

curriculum vitae, and course materials are reviewed by NIOSH to determine if the applicant has developed a program which adheres to the criteria required in the standard. Following approval, any subsequent changes to the course are submitted by course sponsors via letter or email and reviewed by NIOSH staff to assure that the changes in faculty or course content continue to meet course requirements.

Course sponsors also voluntarily submit an annual report to inform NIOSH of their class activity level and any faculty changes. Sponsors who elect to have their approval renewed for an additional 5 year period submit a

renewal application and supporting documentation for review by NIOSH staff to ensure the course curriculum meets all current standard requirements.

Approved course sponsors that elect to offer NIOSH-Approved Spirometry Refresher Courses must submit a separate application and supporting documents for review by NIOSH staff. Institutions and organizations throughout the country voluntarily submit applications and materials to become course sponsors and carry out training. Submissions are required for NIOSH to evaluate a course and determine whether it meets the criteria in the standard and whether technicians

will be adequately trained as mandated under the standard. NIOSH will disseminate a one-time customer satisfaction survey to course directors and sponsor representatives to evaluate our service to courses, the effectiveness of the program changes implemented since 2005, and the usefulness of potential Program enhancements.

The annualized figures slightly overestimate the actual burden, due to rounding of the number of respondents for even allocation over the three-year clearance period. The estimated annual burden to respondents is 201 hours. There are no costs to respondents other than their time.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Potential Sponsors .....	NIOSH-Approved Spirometry Testing Course Application.	3	1	3.5
	Annual Report .....	35	1	30/60
	NIOSH-Example of email request for course change.	12	1	45/60
	NIOSH-Approved Spirometry Course Sponsorship Renewal Application.	13	1	6
	NIOSH-Approved Spirometry Refresher Course Application.	10	1	8
	One-Time Customer Satisfaction Survey .....	23	1	12/60

**Leroy Richardson,**

*Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[Document Identifier: CMS-10518]

**Agency Information Collection Activities: Proposed Collection; Comment Request**

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of

information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by May 6, 2014.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number (OCN). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or

Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number \_\_\_\_\_, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786-1326

**SUPPLEMENTARY INFORMATION:**

## Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see ADDRESSES).

### CMS-10518 Application for Participation in the Intravenous Immune Globulin (IVIG) Demonstration

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

#### Information Collection

**1. Type of Information Collection Request:** New collection (Request for a new OMB control number); **Title of Information Collection:** Application for Participation in the Intravenous Immune Globulin (IVIG) Demonstration; **Use:** Traditional fee-for-service (FFS) Medicare covers some or all components of home infusion services depending on the circumstances. By special statutory provision, Medicare Part B covers intravenous immune globulin (IVIG) for persons with primary immune deficiency disease (PIDD) who wish to receive the drug at home. However, Medicare does not separately pay for any services or supplies to administer it if the person is not homebound and otherwise receiving services under a Medicare Home Health episode of care. As a result, many beneficiaries have chosen to receive the drug at their doctor's office or in an outpatient hospital setting. On Tuesday, January 3, 2012, the President signed into law the "Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012". The act authorizes a 3-year demonstration under Part B of Title XVIII of the Social Security Act to evaluate the benefits of providing payment for items and

services needed for the in-home administration of IVIG for the treatment of PIDD.

The statute limited the demonstration to 4,000 beneficiaries and \$45 million, including administrative expenses for implementation and evaluation as well as benefit costs. The statute also required that an evaluation of the demonstration be conducted. Under this demonstration, Medicare will issue under Part B a bundled payment for all medically necessary supplies and services to administer IVIG in the home to enrolled beneficiaries who are not otherwise homebound and receiving home health care benefits. In order to implement the demonstration and ensure that statutory limits are not exceeded, it is necessary to positively enroll beneficiaries in the demonstration.

This collection of information is for the application to participate in the demonstration. Participation is voluntary and may be terminated by the beneficiary at any time. Beneficiaries who do not participate will continue to be eligible to receive all of the regular Medicare Part B benefits that they would be eligible for in the absence of the demonstration. **Form Number:** CMS-10518 (OCN: 0938-NEW); **Frequency:** Annually; **Affected Public:** Individuals and households; **Number of Respondents:** 4,000; **Total Annual Responses:** 4,000 **Total Annual Hours:** 1,000. (For policy questions regarding this collection contact Jody Blatt at 410-786-6921.)

Dated: March 4, 2014.

**Martique Jones,**  
Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10215 and CMS-10416]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995

(PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by April 7, 2014.

**ADDRESSES:** When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 OR, Email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786-1326.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section