

## 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 (PID) 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 PID.

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

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:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Medicaid Payment for Prescription Drugs—Physicians and Hospital Outpatient Departments Collecting and Submitting Drug Identifying Information to State Medicaid Programs; *Use:* In accordance with the Deficit Act of 2005, states are required to provide for the collection and submission of utilization data for certain physician-administered drugs in order to receive federal financial participation for these drugs. Physicians, serving as respondents to states, submit National Drug Code numbers and utilization information for “J” code physician-administered drugs so that the states will have sufficient information to collect drug rebate dollars. *Form Number:* CMS–10215 (OCN: 0938–1026); *Frequency:* Weekly; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 20,000; *Total Annual Responses:* 3,910,000; *Total Annual Hours:* 16,227. (For policy questions regarding this collection contact Bernadette Leeds at 410–786–9463).

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Blueprint for Approval of Affordable Health Insurance Marketplaces; *Use:* All states (including the 50 states, the territories, and the District of Columbia, herein referred to as “states”) had the opportunity under Section 1311(b) of the Affordable Care Act to establish an Exchange, also known as a “Marketplace”, no later than October 1, 2013 (Plan Year 2014). This current submission reduces the number of potential respondents due to various states electing to rely on the Federally-facilitated Marketplace (FFM). Also, at the time of the original request, the tool was partially paper-based. During the intervening time, we have developed the on-line implementation of the tool and will transition all future applications to that system.

States seeking to establish a Marketplace must build one that meets the requirements set out in Section 1311(d) of the Affordable Care Act and 45 CFR 155.105. In order to ensure that a State seeking approval as a State-based Marketplace, State-based SHOP Marketplace, or State Partnership Marketplace meet all applicable requirements, the Secretary will require a state to submit a Blueprint for approval and to demonstrate operational readiness through virtual or on-site readiness review. *Form Number:* CMS–10416 (OCN: 0938–1172); *Frequency:* Once; *Affected Public:* State, Local, or Tribal governments; *Number of Respondents:* 31; *Number of Responses:* 31; *Total Annual Hours:* 5,552. (For policy questions regarding this collection, contact Sarah Summer 301–492–4443.)

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**

**Administration for Children and Families**

[CFDA Numbers: 93.612, 93.602]

**Notice for Public Comment on the Adoption of Program Policies and Procedures for the Native Asset Building Initiative, a Joint Funding Opportunity Announcement Between the Administration for Native Americans and the Office of Community Services**

**AGENCY:** Administration for Native Americans, ACF, HHS.

**ACTION:** Notice for Public Comment.

**SUMMARY:** Pursuant to Section 814 of the Native American Programs Act of 1974 (NAPA), as amended, the Administration for Native Americans (ANA) is required to provide members of the public an opportunity to comment on changes in interpretive rules, general statements of policy, and rules of agency procedure or practice that affect programs, projects, and activities authorized under the NAPA. In accordance with notice requirements of NAPA, ANA herein describes its planned changes to interpretive rules, general statements of policy, and rules of agency procedure or practice as they relate to the Fiscal Year (FY) 2014 Funding Opportunity Announcement

(FOA) for the Native Asset Building Initiative, HHS–2014–ACF–ANA–NO–0786 (hereinafter referred to as NABI).

Projects funded under this initiative receive two grant awards from two Administration for Children and Families (ACF) Program Offices—ANA and the Office of Community Services (OCS). Grantees under the NABI program implement economic capacity building projects that are targeted toward increasing the economic stability of low-income individuals and families, through the establishment of Individual Development Accounts (IDAs) and related services that motivate individuals to save, invest, and accumulate assets. NABI is part of a national Assets for Independence (AFI) demonstration project, authorized under the Assets for Independence Act of 1998, to test, demonstrate, and develop knowledge about the impact of IDAs and related services. For additional information about NABI, please see the Health and Human Services (HHS) Grants Forecast at the following link: [http://www.acf.hhs.gov/hhsgrantsforecast/index.cfm?switch=grant.view&gff\\_grants\\_forecastInfoID=66481](http://www.acf.hhs.gov/hhsgrantsforecast/index.cfm?switch=grant.view&gff_grants_forecastInfoID=66481).

**DATES:** The deadline for receipt of comments is April 7, 2014.

**ADDRESSES:** Comments in response to this notice should be sent via email to Lillian Sparks Robinson, Commissioner, Administration for Native Americans, at [ANACommissioner@acf.hhs.gov](mailto:ANACommissioner@acf.hhs.gov). Comments will be available for inspection by members of the public at the Administration for Native Americans, 901 D Street SW., Washington, DC 20024.

**FOR FURTHER INFORMATION CONTACT:** Carmelia Strickland, Director, Division of Program Operations, ANA, (877) 922–9262.

*A. Administrative Policies:* ANA would make the following changes to the Administrative Policies in the NABI FOA.

1. ANA will clarify the conflict of interest standards to ensure they align with the rule at 45 CFR 1336.50(f). This rule authorizes the Office of the Chief Executive of a federally recognized Indian tribal government to be paid salary and expenses with ANA grant funds provided such costs are related to a project funded under ANA FOAs and that the costs exclude any portion of salaries and expenses that are a cost of general government. Given this rule regarding the allowable use of grant funds, we would adopt a limited exception to previously published conflict of interest standards that previously did not include the