

appears to have no conflict of interest that would preclude membership.

We are requesting that all curricula vitae include the following:

- List of areas of expertise
- Title and current position
- Professional affiliation
- Home and business address
- Telephone numbers (Please specify if the number is for: home, office, or cell phone)
- Email address (Please specify if the email address is for work/personal)

In the nomination letter, we are requesting that nominees specify whether they are applying for a patient advocate position, an at-large standing position, or as an industry representative. Potential candidates will be asked to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts in order to permit evaluation of possible sources of financial conflict of interest. Department policy prohibits multiple committee memberships. A federal advisory committee member may not serve on more than one committee within an agency at the same time.

Members may be invited to serve for overlapping 2-year terms. A member may continue to serve after the expiration of the member's term until a successor is named. Any interested person may nominate one or more qualified persons. Self-nominations are also accepted. Individuals interested in the representative positions are encouraged to include a letter of support from the organization or interest group they would represent.

### III. Collection of Information

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Chief Medical Officer and Director of the Center for Clinical Standards and Quality for the Centers for Medicare & Medicaid Services (CMS), Dora Hughes, having reviewed and approved this document, authorizes Chyana Woodyard, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

**Chyana Woodyard,**

*Federal Register Liaison, Centers for Medicare & Medicaid Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Proposed Information Collection Activity; Tribal Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Community Needs and Readiness Assessment Guidance and Implementation Plan Guidance (Office of Management and Budget #: 0970-0611)

**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 Program Community Needs and Readiness Assessment Guidance and Implementation Plan Guidance (Office of Management and Budget (OMB) #: 0970-0611; expiration June 30, 2026) and a 3-year extension of approval.

**DATES:** *Comments due March 17, 2025.* 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](mailto: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 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.

ACF ECD, in collaboration with the Health Resources and Services Administration's 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 conduct rigorous evaluation activities to build the knowledge base on home visiting among Native populations.

During the first grant year, Tribal Home Visiting grantees must comply with the requirement to conduct a Community Needs and Readiness Assessment (CNRA) and 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 a CNRA and implementation guidance for grantees to use when writing their plans. The CNRA Guidance and Implementation Plan Guidance (IPG) specifies that grantees must provide a plan to address the following areas:

- CNRA
- Program Design
- Program Blueprint
- Plan for Data Collection, Management, and Performance Measurement
- Fidelity Monitoring and Quality Assurance

The previous guidance included information about the CNRA and the implementation plan for grant recipients. This extension request updates the guidance by separating the CNRA Guidance from the IPG. This separation allows the CNRA Guidance to function as an independent document, enhancing clarity and usability instead of being incorporated within the IPG.

Additionally, significant modifications have been made to the guidance compared to earlier versions, with a primary focus on reducing the burden on grant recipients. These changes include eliminating redundant sections that overlap with other reporting requirements, reducing the number of guiding questions, and allowing for shorter responses.

*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	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Implementation Plan Guidance for Development and Implementation Grantees .....	27	1	450	12,150	4,050
DIG Community Needs and Readiness Assessment .....	27	1	450	12,150	4,050
Totals: .....	.....	.....	.....	24,300	8,100

*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) & 511(h)(2)(A)

Mary C. Jones,  
ACF/OPRE Certifying Officer.

[FR Doc. 2025-00556 Filed 1-13-25; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2024-N-5890]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Drug User Fee Program**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and

to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with our generic drug user fee program.

**DATES:** Either electronic or written comments on the collection of information must be submitted by March 17, 2025.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 17, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

*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.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2024-N-5890 for “Generic Drug User Fee Program.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed