WASHINGTON STATE

Date: January 8, 2025

To: Washington State Board of Health Members

From: Kelly Oshiro, Board Member

Subject: 2024 Newborn Screening Criteria Review Project

Background and Summary:

The Washington State Board of Health (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 for inclusion on the state's newborn screening panel. To determine which conditions to include, the Board may convene an advisory committee to evaluate candidate conditions using <u>guiding principles</u> and an established set of criteria.

During the November 2024 Board meeting, the Board approved the following recommendations from the Newborn Technical Advisory Committee (TAC):

- 1) All conditions added to the Federal <u>Recommended Uniform Screening Panel</u> (<u>RUSP</u>) meet the Board's qualifying assumption.
- 2) The Board should continue convening TACs to review conditions on the RUSP to determine if they should be added to Washington's mandatory newborn screening panel using the state's criteria.
- 3) The Board should convene a TAC to review a condition within two years of its addition to the RUSP.

Board staff also brought forward additional considerations regarding petitions for conditions that are undergoing federal review or have been denied addition to the federal RUSP:

- For petitions or review requests concerning conditions under review by the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC), the Board should delay convening a TAC until the ACHDNC has made a final decision.
- For petitions or requests related to conditions that have previously been reviewed and rejected by the ACHDNC for inclusion on the RUSP, Board staff may work with the petitioner to address any deficiencies or recommendations identified by the ACHDNC as a part of Washington's initial evidence review.

With the adoption of the TAC's recommendations to review RUSP conditions, the Board must conduct reviews for MPS-II and Krabbe disease. These conditions were added prior to the Board's approval November 2024.

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Recommended Board Action:

The Board may wish to consider and amend, if necessary, the following motion:

For the conditions MPS-II and Krabbe Disease that were added to the RUSP prior to the Board's recommendations, the two-year review timeline begins from the November 2024 Board recommendation date instead of date of the federal recommendations.

• The TACs for MPS-II and Krabbe Disease must be completed by November 2026.

Staff Kelly Kramer, Newborn Screening Policy Advisor

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