

# WASHINGTON STATE BOARD OF HEALTH

**Date:** August 7, 2024

**To:** Washington State Board of Health Members

**From:** Kelly Oshiro, Board Member

**Subject:** Briefing – Newborn Screening Rulemaking for Ornithine Transcarbamylase Deficiency (OTCD), Guanidinoacetate Methyltransferase Deficiency (GAMT), and Arginase 1 Deficiency (ARG1-D) – Chapter 246-650 WAC

## Background and Summary:

The Washington State Board of Health (Board) has the authority under RCW 70.82.050 to define and adopt rules for screening of Washington-born infants for hereditary conditions. WAC 246-650-010 defines the conditions and WAC 246-650-020 lists conditions for which all Washington-born newborns are to be screened. The Board convenes a technical advisory committee (TAC) in order to determine which conditions to include in the newborn screen (NBS) panel. The TAC evaluates candidate conditions using an established set of criteria. The Board directed Board and the Department of Health (Department) staff to convene technical advisory committees (TAC) to evaluate three conditions for possible inclusion in the NBS panel: Ornithine Transcarbamylase Deficiency (OTCD), Guanidinoacetate methyltransferase (GAMT) Deficiency, and Arginase 1 Deficiency (ARG1-D). The TACs are tasked with evaluating the conditions against the Board's five screening criteria.

The OTCD TAC convened June 16 and July 7, 2021 and voted to recommend the inclusion of OTCD in the NBS panel, and the Board approved this recommendation at its October 2021 meeting. Board staff filed a CR-101 on February 4, 2022, to initiate the rulemaking process.

On September 8, 2023, the TACs met and evaluated GAMT and ARG1-D. The TACs voted to recommend the inclusion of GAMT and ARG1-D in the NBS panel. On October 9, 2023, staff presented the findings and recommendation of the TAC to the Board, at which time the Board approved a motion to initiate rulemaking for the inclusion of both GAMT and ARG1-D to the NBS panel. Board staff filed a CR-101 on November 28, 2023, to initiate the rulemaking process.

The inclusion of OTCD, GAMT, and ARG1-D in the NBS panel, as indicated in the Department's cost-benefit analysis, will require an increase to the NBS fee. This fee is collected for each infant in Washington State and covers the costs of the screening, follow-up services, and coordination with specialty services.

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I have invited Dr. John Thompson, Director of the Newborn Screening Program at the Department of Health, and Kelly Kramer, Policy Advisor to the Board, to provide an update on the current progress of the rule update ahead of an anticipated rules hearing in October.

**Staff**

Kelly Kramer

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