physicians, and post-acute providers for an episode of care consisting of an inpatient hospital stay followed by post-acute care.

- Model 3—Retrospective bundled payment models for post-acute care where the episode does not include the acute inpatient hospital stay.
- Model 4—Prospectively administered bundled payment models for the acute inpatient hospital stay and related readmissions.

## II. Provisions of the Notice

To help us achieve the implementation goals noted previously, the Innovation Center is announcing a 2014 winter open period for additional organizations to be considered for participation in Models 2, 3, and 4 of the initiative. We believe that increasing the number of Awardees and the types of episodes being tested would result in an even more robust data set and improve our evaluation of the models. Interested organizations must submit Model 2, 3 or 4 Open Period forms as specified in the **DATES** and **ADDRESSES** sections of this notice. Organizations may participate in more than one model. Organizations who are interested in participating in more than one model should submit a request to participate in each model using separate Open Period forms. Interested organizations can find information about the intake process, eligible organizations and providers, and model requirements on the Innovation Center Web site as specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

We will review the submitted intake forms and evaluate organizations for participation in Models 2, 3, and 4. We expect to offer Model 2, 3, or 4 participation agreements to those organizations that demonstrate their fitness for participation in the applicable Model. For information on the screening process go to the CMS Center for Medicare and Medicaid Innovation Web site as specified at: *http://innovation.cms.gov/initiatives/Bundled-Payments/Models2-4OpenPeriod.html*

## III. Collection of Information Requirements

Section 1115A(d) of the Act waives the requirements of the Paperwork Reduction Act of 1995 for purposes of testing and evaluation of new models or expansion of such models under section 1115A of the Act.

**Authority:** Section 1115A of the Social Security Act (42 U.S.C. 1315a)

(Catalog of Federal Domestic Assistance No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Hospital Insurance Program; and No. 93.774, Medicare Supplementary Medical Insurance Program)

Dated: February 10, 2014.

**Marilyn Tavenner,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2014–03311 Filed 2–13–14; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

**[CFDA Numbers: 93.581, 93.587, 93.612]**

### Notice of Final Issuance on the Adoption of Administration for Native Americans (ANA) Program Policies and Procedures

**AGENCY:** Administration for Native Americans (ANA), ACF, HHS.

**ACTION:** Issuance of Final Policy Relating to Funding Opportunity Announcements.

**SUMMARY:** The Administration for Native Americans (ANA) is issuing final interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice relating to the following Funding Opportunity Announcements (FOAs): Social and Economic Development Strategies (hereinafter referred to as SEDS), Sustainable Employment and Economic Development Strategies (hereinafter referred to as SEEDS), Native Language Preservation and Maintenance (hereinafter referred to as Language Preservation), Native Language Preservation and Maintenance—Esther Martinez Immersion (hereinafter referred to as Language—EMI), and Environmental Regulatory Enhancement (hereinafter referred to as ERE).

**DATES:** The policies proposed in the **Federal Register** Notice for Public Comment (78 FR 76834, Dec. 19, 2013) are final and effective immediately upon this publication.

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

**SUPPLEMENTARY INFORMATION:** Section 814 of the Native American Programs Act of 1974 (NAPA), as amended, requires ANA to provide notice of its proposed interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice. The proposed clarifications, modifications, and new text will appear in the five Fiscal Year (FY) 2014 FOAs: SEDS, SEEDS, Language Preservation, Language—EMI, and ERE. ANA published a Notice of Public Comment (NOPC) in the **Federal Register** (78 FR 76834, Dec. 19, 2013), with proposed policy and program clarifications, modifications, and activities governing standing FOAs beginning with FY 2014 FOAs. The public comment period was open for 30 days.

This notice transmits ANA's final policy governing standing FOAs to be published in FY 2014. ANA received 20 comments from entities affected by the FOAs including 1 Native Hawaiian organization and 4 federally recognized Indian tribes. Each comment was fully considered. This final notice summarizes all comments received and ANA's responses to them.

### A. Comments and Responses

1. *Comment:* ANA received two comments in reference to ANA's change to the frequency with which program progress reports must be submitted. Beginning with awards issued under the FY 2014 FOAs, program progress reports must be submitted semi-annually instead of quarterly. One commenter disagreed with the proposed change and recommended a program progress report frequency of no less than three times a year in order to ensure that grantees had time to analyze the progress of project goals and demonstrate financial accountability. Another commenter expressed support for the change to semi-annual reporting, expressing the belief that such reporting frequency could be just as effective as quarterly reporting provided there was effective communication between ANA and grantees.

*Response:* ANA considered establishing a requirement for more frequent program progress reports but determined that semi-annual reporting is sufficient to provide grantees with opportunities to demonstrate the results of their on-going monitoring of project progress and provide ANA adequate information to maintain project accountability. ANA plans to increase the interaction it has with grantees through means other than reporting, including monthly one-on-one telephone calls and weekly webinars.

2. *Comment:* ANA received two comments related to proposed language requiring community involvement in both the development of proposed projects and in their implementation. One commenter praised ANA for clarifying that community involvement in the development of the project is required, as well as in the implementation of the project, and expressed the recommendation that the

FOA include language related to how such required community involvement could be reflected. The other commenter requested clarification on how community members were expected to be involved in project implementation given that different community members may be involved in the implementation of a project than those involved in the planning and development of a project.

*Response:* In *Section IV.2. Content and Form of Application Submission* of the FOA, ANA has included text providing examples of community input in the development of projects (e.g., community meetings and surveys) and in the implementation of projects (e.g., recruitment strategies and outreach activities). We believe the language related to community involvement in *Section IV.2. Content and Form of Application Submission* provides sufficient detail in its examples to provide clear guidance to applicants.

3. *Comment:* ANA received one comment related to language proposed in *Section III.3. Other* of the FOA clarifying the types of projects that ANA will not fund as prescribed by 45 CFR 1336.33(b). The commenter asked for clarification of the scope of the funding prohibition as applied to on-going social service delivery systems.

*Response:* The text in *Section III.3. Other* of the FOA includes an explanation of the types of projects that ANA will not fund under the categorical prohibitions specified in 45 CFR 1336.33(b). Such ineligible projects are those that ''provide or expand ongoing social services that involve cash transfers or other material assistance such as food, medicine, child care, or income support to individuals.'' Here, we sought to make clear that if, prior to submission of an application for funding, an applicant was already or had been delivering social services that involved cash transfers or other material support, ANA would not fund a project that proposed to use ANA grant funds to replace or supplant existing sources of funding or to expand existing social services on an on-going basis.

4. *Comment:* ANA received one comment related to another part of *Section III.3. Other* of the FOA clarifying the kinds of third-party technical assistance (TA) ANA will not fund as specified by 45 CFR 1336.33(b) and what types of TA are permissible.

*Response:* The text in *Section III.3. Other* of the FOA related to third-party TA that cannot be funded under 45 CFR 1336.33(b) includes clarification that the prohibition applies only to TA ''that is intended to be provided to other tribes or Native American organizations or to non-members of the grantee organization where 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.'' Such clarification makes clear the scope of activities that fall into the regulatory prohibition regarding TA ineligible for ANA funding.

5. *Comment:* ANA received one comment expressing belief that the technology to enable all applicants to comply with a two-file application upload limitation was available and that an exemption from the requirement was unnecessary.

*Response:* The burden that the two-file application upload requirement imposed on applicants and potential applicants to convert and consolidate multiple documents comprised a significant amount of feedback received related to last year's FOAs. In addition, application of the two-file upload requirement required ACF to independently determine what files, or parts of files, to accept when more than two files were received and page limitations otherwise satisfied. Finally, in the absence of a tribal consultation (including through a **Federal Register** notice soliciting input) we determined that it would not accord with our Tribal Consultation Policy to impose this requirement on tribes.

6. *Comment:* One commenter disagreed with ANA's proposed policy to move the concept previously articulated in *Section V.I. Criteria* in the FOAs as ''Project Integration'' to the stand-alone criterion, ''Objective Work Plan (OWP),'' believing that merely requiring applicants to complete the OWP form was insufficient to allow reviewers to evaluate whether all aspects of a proposed project were fully integrated with one another.

*Response:* The change ANA proposed to *Section V.I. Criteria* was made to facilitate more focused attention on the applicant's integration of multiple project components documented through completion of the OMB-approved OWP form. The form requires that the connections among project goals, objectives, results expected, benefits expected, and activities be addressed. We believe the OWP form allows for adequate demonstration of how all aspects of the proposed project are integrated with one another and do not believe any change to the proposed policy is necessary.

7. *Comment:* One commenter objected to ANA's proposed policy establishing a 150 page limitation for all applications, including those that allowed for 5-year project periods. The commenter reasoned that a longer project period and larger budget made such projects more complex and required more explanation than 150 pages would allow.

*Response:* We believe 150 pages provide ample opportunity to respond to FOAs, including those proposing 5-year projects. The FOA makes clear the maximum page limit excludes required Standard Forms and OMB-approved forms. On the basis of ANA's consideration of recent grant competitions, we are confident the maximum 150 page limit applicable to all FOAs for all project periods is sufficient. Applications that exceed the maximum page limitation will have excess pages removed.

8. *Comments:* One federally recognized Alaska Native tribe submitted comments on 11 separate issues. The commenter expressed ''no issues or concerns'' related to the name change of one FOA, ANA's administrative policies, name change of one disqualification factor, projects ineligible for funding, organizational changes to the evaluation criteria, and outcomes expected for SEEDS applications. Regarding the proposed language related to protection of sensitive and/or confidential information, the proposed weights assigned the evaluation criteria, the proposed clarification related to the requirement for community involvement, and language related to ANA's internal review process, the commenter also expressed support for ANA's changes. The commenter expressed disagreement with ANA's conflict of interest administrative policy in *Section I. Funding Opportunity Description,* under which, with one categorical exception, staff employed through an ANA-funded project cannot also serve as a member of the governing body for the grantee organization. The commenter characterized the policy as burdensome on communities or villages with small populations.

*Response:* With regard to the disagreement with ANA's conflict of interest administrative policy, ANA believes such policy is an appropriate risk management strategy that, with the categorical exception, best ensures appropriate grant oversight and independent judgment in the discharge of obligations under ANA-funded grants.

**B. Funding Opportunity Announcements**

For information on the projects funded by ANA, please refer to ANA's Web site for information on our program areas and FOAs: *http://*

*www.acf.hhs.gov/programs/ana.* We encourage interested applicants to sign up for updates on these FOA at HHS Grant Forecast at *www.acf.hhs.gov/hhsgrantsforecast.*

Once ANA's FOAs have been published, the FY 2014 FOAs can be accessed at *http://www.acf.hhs.gov/grants/open/foa/office/ana* or *http://www.acf.hhs.gov/grants/open/foa/.* Synopses and application forms will be available at *www.Grants.gov.*

**Statutory Authority:** This notice for public comment is required by Section 814 of the Native American Programs Act of 1974 (NAPA), as amended.

**Lillian A. Sparks Robinson,**

*Commissioner, Administration for Native Americans.*

[FR Doc. 2014–03282 Filed 2–13–14; 8:45 am]

**BILLING CODE 4184–34–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2008–N–0393]**

### Questions and Answers About Electronic Medical Device Reporting; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Questions and Answers About eMDR—Electronic Medical Device Reporting.'' FDA has published a final rule that requires device manufacturers and importers to submit mandatory reports of individual medical device adverse events, also known as medical device reports (MDRs), to the Agency in an electronic format that FDA can process, review and archive. This guidance provides general information regarding how to prepare and send an electronic postmarket medical device report to the Center for Devices and Radiological Health (CDRH) in FDA. The guidance also identifies where to find more detailed information on the preparation and transmission of the reports.

**DATES:** Submit either electronic or written comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled ''Questions and Answers About eMDR—Electronic Medical Device Reporting'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Tahseen Mirza, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2312, Silver Spring, MD 20993–0002, 301–796–7645.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

Section 519 of the Federal Food, Drug and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i) is FDA's authorization to issue a regulation to require mandatory reporting of device-related adverse events. The Medical Device Reporting (MDR) regulation, 21 CFR part 803, effective December 13, 1984, contained reporting requirements for device manufacturers and importers. Amendments to the FD&C Act under the Safe Medical Devices Act of 1990 and the Medical Device Amendments of 1992 introduced mandatory reporting by device user facilities and changed the requirements for device manufacturers, importers and distributors. FDA revised the MDR regulation (part 803) effective July 31, 1996, to address the reporting changes. On February 28, 2005, FDA revised the MDR regulation into plain language.

On August 21, 2009, FDA published a proposed rule (74 FR 42203) to amend part 803 to require manufacturers, importers, and user facilities to submit MDRs to the Agency in an electronic format. Because of concerns over the cost of implementation for user facilities, and the relatively low volume of reports FDA receives from such facilities, the final rule does not require user facilities to adopt electronic reporting. Although FDA encourages user facilities to file reports electronically, they may continue to use only paper forms for MDR reporting. The final rule for electronic submission of MDRs to FDA anticipates that there will be a reduction in costs and time associated with the submission of MDR reports, elimination of transcription errors associated with paper reports, and both expedited access to safety information and enhanced ability to communicate information about suspected problems. This question and answer guidance provides general information on how to prepare and send an electronic postmarket medical device report to FDA and identifies where to find more detailed information on how to prepare and transmit eMDRs.

The draft eMDR guidance document was published in the **Federal Register** of August 21, 2009. No significant comments were received.

#### II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on electronic MDR reporting. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

#### III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive ''Questions and Answers about eMDR—Electronic Medical Device Reporting,'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1679 to identify the guidance you are requesting. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.*

#### IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 803 have been approved under OMB control numbers 0910–0291 and 0910–0437.