DATE: December 30, 2025

TO: Hearing Attendees and Commenters –
Oregon Administrative Rules chapter 333, divisions 20, 77, 505, 520 - "Newborn Cytomegalovirus Screening and Diagnosis"

FROM: Brittany Hall, Hearing Officer and Administrative Rules Coordinator

cc: Gianna Bortoli, Early Hearing Detection and Intervention (EHDI) Program Coordinator
Family and Child Health, Public Health Division

SUBJECT: Presiding Hearing Officer's Report on Rulemaking Hearing and Public Comment Report

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Date of Hearing: December 17, 2025, via Microsoft Teams

Purpose of Hearing: The purpose of this hearing was to receive public testimony regarding the Oregon Health Authority (Authority), Public Health Division's proposed permanent amendments to Oregon Administrative Rules (OARs) in chapter 333, division 20, "Early Hearing Detection and Intervention" and adoption of new rules in this division to reorganize and update rules relating to hearing screening requirements. Additionally, the Oregon Health Authority, Public Health Division is proposing to adopt new rules in OAR in chapter 333, division 20 relating to the passage of HB 2685 (Oregon Laws 2025, Chapter 488) during the 2025 legislative session and permanently amend OAR chapter 333, division 077 relating to birthing centers and OAR chapter 333, divisions 505 and 520 relating to hospitals to ensure compliance with new congenital cytomegalovirus screening requirements.

The need for these rule changes arises from the passage of HB 2685 (2025), which mandates expanded targeted newborn screening for congenital cytomegalovirus (CMV) in Oregon. CMV is a common congenital infection that can cause significant health conditions in newborns, including hearing loss and developmental delays. Early detection through screening enables timely intervention and treatment, improving health outcomes and reducing long-term impacts. The existing rules did not include a standardized, evidence-based CMV screening protocol, nor did they address the associated reporting, education, and parent notification requirements now required by statute. This rule change ensures compliance with state law, improves consistency of care, and addresses documented disparities in access to early diagnosis and treatment among racial, ethnic, and linguistically diverse communities. By adopting these amendments and rules, the Oregon Health Authority aims to enhance newborn health, reduce inequities in care delivery, and fulfill its obligation to implement legislatively mandated public health practices.

Other proposed changes to the rules will clarify vague or inaccurate language. For OARs that are being updated to clarify vague or inaccurate language, the goal is to group sections of related topics together so information can be easily found, to make the rules easier to read, and to use inclusive and equity-focused language. Some language is proposed to be shortened or removed from OARs because it is already covered by Oregon Revised Statute.

Hearing Officer: Brittany Hall

Testimony Received: One individual provided testimony at the hearing.

Other Comments: Two individuals or organizations submitted written comments to OHA within the period allotted for public comment, which closed at 5:00 PM on December 22, 2025. Written comments are attached to this report as **EXHIBIT 1**.

Summary of Comments and Agency Responses:

OHA received written comments noting corrections needed throughout the proposed rule text and the associated protocols, which are detailed in the attached EXHIBIT 1.

Agency response: Thank you for your careful review, corrections have been made to the final rule text and protocols.

In written comments and oral testimony, OHA heard support for "Oregon's enactment of HB 2685 and the goal of earlier, targeted newborn screening for congenital cytomegalovirus (cCMV)." Oral testimony and written comments expressed concern that the draft structure of the OARs and the protocols "may unintentionally diminish otolaryngology (ENT) involvement in diagnostic evaluation and early management," and "places routine diagnostic and longitudinal 'touch points' predominantly with audiology without clearly defining when ENT involvement is required or expected." Written comments and oral testimony note that "the proposed rule only says that referral to otolaryngology 'should be considered' if audiological testing identifies hearing loss," which "is not sufficient." Written comments and oral testimony note that "early ENT involvement ensures families receive expert guidance regarding progressive hearing loss risk, middle-ear or structural concerns, and appropriate antiviral treatment, which may require coordination with infectious disease specialists. Without early ENT input, delays in care could lead to untreated hearing loss, especially in medically complex cases." Written comments and oral testimony acknowledge that "this may make initial testing more cumbersome in rural or limited-resource settings," but that "it is critical for timely, high-quality care."

Written comments and oral testimony request the following revisions:

1. Amend the list of recommendations following a positive urine PCR test to explicitly include referral to an ENT.
2. Include language that allows for referral to an ENT via telehealth.

Agency response: The Oregon Health Authority (OHA), Public Health Division, Early Hearing Detection and Intervention Program appreciates the feedback provided and remains committed to ensuring the health and wellbeing of newborns newly diagnosed with congenital cytomegalovirus. We have made changes to the protocol language to further highlight the involvement of pediatric otolaryngologists (Ear, Nose, and Throat, ENT) as important care providers for children diagnosed with congenital cytomegalovirus. The new language reads "A pediatric otolaryngologist can assess ear conditions and works closely with

audiologists to monitor a hearing loss. If hearing loss is identified by an audiologist, newborns should be referred to a pediatric otolaryngologist for additional evaluation and monitoring. Families may choose to learn more about the availability of hearing technology and a pediatric otolaryngologist can discuss available options." Telehealth referrals are not explicitly referenced in the protocol since they are considered inclusive of the term "referral."

EXHIBIT 1

From: Bortoli Gianna A
To: Dawn Nolt
Cc: Louise Vaz; Lorne Walker; HALL Brittany A; Mellony Bernal
Subject: RE: Notice of Proposed Rulemaking Has Been Filed for Congenital CMV Screening
Date: Wednesday, November 19, 2025 8:23:20 AM

Hi Dawn,

Thank you so much for reviewing these documents and offering those corrections, I'll make a note for the final versions. Please let us know if you have any additional comments and questions.

Kind Regards,
Gianna Bortoli (*she/her*)
Early Hearing Detection and Intervention (EHDI) Program Coordinator and Title V Child Health Lead
Phone (text message available): (971)442-7037
OHA Customer Service Survey

From: Dawn Nolt <[redacted]>
Sent: Tuesday, November 18, 2025 8:49 PM
To: Bortoli Gianna A <Gianna.A.Bortoli@oha.oregon.gov>
Cc: Louise Vaz <[redacted]>; Lorne Walker <[redacted]>
Subject: Fw: Notice of Proposed Rulemaking Has Been Filed for Congenital CMV Screening

Hi Gianna,

I hope this finds you well. I am a Peds ID colleague of Dr. Vaz. She is working with Dr. Walker on our institutional process.

Dr. Vaz forwarded the OHA document to me. I have a few corrections. The page numbers

refer to the entire PDF.

Page 12 and page 13: the following paragraph appears twice (and thus one can be removed): "The screening must be completed prior to discharge or within 14 days of age, whichever occurs earlier, unless parents or guardians refuse in writing. If the hospital or birthing center is part of a licensed Health Maintenance Organization facility, Screening must occur within 14 days of age.

Page 13: Under section "Diagnostic Testing, Imaging, Exams, and Referrals," a sentence should have the following correction: "confirmed by a positive urine PCR test within 21 days of age."

Pages 14, 20, and 26. for the Peds ID referral, a CMP should be included (CBC is listed twice).

Page 36. The first mention of initial screening is that it should be completed by 12 hours of birth. All subsequent mention indicate 8 hours of birth. This is a discrepancy.

A suggestion (not a correction): would be great that "mother" is changed to "birth parent." On pages 62, 66, and 67.

Have a lovely evening.

From: Louise Vaz <[redacted]>
Sent: Monday, November 17, 2025 7:58 AM
To: James Becton <[redacted]>; Gianou Knox <[redacted]>; Darren Malinoski <[redacted]>
Cc: Dawn Nolt <[redacted]>; Lorne Walker <[redacted]>; Van Ross <[redacted]>
Subject: FW: Notice of Proposed Rulemaking Has Been Filed for Congenital CMV Screening

Hello folks,
This is the latest from OHA to reference.

From: Bortoli Gianna A <Gianna.A.Bortoli@oha.oregon.gov>
Sent: Friday, November 14, 2025 11:27 AM
To: Louise Vaz <[redacted]>; Sheevaun Khaki <[redacted]>; Atwill Shelby N <Shelby.N.Atwill@odhsoha.oregon.gov>; Heather Durham <[redacted]>; Mandie Wiebers Jensen <[redacted]>; [redacted]; [redacted]; [redacted]; Stirling, Kara <[redacted]> <[redacted]>; Ben Hoffman

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OTOLARYNGOLOGY–
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Gianna Bortoli
Public Health Division Rules Coordinator
Oregon Health Authority
800 NE Oregon Street, Suite 825
Portland, OR 97232

December 19, 2025

Re: Public Comment on Proposed Rulemaking — "Newborn Cytomegalovirus Screening and Diagnosis (HB 2685, 2025)" OAR Chapter 333, Division 20 (Early Hearing Detection & Intervention), and related rules

From: American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS)

The American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) is the world's largest organization representing physicians specializing in the treatment of ear, nose, throat, and related head and neck conditions. Our more than 13,000 members include the nation's pediatric otolaryngologists—physicians who diagnose and manage congenital and acquired hearing loss, structural ear disorders, airway anomalies, and other conditions central to newborn hearing and cCMV follow-up.

AAO-HNS works closely with federal and state health agencies on early hearing detection, intervention, clinical guidelines, and quality-improvement efforts to ensure timely detection and medical-surgical care for infants with hearing loss.

The AAO-HNS strongly supports Oregon's enactment of HB 2685 and the goal of earlier, targeted newborn screening for congenital cytomegalovirus (cCMV). We applaud the Oregon Health Authority (OHA) for proposing updated Early Hearing Detection & Intervention (EHDI) rules to implement the law and for incorporating an equity lens into follow-up and family education.

At the same time, AAO-HNS is concerned that the proposed rule, as currently structured, may unintentionally diminish otolaryngology (ENT) involvement in diagnostic evaluation and early management.

T: 1-703-836-4444
F: 1-703-683-5100
W: www.entnet.org
A: 1650 Diagonal Road, Alexandria, VA 22314

We received feedback from practicing ENTs in Oregon, and they emphasized that all infants with confirmed cCMV, whether they fail the newborn hearing screen or not, should receive an initial ENT evaluation.

Early ENT involvement ensures that families receive expert guidance regarding progressive hearing loss risk, middle-ear or structural concerns, and appropriate antiviral treatment, which may require coordination with infectious disease specialists. Without early ENT input, delays in care could lead to untreated hearing loss, especially in medically complex cases. While we acknowledge this may make initial testing more cumbersome in rural or limited-resource settings, it is critical for timely, high-quality care.

HB 2685 directs OHA to develop and distribute a targeted newborn cCMV screening protocol and to adopt rules implementing that protocol. OHA has filed Notice of Proposed Rulemaking to amend OAR 333-020 and related OARs to implement the statute and to reorganize EHDI program rules. These rules rightly emphasize robust audiologic surveillance for infants identified via cCMV screening. However, the draft structure places routine diagnostic and longitudinal "touch points" predominantly with audiology without clearly defining when ENT involvement is required or expected.

To ensure optimal, equitable care for infants with suspected or confirmed cCMV-related hearing loss, we respectfully request targeted revisions to the proposed rules.

1. Amend the list of recommendations following a positive urine PCR test to explicitly include referral to an ENT.
2. Include language that allows for referral to an ENT via telehealth.

Include ENT as a "First-Line" Referral

The proposed rule only says that referral to otolaryngology "should be considered" if audiological testing identifies hearing loss. This is not sufficient. ENTs are the most highly trained and educated hearing health professionals. Our involvement is medically necessary in many cases, and the rules should clearly reflect that. We are much more aware of the implications of cCMV and understand the full spectrum of

treatment options available. Early ENT assessment can significantly change the patient's care plan and outcomes.

ENTs are the providers best able to answer parents' questions about the life-long implications of congenital cCMV infection and the possibility of future hearing loss and other symptoms.

Further, ENTs are the only healthcare providers specifically trained in medical and surgical interventions for cCMV infections. This includes the administration of anti-viral medications and determining whether surgical intervention is appropriate.

Including ENT evaluation earlier in the process will ensure that all cCMV positive newborns will receive the care that they need. Without ENT evaluation, there will be delays in care that can lead to untreated hearing loss.

Requested change: Add otolaryngology as a recommended referral after a confirmed cCMV infection, not just after hearing loss is identified.

Equity and access protections

While we do firmly believe that ENT evaluation is necessary for all cCMV positive newborns, we also recognize that rural regions of Oregon often have limited ENT access.

Allowing ENT consultation via telehealth will help ensure infants statewide receive timely specialty input. For those cases where a patient does not have access to an ENT, or their symptoms require specialized care, the AAO-HNS would welcome language that provides the flexibility for patients to be referred to an ENT via telehealth.

Requested change: Include language permitting ENT consult via telemedicine, when in-person ENT access would cause unacceptable delay.

This change ensures infants in underserved areas still receive timely specialty input and reduces disparities.

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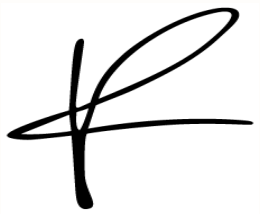
AAO-HNS again applauds Oregon's leadership in adopting targeted newborn cCMV screening. We welcome the opportunity to assist OHA staff with draft rule language, parent education materials, and reporting templates that ensure audiologic surveillance and timely access to otolaryngology care for cCMV infected newborns.

Thank you for your attention to this critical public health measure. Should you have any questions, please contact Aaron Castelo, Senior Advisor for State Advocacy, at acastelo@entnet.org.

Sincerely,



Rahul K. Shah, MD, MBA
Executive Vice President and Chief Executive Officer
American Academy of Otolaryngology–Head and Neck Surgery

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