

# WASHINGTON STATE BOARD OF HEALTH

**Date:** March 10, 2021

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

**From:** Dr. Thomas Pendergrass, Board Vice Chair

**Subject:** Petition for Rulemaking – Petition for Rulemaking, chapter 246-650 WAC, Newborn Screening – Congenital Cytomegalovirus

## Background and Summary:

The Administrative Procedures Act (RCW 34.05.330) allows any person to petition a state agency to request 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 February 8, 2021 the Board received a petition for rulemaking from Mallory Baker, requesting new section in chapter 246-650 WAC requiring newborn screening for congenital cytomegalovirus (cCMV) for infants failing the newborn hearing screening. The petition states that six states have adopted mandates for cCMV and that several Washington State hospitals have existing processes for such screenings.

Congenital cytomegalovirus occurs when a pregnant individual is infected with cytomegalovirus (CMV) and subsequently passes the infection to their unborn child. cCMV is the most common congenital infection with a prevalence of approximately 0.58 percent. cCMV can result in hearing loss and is the leading cause of nonhereditary, sensorineural hearing loss. Additionally, cCMV can lead to developmental delay, vision loss, and seizures.

Currently, six states require targeted newborn screening for cCMV and an additional six states require education for the public and health professionals regarding cCMV. In addition, Ontario, Canada has implemented universal screening for cCMV. In Washington State, some healthcare facilities provide screening for cCMV in infants who fail the newborn hearing screening, including Seattle Children's Hospital and Sacred Heart Medical Center in Spokane.

The Board's authority under RCW 70.83.050 provides for the authority to define and adopt rules for screening Washington-born infants for heritable conditions. The Board uses a defined set of criteria that conditions are evaluated against to assess 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.

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I have invited Sam Pskowski, 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 to share background information on cCMV.

**Recommended Board Actions:**

The Board may wish to consider, amend if necessary, and adopt one of the following motions:

The Board accepts the petition for rulemaking to establish new sections in chapter 246-650 WAC to require newborn screening for congenital cytomegalovirus for infants who fail the newborn hearing 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

At this time, the Board declines the petition for rulemaking to establish new sections in chapter 246-650 WAC to require newborn screening for congenital cytomegalovirus for infants who fail the newborn hearing screening, but directs staff to compile additional preliminary information for presentation at the Board's October meeting so the Board can determine whether to establish a technical advisory committee to evaluate cCMV against the Board's criteria for adding conditions to the newborn screening rule.

**Staff**

Samantha Pskowski

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