OIG Provider Self-Disclosure Considerations

 The Department of Health and Human Services (HHS), Office of Inspector General (OIG) has historically emphasized the importance of “square dealing” with government supported health care programs and urged health care providers to adopt effective practices and procedures that are designed to promote compliance with applicable statutory and regulatory requirements and detect and prevent fraud. Toward that end, the OIG has stressed the importance of self-policing and the obligations of health care providers to disclose improper conduct and take remedial steps to both repay any amounts owed and prevent future re-occurrences of the wrongful practices.

I. Historical Background of the OIG's Provider Self-Disclosure Protocol:

In 1995, as part of the joint Department of Justice/ OIG health care fraud enforcement initiative known as ***“Operation Restore Trust,"*** the OIG announced the creation of a pilot Voluntary Disclosure Program. The program was limited to five states (New York, Florida, Illinois, Texas and California) and four health care provider types (home health agencies, skilled nursing facilities, durable medical equipment suppliers, hospices and providers were given an opportunity to voluntarily return monies owed and, potentially, receive preferential consideration from the government, albeit without any promises or guarantees. The pilot project ran until 1997 and although only a limited number of eligible providers chose to participate, the value of the program to both well-meaning providers and the government was unmistakable.

II. Issuance of the OIG's Provider Self-Disclosure Protocol in 1998:

On October 30, 1998, shortly after the conclusion of the Operation Restore Trust pilot, the OIG announced the creation of a broad Provider Self-Disclosure Protocol that was “open to all health care providers” and “not limited to any particular industry, medical specialty or type of service.” **[1]** Unlike the pilot program, the Provider Self-Disclosure Protocol was not limited to any particular industry, medical specialty or type of service and providers could seek to participate in the program even if they were already under investigation by OIG or DOJ. The OIG also issued open letters to the health care community in 2006, 2008 and 2009 to provide additional guidance, but in 2013 the OIG issued an Updated Self-Disclosure Protocol to address some of the concerns within the health care legal community and encourage participation in the process.**[2]**

III. Issuance of the OIG's Updated Provider Self-Disclosure Protocol in 2013:

In 2013, the OIG issued an updated version of its Provider Self-Disclosure Protocol. As the OIG has consistently publicized, the program is intended to give providers an opportunity to voluntarily disclose problematic conduct that resulted in a loss to the government and would likely result in a civil money penalty (or worse) if it was discovered through an investigation or other means. In return for voluntarily disclosing the conduct, providers that act like good corporate citizens get a discount on the penalty they pay. The protocol is available and intended *"to facilitate the resolution of matters that, in the disclosing party's reasonable assessment, potentially violate Federal criminal, civil or administrative laws for which CMPs are authorized*." Thus, while parties are not required to admit wrongdoing and settlements do not contain typically do not contain admissions, *"a disclosing party must acknowledge that the conduct is a potential violation…[and] explicitly identify the laws that were potentially violated."***[3]**

IV. Conduct Ineligible for the Program:

The OIG specifically states that overpayments or errors that do not potentially violate Federal criminal, civil or administrative are not eligible for the Self-Disclosure Protocol. Instead, they should be reported and repaid through the appropriate contractor voluntary refund process. In other words, if after a "*reasonable assessment*" of the conduct you feel that all you have found is an error or an overpayment that doesn't potentially violate Federal criminal, civil or administrative laws for which CMPs are authorized, the OIG does not want you (and in all likelihood, you do not want the OIG).

The program also isn't available for an opinion as to whether conduct or relationships violate the Anti-Kickback Statute or Stark laws. The Advisory Opinion process is the proper vehicle for obtaining a formal OIG advisory opinion. Finally, the Provider Self-Disclosure Protocol is not available for disclosures that only involve Stark violations. Those should be reported through the CMS Stark Self-Referral Disclosure Protocol. **[4]**

V. Components to be Included in a Self-Disclosure:

Providers present the findings of its internal investigation in the form of a detailed narrative the following information:

- *Basic provider information such as identification number(s)and tax identification number(s), Government payors (including contractors), etc. ;*
- *Description of ownership and related entities with organizational charts;*
- *Detailed description of the conduct and the individuals or entities involved;*
- *Identification of the federal criminal, civil or administrative laws potentially violated and the health care programs affected by the conduct;*
- *The corrective actions taken upon discovery of the conduct;*
- *Disclosure of any other inquiries relating to a Federal health care programs;*

- *The provider's representative and the individual authorized to enter into a settlement;*
- *A certification that the submission is truthful and based on a good faith effort to disclose for the purpose of resolving potential liability.* **[5]**

VI. Anti-Kickback Statute, Exclusion and False Billing Guidance:

One of the major improvements in the 2013 Update was its addition of specific sections for potential violations of the Anti-Kickback Statute, exclusion regulations and for the submission of false billings:

Disclosures Involving Violations of the Anti-Kickback Statute

- Disclosing providers include a narrative describing each arrangement and why it potentially violated the Anti-Kickback Statute and, if applicable, the Stark Law.
- The Self-Disclosure Protocol also lists several examples of the type of information that the OIG finds helpful in assessing and resolving disclosed conduct.
- Additionally, the OIG reaffirmed that its general approach for resolving potential Anti-Kickback Statute violations is to apply a multiplier to the remuneration conferred by the disclosing party to the entity or individual making the referral.

Disclosures involving Excluded Persons

- The original guidance made no mention of exclusion related disclosures and the Update provides a detailed disclosure protocol.
- The Self-Disclosure Protocol contains fairly detailed guidance for calculating single damages involving persons that do not provide directly billable services where none previously existed.

Disclosures Involving False Billings

- Requires an estimate the financial impact to all government health care programs that considers all affected claims or a statistically valid sample of all claims.
- Provides guidance on the creating statistically valid samples.

VII. Potential Benefits of Participating in the Provider Self-Disclosure Protocol:

The OIG identifies the following benefits that can result from participation in the self- disclosure program:

- The OIG believes that individuals or entities that use the Self-Disclosure Protocol and cooperate during the process deserve to pay a lower multiplier on single damages than

would normally be required in resolving a Government-initiated investigation.
- There is a presumption against requiring integrity agreements where there is a good faith disclosure of potential fraud;
- Potential for mitigation of exposure under the “60-day rule.”
- A commitment by the OIG to “working with” those who avail themselves of the Self-Disclosure Protocol in good faith and in full cooperation.

Other potential benefits include:

- “Good Corporate Citizen” label and potential for an expedited resolution.
- You are better situated to give positive, balanced impression.
- Reduced likelihood of the imposition of exclusion or an integrity agreement.
- Potential benefits under the sentencing guidelines.
- Reduced likelihood a *qui tam* (you reported the problem, not a whistleblower).
- Reducing the need for an outside investigation.
- Permits a disclosing provider to maintain a greater degree of control, minimize expense and disruption.

VIII. Things to Consider When Deciding Whether or Not to Participate in the Provider Self-Disclosure Protocol:

Whenever faced with the realization that your practice or clinic has engaged in wrongful conduct which has resulted in improper billings to one or more government health care programs, it is important to remember one of life’s first lessons — *“If it doesn’t belong to you, give it back.”* Here are a few other things to think about:

- The Provider Self-Disclosure Protocol does not cover errors or mistakes. By participating, what are you saying about the conduct at issue?
- When you participate, you will be asked to explain why you believe a federal civil, criminal or administrative law has been violated.
- You are going to be asked to identify the individuals responsible for the improper conduct or practice.
- You are going to be asked about the corrective measures you have taken and whether any disciplinary action was taken against the individual(s) responsible for the problems now being disclosed.
- There are no promises or guarantees inherent in the protocol.
- The OIG cannot waive rights of third parties—other Federal agencies and private payors can still come after your organization for improper claims you may have submitted to their programs.
- The internal investigation you conducted could serve as a roadmap for prosecutors.
- Admissions against interest may be used against you.
- Neither the OIG nor the DOJ is limited to investigating only what you disclosed to the OIG in

connection with the program.
- The investigation may be expanded to other billing areas.
- Be prepared to share all audit work papers.

IX. Other Self-Disclosure Options Available to You and Your Organization:

Always remember that the point of the Provider Self-Disclosure Protocol is to create a vehicle for providers to: (1) Disclose problematic conduct, that (2) Resulted in a loss to the government, which (3) Would likely to result in a civil money penalty (or worse) once discovered. In return for the disclosure, providers get a discount on the penalty they pay – but they will still have to pay some amount as a penalty. Therefore, if a reasonable assessment of the conduct under your consideration didn't violate any rules that warrant a penalty, you can and should, consider other options. After all, the OIG specifically states that errors or overpayments are not eligible for the program. Alternative disclosure options include:

***(1) Contractor Disclosure Programs*:** All CMS Contractors are required to have provider disclosure programs for overpayments and/or errors. While Contractor programs can also be difficult to navigate, they are generally not as onerous as the OIG's protocol and, more importantly, there is no expectation of penalties. If appropriate, this if often an excellent option for consideration.

***(2) CMS Stark Self-Disclosure Protocol (SSDP)*:** The SSDP is complex protocol that is similar to the OIG's protocol in that it requires full disclosure of all of the underlying facts and circumstances of the potential violation. Consideration of the SSDP should be made with the full participation of counsel.

(3) Disclosing Directly to the Department of Justice*:** Under certain limited circumstances, disclosure to the DOJ might be a provider's best option. For example, there is a provision under the Federal False Claims Act that allows for a reduction of penalties for providers that self-disclose to the agency. There may also be considerations of criminal law that might suggest this approach. ***HOWEVER, a provider should never consider taking this approach without the full consultation and participation of counsel.

As the above outline reflects, there are a number of factors to be considered prior to deciding whether or not to participate in the OIG's Provider Self-Disclosure Protocol. If you are considering the protocol, we recommend that you first contact qualified health law counsel for assistance. Liles Parker attorneys include a number of former Federal

prosecutors, all of whom served in significant positions at the Department of Justice. Our attorneys have extensive experience counseling health care clients regarding the benefits and disadvantages of participating in the program. For a free consultation regarding your case, give us a call. 1 (800) 475-1906.

[1] The 1998 Self-Disclosure Protocol is found at: **https://oig.hhs.gov/authorities/docs/selfdisclosure.pdf**

[2] The OIG's Updated Self-Disclosure Protocol can be found at the following link: **https://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf**

[3] 2013 Updated Self-Disclosure, at pg. 3

[4] See, **http://www.cms.gov/PhysicianSelfReferral**

[5] 2013 Updated Self-Disclosure, at pgs. 5–6.