

evaluation and reporting process have become necessary to ensure CDC receives standardized, accurate, thorough evaluation data from both health department and CBO grantees. For these reasons, CDC developed PEMS and consulted with representatives from health departments, CBOs, and national partners (e.g., The National Alliance of

State and Territorial AIDS Directors, Urban Coalition of HIV/AIDS Prevention Services, and National Minority AIDS Council).

Respondents will collect, enter, and report general agency information, program model and budget data, and client demographics and behavioral characteristics. (After initial set-up of

the PEMS, data collection will include searching existing data sources, gathering and maintaining data, document compilation, review of data, and data entry into the web-based system.) Agents will submit data quarterly. There are no costs to respondents other than their time.

#### ESTIMATE OF ANNUALIZED BURDEN

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Health jurisdictions .....	59	4	137	32,332
Health jurisdictions (CTR) .....	30	4	174	20,880
Health jurisdictions (Training) .....	59	4	10	2,360
Community-Based Organizations .....	160	4	84	53,760
Community-Based Organizations (CTR) .....	70	4	23	6,440
Community-Based Organizations (Training) .....	160	4	10	6,400
Annual total .....	.....	.....	.....	122,172

Dated: November 14, 2006.

**Joan F. Karr,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Notice of Public Comment on the Proposed Adoption of ANA Program Policies and Procedures

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

**SUMMARY:** Pursuant to section 814 of the Native American Programs Act of 1974 (the Act) 42 U.S.C. 2992b-1, ANA herein describes its proposed interpretive rules, statements of general policy and rules of agency procedure or practice in relation to the Social and Economic Development Strategies (hereinafter referred to as SEDS), Native Language Preservation and Maintenance (hereinafter referred to as Native Language), Environmental Regulatory Enhancement (hereinafter referred to as Environmental), Environmental Mitigation (hereinafter referred to as Mitigation), Improving the Well-Being of Children—Native American Healthy Marriage Initiative (hereinafter referred to as Healthy Marriage) programs and any Special Initiatives. Under the

statute, ANA is required to provide members of the public an opportunity to comment on proposed changes in interpretive rules, statements of general policy and rules of agency procedure or practice and to give notice of the final adoption of such changes at least thirty (30) days before the changes become effective. This Notice also provides additional information about ANA's plan for administering the programs.

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

**ADDRESSES:** Comments in response to this Notice should be addressed to Sheila K. Cooper, Director of Program Operations, Administration for Native Americans, 370 L'Enfant Promenade, SW., Mail Stop: Aerospace 8—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, Aerospace Center, 901 D Street, SW., Washington, DC 20024.

**FOR FURTHER INFORMATION CONTACT:** Sheila K. Cooper, Director of Program Operations, toll-free at (877) 922-9262.

**SUPPLEMENTARY INFORMATION:** Section 814 of the Native American Programs Act of 1974, as amended, requires ANA to provide notice of its proposed interpretive rules, statements of general policy and rules of agency procedure or

practice. These proposed clarifications, modifications and new text will appear in the ANA FY 2006 Program Announcements (PAs): SEDS, Native Language, Environmental, Mitigation, Healthy Marriage and Special Initiatives. This Notice serves to fulfill this requirement.

#### Additional Information

##### *I. Objective Progress Report (OPR) Form*

ANA has updated the OPR form to capture grantee project information that is needed in order to make a determination that the project is progressing as planned. The quarterly report will be used to support a request for additional technical assistance, should the need exist. Quarterly reporting has been a requirement for ANA grantees since FY 2005 and the new format will yield uniform data. The new format has been submitted for Office of Management and Budget approval and will be a requirement beginning January 2007. (Legal authority: Section 803B of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991B-2.)

##### *II. Native Language Preservation and Maintenance*

ANA Categories: In an effort to adhere to the Congressional intent of the legislation and to clarify the Native Language program in response to the needs of Native communities, ANA is creating a marked separation of the longstanding Category I: Assessment and Category II: Planning and/or

Implementation. ANA is proposing three distinct priority areas within the Native Language program area. The proposed categories are:

*Category I:* Language Assessment will remain as a 12-month project period with the primary activity of assessing the current status of the Native Language for the identified Native community.

*Category II:* Language Project Planning will have up to 24-month project period with the primary activity of planning a Native Language project for the Native community to be impacted by the project.

*Category III:* Language Project Implementation will have up to a 36-month project period to support such activities consistent with legislative and regulatory requirements.

An award in Categories II and III is not contingent upon having received previous funding from ANA for language preservation and maintenance; however, current language-assessment data and language-delivery methods will need to be provided. (Legal authority: Section 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b–c.

### III. Application—Project Development

During the FY 2006 competitions, ANA participated in the electronic application submission process. Based upon this experience, ANA has analyzed the submission procedure. To eliminate future concerns with uploading attachments, ANA has determined that all applications (hard-copy and electronic) should be submitted with no more than three (3) objectives per 12-month budget period for any given competition. This limitation will still allow an applicant to convey adequately the proposed project goals, activities and results expected. (Legal authority: Section 803 (a) and (d) and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b–3.)

### IV. Special Initiative

Under legislative authority, ANA can provide funding for Special Initiatives that focus on specifically identified needs within Native communities. Applicants must submit projects that are responsive to the specific competitive program area. Last year ANA offered a specific program announcement to fund projects that support healthy families titled, Improving the Well-Being of Children—Native American Healthy Marriage Initiative (NAHMI). This Special Initiative will be supported

again in FY 2007. Applicants requesting funding for these types of initiatives will need to submit projects under this designated Special Initiative competitive area only. (Legal authority: Section 803 (a) and (d) and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b–3.

### V. ANA Funding Restriction Policy

In order to ensure that ANA manages proper fiscal responsibility in the dispensing of Federal funds, a list of actions and activities, which will not be considered as eligible activities for funding, is maintained. ANA has observed that projects including such contingency activities as permits, licenses, outside or internal certification, Federal or State agency approvals, or project activities that are contingent on the outcome of a court decision, do not complete projects within the approved project period. As a result of these situation, grantees often do not complete project objectives or expend approved funding. Based upon agency reviews and on-site visits, ANA will implement the following new funding restriction policy:

ANA will not consider projects that contain contingency activities that impede or indefinitely delay the ongoing progress of the proposed project. Applicants must demonstrate the project planning considered potential contingency activities and provide adequate assurance that such activities will not impede the progress of the project. (Legal authority: Section 803 (a) and (d) and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b–3.

Dated: November 9, 2006.

**Sheila K. Cooper,**

*Director of Program Operations,  
Administration for Native Americans.*

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**BILLING CODE 4184–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006N–0464]

### Electronic Submission of Regulatory Information, and Creating an Electronic Platform for Enhanced Information Management; Public Hearing

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

**ACTION:** Notice of public hearing; request for comment.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a

public hearing to solicit general views and information from interested persons on issues concerning the electronic submission of product information to the agency. In particular, FDA is seeking these views and information from interested persons on the feasibility and effect of an all-electronic submission environment, as well as issues related to an electronic regulatory information exchange platform. To help solicit such information and views, FDA is seeking responses to specific questions (see section IV of this document).

**DATES:** *Public Hearing:* The public hearing will be held on December 18, 2006, from 9 a.m. to 5 p.m. However, depending on the level of public participation, the meeting may be extended or may end early.

*Registration and Participation:* Registration on the day of the public hearing will be provided on a space available basis beginning at 7:30 a.m. Because seating is limited, we recommend arriving early. See section I of the **SUPPLEMENTARY INFORMATION** section of this document for information on how to participate in the meeting. If you need special accommodations due to a disability, please contact Paula S. McKeever (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

*Comments:* Submit written or electronic notices of participation and comments by December 8, 2006. The administrative record of the hearing will remain open to receive additional comments until February 16, 2007.

**ADDRESSES:** The public hearing will be held at the Advisors and Consultants Staff Conference Room, Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857. Additional information on parking and public transportation may be accessed at <http://www.fda.gov/oc/initiatives/criticalpath/>.

Submit written notices of participation and comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. Submit electronic notices of participation and comments to <http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm>. Identify all submissions to the docket with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Paula S. McKeever, Office of Critical Path Programs (HF–18), Food and Drug Administration, 5600 Fishers Lane, rm. 14B–45, Rockville, MD 20857, 301–827–1520, [paula.mckeever@fda.hhs.gov](mailto:paula.mckeever@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**