

Supporting Statement for Paperwork Reduction Act Submissions

Worksheet for Recording Results of Medicare Site Visits of Independent Diagnostic Testing Facilities (IDTFs)

A. BACKGROUND

The CMS-10221 worksheet (form) was developed, approved through the Office of Management and Budget and implemented to allow for CMS to have a standard format to collect and verify information regarding the compliance of independent diagnostic testing facilities (IDTFs) with the performance standards found in 42 CFR § 410.33(g). This previously approved form was allowed to expire in error. CMS is now seeking re-instatement of the use of this form.

JUSTIFICATION

1. Need and Legal Basis

Per 42 CFR § 410.33, any IDTF that wishes to enroll in the Medicare program must undergo a site visit. The purpose of the site visit 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.

2. Purpose and users of the information

The CMS-10221 worksheet is used to collect and record information obtained on IDTF site visits; the data collected during site visits facilitates the verification of the accuracy and completeness of the information the IDTF furnished on its CMS-855B enrollment application.

The CMS-10221 worksheet itself is completed by CMS or its contractors. Some of the answers to the questions/data elements on the worksheet are verbally furnished by the IDTF during the site visit.

3. Improved Information Techniques

This collection does not lend itself to electronic collection methods.

4. Duplication and Similar Information

There is no duplicative information collection instrument or process.

5. Small Business

This worksheet will not affect small businesses. These businesses are currently required to provide CMS with this information during IDTF site visits.

6. *Less Frequent Collections*

This information is collected on an as needed basis.

7. *Special Circumstances*

There are no special circumstances associated with this collection.

8. *Federal Register Notice/Outside Consultation*

The 60-day *Federal Register* notice for this collection will be published on December 16, 2011.

9. *Payment/Gift to Respondents*

N/A

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)*

The current total annual hour burden for respondents is 4,000 hours. CMS is not changing this estimate. This is based on the following estimates.

2,000 respondents per year @ 2 hours each = 4,000 hours

Although the CMS-10221 worksheet itself is completed by CMS or its contractors, some of the answers to the questions/data elements on the CMS-10221 worksheet are verbally furnished by the IDTF during the site visit.

Currently the cost to the respondents was calculated as follows based on the following assumptions:

Cost per CMS-10221 Worksheet = \$100.00 X 2,000 Respondents = \$200,000

The cost per respondent per form was determined using the follow wages:

\$50.00 per hour (administrator wage) X 2 hours per Respondent

For this reinstatement, CMS has determined there is no financial cost to the respondents since

they do not complete the worksheet. Therefore, CMS is reducing the cost burden to \$0.00.

13. *Cost to Respondents (Capital)*

There are no capital costs associated with this collection.

14. *Cost to Federal Government*

There is no additional cost to the Federal government.

15. *Changes in Burden/Program Changes*

CMS has removed the financial burden as previously reported. It has been determined there is no cost to the respondent in association with the use of this worksheet.

16. *Publication/Tabulation*

N/A

17. *Expiration Date*

We are planning on displaying the expiration date.

18. *Certification Statement*

There are no exceptions to item 19 of OMB Form 83-I.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

N/A