

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Tribal Maternal, Infant, and Early Childhood Home Visiting Program: Guidance for Submitting Reports (Office of Management and Budget#: 0970-0409)

AGENCY: Office of Early Childhood Development, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF), Office of Early Childhood Development (ECD) is requesting revisions to the Tribal Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program: Guidance for Submitting Reports (Office of Management and Budget (OMB)#: 0970-0409; expiration March 31, 2026) and a 3-year extension of approval.

DATES: *Comments due* August 5, 2024. In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing infocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Section 511(e)(8)(A) of title V of the Social Security Act requires that grantees under the MIECHV program for states and jurisdictions submit an annual report to the Secretary of Health and Human Services regarding the program and activities carried out under the program, including such data and information as the Secretary shall require. Section 511(h)(2)(A) further states that the requirements for the MIECHV grants to Tribes, Tribal organizations, and urban Indian organizations are to be consistent, to the greatest extent practicable, with the requirements for grantees under the MIECHV program for states and jurisdictions.

ECD, in collaboration with the Health Resources and Services Administration, Maternal and Child Health Bureau awarded grants for the Tribal MIECHV Program (Tribal Home Visiting) to support 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; establish, measure, and report on progress toward meeting performance measures in six legislatively mandated benchmark areas; and participation in research and evaluation activities to build the knowledge base on home visiting among Native populations.

After the first grant year, Tribal Home Visiting grantees must comply with the requirement to submit an Annual Report

to the Secretary that should feature activities carried out under the program during the past reporting period. To assist grantees with meeting these requirements, ACF created guidance for grantees to use when writing their annual reports. The guidance specifies that grantees must address the following:

- Update on the implementation of the Home Visiting Program in targeted community(ies)
- Update on the collection, reporting, and use of data
- Progress toward fidelity monitoring, program management, and improvement
- Update on contribution to MIECHV Learning Agenda through participation in research and evaluation projects
- Dissemination
- Technical Assistance Supports

Previously, the guidance included information about both the annual and the final reports from grantees. This extension request includes updates to the guidance to make it specific to just the annual reports. Guidance specific to the final report may be submitted for review and approval by OMB in the future. A comment period will accompany that request.

Respondents: Tribal Home Visiting Managers (information collection does not include direct interaction with individuals or families that receive the services).

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Guidance for Submitting Annual reports	51	1	25	1,275

Comments: 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.

Authority: Title V of the Social Security Act, sections 511(e)(8)(A) and 511(h)(2)(A).

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

Food and Drug Administration

[Docket No. FDA-2024-D-2221]

Standardized Format for Electronic Submission for Marketing Applications Content for the Planning of Bioresearch Monitoring Inspections for Center for Biologics Evaluation and Research Submissions; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is