United States Department of Health and Human Services

Report to the Congress: Implementation of the Medicare Self-Referral Disclosure Protocol

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CMS Voluntary Self-Referral Disclosure Protocol

Executive Summary

Section 1877 of the Social Security Act, also known as the physician self-referral statute (the 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 of such physician) has a financial relationship (ownership, investment, or compensation), unless an exception applies. The consequence for violating the statute, even unintentionally, is severe. No payment shall be made by Medicare for claims associated with prohibited referrals for DHS, even if medically necessary. As a result, providers of services and suppliers who submit claims to Medicare pursuant to prohibited referrals are subject to overpayment liability that may be disproportionate to the severity of the violation.

The Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111-148) was enacted on March 23, 2010. Section 6409 directed the Secretary of the Department of Health & Human Services (HHS) to develop and implement the Medicare Self-Referral Disclosure Protocol (SRDP). The SRDP is intended to facilitate the resolution of matters that, in the disclosing party's reasonable assessment, are actual or potential violations of the physician self-referral statute. The Affordable Care Act also granted the Secretary authority to reduce amounts due and owing for actual or potential violations of the statute disclosed under the SRDP. Lastly, the Secretary was required to submit a report to Congress on the implementation of the SRDP no later than 18 months after the date on which it was established.

The Secretary submits this report in response to the statutory requirements under section 6409 of the Affordable Care Act. This report includes a description of the SRDP implementation, the number of health care providers of services and suppliers making disclosures pursuant to the SRDP, the amounts collected pursuant to the SRDP, and the types of violations reported under the SRDP. It also explains the challenges faced by providers of services and suppliers who sought to disclose actual or potential violations of the statute before the passage of the Affordable Care Act and the Centers for Medicare & Medicaid Services (CMS)' early experience with the SRDP.

Prior to the Affordable Care Act, the Secretary had limited authority to compromise overpayments associated with violations of the statute, and alternative avenues to disclose violations were not appropriate for all circumstances or were foreclosed due to the nature of the violation. Through its grant of authority to the Secretary, Congress created a much needed avenue for providers of services and suppliers to seek appropriate resolution of actual or potential violations of the statute.

Under delegated authority from the Secretary, CMS, in cooperation with the HHS Office of Inspector General (OIG), established and implemented the SRDP on September 23, 2010. Further, CMS developed an internal process and procedures to efficiently resolve disclosures with the assistance of the HHS Office of the General Counsel (OGC) and law enforcement partners at OIG and the United States Department of Justice (DOJ).

Since September 23, 2010, when the SRDP was posted on the CMS public website[1], 148 providers of services and suppliers submitted a total of 150 disclosures (two providers submitted multiple disclosures involving different violations). As of the date of this report, CMS has resolved six disclosures through settlement, collecting $783,060. In addition, 51 disclosures are under CMS review and CMS is awaiting additional information from the disclosing party for 61 disclosures.[2] The remaining disclosures are no longer in the SRDP or are being held due to circumstances outside of CMS's control.

With the enactment of the Affordable Care Act, Congress authorized the Secretary to resolve violations of the statute that may otherwise have resulted in overpayment amounts significantly disproportionate to the severity of the violation. The establishment of the SRDP permitted CMS to respond to concerns raised by the health care industry and create a clear process for providers of services and suppliers to disclose and resolve potential and actual violations of the statute. CMS successfully implemented the Affordable Care Act's mandate and intends to build upon its initial success in implementing the SRDP.

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[1] *See* Centers for Medicare & Medicaid Services, Voluntary Self-Referral Disclosure Protocol, available at http://www.cms.gov/PhysicianSelfReferral/98_Self_Referral_Disclosure_Protocol.asp#TopOfPage.
[2] For an accounting of the remainder of the disclosures in process, please see Figure C and the related discussion in the body of the report.

Final Report

I. Introduction

Section 6409(a) of the Affordable Care Act requires the Secretary of the Department of Health and Human Services (HHS), in cooperation with the HHS Office of Inspector General (OIG), to establish a Medicare Self-Referral Disclosure Protocol (SRDP). The SRDP is intended to facilitate the resolution of matters that, in the disclosing party's reasonable assessment, are actual or potential violations of Section 1877 of the Social Security Act, commonly known as the physician self-referral statute (the statute). Section 6409(b) of the Affordable Care Act gives the Secretary of HHS the authority to reduce the amount due and owing for violations of the statute that are disclosed under the SRDP.

Under delegated authority from the Secretary, the Centers for Medicare & Medicaid Services (CMS), in cooperation with OIG, successfully established and implemented the SRDP on September 23, 2010, and published the SRDP on its website, as required by the Affordable Care Act (see Attachment 1). In drafting the SRDP, CMS referenced and built upon OIG's existing Provider Self-Disclosure Protocol (SDP).[3]

To implement the SRDP, CMS established a review and resolution process that involves multiple components within CMS, including the Center for Medicare, the Center for Program Integrity, and the Office of Financial Management, as well as the HHS Office of the General Counsel (OGC). As part of the SRDP procedures, CMS also coordinates its review and resolution of disclosures with OIG and the United States Department of Justice (DOJ).

As a result of the Affordable Care Act, providers of services and suppliers (collectively referred to herein as "providers") are able to voluntarily disclose violations of the statute to CMS through the SRDP, and, when submitted in good faith, seek resolution of the disclosed matters. Since the implementation of the SRDP, numerous providers have taken advantage of the new opportunity to resolve liabilities under the statute. CMS has received a significant number of disclosures and is actively working to bring them to resolution while using the authority granted by Congress to reduce disclosed overpayments in a manner that is proportional to the nature of the disclosed violations.

In the Affordable Care Act, section 6409 requires that the Secretary submit this report and specified that the report explain the implementation of the SRDP and include information regarding: (1) the number of health care providers making disclosures pursuant to the SRDP; (2) the amounts collected pursuant to the SRDP; (3) the types of violations reported under the SRDP; and (4) such other information as may be necessary to evaluate the impact of section 6409 of the Affordable Care Act. The Secretary submits this report in response to that directive and provides the data requested by the Congress.

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[3] *See* U.S. Dept. of Health & Human Services, Office of Inspector General, Provider Self-Disclosure Protocol, available at http://oig.hhs.gov/compliance/self-disclosure-info/index.asp.

II. Self-Disclosure of Physician Self-Referral Statute Violations

A. The Physician Self-Referral Statute

The 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 of such physician) has a financial relationship (ownership, investment, or compensation), unless an exception applies. The statute also 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. The statute establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.[4]

The consequences for noncompliance with the statute are the denial of payment or recoupment of overpayment. Specifically, the statute states, "no payment may be made" for DHS provided in violation of the physician self-referral statute and that "if a person collects any amounts that were billed in violation of the statute, the person shall be liable to the individual for, and shall refund on a timely basis to the individual, any amounts so collected."[5]

Sanctions for violating the statute are often severe and sometimes lead to disproportionally large damage amounts compared to the severity of the violation. Because all claims associated with the prohibited referrals for DHS, even if medically necessary, are not payable, providers who submit such claims are subject to significant overpayment liability. The statute's overpayment sanction creates a significant potential financial burden on health care providers. And prior to the Affordable Care Act, the Secretary had limited authority to compromise or to minimize an overpayment associated with a violation.

B. Disclosures to CMS Prior to the SRDP

Prior to the SRDP, providers did not have a clearly established avenue through which to disclose and resolve violations of the statute. As a result, such matters were handled by CMS on a case-by case-basis. Providers have always had the option to make unsolicited or voluntary refunds to Medicare administrative contractors who process claims and issue payments on behalf of CMS. Generally, these refunds are in the form of adjustment bills or checks. The Medicare contractors process the refunds and review the circumstances surrounding the overpayment and take appropriate steps to resolve the issue.[6]

The CMS sanction authority for violating the statute is nonpayment of all tainted DHS claims. Under the statute, CMS must deny payment of claims and recoup overpayments that result from

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[4] *See* section 1877 of the Social Security Act. *See also* 42 CFR §§ 411.350 – 411.389 for the corresponding regulations for the statute.
[5] *See* sections 1877(g)(1) and (2) of the Social Security Act. In addition, civil monetary penalties may be imposed for noncompliance with the statute. *See* sections 1877(g)(3) & (4) of the Social Security Act.
[6] *See* Medicare Program Integrity Manual, Chapter 4 - Benefit Integrity, Section 4.16 - AC, MAC, PSC, and ZPIC Coordination on Voluntary Refunds. *See also*, Medicare Financial Management Manual, Pub 100-06, Chapter 5 – Financial Reporting, Section 410 – Unsolicited Voluntary Refunds.

noncompliance with the statute.[7] Prior to the Affordable Care Act, CMS's compromise authority for overpayments under the statute was limited to $100,000 under the Federal Claims Collection Act.[8] For debts determined under the statute that exceeded this limit, CMS was required to seek approval from either DOJ or the Government Accountability Office.

Some providers attempted to use the CMS advisory opinion process as an avenue to resolve violations of the statute. For an advisory opinion request to be accepted by CMS, the requestor must be a party to the existing or proposed arrangement and is the only individual or entity that may rely on the advisory opinion.[9] Advisory opinions are not retrospective. Accordingly, the advisory opinion process provides a means to inform providers of whether a violation of the statute may occur, or is occurring, based on the facts presented; it is not an avenue to resolve an actual or potential violation of the statute.

C. Disclosures to OIG through the SDP

Providers also disclose noncompliance with the statute through the OIG's Provider Self-Disclosure Protocol (SDP), which was issued to encourage providers to make voluntary disclosures. OIG has sanction authority to impose civil monetary penalties and assessments for "knowing violations" of the statute and circumvention schemes.[10] The SDP was first displayed in the Federal Register in 1998,[11] after being created out of a pilot program operated by OIG and DOJ. OIG relies heavily upon the health care industry to help identify and resolve matters that adversely affect the federal health care programs.

The SDP is open to all health care providers, whether individuals or entities, and is not limited to any particular industry, medical specialty, or type of service. It is intended to facilitate the resolution of only matters that, in the provider's reasonable assessment, potentially violate federal criminal, civil, or administrative laws.[12]

Previously, through the SDP, OIG investigated and settled voluntary self-disclosure matters that involved violations of the statute and the federal anti-kickback statute.[13] However, in March 2009, OIG narrowed the scope of the SDP. OIG no longer accepts the disclosure of matters that involve only liability under the statute. Instead, OIG requires that matters disclosed under the SDP include a colorable violation of the anti-kickback statute.[14]

D. Disclosures to the DOJ or the United States Attorney's Office

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[7] Section 1877(g)(1) of the Act.
[8] 31 U.S.C. § 3711(a)(2); 42 CFR §§ 401.601 – 401.625.
[9] 42 CFR § 411.370.
[10] Sections 1877(g)(3) and (4) of the Act.
[11] 63 Fed Reg. 58399 - 58400 (October 30, 1998).
[12] *Id.*
[13] *See* 42 U.S.C. § 1320a-7b.
[14] *See* OIG's "An Open Letter to Health Care Providers," March 24, 2009; available at http://oig.hhs.gov/compliance/open-letters/index.asp .

A third and final avenue that providers have to disclose noncompliance with the statute is through DOJ or a local United States Attorney's Office (collectively DOJ). DOJ has the authority to resolve liability to the government under the common law theories of payment by mistake and unjust enrichment. DOJ also has the ability to release providers from any civil or administrative monetary claim under the False Claims Act[15], the civil monetary penalties law[16], and the Program Fraud Civil Remedies Act.[17] However, many potential violations associated with the statute do not violate the False Claims Act (*e.g.* the requisite intent is absent).

III. The SRDP Process

A. Background

In requiring the creation of the SRDP, Congress solved a problem faced by the provider community - the absence of one centralized avenue to resolve liability under the statute. The Secretary was required to inform providers how to disclose an actual or potential violation of the statute through publication of the SRDP on the CMS website, which was accomplished on September 23, 2010.

The granting of authority by Congress to the Secretary to reduce the amount due and owing for all violations of the statute was the most significant part of section 6409 of the Affordable Care Act. For the first time, the Secretary has the ability to take into consideration the severity of a physician self-referral statute violation and, as appropriate, reduce the amount owed to the government based upon an assessment of the conduct at issue. In establishing the amount by which an overpayment resulting from a violation may be reduced, the Secretary may consider: the nature and extent of the improper or illegal practice; the timeliness of such disclosure; the disclosing party's cooperation in providing additional information related to the disclosure; and other factors that the Secretary considers appropriate.

The Affordable Care Act also establishes a deadline for reporting and returning overpayments if a person received an overpayment.[18] This obligation to report and return an overpayment provides impetus for providers to disclose and seek resolution of known statutory violations through the SRDP. Disclosure to the SRDP temporarily tolls the provider's obligation to return overpayments, and may result in a reduced amount due and owing. At the time the provider electronically submits a disclosure under the SRDP (and receives email confirmation from CMS that the disclosure has been received), the obligation to return the overpayment within 60 days of identification is suspended until a settlement agreement is entered, the provider withdraws from the SRDP, or CMS removes the provider from the SRDP.

It is important to note 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 may not

[15] 31 U.S.C. §§ 3729-3733.
[16] 42 U.S.C. § 1320a-7a.
[17] 31 U.S.C. §§ 3801-3812.
[18] *See* section 6402 of the Affordable Care Act; *see also*, Reporting and Returning of Overpayments, 77 Fed. Reg. 9179 (proposed February 16, 2012).

disclose an actual or potential violation through the SRDP and request an advisory opinion for conduct underlying the same arrangement concurrently.

B. SRDP Requirements and Review Process

i. SRDP Requirements

All providers, whether individuals or entities, may submit disclosures under the SRDP. Submissions are not limited to any particular industry, medical specialty, or type of service. CMS is not bound by any conclusions made by the disclosing party under the SRDP and is not obligated to resolve the disclosure in any particular manner. Nevertheless, CMS works closely with a disclosing party that structures its disclosure in accordance with the SRDP to reach an effective and appropriate resolution. Parties that are currently subject to a government audit or investigation are not barred from submitting a disclosure through the SRDP; however, CMS requires that the disclosure be made in good faith. A disclosing party that attempts to circumvent an ongoing inquiry or fails to fully cooperate during the course of participation in the SRDP process will be removed from the SRDP.

Participation in the SRDP is limited to actual or potential violations of the statute. CMS instructs disclosing parties to not disclose the same conduct under both the SRDP and OIG's SDP. The SRDP also instructs disclosing parties that have corporate integrity agreements or certification of compliance agreements with OIG to comply with any disclosure or reportable event requirements under such agreements.

Disclosure submissions under the SRDP must be submitted both electronically and in hard copy. Upon receipt of the electronic submission, CMS automatically sends a response email acknowledging receipt of the disclosure. This acknowledgement email temporarily suspends the disclosing party's obligation under section 6402 of the Affordable Care Act to return any overpayment.

Disclosing parties must submit the following information related to the matter disclosed in order to provide a complete disclosure submission under the SRDP: (1) identifying information of disclosing party; (2) a description of the nature of the matter being disclosed; (3) duration of violation; (4) circumstances under which the matter was discovered and measures taken to address the issue and prevent future abuses; (5) a statement identifying a history of similar conduct or enforcement action; (6) a description of any compliance program; (7) if applicable, a description of appropriate notices provided to other government agencies; and (8) whether the matter is under current inquiry by the government.

In addition, the SRDP requires the disclosing party to submit a legal analysis of how the disclosed matter violated the statute and to identify which elements of an applicable exception the arrangement satisfied, as well as those elements the arrangement did not satisfy. The SRDP also requires disclosing parties to specify a "look back" period, the total time frame in which the arrangement violated the statute.

Disclosing parties must also provide a financial analysis that includes a total amount actually or potentially due and owing as a result of the disclosed violation, a description of the methodology used to determine the amount due and owing, the total amount of remuneration involved physicians (or an immediate family member of such physicians) received as a result of an actual or potential violation, and a summary of audit activity and documents used in the audit. If a disclosing party is unable to calculate the potential amount due and owing for reasons including the unavailability of historical records or the prohibitive cost of retrieving such data, CMS permits the disclosing party to use a reasonable method to estimate the amount. CMS requires, however, that the disclosing party explicitly state in its submission that estimates were used and provide the rationale supporting the methodology it adopted.

Disclosing parties are also required to submit a certification that the disclosure contains, to the best of the disclosing party's knowledge, truthful information and is based on a good faith effort to bring the conduct to the government's attention for the purpose of resolving any potential liabilities. This certification may be signed by the disclosing party's chief executive officer, chief financial officer, or another authorized representative.

The CMS website provides instructions and information about the procedures and the requirements of the SRDP for providers who wish to disclose potential or actual violations of the statute. The website also provides a telephone number for the CMS Physician Self-Referral Call Center for providers that have questions regarding the SRDP.

On May 6, 2011, CMS clarified on the website the information that should be submitted by disclosing parties. Specifically, the agency added the requirement that, as part of the initial submission to the SRDP, disclosing parties should provide the total amount of remuneration a physician received as a result of an actual or potential violation during the applicable "look back" period.

ii. SRDP Review Process

CMS established a detailed internal review and resolution process that involves multiple components of CMS as well as OGC. CMS also coordinates efforts with OIG and DOJ to ensure that the SRDP does not circumvent other law enforcement activities and to determine whether administrative resolution is appropriate for the disclosed matters.

Once received, the disclosure is subject to an initial review to determine if the submission meets the minimum disclosure requirements of the SRDP. After reviewing the submission, CMS sends a letter to the disclosing party or its representative to accept the disclosure or request additional information. Once the disclosure has been accepted into the SRDP, CMS reviews the circumstances surrounding the disclosed violation to determine an appropriate resolution.

In some instances, after a more thorough review of the disclosure, CMS may determine that the disclosure is not appropriate for resolution under the SRDP. For example, some disclosures are referred to OIG or DOJ if the matter warrants law enforcement consideration under civil and/or criminal authorities. In other instances, a disclosing party may, after consultation with CMS, withdraw from the SRDP.

For disclosures that CMS determines should be resolved under the SRDP, the internal review process involves coordination with law enforcement agencies as well as CMS Program Safeguard Contractors and CMS Zone Program Integrity Contractors (collectively referred to herein as "program integrity contractors") to ensure that such a resolution would not interfere with an existing law enforcement investigation or other action against a disclosing provider. If OIG, DOJ, or the program integrity contractors have an ongoing investigation of, or action against, a disclosing party, individual, or entity, the agencies collaborate to determine the appropriate next steps.

If a determination is made that it is appropriate to resolve the disclosure and the analysis of the submission is complete, CMS determines whether a reduction in the amounts due and owing is appropriate based on the facts and circumstances of the disclosed actual or potential violation. To determine whether a reduction is appropriate, and, if so, the amount of such reduction, CMS considers the following factors identified by the Affordable Care Act: (1) nature and extent of the improper or illegal practice, (2) timeliness of the self-disclosure, and (3) cooperation in providing additional information related to the disclosure, along with any other factors CMS deems appropriate when deciding on a reduction of the amount due and owing.

CMS takes its fiscal responsibility to protect the Medicare Trust Funds seriously; therefore, the agency carefully weighs the nature and extent of disclosed conduct against the amount of total dollars owed to the Federal Government before making any compromise determination. After determining the appropriate reduction, CMS contacts the disclosing party to discuss the agency's reduction of the amount due and owing. After receiving the agency's determination, if a disclosing party is under financial difficulty, it can discuss with CMS alternative arrangements to reach a financial resolution, including entering into a long-term payment plan. In limited circumstances, CMS may engage in an ability-to-pay analysis that could result in further reductions to the amount due and owing.

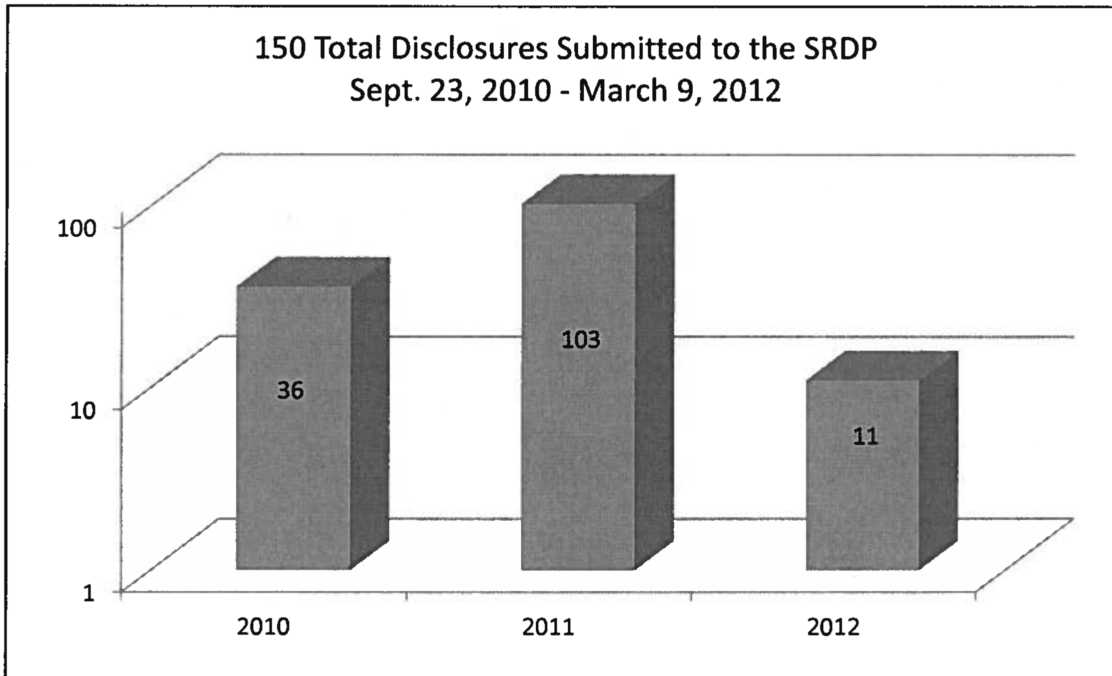
Once the settlement amount is agreed upon by CMS and the disclosing party, a formal settlement agreement is executed, releasing the disclosing party from liability under CMS's administrative authority in the statute for the disclosed violation. As part of the agreement, the disclosing party acknowledges in writing that CMS's acceptance of the settlement amount does not constitute the Government's agreement as to the amount of losses suffered by the Medicare program as a result of the disclosed violation, 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.

IV. Implementation of the SRDP

The SRDP has proven to be a viable option for providers to disclose and resolve actual and potential violations of the statute. Since September 23, 2010, CMS has received 150 disclosures from 148 providers (two providers submitted multiple disclosures involving different actual or potential violations). As displayed in Figure A below, CMS received 36 disclosure submissions

in 2010[19], 103 in 2011, and 11 through March 9, 2012.

Figure A: Yearly Calculation of Self-Referral Disclosures Submitted to CMS



The types of disclosing parties that submitted disclosures under the SRDP vary. As displayed in Figure B below, CMS has received disclosure submissions from 125 hospitals, 11 clinical laboratories, eight physician group practices, two community mental health centers, one ambulance services company, and two durable medical equipment suppliers. CMS also received disclosures from one non-provider classified as "other" in Figure B, a health care foundation that has withdrawn its disclosure from the SRDP after consultation with CMS.

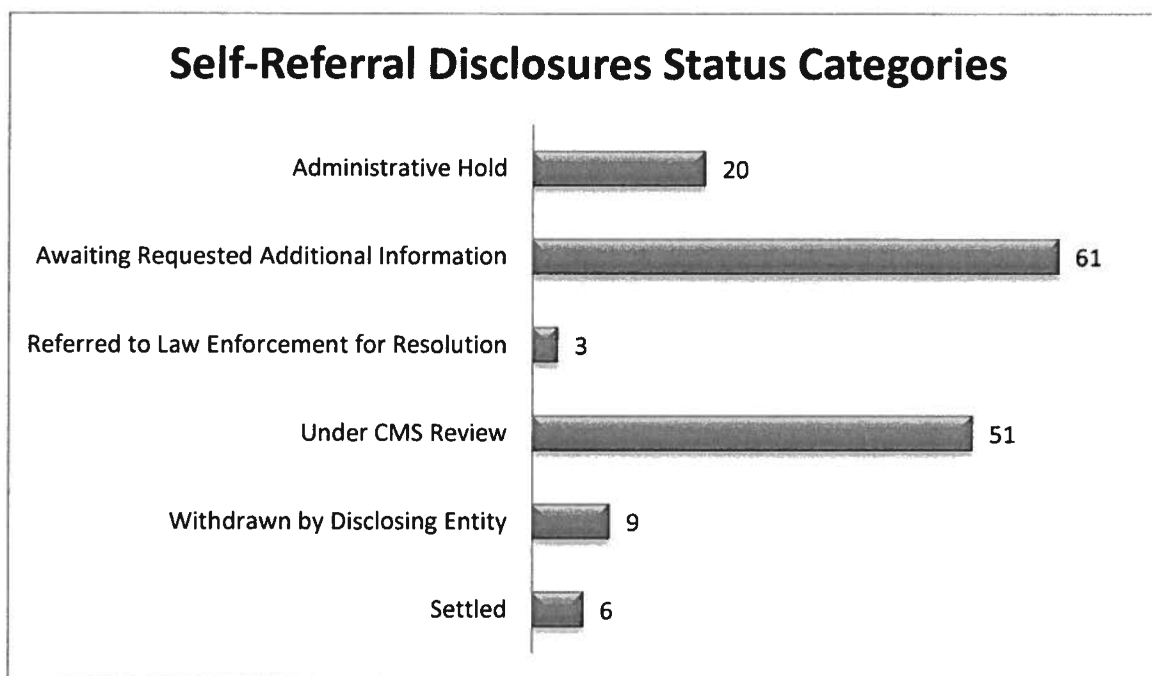
[19] Of the 36 disclosures received by CMS in 2010, 22 were submitted prior to the release of the SRDP on September 23, 2010. Figure A accounts for these 22 disclosures in the year 2010.

Figure B: Types of Disclosing Parties Submitting Disclosures through the SRDP

Providers	
Hospital	125
Community Mental Health Center	2
Suppliers	
Clinical Laboratory	11
Durable Medical Equipment	2
Ambulance Services Company	1
Group Practice	8
Other	
	1
Total	
	150

Just as the types of providers submitting disclosures under the SRDP vary, the types of violations disclosed also vary. The most common disclosed violations involve a failure to comply with the personal service arrangements exception (42 C.F.R. § 411.357(d)), the nonmonetary compensation exception (42 C.F.R. § 411.357(k)), the rental of office space exception (42 C.F.R. § 411.357(a)), and the physician recruitment arrangements exception (42 C.F.R. § 411.357(e)). In addition, there has been a wide variation in the complexity and number of violations disclosed by disclosing parties. Although some disclosures involve less complicated financial arrangements, many disclosures involve multiple parties (including hospitals and physicians) and multiple complex financial arrangements. CMS analyzes each disclosed noncompliant arrangement separately prior to making its determination of whether it is appropriate to reduce the amounts due and owing.

Figure C: SRDP Status Categories



As displayed in Figure C above, of the 150 disclosures received by CMS since the implementation of the SRDP, CMS has resolved six disclosures through settlement, 51 are under CMS review, 61 require additional information from the disclosing party and CMS is waiting for responses, nine disclosures have been withdrawn by the disclosing party after consultation with CMS, three have been referred to law enforcement for resolution, and 20 disclosures are in administrative hold.[20]

As displayed in Figure D, for the disclosures settled by CMS, the total reduced amount due and owing collected from those disclosing providers is $783,060. The settlement information has been published on the CMS website and CMS anticipates publishing many more in the near future.

[20] Certain disclosures are under an administrative hold for reasons including, but not limited to, pending bankruptcy proceedings and ongoing law enforcement activities.

Figure D: Self-Referral Disclosure Settlements and Reduced Settlement Amounts

Date	Description	Amount
02/10/2011	CMS settled several violations of the physician self-referral statute disclosed under the SRDP by a general acute care hospital located in Massachusetts. The Hospital disclosed that it: (1) failed to satisfy the requirements of the personal services arrangements exception for arrangements with certain hospital department chiefs and the medical staff for leadership services; and (2) failed to satisfy the requirements of the personal services arrangements exception for arrangements with certain physician groups for on-site overnight coverage for patients at the Hospital.	$579,000.00
09/11/2011	CMS settled a violation of the physician self-referral statute disclosed under the SRDP by a physician group practice located in Ohio. The disclosing party failed to satisfy the in-office ancillary services exception for the submission of two claims that were submitted to and paid for by Medicare.	$60.00
11/09/2011	CMS settled several violations of the physician self-referral statute disclosed under the SRDP by a critical access hospital located in Mississippi. The Hospital disclosed that it failed to satisfy the requirements of the personal services arrangements exception for arrangements with certain hospital and emergency room physicians.	$130,000.00
01/05/2012	CMS settled two violations of the physician self-referral statute disclosed under the SRDP by a hospital located in California. The Hospital disclosed that it exceeded the calendar year non-monetary compensation limit for a physician.	$6,700.00
01/05/2012	CMS settled two violations of the physician self-referral statute disclosed under the SRDP by a hospital located in Georgia. The Hospital disclosed that it exceeded the calendar year non-monetary compensation limit for two physicians.	$4,500.00
03/9/2012	CMS settled a violation of the physician self-referral statute disclosed under the SRDP by a group practice located in Iowa. The Practice disclosed that it failed to satisfy certain requirements of the bona fide employment relationship exception for a number of employed physicians.	$74,000.00

After establishing and implementing the SRDP, CMS has thoroughly and efficiently worked to resolve disclosures. In carrying out its fiscal responsibility, CMS must understand all facts of a particular disclosed matter. Due to the variation in the nature and complexity of disclosed matters, disclosure submissions range from a few pages to hundreds of pages. This variation can be attributed to the fact that the larger disclosures each address a variety of violations among a number of providers over a period of years. As displayed in Figure C, CMS has found that many of the initial disclosure submissions do not provide all of the relevant information that CMS requires to conduct its analysis. Specifically, disclosing parties have not performed an adequate legal analysis, provided sufficient financial information, or provided relevant documentation of the disclosed noncompliant arrangements, i.e., copies of contracts. Therefore, CMS has had to request additional information, which has slowed down the agency's ability to review and resolve disclosures.

Through much communication and education, CMS has worked to collect data and information necessary to reach resolution under the SRDP. Specifically, CMS has communicated with providers and their attorneys at various conferences and forums to educate them on the level and scope of information needed to move a disclosure through the review process. The process of education continues, and CMS has seen improvement in the quality of the disclosures submitted to the SRDP. Over time, this will allow CMS to resolve disclosures more rapidly while upholding its fiscal responsibility.

The SRDP has served as a viable path for providers in varying circumstances to resolve liabilities under the statute. In particular, CMS recognizes that the SRDP provides a path for distressed hospitals to resolve outstanding physician self-referral liabilities. In certain cases, hospitals facing financial and operational difficulties are either in the process of sale or asset acquisition. Before completing the financial transaction, these providers have attempted to use the SRDP to resolve outstanding actual or potential violations of the statute. These cases are often complex, involve multiple providers, and different types of conduct spanning a number of years. Because the providers seek quick resolution to ensure fiscal solvency and, in some cases, continued operation, the information provided in these disclosures is often insufficient. CMS has worked diligently with these providers to obtain the information necessary for CMS to adequately review the submission and make a proper determination regarding an appropriate financial resolution.

V. Conclusion

The Secretary has met the deadline set forth by the Congress for establishing and implementing the SRDP. The SRDP offers a clear avenue for providers to disclose and resolve actual and potential violations of the statute. Many of the disclosures received during the early months after implementation of the SRDP did not contain adequate information for CMS to conduct a complete factual and legal analysis and required the submission of additional information prior to resolution. However, with CMS's continuing education efforts, the quality of disclosure submissions is improving. CMS will continue to build upon its operational success with the SRDP, including conducting significant provider outreach. As more resolutions are reached, we anticipate the provider community will recognize that CMS is working to approach all disclosures reasonably, with the goal of reaching a fair resolution based on its responsibility to Medicare beneficiaries and the Medicare Trust Funds. In addition, we believe this will help to

encourage more providers to come forward and avail themselves of the SRDP. CMS intends to build upon its initial success implementing the SRDP by continually improving the SRDP process.

Attachment 1

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 physicians 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 disclosure must be submitted electronically to 1877SRDP@cms.hhs.gov. In addition, the disclosing party must submit an original and 1 copy by mail to the 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 21244-1850. 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.