Strategic Plan goals and objectives related to improving minority health and eliminating health disparities.

- Develops an Agency-wide data collection infrastructure for minority health activities and initiatives.
- Implements activities to increase the availability of data to monitor the impact of CMS programs in improving minority health and eliminating health disparities.
- Participates in the formulation of CMS goals, policies, legislative proposals, priorities and strategies as they affect health professional organizations and others involved in or concerned with the delivery of culturally and linguistically-appropriate, quality health services to minorities and disadvantaged populations.
- Consults with HHS Federal agencies and other public and private sector agencies and organizations to collaborate in addressing health equity.
- Establishes short-term and long-range objectives and participates in the focus of activities and objectives in assuring equity of access to resources and health careers for minorities and disadvantaged populations.

Authority: 44 U.S.C. 3101.

Dated: July 12, 2011.

Donald Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2011–19000 Filed 7–26–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Child Care Quarterly Case Record Report—ACF–801.

OMB No.: 0970–0167.

Description: Section 658K of the Child Care and Development Block Grant Act of 1990 (Pub. L. 101–508, 42 U.S.C. 9858) requires that States and Territories submit monthly case-level data on the children and families receiving direct services under the Child Care and Development Fund. The implementing regulations for the statutorily required reporting are at 45 CFR 98.70. Case-level reports, submitted quarterly or monthly (at grantee option, include monthly sample or full population case-level data. The data elements to be included in these reports are represented in the ACF–801. ACF uses disaggregate data to determine program and participant characteristics as well as costs and levels of child care services provided. This provides ACF with the information necessary to make reports to Congress, address national child care needs, offer technical assistance to grantees, meet performance measures, and conduct research. Consistent with the statute and regulations, ACF requests extension of the ACF–801. With this extension, ACF is proposing to add several new data elements as well as some minor changes and clarifications to the existing reporting requirements and instructions. These proposed revisions to the ACF–801 would allow OCC to capture child-level data on provider quality for each child receiving a child care subsidy.

Respondents: States, the District of Columbia, and Territories including Puerto Rico, Guam, the Virgin Islands, American Samoa, and the Northern Marianna Islands.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–801	56	4	25	5,600

Estimated Total Annual Burden Hours: 5,600.

In compliance with the requirements of Section 506(c) (2) (A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Planning Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. *e-mail address: infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: July 20 2011.

Steven M. Hanmer,

Reports Clearance Officer.

[FR Doc. 2011–18787 Filed 7–26–11; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children And Families

Announcement of Five Single Source Grant Awards

AGENCY: Office of Child Care, ACF, HHS.

ACTION: Award of five single source grants under the Tribal Home Visiting Program to the Eastern Band of Cherokee Indians, Cherokee, NC; Native American Health Center, Inc., Oakland, CA; Riverside-San Bernardino County Indian Health, Inc., Banning, CA; Taos Pueblo, Taos, NM; and United Indians of All Tribes Foundation, Seattle, WA.

CFDA Number: 93.508.

Statutory Authority: Section 511(h)(2)(A) of Title V of the Social Security Act, as added by Section 2951 of the Affordable Care Act of 2010 (Pub. L. 111–148, ACA), authorizes the Secretary of HHS to award grants to

Indian Tribes (or a consortium of Indian Tribes), Tribal Organizations, or Urban Indian Organizations to conduct an early childhood home visiting program. Specifically, the legislation provides for a 3 percent set-aside of the total Maternal, Infant, and Early Childhood Home Visiting Program appropriation (authorized in Section 511(j)) for discretionary competitive grants to Tribal entities.

Summary: The Administration for Children and Families (ACF), Office of Child Care (OCC) announces the award of five Fiscal Year 2011 Tribal Maternal, Infant, and Early Childhood Home Visiting single source grants to the following:

Eastern Band of Cherokee Indians: $205,000. Cherokee, NC.

Eastern Band of Cherokee Indians will provide home visiting services to children under the age of 5 and their families on the Qualla Boundary.

Native American Health Center, Inc.: $227,000. Oakland, CA.

Native American Health Center, Inc. is an urban Tribal organization that will provide home visiting services to the American Indian and Alaska Native (AIAN) population in a five-county region in Northern California, which includes Oakland and San Francisco.

Riverside-San Bernardino County Indian Health, Inc.: $348,000. Banning, CA.

Riverside-San Bernardino County Indian Health, Inc. is a tribally controlled health care organization that will provide home visiting services to approximately 2,000 families on 10 tribal reservations in Riverside and San Bernardino Counties.

Taos Pueblo: $340,000. Taos, NM.

At the Taos Pueblo, there are currently no services for infants under the age of 18 months and their parents. The award will allow the Taos Pueblo to provide home visiting services for up to 300 families in order to complete the continuum of services for children, aged birth to age 5, and their families.

United Indians of All Tribes Foundation: $182,000. Seattle, WA.

This is an urban Indian organization that will provide home visiting services to the AIAN population in King County, WA, which represents more than 100 different Tribal entities.

The Tribal Maternal, Infant, and Early Childhood Home Visiting single source awards will support the grantees in conducting community needs assessments; planning for and implementation of high-quality, culturally relevant, evidence-based home visiting programs in at-risk Tribal communities for pregnant women and families with young children aged birth to kindergarten entry; and participate in research and evaluation activities to build the knowledge base on home visiting among American Indian and Alaska Native populations.

It is expected that the five grantees will continue with their projects for the remainder of a projected five-year project period by implementing home visiting activities for which grantees may receive noncompetitive continuation awards. Home visiting programs are intended to promote outcomes such as improvements in maternal and prenatal health, infant health, and child health and development; reduced child maltreatment; improved parenting practices related to child development outcomes; improved school readiness; improved family socio-economic status; improved coordination of referrals to community resources and supports; and reduced incidence of injuries, crime, and domestic violence.

Dates: July 1, 2011–June 30, 2016.

FOR FURTHER INFORMATION CONTACT: Carol Gage, Office of Child Care, 370 L'Enfant Promenade SW., Washington, DC 20047, *Telephone:* 202–690–6243, *e-mail: carol.gage@acf.hhs.gov*.

Dated: July 21, 2011.

Shannon L. Rudisill,

Director, Office of Child Care.

[FR Doc. 2011–18960 Filed 7–26–11; 8:45 am]

BILLING CODE 4184–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0453]

Draft Guidance for Industry and Food and Drug Administration Staff; 510(k) Device Modifications: Deciding When To Submit a 510(k) for a Change to an Existing Device; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''510(k) Device Modifications: Deciding When To Submit a 510(k) for a Change to an Existing Device.'' The recommendations in this guidance document are intended to describe when a new 510(k) should be submitted for a change or modification to a legally marketed device. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 25, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''510(k) Device Modifications: Deciding When To Submit a 510(k) for a Change to an Existing Device'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Michael J. Ryan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1615, Silver Spring, MD 20993–0002, 301–796–6283.

SUPPLEMENTARY INFORMATION:

I. Background

Since the amendment of the Federal Food, Drug, and Cosmetic Act by the Medical Device Amendments of 1976, FDA has attempted to define with greater clarity when a modification to an existing medical device would trigger the requirement that a new premarket notification (510(k)) be submitted to the Agency and cleared prior to marketing. FDA regulations state in 21 CFR 807.81(a)(3) when a 510(k) must be submitted, but the language used in this regulation sometimes leads to varying interpretations of when a 510(k) is required for a device modification. In order to address this issue, FDA issued in 1997 the guidance document entitled ''Deciding When To Submit a 510(k) for a Change to an Existing 510(k)''; however, regulatory changes such as the implementation of the Quality System Regulation have occurred since that time, and medical device technology has evolved.