

permits some beneficiaries to self-administer the immunoglobulin (IG) safely at home without an attending healthcare professional. SCIG at home is reimbursed by Medicare. However, there are limitations to SCIG—*e.g.*, the need for more frequent administration and higher volumes of solution, which can reach a maximum absorbable level for some patients that is below their optimum IG treatment level—that inhibit more widespread use of SCIG.

Under the Medicare Patient IVIG Access Demonstration project, by paying for the items and services needed to administer the IVIG drug in-home, Medicare will enable beneficiaries and their physicians to have greater flexibility in choosing the option that is most appropriate for the beneficiary. With the exception of coverage of these items and services, no other aspects of Medicare coverage for IVIG (*e.g.*, drugs approved for coverage or PIDD diagnoses covered) will change under the demonstration.

The Medicare Patient IVIG Access Demonstration project mandates CMS to:

- Evaluate the impact of the Medicare IVIG Access Demonstration project on Medicare beneficiary access to IVIG at home,
- Determine the appropriateness of implementing a new payment methodology for IVIG in all settings and determining an appropriate payment amount, and
- Update the existing 2007 Office of the Assistant Secretary for Planning and Evaluation (ASPE) report *Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV)* (2007 ASPE Report).

The impact evaluation seeks to understand the experiences of demonstration participants and non-participants, to update the 2007 ASPE report, and to support the payment methodology through the use of qualitative and quantitative data collection. The qualitative data collection will consist of a series of stakeholder interviews. Interviews with IVIG/SCIG physicians and nurses will provide information on the experiences of beneficiaries from the perspective of those who have significant, in-depth and practical hands-on experience with delivering IG to Medicare beneficiaries with and without access to home infusions. We will be able to gather their knowledge of beneficiaries' experiences with the care, as well as information on any potential health consequences due to changes in IG medication or participation in the Demonstration. Lastly, we will gather the physicians

and nurses' views of the degree to which beneficiaries believe the program is effective, including the cost effectiveness for beneficiaries who use the services provided under the Demonstration. *Form Number:* CMS-10600 (OMB control number: 0938-NEW); *Frequency:* Annually; *Affected Public:* Individuals and Households; State, Local or Tribal Governments; Private Sector (Business or other for-profit); *Number of Respondents:* 2,488; *Total Annual Responses:* 2,488; *Total Annual Hours:* 483. (For policy questions regarding this collection contact Pauline Karikari-Martin at 410-786-1040).

Dated: February 5, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-1728-94]

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 March 11, 2016.

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.

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.
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 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Home Health Agency Cost Report; *Use:* Providers of Services participating in the Medicare program are required under sections 1815(a), 1833(e) and 1861(v)(1)(A) of the Social Security Act (42 U.S.C. 1395g) to submit annual information to achieve

settlement of costs for health care services rendered to Medicare beneficiaries. In addition, regulations at 42 CFR 413.20 and 413.24 require adequate cost data and cost reports from providers on an annual basis. The Form CMS-1728-94 cost report is needed to determine a provider's reasonable cost incurred in furnishing medical services to Medicare beneficiaries and reimbursement due to or from a provider. *Form Number:* CMS-1728-94 (OMB control number: 0938-0022); *Frequency:* Annually; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 11,352; *Total Annual Responses:* 11,352; *Total Annual Hours:* 2,576,904. (For policy questions regarding this collection contact Angela DiGorgio at 410-786-4516.)

Dated: February 5, 2016.
William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: State Self-Assessment Review and Report.
OMB No.: 0970-0223.
Description: Section 454(15)(A) of the Social Security Act, as amended by the

Personal Responsibility and Work Opportunity Reconciliation Act of 1996, requires each State to annually assess the performance of its child support enforcement program in accordance with standards specified by the Secretary of the Department of Health and Human Services, and to provide a report of the findings to the Secretary. This information is required to determine if States are complying with Federal child support mandates and providing the best services possible. The report is also intended to be used as a management tool to help States evaluate their programs and assess performance.

Respondents: State Child Support Enforcement Agencies or the Department/Agency/Bureau responsible for Child Support Enforcement in each State.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Self-assessment report	54	1	4	216

Estimated Total Annual Burden Hours: 216.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202-395-7285, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for

the Administration for Children and Families.

Robert Sargis,
Reports Clearance Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Refugee Microenterprise and Refugee Home-Based Child Care Microenterprise Development Programs
OMB No.: New
Description: The Office of Refugee Resettlement (ORR) within the Administration for Children and Families (ACF) is responsible for resettling thousands of refugees every year from all over the world. The main goal of the ORR (US) refugee domestic resettlement program is to assist the refugees in becoming self-reliant at the shortest time possible. ORR has many different discretionary grants that it employs to accomplish this goal. Two of the discretionary grants are the Refugee Microenterprise Development (MED) and the Refugee Home-Based Child Care

Microenterprise Development (HBCC MED) Programs. The goals of the MED program are to assist refugees in becoming economically self-sufficient, assist refugee serving organizations galvanize resources to strengthen their capacities to expand and continue their microenterprise services at an expanded and sustainable level, and enhance the integration to the mainstream and realize the American Dream. The focus of the HBCC Program is on women that have limited opportunity to get employment at livable wages because of limited transferable skills and lack of knowledge of the English language. Through the program women refugees are provided basic training in child care and development, state and local legal requirements to get a license and to establish a home-based child care service. The ultimate goal of the program is to enable the women refugees establish a home-based child care service in their neighborhood.

ORR works with nonprofit organizations in implementing these projects. Currently, there are 22 projects in the Refugee Microenterprise Development Program and 23 projects in the Refugee Home-Based Child Care Microenterprise Development Program. It is critical to collect data through a semi-annual report in order to determine whether or not the programs are achieving their intended goals, to address concerns, issues, and challenges