

a disaster or emergency, waivers and flexibilities assist health care providers/suppliers in providing timely healthcare and services to people who have been affected and enables states, Federal districts, and U.S. territories to ensure Medicare and/or Medicaid beneficiaries have continued access to care. During disasters and emergencies, it is not uncommon to evacuate Medicare-participating facilities and relocate patients/residents to other provider settings or across state lines, especially, during hurricane and tornado events. CMS must collect relevant information for which a provider is requesting a waiver or flexibility to make proper decisions about approving or denying such requests. Collection of this data aids in the prevention of gaps in access to care and services before, during, and after an emergency. CMS must also respond to inquiries related to a PHE from providers and beneficiaries. CMS is not collecting information from these inquiries; we are merely responding to them.

Prior to this request, CMS did not have a standard process or OMB approval for providers/suppliers impacted to submit 1135 waiver/flexibility requests or inquiries, as these were generally seen on a smaller scale (natural disasters) prior to the COVID-19 public health emergency. CMS has provided general guidance to Medicare-participating facilities which can be viewed at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers>. The requests and inquiries would be sent directly, via email, to the Survey Operations Group in each CMS Location (previously known as CMS Regional Offices) and the entity would provide a brief summary to CMS for a waiver/flexibility request or an answer to an inquiry. We are now developing a streamlined, automated process to standardize the 1135 waiver requests and inquiries submitted based on lessons learned during COVID-19 PHE, primarily based on the volume of requests to ensure timely response to facility needs. The waiver request form was approved under an Emergency information collection request on October 15, 2020.

Furthermore, the normal operations of a healthcare provider are disrupted by emergencies or disasters occasionally. When this occurs, State Survey Agencies (SA) deliver a provider/beneficiary tracking report regarding the current status of all affected healthcare providers and their beneficiaries. This report includes demographic information about the provider, their operational status, beneficiary status,

and planned resumption of normal operations. This information is provided whether or not a PHE has been declared. We are now developing a streamlined, automated process to standardize submission of this information directly by the provider during emergencies and eliminating the need for SA to provide it. It will consist of a public facing web form.

This information will be used by CMS to receive, triage, respond to and report on requests and/or inquiries for Medicare, Medicaid, and CHIP beneficiaries. This information will be used to make decisions about approving or denying waiver and flexibility requests and may be used to identify trends that inform CMS Conditions for Coverage or Conditions for Participation policies during public health emergencies, when declared by the President and the HHS Secretary.

Subsequent to the Emergency information collection request, we revised the package to include a second form, Healthcare Facility Status Workflow, which is for operational status information which will be used to assist providers in delivering critical care to beneficiaries during emergencies. Subsequent to the 60-day **Federal Register** notice which published on October 21, 2020 (85 FR 66990), we conducted user acceptance testing, resulting in enhancements to the public-facing web form that streamline the submission process and improve the flow and readability of the web form. These enhancements make the automated process easier to use for healthcare providers. We are also remediating a violation of the Paperwork Reduction Act by adding the Acute Hospital Care at Home waiver to this package. The initiative was established on November 23, 2020, in response to the unprecedented strain on hospital capacity due to the severe national increase in coronavirus disease 2019 (COVID-19). There is an increase in burden due to adding this waiver initiative to this package. *Form Number:* CMS-10752 (OMB control number: 0938-1384); *Frequency:* Occasionally; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions and State, Local or Tribal Governments; *Number of Respondents:* 5,729; *Total Annual Responses:* 5,729; *Total Annual Hours:* 5,729. (For policy questions regarding this collection, contact Adriane Saunders at 404-562-7484.)

Dated: February 16, 2021.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Numbers: 93.581, 93.587, 93.612]

Notice for Public Comment on Administration for Native Americans' Program Policies and Procedures

AGENCY: Administration for Native Americans (ANA), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice for public comment.

SUMMARY: Pursuant to Section 814 of the Native American Programs Act of 1974 (NAPA), as amended, ANA is required to provide members of the public an opportunity to comment on proposed changes in interpretive rules and general statements of policy and to give notice of the proposed changes no less than 30 days before such changes become effective. In accordance with notice requirements of NAPA, ANA herein describes proposed interpretive rules and general statements of policy that relate to ANA's funding opportunities in Fiscal Year (FY) 2021. Changes to FY 2021 funding opportunity announcements (FOAs) will be based on the following previously published programs: Environmental Regulatory Enhancement (ERE), HHS-2021-ACF-ANA-NR-1907; Native American Language Preservation and Maintenance-Esther Martinez Immersion (EMI), HHS-2021-ACF-ANA-NB-1958; Native American Language Preservation and Maintenance (P&M), HHS-2021-ACF-ANA-NL-1924; Social and Economic Development Strategies (SEDS), HHS-2021-ACF-ANA-NA-1906; Social and Economic Development Strategies-Alaska (SEDS-AK), HHS-2021-ACF-ANA-NK-1902; and Social and Economic Development Strategies-Growing Organizations (SEDS-GO), HHS-2021-ACF-ANA-NN-1918.

DATES: Comments are due by March 22, 2021. If ANA does not receive any significant comments within the 30-day comment period, ANA will proceed with the proposed changes in the respective published FOAs. The FOAs

will serve as the final notice of these proposed changes.

ADDRESSES: Comments may be submitted to Carmelia Strickland, Director of Program Operations, Administration for Native Americans, 330 C Street SW, Washington, DC 20201 or via email to ANAComments@acf.hhs.gov.

FOR FURTHER INFORMATION CONTACT:

Carmelia Strickland, Director, Division of Program Operations, Administration for Native Americans, 330 C Street SW, Washington, DC 20201. Telephone: (877) 922-9262; Email: ANAComments@acf.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 814 of NAPA, as amended, (42 U.S.C. 2992b-1) incorporates provisions of the Administrative Procedure Act that require ANA to provide notice of its proposed interpretive rules and statements of policy, and to seek public comment on such proposals. This notice serves to fulfill the statutory notice and public comment requirement. ANA voluntarily includes rules of practice and procedures in this notice in an effort to be transparent. The proposed interpretive rules, statements of policy, and rules of ANA practice and procedure reflected in clarifications, modifications, and new text will appear in the following six FY 2021 FOAs: ERE, EMI, P&M, SEDS, SEDS-AK, and SEDS-GO.

ANA's past FOAs can be accessed at <https://ami.grantsolutions.gov/index.cfm?switch=searchresult&type=office¶m=ANA&page=ANA>. Synopses and application forms will be available on <https://www.grants.gov>.

A. Interpretive rules, statements of policy, procedures, and practice. The proposals below reflect ANA's proposed changes in rules, policy, or procedures that will take effect in the FY 2021 FOAs.

1. Letter of Intent—ANA will include a provision in all of its FOAs to ask potential applicants to submit a Letter of Intent within 30 days of publication, but it is not mandatory. By doing so, respondents will receive information about ANA's training and technical assistance support for applicants. This will also enable ANA to estimate the number of applications that will be submitted in order to plan for the peer review process.

2. Intellectual Property—Based on feedback from grantees and through tribal consultations, ANA is concerned about the protection of intellectual property of materials created with grant funding. Therefore, ANA will include information in all FOAs that encourages applicants to educate themselves on

intellectual property rights and the protection of ownership of Native language materials, ceremonies, music and dance, and other forms of knowledge and cultural practices that originate from Native communities.

3. Previously Funded Projects—ANA has a long-standing policy in place that it provides project-specific funding and not ongoing program funding. There is existing authority for ANA to choose not to fund a project that 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 duplicate activities for which any consortium member also receives or has received funding from ANA. It will be clarified in the FOAs this year that applicants that propose a project similar to a previously funded ANA grant should acknowledge past funding and explain what was accomplished. In addition, the applicant should be explicit and provide a detailed description of how the new project is different and is not duplicative of the past project.

4. Eligibility—In December, Congress passed the Indian Community Economic Enhancement Act of 2020, which reauthorized certain sections of NAPA related to funding for economic development projects including adding Native community development financial institutions (CDFIs) as an eligible entity; therefore, ANA will add Native CDFIs to the list of eligible applicants. In addition, during tribal consultation in 2020, a comment was received that asked ANA to ensure that Urban Indian Organizations were eligible to apply for ANA grants. Therefore, ANA will clarify in the FOAs that Urban Indian Organizations (UIOs), as defined by 25 U.S.C.1603(29), are eligible under current regulations (45 CFR1336.33) as "incorporated non-profit multi-purpose community-based Indian organizations" and as "urban Indian centers". However, Native CDFIs and UIOs are not eligible to apply for the ERE program, which is limited to tribes and tribal entities. Additionally, like all applicants that are not tribes or Alaska Native Villages, Native CDFIs and UIOs must also meet the ANA's Assurance of Community Representation on the Board of Directors.

5. Application Requirements and Evaluation Criteria Scores—Sections 803 and 806 of NAPA, 42 U.S.C. 2991b; 2991d-1. In FY 2018, ANA made substantial revisions to the application requirements and evaluation criteria included in our FOAs. The purpose of the revisions was to shift from a deficit-

based to a strengths-based approach for application planning and development, to design each project to follow the ANA Project Framework, and to emphasize a community-based approach to project planning and implementation. ANA stands behind the revisions made in FY 2018 and does not plan to change the information being requested; however, efforts have been made to reduce redundancy and number of scoring criteria. ANA proposes the following evaluation criteria scores for the SEDS, SEDS-AK, ERE, and P&M FOAs for FY 2021:

Approach for a maximum of 73 points, to consist of the following: Long Term Community Goal (2 points), Current Community Condition (3 points); Project Goal (2 points); Objectives (6 points); Outcomes and Indicators (5 points); Outputs (3 points); Outcome Tracker and Outcome Tracking Strategy (7 points). Community-Based Strategy (10 points), Readiness and Implementation Strategy (20 points); and the Objective Work Plan (OWP) (15 points).

Organizational Capacity for a maximum of 12 points.

Budget and Budget Justification for a maximum of 15 points, to consist of the following: Line Item Budget (5 points) and Budget Justification (10 points).

These changes are meant to streamline the information required for a successful grant application and provide specific point allotments in order to make ANA's evaluation criterion more approachable. In addition, it is intended to provide greater guidance to panel reviewers on how to allocate scores.

6. Changes to the SEDS-FOA—Priorities and bonus points—Sections 803 and 803B of NAPA, 42 U.S.C. 2991b; 2991b-2. As previously mentioned, recently passed legislation requires ANA to prioritize applications seeking assistance for the following: (1) The development of a tribal code or courts system for purposes of economic development, including commercial codes, training for court personnel, and the development of nonprofit subsidiaries or other tribal business structures; (2) the development of a native community development financial institution, including training and administrative expenses; (3) the development of a tribal master plan for community and economic development and infrastructure. The new economic development legislative priorities will be incorporated into the new program areas of interest for the SEDS FOA. Ten bonus points will be awarded to applications that address one or more of these priority areas. Applications that

propose a legislative priority project should include the priority area(s) in the project goal, all objectives and indicators as reflected in the project's framework, project approach, Objective Work Plan and Outcome Tracker. Reviewers should provide 10 points if all elements are included in the application to address one or more of the economic development priority areas.

In addition, during tribal consultation, additional social development priorities areas were identified by Native communities to potentially fund through the SEDS program. Therefore, 5 bonus points will be awarded to applications that address one or more of the following Native community priority areas: Native Veterans, Missing and Murdered Native Americans (MMNA), or Emergency Preparedness and Response. Applications that address one or more of these priorities areas should include the priority area in the project goal, all objectives, indicator(s), and target population (either as participants or beneficiaries). Reviewers should provide 5 points if all elements are included in the application to address one or more priority areas. Since social and economic development projects have different project goals, no application will be eligible to receive both sets of bonus points. In addition, the SEDS program areas of interest will be expanded to include MMNA and Anti-Human Trafficking.

7. Changes to SEDS-AK FOA—Section 803 of NAPA, 42 U.S.C. 2991b. ANA will also incorporate the new legislative economic development priorities into the SEDS-AK FOA. Therefore, new program areas of interest for SEDS-AK will include the following: (1) The development of a Tribal code or court system for purposes of economic development, including commercial codes, training for court personnel, and the development of nonprofit subsidiaries or other tribal business structures; (2) the development of native community development financial institutions, including training and administrative expenses; (3) the development of a tribal master plans for community and economic development and infrastructure. Therefore, 10 bonus points will be awarded to applications that address one or more of these priority areas. Applications that propose a legislative priority project should have it included in the project goal, all objectives and indicators as reflected in the project's framework, the project approach, and the Objective Work Plan and Outcome Tracker. Reviewers should provide 10 points if all elements are

included in the application to address one or more of the economic development priority areas. In addition, ANA plans to modify the description of the program purpose for the SEDS-AK FOA to provide a competitive advantage for smaller Alaska Native villages or organizations that have never received ANA funding. Therefore, the FOA will state that reviewers should award 5 bonus points in the scoring criteria if an eligible entity has never received an ANA award. ANA staff will confirm during the objective review process if an applicant organization for SEDS-AK has received a past ANA award.

8. Changes to EMI FOA—Section 803C of NAPA, 42 U.S.C. 2991b–3. In accordance with 42 U.S.C. 2991b–3(c)(7), applicants for an EMI grant must submit an official document that certifies the applicant has at least 3 years of experience in operating and administering a Native American language survival school, a Native American language nest, or any other educational program in which instruction is conducted in a Native American language, in accordance with Public Law 109–394. Therefore, the EMI FOA will have a new evaluation criterion to score 10 points to ensure the application includes a certification document that demonstrates the applicant has at least 3 years of experience in operating a language nest, survival school, or other native language educational program. As a result, the EMI FOA's scoring criteria will change as follows:

Approach for a maximum of 75 points, to consist of the following: Nest or Survival School Certification (10 points); Long Term Community Goal (2 points); Current Community Condition (3 points); Project Goal (2 points); Objectives (6 points); Outcomes and Indicators (5 points); Outputs (3 points); Outcome Tracker and Outcome Tracking Strategy (7 points); Community-Based Strategy (8 points); Readiness and Implementation Strategy (16 points); and the Objective Work Plan (OWP) (13 points).

Organizational Capacity for a maximum of 10 points.

Budget and Budget Justification for a maximum of 15 points, to consist of the following: Line Item Budget (5 points) and Budget Justification (10 points).

9. Changes to SEDS-GO FOA—Sections 803 and 803B of NAPA, 42 U.S.C. 2991b; 2991b–2. In FY 2020, ANA introduced a new FOA as a special initiative under the SEDS program to support growing organizations to provide funding to enhance their internal capacity and infrastructure to better serve their members or their

communities. There will be no substantive changes to application requirements in the FY 2021 SEDS-GO FOA. There will be slight changes to the evaluation scoring criteria, which will be as follows:

Approach (for a maximum of 70 points) to consist of the following: Introduction to the Applicant Organization (6 points); Targeted Challenge (6 points); Project Goal (6 points); SMART Objectives (6 points); Outcomes and Indicators (6 points); Description of Project Implementation Strategy (25 points); Objective Work Plan (OWP) (15 points).

Organizational Capacity—15 points.
Budget and Budget Justification (for a maximum of 15 points) to consist of a Line Item Budget (5 points) and a Budget Justification (10 points).

Bonus Points—5 bonus points may be provided to applicants that have never received an ANA grant award.

Statutory Authority: Section 814 of the Native American Programs Act of 1974, as amended.

Elizabeth Leo,

Senior Grant Policy Specialist, Office of Administration, Administration for Children and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1136]

Guidance Documents Related to Coronavirus Disease 2019; 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 FDA guidance documents related to the Coronavirus Disease 2019 (COVID–19) public health emergency (PHE). This notice of availability (NOA) is pursuant to the process that FDA announced, in the **Federal Register** of March 25, 2020, for making available to the public COVID–19-related guidances. The guidances identified in this notice address issues related to the COVID–19 PHE and have been issued in accordance with the process announced in the March 25, 2020, notice. The guidances have been implemented without prior comment, but they remain subject to comment in accordance with the Agency's good guidance practices.