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

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, to establish a Medicare self-referral disclosure protocol ("SRDP"). The SRDP enables 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 owed 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. The most recent approval of this information collection request ("ICR") was issued by the Office of Management and Budget on August 26, 2014.

We are now seeking approval to revise the currently approved ICR. Under the currently approved collection, a party must provide a financial analysis of overpayments arising from actual or potential violations of section 1877 of the Act based on a 4-year lookback period. On February 12, 2016, CMS published a final rule on the reporting and returning of overpayments. See CMS-6037-F, Medicare Program; Reporting and Returning of Overpayments, 81 FR 7654 (Feb. 12, 2016) (the "final overpayment rule"). The final overpayment rule establishes a 6-year lookback period for reporting and returning overpayments. We are revising the information collection for the SRDP to reflect the 6-year lookback period established by the final overpayment rule. The revision is necessary to ensure that parties submitting self-disclosures to the SRDP report overpayments for the entire 6-year lookback period. The 6-year lookback period applies *only* to submissions to the SRDP received *on or after* March 14, 2016, the effective date of the final overpayment rule; parties submitting self-disclosures to the SRDP prior to March 14, 2016 need only provide a financial analysis of potential overpayments based on a 4-year lookback period.

We are also taking the opportunity to streamline and simplify the SRDP by issuing a required form for SRDP submissions. The SRDP Form will reduce the burden on disclosing parties by reducing the amount of information that is required for submissions to the SRDP and providing a streamlined and standardized format for the presentation of the required information.

A. 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 relevant information regarding the arrangements and financial relationships at issue from disclosing parties. The Secretary may also collect supporting documentation, such as contracts, leases, communications, invoices, or other documents bearing on the actual or potential violation(s). 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.

2. Information Users

The SRDP is a voluntary self-disclosure process 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

Disclosing parties are required to submit all materials to the SRDP electronically. Disclosing parties must send an electronic copy of the complete disclosure and all relevant supporting documents to CMS via email. For legal reasons, 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 hardcopy 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 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. We are reducing the burden on all respondents, including small businesses, by establishing a standard form. 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

No special circumstances exist.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on May 6, 2016. We did not receive any comments pertaining to the ICR.

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) is password protected. Files containing hardcopies of the certification statements 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 Estimate s (Hours & Wages)

Based on our experience with the SRDP and our recent issuance of guidance to facilitate compliance (see 80 FR 70886, 71300 et seq. (Nov. 16, 2015)), we estimate that providers of services and suppliers will submit approximately 100 disclosures per year. The burden on providers of services and suppliers varies widely because of differences in the nature and extent of the conduct, the size of the entity, and the number of potentially noncompliant financial relationships. While disclosures of a single noncompliant financial arrangement are not uncommon, most of the self-disclosures we receive cover more than one actual or potential violation of the physician self-referral law. The collection involves both legal and financial review.

Legal review: The initial burden involves the production and review of various contracts and other documents to determine whether a party complied with the physician self-referral law. The burden on providers of services and suppliers related to this activity depends in large part on the number of potentially noncompliant financial relationships under investigation. For example, if a personal service arrangement is not "in writing" and "signed by the parties," the parties cannot satisfy the requirements of the personal service arrangements exception of the physicians self-referral law, 42 C.F.R. § 411.357(d). We estimate that a small entity with relatively few potentially problematic personal service arrangements can identify and review documentation relevant to a disclosure in ten (10) 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). On average, it will take providers of services and suppliers approximately thirty (30) hours to produce and review documents to determine compliance with the physician self-referral law.

After the disclosing party has collected and reviewed documentation to determine whether the party complied with the physician self-referral law, the disclosing party must prepare the disclosure for submission. The SRDP Form will provide a streamlined and standardized method for parties to report potential or actual noncompliance. Where the currently approved ICR requires detailed explanations of noncompliance, the SRDP Form provides checkboxes that allow parties to quickly identify those elements of an applicable exception that a financial relationship satisfied and those elements that the relationship failed to satisfy. In addition, the SRDP Form does not require some information that is required under the current collection, such as a description and evaluation of the disclosing party's pre-existing compliance program. For these reasons, we have revised our estimate of the burden associated with preparing the submission downward. Previously we estimated that it would take between five (5) and (15) hours to prepare the submission, depending on the number of noncompliant financial relationships covered by the self-disclosure. With the SRDP Form, we estimate it will take between two (2) to eight (8) hours to prepare the submission, depending on the number of noncompliant financial relationships. On average, it will take approximately five (5) hours to complete the SRDP Form.

In sum, the annualized hour burden to the industry for legal review (including production and review of documents and completion of the SRDP Form) ranges from 1200 hours (12 hours for

legal review x 100 disclosures) to 5800 hours (58 hours for legal review x 100 disclosures). The average hour burden to the industry for legal review is 3500 (35 hours for legal review x 100 disclosures).

Typically compliance officers and legal counsel for providers of services and suppliers are responsible for producing and reviewing the contracts/arrangements and preparing the disclosure for submission. According the Bureau of Labor Statistics ("BLS") data for May 2014, the national estimated mean hourly wage for the category of "compliance officers" was $32.69, and the national estimated mean hourly wage for the category of "lawyers" was $64.17. The average of these two figures is $48.43. This does not include fringe benefits, which are generally calculated as being 100% of salary. This means that the cost of an hour of work for personnel responsible for the legal analysis, including both the production and the review of documents, is $96.86 per hour. Thus, the cost per disclosure for legal review is estimated to range from $1,162.32 ($96.86 per hour x 12 hours) to $5,617.88 ($96.86 per hour x 58 hours), with an average cost of $3,390.10 ($96.86 per hour x 35 hours). Therefore, the annualized cost to the industry for legal review ranges from $116,232 ($1,162.32 x 100 disclosures) to $561,788 ($5,617.88 x 100 disclosures).
The average annualized cost to the industry for legal review is $339,010 ($3,390.10 x 100 disclosures).

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 potential overpayment for each noncompliant financial relationship by reviewing billing and claims data.

On March 14, 2016, the effective date of the final overpayment rule, the lookback period for the financial analysis increased from 4 years to 6 years. The increase in the length of the lookback period will result in an increase in the number of burden hours for financial review for those parties who are disclosing financial relationships that were noncompliant for over 4 years. To reflect the increase in the lookback period from 4 years to 6 years, we have revised our estimate of the burden hours associated with financial analysis upward by 50%. Previously we estimated that the financial analysis would take between five (5) and fifteen (15) hours, depending on the number of noncompliant financial relationships disclosed, with an average of ten (10) hours. We now estimate that the financial analysis will take between seven and a half hours (7.5) and twenty-two and a half hours (22.5), with an average of fifteen (15). The annualized hour burden to the industry ranges from 750 hours (7.5 hours for financial review x 100 disclosures) to 2,250 hours (22.5 hours for financial review x 100 disclosures), with an average of 1500 hours (15 hours for financial review x 100 disclosures).

We believe that accounting and bookkeeping personnel will be responsible for gathering, reviewing, and submitting the financial data. According to the BLS information for May 2014, the national estimated mean hourly wage for the category of "accountants and auditors" was $35.42, and the national estimated mean hourly wage for the category of "bookkeeping,

accounting, and auditing clerks" was $18.30. The average of these two figures is $26.86. This does not include fringe benefits, which are generally calculated as being 100% of salary. This means that the cost of an hour of work for personnel responsible for the financial analysis of overpayments is $53.72 per hour. Thus, the cost per disclosure for financial review ranges from $402.90 ($53.72 per hour x 7.5 hours) to $1,208.70 ($53.72 per hour x 22.5 hours). The average cost for financial review is $805.80. Therefore, the annualized cost to the industry for financial review ranges from $40,290 ($402.90 x 100 disclosures) to $120,870 ($1,208.70 x 100 disclosures). The average annualized cost to the industry for financial review is $80,580 ($805.80 x 100 disclosures).

In sum, the estimated average total burden per disclosure is fifty (50) hours. The average cost per disclosure is $4,195.90 ($3,390.10 for the average legal review per disclosure + $805.80 for the average financial review per disclosure). The total annualized cost burden for both legal and financial review to the industry ranges from $156,522 ($116,232 for legal review + $40,290 for financial review) to $682,658 ($561,788 for legal review + $120,870 for financial review). The average annualized cost is $419,590.

13. Capital Costs

This collection will not require capital costs.

14. Cost to Federal Government

There is no additional cost to the Federal Government. Disclosures will be processed in the normal course of Federal duties.

15. Changes to Burden

In the revised collection, the lookback period for reporting overpayments arising from actual or potential violations of section 1877 of the Act has been increased from 4 to 6 years, consistent with the final overpayment rule. The longer lookback period will result in an increase in the burden hours associated with identifying overpayments. Specifically, we believe the burden associated with the financial review of overpayments will increase from an average of 10 hours per submission to an average of 15 hours. However, we estimate that the total burden hours for submissions to the SRDP will not increase because we will no longer collect certain information and because the SRDP Form will streamline and standardize the reporting process. In particular, we anticipate that the burden associated with legal review and the preparation of the submission will decrease from an average of 10 hours per submission to an average of 5 hours. We believe that, as the industry becomes more familiar with the SRDP Form, the burden will diminish in the future.

The estimated annual cost to the Federal Government has been corrected to indicate that there are no additional costs as a result of this ICR. The previous estimate was erroneous.

Since the 60-day notice, we have made a few minor terminology and formatting changes to

the SRDP Form. For example, the phrase “physician self-referral statute” had been replaced with “physician self-referral law,” and separate boxes for reporting the pervasiveness of the noncompliance have been formatted as one consolidated fillable box. The changes do not affect the burden.

16. Publication/Tabulation Dates

Not applicable to this collection.

17. Expiration Date

CMS will display the expiration date on the SRDP Form.

18. Certification Statement

There are no exceptions to the certification statement.