

**Paperwork Reduction Act - Supporting Statement**  
**Center for Medicare and Medicaid Services**  
**Medicare 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, 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 law, 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. The most recent approval of this information collection request (“ICR”) was issued by the Office of Management and Budget on January 23, 2017. We are now seeking to extend the information collection without modification. We have updated the cost estimate to account for the current Bureau of Labor Statistics (BLS) wage estimates.

**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 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. The standard form minimizes burden on all respondents, including small businesses. The SRDP does 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 notice published on June 26, 2019(84FR30123) and the 30-day notice published on September 11, 2019(84FR47958) with no comments received.

## **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 Estimates (Hours & Wages)**

Based on our experience with the SRDP, 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 provides a streamlined and standardized method for parties to report potential or actual noncompliance, including 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. 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 prepare the submission.

In sum, the annualized hour burden to the industry for legal review (including production and review of documents and preparation of the submission) 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 to the Bureau of Labor Statistics (BLS) data for May 2018, the national estimated mean hourly wage for the category of “compliance officers” was \$34.86, and the national estimated mean hourly wage for the category of “lawyers” was \$69.34. (See [https://www.bls.gov/oes/current/oes\\_nat.htm#00-0000](https://www.bls.gov/oes/current/oes_nat.htm#00-0000)). The average of these two figures is \$52.10. 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 \$104.20 per hour. Thus, the cost per disclosure for legal review is estimated to range from \$1,250.40 (\$104.20 per hour x 12 hours) to \$6,043.60 (\$104.20 per hour x 58 hours), with an average cost of \$3,647 (\$104.20 per hour x 35 hours). Therefore, the annualized cost to the industry for legal review ranges from \$125,040 (\$1,250.40 x 100 disclosures) to \$604,360 (\$6,043.60 x 100 disclosures). The average annualized cost to the industry for legal review is \$364,700 (\$3,647 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.

We estimate that the financial analysis takes 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 2018, the national estimated mean hourly wage for the category of “accountants and auditors” was \$37.89, and the national estimated mean hourly wage for the category of “bookkeeping, accounting, and auditing clerks” was \$20.25. (See [https://www.bls.gov/oes/current/oes\\_nat.htm#00-0000](https://www.bls.gov/oes/current/oes_nat.htm#00-0000)). The average of these two figures is \$29.07. 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 \$58.14 per hour. Thus, the cost per disclosure for financial review ranges from \$436.05 (\$58.14 per hour x 7.5 hours) to \$1,308.15 (\$58.14 per hour x 22.5 hours). The average cost for financial review is \$872.10. Therefore, the annualized cost to the industry for financial review ranges from \$43,605 (\$436.05 x 100 disclosures) to \$130,815 (\$1,308.15 x 100 disclosures). The average annualized cost to the industry for financial review is \$87,210 (\$872.10 x 100 disclosures).

In sum, the estimated average total burden per disclosure is fifty (50) hours. The average cost per disclosure is \$4,519.10 (\$3,647.00 for the average legal review per disclosure + \$872.10 for the average financial review per disclosure). The total annualized cost burden for both legal and financial review to the industry ranges from \$168,645 (\$125,040 for legal review + \$43,605 for financial review) to \$735,175 (\$604,360 for legal review + \$130,815 for financial review). The average annualized cost is \$451,910.

### **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**

We have not changed the information collection requirements in any way. We updated the cost estimate to account for the current BLS wage estimates. The previous average annualized cost estimate was \$419,590. The current average annualized cost is \$451,910.

### **16. Publication/Tabulation Dates**

Not applicable to this collection.

**17. Expiration Date**

CMS will display the expiration date on the SRDP Form at the bottom left of the form.

**18. Certification Statement**

Not applicable to this collection.