2400.13. SELF-REFERRAL DISCLOSURE PROTOCOL

A. Background, Need for the Protocol, and Statutory Mandate

The Patient Protection and Affordable Care Act directed the Secretary of Health and Human Services, in cooperation with the HHS Office of Inspector General, to establish ''a protocol to enable health care providers of services and suppliers to disclose an actual or potential violation of section 1877 of the Social Security Act (42 U.S.C. 1395nn)'' and authorized the secretary ''to reduce the amount due and owing for all violations under section 1877 of the Social Security Act to an amount less than that specified in subsection (g) of such section.''[1]

Before Congress made the explicit grant of authority to compromise claims under the Stark law, CMS consistently maintained that it had no authority to settle an overpayment resulting from a violation of the law for less than the full overpayment amount because Stark is a strict liability statute.[2]

Moreover, the practical need for a mechanism to allow for the settlement of Stark law liability was made more compelling by the April 2009 announcement by the Health and Human Services Office of Inspector General that it would no longer accept disclosure of Stark violations under the OIG's self-disclosure protocol, unless the disclosed conduct also presented a colorable violation of the anti-kickback statute, 42 U.S.C. § 1320a-7b(b), and that it would require a minimum settlement amount of $50,000 under its protocol.[3]

When combined with ''strict liability'' for all DHS billed in violation of the Stark law, the above factors produced what was widely believed in the health care industry to be intolerable results in the many situations in which application of the Stark law is uncertain or conduct satisfies the essential substance of the law, but fails to meet all technical requirements (e.g., a failure to reduce an otherwise compliant compensation arrangement to a signed writing).[4] Section 6402 of the Affordable Care Act exacerbated the problem by requiring that overpayments be reported and returned within 60 days of identification (or, if later, the due date of any corresponding cost report, if applicable)[5], especially in light of the amended provisions of the False Claims Act and Civil Monetary Penalties law that significantly increased liability exposure for failure to return an overpayment.[6]

Comment: CMS's SRDP was, therefore, eagerly anticipated as a much-needed mechanism for hospitals, phy-

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[1] Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (Mar. 23, 2010), § 6409(a)(1) and 6409(b). The act, as amended by the Health and Education Reconciliation Act of 2010, Pub. L. No. 111-152 (Mar. 30, 2010) are hereinafter collectively referred to as the Affordable Care Act.

[2] *See, e.g.*, CMS commentary explaining its reasoning in providing only very limited relief from the Stark law's reach through regulatory exceptions: ''As we stated in the proposed rule [72 FR 38185] we do not have the authority to waive violations of the physician self-referral law, regardless of their nature. We have the authority under section 1877(b)(4) of the Act to create (or modify) regulatory exceptions only to the extent that there is no risk of program or patient abuse.'' 73 Fed. Reg. at 48705 (excerpt from the final fiscal year 2009 inpatient prospective payment system rule, 73 Fed. Reg. 48434 (Aug. 19, 2008)). *See also* 73 Fed. Reg. at 48707 (discussing whether to provide an alternate method for satisfying certain requirements of the exceptions). CMS ultimately adopted regulatory exceptions only for: entities that did not have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the identity of the referring physician, if the claim otherwise complies with all laws and regulations, 42 C.F.R. § 411.353(e)); certain arrangements involving temporary noncompliance, 42 C.F.R. § 411.353(f); and certain arrangements involving temporary noncompliance with signature requirements, 42 C.F.R. § 411.353(g).

[3] Daniel R. Levinson, Inspector General, Department of Health of Human Services, An Open Letter to Health Care Providers (Mar. 24, 2009), *reproduced at Health Care Fraud and Abuse: Enforcement and Compliance* (BNA's Health L. & Bus. Series No. 2600), Doc. 20. Doc. 20 also reproduces other open letters from the inspector general modifying the OIG self-disclosure protocol, which was originally set out at 63 Fed. Reg. 58399 (Oct. 30, 1998), and is *reproduced at* BNA's Health L. & Bus. Series No. 2600, Doc. 19. For a discussion of the OIG self-disclosure protocol for violations of the anti-kickback statute, see W. Bradley Tully, *Federal Anti-Kickback Law* (BNA's Health L. & Bus. Series No. 1500), § 1500.02.D.7. For a detailed discussion of the OIG's self-disclosure protocol and factors that should be considered in deciding whether to self-disclose, see BNA's Health L. & Bus. Series § 2600.09.

[4] *See, e.g.*, American Health Lawyers Association, ''A Public Policy Discussion: Taking the Measure of the Stark Law'' (2009).

[5] *See* 42 U.S.C. § 1320a-7k(d), Social Security Act § 1128J(d), Medicare and Medicaid program integrity provisions enacted by the Affordable Care Act § 6402(a).

[6] *See* 31 U.S.C. § 3729 et seq., as amended by the Fraud Enforcement and Recovery Act of 2009 (FERA), Pub. L. 111-21 (enacted May 20, 2009) and again by the Affordable Care Act. 31 U.S.C. § 3729(a)(1)(G) imposes ''reverse'' FCA liability on a person who ''knowingly conceals or knowingly and improperly avoids or decreases *an obligation* to pay or transmit money or property to the Government (emphasis added). '' 31 U.S.C. § 3729(b)(3) in turn defines ''obligation'' as ''an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment.''

See also Affordable Care Act § 6402(d)(2)(A), which amended the CMP law, 42 U.S.C. § 1320a-7a, to make a person who ''knows of an overpayment (as defined in paragraph (4) of section 1128J(d) [42 U.S.C. § 1320a-7k(d)]) and does not report and return the overpayment in accordance with such section'' liable for CMPs. Note that confusion in the numbering of the provision was created by inconsistencies between the Affordable Care Act Affordable Care Act §§ 6402(d)(2)(A) and 6408(a); § 6402(d)(2)(A) designated the quoted provision as 42 U.S.C. § 1320a-7a(a)(10). 42 U.S.C. § § 1320a-7k(d)(4)(B), for this purpose, in turn defines ''overpayment'' as ''any funds that a person receives or retains under title XVIII or XIX to

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sician practices, and other DHS entities to obtain a reasonable resolution following the discovery of an actual or potential Stark violation.[7] Whether the SRDP will measure up to its promise remains to be seen. As published, the SRDP provides little more than detailed instructions to DHS entities for submitting a disclosure, and the instructions largely mirror the OIG's voluntary disclosure protocol. The SRDP offers virtually no insight into how CMS might view specific types of actual or potential Stark violations, including how CMS will apply its stated criteria for arriving at settlement at less than the maximum overpayment liability. The ultimate utility of the SRDP will thus largely be determined as CMS applies the protocol to specific disclosures. The overall tone of the SRDP and CMS's historic unwillingness to compromise Stark liability may initially dissuade Medicare providers and suppliers with significant potential overpayment liability from diving into these uncharted waters, even though there are no safer places to swim.

B. Parties and Matters Eligible for the SRDP

The SRDP is available to all Medicare providers and suppliers (''disclosing parties'') for resolution of actual or potential violations of the Stark law. A disclosing party already being the subject of a government inquiry, whether an investigation, an audit or a routine oversight activity, will not automatically preclude 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 in the self-disclosure process will be removed from the SRDP.''[8]

Consistent with its statutory mandate,[9] the SRDP is not available for conduct that is concurrently the subject of a request for an advisory opinion under the Stark law.[10]

The SRDP states:

> 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. . . . 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. As provided in the physician self-referral law, no payment may be made for designated health services that are provided in violation of the physician self-referral law.[11]
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> **Comment:** The above statement is one of several in the protocol that may, at least initially, give DHS entities with substantial potential overpayment liability pause before deciding to participate in the SRDP, particularly if the basis for that potential liability is not clear, since it strongly suggests that a disclosure will not be resolved without the disclosing party making at least some payment. Although the prohibition on a disclosing party's simultaneously seeking an advisory opinion may be reasonable, the statement's implication that a ''potential'' violation always requires some payment does not necessarily follow from the Affordable Care Act's directive to create a self-disclosure protocol. Perhaps CMS wishes to avoid opening the doors to disclosures under the SRDP by parties who believe it likely that no violation has occurred but prefer to try the SRDP process rather than attempt to obtain an advisory opinion.

The protocol similarly states that parties should not disclose the same conduct under both the SRDP and the HHS OIG's self-disclosure protocol:

> 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.[12]

A party who is operating under a corporate integrity agreement or certification of compliance agreement with the HHS OIG may use the SRDP to disclose to CMS events solely related to a Stark issue. The disclosing party should provide a copy of the SRDP submission to the disclosing party's OIG monitor and should also continue to comply with any disclosure or reportable event requirements under the CIA or CCA.[13]

C. SRDP Disclosure Submission

The disclosure must be submitted electronically to CMS and an original and one copy also must be submitted by regular mail. CMS will not accept facsimile submissions.[14]

The SRDP outlines in detail the information that must be part of a disclosure submission, grouping the required information by type, as discussed below.

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which the person, after applicable reconciliation, is not entitled under such title.''

[7] *See, e.g.*, letter from Rick Pollack, Executive Vice President, American Hospital Association, to Kathleen Sebelious, Secretary, Department of Health and Human Services (July 16, 2010), *available at* http://www.aha.org/aha/letter/2010/100716-cl-ppaca.pdf.

[8] SRDP § II.

[9] Affordable Care Act § 6409(a)(3) states: ''The SRDP shall be separate from the advisory opinion process set forth in regulations implementing section 1877(g) of the Social Security Act.''

The regulations implementing the advisory opinion process are 42 C.F.R. §§ 411.370-42 C.F.R. § 411.389, *reproduced at* Doc. 9. The process for obtaining an opinion, which has been little used to date, is discussed a *Advisory Opinions, supra* § 2400.02.F.

[10] SRDP § I.

[11] SRDP § II.

[12] SRDP § III.

[13] SRDP § III.

[14] SRDP § IV.A.

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1. Disclosing party and its representative

The SRDP requires the following information to be included in the submission:

- the disclosing party's name, address, national provider identification numbers (NPIs), CMS Certification Number(s) (CCN), and tax identification number(s);
- if the disclosing party is an entity that is owned, controlled or is otherwise part of a system or network, a description of, 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; and
- the name and address of the disclosing party's designated representative for purposes of the disclosure.[15]

2. Actual or potential violations

The protocol requires extensive and specific information about the actual or potential violations the disclosing party wishes to settle, as well as information about the underlying conduct and the disclosing party's response to the discovery of the potential violations.[16] Specifically, the disclosing submission must include the following:

- 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) when the conduct was cured), and the type of DHS claims at issue, as well as 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;
- a statement indicating why the disclosing party believes a Stark violation 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 elements of the applicable exception were met and which were not, as well as describe the potential causes of the incident or practice, e.g., intentional conduct, lack of internal controls, circumvention of corporate procedures or government regulations);
- a description of the circumstances under which the disclosed matter was discovered and the measures the disclosing party took upon discovery to address it and prevent future abuses;
- a statement indicating whether the disclosing party has a history of ''similar conduct,'' or was the subject of any prior criminal, civil, and regulatory enforcement actions (including payment suspensions);
- a description of the existence and adequacy of the disclosing party's preexisting compliance program, its efforts to prevent a recurrence of the incident or practice in the affected division and in any related health care entities (including, e.g., implementation of new accounting or internal control procedures, increased internal audit efforts, increased supervision by higher management or through training), and measures or actions it took to restructure the arrangement or noncompliant relationship;
- a description of any appropriate notices the disclosing party provided to other government agencies (e.g., the Securities and Exchange Commission or Internal Revenue Service) in connection with the disclosed matter;
- an indication of whether the disclosing party has knowledge that the matter is under current inquiry by a government agency or contractor, and if it does have knowledge of a pending inquiry, the identify of the government entity or individual representatives involved; and
- if the disclosing party is under investigation or other inquiry for any other matters relating to a federal health care program (including matters it disclosed to other government entities), similar information relating to those other matters.

3. Financial analysis and report

The disclosing party must conduct a financial analysis that would demonstrate to CMS that a full examination of the disclosed conduct has occurred and report its findings to CMS.[17] The financial analysis report submitted must:

- set forth the total amount, itemized by year, that is actually or potentially due, based upon the applicable ''look back'' period (the entire time period during which the disclosing party may not have been in compliance);
- describe the methodology used to determine the amount that is actually or potentially due, including whether estimates were used, and, if so, how they were calculated; and
- summarize the auditing activity the disclosing party undertook and the documents it relied upon.

Comment: Before deciding to participate in the SRDP, a health care entity should take careful note of the requirement to set out an itemized, total dollar amount due, particularly if the conduct is long-standing and many referrals and claims are in issue. If the disclosing party should fail to reach a settlement with CMS under the SRDP, the disclosure of even *potential* liability, because of the required quantification, could possibly

[15] *See* SRDP § IV.B.1.a.
[16] *See* SRDP § IV.B.1.b-IV.B.1.h.
[17] *See* SRDP § IV.B.2.

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be used to support the contention that the disclosing party is a person who ''knows of an overpayment'' and does not return it, thus potentially triggering enhanced CMPs under the amendments made by the Affordable Care Act § 6402 and possible ''reverse'' FCA liability for retention of an overpayment.

4. Certification

The submission must include a signed certification by the disclosing party (or, in the case of an entity, its chief executive officer, chief financial officer, or other authorized representative) stating that, to the best of the individual's knowledge, the information provided is truthful and is based on a good faith effort to bring the matter to CMS's attention for the purpose of resolving any potential liabilities relating to the physician self-referral law.[18]

D. CMS Processing of the Disclosure Submission

CMS will immediately send an email to the disclosing party acknowledging receipt of the disclosing party's email submission. After reviewing and verifying the information in the disclosure submission, CMS will send a letter to the disclosing party or its representative either accepting or rejecting the disclosing party's entry into the SRDP.[19]

The protocol describes the extent and purpose of CMS review as follows:

> CMS will review the circumstances surrounding the matter disclosed to determine an appropriate resolution. . . . CMS is not bound by any conclusions made by the disclosing party under this protocol 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.[20]

To facilitate CMS's verification and validation processes, the protocol asserts that 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.''[21] The protocol provides, however, that CMS will not normally request production of written communications subject to the attorney-client privilege and will discuss with the disclosing party's counsel ways for CMS to obtain information covered by the work product doctrine that it deems ''critical to resolving the disclosure'' without the disclosing party waiving ''the protections provided by an appropriately asserted claim of privilege.''[22]

CMS may request additional information, such as financial statements, income tax returns, and other documents, if needed, and will give the disclosing party at least 30 days to furnish the requested information during the review and verification process. Matters uncovered during the verification process that are outside the scope of the matter disclosed to CMS may be treated as new matters outside the SRDP.[23]

The protocol emphasizes that the disclosing party's diligent and good faith cooperation throughout the entire process is essential and that, on the other hand, ''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.''[24]

The protocol itself cautions potential disclosing parties of the possible liability exposure through participation:

> 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 refer a matter involving noncompliance with section 1877 of the Social Security Act should be made carefully.[25]

Comment: The final sentence quoted above appears to be based upon a similar statement contained in the HHS OIG's voluntary disclosure protocol, which was made in the context of a discussion of whether a party should make a disclosure under the protocol or simply report to the Medicare administrative contractor.[26] This choice has little relevance under the SRDP; since a Medicare contractor cannot compromise potential Stark liability, disclosure and payment to the Medicare contractor is not an option unless a party wishes to return the full overpayment resulting from an alleged Stark violation. A party planning to return the entire overpayment would have no need to participate in the SRDP. Moreover, the protocol itself specifies the appropriate vehicle for disclosure and potential compromise: for Stark-only issues, that vehicle is the SRDP, and for conduct that also potentially implicates other statutes, the vehicle is the OIG's voluntary disclosure protocol.

E. Criteria for Settlement

The protocol outlines the following as factors CMS may consider in reducing the overpayment otherwise owed:

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[18] SRDP § IV.C.
[19] SRDP § IV.A.
[20] SRDP § II.
[21] SRDP § V.
[22] SRDP § V.
[23] SRDP § V.
[24] SRDP § VII.
[25] SRDP § III.
[26] 63 Fed. Reg. 58399, 58400-58401 (Oct. 30, 1998).

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- the nature and extent of the improper or illegal practice;
- the timeliness of the self-disclosure;[27]
- the cooperation in providing additional information related to the disclosure;
- the litigation risk associated with the matter disclosed; and
- the financial position of the disclosing party.[28]

Although CMS may consider these factors in determining whether reduction in an overpayment is appropriate, it is not required to reduce any amounts due:

> 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, it is necessary for CMS to evaluate each matter to determine the severity of the violation and an appropriate resolution for the conduct.[29]

> **Comment:** Perhaps the most disappointing aspect of the SRDP is CMS's failure to provide meaningful guidance on how it will typically resolve disclosures of different types of actual or potential Stark law violations. For example, how will inadvertent technical violations and other innocent mistakes, situations presenting ambiguity under the law or regulations, or instances where all services are clinically appropriate, well documented, and there is no harm to the Medicare program or beneficiaries be treated? How will the treatment of those circumstances differ from knowing or reckless violations? Insight into CMS's approaches to various scenarios must therefore await its actual disposition of disclosures under the SRDP. It also is unclear whether CMS will timely report individual settlements under the SRDP,[30] as the HHS OIG does for settlements under its voluntary disclosure protocol.[31]

F. Consequences of Disclosure under the SRDP

1. Payment

While a disclosure is pending before CMS under the SRDP:

> 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.[32]

The disclosing party is, however, ''encouraged to place the funds in an interest-bearing escrow account to ensure adequate resources have been set aside to repay amounts owed.''[33]

2. Suspension of time for returning overpayment under Affordable Care Act § 6402

The disclosing party's electronic submission under the SRDP and receipt of email confirmation from CMS that the disclosure has been received, suspends ''the obligation under Section 6402 of the ACA to return any potential overpayment within 60 days . . . 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.''[34]

> **Note:** As discussed above, Affordable Care Act § 6402 requires that an overpayment be returned by the later of (a) the date which is 60 days after the date on which the overpayment was identified, or (b) the date any corresponding cost report is due, if applicable. As drafted, the SRDP would not provide any relief for an overpayment disclosed more than 60 days after identification but before the due date of the applicable cost report.

3. Appeal rights

A party that resolves voluntarily disclosed actual or potential Stark liability through a settlement agreement under the SRDP has no appeal rights for claims relating to the conduct disclosed.[35] 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. Also as a condition of entering the SRDP,

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[27] CMS elsewhere elaborates on timeliness as follows: ''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.'' SRDP § VII.

[28] SRDP § VIII. The first three of the factors are mandated by Affordable Care Act § 6409(b).

[29] SRDP § VIII.

[30] Affordable Care Act § 6409(c) requires the HHS secretary, on or before March 23, 2012, to submit to Congress a report on the implementation of the SRDP the includes: (1) the number of health care providers and suppliers making disclosures; (2) the amounts collected; (3) the types of violations reported; and (4) other information that may be necessary to evaluate the impact of the SRDP.

[31] The OIG makes summaries of CMP settlements, including those reached under its self-disclosure protocol, available at http://oig.hhs.gov/fraud/enforcement/cmp/index.asp.

[32] SRDP § VI.

[33] SRDP § VI.

[34] SRDP § I.

[35] SRDP § II. The disclosing party is required to waive appeal rights as a condition of disclosing a matter pursuant to the SRDP.

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a disclosing party must agree that if it is denied acceptance into or withdraws from the SRDP or is removed from the SRDP by CMS, the reopening rules at 42 C.F.R. §§ 405.980 through 405.986 apply from the date of the initial disclosure to CMS.

4. Refunds to Medicare beneficiaries

CMS ''remind[s] disclosing parties, that under 42 U.S.C. § 1395nn(g)(2) 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.''[36]

Comment: The above statement does not indicate whether a disclosing party's obligations to beneficiaries are reduced, if CMS allows a reduction in the government's overpayment under the SRDP. This omission is significant, because failure to repay beneficiaries for amounts collected in violation of Stark creates liability under the Civil Monetary Penalties law.[37]

[36] SRDP § VI.

[37] *See* 42 C.F.R. § 1003.102(b)(9).

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