Supporting Statement-A
Medicare Self-Referral Disclosure Protocol
(CMS-10328, OMB 0938-1106)

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 October 18, 2019. We are now seeking to extend the information collection with certain modifications.

Under the currently approved collection, all entities submitting self-disclosures to the SRDP, including hospitals, home health agencies, clinical laboratories, and physician practices, must report noncompliance using a form consisting of three components: (1) the SRDP Disclosure Form, (2) separate Physician Information Forms for each physician covered in the self-disclosure, and (3) a Financial Analysis Worksheet. We propose to require physician practices who are reporting noncompliance arising solely from the failure of the practice to qualify as a group practice under §411.352 ("group practice noncompliance") to complete a new Group Practice Information Form in lieu of separate Physician Information Forms for each physician in the practice who made prohibited referrals. Specifically, under the proposal a physician practice disclosing group practice noncompliance will submit an SRDP form consisting of the following components: (1) the SRDP Disclosure Form, (2) a single Group Practice Information Form covering all the physicians in the practice who made prohibited referrals to the practice, and (3) a Financial Analysis Worksheet. All other entities will continue to submit disclosures using the SRDP Disclosure Form, separate Physician

Information Forms for each physician covered in the self-disclosure, and a Financial Analysis Worksheet.

The proposed Group Practice Information Form includes questions that are specifically tailored to physician practices that failed to qualify as group practices under §411.352. This information is currently collected in a few disparate questions on the SRDP Disclosure Form and the Physician Information Form. The new Group Practice Information Form consolidates all questions relevant to group practice noncompliance in one place, eliminates duplicative questions, and provides clearer instructions to physician practices on how to report group practice noncompliance. As such, the Group Practice Information Form will facilitate submissions to the SRDP and allow CMS to better assess group practice noncompliance.

We believe that the Group Practice Information Form will not increase burden. As noted above, the information being collected is currently collected in the SRDP Disclosure Form and the Physician Information Forms. No new information is being collected. More generally speaking, as noted in section B.12 below, the majority of the burden associated with the SRDP consists of the collection of documents, legal review of documents to determine compliance with the law, and the financial analysis of the potential overpayment; this burden is unchanged by the addition of the new Group Practice Information Form. With the new Group Practice Information Form, the burden of preparing the submission may be slightly lower in certain cases, because physician practices will no longer be required to complete separate Physician Information Forms for every physician in the practice who made prohibited referrals; instead, the physician practice will complete a single Group Practice Information Form covering all the physicians in the practice who made prohibited referrals. We believe that the decrease in burden, if any, is marginal and does not affect the overall burden associated with the SRDP.

We are also taking this opportunity to revise the instructions to the SRDP, to clarify existing policies and to align language with the final rule CMS-1720-F, *Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations* (85 FR 77492). In addition, we are replacing expandable fields with static fields to facilitate completion of the form. Lastly, we are modifying the instructions to require electronic, rather than hard copy, submission of the signed certification statement, so the submission process will now be fully electronic. These changes do not affect the burden estimates for this information collection instrument. 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. For purposes of the SRDP, a person submitting a disclosure to the SRDP will be referred to as a "disclosing party." 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 law's referral and billing prohibitions. 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.

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

The SRDP enables providers of services and suppliers to self-disclose actual or potential violations of the physician self-referral law to CMS, and section 6409(b) of the ACA gives the Secretary the authority to reduce the amount due and owing for such violations. If we did not collect this information, providers and suppliers would be deprived of the option to self-disclose and would be required to repay the entire amount due and owing for all violations of the physician self-referral law. This information collection merely provides a standardized form for a disclosing party to voluntarily submit a self-disclosure to CMS. A disclosing party wishing to participate in the SRDP will be able to use this information collection instrument to furnish a complete and specific description of all relevant information necessary with the intention of resolving its overpayment liability exposure for the conduct it identifies. There is no obligation for providers and suppliers to self-disclose violations of the physician self-referral law to the SRDP. Participation in the SRDP is completely voluntary, and the frequency with which a disclosing party submits the information required by the SRPD is determined entirely by the disclosing party.

7. Special Circumstances

There are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;

- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

The 60-day Federal Register Notice published on 06/09/2022 (87 FR 35218). We received two comments. Each commenter provided multiple comments on the SRDP Forms and instructions. We responded to the comments and made certain minor adjustments to the SRDP Disclosure Form and the Group Practice Information Form to address the commenters' concerns. The modifications to the SRDP Forms do no impact the burden estimates.

The 30-day Federal Register Notice published on TBD (87 FR).

9. Payments/Gifts to Respondents

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

10. Confidentiality

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 physician 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 service 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 2021, the national estimated mean hourly wage for the category of "compliance officers" was $36.45, and the national estimated mean hourly wage for the category of "lawyers" was $71.17. (See https://www.bls.gov/oes/current/oes_nat.htm#00-0000). The average of these two figures is $53.81. 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 $107.62 per hour. Thus, the cost per disclosure for legal review is estimated to range from $1291.44 ($107.62 per hour x 12 hours) to $6241.96 ($107.62 per hour x 58 hours), with an average cost of $3766.70 ($107.62 per hour x 35 hours). Therefore, the annualized cost to the industry for legal review ranges from $129,144 ($1291.44 x 100 disclosures) to $624,196 ($6241.96 x 100 disclosures). The average annualized cost to the industry for legal review is $376670 ($3,766.70 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 2021, the national estimated mean hourly wage for the category of "accountants and auditors" was $40.37, and the national estimated mean hourly wage for the category of "bookkeeping, accounting, and auditing clerks" was $21.70. (See https://www.bls.gov/oes/current/oes_nat.htm#00-0000). The average of these two figures is $31.04. 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 $62.08 per hour. Thus, the cost per disclosure for financial review ranges from $465.60 ($62.08 per hour x 7.5 hours) to $1396.80 ($62.08 per hour x 22.5 hours). The average cost for financial review is $931.20 ($62.08 per hour x 15 hours). Therefore, the annualized cost to the industry for financial review ranges from $46,560 ($465.60 x 100 disclosures) to $139,680 ($1396.8 x 100 disclosures). The average annualized cost to the industry for financial review is $93,120 ($931.20 x 100 disclosures).

In sum, the estimated average total burden per disclosure is fifty (50) hours. The average cost per disclosure is $4,697.90 ($3766.70 for the average legal review per disclosure + $931.20 for the average financial review per disclosure). The total annualized cost burden for both legal and financial review to the industry ranges from $175,704 ($129,144 for legal review + $46,560 for financial review) to $763,876 ($624,196for legal review + $139,680 for financial review). The average annualized cost is $469,790. See table below.

	Legal Review	Financial Review	Total
Cost per disclosure:			
- Range:	$1,291.44 - $6,241.96	$465.60 - $1,396.80	$1,757.04 - $7,638.76
- Average:	$3,766.70	$931.20	$4,697.90
Hourly burden per disclosure			
- Range:	12 – 58 hours	7.5 – 22.5 hours	19.5 – 80.5 hours
- Average:	35 hours	15 hours	50 hours
Annualized cost (100 disclosures per year)			
- Range	$129,144 - $624,196	$46,560 - $139,680	$175,704 - $763,876
- Average	$376,670	$93,120	$469,790
Annualized hourly burden			
- Range:	1200 – 5800 hours	750 – 2250 hours	1950 – 8050 hours
- Average:	3500 hours	1500 hours	5000 hours

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 are now seeking to extend the information collection with certain revisions. As explained in section A. above, for physician practices disclosing group practice noncompliance, we are requiring the practice to submit a single Group Practice Information Form instead of separate Physician Information Forms for each physician in the practice who made prohibited referrals. We do not believe that this modification will affect the burden estimates for this collection, because: (1) The information being collected in the Group Practice Information Form is already collected in the SRDP Disclosure Form and the Physician Information Form; the Group Practice Information Form consolidates all questions relevant to group practice noncompliance and eliminates certain duplicative questions. (2) As detailed in section B.12 above, the majority of the burden associated with the SRDP consists in production and legal review of documents to determine compliance with the physician self-referral law (30 hours) and financial analysis of the potential overpayment (15 hours); the addition of the Group Practice Information Form does not affect this burden. With the new Group Practice Information Form, the burden of preparing the submission will not be increased and may be slightly lower in certain cases, because physician practices will no longer be required to complete separate Physician Information Forms for every physician in the practice who made prohibited referrals; instead, the physician practice will complete a single Group Practice Information Form covering all the physicians in the practice who made prohibited referrals. However, we believe that this decrease in burden, if any, is marginal and does not affect the overall burden associated with the SRDP

For all disclosures other than disclosures by physician practices reporting group practice noncompliance, the requirements for a complete submission remain unchanged. We are revising the instructions to clarify existing policies and to align language with the Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations Final Rule (85 FR 77492). We are also replacing expandable fields with static fields to facilitate completion of the form. Lastly, we are modifying the instructions to require electronic, rather than hard copy, submission of the signed certification statement, so the submission process will now be

fully electronic. These changes do not affect the burden estimates for this information collection instrument. We updated the cost estimate to account for the current BLS wage estimates. The previous average annualized cost estimate was $451,910. The current average annualized cost is $469,794.

In response to comments, we have made a few minor edits to the SRDP Disclosure Form and the Group Practice Information Form. In the instructions for the SRDP at section IV.B.2.b, we clarified a statement on the applicability of the physician services exception at §411.355(a) and the in-office ancillary services exception at §411.355(b) to physician practices consisting of two or more physicians. In the SRDP Disclosure Form, we added a statement that disclosing parties may rely on reasonable estimates when reporting the pervasiveness of noncompliance. In the Group Practice Information Form, we clarified in the instructions that the form may not be used by solo physician practices or physician practices that qualify as group practices under §411.352 to report the failure to satisfy an exception in §411.355, including the in-office ancillary services exception. Also in the Group Practice Information Form, we clarified an example of how to report compensation that took into account the volume or value of a physician's referrals, and stated that requested information on CPT/HCPCS codes should be provided "if available." These minor editorial changes to the SRDP Forms do not impact the burden estimate.

16. Publication/Tabulation Dates

No publication or tabulation of data expected.

17. Expiration Date

CMS will display the expiration date on the SRDP Form at the top right corner of the form.

18. Certification Statement

Not applicable to this collection.