

Supporting Statement for Paperwork Reduction Act Submissions

*Independent Diagnostic Testing Facilities (IDTFs) Site Investigation Form Revisions
(CMS-10221/OMB Control Number: 0938-1029)*

BACKGROUND

CMS enrolls Independent Diagnostic Testing Facilities (IDTFs) into the Medicare program via a uniform application, the CMS-855B. Implementation of enhanced procedures for verifying the enrollment information has improved the enrollment process as well as identified and prevented fraudulent IDTFs from entering the Medicare program. As part of this process, verification of compliance with IDTF performance standards is necessary. The primary function of the CMS- 10221 (Independent Diagnostic Testing Facilities – Site Investigation Form) is to provide a standardized, uniform tool to gather information from an IDTF that tells us whether it meets certain standards to be a IDTF (as found in 42 CFR § 410.33(g)) and where it practices or renders its services. The site investigation form is used to aid the National Site Visit Contractors (NSVCs) Eastern and Western Regions in verifying compliance with the required performance standards found in 42 CFR § 410.33(g). CMS is making revisions to the currently approved information collection. The revisions to the form include the following:

- Section 2: Options for "fixed", "mobile", and "indirect"
- Performance standards throughout the form having specific reference to match up with the application certification standards under 410.33(g)
- N/A option added to all sections on the form including to the description boxes
- Section 3.A.1. grammar correction: "ITDF" changed to "IDTF"
- Section 3.G. language under Section G Performance standard changed from "requires IDTF's to post these standards for beneficiary review" to "'The IDTF must openly post the standards outlined in § 410.33(g) for review by patients and the public. "
- Section 3.H.1. language added to describe diagnostic equipment as being "self or manually" calibrated
- Section 3.I.3. language with more description added so the question reads "Is the supervising physician(s) identified by the technical staff on site?"
- Section 4. B. the free form box was expanded
- Section 4.D. the two requirements were removed and replaced with the language "Refer to the contractor's statement of work."

JUSTIFICATION

1. Need and Legal Basis

Any IDTF that wishes to enroll in the Medicare program must undergo a site investigation per 42 CFR § 410.33. The purpose of the site investigation is to ensure that the IDTF is in compliance with the provisions of 42 CFR § 410.33, as well as all other applicable Federal, State and local laws and regulations. It is also used to verify the information the IDTF

furnished on its CMS- 855B enrollment application.

Sections 1814(a), 1815(a), and 1833(e) of the Act require the submission of information necessary to determine the amounts due to a provider or other person. To fulfill this requirement, CMS must collect information on any IDTF supplier who submits a claim to Medicare or who applies for a Medicare billing number before allowing the IDTF to enroll. This information must, minimally, clearly identify the provider and its' place of business as required by C.F.R. § 424.500 (Requirements for Establishing and Maintaining Medicare Billing Privileges) and provide all necessary documentation to show they are qualified to perform the services for which they are billing. The site inspection form allows inspectors to verify the information using a standardized information collection methodology.

2. Information Users

C.F.R. section 424.500 states the requirements for enrollment, periodic resubmission and certification of enrollment information for revalidation, and timely reporting of updates and changes to enrollment information. These requirements apply to all providers and suppliers except for physicians and practitioners who have entered into a private contract with a beneficiary as described in part 405, subpart D of this chapter. Providers and suppliers must meet and maintain these enrollment requirements to bill either the Medicare program or its beneficiaries for Medicare covered services or supplies. Sections 1814(a), 1815(a), and 1833(e) of the Act require the submission of information necessary to determine the amounts due to a provider or other person.

The CMS-10221 form is used by the National Site Visit Contractors (NSVCs) Eastern and Western Regions on site visits to verify compliance with required IDTF performance standards.

The collection and verification of this information defends and protects our beneficiaries from illegitimate IDTFs. These procedures also protect the Medicare Trust Fund against fraud. The data collected also ensures that the applicant has the necessary credentials to provide the health care services for which they intend to bill Medicare. This is sole instrument implemented for this purpose.

3. Use of Information Technology

This form does not use information technology, as all the site inspections must be individually performed.

4. Duplication of Efforts

There is no duplicative information collection instrument or process.

5. Small Business

A Medicare billing number is required of all health care suppliers/providers who wish to submit claims for payment to the Medicare Trust Fund so this worksheet will affect small IDTF businesses who wish to have a Medicare billing number. However, these IDTFs have always been required to provide CMS a site visit to verify information collected on the CMS-855B application, including site investigations, as a condition of enrollment. Accordingly, the impact is minimal – CMS carries the burden of the cost; the IDTF supplier must allocate a small amount of time to this effort.

6. Less Frequent Collection

After the initial enrollment and approval, this information is collected on an as needed basis. It is necessary for verification of enrollment information. It will be collected upon initial enrollment, revalidation (currently every five years) and when the NSVCs conduct unannounced site visits in accordance with special fraud initiatives. If it were collected less frequently, CMS would not be able to determine the legitimacy of the IDTF suppliers in the Medicare program.

7. Special Circumstances

There are no special circumstances associated with this collection.

8. Federal Register Notice/Outside Consultation

A 60-day notice published in the Federal Register on March 27, 2023 (88 FR 18141). The 30-day notice published in the Federal Register on June 1, 2023 (88 FR 35878).

No outside consultation was sought.

9. Payment/Gift to Respondents

There are no payments or gifts to respondents.

10. Confidentiality

CMS will comply with all Privacy Act, Freedom of Information laws and regulations that apply to this collection. Privileged or confidential commercial or financial information is protected from public disclosure by Federal law 5 U.S.C. 522(b)(4) and Executive Order 12600.

The SORN title is Provider Enrollment, Chain and Ownership System (PECOS), number 09- 70-0532.

11. Sensitive Questions

There are no sensitive questions associated with this collection.

12. Burden Estimate (Hours and Wages)

Burden Hours

For this proposed revision of the CMS-10221, CMS is basing the burden amounts on data compiled from the Provider Enrollment, Chain and Ownership System (PECOS) and the National Site Visit Contractors (NSVCs) and are taken directly from the actual site investigation forms processed for fiscal year 2022. The new figures of processed IDTF site investigations are exact.

The hour burden to the respondents is calculated based on the following assumptions:

- NSVCs currently process approximately 652 CMS-10221 IDTF site investigation forms per year (as seen in Table A).
- Hour burden of the respondents is calculated as follows based on the following assumptions:
 - o The CMS-10221 will be completed by the NSVCs.
 - o The record keeping burden is included in the time determined for completion by the NSVCs.
 - o The CMS-10221 site investigation forms are reviewed with the enrolling or enrolled IDTF (BLS category = health diagnosing and treating practitioners).

A) Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Average of Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Burden (in hours)
Independent Diagnostic Testing Facilities	Independent Diagnostic Testing Facilities – Site Investigation 42 CFR §410.33	652 ¹	1	2 hours	1,304 hours

Burden Cost

For this proposed revision of the CMS-10221, CMS has recalculated the estimated burden cost. CMS believes this recalculation is necessary because the number of respondents, average burden and the wages of the respondents has changed. CMS is basing the new burden amounts on data compiled from PECOS and the NSVCs. To derive average costs, CMS used data from the U.S. Bureau of Labor Statistics’ (BLS) May 2021 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). For the purposes of this IDTF site investigation form, CMS used the wages under the general category of “Healthcare Diagnosing or Treating Practitioners.” In this regard, CMS adjusted the employee hourly

¹ PECOS data from 2022.

wage estimates by a factor of 100 percent. This is necessarily an estimated adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and CMS believes that doubling the hourly wage to estimate total cost is an accurate estimation method that has been used successfully in previous burden calculations.

The cost burden to the respondents is calculated based on the following assumptions:

- NSVCs currently process approximately 652 IDTF site investigation forms per year.
- Completion of the CMS-10221 cost burden is determined by the wage of the IDTF senior staff (Healthcare Diagnosing or Treating Practitioners) who review the information gathered during the site investigation.
- Cost to the respondents is calculated as follows based on the following assumptions (as seen in Table B):
 - o The most recent wage data provided by the Bureau of Labor Statistics (BLS) for May 2021, the mean hourly wage for the general category of for the general category of "Healthcare Diagnosing or Treating Practitioners" is \$40.65 per http://www.bls.gov/oes/current/oes_nat.htm).
 - o With fringe benefits and overhead, the total hourly rate for “Health Diagnosing and Treating Practitioners” is \$81.30.

B) Estimated Annualized Burden Costs

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Hourly Wage Rate	Total Burden (cost)
Independent Diagnostic Testing Facilities	652	1	2	\$81.30	\$106,015

The three-year summary of all burden hours and costs are reflected in Table C (below).

Regulation Section(s)	OMB Control No.	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting (\$) includes 100% fringe benefits	Total Cost (\$)
Independent Diagnostic Testing	0938-1029	652	652 per year	2 hours by Healthcare Diagnosing	1,304 Hours	Health Diagnosing and Treating	\$106,015.20

Facilities (IDTFs) Site Investigation Form per 42 CFR § 410.33 (CMS-10221)				or Treating Practitioners		Practitioners at \$81.30 per hour	
3-year total	0938-1029	1,956 Respondents	1,956 Responses	6 hours by Healthcare Diagnosing or Treating Practitioners	3,912 hours	\$243.90 for Health Diagnosing and Treating Practitioners	\$318,045.60

13. Capital Costs

There are no capital costs associated with this collection.

14. Cost to Federal Government

The estimated annualized cost to the government is \$130,400. The table below describes itemized cost components.

\$200 per site investigation multiplied by 652 site investigations = \$130,400.

Item	Estimated Annualized Cost
National Site Visit Contractor	\$200 ² per site visit
Number of IDTF Site Investigations per year	652 site visits
Total	\$130,400

15. Changes to Burden

The currently approved burden estimate was based on 727 respondents annually with an annual total burden hours of 1,454. This was calculated at an hour amount per application (two hours per application). Based on these numbers, there is an annual decrease in respondents of 75 (from 727 to 652). CMS believes this decrease is due to less IDTFs entering the Medicare program. Over a three-year period, the hour burden has decreased by 450 hours (from 4,362 to 3,912 hours).

² Cost figure for site visit (\$200) derived from National Site Visit Contractor Data.

16. Publication/Tabulation Dates

There are no plans to publish the outcome of the data collection.

17. Expiration Date

The expiration date will be displayed on the top, right-hand corner of page 1 of the CMS-10221 site investigation form.