reporting and Returning Overpayments, 42 C.F.R. Part 401-405. Providers may also take advantage of the False Claims Act, which states that a self-disclosure made within 30 days after obtaining the information may limit damages to double damages rather than treble damages. 31 U.S.C. §3729(a)(7)(A)–(C). The application of this disclosure incentive varies from case to case, and consultation with counsel is recommended before relying on this False Claims Act statutory provision.

* Submit the self-disclosure following these elements of the OIG SDP (which can also be used as a guideline for self-disclosure to DOJ):
	+ Submit a complete description of the conduct being disclosed in accordance with the SDP Voluntary Disclosure Submission of Basic Information, including: the name, address, PIN, tax ID number, and disclosure of pertinent relationships and names and addresses of any related entities, and all other requested information.
	+ Submit a description of the provider's internal investigation findings or a commitment regarding when it will be completed, including the nature and extent of the improper or illegal practice and the circumstances of discovery and corrective action related to the matter.
	+ Submit an estimate of the damages to Federal health care programs and the methodology used to calculate that amount, or a commitment regarding when the provider will complete such an assessment, in accordance with the Self-Assessment Guidelines listed in the OIG-SDP. This self-assessment may be performed at the same time as the internal investigation, or commenced after the scope has been established of the noncompliance with program requirements.

 **Comment:** A provider must be in a position to complete the investigation and damages assessment within three months of submission to the OIG-SDP. *See* OIG Open Letter to Health Care Providers (4/15/08) and OIG-SDP.

* + Submit a certification stating that, to the best of the individual's knowledge, the report contains truthful information and is based on a good faith effort to assist OIG in its inquiry and verification of the disclosed matter.

 **Comment:** After receiving a self-disclosure, the OIG confers with DOJ and even other affected agencies to ensure that those agencies are aware of each disclosure before the OIG accepts a provider into the SDP. An acceptance into the OIG-SDP will suspend the obligation to report and return an overpayment within sixty (60) days of identification until a resolution of the self-disclosed matters. *See* OIG-SDP. The OIG also presents its review of the SDP matter to DOJ before the OIG resolves the matter. Ultimately, the OIG's agreement to resolve an SDP matter is not binding upon DOJ. *See* OIG Open Letter to Health Care Providers (4/24/06) and OIG-SDP. Additionally, the provider may request the participation of a representative of DOJ or a local U. S. Attorney's Office in settlement discussions in order to resolve potential parallel liability under the False Claims Act or other laws.

* + Submit the disclosure to: Assistant Inspector General for Investigative Operations, Office of Inspector General, Department of Health and Human Services, 330 Independence Avenue, S.W., Cohen Building, Room 5409, Washington, DC 20201.

**Submitting the Self-Disclosure Through CMS' Stark Self-Referral Disclosure Protocol. Voluntary Self-Referral Disclosure Protocol (revised March 27, 2017) (SRDP”), available at: https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/6409\_SRDP\_Protocol.pdf**The CMS Self-Referral Disclosure Protocol is open to all health care providers and suppliers, whether individuals or entities, and is not limited to any particular industry, medical specialty, or type of service.

* In deciding whether to self-disclose under CMS' SRDP over OIG's SDP, consider the following:
	+ The SRDP is intended to facilitate the resolution of only matters that, in the disclosing party's reasonable assessment, are actual or potential violations of the physician self-referral ("Stark") law. As stated above, the OIG's SDP will not apply to disclosure of a matter that involves only liability under the Stark law in the absence of a colorable anti-kickback statute violation. *See* OIG Open Letter to Health Care Providers (3/24/09) and OIG-SDP and SRDP. Thus, for matters dealing purely with Stark law issues, CMS' SRDP should be used over OIG's SDP. In the event a matter could be disclosed under both protocols, disclosing parties must choose, and should not disclose the same conduct under both CMS' SRDP and OIG's SDP. A potential Stark violation alone should be disclosed through the CMS SRDP. A Stark violation with a colorable anti-kickback violation with damages of at least $50,000.00 can be disclosed through the OIG SDP.
	+ On a basic level, the Stark law essentially prohibits certain physician self-referrals, which can be in the form of physician requests for an item or service and/or establishing a plan of care that involves furnishing designated health services under the statute. 42 U.S.C. §1395nn(c); 42 C.F.R. §411.350 et seq.
	+ The Stark law has a series of exceptions that generally apply to ownership interests, 42 U.S.C. §1395nn(c), and/or compensation arrangements, 42 U.S.C. §1395nn(e).

 **Comment:** The Stark law is a civil law and a strict liability statute and does not assess a parties' intent, and the conduct in question is clearly defined as lawful if it falls within an exception. The anti-kickback statute is primarily a criminal law, requires intent, and the conduct could still be considered lawful even if it does not meet any statutory exceptions or regulatory safe harbors. 64 Fed. Reg. 63518, 63520 (11/19/99). Thus, circumstances may arise where intentional inducement of referrals could be lawful under a Stark law exception, but at the same time violate the anti-kickback statute. These are issues and assessments which should be addressed with competent and experienced counsel.

* + CMS will coordinate, as necessary, with the OIG and DOJ, and may refer the matter to law enforcement for consideration under its criminal and/or civil authorities. *See* SRDP.
	+ The deadline for reporting and returning overpayments is the later of: (1) 60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable. *See* Affordable Care Act at Section 6402(a) and 42 C.F.R. Part 401-405.
	+ An acceptance into the SPDP will suspend the obligation to report and return an overpayment within sixty (60) days of identification until a resolution of the self-disclosed matter. *See* SRDP.
	+ Submit the self-disclosure following the requirements of CMS' SRDP:
		- Submit a description of actual or potential violations, including the specific information requested in the SRDP.
		- Submit the findings of a full examination including financial analysis, providing the specific information requested in the SRDP.
		- Include with all submissions a signed certification stating that, to the best of the individual's knowledge, the information provided contains truthful information and is based on a good faith effort to bring the matter to CMS' attention for the purpose of resolving any potential liabilities relating to the physician self-referral law. SRDP.
		- Submit the disclosure electronically to 1877SRDP@cms.hhs.gov. In addition, the disclosing party must submit an original and one copy by mail to the Division of Technical Payment Policy, ATTN: Provider and Supplier Self-Disclosure, Centers for Medicare & Medicaid Services, 7500 Security Blvd., Mailstop C4-25-02, Baltimore, MD 21224-1850.
	+ Be prepared to give CMS access to all financial statements, notes, disclosures, and other supporting documents.
	+ Be aware that CMS may consider the following factors in reducing the amounts otherwise due and owing: (1) the nature and extent of the improper or illegal practice; (2) the timeliness of the self-disclosure; (3) the cooperation in providing additional information related to the disclosure; (4) the litigation risk associated with the matter disclosed; and (5) the financial position of the disclosing party. *See* Affordable Care Act §6409(b).
	+ The time to complete the resolution of a self-disclosure under the SRDP will vary and depend to a large degree on the quality and thoroughness of the submissions received. *See* SRDP.

**Making a Self-Disclosure to the Department of Justice**

Like the OIG, DOJ is a law enforcement agency. However, unlike the OIG and CMS, DOJ does not have a formal protocol for a provider or supplier to follow in making a self-disclosure. DOJ has criminal jurisdiction and also civil authority under the False Claims Act. Thus, the FCA raises another basis for liability the provider should be aware of when going through the investigation, determination and disclosure process:

* FCA makes it illegal for any person who: (1) knowingly presents or causes the presentment of a false or fraudulent claim; (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to get a false or fraudulent claim paid; (3) conspires to do either of the above prohibitions; (4) knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly concealing or avoiding or decreasing an obligation to pay or transmit money or property to the government. 31 U.S.C. §3729(a)(1)(G); Fraud Enforcement and Recovery Act of 2009 (FERA), Pub. L. 111-21 (i.e. known overpayment) and the existence of a “known overpayment” without repayment within sixty (60) days from identification is enough to cause a violation, even without concealment.

**Comment**: The DOJ generally considers self-disclosed matters pursuant to resolution of False Claims Act liability and generally follows a policy of imposing a multiplier of damages of 2.0 or greater.

**General Guideline for Self-Disclosure Decision-Making**A general guideline for options for voluntary self-disclosure may be based on the nature of the matter:

* In an overpayment matter where the evidence, on balance, suggests billing errors as the result of "mistakes" — disclose to the entity that processes the claims and issues payment for a particular health care program (i.e., administrative contractor for Medicare and/or Medicaid programs);
* In an overpayment matter where the evidence suggests noncompliant conduct which may form the basis for liability under the Civil False Claims Act — disclose to the Department of Justice and/or the OIG-HHS; and
* In a matter where the evidence suggests noncompliant conduct forming the basis for criminal liability — disclose to the Department of Justice and/or OIG-HHS.

 **Comment:** There are pros and cons to each option and "one size definitely does not fit all" situations and an assessment of the risk of non-disclosure is always necessarily involved. The decision to make a self-disclosure and where, when, and how to make it can be a complex undertaking. These decisions should be made with the assistance of competent and experienced counsel to ensure that the important considerations can be taken into account and that navigation with the agency receiving the voluntary self-disclosure will be properly completed.

 **Additional Resources**

OIG Provider Self Disclosure Protocol, (update April 17 2013), *available at* https://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf

CMS Voluntary Self-Referral Disclosure Protocol, (revised Mar. 27, 2017), *available at* https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/6409­\_SRDP\_Protocol.pdf