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). In accordance with the ACA, the SRDP was established on September 23, 2010, six months after the date of enactment, and information concerning how to disclose an actual or potential violation of section 1877 of the Act was posted on the CMS website.

We believe that in order to effectively evaluate a self-disclosure submission, the SRDP must require health care providers of services and suppliers to submit all information necessary for CMS to analyze the actual or potential violation of section 1877 of the Act. Therefore, in accordance with section 6409(a)(1) of the ACA, this information collection request identifies the specific information describing the actual or potential violation(s) and the related financial analysis that must be furnished by providers of services and suppliers as part of their voluntary disclosure submissions. The collection may seek additional financial documentation and other information that the Secretary considers appropriate to establish the amount due and owing for the violation.

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 resulting from an actual or potential violation(s) 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.

We anticipate that 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 and post information on the CMS' public Internet website concerning a SRDP that sets forth a process for 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.

This information collection request is necessary in order to inform the public of the process and the types of information needed to participate in the SRDP.

For purposes of the PRA package, we assume that all activities needed to develop and implement the SRDP will be conducted by CMS in cooperation with the Inspector General.

2. Information Users

The SRDP is a voluntary self-disclosure instrument that will allow providers of services and suppliers to disclose actual or potential violations of section 1877 of the Act. CMS will analyze 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 consists of a voluntary submission describing an actual or potential violation of section 1877 of the Act and the submission of relevant documentation, including a financial analysis. The SRDP provides that if the disclosing provider of services or supplier is an entity that is owned, controlled, or is otherwise part of a system or network, the submission must include a description or diagram that explains the pertinent relationships and the names and addresses of related entities. In addition, the submission should include a complete description of the matter being disclosed. We believe this may result in the submission of large amounts of relevant information and documents, including contracts, agreements, and any other arrangements bearing on the actual or potential violation.

We explored various methods of data collection; however, due to the unique and variable nature of the actual or potential violations, we concluded that electronic only completion and submission of the documentation is not feasible. Therefore, providers of services and suppliers will be required to submit, in paper format, the original and one copy of the complete disclosure and relevant documentation. In addition to sending the documents by mail, providers of services and suppliers are required to send an electronic copy of all 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, along with all submissions, 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.

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 January 14, 2011.

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 will be kept in a physically secured area. The electronic information stored on a computer system(s) and related database(s) will be password protected. Files containing hardcopies of the actual disclosed information will be safeguarded in a physically secured area.

The information collected will be 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.

Section 6409(c) of the ACA requires the Secretary to submit a report to Congress on the implementation of the SRDP not later than 18 months from the date on which the SRDP is established, by March 23, 2012. The report shall include: (1) the number of health care providers of services and suppliers making disclosures in accordance with the SRDP; (2) the amounts collected in accordance with 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 the SRDP. The report to Congress may include aggregate information in compliance with the reporting requirements. At this time, CMS does not intend to use any case-specific information in the report to Congress.

11. Sensitive Questions

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

12. Burden Estimates (Hours & Wages)

We anticipate that providers of services and suppliers will self-disclose a total of 50 actual or potential violations per year. The collection will involve both the information collected from disclosing providers of services and suppliers, as well as the compilation of a report to Congress, each with separate burdens.

The initial burden involves the review of various contracts and agreements, 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 is expected to vary widely because of differences in the nature and extent of the conduct, the size of the entity, and the number of arrangements. For example, the lack of a signature on a personal services contract would preclude providers of services and suppliers from meeting the personal services exception pursuant to 42 C.F.R. § 411.357(d) of the physician self-referral regulations. Reviewing and analyzing contractual agreements in an entity with few contracts may take only five (5) hours to identify and produce documentation relevant to a disclosure. However, the failure to satisfy this element of the personal services exception by a large entity with multiple contracts and multiple parties may take twenty-four (24) hours, at the outer limit, to track all of the complex relationships and to produce relevant documentation of the actual or potential violation. Therefore, we estimate that the hour burden range will be from five (5) to twenty-four (24) hours to complete the original submission to CMS, with an average of fifteen (15) hours. The annualized hour burden to the industry for legal review would range from 250 hours (5 hours for legal review x 50 disclosures) to 1200 hours (24 hours for legal review x 50 disclosures).

We anticipate that legal counsel for the providers of services and suppliers will be responsible for reviewing the contracts/arrangements prior to disclosure. We estimate that, on average, the cost for such personnel is $93.00 per hour (based on 2010 Bureau of Labor Statistics for Legal Services). Thus, the cost per disclosure is estimated to range from $465.00 ($93.00 per hour x 5 hours) to $2232.00 ($93.00 per hour x 24 hours), with an average cost of $1348.50. Therefore, the annualized cost to the industry for legal review would range from $23,250.00 ($465.00 x 50 disclosures) to $111,600.00 ($2232.00 x 50 disclosures). The average annualized cost to the industry for legal review is $67,425.00.

Providers of services and suppliers will also incur a burden associated with the financial analysis related to the actual or potential violation. Similar to the process above, this would involve the review and submission of financial documents and other relevant information required as part of the original submission to CMS. The internal review and submission by the provider of services or supplier may only take six (6) hours per disclosure for a smaller entity with limited financial information. However, a larger entity may require a more complex review involving twelve (12) hours per disclosure. The average hours for financial review would be nine (9) hours. The annualized hour burden to the industry would range from 300 hours (6 hours for accounting review x 50 disclosures) to 600 hours (12 hours for accounting review x 50 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 $50.00 per hour (based on 2010 Bureau of Labor Statistics for Accounting and Bookkeeping personnel). Thus, the cost per disclosure for accounting review is estimated to range from $300.00 ($50.00 per hour x 6 hours) to $600.00 ($50.00 per hour x 12 hours). The average cost for financial review would be $450.00. Therefore, the annualized cost to the industry for accounting review would range from $15,000.00 ($300.00 x 50 disclosures) to $30,000.00 ($600.00 x 50 disclosures). The average annualized cost to the industry for financial review is $22,500.00.

The average cost per disclosure is $1798.50 ($1,348.50 for the average legal review per disclosure + $450.00 for the average financial review per disclosure). The total annualized cost burden for both legal and accounting review to the industry would range from $38,250.00 ($23,250.00 for legal review + $15,000.00 for accounting review) to $141,600.00 ($111,600.00 for legal review + $30,000.00 for accounting review). The average annualized cost would be $89,925.00.

13. Capital Costs

This collection will not require capital costs.

14. Cost to Federal Government

CMS anticipates 50 self-disclosures per year. CMS anticipates the cost of review, analysis, and negotiation as shown in the table below. The total annualized cost for review, legal analysis, financial analysis, and resolution negotiation is set forth in Table 1. 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

Grade Level	No. of staff	Hr. Per Disclosure	Salary per Hr.	No. of disclosures	Total
GS-13	2	112 (56 per employee)	$43.00	50	$240,800.00
GS-14	2	20 (10 per employee)	$52.00	50	$52,000.00
GS-15	2	10 (5 per employee)	$61.00	50	$30,500.00
SES	2	4 (2 per employee)	$75.00	50	$15,000.00

Total annualized cost of SRDP = $338,300.00.

Section 6409(c) of the ACA requires CMS to submit a report to Congress on the implementation of the SRDP by March 23, 2012. The report will consist of (1) the number of health care providers of services and suppliers making disclosures in accordance with the SRDP; (2) the amounts collected in accordance with 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 the SRDP.

CMS does not anticipate additional costs as a result of the report to Congress. The estimated cost for review, analysis, and production of the report is depicted in Table 2 below.

TABLE 2

Grade Level	No. of Staff	Hr. Per Employee	Salary Per Hr.	Total
GS-13	1	5	$43.00	$215.00
GS-14	2	20	$52.00	$2,080.00
GS-15	3	4	$61.00	$732.00
SES	2	1	$75.00	$150.00

Total, one-time cost of the report to Congress = $3,177.00

15. Changes to Burden

There were no changes to the hour burden estimates; however, the cost estimate for the average annualized cost to the industry for legal review was revised to correct an arithmetic error. The number was corrected to $67,425.00 from $39,150.00.

16. Publication/Tabulation Dates

In accordance with section 6409(c) of the ACA, the Secretary is required to submit a report to Congress on the implementation of the SRDP by March 23, 2012. The report to Congress shall include: (1) the number of health care providers of services and suppliers making disclosures in accordance with the SRDP; (2) the amounts collected in accordance with 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 the SRDP. At this time, CMS intends to submit aggregate information in compliance with the reporting requirements.

17. Expiration Date

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

18. Certification Statement

Not applicable to this collection.