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") 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 December 28, 2022. We are now seeking to extend the ICR with limited modifications and editorial changes. These changes, which are further described below, decrease the burden estimates for this information collection instrument. We also updated the cost estimate to account for the current Bureau of Labor Statistics (BLS) wage estimates.

Under the currently approved ICR, all entities submitting self-disclosures to the SRDP, including but not limited to hospitals, home health agencies, clinical laboratories, and physician practices, must report noncompliance using the SRDP Disclosure Form and a Financial Analysis Worksheet. Depending on the type of noncompliance being reported, entities must also complete and submit the following: (i) a single Group Practice Information Form, to report noncompliance resulting from the failure of a physician practice to qualify as a "group practice" under § 411.352 ("group practice noncompliance"); or (ii) for reporting all other types of noncompliance, separate Physician Information Forms for each physician who made prohibited referrals to the entity that is the subject of the self-disclosure. Currently, there is a special rule that permits entities to use *one* Physician Information Form to cover *multiple* physicians if the physicians "stand in the shoes" of a physician organization that is the subject of the disclosure. This special rule reduces burden on parties disclosing identical noncompliance involving multiple physicians because an entity is not required to complete

and submit multiple, largely duplicative Physician Information Forms for each physician that stands in the shoes of the organization.

We are proposing several changes to further reduce burden and clarify the information requested. First, in line with the current special rule for physicians who "stand in the shoes" of their physician organization, we are proposing to allow entities to submit *one* Physician Information Form covering *multiple* physicians for the following type of noncompliance: the failure of physicians relying on the in-office ancillary services exception (IOAS exception) to provide the required written notice for certain imaging services (see § 411.355(b)(7)) ("imaging notice noncompliance"). This new special rule will decrease burden by no longer requiring entities disclosing imaging notice noncompliance to complete and submit multiple, largely duplicative Physician Information Forms for each physician that failed to provide the required notice.

Second, we propose to highlight in the instructions on the SRDP Disclosure Form a potentially less burdensome alternative to the SRDP for some parties. In the revised instructions, we explain that a disclosing party may also satisfy the requirement at § 401.305 to report and return overpayments arising from violations of the physician self-referral law by reporting and refunding the full overpayment directly to the party's Medicare Administrative Contractor (MAC). We believe that, in some instances, the cost of preparing and submitting a self-disclosure to the SRDP may exceed the amount of the disclosed overpayment; in other instances, it may be preferable to the entity for business reasons, such as satisfaction of the report and return obligation prior to an imminent transaction, to report and return the overpayment directly to the MAC. The revised instructions inform disclosing parties that they may consider reporting and refunding the full overpayment directly to their MAC, as opposed to submitting a self-disclosure to the SRDP, thus decreasing burden related to the time and effort required to complete all SRDP forms and provide any additional information needed by CMS during the disclosure review process.

Third, we are clarifying the type of information regarding the date that the entity first discovered the reported noncompliance that is currently required in the Physician Information Form and Group Practice Information Form. Based on our administration of the SRDP, we have observed that many parties report the date of discovery as the date on which they complete their investigation and quantify the overpayment, as opposed to the date that they originally discovered the potential noncompliance and began their investigation, even though the current instructions note that these dates are not the same in most instances. The conflation of discovery date and identification date has led CMS in certain circumstances to request additional information from parties that have already submitted their self-disclosures, potentially increasing burden. We propose to further clarify the instructions regarding reporting the discovery date, thus making requests for more information less likely, and also to move the information request from the Physician Information Form and Group Practice Information Form to the SRDP Disclosure Form, to make the explanation itself more

prominent and because most parties report one date of discovery for all physicians covered in the disclosure.

We believe that these suggested changes and editorial modifications will decrease the burden for entities submitting self-disclosures, as noted above. The three proposed changes do not increase the amount of information beyond what is already collected under the SRDP.

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 SRDP is determined entirely by the disclosing party.

A disclosing party may also satisfy the requirement at § 401.305 to report and return overpayments arising from violations of the physician self-referral law by reporting and refunding the full overpayment directly to the party's MAC leading to less frequent collection. In certain instances, the cost of preparing and submitting a self-disclosure to the SRDP may exceed the amount of the overpayment. Disclosing parties in such circumstances

are encouraged to consider reporting and refunding the full overpayment directly to their MAC.

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 notice published in the Federal Register on July 3, 2025 (90 FR 29551). A total of zero (0) comments were received.

A 30-day notice published in the Federal Register on September 24, 2025 (90 FR 45951).

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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 and submit the disclosure. 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 one (1) to eight (8) hours to prepare the submission, depending on the number of noncompliant financial relationships. On average, it will take approximately four and a half (4.5) 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 1100 hours (11 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 3450 (34.5 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 BLS data for May 2024, the national estimated mean hourly wage for the category of "compliance officers" was $40.86, and the national estimated mean hourly wage for the category of "lawyers" was $87.86. (See https://www.bls.gov/oes/current/oes_nat.htm#00-0000). The average of these two figures is $64.36. 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 $128.72 per hour. Thus, the cost per disclosure for legal review is estimated to range from $1,415.92 ($128.72 per hour x 11 hours) to $7,465.76 ($128.72 per hour x 58 hours), with an average cost of $4,440.84 ($128.72 per hour x 34.5 hours).
Therefore, the annualized cost to the industry for legal review ranges from $141,592 ($1,415.92 x 100 disclosures) to $746,576 ($7,465.76 x 100 disclosures). The average annualized cost to the industry for legal review is $444,084 ($4,440.84 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 2024, the national estimated mean hourly wage for the category of "accountants and auditors" was $44.96, and the national estimated mean hourly wage for the category of "bookkeeping, accounting, and auditing clerks" was $25.01. (See https://www.bls.gov/oes/current/oes_nat.htm#00-0000). The average of these two figures is $34.99. 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 $69.98 per hour. Thus, the cost per disclosure for financial review ranges from $524.85 ($69.98 per hour x 7.5 hours) to $1,574.55 ($69.98 per hour x 22.5 hours). The average cost for financial review is $1,049.70 ($69.98 per hour x 15 hours). Therefore, the annualized cost to the industry for financial review ranges from $52,485 ($524.85 x 100 disclosures) to $157,455 ($1,574.55 x 100 disclosures). The average annualized cost to the industry for financial review is $104,970 ($1049.70 x 100 disclosures).

In sum, the estimated average total burden per disclosure is forty nine and a half (49.5) hours. The average cost per disclosure is $5,490.54 ($4,440.84 for the average legal review per disclosure + $1049.70 for the average financial review per disclosure). The total annualized cost burden for both legal and financial review to the industry ranges from $194,077 ($141,592 for legal review + $52,485 for financial review) to $904,031.00 ($746,576 for legal review + $157,455 for financial review). The average annualized cost is $549,054.00. See table below.

	Legal Review	Financial Review	Total
Cost per disclosure:			
- Range:	$1,415.92 - $7,465.76	$524.85 - $1,574.55	$1,940.77 - $9,040.31
- Average:	$4,440.84	$1,049.70	$5,490.54
Hourly burden per disclosure			
- Range:	11 – 58 hours	7.5 – 22.5 hours	18.5 – 80.5 hours
- Average:	34.5 hours	15 hours	49.5 hours
Annualized	100	100	100

cost (100 disclosures per year)			
- Range	$141,592.00 - $746,576.00	$52,485.00 - $157,455.00	$194,077.00 - $904,031.00
- Average	$444,084.00	$104,970.00	$549,054.00
Annualized hourly burden			
- Range:	1100 – 5800 hours	750 – 2250 hours	1850 – 8050 hours
- Average:	3450 hours	1500 hours	4950 hours

13. <u>Capital Costs</u>

This collection will not require capital costs.

14. <u>Cost to Federal Government</u>

The yearly average cost to the Government to administer the SRDP, including the analysis and review of submissions to the SRDP, is estimated to be $883,820. This is a decrease of $37,653.70 from the last ICR total cost to the Government of $921,473.70. The analysis and review of disclosures is performed by CMS employees and HHS attorneys, including approximately four GS-13, step 5 FTEs; one GS-14, step 2 FTE; and one GS-15, step 5 FTE. The salary for employees, which includes the locality pay adjustment for the area of Washington-Baltimore-Arlington, is listed in the table below. *See* OPM 2025 General Schedule (GS) Locality Pay Tables, https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2025/general-schedule/. The review and analysis of self-disclosures by CMS employees and HHS attorneys includes legal analysis of submissions, project management, communications with disclosing parties, calculation of damages, and preparation of various legal documents, including settlement agreements. The cost to the Government decreased because of staffing changes, processing efficiencies gained due to the use of the SRDP forms that are the subject of this ICR, and improved internal processes like switching from individual to team-based processing of disclosures.

Employees	**Annual salary**	**Number of annual FTEs**	**Annual cost to government**
GS-13, step 5	$136,658	4	$546,632
GS-14, step 2	$147,238	1	$147,238

GS-15, step 5	$189,950	1	$189,950
			TOTAL: $883,820

15. Changes to Burden

We are now seeking to extend the information collection with certain revisions. As explained in section A. above, for a disclosing party that is disclosing noncompliance arising from the failure of a physician or physicians in a practice that qualifies as a group practice under § 411.352 to satisfy the disclosure requirement for certain imaging services required at § 411.355(b)(7) to submit only one Physician Information Form instead of separate Physician Information Forms for each physician in the practice who made prohibited referrals. We believe that this modification will decrease the burden estimates for this collection, because as detailed in section B.12 above, much 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 this qualifier will decrease the burden estimates. With the new qualifer, the burden of preparing the submission will not be increased and may be slightly lower in certain cases, because a disclosing party who meets this qualifier will no longer be required to complete separate Physician Information Forms for each physician in the practice who made prohibited referrals; instead, a disclosing party will complete a single Physician Information Form covering all the physicians in the practice who made prohibited referrals.

We also propose to reduce burden by adding a statement that overpayments arising from physician self-referral law violations can be reported and refunded directly to the MAC and providing additional instructions on how to determine the date of discovery. These changes decrease the total average burden estimate for this information collection instrument. We updated the total average cost estimate to account for the current BLS wage estimates. The previous average annualized cost estimate was $469,790. The current average annualized cost is $549,054.00.

16. Publication/Tabulation Dates

No publication or tabulation of data expected.

17. Expiration Date

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

18. Certification Statement

Not applicable to this collection.