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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10600]

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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**:

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

E-mail: *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. E-mail 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: New collection (Request for a new OMB control number); Title of Information Collection: Evaluation of the Medicare Patient Intravenous Immunoglobulin Demonstration; Use: Primary Immune Deficiency Diseases (PIDD) are caused by genetic defects that result in a lack of and/or impaired antibody function. Without antibodies, the body's immune system is not able to function effectively. Immunoglobulin (IG) therapy is used to temporarily replace some of the antibodies (immunoglobulins) that are missing or not working properly in people with PIDD.

By special statutory provision, Medicare Part B covers intravenous immunoglobulin (IVIG) for persons with PIDD who wish to receive the drug in-home, but does not allow for Medicare to cover any of the items and services needed to administer the drug unless the person is homebound or otherwise receiving services under a Medicare home health episode of care. Therefore, most beneficiaries with PIDD receive treatment at hospital outpatient departments, physicians' offices, and other outpatient settings. A current alternative to IVIG is subcutaneous immunoglobulin (SCIG), a product that 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: April 19, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

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