

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No.: 0970-0389]

Proposed Information Collection Activity; Comment Request

Proposed Project: Tribal Maternal, Infant, and Early Childhood Home Visiting Program Demographic and Service Utilization Data Form.

Title: Tribal Maternal, Infant, and Early Childhood Home Visiting Program Form 1: Demographic and Service Utilization Data.

Description: The Bipartisan Budget Act of 2018 (Pub. L. 115-123). Section 511(h)(2)(A) of Title V of the Social Security Act, created the Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV) and authorized the Secretary of HHS (in Section 511(h)(2)(A)) 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. The legislation set aside 3 percent of the total MIECHV program appropriation for grants to tribal entities. Tribal MIECHV grants, to the greatest extent practicable, are to be consistent with the requirements of the MIECHV grants to states and jurisdictions and include conducting a needs assessment and establishing quantifiable, measurable benchmarks.

The Administration for Children and Families, Office of Child Care, in collaboration with the Health Resources and Services Administration, Maternal and Child Health Bureau, awards grants for the Tribal MIECHV Program. The Tribal MIECHV grant awards support 5-year cooperative agreements to conduct community needs assessments, plan for and implement high-quality, culturally-relevant, evidence-based home visiting programs in at-risk Tribal communities, and participate in research and evaluation activities to build the

knowledge base on home visiting among Native populations.

In Year 1 of the cooperative agreement, grantees must (1) conduct a comprehensive community needs and readiness assessment and (2) develop a plan to respond to identified needs. Following each year that Tribal MIECHV grantees implement home visiting services, they must submit Form 1: Demographic and Service Utilization Data. The Form 1 data are used to help ACF better understand the population receiving services from Tribal MIECHV grantees and the degree to which they are using services, as well as better understanding of the Tribal MIECHV workforce. Overall, this information collection will provide valuable information to HHS that will guide understanding of the Tribal MIECHV Program and the provision of technical assistance to Tribal MIECHV Program grantees.

Respondents: Tribal Maternal, Infant, and Early Childhood Home Visiting Program Grantees.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|-----------------------|------------------------------------|-----------------------------------|--------------------|
| Tribal MIECHV Form 1 | 25 | 1 | 500 | 12,500 |
| Estimated Total Annual Burden Hours | | | | 12,500 |

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chap 35), 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 may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attn: ACF Reports Clearance Officer. Email 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.

Mary B. Jones,
ACF/OPRE Certifying Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0829]

Pediatric Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pediatric Advisory Committee (PAC). The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on April 8, 2019, from 9 a.m. to 4:40 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2019-N-0829. The docket will close on April 4, 2019. Submit either electronic or written