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CMS ISSUES LONG-AWAITED SELF-REFERRAL DISCLOSURE PROTOCOL

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Evolving from the Operation Restore Trust, part of the Clinton Administration's early efforts to develop new methods to combat health care fraud¹, the Self-Referral Disclosure Protocol ("SRDP"), recently posted by the Centers of Medicare and Medicaid Services ("CMS"), offers a process through which providers and suppliers who discover Stark self-referral violations can disclose the violations and, potentially, avoid significant damages. The SRDP was developed by the Secretary of the Department of Health and Human Services ("HHS") and the Office of the Inspector General of the HHS ("OIG"), pursuant to a mandate in Section 6409 of the Patient Protection and Affordable Care Act (the "ACA"), enacted March 23, 2010. Prior to the SRDP's development, CMS believed that it lacked the statutory authority and/or flexibility to address any compromise of self-disclosed Stark violations. With the advent of the SRDP, any reportable event solely involving a potential or actual Stark law violation should, effective September 23, 2010, utilize the SRDP.

This SRDP represents a significant enhancement and expansion of self-disclosure mechanisms available to health care providers. Unlike other self-disclosure programs, the SRDP is available to *all* health care providers of services and suppliers, whether individuals or entities, and is not limited to any medical specialty or type of service. Other options include, of course, the Advisory Opinion process and, since 1998, the OIG's Self-Disclosure Protocol, available for disclosing conduct that raises potential liabilities under other federal criminal, civil, or administrative laws (See 63 Fed. Reg. 58399 (October 30, 1998)).

¹ Voluntary disclosure programs in the health care industry have developed as successors to parallel programs in the defense industry (e.g., the 1986 Voluntary Disclosure Program that applied to defense contractors who discovered billing errors forwarded to the Department of Defense).



While the disclosure requirements are rigorous and while there are no objective guidelines for specific relief², the ACA expressly identifies several mitigating factors that CMS may consider as justification for reducing potential penalties and payment obligations including, without limitation, (a) the nature and extent of the improper or illegal practice, (b) the timeliness of the self-disclosure, (c) the cooperation in providing additional information related to the disclosure, (d) the litigation risk associated with the matter disclosed, and (e) the financial position of the disclosing party. Indeed, diligent and good faith cooperation by the disclosing party is emphasized in the program and represents one of the most significant balancing tests for providers and suppliers considering the SRDP because, once initiated, the SRDP requires the disclosing provider or supplier to provide information freely when requested by CMS.

As intimated above, disclosures pursuant to the SRDP require submission of a significant amount of data. For example, a disclosing party must, as part of its initial disclosure, include information identifying the disclosing party and an organizational chart, if the party is owned or controlled by a system or network. A disclosing party must also identify all entities and individuals believed to be implicated and an explanation of their roles in the matter, the time periods, and the types of financial relationships involved, and provide a statement regarding why the violation occurred (e.g., intentional conduct or lack of internal controls or circumvention of corporate procedures or Government regulations). This latter component of the disclosure must be thorough. It should include the existence and adequacy of a pre-existing compliance program, and show all efforts that the disclosing party has taken or is taking to prevent a recurrence of the incident. For example, a disclosing party should disclose new accounting or internal control procedures, increased internal audit efforts, increased supervision or additional training.

The disclosing party must also submit a complete legal analysis showing which elements of an exception were met, and which elements were not. Furthermore, the disclosing party must provide information regarding current compliance programs and a complete history of the disclosing party's prior criminal, civil, and regulatory enforcement actions including even payment suspensions. Although perhaps not involved with the incident(s) that triggered the self-reporting, any prior enforcement actions will need to be discussed in detail.

The disclosing party will also be expected to conduct a financial analysis setting forth the total amount due and owing based on the applicable "look back" period. According to CMS, the "look back" period is the length of time of noncompliance without regard to potential claims under applicable statutes of limitations, and the financial disclosures must include the methodology for computing the amounts actually or potentially due, the assumptions and estimates used, and a summary of the audit activity undertaken. Finally, the disclosing party must, if it is aware of a pending inquiry into the conduct at issue, identify the Government entity or individual representatives involved as well as information about *any* other investigation or inquiry relating to any

² The SRDP expressly declines to impose a requirement on CMS to accept any terms of a self-disclosure arrangement and states "CMS has no obligation to reduce any amounts due and owing."



Federal health care program with parallel, extensive disclosures about the separate investigations or inquiries.

CMS will verify all the information submitted. As part of the verification, CMS states that it “must have access to all financial statements, notes, disclosures, and other supporting documents *without* the assertion of privileges or limitations on the information produced” (emphasis added). It is anticipated that disclosing parties will have sufficient time to respond to additional information requests, and CMS has indicated that thirty (30) days response time will be its minimal standard. CMS also states, however, that, in the normal course, it will not seek written communications subject to the attorney-client privilege, but there is no guarantee that even the attorney-client privilege will be honored. Providers and suppliers should approach the SRDP under the assumption that disclosure will be absolute.

A disclosing party will make its submission electronically, and receive an email response from CMS. There is no provision for paper processing. In general, the deadline for reporting and returning overpayments is sixty (60) days after the overpayment is identified or the date any corresponding cost report is due, if applicable. If a provider or supplier electronically submits a disclosure under the SRDP (and receives email confirmation from CMS), the obligation to return an overpayment will be suspended until a settlement is reached or either party withdraws from the SRDP. However, as a condition of disclosing information through the SRDP, the disclosing party must agree that no appeal rights attach to claims relating to the conduct disclosed if resolved through a settlement agreement.

Importantly, CMS reserves multiple rights to the information disclosed and relative to the disclosing party. For example, just because a provider may elect to participate in the SRDP does not mean that CMS is obligated to participate, and CMS reserves the right to remove disclosing parties from the SRDP. CMS also reserves the right to reject, partially or in toto, the financial and other analyses of a disclosing party. Furthermore, new information discovered by CMS during its verification process may be treated as outside the SRDP and, therefore, subject to CMS’s perceived obligation to seek reimbursement consistent with the statutory mandates and without compromise. Perhaps more ominous, CMS reserves the right to refer the disclosed information and the disclosing party to law enforcement for consideration under its separate criminal and civil authorities and may make recommendations to OIG or the Department of Justice for resolution of separate False Claims Act violations, civil monetary penalties, or other liability. As a result, CMS itself admonishes that a disclosing party’s decision to participate in the SRDP “should be made carefully.”

Again, distinguishing the SRDP from other previous or current self-disclosure programs, the SRDP does not provide a disclosing party with insulation from other criminal or civil allegations and should not be treated as such. Furthermore, CMS admonishes that the SRDP should not be utilized as an advisory opinion process. It is not.

What the SRDP does appear to offer however is the potential—but discretionary—avoidance of significant penalties and recoupments. In contrast with, for example,



Operation Restore Trust that offered a reduction in the statutorily required treble damages, the SRDP provides CMS with the unfettered discretion, depending upon the facts and circumstances involved and, apparently, the contrition and cooperation of a disclosing party, to reduce or eliminate repayment obligations and statutorily required penalties. It is a volatile, but potentially attractive, risk/reward ratio. Given the amount of disclosure and the waiver of other procedural rights and privileges that are cornerstones of the SRDP as well as the reserved rights of CMS to remove a disclosing provider from the SRDP or to refer disclosing parties to applicable law enforcement personnel or other administrative agencies, providers would be wise, as admonished by CMS, to consider the SRDP “carefully.”

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