

1 and “Homeless” sub-categories from 3 to 2.

- *Form 2, Performance Measure 3:* Add a sub-measure to collect data on anxiety screening.

- *Form 2, Performance Measure 5:* Expand the postpartum visit window to within 12 weeks (84 days) of delivery.

- *Form 2, Performance Measure 6:* Update the measure definition of “tobacco use” to explicitly mention inclusion of e-tobacco use.

- *Form 2, Performance Measure 7:* Update the safe sleep measure to specify a 2-week lookback period for the reporting window.

- *Form 2, Performance Measure 17:* Add a sub-measure to collect data on completed anxiety referrals.

- *Form 4, Table A2:* Remove the table from Form 4; the table will be moved to Form 1.

- *Form 4, Table A3:* Remove this table from data collection.

- *Forms 1, 2, and 4:* Update Definition of Key Terms to reflect the changes.

Need and Proposed Use of the Information: HRSA uses performance information to demonstrate program accountability and continuously monitor and provide oversight to MIECHV Program awardees. The information is also used to provide quality improvement guidance and technical assistance to awardees and help inform the development of early childhood systems at the national, state,

and local level. HRSA is seeking to revise and extend collection of (1) demographic, service utilization, and select clinical indicators for participants enrolled in home visiting services, and location of services (annually via Form 1); (2) a set of standardized performance and outcome indicators that correspond with the statutorily identified benchmark areas (annually via Form 2); and (3) home visiting program capacity and staffing data (quarterly via Form 4).

This information will be used to demonstrate awardees’ compliance with legislative and programmatic requirements. It will also be used to monitor and provide continued oversight of awardee performance and target technical assistance resources for awardees. Revisions to the forms meet a statutory requirement to reduce administrative burden for MIECHV funding recipients (Section 511(h)(6)(A) of the Social Security Act). HRSA reviewed the information collected and streamlined, where possible, to collect the optimum amount of data necessary to fulfill awardee performance measurement and demonstration of improvement requirements.

Additionally, other revisions have been made to align performance measures with other maternal and child health programs, with current Statistical Policy Directive 15 (Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity), and current clinical and evidence-based guidelines.

The revisions reflect feedback from current MIECHV funding recipients, home visiting model developers, and federal partners.

Likely Respondents: MIECHV Program funding recipients that are states, jurisdictions, and, where applicable, nonprofit organizations providing home visiting services within states.

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.

HRSA updated the estimated burden hours based on data collected in summer 2024 under OMB No. 0906-0094, titled “Implement MIECHV Program 2022 Legislative Changes: Assessment of Administrative Burden.” The same group of 56 respondents will complete each form.

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
<i>Form 1: Demographic, Service Utilization, and Select Clinical Indicators</i>	56	1	56	448	25,088
<i>Form 2: Performance Indicators and Systems Outcome Measures</i>	56	1	56	723	40,488
<i>Form 4: Section A—Quarterly Performance Report</i>	56	4	224	35	7,840
Total	56	336	73,416

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

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Ending the HIV Epidemic in the U.S. (EHE) Initiative Triannual Report, OMB No. 0906-0051—Revision

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

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 21, 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: Ending the HIV Epidemic (EHE) Initiative in the U.S. Triannual Report OMB No. 0906-0051—Revision.

Abstract: HRSA’s Ryan White HIV/AIDS Program (RWHAP) funds and coordinates with cities, states, counties, and local clinics to deliver efficient and effective HIV care, treatment, and support services to low-income people with HIV. Since 1990, the RWHAP has developed a comprehensive system of providers who deliver high quality direct health care and support services to over half a million people with HIV—more than 50 percent of all people with diagnosed HIV in the United States. Nearly two-thirds of clients live at or below 100 percent of the Federal Poverty Level.¹

The federal Ending the HIV Epidemic in the U.S. (EHE) initiative focuses on reducing the number of new HIV infections in the United States.² Authorized by section 311(c) and title XXVI of the Public Health Service Act, this initiative began in fiscal year 2020 and focuses on 48 counties, Washington, DC; San Juan, Puerto Rico; as well as seven states that have a substantial number of HIV diagnoses in rural areas. The EHE initiative efforts focus on the following four key strategies that together can end the HIV epidemic in the United States:

1. *Diagnose* all people with HIV as early as possible.

2. *Treat* people with HIV rapidly and effectively to reach sustained viral suppression.

3. *Prevent* new HIV transmissions by using proven interventions.

4. *Respond* quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.

The EHE initiative is a collaborative effort among key Department of Health and Human Services agencies, primarily HRSA, the Centers for Disease Control and Prevention, the National Institutes of Health, the Indian Health Service, and the Substance Abuse and Mental Health Services Administration. Through HRSA’s RWHAP and Health Center Program, the agency has a leading role in helping diagnose, treat, prevent, and respond to end the HIV epidemic in the United States.

In June 2025, HRSA awarded more than \$146 million to 49 EHE recipients to continue the efforts of the EHE initiative. This funding helps states and metropolitan areas with the highest levels of HIV transmission link people with HIV who are either newly diagnosed, or are diagnosed but currently not in care, to essential HIV care to continue the efforts of the EHE initiative. This funding helps states and metropolitan areas with the highest levels of HIV transmission link people with HIV who are either newly diagnosed, or are diagnosed but currently not in care, to essential HIV care, treatment and support services, as well as to provide workforce training, technical assistance, and support services. HRSA is making one minor revision to a footnote to clarify an existing instruction. There are no other changes to the collection.

A 60-day notice published in the **Federal Register** on August 5, 2025, vol. 90, No. 148; pp. 37528–29. There were no public comments.

Need and Proposed Use of the Information: To support federal requirements to monitor and report on funds distributed through the EHE initiative, HRSA created a reporting module, the EHE Triannual Report,

which is an aggregate data report submitted three times a year by EHE recipients and providers of services. EHE-funded providers will report aggregate information on the number of clients receiving specific services and the number of clients who were prescribed antiretroviral medications in the four-month reporting period. This module provides HRSA with frequent and timely data on EHE initiative progress by providing information on the number of clients who are reached through the EHE initiative. This will provide valuable information on the scope of outreach to new clients and clients who have had a lapse in service, which could be an indication of reengagement in care. This module will support project officer monitoring and HRSA’s understanding of service provision. Finally, the information collected in the EHE Triannual Report will complement the annual information collected through the RWHAP Services Report and other reporting mechanisms and support HRSA to monitor EHE initiative activities and assess progress toward meeting national goals for ending the HIV epidemic.

Likely Respondents: RWHAP Part A and Part B recipients and subrecipients funded by the EHE initiative.

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
EHE Module	942	3	2,826	2	5,652

¹ HRSA. Ryan White HIV/AIDS Program Data Report, 2020.

² HRSA. Ending the HIV Epidemic in the U.S. <https://www.hrsa.gov/ending-hiv-epidemic>. Accessed September 29, 2025.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Total	942	2,826	5,652

Maria G. Button,
Director, Executive Secretariat.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Addition of Metachromatic Leukodystrophy to the Recommended Uniform Screening Panel

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

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) published a **Federal Register** notice on August 14, 2025 (90 FR 39196), requesting comments from the public on the potential recommendation of adding Metachromatic Leukodystrophy (MLD) to the Recommended Uniform Screening Panel (RUSP). After consideration of public comments and evidence-based reports, HRSA recommended to the Secretary of Health and Human Services (HHS) that MLD be added to the RUSP. The Secretary of HHS has accepted the recommendation as detailed in this notice. Conditions listed on the RUSP are part of the evidence-informed preventive health guidelines supported by HRSA for infants, children, and adolescents. Non-grandfathered group health plans and group health insurance issuers are required to cover screenings included in these HRSA-supported comprehensive guidelines without cost-sharing (e.g., copayment, co-insurance, etc.). Please see the RUSP (<https://newbornscreening.hrsa.gov/about-newborn-screening/recommended-uniform-screening-panel>) for additional information.

FOR FURTHER INFORMATION CONTACT: CDR Leticia Manning, Newborn Screening Team Lead, Division of Services for Children with Special Health Needs, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857 or NBSPrograms@hrsa.gov.

SUPPLEMENTARY INFORMATION: The RUSP is a list of conditions that the Secretary of HHS recommends for states to screen as part of their state universal newborn screening (NBS) programs. Conditions on the RUSP are chosen based on evidence that supports the potential net benefit of screening, the ability of states to screen for the disorder, and the availability of effective treatments. Although states ultimately determine what conditions their NBS program will screen for, it is recommended that every newborn be screened for all conditions on the RUSP. Conditions listed on the RUSP are part of the comprehensive preventive health guidelines supported by HRSA for infants, children, and adolescents under section 2713 of the Public Health Service Act. Non-grandfathered group health plans and health insurance issuers are required to cover screenings included in these HRSA-supported comprehensive guidelines without charging a copayment, co-insurance, or deductible for plan years beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

The Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC), now inactive, was tasked with reviewing available scientific evidence and then making recommendations to the Secretary of HHS regarding what conditions should be on the RUSP. When a condition is nominated, ACHDNC determines whether there is sufficient evidence available for early screening and refers it to ACHDNC's Evidence Review Group (ERG). The ERG is responsible for identifying and assessing all available evidence and summarizing for ACHDNC the strength and effectiveness of the evidence found on the net benefit of screening, the ability of states to screen for the condition, and the availability of effective treatments. The ERG completed an evidence review for MLD. Following the completion of the evidence review for MLD, but prior to issuing a recommendation to the Secretary on the inclusion of MLD to the RUSP, the ACHDNC was terminated.

The condition for addition, MLD, is a rare genetic condition that leads to progressive motor and brain damage. Children with early-onset forms of the

condition who do not receive treatment before symptom onset experience motor function loss/paralysis and neurological impairment followed by death at 5–6 years of age. Gene therapy is extremely effective if started early in life, with those who were placed on the earliest treatment pilots continuing to live into their mid-teen years today.

Summary of Public Comments

A **Federal Register** notice sought public comment on the potential recommendation of including or not including MLD on the RUSP. HRSA requested that the respondents consider the ERG's report summary on MLD and the suitability of state NBS programs screening for MLD within the newborn period in their response. HRSA considered all public comments as part of its deliberative process along with review of the completed MLD evidence review report prior to making a recommendation to the Secretary of HHS. A total of 98 respondents commented on the inclusion of MLD on the RUSP. Of these, 96 responses (98 percent) expressed support to add MLD to the RUSP, 1 response (1 percent) opposed its addition, and 1 response (1 percent) provided feedback on awaiting results from pilot studies and early adopting states to inform implementation. The responses in support of or against adding MLD to the RUSP are summarized below.

Comments on Adding MLD to the RUSP

The majority of respondents (96 responses or 98 percent) described benefits of adding MLD to the RUSP including highly accurate screening for MLD with minimal false positives, if any; an FDA-approved gene therapy proven to prevent symptoms if administered before onset of disease; and early diagnosis can save lives of children with MLD.

The respondent that opposed adding MLD to the RUSP cited resource challenges for implementing MLD screening in public health laboratories and the high cost of treatment as reasons why MLD should not be added to the RUSP. However, HRSA notes that adding a condition to the RUSP does not require states to implement screening immediately. States determine their