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.*

[FR Doc. 2025–23605 Filed 12–19–25; 8:45 am]

**BILLING CODE 4165–15–P**

## 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 co-payment, 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

resource allocations for NBS screening based on their specific state budget and public health priorities.

After consideration of the evidence review report and public comments, no changes were made to the recommendation and HRSA recommended to the Secretary of HHS that MLD be included for addition to the RUSP.

**Acceptance of Recommendation**

On December 16, 2025, the HHS Secretary accepted HRSA's recommendation. The RUSP is updated and can be accessed at the following link: *https://mchb.hrsa.gov/programs/newborn-screening.*

**Thomas J. Engels,**

*Administrator.*

[FR Doc. 2025–23574 Filed 12–19–25; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute on Aging; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NIA.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual grant applications conducted by the National Institute On Aging, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors, NIA.

*Date:* March 30–31, 2026.

*Closed:* March 30, 2026, 8:00 a.m. to 9:00 a.m.

*Agenda:* Executive Session and Board Business.

*Address:* National Institutes of Health, National Institute on Aging, Biomedical Research Center, 3rd Floor, Room 3C211/Virtual, 251 Bayview Boulevard, Baltimore, MD 21224.

*Meeting Format:* Hybrid.

*Open:* March 30, 2026, 9:00 a.m. to 11:45 a.m.

*Agenda:* Review of Labs and PI's.

*Address:* National Institutes of Health, National Institute on Aging, Biomedical Research Center, 3rd Floor, Room 3C211/Virtual, 251 Bayview Blvd., Baltimore, MD 21224.

*Meeting Format:* Hybrid.

*Closed:* March 30, 2026, 11:45 a.m. to 2:15 p.m.

*Agenda:* Review of Labs and PI's; Executive Session Luncheon.

*Address:* National Institutes of Health, National Institute on Aging, Biomedical Research Center, 3rd Floor, Room 3C211/Virtual, ,251 Bayview Boulevard, Baltimore, MD 21224.

*Meeting Format:* Hybrid.

*Open:* March 30, 2026, 2:15 p.m. to 3:15 p.m.

*Agenda:* Review PI's.

*Address:* National Institutes of Health, National Institute on Aging, Biomedical Research Center, 3rd Floor, Room 3C211/Virtual, 251 Bayview Boulevard, Baltimore, MD 21224.

*Meeting Format:* Hybrid.

*Closed:* March 30, 2026, 3:15 p.m. to 3:30 p.m.

*Agenda:* Discussion with the BSC Members.

*Address:* National Institutes of Health, National Institute on Aging, Biomedical Research Center, 3rd Floor, Room 3C211/Virtual, 251 Bayview Boulevard, Baltimore, MD 21224.

*Meeting Format:* Hybrid.

*Open:* March 30, 2026, 3:30 p.m. to 4:15 p.m.

*Agenda:* Review of Labs and PI's.

*Address:* National Institutes of Health, National Institute on Aging, Biomedical Research Center, 3rd Floor, Room 3C211/Virtual, 251 Bayview Boulevard, Baltimore, MD 21224.

*Meeting Format:* Hybrid.

*Closed:* March 30, 2026, 4:15 p.m. to 5:30 p.m.

*Agenda:* Executive Session, Adjournment.

*Address:* National Institutes of Health, National Institute on Aging, Biomedical Research Center, 3rd Floor, Room 3C211/Virtual, 251 Bayview Boulevard, Baltimore, MD 21224.

*Meeting Format:* Hybrid.

*Closed:* March 31, 2026, 8:00 a.m. to 9:00 a.m.

*Agenda:* Executive Session; Board Business.

*Address:* National Institutes of Health, National Institute on Aging, Biomedical Research Center, 3rd Floor, Room 3C211/Virtual, 251 Bayview Boulevard, Baltimore, MD 21224.

*Meeting Format:* Hybrid.

*Open:* March 31, 2026, 9:00 a.m. to 11:00 a.m.

*Agenda:* Review of Labs and PI's.

*Address:* National Institutes of Health, National Institute on Aging, Biomedical Research Center, 3rd Floor, Room 3C211/Virtual, 251 Bayview Boulevard, Baltimore, MD 21224.

*Meeting Format:* Hybrid.

*Closed:* March 31, 2026, 11:00 a.m. to 4:30 p.m.

*Agenda:* Executive Session Luncheon; Review of Lab's and PI's; Executive Session; Adjournment.

*Address:* National Institutes of Health, National Institute on Aging, Biomedical Research Center, 3rd Floor, Room 3C211/Virtual, 251 Bayview Boulevard, Baltimore, MD 21224.

*Meeting Format:* Hybrid.

*Contact Person:* Luigi Ferrucci, M.D., Ph.D., Scientific Director, National Institute on Aging, National Institutes of Health, 251 Bayview Boulevard, Suite 100, Room 4C225, Baltimore, MD 21224, 410–558–8110, *lf27z@nih.gov.*

Registration is not required to attend the open portion of this meeting.

In the interest of security, NIH has procedures at *https://security.nih.gov/visitors/Pages/visitor-campus-access.aspx* for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 18, 2025.

**Margaret Vardanian,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2025–23597 Filed 12–19–25; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Environmental Health Sciences; Notice of Partially Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Environmental Health Sciences Council.

The meeting will be partially open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend as well as those who need special assistance, such as sign language interpretation or other reasonable accommodations, must notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*https://www.niehs.nih.gov/news/webcasts*).