

Dated: November 24, 2010.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Request for Public Comment on the Proposed Adoption of Administration for Native Americans (ANA) Program Policies and Procedures

AGENCY: Administration for Native Americans, ACF, HHS.

ACTION: Notice.

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 proposed changes in interpretive rules, general statements of policy, and rules of agency procedure or practice, and to give notice of the final adoption of such changes at least 30 days before the changes become effective. In accordance with notice requirements of NAPA, ANA herein describes its proposed interpretive rules, general statements of policy, and rules of agency procedure or practice as they relate to the Fiscal Year (FY) 2011 Funding Opportunity Announcements (FOA) for the following programs: Social and Economic Development Strategies (SEDS), Social and Economic Development Strategies—Tribal Governance (SEDS—TG), Social and Economic Development Strategies—Assets for Independence (SEDS—AFI), Native Language Preservation and Maintenance (Language P&M), Native Language Preservation and Maintenance—Esther Martinez Initiative (Language—EMI), and Environmental Regulatory Enhancement (ERE). This notice also provides additional information about ANA's plan for administering the programs.

DATES: The deadline for receipt of comments is 30 days from the date of publication in the **Federal Register**.

ADDRESSES: Comments in response to this notice should be addressed to Lillian Sparks, Commissioner, Administration for Native Americans, 370 L'Enfant Promenade, SW., Mail Stop: Aerospace 2—West, Washington, DC 20447. Delays may occur in mail delivery to Federal offices; therefore, a copy of comments should be faxed to

(202) 690-7441. Comments will be available for inspection by members of the public at the Administration for Native Americans, 901 D Street, SW., Washington, DC 20447.

FOR FURTHER INFORMATION CONTACT:

Kathy Killian, Program Specialist, (877) 922-9262.

SUPPLEMENTARY INFORMATION: Section 814 of 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 FY 2011 FOAs: SEDS, SEDS—TG, SEDS—AFI, Language P&M, Language—EMI, and ERE. This notice serves to fulfill this requirement.

A. Funding Opportunity Announcements

1. Social and Economic Development Strategies (SEDS)

In FY 2011, ANA will combine the SEDS and SEDS—Special Initiative (SEDS—SI) FOAs from FY 2010 into one SEDS FOA. The SEDS FOA will include all program areas of interest from the previous FOAs which address Social Development, Economic Development, and Strengthening Families. Governance projects will be addressed in a separate FOA (see SEDS—TG, below). The SEDS FOA will include two funding ranges with the higher funding amount being the disqualification factor for applications (see Section C of this Notice for more information on funding ranges). Furthermore, through the SEDS FOA, ANA will fund project proposals from Tribes to prepare applications for Federal recognition. Tribes will only be allowed to receive funding for this priority area once, as per the funding restriction which states, "ANA does not fund projects that are 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 funding from ANA." This is a return to the ANA priority of the 1990s. (Legal authority: Section 803(a) of NAPA, as amended.)

2. SEDS—Tribal Governance (TG)

In FY 2011 ANA will introduce SEDS—TG to fund tribal governance projects. These types of projects were formerly funded under SEDS. ANA will expand the governance priority to emphasize projects that strengthen the internal capacity and infrastructure of tribal governments to increase services

provided to children and families. The FOA will also emphasize increasing the tribal government's ability to exercise local control and decision making over their resources. ANA is particularly interested in projects designed to develop strong linkages between social services, health programs, and schools serving Native children. Program areas of interest will be expanded to include:

(1) *Interoperability:* Promote program coordination among human and social service programs for tribal communities to strengthen the programs they provide to their children, youth, and families.

(2) *Comprehensive Strategies:* Develop comprehensive intergovernmental strategies involving tribal, State and Federal governments to meet the needs of tribal children and youth.

(3) *Self-Governance:* Build the capacity and infrastructure of tribal governments to enter into self-governance compacts.

ANA believes this FOA will encourage Tribes and Native communities to look at new opportunities and methods for providing services to their communities. Applicants eligible for this FOA are the same as those identified for SEDS. (Legal authority: Section 803(a) of NAPA, as amended.)

3. SEDS—Assets for Independence (AFI)

ANA is partnering with the Office of Community Services' (OCS) AFI program to support Tribes and Native organizations in planning and implementing comprehensive asset-building projects. ANA and OCS are providing this support through funding opportunities, training, and technical assistance. The AFI program is an assets-based approach for assisting low-income families out of poverty. The program assists individuals and families to save earned income in special-purpose, matched savings accounts called Individual Development Accounts (IDAs). Every dollar in savings deposited into an IDA by a participant will be combined with non-participant funds (from \$1 to \$8 combined Federal (AFI) and non-Federal funds). The program promotes savings and enables a participant to acquire a lasting asset. An AFI participant can use the IDA savings to achieve any of three objectives: acquire a first home, capitalize a small business, or enroll in postsecondary education or training.

ANA, through its SEDS program, and OCS, through its AFI program, are offering Tribes and Native organizations a joint funding initiative. The purpose of the joint SEDS—AFI funding is to support Tribes and Native organizations

implement asset building projects with an AFI-funded IDA component. The ANA-SEDS portion of the funding will focus on the operational and staffing costs necessary to implement the project, financial literacy training, capacity building, and other activities. The OCS-AFI portion will be used to provide funding for IDAs and limited administrative costs. This FOA will request one application with two project budgets to complete the project. The two project budgets will separately identify the SEDS portion of the funding and corresponding match and the AFI portion of the funding and corresponding match. These two project budgets will be the basis for two awards needed to complete the project. The project will be monitored by a team representing both ANA and OCS. ANA will provide a funding opportunity for applicants to apply for a 5-year (five 12-month budget periods) grant to accompany award of a standard 5-year AFI grant.

Eligible applicants include non-profit organizations that serve Native American populations, or Tribes, and Alaska Native villages if they are joint applicants with a non-profit organization serving Native American populations. The eligibility reflects the overlap between ANA's target populations and the AFI program's legislative eligibility requirements. Individual participants who open IDAs under this program must meet AFI participant guidelines, which are: Members of a household that is eligible for assistance under Temporary Assistance for Needy Families (TANF), or whose adjusted gross income is either equal to or less than 200 percent of the Federal poverty line, or is eligible for Federal Earned Income Tax Credit and has less than \$10,000 in assets (excluding the value of a primary dwelling unit and one motor vehicle).

The partnership includes a training and technical assistance (T/TA) component, through which ANA's T/TA providers will conduct pre-application trainings and provide one-on-one technical assistance to potential SEDS-AFI applicants.

This partnership between OCS and ANA will allow these two programs to provide enhanced funding opportunities to our common target communities and maximize the impact of grant dollars. Interoperability between programs within ACF is an ACF priority. (Legal authority: Section 803(a) of NAPA, as amended.)

4. Native Language Preservation and Maintenance (Language P&M) and Esther Martinez Initiative (Language—EMI)

All Language P&M and Language—EMI projects funded in FY2011 will have a start date of August 1, 2011. The revision to the start date will allow projects to better align with most school schedules throughout ANA's target communities. To accommodate this revision, the Language FOAs will be published and application due dates will be earlier in the year than all other FOAs. (Legal authority: Section 803(a) and 803C of NAPA, as amended, 42 U.S.C. 2991b and § 2991b-3 and Pub. L. 109–394.)

B. Administrative Policies: In FY 2011, ANA will add five administrative policies.

1. Grantees can have only one active grant per Catalog of Federal Domestic Assistance (CFDA) number.

2. ANA will increase the reach of its limited funding. Therefore, applicants that have received funding from ANA for at least two projects consecutively and within one CFDA number may not be funded for a third consecutive project within the same CFDA number if other applicants who have not received ANA funding in the past 3 years are within the scoring range to be funded.

3. Applicants are requested to identify a target amount of leveraged resources (target of zero is acceptable) and a target number of partnerships. The value of the targets will not be evaluated and scored; however, the indicators' contribution within the overall strategy of project implementation and its sustainability is included in the evaluation criteria. Grantees will be required to track these indicators quarterly throughout the project period. Leveraged resources are in addition to the statutory matching requirement of 20 percent and are not a requirement of this grant.

4. Business plans should be submitted for all SEDS applications requesting an equity investment on behalf of the Federal government.

The first two administrative policies will allow ANA to maximize its limited funding to benefit the most communities. The intent of the first policy, to restrict funding to one grant per entity per CFDA number, will also be stated in the eligibility and funding restriction sections of all FOAs. Due to the change in the project period start date for language projects, ANA will waive this restriction if a language project is ending within 2 months of a new project start date (*i.e.*, organizations or Tribes with projects ending 9/29/

2011 can receive new awards with a 8/1/2011 start date). In addition to maximizing the benefit of ANA's limited funds, the first administrative policy will encourage current grantees to successfully complete project objectives within the originally defined project periods and avoid requests for No Cost Extensions (NCEs). Past experience has shown that project success is increased when a grantee can complete one project prior to starting a second project. Overlapping projects, specifically a new award and an extension, can result in delays or significant challenges to one or both projects because of limited financial and personnel resources.

The second administrative policy allows the ANA commissioner to limit the frequency of the same organizations receiving funding, thus allowing it to address more communities. (Legal authority: Section 803(a), 803(d), and 803C of NAPA, as amended, 42 U.S.C. 2991b and 2991b–3 and Pub. L. 109–394.)

The third administrative policy allows ANA to continue to measure leveraged resources and partnerships for all funded projects, but removes the target numbers for these indicators from being evaluated and scored by panel reviewers. ANA is required to measure these important indicators, as per the Government Performance Reporting Act (GPRA) for all negotiated awards. (Legal authority: Section 803(a), 803(d), and 803C of NAPA, as amended, 42 U.S.C. 2991b and 2991b–3 and Pub. L. 109–394.)

The last administrative policy is specific to SEDS FOA. The business plan will not be evaluated for the merit of the plan itself; however, the business plan will be reviewed to ensure that the project strategy is in line with the business plan. (Legal authority: Section 803(a) of NAPA, as amended.)

C. Award Information: In all FOAs, ANA identifies funding floors and funding ceilings, as well as project periods. In FY 2011, the thresholds and project periods for SEDS, SEDS—TG, and SEDS—AFI are new or have changed.

The funding ranges and project periods for the combined and new FOAs (see Section A of this Notice) will be as follows:

SEDS

\$50,000 to \$149,999 per budget period, and
\$150,000 to \$400,000 per budget period.
12-month project and budget period, or
24-month project period with two 12-month budget periods, or

36-month project period with three 12-month budget periods.

The SEDS FOA will identify how many applications will be funded in each of the two funding ranges. Only the upper limit of the two ranges (\$400,000) will be used as a disqualification factor.

SEDS—TG

\$50,000 to \$375,000 per budget period. 12-month project and budget period, or 24-month project period with two 12-month budget periods, or 36-month project period with three 12-month budget periods.

SEDS—AFI

\$50,000 to \$250,000 per budget period. 60-month project period with five 12-month budget periods.

The SEDS—AFI range reflects the ANA portion of the funding only. OCS will provide up to \$1 million for a 5-year budget and project period. (Legal authority: Section 803(a) of NAPA, as amended.)

Disqualification Factors: ANA will revise for clarification two factors that are specific to applications submitted for ANA funding. Applications that are submitted without this documentation will be considered non-responsive to the FOA and will not be considered for competition.

The first ANA-specific disqualification factor applies to all applicants. The documentation required from the Tribe, Alaska Native village or organization stating approval of the proposed project must come in the form of a Board Resolution.

The second ANA-specific disqualification factor applies only to applicants that are *not* Tribes or Native Alaska villages. Organizations applying for funding must show that a majority of board members approving the project proposal are representative of the community to be served. ANA will revise the categories of representatives of the community to be served to include: (1) Members of Federally or State recognized Tribes; (2) persons eligible to be a participant or beneficiary to the project to be funded; (3) persons who are recognized by the eligible community to be served as having a cultural relationship with the community to be served; or (4) persons considered to be Native American as defined in title 45, part 1336, section 10 of the Code of Federal Regulations (CFR), and Native American Pacific Islander as defined in the Native American Programs Act.

These disqualification factors will be revised to better establish board support for a project and to demonstrate a

stronger link between an organization's board and the community to be served. (Legal authority: Section 803(a) and 814 of NAPA, as amended.)

D. Definitions: ANA will revise and add definitions for terms used in the FOA.

Leveraged Resources—Any resource, not including the Federal share, non-Federal contribution, and program income, acquired or utilized during the project period that supports the project. Leveraged resources are expressed as a dollar amount and may include natural, financial, personnel, and physical resources provided to assist in the successful completion of the project.

Interoperability—Collaborative administration or information sharing that integrates the efforts of individual programs, projects, departments, etc. in order to strengthen programs and provide comprehensive service.

Program Income—Gross income earned by a recipient and/or subrecipient that was directly generated by the grant-supported activity or earned as a result of the award. Program income includes (but is not limited to) fees for services performed, the use or rental of real or personal property acquired under the grant, the sale of commodities or items fabricated under an award, license fees and royalties on patents and copyrights, and payments of interest on loans made with grant funds. Except as otherwise provided in statute, regulation, or the terms and conditions of the award, program income does not include rebates, credits, discounts, or interest earned in relation to program income; the receipt of principal on loans or interest the recipient earns on those amounts after receiving them from the borrower; taxes, special assessments, levies, fines, or similar revenues raised by a governmental recipient or subrecipient. The term also does not include interest earned on advances of Federal funds and proceeds from the sale of equipment or real property acquired under an award, which have distinct accountability requirements.

The leveraged resources definition will be revised to state that program income cannot be included. Interoperability is defined because the evaluation criteria will include a reference to the integration of the proposed project into other programs, if appropriate for the proposed project. Interoperability is an ACF priority, both within ACF and in the entities it funds. Program income is defined to clarify the definition of leveraged resources. (Legal authority: Section 803(b) and 814 of NAPA, as amended and 42 U.S.C. 2991b-3(b)(7)(C).)

E. Cost Sharing or Matching: The matching requirement waiver for Insular Areas will no longer be available for nongovernmental entities.

1. All matching is waived for consolidated grants to governments of the Insular Areas;

2. The first \$200,000 of matching is waived for non-consolidated grants to governments of American Samoa, Guam, the Virgin Islands, or the Northern Mariana Islands; however, matching over the first \$200,000 is not waived;

3. Matching is not waived for grants to nongovernmental entities of the Insular Areas.

Although there is not an automatic waiver for all applicants from the Insular Areas, any applicant may request an individual match requirement waiver, in accordance with NAPA. (Legal authority: 48 U.S.C. 1469(a)(d) and 45 CFR 1336.50(b)(3).)

F. Funding Restrictions: The restriction that prevents ANA from funding "counseling or therapeutic activities that are medically-based" will not be included in the following FOAs: Language—P&M, Language—EMI, SEDS—AFI, SEDS—TG, and ERE. In the SEDS FOA, the restriction will be revised to state:

ANA does not fund couples or family counseling activities that are medically based.

ANA will revise this restriction in SEDS in order to fund medically based activities in projects that address such health issues as diabetes prevention and care projects, elder health care, or other similar types of health issues. This funding restriction will not appear in other FOAs. (Legal authority: Sections 803(a) and 814 of NAPA, as amended.)

G. ANA Application Evaluation Criteria: ANA will revise the evaluation criteria throughout the Language—P&M, Language—EMI, SEDS—TG, and ERE FOAs to clarify how reviewers will evaluate and score applications. The content of evaluation criteria will mirror the content of the project description section of the FOAs, which instructs applicants on what to include in an application.

i. *Titles and Assigned Weight:* In FY 2011, ANA will rename the criteria and adjust the weighted scores.

For FY 2011, the criteria will be titled and weighted as follows:

- Objectives and Need for Assistance* 20 points;
- Outcomes Expected* 15 points;
- Approach* 50 points;
- Sub-criterion—Project Strategy* 30 points;
- Sub-criterion—Objective Work Plan (OWP)* 20 points and

—*Budget and Budget Justification 15 points.*

For FY 2011, the two criteria for the SEDS-AFI FOA will be titled and weighted as follows:

—*Approach 90 points and*
—*Budget and Budget Justification 10 points.*

The criteria titles will match the titles found in the project description section of the FOAs. Matching titles will help applicants to better understand the connection between the two sections of the FOAs. The assigned weights better reflect what ANA considers to be the most important elements of the project application. (Legal authority: Section 803(c) of NAPA, as amended.)

ii. *ANA Evaluation Criteria:* Included here is a summary of each criterion. The FOAs will include a more detailed description of the evaluation criteria and the associated project description.

(a) *Objectives and Need for Assistance:* Under this criterion, applications will be evaluated on the applicant's community and applicant identification, connection to the community, community participation in the project development, the problem statement, and the briefly stated objectives.

(b) *Outcomes Expected:* Under this criterion, applications will be evaluated on the strength of the project outcomes expected, which include the project goal, the results and benefits expected, and one project-specific impact indicator. For language applications that are designed to teach a Native language, applicants must include an impact indicator that shows advancement of language fluency. All other language projects should provide an impact indicator that measures an increase in community interest to preserve the language.

(c) *Approach:* Under this criterion, the application will be evaluated on the strength of the project approach. This criterion includes two sub-criteria: The project strategy and the OWP. The project strategy sub-criterion includes a detailed description of the implementation plan, community involvement and outreach during implementation, and contingency planning to support project implementation. In addition, partnerships and leveraged resources will be evaluated as to their contribution within the overall strategy of project implementation and its sustainability; however, the target numbers will not be evaluated or scored. In this section reviewers will also consider organizational capacity and project sustainability. The OWP

sub-criterion includes a review of the OWP form and its strength as an effective implementation tool.

(d) *Budget:* Under this criterion, the application will be evaluated on the strength of the budget and how well it supports successful completion of the project objectives. This criterion includes a line-item budget and budget justification for each line item for each budget period.

The changes to the content of evaluation criteria, and the complementary changes to the project description section of the FOA, will more effectively guide panel reviewers and applicants on what ANA believes are critical components of a project application. (Legal authority: Section 803(c) of NAPA, as amended.)

Dated: November 22, 2010.

Lillian Sparks,

Commissioner, Administration for Native Americans.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0583]

Agency Information Collection Activities: Proposed Collection; Comment Request; Radioactive Drug Research Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection contained in regulations governing the use of radioactive drugs for basic informational research (21 CFR 361.1).

DATES: Submit either electronic or written comments on the collection of information by January 31, 2011.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written

comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane., rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3792, Elizabeth.Berbakos@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: 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. "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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Radioactive Drug Research Committees—(OMB Control Number 0910-0053)

Under sections 201, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 355, and 371), FDA has the authority to issue regulations governing the use of radioactive drugs