



STATE OF WASHINGTON

DEPARTMENT OF HEALTH

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September 15, 2025

Leticia Manning, MPH

Newborn Screening Team Lead, Division of Services for Children with Special Health Needs  
Health Resources Service Administration/Maternal and Child Health Bureau  
5600 Fishers Lane, Rockville, Maryland 20857

Re: Notice With Request for Comment: Consideration of Adding Metachromatic Leukodystrophy to the Recommended Uniform Screening Panel [**FR Doc. 2025-15432**].

Dear Ms. Manning,

The Washington State Department of Health (DOH) carefully reviewed the recent Lam et al. article in the medical journal Pediatrics regarding metachromatic leukodystrophy (MLD) as a candidate for newborn screening. DOH staff performed a preliminary review of several other MLD-related articles in the published medical literature. This study showed that MLD meets many of the traditional criteria for newborn screening.

- A good screening test exists using liquid-chromatography tandem mass spectrometry to measure sulfatides with ARSA enzyme activity as a second-tier test and ARSA genetic analysis as an optional third-tier test. A prospective pilot study in Germany identified three cases of MLD among more than 100,000 babies screened. Sulfatide analysis can be multiplexed with other newborn screening conditions.
- A good treatment exists and early identification and intervention provides benefit to the newborn: arsa-cel gene therapy has shown to improve mortality and morbidity rates for patients treated early and is the recommended course for babies with late-infantile and early-juvenile forms of MLD.
- Most babies with MLD do not have a family history, so presymptomatic detection via newborn screening is the best option to identify patients.

Questions that were unanswered by DOH preliminary review are:

- Is there equitable access for all babies for gene therapy and will private and public insurance cover the costs of care?
- What medical support will babies have who are diagnosed with late-onset MLD, or who have gene variants of unknown significance (may represent up to 25% of patients)? How will their families be supported with the uncertainty?

DOH expects that pilot studies and early adopter states (Illinois and Minnesota) will provide valuable data and experiences to inform policy decisions regarding MLD in other states.

Thank you for the opportunity to provide these comments. If you have any questions, please contact Mike Ellsworth at [Michael.Ellsworth@doh.wa.gov](mailto:Michael.Ellsworth@doh.wa.gov) or the Director, Federal and Inter-State Affairs for Governor Ferguson's Washington, D.C. office Rose Minor at [Rose.Minor@gov.wa.gov](mailto:Rose.Minor@gov.wa.gov)

Sincerely,

A handwritten signature in blue ink that reads "Angi Miller". The signature is fluid and cursive, with the first name "Angi" and last name "Miller" clearly distinguishable.

Angi Miller  
Acting Assistant Secretary  
Disease Control and Health Statistics  
Washington State Department of Health