WASHINGTON STATE BOARD OF HEALTH

Date: March 8, 2023

To: Washington State Board of Health Members

From: Kelly Oshiro, Board Vice Chair

Subject: Briefing – Chapter 246-650 WAC, Newborn Screening; Mucopolysaccharidoses Type II (MPS II) Qualifying Assumption Analysis Findings

Background and Summary:

The 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 for which all Washington-born newborns are to be screened.

On October 26, 2022, the Board received a petition for rulemaking requesting an amendment to Chapter 246-650 WAC to add Mucopolysaccharidoses Type II (MPS II) as a condition for newborn screening. MPS II, also known as Hunter's Syndrome, is a rare hereditary metabolic condition that prevents the body from properly breaking down and processing complex sugars, or glycosaminoglycans (GAGs).[1,2] This condition occurs when the body lacks an enzyme called iduronate-2-sulfatases (I2S), or these enzymes aren't functioning as they should. When the body has high levels of complex sugars, or they aren't breaking down, it causes the buildup of certain waste products in a person's cells and causes damage to many parts of the body, including bones, muscles, connective tissues, and organs.

MPS II was added as a condition on the Secretary of the Department of Health and Human Services (HSS) Recommended Uniform Screening Panel (RUSP) in 2022.[3] Missouri and Illinois currently screen for MPS II as part of their state newborn screening programs.[4] In addition, pilot programs in New York and Taiwan are also testing MPS II screening.

At its November 9, 2022, meeting, the Board denied the petition for rulemaking and directed Board staff to work with the Department of Health to conduct a qualifying assumption analysis to determine if there is enough scientific evidence to evaluate MPS II for inclusion in chapter 246-650 WAC. The Board uses a defined set of criteria to evaluate conditions for inclusion on the panel. These criteria are: available screening technology, diagnostic testing and treatment available, prevention potential and medical rationale, public health rationale, and cost-benefit/cost-effectiveness. If there is enough scientific evidence available to apply these criteria to a condition, the Board may then

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decide to convene a technical advisory committee (TAC) to inform its decision on whether a condition should be included in the newborn screening (NBS) panel.
I have invited Molly Dinardo, Board Staff, and John Thompson, Director of the Department of Health's Newborn Screening Program, to provide an update on MPS II and report on findings from the qualifying assumption analysis.

Recommended Board Actions:

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

The Board directs staff to work with the Department of Health to convene a technical advisory committee to evaluate Mucopolysaccharidoses Type II (MPS II) 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 determines that there is insufficient information available at this time to know whether Mucopolysaccharidoses Type II (MPS II) meets the qualifying assumption for the Board's criteria for evaluating conditions for inclusion in the rule. The Board directs staff to update the information in two years and return to the Board for consideration at that time.

Staff

Molly Dinardo

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1. National Institute of Health | Mucopolysaccharidoses Fact Sheet | National Institute of Neurological Disorders and Stroke. Updated July 2022. Accessed February 21, 2023. https://www.ninds.nih.gov/mucopolysaccharidoses-fact-sheet
2. Health Resources and Services Administration | Mucopolysaccharidosis type II | Newborn Screening. Updated September 2022. Accessed February 21, 2023. https://newbornscreening.hrsa.gov/conditions/mucopolysaccharidosis-type-ii
3. Health Resources and Services Administration (HRSA) | Recommended Uniform Screening Panel. Updated February 2023. Accessed February 21, 2023. https://www.hrsa.gov/advisory committees/heritabledisorders/rusp
4. Health Resources and Services Administration (HRSA) | Evidence-Based Review of Newborn Screening for Mucopolysaccharidosis Type II: Final Report. Prepared for the Maternal and Child Health Bureau. Published February 20, 2022. Accessed February 21, 2023. https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/heritable-disorders/meetings/mps-ii-final-report-3-28-2022.pdf