

Supporting Statement for Paperwork Reduction Act Submissions

*Worksheet for Recording Results of Medicare Site
Visits of Independent Diagnostic Testing Facilities (IDTFs)
(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 has been used in the past to aid the Medicare contractors and/or its subcontractors in verifying compliance with the required performance standards found in 42 CFR § 410.33(g). This site investigation form collects the same information as its predecessor, with no exceptions. All information collected on this site investigation remains unchanged. The OMB approval for the IDTF site investigation form approved under OMB control number 0938-1079, expired August 31, 2015. With this revised information collection request, CMS is seeking to reinstate the OMB control number and obtain approval for another three years.

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) 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 the Budget Reconciliation Act of 1985 (P.L. 99-272) [42 U.S.C. § 9202(g)] 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

The CMS-10221 form is used by Medicare contractors and/or their subcontractors on site visits to verify compliance with required IDTF performance standards. If a subcontractor is used, the subcontractor collects the information from the IDTF through an interview and forwards it to the Medicare contractor for evaluation.

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

This worksheet will affect small businesses. However, these IDTFs have always been required to provide CMS with documentation 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

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 Medicare contractor conducts 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

The 60-day Federal Register notice published on January 16, 2015 (80 FR 2430). No comments were received. No outside agencies were contacted as part of this information collection.

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.

11. Sensitive Questions

There are no sensitive questions associated with this collection.

12. Burden Estimate (Hours and Wages)

CMS has recalculated the burden hours. CMS believes the burden hours accurately reflect the current burden when completing this site investigation. The burden amounts are taken directly from the actual site investigations conducted by the site investigation contractor for the most recent contract period of performance (December, 2013 through November, 2014). The number of inspections is an exact figure.

900 respondents per year @ 2 hours each = 1,800 hours.

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	900 ¹	1	2	1,800

b) Estimated Annualized Cost to Respondents

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	900	1	2	\$81.78	**\$147,204

¹ MAC contractor data from 2015.

Testing Facilities					
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**The hourly wage rate is based on the most recent wage data provided by the BLS for May, 2015 (see http://www.bls.gov/oes/current/oes_nat.htm#43-0000), the mean hourly wage for the general category of “Health Diagnosing and Treating Practitioners, All Other” is \$40.89. With fringe benefits and overhead, the total per hour rate is \$81.78.

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 \$180,000. The table below describes itemized cost components.

\$200/site visit X 900 site visits = \$180,000

Item	Estimated Annualized Cost
Medicare Contractor Site Investigator	\$200 ² per site visit
Number of Site Investigations per year	900 site visits
Total	\$180,000

15. Changes to Burden

The previously approved total annual hour burden for the respondents in 2012 was 2,000 hours. That figure was based on an estimation gathered from the appropriate contractors and has now been determined to be high, due to the current lesser number of respondents. In 2012, our reported estimation was 1,000 respondents at 2 hours each equaling 2,000 hours. Due to better reporting methods and more accurate data collection, CMS now determines the total burden hours for this information collection to be 1,800 hours with 900 respondents.

16. Publication/Tabulation Dates

There are no plans to publish or tabulate the information collected.

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

17. Expiration Date

There is no objection to displaying the expiration date. The expiration date and OMB control will be displayed on all instruments.