

WASHINGTON STATE BOARD OF HEALTH

Date: November 13, 2024

To: Washington State Board of Health Members

From: Kelly Oshiro, Board Chair

Subject: Newborn Screening Technical Advisory Committee, Review of Newborn Screening Process and Criteria

Background and Summary:

The Washington State Board of Health (Board) has the authority under RCW 70.83.050 to define and 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 for which all newborns are to be screened.

The Board convenes a technical advisory committee (TAC) to review conditions and make recommendations to Board regarding possible inclusion in the newborn screen (NBS) panel. The TAC evaluates candidate conditions using the Board's [guiding principles and an established set of criteria](#). Before the Board convenes a TAC, sufficient scientific evidence should be available to apply the Board's criteria for inclusion, which may require a preliminary review. This is known as the qualifying assumption. The Board's process and criteria were last reviewed in 2014 and 2015.

Since 2022, the Board has received five petitions requesting the addition of new conditions to the screening panel. These conditions were: congenital Cytomegalovirus (cCMV), Mucopolysaccharidoses II (MPS II), Guanidinoacetate methyltransferase (GAMT) deficiency, Arginase 1 deficiency (ARG1-D), and Wilson's Disease. The Board convened TACs for cCMV, ARG1-D and GAMT. The TACs recommended adding ARG1-D and GAMT, but not cCMV. The Board accepted the TAC recommendations and ARG1-D and GAMT will be added when funding is available. During the 2024 legislative session, the Legislature required the Board to review branched-chain ketoacid dehydrogenase kinase (BCKDK) deficiency and re-review cCMV. Staff also anticipate reviewing MPSII and Wilson's disease in Spring 2025. The Department of Health (Department) is currently monitoring five to seven other potential conditions that may be proposed for review soon.

Given the recent increase in condition review requests and anticipated workload, the Board and Department acknowledged the need to review and update the current process and convened a TAC to identify strategies to streamline the condition review request process, modernize the evaluation criteria, and strengthen the overall process to address current program demands.

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The TAC met on October 28, 2024 to review Washington's current process and criteria. Staff presented information about the federal new condition nomination and review process and potential options to update the Board's current process. The TAC voted and proposed the following recommendations for the Board's consideration:

- 1) All conditions added to the Federal [Recommended Uniform Screening Panel \(RUSP\)](#) meet the Board's qualifying assumption.
- 2) The Board should continue convening TACs to review these conditions in order to determine if they should be added to Washington's mandatory newborn screening panel using Washington's criteria.
- 3) The Board should convene a TAC to review a condition within two years of its addition to the RUSP.

The TAC also began reviewing the five newborn screening criteria. During discussions, TAC members suggested initial updates to the criteria such as strengthening definitions of "available treatment" and "screening test sensitivity and specificity" and considering community resources. TAC members will continue this review at the next TAC meeting.

I have invited Kelly Kramer, Board Staff, to provide an overview of the TAC's process and criteria review recommendations.

Recommended Board Actions:

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

The Board declines the Newborn Screening Technical Advisory Committee's (TAC's) recommendation for the Board to assume that conditions on the Federal Recommended Uniform Screening Panel meet the Board's qualifying assumption. The Board directs the TAC to continue reviewing the newborn screening process criteria and make recommendations to the Board.

OR

The Board accepts the Newborn Screening Technical Advisory Committee's (TAC's) recommendation for the Board to assume that conditions on the Federal Recommended Uniform Screening Panel meet the Board's qualifying assumption and directs staff to update the Board newborn screening process document accordingly. The Board also directs the TAC to continue reviewing the newborn screening criteria and provide recommendations to the Board.

Staff

Kelly Kramer

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