

By Order of the Federal Maritime Commission.

Dated: November 1, 2017.

JoAnne D. O' Bryant,

Program Analyst.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Numbers: 93.581, 93.587, 93.612]

Notice of Final Issuance Adopting Administration for Native Americans Program Policies and Procedures

AGENCY: Administration for Native Americans, ACF, HHS.

ACTION: Issuance of final policies.

SUMMARY: 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 six proposed FY2018 Funding Opportunity Announcements (FOAs): Environmental Regulatory Enhancement (HHS-2018-ACF-ANA-NR-1344); Native American Language Preservation and Maintenance—Esther Martinez Immersion (HHS-2018-ACF-ANA-NB-1343); Native American Language Preservation and Maintenance (HHS-2018-ACF-ANA-NL-1342); Social and Economic Development Strategies (HHS-2018-ACF-ANA-NA-1339); Social and Economic Development Strategies—Alaska (HHS-2018-ACF-ANA-NK-1340); and Native Youth Initiative for Leadership, Empowerment, and Development (HHS-2018-ACF-ANA-NC-1341).

DATES: The policies described in the Notice for Public Comment (NOPC), as amended in this notice if applicable, are effective immediately upon publication of this notice.

FOR FURTHER INFORMATION CONTACT: Carmelia Strickland, Director, Division of Program Operations, Administration for Native Americans, (877) 922-9262, ANAComments@acf.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 814 of the Native American Programs Act of 1974 (NAPA), as amended, requires ANA to provide notice and allow for comment on its proposed interpretive rules and general statements of policy. On August 14, 2017, ANA published a NOPC with proposed policy and program clarifications for the FY 2018 FOAs. ANA also follows the ACF Tribal

Consultation Policy, and sent a Dear Tribal Leader letter informing tribes of the NOPC and made them aware of the September 15 deadline for comment submission. This Notice responds to comments regarding ANA's August 14, 2017, NOPC (82 FR 37861) and the tribal consultation afforded through the Dear Tribal Leader letter issued August 14, 2017. In addition, this notification includes a clarification in a new administrative policy, a modification to the project start date for Native Language programs, and a notification regarding the application period for FY 2018 FOAs.

A. Comments and Responses to the August 14, 2017, NOPC

ANA published a NOPC in the **Federal Register** on August 14, 2017, with proposed policy and program clarifications, modifications, and activities for the FY 2018 FOAs. ANA sent a Dear Tribal Leader letter electronically and via U.S. mail the same day with the NOPC attached. The NOPC provided proposed clarifications, modifications, and new text for six proposed FY 2018 FOAs. The FY 2018 FOAs are based on the FY 2017 FOAs, previously published as: Environmental Regulatory Enhancement (HHS-2017-ACF-ANA-NR-1221); Native American Language Preservation and Maintenance—Esther Martinez Immersion (HHS-2017-ACF-ANA-NB-1226); Native American Language Preservation and Maintenance (HHS-2017-ACF-ANA-NL-1235); Social and Economic Development Strategies (HHS-2017-ACF-ANA-NA-1236); Social and Economic Development Strategies—Alaska (HHS-2015-ACF-ANA-NK-0960); and Native Youth Initiative for Leadership, Empowerment, and Development (HHS-2017-ACF-ANA-NC-1263). The public comment period was open for 30 days. ANA also publicized a background call on the NOPC for August 23, 2017, and had 14 callers on the line.

ANA did not receive any feedback on the FOA changes from tribal governments. ANA received one response to the NOPC from the Sisseton-Wahpeton Oyate Dakotah Language Institute. Comments expressed concerns or made suggestions about some of the changes. ANA considered the comments and determined there to be none that required changes to any of the FOAs. The following includes comments from the Sisseton-Wahpeton Oyate Dakotah Language Institute and responses provided by ANA:

Comment:

When changing the application criteria, please make the changes effective two grant

cycles from the adoption date. Sometimes the application due dates are changed because there are upcoming changes to the Funding Opportunity Announcement and a comment period has to be allowed. And then, the grant start dates are pushed back and then the entire timeline developed in the project planning is no longer applicable.

Response: The FOAs, which contain the application criteria specific to each program area, are published on an annual basis. Through the NOPC, ANA provided advance notice to applicants about the proposed changes in FY 2018 to its six FOAs. ANA is unable to provide specific language until the publication of the actual FOAs. Therefore, ANA is not able to make changes to the application criteria prior to the effective date.

Comment: Regarding the Paperwork Reduction Act (PRA) Notice inaccurately reflecting the amount of time it takes to file an ANA application:

Each hour spent on a grant application is one less hour that can be spent working on our endangered language, especially for a small program like ours. A more accurate Paperwork Reduction Notice may have weight in deciding whether it is actually worth it to invest the amount of time it takes to complete the process with very little chance of success.

Response: ANA's FOAs are drafted within the context of a Uniform Project Description (UPD), which serves to provide the overall structure for all applications submitted to the Administration for Children and Families (ACF). The UPD includes specific standard text that applies to all ACF programs, in combination with program-specific text that is added by individual program offices. The PRA notice is part of the ACF UPD, which is managed ACF-wide, and determined based on the average amount of time it takes to complete the project description and the budget and budget justification for ACF programs as a whole. The estimated burden of 60 hours does not include supplementary information that an applicant may want to include. While there is likely to be variation among different programs and applicants, the average estimated time to complete an application for ACF programs is 60 hours. ANA will forward the comment to the ACF branch that handles the UPD to be considered upon the renewal of the PRA clearance for the UPD.

Comment:

If you are putting in new terms that are common terms to those working in a federal program accepting grant applications, please make sure the new terms are adequately explained. How can a person comment about changing from "results" and "benefits" to

“outcomes” and “outputs” if I don’t know what they mean to you? Or are they the same meaning to you and it’s just a change in the words that are going to be used?

Response: ANA’s intent is to provide more universally accepted terminology, especially for evaluation requirements and criteria. Definitions and examples of all new terms will be provided in each of the FY 2018 FOAs. Any new terminology will be addressed in Section I. Program Description of the FOA. ANA will explain each term and include examples of each. Definitions will be included in the appendix of each FOA.

B. ANA Administrative Policy Regarding Prioritized Funding for Local, Community-Based, Native American Organizations as Described in the August 14, 2017, NOPC (82 FR 37861)

ANA has edited the description of this policy since it was published in the **Federal Register**, to further clarify the requirements for non-local, national, and regional organizations. If approved, ANA intends to include this policy in all FY 2018 FOAs as stated below:

Prioritized Funding for Community-based Native American Organizations:

ANA reserves the right to prioritize funding to community-based Native American organizations serving their local communities and populations. Applications from non-local, national, and regional organizations that propose projects to serve multiple communities, or to be performed in a different geographic location, must clearly demonstrate that the need for the project was originated by the each community being served, and that the community and/or tribal government supports the proposed project. They must also describe how each community was selected, identify and describe the intended beneficiaries, demonstrate community involvement in the development of the project, and discuss a community-based delivery strategy for the project. The proposed project goals, objectives, and outcomes must address goals of the community being served. National and regional organizations must describe their membership, and define how the organization operates. The type of community to be served will determine the type of documentation necessary to support the project.

C. Additional Information Regarding Project Start Dates for Language Preservation and Maintenance, and Native Language Esther Martinez Immersion Grants

Through continued discussions with ANA grantees and stakeholders, ANA has determined that moving the start date from August 1 to July 1 for projects funded under the Native Language Preservation and Maintenance and the

Native Language Esther Martinez Immersion programs will align reporting requirements to reduce the number of required federal financial reports, thereby reducing the reporting burden for grantees. In addition, an earlier start date will provide projects with additional time for planning and start up prior to the start of the school year, which marks the beginning of instruction for many Native Language projects. Therefore, ANA intends to implement a July 1 start date for all projects funded under the Native Language Preservation and Maintenance and Native Language Esther Martinez Immersion FOAs for FY 2018.

D. Application Period Notification

ANA would like to notify potential applicants that the open application period to respond to FOAs has been updated to a minimum of 60 days to support the timely award of new grants.

E. Funding Opportunity Announcements

For information on the types of projects funded by ANA, please refer to ANA’s Web site for information on our program areas and FOAs: <https://www.acf.hhs.gov/programs/ana>. Pre-publication information on ANA’s FOAs will be available at <https://www.grants.gov/web/grants/search-grants.html> by clicking on ‘Forecasted’ under Opportunity Status and ‘Administration for Children and Families—ANA [HHS-ACF-ANA]’ on the left side of the page. Synopses and application forms will be available on www.Grants.gov.

Stacey Ecoffey,

Acting Commissioner, Administration for Native American, ACF, Acting Deputy Assistant Secretary for Native American Affairs, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0221]

Formal Dispute Resolution: Sponsor Appeals Above the Division Level; Guidance for Industry and Review Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is

announcing the availability of a guidance for industry and review staff entitled “Formal Dispute Resolution: Sponsor Appeals Above the Division Level.” This guidance provides recommendations for industry and review staff on the procedures in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) for resolving scientific and/or medical disputes between CDER or CBER and sponsors that cannot be resolved at the division level. This guidance describes the formal dispute resolution procedures for sponsors that wish to appeal a scientific and/or medical issue to the office or center level and provides a structured process for resolving disputes. This guidance finalizes the revised draft guidance entitled “Formal Dispute Resolution: Appeals Above the Division Level” issued September 9, 2015, and replaces the guidance of the same name issued February 2000.

DATES: The announcement of the guidance is published in the **Federal Register** on November 6, 2017.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows: