

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

[OMB No. 0970-0160]

**Submission for Office of Management and Budget Review; Procedures for Requests from Tribal Lead Agencies To Use Child Care and Development Fund Funds for Construction or Major Renovation of Child Care Facilities**

**AGENCY:** Office of Child Care, 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) is proposing to collect data for the Procedures for Requests from Tribal Lead Agencies to use Child Care and Development Fund (CCDF) Funds for Construction or Major Renovation of Child Care Facilities. This information collection was previously approved by the Office of Management and Budget (OMB). The Office of Child Care is proposing to reinstate the information collection with changes.

**DATES:** *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. You can also obtain copies of the proposed collection of information by emailing [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). Identify all emailed requests by the title of the information collection.

**SUPPLEMENTARY INFORMATION:**

*Description:* 42 U.S.C. 9858m(c)(6) of the Child Care and Development Block Grant Act allows Tribal Lead Agencies to use CCDF grant awards for construction and renovation of child care facilities. A tribal grantee must first request and receive approval from the

ACF before using funds for construction or major renovation. To use CCDF funds awarded in a given fiscal year (FY) on construction or major renovation, a Tribal Lead Agency must submit an application prior to July 1 of that FY. The application deadline applies to direct funded tribes and tribes with CCDF funds integrated into a 477 plan.

This information collection contains the statutorily mandated uniform procedures for the solicitation and consideration of requests, protection of federal interest, and instructions for preparation of environmental assessments in conjunction with the National Environmental Policy Act.

Changes requested to the form clarify the process to align with ACF Real Property Guidance, update language regarding submission of the Standard Form (SF)-429 cover page, include technical changes regarding the official title of Public Law 102-477 to reflect as the Indian Employment, Training and Related Services Consolidation Act of 2017, and include the correct contact for submission of SF-429 information and updated OMB circular references.

*Respondents:* Tribal Child Care Lead Agencies acting on behalf of tribal governments.

**ANNUAL BURDEN ESTIMATES**

Instrument	Type of burden	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Procedures for Requests from Tribal Lead Agencies to use CCDF Funds for Construction or Major Renovation of Child Care Facilities.	Reporting .....	75	2	5	750	250
	Record-keeping .....	.....	.....	15	2,250	750

*Estimated Total Annual Burden Hours:* 1000.

*Authority:* 42 U.S.C. 9858(c)(6).

Mary B. Jones,

ACF/OPRE Certifying Officer.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for Office of Management and Budget (OMB) Review; Tribal Maternal, Infant, and Early Childhood Home Visiting Program: Implementation Plan Guidance for Development and Implementation and Implementation and Expansion Grantees**

**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 Office of Management and Budget (OMB) approval of Tribal Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Implementation Plan Guidance for Tribal Home Visiting Development and Implementation Grants (DIG) and Tribal Home Visiting Implementation and Expansion Grants (IEG).

**DATES:** *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect

if OMB receives it within 30 days of publication.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. You can also obtain copies of the proposed collection of information by emailing [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). Identify all emailed 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 Tribal MIECHV program, in the first year of their grants, submit an implementation plan on how they will meet the requirements of the program. 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.

The ACF Office of Early Childhood Development, in collaboration with the Health Resources and Services Administration, Maternal and Child Health Bureau awarded grants for the Tribal MIECHV Program 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 conduct rigorous evaluation activities to build the knowledge base on home visiting among Native populations.

During the first grant year, Tribal Home Visiting DIG and IEG grantees

must comply with the requirement to submit an implementation plan that should feature planned activities to be carried out under the program in years 2–5 of their cooperative agreements. To assist grantees with meeting these requirements, ACF created guidance for grantees to use when writing their plans. The DIG and IEG guidance specify that grantees must provide a plan to address the following areas:

- Community Needs and Readiness Assessment
- Program Design
- Program Blueprint
- Plan for Data Collection, Management and Performance Measurement
- Fidelity Monitoring and Quality Assurance

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

**TOTAL BURDEN ESTIMATES**

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Implementation Plan Guidance for Development and Implementation Grantees .....	13	1	1000	13,000
Implementation Plan Guidance for Implementation and Expansion Grantees .....	35	1	1000	35,000
Estimated Total Annual Burden Hours: .....	.....	.....	.....	48,000

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

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2023–07845 Filed 4–12–23; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2023–D–1188]

**Over-the-Counter Monograph Order Requests: Format and Content; 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 announcing the availability of a draft guidance for industry entitled “Over-the-Counter Monograph Order Requests (OMORs): Format and Content.” This

draft guidance provides recommendations on the format and content of the information that a requestor should provide in an over-the-counter (OTC) monograph order request (OMOR) and identifies relevant guidance documents to assist requestors in preparing their OMORs.

**DATES:** Submit either electronic or written comments on the draft guidance by June 12, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your

comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.