

## CMS Voluntary Self-Referral Disclosure Protocol

*I. Introduction*

The Affordable Care Act (ACA), enacted on March 23, 2010, provides for the establishment of a voluntary self-disclosure protocol, under which providers of services and suppliers may self-disclose actual or potential violations of the physician self-referral statute (section 1877 of the Social Security Act). The physician self-referral statute prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation), unless an exception applies; prohibits the entity from presenting or causing to be presented claims to Medicare (or billing another individual, entity, or third-party payer) for those referred services; and establishes a number of specific exceptions and grants the Secretary of Health and Human Services (HHS) the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.

Specifically, section 6409 of the ACA requires the Secretary of HHS, in cooperation with the Inspector General of HHS to establish a Medicare self-referral disclosure protocol (SRDP) that sets forth a process for providers of services and suppliers to self-disclose actual or potential violations of the physician self-referral statute. Section 6409 of the ACA requires the Secretary of HHS to inform providers of services and suppliers of how to disclose an actual or potential violation pursuant to the protocol through publication on the CMS website. Furthermore, section 6409 of the ACA mandates that the SRDP include direction to health care providers of services and suppliers on the specific person, official, or office to whom such disclosures shall be made and instruction on the implication of the SRDP on corporate integrity agreements and corporate compliance agreements. Section 6409(b) of the ACA grants the Secretary of HHS the authority to reduce the amount due and owing for all violations of the physician self-referral statute. In establishing the amount by which an overpayment resulting from a violation(s) may be reduced, the Secretary may consider: the nature and extent of the improper or illegal practice; the timeliness of such disclosure; the cooperation in providing additional information related to the disclosure; and such other factors as the Secretary considers appropriate. Section 6409(a)(3) of the ACA explicitly states that the SRDP is separate from the advisory opinion process related to physician referrals set forth in 42 C.F.R. §§ 411.370 through 411.389. Thus, a provider of services or supplier may not disclose an actual or potential violation(s) through the SRDP and request an advisory opinion for conduct underlying the same arrangement(s) concurrently.

Section 6402 of the ACA establishes a deadline for reporting and returning overpayments by the later of: (1) the date which is 60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable. At the time the provider of services or supplier electronically submits a disclosure under the SRDP (and receives email confirmation from CMS that the disclosure has been received), the obligation under section 6402 of the ACA to return any potential overpayment within 60 days will be suspended until a settlement agreement is entered, the provider of services or supplier withdraws from the SRDP, or CMS removes the provider of services or supplier from the SRDP.

## *II. The SRDP*

The SRDP is open to all health care providers of services and suppliers, whether individuals or entities, and is not limited to any particular industry, medical specialty, or type of service. For purposes of the SRDP, “providers of services” and “suppliers” will be referred to as “disclosing parties.” The fact that a disclosing party is already subject to Government inquiry (including investigations, audits or routine oversight activities) will not automatically preclude acceptance of a disclosure. The disclosure, however, must be made in good faith. A disclosing party that attempts to circumvent an ongoing inquiry or fails to fully cooperate during the self-disclosure process will be removed from the SRDP.

The SRDP cannot be used to obtain a CMS determination as to whether an actual or potential violation of the physician self-referral law occurred. As stated above and in section 6409(a)(3) of the ACA, the SRDP is separate from the CMS physician self-referral advisory opinion process. 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 law. Thus, a disclosing party should make a submission to the SRDP with the intention of resolving its overpayment liability exposure for the conduct it identified.

CMS will review the circumstances surrounding the matter disclosed to determine an appropriate resolution. In some instances, Medicare contractors may be responsible for processing any identified overpayment. CMS is not bound by any conclusions made by the disclosing party under the SRDP and is not obligated to resolve the matter in any particular manner. Nevertheless, CMS will work closely with a disclosing party that structures its disclosure in accordance with the SRDP to reach an effective and appropriate resolution. As a condition of disclosing a matter pursuant to the SRDP, the disclosing party agrees that no appeal rights attach to claims relating to the conduct disclosed if resolved through a settlement agreement. If the disclosing party withdraws or is removed from the SRDP, the disclosing party may appeal any overpayment demand letter in accordance with applicable regulations. Furthermore, as a condition of entering the SRDP, providers of services and suppliers agree that if they are denied acceptance into the SRDP, withdraw from the SRDP, or are removed from the SRDP by CMS, the reopening rules at 42 C.F.R. §§ 405.980 through 405.986 shall apply from the date of the initial disclosure to CMS.

## *III. Cooperation with OIG and the Department of Justice (DOJ)*

Participation in the SRDP is limited to actual or potential violations of the physician self-referral statute. The OIG’s Self-Disclosure Protocol is available for disclosing conduct that raises potential liabilities under other federal criminal, civil, or administrative laws. *See* 63 Fed. Reg. 58399 (Oct. 30, 1998); OIG’s Open Letter to Health Care Providers, March 24, 2009. For example, conduct that raises liability risks under the physician self-referral statute may also raise liability risks under the OIG’s civil monetary penalty authorities regarding the federal anti-kickback statute and should be disclosed through the OIG’s Self-Disclosure Protocol. Disclosing parties should not disclose the same conduct under both the SRDP and OIG’s Self-Disclosure Protocol.

Upon review of the disclosing party's disclosure submission(s), CMS will coordinate with the OIG and DOJ. CMS may conclude that the disclosed matter warrants a referral to law enforcement for consideration under its civil and/or criminal authorities. When appropriate, CMS may use a disclosing party's submission(s) to prepare a recommendation to OIG and DOJ for resolution of False Claims Act, civil monetary penalty, or other liability. Accordingly, the disclosing party's initial decision of where to disclose a matter involving non-compliance with section 1877 of the Social Security Act should be made carefully.

Disclosing parties who currently have corporate integrity agreements (CIAs) or certification of compliance agreements (CCAs) with the OIG should also comply with any disclosure or reportable event requirements under such agreements. Effective September 23, 2010, a reportable event solely related to a Stark issue should be disclosed to CMS using the requirements set forth in this self-disclosure protocol with a copy to the disclosing party's OIG monitor. Any further questions about any applicable CIA or CCA requirements should be directed to the disclosing party's OIG monitor.

#### *IV. Instructions Regarding the Voluntary Disclosure Submission*

The disclosing party will be expected to make a submission as follows.

##### A. Disclosure

The complete disclosure and all relevant supporting documents must be submitted electronically to [1877SRDP@cms.hhs.gov](mailto:1877SRDP@cms.hhs.gov). In addition, the disclosing provider of services or supplier, or in the case of an entity, its Chief Executive Officer, Chief Financial Officer, or other authorized representative, must submit a signed certification stating that, to the best of the individual's knowledge and belief, the information provided contains truthful information and is based on a good faith effort to assist CMS in its inquiry and verification of the disclosed matter. A hard copy of the signed certification **only** must be sent to: Division of Technical Payment Policy, ATTN: Provider and Supplier Self-Disclosure, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mailstop C4-25-02, Baltimore, MD 21244-1850. As noted above, the disclosure and all relevant supporting materials must be submitted electronically to [1877SRDP@cms.hhs.gov](mailto:1877SRDP@cms.hhs.gov). Submissions by facsimile will not be accepted.

When the disclosing party submits a disclosure electronically, CMS will immediately send a response email acknowledging receipt of the submission. After reviewing the submission, CMS will send a letter to the disclosing party or its representative either accepting or rejecting the disclosure.

##### B. Required Information Related to the Matter Disclosed

###### 1. Description of Actual or Potential Violation(s)

The submission should include the following—

a. The name, address, national provider identification numbers (NPIs), CMS Certification Number(s) (CCN), and tax identification number(s) of the disclosing party. If the disclosing

party is an entity that is owned, controlled, or is otherwise part of a system or network, include a description or diagram that explains the pertinent relationships and the names and addresses of any related entities, as well as any affected corporate divisions, departments, or branches. Additionally, provide the name and address of the disclosing party's designated representative for purposes of the voluntary disclosure.

b. A description of the nature of the matter being disclosed, including the type of financial relationship(s), the parties involved, the specific time periods the disclosing party may have been out of compliance (and, if applicable, the dates or a range of dates whereby the conduct was cured), and type of designated health service claims at issue. In addition, the description must include the type of transaction or other conduct giving rise to the matter, and the names of entities and individuals believed to be implicated and an explanation of their roles in the matter.

c. A statement from the disclosing party regarding why it believes a violation of the physician self-referral law may have occurred, including a complete legal analysis of the application of the physician self-referral law to the conduct and any physician self-referral exception that applies to the conduct and/or that the disclosing party attempted to use. This analysis must identify and explain which element(s) of the applicable exception(s) were met and which element(s) were not met. In addition, the submission should include a description of the potential causes of the incident or practice (e.g., intentional conduct, lack of internal controls, circumvention of corporate procedures or Government regulations).

d. The circumstances under which the disclosed matter was discovered and the measures taken upon discovery to address the actual or potential violation and prevent future instances of noncompliance.

e. A statement identifying whether the disclosing party has a history of similar conduct, or has any prior criminal, civil, and regulatory enforcement actions (including payment suspensions) against it.

f. A description of the existence and adequacy of a pre-existing compliance program that the disclosing party had, and all efforts by the disclosing party to prevent a recurrence of the incident or practice in the affected division as well as in any related health care entities (e.g., new accounting or internal control procedures, new training programs, increased internal audit efforts, increased supervision by higher management). Further describe the measures or actions taken by the disclosing party to restructure the arrangement or non-compliant relationship.

g. A description of appropriate notices, if applicable, provided to other Government agencies, (e.g., Securities and Exchange Commission, Internal Revenue Service) in connection with the disclosed matter.

h. An indication of whether the disclosing party has knowledge that the matter is under current inquiry by a Government agency or contractor. If the disclosing party has knowledge of a pending inquiry, identify any such Government agency or contractor, and the individual representatives involved, if known. The disclosing party must also disclose whether it is under investigation or other inquiry for other matters relating to a Federal health care program, including any matters it has disclosed to other Government entities, and provide similar information relating to those other matters.

## 2. Financial Analysis

As part of its initial disclosure submission, the disclosing party must conduct a financial analysis relating to the actual or potential violation(s) of the physician self-referral law, and report its findings to CMS. A disclosing party should demonstrate that a full examination of the disclosed conduct has occurred. The financial analysis should—

- a. Set forth the total amount, itemized by year, that is actually or potentially due and owing based upon the applicable “look back” period. The “look back” period is the time during which the disclosing party may not have been in compliance with the physician self-referral law.
- b. Describe the methodology used to set forth the amount that is actually or potentially due and owing. Indicate whether estimates were used, and, if so, how they were calculated.
- c. Set forth the total amount of remuneration a physician(s) received as a result of an actual or potential violation(s) based upon the applicable “look back” period.
- d. Provide a summary of any auditing activity undertaken and a summary of the documents the disclosing party has relied upon relating to the actual or potential violation(s) disclosed.

### C. Certification

The disclosing party, or in the case of an entity its Chief Executive Officer, Chief Financial Officer, or other authorized representative, must submit to CMS, along 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 the disclosed potential liabilities relating to the physician self-referral law.

### *V. CMS’ Verification*

Upon receipt of a disclosing party’s disclosure submission, CMS will begin its verification of the disclosed information. The extent of CMS’ verification effort will depend, in large part, upon the quality and thoroughness of the submissions received. Matters uncovered during the verification process, which are outside of the scope of the matter disclosed to CMS, may be treated as new matters outside the SRDP.

To facilitate CMS’ verification and validation processes, CMS must have access to all financial statements, notes, disclosures, and other supporting documents without the assertion of privileges or limitations on the information produced. In the normal course of verification, CMS will not request production of written communications subject to the attorney-client privilege. However, there may be documents or other materials, which CMS believes are critical to resolving the disclosure, that may be covered by the work product doctrine. CMS is prepared to discuss with a disclosing party’s counsel ways to gain access to the underlying information without waiver of protections provided by an appropriately asserted claim of privilege.

CMS may request additional information, such as financial statements, income tax returns, and other documents, if needed. If additional information is requested, a disclosing party will be given at least 30 days to furnish the information.

#### *VI. Payments*

Because of the need to verify the information provided by a disclosing party, CMS will not accept payments of presumed overpayments determined by the disclosing party prior to the completion of CMS' inquiry. However, the disclosing party is encouraged to place the funds in an interest-bearing escrow account to ensure adequate resources have been set aside to repay amounts owed. While the matter is under CMS inquiry, the disclosing party must refrain from making payment relating to the disclosed matter to the Federal health care programs or their contractors without CMS' prior consent. If CMS consents, the disclosing party will be required to acknowledge in writing that the acceptance of the payment does not constitute the Government's agreement as to the amount of losses suffered by the programs as a result of the disclosed matter, and does not relieve the disclosing party of any criminal, civil, or civil monetary penalty liability, nor does it offer a defense to any further administrative, civil, or criminal actions against the disclosing party. We remind disclosing parties, pursuant to section 1877(g)(2) of the Act, that any amounts collected from individuals that were billed in violation of the physician self-referral law must be refunded to the individuals on a timely basis.

#### *VII. Cooperation and Removal from the SRDP and Timeliness of Disclosure*

The disclosing party's diligent and good faith cooperation throughout the entire process is essential. Accordingly, CMS expects to receive documents and information from the disclosing party that relate to the disclosed matter without the need to resort to compulsory methods. If a disclosing party fails to work in good faith with CMS to resolve the disclosed matter, that lack of cooperation will be considered when CMS assesses the appropriate resolution of the matter. Similarly, the intentional submission of false or otherwise untruthful information, as well as the intentional omission of relevant information, will be referred to DOJ or other Federal agencies and could, in itself, result in criminal and/or civil sanctions, as well as exclusion from participation in the Federal health care programs. Furthermore, it is imperative for disclosing parties to disclose matters in a timely fashion once identified. As stated above, section 6402 of the ACA establishes a deadline for reporting and returning overpayments by the later of: (1) the date which is 60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable.

#### *VIII. Factors Considered in Reducing the Amounts Owed*

The factors CMS may consider in reducing the amounts otherwise owed include: (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. While CMS may consider these factors in determining whether reduction in any amounts owed is appropriate, CMS is not obligated to reduce any amounts due and owing. CMS will make an

individual determination as to whether a reduction is appropriate based on the facts and circumstances of each disclosed actual or potential violation. The nature and circumstances concerning a physician self-referral violation can vary given the scope of the physician self-referral law and the health care industry. Given this variability, CMS needs to evaluate each matter in order to determine the severity of the physician self-referral law violation and an appropriate resolution for the conduct.

#### PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-1106. The time required to complete this information collection is estimated to average 24 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, MD 21244-1850.