

for Medicare Beneficiaries Receiving Implantable Cardioverter-Defibrillators for Primary Prevention of Sudden Cardiac Death; *Use*: CMS provides coverage for implantable cardioverter-defibrillators (ICDs) for secondary prevention of sudden cardiac death based on extensive evidence showing that use of ICDs among patients with a certain set of physiologic conditions are effective. Accordingly, CMS considers coverage for ICDs reasonable and necessary under Section 1862(a)(1)(A) of the Social Security Act. However, evidence for use of ICDs for primary prevention of sudden cardiac death is less compelling for certain patients.

To encourage responsible and appropriate use of ICDs, CMS issued a "Decision Memo for Implantable Defibrillators" on January 27, 2005, indicating that ICDs will be covered for primary prevention of sudden cardiac death if the beneficiary is enrolled in either an FDA-approved category B IDE clinical trial (42 CFR 405.201), a trial under the CMS Clinical Trial Policy (NCD Manual § 310.1) or a qualifying prospective data collection system (either a practical clinical trial or prospective systematic data collection, which is sometimes referred to as a registry). *Form Number*: CMS-10151 (OMB#: 0938-0967); *Frequency*: Occasionally; *Affected Public*: Private Sector; Business or other for-profits, Not-for-profit institutions; *Number of Respondents*: 1,702; *Total Annual Responses*: 82; *Total Annual Hours*: 139,356. (For policy questions regarding this collection contact JoAnna Baldwin at 410-786-7205. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *June 21, 2013*:

1. *Electronically*. You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail*. You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: April 17, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, 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 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 Directive.

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), SEDS—Native Asset Building Initiative (hereinafter referred to as NABI), 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 Initiative (hereinafter referred to as Language—EMI), and Environmental Regulatory Enhancement (hereinafter referred to as ERE). This notice also provides information about how ANA will administer these programs.

DATES: The policies noted in the original Notice of Public Comment (NOPC) are effective immediately upon publication.

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

SUPPLEMENTARY INFORMATION: Section 814 of the Native Americans Programs Act of 1974, 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 six FY 2013 FOAs: SEDS, NABI, SEEDS, Language Preservation, Language—EMI, and ERE. ANA published a NOPC in the **Federal Register** (78 FR 13062) on February 26, 2013, with proposed policy and program clarifications, modifications, and activities for the fiscal year (FY) 2013 FOAs. The public comment period was open for 30 days.

For information on the changes ANA is making, please refer to the NOPC at the following link: <https://www.federalregister.gov/articles/2013/02/26/2013-04383/request-for-public-comment-on-the-proposed-adoption-of-administration-for-native-americans-program>.

ANA received one comment from a Native non-profit organization. ANA considered the comment received and provides responses, clarifications, and modifications in this final directive. The following paragraph summarizes the comment and our response:

A. Comment and Response

Comment: ANA received one comment in reference to ANA's new administrative policy focused on conflict of interest standards that states that staff employed through an ANA-funded project cannot also serve as a member of the governing body for the applicant organization. Therefore, staff employed through an ANA-funded project cannot also serve as a member of the governing body for the applicant organization. During the award negotiation phase, ANA will ask the prospective recipient to modify project personnel if a proposed staff member is also a member of the applicant organization's governing body. In addition, there should be a separation of duties from staff and the governing bodies within an organization to ensure the integrity of internal controls and to minimize disruptions in the continuity of operations.

The commenter stated that this policy would have a negative impact on the commenter's organization's ability to implement a grant as it currently allows two teachers to serve as members of the school board, as required by their bylaws. If this policy were implemented, the applicant would not have the ability to modify project personnel to align with this policy due to the extreme shortage of certified

teachers with requisite language capabilities available to staff an ANA grant. In addition, the commenter stated that the by-laws are written so that teacher members do not have decision-making authority regarding personnel actions, nor to make financial decisions that are of personal benefit, thus insuring internal controls.

Response: ANA offers no change in response to this comment. While ANA is sympathetic to the commenter's concern, it is important that this policy remains as written. Under the standard terms and conditions for discretionary HHS awards (Grants Policy Statement, page II-7 at <https://www.acf.hhs.gov/grants/terms-and-conditions>), grant recipients are required to establish safeguards to prevent employees, consultants, members of governing bodies, and others who may be involved in grant-supported activities, from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others, such as those with whom they have family, business, or other ties.

This has been a long-standing policy of the Administration for Children and Families. All prospective applicants are required to submit the SF-424B Assurances (Non-Construction) agreeing to these terms and conditions at the time of submission. ANA understands this can cause challenges for applicants but it is important that applicants are reminded of the requirement to establish safeguards that prohibit employees from using their position for a purpose that presents a conflict of interest or the appearance of a conflict of interest.

B. 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 funding opportunity announcements: <http://www.acf.hhs.gov/programs/ana>.

Pre-publication information on ANA's FOAs is available at the HHS Forecast Web site at <http://www.acf.hhs.gov/hhsgrantsforecast/>.

Once published, the 2013 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 on www.Grants.gov.

Lillian A. Sparks,

Commissioner, Administration for Native Americans.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Establishment of the Discretionary Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Proposed Establishment of Discretionary Advisory Committee on Heritable Disorders in Newborns and Children.

SUMMARY: The U.S. Department of Health and Human Services announces establishment of the Discretionary Advisory Committee on Heritable Disorders in Newborns and Children.

FOR FURTHER INFORMATION CONTACT: Debi Sarkar, Public Health Analyst, Health Resources and Services Administration, Maternal and Child Health Bureau; telephone: 301-443-1080; email: dsarkar@hrsa.gov.

SUPPLEMENTARY INFORMATION: Under the Public Health Service Act (PHS), 42 U.S.C. 217a, the Secretary of Health and Human Services directed that the Discretionary Advisory Committee on Heritable Disorders in Newborns and Children shall be established within the Department of Health and Human Services (HHS). To comply with the authorizing directive and guidelines under the Federal Advisory Committee Act (FACA), a charter will be filed with the Committee Management Secretariat in the General Services Administration (GSA), the appropriate committees in the Senate and U.S. House of Representatives, and the Library of Congress to establish the Committee as a discretionary federal advisory committee.

Objectives and Scope of Activities. The purpose of the Discretionary Advisory Committee on Heritable Disorders in Newborns and Children (DACHDNC) is to advise the Secretary of Health and Human Services about aspects of newborn and childhood screening and technical information for the development of policies and priorities that will enhance the ability of the state and local health agencies to provide for newborn and child screening, counseling and health care services for newborns and children having, or at risk for, heritable disorders. The DACHDNC will review and report regularly on newborn and childhood screening practices, recommend improvements for newborn and childhood screening programs, as well as fulfill the list of requirements

stated in the original authorizing legislation.

Membership and Designation. The Committee shall consist of up to fifteen (15) voting members, including the Chair. The members of the Committee shall be appointed by the Secretary or his/her designee. Membership will be composed of the Chair, Special Government Employees (SGEs), and federal ex-officio members. Federal ex-officio members shall include the Administrator of the Health Resources and Services Administration; the Directors of the Centers for Disease Control and Prevention; the National Institutes of Health; the Agency for Healthcare Research and Quality; and the Commissioner of the Food and Drug Administration—or their designees. The Chair and other members shall be (a) medical, technical, public health or scientific professionals with special expertise in the field of heritable disorders or in providing screening, counseling, testing, or specialty services for newborns and children at risk for heritable disorders; (b) experts in ethics and heritable disorders who have worked and published material in the area of public health and genetic conditions; and (c) members from the public sector who have expertise, either professional or personal, about or concerning heritable disorders in order to achieve a fairly balanced membership.

Administrative Management and Support. HHS will provide funding and administrative support for the Committee to the extent permitted by law within existing appropriations. Management and oversight for support services provided to the Committee will be the responsibility of the Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB).

A copy of the Committee charter will be made available through access to the FACA database, maintained by the GSA Committee Management Secretariat, or from the designated contacts. The Web site for the FACA database is <http://fido.gov/facadatabase/>.

Authority: The Discretionary Advisory Committee on Heritable Disorders in Newborns and Children is authorized in accordance with the Public Health Service Act (PHS), 42 U.S.C. 222 [217a]; Advisory councils or committees. The Committee is governed by provisions of Public Law 92-463, as amended, (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees.