Paperwork Reduction Act - Supporting Statement
Center for Medicare and Medicaid Services
Physician Self-Referral Disclosure Protocol

A. Background

The Affordable Care Act (ACA) was enacted on March 23, 2010. Section 6409 of the ACA requires the Secretary of the Department of Health and Human Services (the "Secretary"), in cooperation with the Office of Inspector General of the Department of Health and Human Services (the "Inspector General"), to establish a Medicare self-referral disclosure protocol ("SRDP") that sets forth a process to enable providers of services and suppliers to self-disclose actual or potential violations of the physician self-referral statute, section 1877 of the Social Security Act (the Act). Section 6409(b) of the ACA gives the Secretary the authority to reduce the amount due and owing for all violations of section 1877 of the Act. In establishing the amount by which an overpayment may be reduced, the Secretary may consider: the nature and extent of the improper or illegal practice; the timeliness of the self-disclosure; the cooperation in providing additional information related to the disclosure; and such other factors as the Secretary considers appropriate.

In accordance with the ACA, CMS established the SRDP on September 23, 2010, and information concerning how to disclose an actual or potential violation of section 1877 of the Act was posted on the CMS website. We are now seeking to revise the currently approved collection. Specifically, we are: (1) creating an optional expedited SRDP review process (the "Expedited SRDP Review Process") for disclosures that meet certain eligibility requirements; (2) continuing the established SRDP review process (the "Standard SRDP Review Process") for other disclosures; and (3) revising the estimated burden hours based on our experience administering the SRDP over the past three years.

For both the Standard and Expedited SRDP Review Processes, CMS will continue to collect information describing the actual or potential violation(s), financial analysis of the amount due and owing, supporting documentation, certifications from disclosing parties, and other information that the Secretary considers appropriate to assess the nature and extent of the noncompliance and to establish the amount due and owing for the violation. The Standard and Expedited SRDP Review Processes differ in how the collected information will be presented to CMS.

We believe that the Standard SRDP Review Process is appropriate for certain kinds of disclosures, including disclosures that present complex questions of fact or law, disclosures that relate to ownership arrangements, and disclosures that relate to certain compensation arrangements. For submissions to the Standard SRDP Review Process, we continue to require a complete, detailed description and explanation of the actual or potential violation(s). On the other hand, we believe that certain disclosures that have no indicia of fraud and that involve common arrangements, e.g., leasing and personal service arrangements, can be presented in a streamlined format, consisting of certified factual statements and brief narrative summaries. A disclosure will be admitted into the Expedited SRDP Review Process if the disclosure meets all of CMS' eligibility criteria for expedited review, including submission of all supporting documentation, and the disclosing party

requests expedited review. Providers of services and suppliers have no obligation to elect expedited review.

Most of the information and documentation required for submission to CMS in accordance with the SRDP is information that health care providers of services and suppliers keep as part of customary and usual business practices.

B. Justification

1. Need and Legal Basis

Section 6409 of the ACA requires the Secretary to establish a voluntary self-disclosure process that allows providers of services and suppliers to self-disclose actual or potential violations of section 1877 of the Act. In addition, section 6409(b) of the ACA gives the Secretary authority to reduce the amounts due and owing for the violations.

To determine the nature and extent of the noncompliance and the appropriate amount by which an overpayment may be reduced, the Secretary must collect from disclosing parties relevant information regarding the arrangements and financial relationships at issue. The Secretary may also collect supporting documentation, such as contracts, leases, communications, invoices, or other documents bearing on the actual or potential violation(s).

2. Information Users

The SRDP is a voluntary self-disclosure instrument that allows providers of services and suppliers to disclose actual or potential violations of section 1877 of the Act. CMS analyzes the disclosed conduct to determine compliance with section 1877 of the Act and the application of the exceptions to the physician self-referral prohibition. In addition, the authority granted to the Secretary under section 6409(b) of the ACA, and subsequently delegated to CMS, may be used to reduce the amount due and owing for violations.

3. Use of Information Technology

In accordance with section 6409(a)(2) of the ACA, the SRDP was posted on the CMS public Internet website on September 23, 2010. The collection of information for both the Standard and Expedited SRDP Review Processes consists of a voluntary submission describing an actual or potential violation of section 1877 of the Act, and providing a financial analysis of amount potentially due and owing.

For both the Standard and Expedited SRDP Review Processes, providers of services and suppliers must submit supporting documentation. To meet this requirement, providers of services and suppliers typically submit a large amount of information and documentation, including contracts, agreements, and other documents bearing on the actual or potential violation.

In our previous Paperwork Reduction Act submission, we concluded that electronic-only

submissions were not feasible. Based on our experience administering the SRDP to date, we are now requesting electronic-only submission of disclosures and all supporting documentation, though, as noted below, we continue to require the disclosing party to submit a hard copy of its signed certification. Disclosing parties should send an electronic copy of the complete disclosure and all relevant supporting documents via email to 1877SRDP@cms.hhs.gov. The disclosing provider of services or supplier, or in the case of an entity, its Chief Executive Officer, Chief Financial Officer, or other authorized representative, must submit to CMS a signed certification stating that, to the best of the individual's knowledge and belief, the information provided contains truthful information and is based on a good faith effort to assist CMS in its inquiry and verification of the disclosed matter. A hardcopy of the signed certification should be sent 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 21244-1850**.**

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

Participation in the SRDP is voluntary and for the most part requires the submission of relevant information kept as part of the disclosing provider of services or supplier's customary and usual business practices. The voluntary disclosures in accordance with this collection do not require the submission of a specific form. The collection request requires that providers of services or suppliers furnish a complete and specific description of all relevant information and documents, including contracts, agreements, and any other arrangements bearing on the actual or potential violation. The SRDP will not disproportionately affect small businesses.

6. Less Frequent Collection

Because the collection is voluntary, frequency standards of the collection do not apply.

7. Special Circumstances

The collection is voluntary; however, in accordance with the SRDP, once providers of services and suppliers are accepted into the SRDP, CMS may request additional information related to the disclosed actual or potential violation and the amounts due and owing related to that disclosure on a case by case basis.

No other special circumstances exist.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on February 24, 2014. We received one comment in response to the 60-day notice. The commenter expressed general concerns about a variety of issues, including the physician self-referral law. However, the comment did not specifically address the information collection or the burden associated with the SRDP. For this reason, we do not respond to the comment here.

At the time the 60-day notice was published in the Federal Register, the Expedited SRDP Review Process policy was under development and thus not ready for public comment. However, because the burden for both the Expedited and Standard SRDP Review Processes is the same, and because the Expedited SRDP Review Process is voluntary and optional, we believe that this 30-day notice provides sufficient opportunity for public comment on the burden associated with the Expedited SRDP Review Process.

9. Payments/Gifts to Respondents

Payments or gifts to respondents will not be made in accordance with this collection.

10. Confidentiality

Disclosures related to section 6409 of the ACA are kept in a physically secured area. The electronic information stored on a computer system(s) and related database(s) are password protected. Files containing hardcopies of the actual disclosed information are safeguarded in a physically secured area.

The information collected is used to analyze actual or potential violations of section 1877 of the Act and in determining the amount due and owing for a violation. Disclosed information may be shared with other federal agencies and with Congressional committees. We are prevented by the Trade Secrets Act, 18 U.S.C. § 1905, from releasing to the public confidential business information, except to the extent permitted by law. We intend to protect from public disclosure, to the fullest extent permitted by Exemptions 4 and 6 of the Freedom of Information Act, 5 U.S.C. § 552(b)(4) and (6), any individual-specific information collected.

11. Sensitive Questions

No sensitive questions will be asked in accordance with this collection.

12. Burden Estimates (Hours & Wages)

Based on the number of submissions CMS has received to date, we anticipate that providers of services and suppliers will submit 100 self-disclosures to SRDP per year. Most of the self-disclosures will cover more than one actual or potential violation of the physician self-referral law. The collection involves both legal and financial review. We believe that the burden for the Expedited and Standard SRDP Review Processes is the same.

Legal review: The initial burden involves the review of various contracts and documents, the preparation of a specific description of all relevant information bearing on the matter being disclosed, a description of the actual or potential violation, and the preparation and submission of other required information. The burden on providers of services and suppliers related to the first step in the process varies widely because of differences in the nature and extent of the conduct, the size of the entity, and the number of potentially noncompliant arrangements. For example, if a personal service arrangement is not "in writing" and "signed by the parties," the parties cannot rely on the personal service arrangements exception of the physicians self-referral law, 42 C.F.R. § 411.357(d). A small entity with few personal service arrangements can review, identify, and produce documentation relevant to a disclosure in ten (10) hours. It takes an additional five (5) hours for a small entity to draft a written description of the actual or potential violation and to prepare the submission for CMS. Thus, for smaller entities with few noncompliant arrangements, the legal review takes fifteen (15) hours. On the other hand, when a large entity with multiple arrangements fails to satisfy the personal services exception, it likely takes fifty (50) hours to track all of the complex relationships and to produce relevant documentation of the actual or potential violation(s). It takes an additional fifteen (15) hours to analyze the documents and prepare the submission for CMS, for a total of sixty-five (65) hours. Therefore, the hour burden for legal review ranges from fifteen (15) to sixty-five (65) hours to complete the original submission to CMS, with an average of forty (40) hours. The annualized hour burden to the industry for legal review ranges from 1500 hours (15 hours for legal review x 100 disclosures) to 6500 hours (65 hours for legal review x 100 disclosures).

Typically legal counsel for the providers of services and suppliers is responsible for reviewing the contracts/arrangements prior to disclosure. We estimate that, on average, the cost for such personnel is $92 per hour (based on 2012 Bureau of Labor Statistics,). Thus, the cost per disclosure for legal review is estimated to range from $1,380 ($92 per hour x 15 hours) to $5,980 ($92 per hour x 65 hours), with an average cost of $3,680 ($92 per hour x 40 hours). Therefore, the annualized cost to the industry for legal review ranges from $138,000 ($ 1,380 x 100 disclosures) to $598,000 ($5,980 x 100 disclosures). The average annualized cost to the industry for legal review is $368,000.

Financial review: Providers of services and suppliers also incur a burden associated with the financial analysis related to the actual or potential violation. Similar to the process above, this involves the review and submission of financial documents and other relevant information required as part of the original submission to CMS. In particular, parties submitting a disclosure pursuant to the SRDP must determine the amount potentially due and owing for each noncompliant arrangement by reviewing billing and claims data from a period of up to four years from the date of submission, depending upon the amount of time the arrangement was not in compliance. If an entity is disclosing a small number of noncompliant arrangements, each with limited durations of noncompliance, the internal review and submission by the provider of services or supplier may only take five (5) hours per disclosure. However, a larger entity may require a more complex review involving fifteen (15) hours per disclosure. The average time for financial review is ten (10) hours. The annualized hour burden to the industry ranges from 500 hours (5 hours for financial review x 100 disclosures) to 1500 hours (15 hours for financial review x 100 disclosures), with an average of 1000 hours (10 hours for financial review x 100 disclosures).

We believe that accounting personnel will be responsible for gathering, reviewing, and submitting the financial data. We estimate that, on average, the cost for such personnel is $63 per hour (based on 2012 Bureau of Labor Statistics for Accounting and Bookkeeping personnel). Thus, the cost per disclosure for financial review ranges from $315 ($63 per hour x 5 hours) to $945 ($63 per hour x 15 hours). The average cost for financial review is $630. Therefore, the annualized cost to the industry for financial review ranges from $31,500 ($315 x 100 disclosures) to $94,500 ($945 x 100 disclosures). The average annualized cost to the industry for financial review is $63,000.

In sum, the average burden for legal and financial analysis per disclosure is fifty (50) hours. The average cost per disclosure is $4,310 ($3,680 for the average legal review per disclosure + $630 for the average financial review per disclosure). The total annualized cost burden for both legal and financial review to the industry ranges from $169,500 ($138,000 for legal review + $31,500 for financial review) to $692,500 ($598,000 for legal review + $94,500 for financial review). The average annualized cost is $431,000.

13. Capital Costs

This collection will not require capital costs.

14. Cost to Federal Government

CMS anticipates 100 self-disclosures per year. CMS anticipates that approximately 50% of the disclosures we will receive after the implementation of the Expedited SRDP Review Process will request expedited review. We anticipate the cost to the Federal Government for expedited review to be lower than the costs under the Standard SRDP Review Process. The cost of review and analysis for the Standard and Expedited SRDP Review Processes is shown in the tables below. The total annualized cost for review, legal analysis, and financial analysis for the Standard SRDP Review Process is set forth in Table 1. The total annualized cost for review, legal analysis, and financial analysis for the Expedited SRDP Review Process is set forth in Table 2. For both review processes, GS-13 level staff will review and provide preliminary financial and legal analysis. GS-14 and 15 staff will provide legal analysis and reviews, financial analysis and review, and resolution negotiation. SES level staff will provide review, revisions, and authorizations.

TABLE 1 – Standard SRDP Review Process

Grade Level	No. of staff	Hr. Per Disclosure	Salary per Hr.	No. of disclosures	Total
GS-13	1	56 per employee	$43.00	50	$120,400
GS-14	3	30 (10 per employee)	$52.00	50	$78,000
GS-15	2	10 (5 per employee)	$61.00	50	$30,500
SES	2	4 (2 per employee)	$75.00	50	$15,000

TABLE 2 – Expedited SRDP Review Process

Grade Level	No. of staff	Hr. Per Disclosure	Salary per Hr.	No. of disclosures	Total
GS-13	1	10 per employee	$43.00	50	$21,500
GS-14	3	15 (5 per employee)	$52.00	50	$39,000
GS-15	2	10 (5 per employee)	$61.00	50	$30,500
SES	2	4 (2 per employee)	$75.00	50	$15,000

Total annualized cost of SRDP = $ 349,900.

15. Changes to Burden

The revision to the collection will not increase the actual burden on providers of services and suppliers who submit self-disclosures. However, we have changed our estimation of the burden. The average burden per disclosure was adjusted from 24 hours to 50 hours. This adjustment is based on three years of experience administering the SRDP. We have learned that the typical disclosure involves multiple noncompliant arrangements involving numerous physicians, and that the arrangements tend to be more complex than we originally anticipated. We note, however, that as the industry becomes more experienced with the SRDP, the self-disclosure process is becoming more streamlined. Moreover, we believe that the Expedited SRDP Review Process will provide the industry with an opportunity to further streamline the self-disclosure process. Therefore, we anticipate that the burden will diminish in the future.

We also adjusted the average number of self-disclosures per year from 50 to 100, based on the average number of disclosures we have received over the last three years.

16. Publication/Tabulation Dates

Not applicable to this collection.

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement

Not applicable to this collection.