FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the drug products listed are unaffected by the discontinued marketing of the products subject to these applications. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–22681 Filed 12–11–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Maternal, Infant, and Early Childhood Home Visiting Program Model Eligibility Review Survey, OMB No. 0906–XXXX—New

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than January 12, 2026.

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.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

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

Abstract: HRSA's MIECHV Program supports voluntary, evidence-based home visiting services for expectant and new parents with young children up to kindergarten entry living in at-risk communities. The MIECHV Program was last reauthorized in December 2022.[1] One key program requirement is that programs deliver services using models that meet HHS criteria for evidence of effectiveness, referred to as evidence-based models.[2] The Administration for Children and Families administers the Home Visiting Evidence of Effectiveness (HomVEE) review process to identify early childhood home visiting models that demonstrate evidence of effectiveness.[3] 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.

In 2021, HRSA 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.[4] This 2025 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 funding recipients 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 meet core components of the MIECHV Program, including those added during the program's 2022 reauthorization.

Following approval of this ICR request, HRSA will begin the process of assessing all models that meet HHS criteria for evidence of effectiveness, as determined by the HomVEE review, to determine their MIECHV eligibility. It will initiate this process by requesting information from home visiting model developers through a standardized survey. As of November 2025, HomVEE lists 24 models that meet HHS criteria for evidence of effectiveness.[5] 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 statutory criteria will be considered eligible for MIECHV Program implementation and remain eligible for implementation after the end of the current performance period. Models that do not meet these criteria will be deemed ineligible for use by funding recipients (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 funding recipients regarding any changes in model approval that may affect their program implementation; however, funding

[1] 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 fiscal year 2027.

[2] 42 U.S.C. 711(d)(3)(C)(i).

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

[4] 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.*

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

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

HRSA seeks public comment on the proposed methodology to identify service delivery models that meet MIECHV statutory requirements, including how the proposed changes will affect interested parties such as funding recipients, 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.'' [6] 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.[7] 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.'' [8]

To ensure programs comply with MIECHV statutory requirements,[9] service delivery models also must support the delivery of home visiting services through the employment of well-trained and competent staff [10] that receive ongoing high-quality supervision,[11] support programs' strong organizational capacity to implement home visiting activities [12] and ability to establish appropriate linkages and referral networks to other community resources and supports for participating families,[13] monitor the fidelity of program implementation to ensure services are delivered in fidelity to the specified model,[14] and ensure voluntary participation in the program.[15] The 2022 reauthorization also requires MIECHV programs [16] to implement service delivery home visiting models that provide or support targeted, intensive home visiting services for high-risk populations [17] 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.[18]

A 60-day notice was published in the **Federal Register** on January 8, 2025, Vol. 90, No. 5; pp. 1508–1510. There were no public comments.

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, and that are interested in having their models assessed against other MIECHV statutory requirements to establish eligibility for use by MIECHV funding recipients.

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

[6] 42 U.S.C. 711(d)(3)(A)(i)(I).

[7] 42 U.S.C. 711(d)(3)(A)(i)(I).

[8] 42 U.S.C. 711(d)(4)(B).

[9] 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).

[10] 42 U.S.C. 711(d)(3)(C)(ii).

[11] 42 U.S.C. 711(d)(3)(C)(iii).

[12] 42 U.S.C. 711(d)(3)(C)(iv).

[13] 42 U.S.C. 711(d)(3)(C)(v).

[14] 42 U.S.C. 711(d)(3)(C)(vi).

[15] 42 U.S.C. 711(e)(7)(A).

[16] 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 that also support other MIECHV statutory program requirements.

[17] 42 U.S.C. 711(d)(3)(B).

[18] 42 U.S.C. 711(d)(3)(C)(vii), 711(e)(10)(C).

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2025–22609 Filed 12–11–25; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

NIH Policy on Enhancing Security Measures for Human Biospecimens

AGENCY: National Institutes of Health, HHS.

ACTION: Notice of policy.

SUMMARY: This Policy establishes expectations for ensuring the security of human biospecimens whose collection, obtainment, storage, use, or distribution are supported by NIH funds. The policy ensures protections for human participants and vital national security interests, consistent with Executive Order 14117 (see: *https://www.govinfo.gov/content/pkg/FR-2024-03-01/pdf/2024-04573.pdf*) and 28 CFR 202 ''Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons'' (see: *https://www.federalregister.gov/documents/2025/01/08/2024-31486/preventing-access-to-us-sensitive-personal-data-and-government-related-data-by-countries-of-concern*).

DATES: This policy became effective as of October 24, 2025.

FOR FURTHER INFORMATION CONTACT: Further information about this policy notice may be directed to Dr. Adam Berger at 301–496–9838 or *SCIENCEPOLICY@OD.NIH.GOV.*

SUPPLEMENTARY INFORMATION: On April 8, 2025, the Department of Justice (DoJ) implemented a final rule (28 CFR 202) to ''address a national emergency declared by the President in Executive Order 13873 (see: *https://www.federalregister.gov/documents/2019/05/17/2019-10538/securing-the-information-and-communications-technology-and-services-supply-chain*) of May 15, 2019, to deal with the 'unusual and extraordinary threat . . . to the national security and foreign policy of the United States' posed by foreign adversaries' access to Americans' ''vast amounts of sensitive information.'' 28 CFR 202 specifically exempts transactions that are for the conduct of the official business of the United States Government by its employees, grantees, or contractors, any authorized activity of any United States Government department or agency, or transactions conducted pursuant to a grant, contract, or other agreement entered into with the United States Government. Recognizing the need for Departments and Agencies to implement appropriate security policies tailored to the risks posed by their supported or conducted activities, E.O. 14117 (see: *https://www.govinfo.gov/content/pkg/FR-2024-03-01/pdf/2024-04573.pdf*) directs the Secretary of Health and Human Services to ''consider taking steps . . . to prohibit the provision of assistance that enables access by countries of concern or covered persons to United States [U.S.] persons' bulk sensitive personal data, including personal health data and human genomic data, . . . on the recipients of Federal assistance to address this threat.''

NIH Policy on Enhancing Security Measures for Human Biospecimens

Purpose

NIH is implementing additional policies and standard practices to protect Americans' sensitive and personal health-related data from foreign adversary misuse. This NIH Policy on Enhancing Security Measures for Human Biospecimens (herein referred to as NIH Biospecimens Security Policy) establishes expectations for ensuring the security of human biospecimens whose collection, obtainment, storage, use, or distribution are supported by NIH funds. The policy ensures protections for human participants and vital national security interests, consistent with E.O. 14117 (see: *https://www.govinfo.gov/content/pkg/FR-2024-03-01/pdf/2024-04573.pdf*) and 28 CFR 202 ''Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons'' (see: *https://www.federalregister.gov/documents/2025/01/08/2024-31486/preventing-access-to-us-sensitive-personal-data-and-government-related-data-by-countries-of-concern*).

NIH funds and supports the collection, obtainment, storage, use, or distribution of a wide variety of human biospecimens of U.S. persons and is therefore accountable to those individuals from whom the biospecimens were obtained. NIH takes seriously the privacy and security of these individuals and recognizes that human biospecimens may be used to derive sensitive information, such as an individuals' genome sequence.

On April 8, 2025, the Department of Justice (DoJ) implemented a final rule (28 CFR 202) to address a national emergency declared by the President in Executive Order 13873 (see: *https://www.federalregister.gov/documents/2019/05/17/2019-10538/securing-the-information-and-communications-technology-and-services-supply-chain*) of May 15, 2019 to deal with the 'unusual and extraordinary threat . . . to the national security and foreign policy of the United States' posed by foreign adversaries' access to Americans' ''vast amounts of sensitive information.'' The final rule exempts specific types of transactions conducted and authorized by United States Government employees, grantees, or contractors, acknowledging the need for Departments and Agencies to implement appropriate security policies tailored to the risks posed by their supported or conducted activities. Additionally, E.O. 14117 (see: *https://www.govinfo.gov/content/pkg/FR-2024-03-01/pdf/2024-04573.pdf*) directs the Secretary of Health and Human Services to ''consider taking steps . . . to prohibit the provision of assistance that enables access by countries of concern or covered persons to United States [U.S.] persons' bulk sensitive personal data, including personal health data and human genomic data, . . . on the recipients of Federal assistance to address this threat.''

Recent security directives, including E.O. 14117 (*https://www.govinfo.gov/content/pkg/FR-2024-03-01/pdf/2024-04573.pdf*) and 28 CFR 202 ''Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons'' (see: *https://www.federalregister.gov/documents/2025/01/08/2024-31486/preventing-access-to-us-sensitive-personal-data-and-government-related-data-by-countries-of-concern*), have increased the need to set expectations for securing human biospecimens to address national security and related concerns. NIH is enacting the NIH Biospecimens Security Policy in support of these directives to secure Americans' sensitive personal health-related data from exploitation, ensure America's leadership in scientific research and technology development, and protect the privacy and rights of Americans.

Effective Date

This policy became effective as of October 24, 2025.

Definitions

The following definitions are used for the purpose of the NIH Biospecimens Security Policy:

Countries of concern—Those countries as determined under 28 CFR 202.601 (Subpart F: Determination of Countries of Concern)(see: *https://*