

WASHINGTON STATE BOARD OF HEALTH

Date: April 12, 2023

To: Washington State Board of Health Members

From: Socia Love-Thurman, Board Member

Subject: Petition – Chapter 246-650 WAC, Newborn Screening, Request to add Arginase 1 Deficiency (ARG1-D)

Background and Summary:

The Administrative Procedures Act (RCW 34.05.330) allows any person to petition a state agency to request the adoption, amendment, or repeal of any rule. Upon receipt of a petition, the agency has sixty days to either (1) deny the petition in writing, stating the reasons and, as appropriate, offer other means for addressing the concerns raised by the petitioner, or (2) accept the petition and initiate rulemaking.

On March 29, 2023, the Washington State Board of Health (Board) received a rulemaking petition requesting to amend chapter 246-650 WAC to add Arginase 1 deficiency (ARG1-D) as a condition for newborn screening. The petition states that “a diagnosis [of ARG1-D] at birth would allow for more immediate treatment to slow down and prevent severe brain damage from occurring with affected newborns rather than waiting until symptoms appear at a later age.”

ARG1-D is a rare and inherited metabolic disease that prevents the body from correctly breaking down the amino acid arginine, an enzyme present in the blood.^{1,2} Arginase is one of six enzymes responsible for breaking down arginine and is part of an essential process in the body called the urea cycle.^{1,3} The urea cycle helps remove ammonia from the body, a waste product used to process protein. If the arginase enzyme isn't working properly, the body can't break down arginine and get rid of ammonia through the urea cycle. Irregularities in the urea cycle may cause levels of ammonia in the blood to increase.^{1,2,4} If levels of ammonia become too high, it has toxic effects and can cause serious damage to the nervous system and other parts of the body.

Symptoms of ARG1-D include seizures, muscle stiffness, difficulty eating, vomiting, and trouble breathing.^{1,2} People with ARG1-D might also experience delays in both physical and cognitive development, loss of developmental milestones, and intellectual disabilities. According to the Health Resources and Services Administration (HRSA) website, over 30 states currently screen for ARG1-D or argininemia in their newborn screening panel as either a core or secondary condition.⁵ ARG1-D is listed as a secondary condition on the Federal [Recommended Uniform Screening Panel \(RUSP\)](#). In addition, Washington's newborn screening lab currently runs the ARG1-D blood testing for babies born in Idaho.^{6,7}

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The Board has the authority under RCW 70.83.050 to adopt rules for screening Washington-born infants for hereditary conditions. WAC 246-650-010 defines the conditions, and WAC 246-650-020 lists the conditions on the state's required newborn screening panel.

The Board has a process it follows when considering new conditions to include in the state's newborn screening panel. To determine which conditions to include in the panel, the Board may convene an advisory committee to evaluate candidate conditions using [guiding principles and an established set of criteria](#). Before an advisory committee is convened, there should be sufficient scientific evidence available to apply the Board's criteria for inclusion. This may require a preliminary review.

I have invited Molly Dinardo, Board Staff, and John Thompson, Director of the Department of Health's Newborn Screening Program, to provide an overview of the Board's process for adding a condition to the panel, the petition request, and a brief overview of ARG1-D.

Recommended Board Actions:

The Board may wish to consider one of the following motions:

The Board declines the petition for rulemaking to add ARG1-D as a condition for newborn screening in Chapter 246-650 WAC, but directs staff to work with the Department of Health to perform a preliminary review of the condition for inclusion in WAC 246-650-020 and then report back to the Board so the Board can determine whether to establish a technical advisory committee to evaluate ARG1-D against the Board's criteria for adding conditions to the newborn screening rule.

OR

The Board declines the petition for rulemaking to add ARG1-D as a condition for newborn screening in Chapter 246-650 WAC, but directs staff to work with the Department of Health to move forward with convening a technical advisory committee to evaluate ARG1-D using the Board's process and criteria to evaluate conditions for inclusion in WAC 246-650-020 and then make a recommendation to the Board.

OR

The Board accepts the petition for rulemaking to amend Chapter 246-650 WAC to add Arginase 1 deficiency (ARG1-D) as a condition for newborn screening. The Board directs staff to notify the requestor of its decision and to file a CR-101, Preproposal of Inquiry, under its authority in RCW 70.83.050.

Staff

Molly Dinardo

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1. Health Resources and Services Administration (HRSA). Arginase deficiency | Newborn Screening. Published December 2022. Accessed March 29, 2023. <https://newbornscreening.hrsa.gov/conditions/arginase-deficiency>
 2. National Institutes of Health National Library of Medicine. Arginase deficiency: MedlinePlus Genetics. Accessed March 29, 2023. <https://medlineplus.gov/genetics/condition/arginase-deficiency/>
 3. Arginase 1 Deficiency (ARG1D) Foundation. What is Arginase 1 Deficiency? ARG1D. Published January 2023. Accessed March 29, 2023. <https://arg1d.org/>
 4. National Center for Advancing Translational Sciences, Genetic and Rare Diseases Information Center (GARD). Arginase deficiency. Published February 2023. Accessed March 29, 2023. <https://rarediseases.info.nih.gov/diseases/5840/arginase-deficiency>
 5. Newborn Screening in Your State | Newborn Screening. Accessed March 29, 2023. <https://newbornscreening.hrsa.gov/your-state>
 6. Dried Blood Spot and CCHD Newborn Screening | Idaho Department of Health and Welfare. Accessed March 31, 2023. <https://healthandwelfare.idaho.gov/services-programs/children-families/dried-blood-spot-and-cchd-newborn-screening>
 7. Washington State Department of Health. Newborn Screening. Washington State Department of Health. Accessed March 31, 2023. <https://doh.wa.gov/you-and-your-family/infants-and-children/newborn-screening>