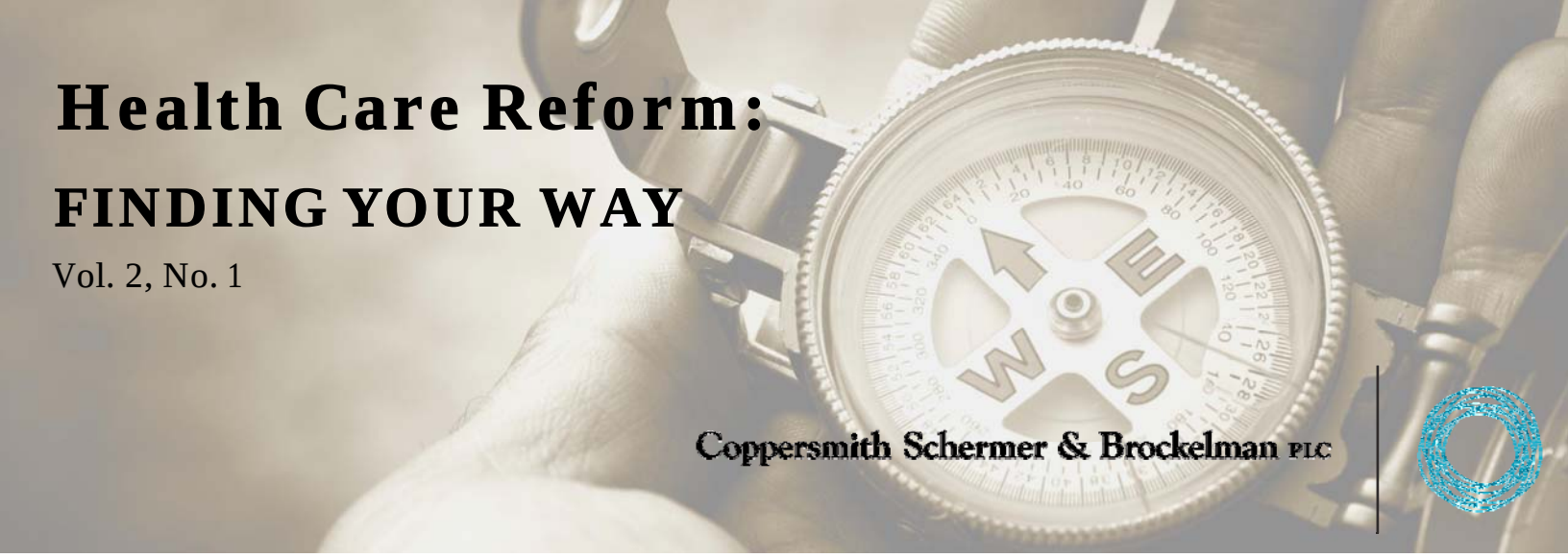

Health Care Reform:

FINDING YOUR WAY

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Coppersmith Schermer & Brockelman PLC

A Practical Guide to The New Self-Disclosure Referral Protocol

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EXECUTIVE SUMMARY

This publication marks the beginning of Coppersmith Schermer & Brockelman's reporting on implementation of the new health care reform law. Over the coming months, we will be flagging key new regulations and other initiatives with a practical focus.

On September 23, 2010, the Secretary of Health and Human Services ("HHS") in cooperation with the Inspector General of HHS ("OIG") published a long awaited "self-referral disclosure protocol" describing how health care providers and suppliers can disclose actual or potential violations of the Stark Law and settle potential repayment obligations that could arise from the facts surrounding the disclosure. The self-disclosure protocol is particularly important for providers in light of amendments under the Accountable Care Act ("ACA") that require providers to repay overpayments within 60 days of the overpayment being identified, and where failure to make this repayment could give rise to claims under the False Claims Act.

While the self-disclosure protocol is new and we have few indications of how it will be implemented, it does create an important path for providers to consider when addressing potential Stark Law concerns.

I. BACKGROUND

a. Stark History. The Stark physician self referral law, 42 U.S.C. § 1395nn, prohibits physicians from referring Medicare patients to a provider for designated health services if the physician has a financial relationship with that provider, unless the relationship meets the requirements of one of the law's exceptions. Stark also prohibits the provider of the

designated health services from billing Medicare for those services. CMS has indicated that the law requires providers to repay all amounts billed to Medicare for designated health services referred in violation of Stark. In addition, failure to repay amounts owed to the federal government can potentially lead to claims under the False Claims Act.

b. No Good Options for Addressing Stark Concerns. In the face of this background, however, providers have not had clear options for addressing and resolving potential Stark concerns. CMS has not (until the protocol) provided significant guidance on the subject, and carriers have not generally identified clear ways for Stark repayments to be made. The OIG has for many years administered a self-disclosure protocol for issues potentially involving the anti-kickback laws; however, in March 2009, the OIG clarified that it would no longer accept disclosures of Stark issues unless the anti-kickback laws were also implicated. Providers have therefore not had a clear place to turn to address "procedural" Stark concerns – situations in which no potential fraud has occurred, but where a financial relationship fell outside of the more procedural requirements of a Stark exception.

The ACA included new repayment obligations when a provider identifies an "overpayment" arising out of participation in a government program. Under the ACA, a provider is required to repay any overpayments within 60 days "after the date on which the overpayment is identified," or the date any corresponding cost report is due, if applicable. Read in tandem with Stark, this provision potentially creates an even clearer path to False Claims Act liability if a provider does not repay amounts arising out of a potential Stark violation within 60 days of "identification" of an overpayment.

c. New Stark Self-Disclosure Protocol. At the same time that Congress raised the stakes for potential Stark violations, it also created a long-anticipated outlet for providers searching for ways to address procedural violations under Stark. In Section 6409 of the ACA, Congress instructed HHS to create a protocol for Stark self-disclosures, explicitly granting HHS the authority to compromise these claims. HHS released the self-referral disclosure protocol (the "SRDP") on the very day of its September 23, 2010 deadline.

II. WHAT DISCLOSURES DOES THE SRDP COVER?

The SRDP allows the self-disclosure of potential or actual violations of Stark. HHS indicates that the SRDP is not to be used for violations implicating the anti-kickback law or other federal laws involving civil or criminal penalties, and providers in those situations should continue to follow the OIG's 1998 self-disclosure protocol. *See* 63 Fed. Reg. 58399. Similarly, if a situation involves both Stark and the anti-kickback laws, providers are also directed to use the OIG self-disclosure protocol.

The SRDP is also not intended as a substitute for obtaining a CMS advisory opinion on whether an arrangement violates Stark in the first place. A provider looking for an opinion about whether a particular arrangement complies with Stark may follow the process for obtaining a physician self referral advisory opinion, as set forth in 42 C.F.R. §§ 411.370 through 411.389.

III. CMS AUTHORITY TO SETTLE (AND REDUCE?) POTENTIAL STARK VIOLATIONS

Before the enactment of ACA, no government agency had the express authority to settle a potential Stark violation for anything less than the full value of all the improperly referred services. This meant that even unintentional and procedural failures to comply with a single element of an exception (such as the failure to obtain a signature on an agreement) could result

in overpayment obligations that many providers felt were disproportionate to the nature of the violation. Now, although CMS is not **obligated** to reduce a claimed overpayment, it does have the authority to negotiate a reduced amount as part of a settlement pursuant to the SRDP.

CMS will make a determination on a case by case basis whether, and to what extent, it will reduce provider and supplier liability in any particular situation. The protocol lists the factors CMS will consider when determining whether and by how much it will reduce the amounts otherwise owed, including: (1) the nature and extent of the improper or illegal practice; (2) the timeliness of the self-disclosure; (3) the provider's cooperation in providing additional information related to the self-disclosure process; (4) the litigation risk associated with the disclosed matter; and (5) the disclosing party's financial position.

Many provider representatives had suggested that CMS expressly acknowledge that purely procedural violations of the regulations would be assessed differently than more substantive concerns. However, while CMS may address these situations differently as it works through self-disclosures it receives, regulators declined to identify a distinction in the SRDP itself.

IV. DISCLOSURE REQUIREMENTS

a. Timing of the Disclosure. A disclosure under the SRDP must be made within 60 days of the date the overpayment is identified or the date any corresponding cost report is due, if applicable, whichever is later. The filing of a disclosure under the SRDP will suspend the 60 days the disclosing party has to make repayment under the ACA until a settlement is reached with CMS, the provider or supplier withdraws the SRDP, or CMS removes the provider or supplier from the SRDP.

b. How and Where to Disclose. A disclosure made under the SRDP must be submitted electronically to CMS at 1877SRDP@cms.hhs.gov. The disclosing party must also submit an original and one copy by mail to:

Division of Technical Payment Policy,
ATTN: Provider and Supplier Self-Disclosure
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Mailstop C4-25-02
Baltimore, MD 21224-1850

CMS will reply to the electronic submission immediately upon receipt acknowledging the submission. CMS will then review the submission and either reject or accept the disclosure.

c. What Must the Disclosure Include? The SRDP requires that the disclosure include the elements set forth below, each of which is described in more detail in the SRDP:

i. Information about the provider making the disclosure.

ii. A description of the matter being disclosed.

iii. A "complete legal analysis" of the matter, including the applicable Stark law exception(s) the disclosing party attempted to use.

iv. A financial analysis of the matter being disclosed including: (i) a breakdown of the total amount potentially owed itemized by year; (ii) a description of the

methodology used to determine the amount, including whether any estimates were used (and if so, how); and (iii) a summary of the auditing undertaken with a summary of the documents relied upon.

v. The circumstances under which the actual or potential violation was discovered and measures taken to cure the violation or to prevent it from recurring.

vi. A statement identifying the disclosing party's history of similar conduct, or history of prior enforcement actions.

viii. A description of any pre-existing compliance program and steps taken to prevent a recurrence.

ix. A description of notices given to other government agencies, as appropriate, in connection with the disclosed matter.

x. Whether the disclosing party has knowledge that the matter is under investigation by a government agency or contractor.

xi. Whether the disclosing party has knowledge of any other matters under investigation or other inquiry relating to a federal health care program.

d. Certification. A disclosure submitted pursuant to the SRDP must include a signed certification that states that to the best of the certifying individual's knowledge, the information in the disclosure is truthful 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 Stark law. If the disclosing party is an entity, the certification must be signed by the entity's Chief Executive Officer, Chief Financial Officer or a representative authorized by the entity for the purpose of making the disclosure.

e. Providers Subject to CIAs and CCAs. A provider that is subject to a Corporate Integrity Agreement ("CIA") or Certification of Compliance Agreement ("CCA") with the OIG should disclose in accordance with the SRDP with a copy to the disclosing party's OIG monitor. Disclosure obligations in a CIA or CCA must also be followed.

V. WHAT HAPPENS AFTER DISCLOSURE?

After CMS receives a disclosure, it will review the submission and possibly ask the disclosing party for additional information. If a request is made for additional information, the disclosing party will have at least 30 days to supplement its initial submission. The SRDP states that CMS must have full access to the disclosing party's financial and other documents, without the assertion of privileges. CMS suggests that it will not seek documents that are covered by the attorney-client privilege, but it may request information and documents covered by the "work product doctrine" to the extent CMS believes the material is "critical to resolving the disclosure." The SRDP states that CMS is prepared to discuss with a disclosing party's counsel ways to obtain access to data without invading the protections of an appropriately asserted privilege.

Based on CMS' review of the information, it will make a decision on an appropriate resolution. Although not explicitly addressed in the SRDP, it is anticipated that CMS will engage in negotiations for a reduced payment amount, assuming CMS deems a reduction in the amount to be appropriate based on the factors set forth above.

Under the SRDP, CMS retains the authority to refer matters to "law enforcement" for consideration under federal/state civil and criminal authorities, and CMS cautions that it may do so based on information included in a self-disclosure. CMS may also use the information contained in a disclosure to prepare a recommendation to the DOJ and OIG for resolution of a False Claims Act matter, or other civil or criminal matter.

VI. SHOULD PROVIDERS AND SUPPLIERS MAKE REPAYMENT WITH A DISCLOSURE?

CMS will not accept any repayment with a disclosure and no repayment related to a matter disclosed under the SRDP may be made to any federal health care program or contractor without CMS' consent. CMS suggests, but does not require, that disclosing parties place funds in an interest-bearing escrow account to await final determination of the matter.

VII. PROVIDER COOPERATION IN CMS REVIEW

Good faith cooperation with CMS is a critical element of the SRDP. Failure to cooperate may lead to removal from the SRDP process. In addition, intentional submission of false information, or the omission of relevant information, "will be" referred to DOJ or other federal agencies and could result in sanctions, including exclusion from federal health care programs.

It should also be noted that a provider that discloses a matter under the SRDP must agree to waive any appeal rights if a settlement agreement is reached.

VIII. FINAL THOUGHTS

The SRDP provides a long-awaited avenue for health care providers with potential concerns that resulted solely from procedural noncompliance with the Stark law without any suggestion of fraud and abuse. The SRDP is particularly important in light of the new repayment obligations under ACA.

Decisions about whether to self-disclose should be made carefully. Providers should remember that a self-disclosure made under the SRDP may not resolve the issues relating to the overpayment. Indeed, CMS may use a provider's disclosure to make referrals or recommendations to other government agencies, including the DOJ and OIG, for resolution of other civil and/or criminal matters. Providers seeking to avail themselves of the SRDP must remember that the process requires full cooperation on their behalf.

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concerning fact-specific situations and any specific legal questions you may have, please consult the attorney with whom you regularly work or contact one of our attorneys listed above.

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