

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

regulatory exception applicable to the Office of the Chief Executive of federally recognized Indian tribes.

2. ANA intends to adopt the following policy for the NABI FOA:

ACF encourages all eligible applicants to participate in the Assets for Independence demonstration project; therefore awards made under this FOA will be exempt from the following Administrative Policies regarding limitation of ANA awards: "Limitation on the Number of Awards under a Single CFDA Number," and "Limitation on the Number of Awards Based on Two Consecutive Funding Cycles." (Please see FOA Index for a full statement of these policies).

Since NABI was developed as a special initiative between ANA and OCS to increase Native American participation in the national Asset for Independence demonstration project, ANA also will remove the related disqualification factor titled "Only One Active Award per CFDA." This disqualification factor had been included in the FY 2013 version of the NABI FOA to ensure the "Limitation on Number of Awards per CFDA Number" Administrative Policy. The exemption from the Administrative Policy coupled with the removal of the disqualification factor is intended to encourage increased participation in the NABI program.

*B. Federal Evaluation:* ANA intends to include the following language:

ANA and OCS are required by statute to evaluate the impact of their funding. To fulfill the evaluation requirements, ANA and OCS will implement a federally sponsored evaluation strategy to assess the success and impact of approved projects. The federal evaluation strategy will include grantee-level documentation. In accepting a grant award, all grantees will agree to participate fully in the federal evaluation if selected and to follow all evaluation protocols established by ANA and OCS or their designee contractor.

*C. Name Change of a Disqualification Factor:* ANA would change the name of the disqualification factor titled "Board Documentation" to "Assurance of Community Representation on Board of Directors" in order to further clarify what is being requested of applicants regarding demonstration of community representation. The content of this requirement will not change, and it still will *not* apply to tribes or Alaska Native Villages. All disqualification factors will be in *Section III.3. Other* of the published FOA.

*D. Eligible Applicants:* ANA intends to clarify eligible applicants. Eligible

applicants will remain the same as those entities noted in the FY 2013 version of the NABI FOA (HHS-2013-ACF-ANA-NO-0587, available at: <http://www.acf.hhs.gov/grants/open/foa/index.cfm?switch=foa&fon=HHS-2013-ACF-ANA-NO-0587>) and will include Native 501(c)(3) non-profit organizations, federally recognized tribal governments and Alaska Native Villages, Native non-profit organizations designated by the Secretary of the Treasury as Community Development Financial Institutions (CDFIs), and Native non-profit credit unions designated as low-income credit unions by the National Credit Union Administration (NCUA). The bulleted lists of example organizations under each type of applicant will be removed and clarifying language will be added that describes the following eligibility rules: Native non-profits must have 501(c)(3) status with the Internal Revenue Service; tribes and Alaska Native Villages may only apply jointly with a non-profit with 501(c)(3) status; Tribal Colleges may apply as either a non-profit with 501(c)(3) status or jointly with a non-profit with 501(c)(3) status.

*E. Projects Ineligible for Funding:* ANA would revise language in this section to provide clarification on two of the types of projects ANA will not fund under regulations at 45 CFR 1336.33(b), as follows:

1. Projects for which a grantee would provide training and technical assistance to other tribes or Native American organizations to the extent such training or technical assistance is duplicative of ANA-funded training and technical assistance available to tribes and other entities that are eligible to apply for ANA funding. This does not apply to "train-the-trainer" capacity building projects.

2. Projects from consortia of tribes that do not include documentation from each participating consortium member specifying their role and support. Projects from consortia must have goals and objectives that will encompass the participating communities. ANA will not fund projects by a consortium of tribes that duplicates activities for which participating member tribes also receive funding from ANA.

*F. Page Limits for NABI Applications:* ANA would change the maximum page limit for applications submitted in response to the FY 2014 NABI FOA from 200 pages to 150 pages. This page limit excludes business plans (if applicable) and mandatory grant forms (Standard Forms and ANA's Objective Work Plan form). The 150-page limit is consistent with ANA's other FY 2014

FOAs. Applications that exceed the page limit will have excess pages removed from consideration during the panel review process.

*G. Two-File Application Upload Requirement:* ANA would exempt applicants from the ACF application two-file upload requirement for electronically submitted applications when responding to all FY 2014 ANA FOAs, including NABI, in order to reduce the technical burden on such applicants and to ensure that lack of technical resources, not otherwise required of applicants, does not unintentionally act to disqualify an applicant, otherwise eligible, from applying under ANA FOAs.

*H. Outcomes Expected for NABI Applications:* ANA intends to emphasize monitoring of outcomes specific to the AFI initiative by requiring applicants to provide annual targets for the following: The number of IDAs opened per savings goal (home ownership, education, and entrepreneurship); the number of participants completing financial education trainings; the number of individuals completing an asset purchase; the amount of non-federal cash contribution deposited in the Project Reserve Fund; and the percentage of the 5-year federal AFI budget that will be drawn down annually. Target numbers for the entire 5-year project period were requested in previous FOAs.

*I. Protection of Sensitive and/or Confidential Information:* ANA intends to add the following application requirement to all FY 2014 FOAs in order to ensure the protection of confidential and/or sensitive information:

If any confidential or sensitive information will be collected during the course of the project, whether from staff (e.g., background investigations) or project participants and/or project beneficiaries, then provide a description of the methods that will be used to ensure that confidential and/or sensitive information is properly handled and safeguarded. Also provide a plan for the disposition of such information at the end of the project period.

*J. ANA Application Evaluation Criteria:*

1. Changes to Criteria: ANA would add three additional criteria to the FOA, titled: Need for Assistance, Objective Work Plan (OWP), and Organizational Capacity. The concept of Need for Assistance was articulated as the Problem Statement and was evaluated under the Outcomes Expected criteria in prior years' FOAs. The OWP and Organizational Capacity were

previously listed and evaluated as part of the Approach section. They will be listed as separate criteria to highlight the critical nature of these elements to project success. Bonus Points that appeared in prior years' FOAs will be removed from the evaluation criteria.

2. Titles and Assigned Weight: ANA would adjust the maximum point values of the evaluation criteria scores to further prioritize elements that are important to project monitoring and success. ANA proposes to use the following criteria values for the FY 2014 NABI FOA:

*Need for Assistance—15 points;*  
*Outcomes Expected—10 points;*  
*Project Approach—20 points;*  
*Organizational Capacity—25 points;*  
*Objective Work Plan—20 points;*  
*Budget and Budget Justification—10 points.*

3. Scoring Guidance: ANA intends to provide guidance to reviewers to utilize the table below when allocating points for applications in order to ensure consistency and equivalence in scoring between different panels and panel reviewers. ANA would add the following table to all FY 2014 FOAs:

Excellent .....	93–100
Very Good .....	86–92
Good .....	78–85
Fair .....	70–77
Needs Significant Improvement	0–69

*K. ANA Internal Review of Proposed Projects:* ANA proposes to clarify the language in *Section V.2. Review and Selection Process* of all FY 2014 FOAs to clarify the scope of discretion to be exercised in making funding decisions as follows:

Based on the ranked order of applications, ANA staff will perform an internal review and analysis of the highest ranked applications in order to determine their consistency with the purposes of NAPA, all relevant statutory and regulatory requirements, and the requirements of this FOA. ANA's Commissioner has discretion to make all final funding decisions. In the exercise of such discretion, the Commissioner would consider whether the project:

1. Would further the purpose of this funding opportunity as described in *Section I. Description*, or is likely to be successful or cost effective based on what is submitted for evaluation in response to *Section IV.2. Project Description*.

2. Fails to provide documented commitment of non-federal cash contributions as described in *Section III.2. Cost Sharing or Matching* and *Section IV.2. Project Description, Commitment of Non-Federal Resources*.

3. Allows any one community, or region, to receive a disproportionate share of the funds available for award.

4. Is essentially identical or similar in whole, or in part, to previously funded projects proposed by the same applicant, or activities or projects proposed by a consortium that duplicates activities for which any consortium member also receives funding from ANA.

5. Provides couples or family counseling activities that are medically based.

6. Originated with and/or was designed by consultants who provide a major role for themselves and are not members of the applicant organization, tribe, or village.

7. Contains contingent activities that may impede, or indefinitely delay, the progress of the project.

8. Has the potential to cause unintended harm or that could negatively impact the safety or privacy of individuals.

9. May be used for the purpose of providing loan capital. Federal funds awarded under this FOA may not be used for the purpose of providing loan capital. This is not related to loan capital authorized under Sec. 803A of NAPA [42 U.S.C. 2991b-1(a)(1)] for the purpose of the Hawaiian Revolving Loan fund.

10. Includes human subject research as defined at 45 CFR 45.102(d) and (f).

*L. Reporting:* ANA would change the reporting requirement from quarterly to semi-annual for Objective Progress Reports (OPR) and Financial Status Reports (FSR). Therefore, grantees will be required to submit an OPR and an FSR every 6 months instead of every 3 months. Please note grantees will still be required to submit a Federal Financial Report—Federal Cash Transaction Report to the Division of Payment Management on a quarterly basis.

**Lillian Sparks Robinson,**

*Commissioner, Administration for Native Americans.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2014-D-0191]

**Advancing Regulatory Science for High Throughput Sequencing Devices for Microbial Identification and Detection of Antimicrobial Resistance Markers**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled “Advancing Regulatory Science for High Throughput Sequencing Devices for Microbial Identification and Detection of Antimicrobial Resistance Markers.” The purpose of the public workshop is to discuss the clinical and public health applications and performance validation of these devices, the quality criteria for establishing the accuracy of reference databases for regulatory use and ways to streamline clinical trials for microbial identification. This discussion is essential to establish the safety and effectiveness of high throughput sequencing devices when used to test human specimens or clinical isolates for the diagnosis of infectious diseases and detection of antimicrobial resistance markers.

**DATES: Date and Time:** The public workshop will be held on April 1, 2014, from 9 a.m. to 4:30 p.m.

**Location:** The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. For parking and security information, please visit the following Web site: <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

**Contact Person:** Heike Sichtig, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5269, Silver Spring, MD 20993-0002, email: [Heike.Sichtig@fda.hhs.gov](mailto:Heike.Sichtig@fda.hhs.gov).

**Registration:** Registration is free and on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 5 p.m. on March 25, 2014. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization based on space limitations.