

WASHINGTON STATE BOARD OF HEALTH

Date: November 9, 2022

To: Washington State Board of Health Members

From: Kelly Oshiro, Board Vice Chair

Subject: Petition for Rulemaking – Chapter 246-650 WAC, Newborn Screening; Mucopolysaccharidoses Type II (MPS II)

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 October 26, 2022, the Washington State Board of Health (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. The petition states that MPS II is a “devastating disease with a better outcome the earlier it is diagnosed, and treatment begins.” The petitioner requests this change because MPS II was recently added to the federal Recommended Uniform Screening Panel (RUSP). The RUSP provides a list of disorders that the Secretary of the Department of Health and Human Services (HHS) recommends for states to screen as part of their universal newborn screening programs.¹

MPS II, also known as Hunter’s Syndrome, is a rare hereditary metabolic condition that prevents the body’s ability to break down and process complex sugars, or glycosaminoglycans (GAGs), properly.^{2,3} This disease 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.

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

1. Health Resources and Services Administration (HRSA) | Recommended Uniform Screening Panel. Updated August 2022. Accessed October 27, 2022. <https://www.hrsa.gov/advisory-committees/heritable-disorders/rusp>
2. National Institute of Health | Mucopolysaccharidoses Fact Sheet | National Institute of Neurological Disorders and Stroke. Updated July 2022. Accessed October 27, 2022. <https://www.ninds.nih.gov/mucopolysaccharidoses-fact-sheet>
3. Health Resources and Services Administration | Mucopolysaccharidosis type II | Newborn Screening. Updated September 2022. Accessed October 27, 2022. <https://newbornscreening.hrsa.gov/conditions/mucopolysaccharidosis-type-ii>

(continued on the next page)

WAC 246-650-020 lists the conditions for which all Washington-born newborns are to be screened.

I have invited Molly Dinardo, Board Staff, and John Thompson, Director of the Department of Health's Newborn Screening Program, to provide a brief overview of the Board's process for adding a condition to the panel and share some brief background information on MPS II.

Recommended Board Actions:

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

The Board accepts the petition for rulemaking to amend Chapter 246-650 WAC to add Mucopolysaccharidoses Type II (MPS II) 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.

OR

The Board declines the petition for rulemaking to add MPS II as a condition for newborn screening in Chapter 246-650 WAC, and directs staff to work with the Department of Health to perform a qualifying assumption analysis to evaluate MPS II 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 MPS II against the Board's criteria for adding conditions to the newborn screening rule.

Staff

Molly Dinardo

To request this document in an alternate format or a different language, please contact Kelie Kahler, Washington State Board of Health Communication Manager, at 360-236-4102 or by email at kelie.kahler@sboh.wa.gov. TTY users can dial 711.

PO Box 47990 • Olympia, WA 98504-7990
360-236-4110 • wsboh@sboh.wa.gov • sboh.wa.gov