

facts supporting the unfavorable factors outweigh those supporting the favorable factor, and therefore warrant imposition of a five-year period of debarment.”

### III. Findings and Order

Therefore, the OSI Director, under section 306(b)(1) of the FD&C Act and authority delegated to him by the Commissioner of Food and Drugs, finds that Jiao has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance and is subject to debarment, as set forth in section 306(b)(3)(C) of the FD&C Act. FDA has considered the applicable factors listed in section 306(c)(3) of the FD&C Act and determined that a debarment period of 5 years is appropriate.

As a result of the foregoing finding, Jiao is debarred for a period of 5 years from importing or offering for import any drug into the United States, effective January 8, 2025. Pursuant to section 301(cc) of the FD&C Act, the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Jiao, is a prohibited act.

Dated: December 31, 2024.

**George M. Warren,**

*Director, Office of Scientific Integrity.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Maternal, Infant, and Early Childhood Home Visiting Program Model Eligibility Review Survey

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice with request for comment.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate,

below, or any other aspect of the ICR. Specifically, HRSA is inviting public comment on its proposed survey to identify evidence-based service delivery models that funding recipients may use to provide services under HRSA’s MIECHV Program.

**DATES:** Comments on this ICR should be received no later than March 10, 2025.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14NWH04, 5600 Fishers Lane, Rockville, Maryland, 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the ICR title for reference.

*Information Collection Request Title:* Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Model Eligibility Review Survey, OMB No. 0915–xxxx—New

*Abstract:* HRSA, through its Maternal and Child Health Bureau, oversees the MIECHV Program in partnership with the Administration for Children and Families (ACF) within HHS. The MIECHV Program supports voluntary, evidence-based home visiting services during pregnancy and to families with young children up to kindergarten entry living in at-risk communities. The MIECHV Program was last reauthorized in December 2022.<sup>1</sup> One key program requirement is that programs deliver services using models that meet HHS criteria for evidence of effectiveness.<sup>2</sup> HRSA and ACF define such service delivery models as “evidence-based.” ACF administers the Home Visiting Evidence of Effectiveness (HomVEE) review process to identify early childhood home visiting models that demonstrate evidence of effectiveness.<sup>3</sup> However, not all evidence-based service delivery models approved through the HomVEE process meet MIECHV statutory requirements as enacted in the last reauthorization of the program in

2022 such that they may be used to carry out the MIECHV Program in fidelity to applicable program requirements.

HRSA previously issued a Request for Information notice and request for comment regarding its proposal to standardize criteria for assessing model eligibility to be implemented using MIECHV Program funds in 2021.<sup>4</sup> This ICR reflects new MIECHV statutory provisions that were added in December 2022 and thus replaces that 2021 notice. HRSA is issuing this ICR to propose a survey to identify service delivery models that meet both HHS criteria for evidence of effectiveness, as determined by HomVEE review, and applicable MIECHV statutory requirements, and therefore may be used by eligible entities to provide home visiting services through the MIECHV Program. This will be accomplished by validating whether evidence-based models, as determined by HomVEE, align with the MIECHV Program’s statutory requirements, as further discussed in this notice. This process will ensure that models used by funding recipients (and their local implementing agencies) to deliver MIECHV Program services effectively support programs in meeting core components of the MIECHV Program, including those added during the program’s 2022 reauthorization.

Following approval of this ICR request, HRSA will assess all models that meet HHS criteria for evidence of effectiveness, as determined by the HomVEE review, to determine their MIECHV eligibility by requesting information from home visiting model developers through a standardized survey. As of November 20, 2024, HomVEE lists 24 models that meet HHS criteria for evidence of effectiveness.<sup>5</sup> Upon receiving the survey from HRSA, model developers will have 30 days to provide requested information on model characteristics, resources, and processes. A panel of HRSA reviewers will assess the survey responses against the MIECHV statutory requirements. Any of the 24 evidence-based models that also meet these criteria will be considered eligible for MIECHV Program implementation and remain eligible for implementation after the end of the current performance period.

<sup>1</sup> Section 6101 of the Consolidated Appropriations Act, 2023, Public Law 117–328, recently amended Section 511 of the Social Security Act, as added by the Patient Protection and Affordable Care Act, Public Law 111–148, section 2951, and extended appropriated funding through FY 2027.

<sup>2</sup> 42 U.S.C. 711(d)(3)(C)(i).

<sup>3</sup> The current HHS criteria for evidence-based models can be found at: <https://homvee.acf.hhs.gov/about-us/hhs-criteria>.

<sup>4</sup> HRSA, HHS, “Statutory Requirements and Process Standardization: Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Model Eligibility Review.” *Federal Register* 86, no. 184 (September 27, 2021): 53329. <https://www.federalregister.gov/d/2021-20853>.

<sup>5</sup> HomVEE lists home visiting models that meet HHS criteria for evidence of effectiveness at: <https://homvee.acf.hhs.gov/HRSA-Models-Eligible-MIECHV-Grantees>.

Models that do not meet these criteria will not be eligible to be used by eligible entities (and their local implementing agencies) to carry out the MIECHV Program and may continue to be used only through the currently applicable period of performance. HRSA will work with eligible entities regarding any changes in model approval that may affect their program implementation because certain models will no longer be available for use; however, eligible entities will be expected to propose projects using models approved for MIECHV Program implementation under future funding awards. Model developers may submit a written request for reconsideration of HRSA's decision within 15 days of receiving a negative determination and should provide any available supporting information for their request. HRSA will have 45 days after the receipt of the request to reassess the model.

After HRSA completes the initial review, all eligible models may be reassessed against the statutory requirements through the routine, periodic HomVEE review process for models that have already met HHS criteria for evidence of effectiveness. HRSA and ACF will continue to collaborate in future years to assess home visiting models against MIECHV statutory requirements.

HRSA seeks public comment on the proposed methodology HRSA proposes to use to identify service delivery models that meet MIECHV statutory requirements, including how the proposed changes will affect interested parties such as eligible entities, model developers, and eligible families receiving MIECHV services.

**MIECHV Program Statutory Requirements for Home Visiting Models:** The MIECHV Program's authorizing statute mandates that funding recipients

implementing the program use a service delivery model that meets specific statutory requirements. Models must "conform to a clear consistent home [visiting] model that has been in existence for at least 3 years and is research-based, grounded in relevant empirically-based knowledge, linked to program determined outcomes, [and is] associated with a national organization or institution of higher education that has comprehensive home visitation program standards that ensure high-quality service delivery and continuous program quality improvement."<sup>6</sup> Under the statute, the model must also have demonstrated significant sustained positive outcomes in statutory benchmark areas and participant outcomes when evaluated using well-designed and rigorous randomized controlled research designs, and the evaluation results have been published in a peer-reviewed journal; or quasi-experimental research designs.<sup>7</sup> The 2022 reauthorization also added a new requirement that the "standards for training requirements applicable to virtual service delivery under a home visiting model shall be equivalent to those that apply to in-person service delivery under the model."<sup>8</sup>

To ensure programs comply with MIECHV statutory requirements,<sup>9</sup> service delivery models also must support the delivery of home visiting services through the employment of well-trained and competent staff<sup>10</sup> that receive ongoing high-quality supervision,<sup>11</sup> support programs' strong organizational capacity to implement home visiting activities<sup>12</sup> and ability to establish appropriate linkages and referral networks to other community resources and supports for participating families,<sup>13</sup> monitor the fidelity of program implementation to ensure

services are delivered in fidelity to the specified model,<sup>14</sup> and ensure voluntary participation in the program.<sup>15</sup> The 2022 reauthorization also requires MIECHV programs<sup>16</sup> to implement service delivery home visiting models that provide or support targeted, intensive home visiting services for high-risk populations<sup>17</sup> and support the delivery of home visiting services through at least one in-person home visit for each participating family during each 12-month period of enrollment.<sup>18</sup>

**Need and Proposed Use of the Information:** Section 711 establishes statutory requirements for the MIECHV Program. Information gained from this information collection will inform determinations of which service delivery models are eligible to be implemented in the MIECHV Program.

**Likely Respondents:** Organizations that develop, support implementation of, and implement early childhood home visiting models that meet HHS criteria for evidence of effectiveness, as determined by HomVEE review.

**Burden Statement:** Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
MIECHV Program Model Eligibility Review Survey .....	24	1	24	3	72
Total .....	24	.....	24	.....	72

<sup>6</sup> 42 U.S.C. 711(d)(3)(A)(i)(I).

<sup>7</sup> 42 U.S.C. 711(d)(3)(A)(i)(I).

<sup>8</sup> 42 U.S.C. 711(d)(4)(B).

<sup>9</sup> HRSA proposes to identify service delivery models that may be used by MIECHV funding recipients because they comply with statutory requirements applicable to service delivery models and support MIECHV statutory program requirements. Such models, in addition to meeting

the service delivery model requirements in subsections 711(d)(3)(A)(i) and 711(d)(4)(B), must also support program requirements, including those in subsections 711(d)(3)(C) and 711(e).

<sup>10</sup> 42 U.S.C. 711(d)(3)(C)(ii).

<sup>11</sup> 42 U.S.C. 711(d)(3)(C)(iii).

<sup>12</sup> 42 U.S.C. 711(d)(3)(C)(iv).

<sup>13</sup> 42 U.S.C. 711(d)(3)(C)(v).

<sup>14</sup> 42 U.S.C. 711(d)(3)(C)(vi).

<sup>15</sup> 42 U.S.C. 711(e)(7)(A).

<sup>16</sup> HRSA proposes to identify service delivery models that may be used by MIECHV funding recipients because they comply with statutory requirements applicable to service delivery models and support MIECHV statutory program requirements.

<sup>17</sup> 42 U.S.C. 711(d)(3)(B).

<sup>18</sup> 42 U.S.C. 711(d)(3)(C)(vii), 711(e)(10)(C).

HRSA specifically requests comments on: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Maria G. Button,**

*Director, Executive Secretariat.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Center for Indigenous Innovation and Health Equity Tribal Advisory Committee; Solicitation of Nominations for Delegates

**AGENCY:** Office of Minority Health, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** The U.S. Department of Health and Human Services (HHS) Office of Minority Health (OMH) hereby gives notice that OMH is accepting nominations of candidates to serve as primary and alternate delegates for the Center for Indigenous Innovation and Health Equity Tribal Advisory Committee (CIIHE TAC).

**DATES:** Tribal leaders are encouraged to submit their nomination letters for CIIHE TAC delegates by January 17, 2024, at the address listed below. OMH will continue to receive nominations until all CIIHE TAC primary and alternate delegate positions are filled.

**ADDRESSES:** All nominations should be emailed to [minorityhealth@hhs.gov](mailto:minorityhealth@hhs.gov). Please use the subject line "CIIHE TAC Nomination."

**FOR FURTHER INFORMATION CONTACT:** For information and guidance about the nomination process for CIIHE TAC delegates, please contact Rochelle Rollins, Senior Policy Advisor, at [Rochelle.Rollins@hhs.gov](mailto:Rochelle.Rollins@hhs.gov). Sample CIIHE TAC nomination letters are available on the OMH website: <https://minorityhealth.hhs.gov/ciihe-tribal-advisory-committee-tac>.

**SUPPLEMENTARY INFORMATION:** Authorized under Section 1707 of the Public Health Service Act, 42 U.S.C. 300u-6, as amended, the mission of OMH is to improve the health of racial and ethnic minority and American Indian and Alaska Native (AI/AN)

populations through the development of health policies and programs that help eliminate health disparities. OMH awards and other activities are intended to support the identification of effective policies, programs, and practices that improve health outcomes and to promote the sustainability and dissemination of these approaches.

Through the Joint Explanatory Statement (JES) accompanying the 2021 Consolidated Appropriations Act, Congress directed OMH to create the CIIHE to advance Indigenous solutions that ultimately address health disparities in AI/AN and Native Hawaiian and Pacific Islander populations. Congress identified four CIIHE priority areas: research, education, service, and policy development. The JES accompanying the subsequent annual appropriations acts has included language for OMH to continue funding the CIIHE.

OMH established the CIIHE TAC to provide Tribal leaders a venue to exchange views, share information, and provide feedback to OMH on the development of activities addressing the four CIIHE priority areas. The CIIHE TAC shall support, but not supplant, government-to-government consultation activities that OMH undertakes.

**TAC Membership:** The CIIHE TAC will consist of 16 delegate positions: one from each of the 12 geographic areas served by the Indian Health Service (IHS) and four National At-Large Member positions.

Alaska Area  
Albuquerque Area  
Bemidji Area  
Billings Area  
California Area  
Great Plains Area  
Nashville Area  
Navajo Area  
Oklahoma Area  
Phoenix Area  
Portland Area  
Tucson Area  
National At-Large Members (4)

The CIIHE TAC charter establishes a two (2) year term length for each delegate. There are vacancies for all IHS areas, except the Navajo and Tucson Areas, due to the ending of the CIIHE TAC members' 2-year terms.

**Eligibility:** The CIIHE TAC delegates must be: (1) Elected Tribal officials from a federally recognized Tribe acting in their official capacity as elected officials of their Tribe, with authority to act on behalf of the Tribe; or (2) individuals designated by an elected Tribal official. Designees must have the authority to act on behalf of the Tribal official and the Tribe and be qualified to represent the

views of the AI/AN Tribes in the area from which they are nominated. No delegate of the CIIHE TAC may be an employee of the federal government.

**Nomination Procedures:** CIIHE TAC candidates must be nominated by an elected Tribal leader. The nomination letter must be on Tribal letterhead and signed by an elected Tribal leader, and must include the following information:

- Name of the nominee
- Nominee's official title
- Name of the nominee's tribe
- Date of nominee's election to official Tribal position and term length
- Nominee's contact information (mailing address, phone, and email)
- Nominee's expertise that is relevant to the CIIHE TAC
- Name of Tribal leader submitting the nomination
- Official title of Tribal leader submitting the nomination
- Contact information for Tribal leader submitting the nomination and/or the administrative office for the Tribal government

Sample CIIHE TAC nomination letters are available on the OMH website: <https://minorityhealth.hhs.gov/ciihe-tribal-advisory-committee-tac>.

**Selection Process:** OMH is responsible for selecting and finalizing CIIHE TAC delegates.

Eligible nominees will be considered in the following priority order:

1. Tribal President/Chairperson/Governor
2. Tribal Vice-President/Vice-Chairperson/Lt. Governor
3. Elected or Appointed Tribal Official
4. Designated Tribal Official with authority to act on behalf of the Tribal Leader

In the event there are multiple nominations for a given IHS area, OMH will determine the delegates based on a review of the submitted nomination materials.

Nominees will be notified of the status of delegate selection in February 2024.

Dated: December 16, 2024.

**Capt. Tarsha Cavanaugh,**

*Principal Deputy Director, Office of Minority Health.*

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