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RULES:

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AMEND: 333-020-0125

NOTICE FILED DATE: 11/13/2025

RULE SUMMARY: 333-020-0125 Definitions:

- The following definitions are added to this rule. These were not previously defined in these rules, but are used in these rules so a definition is needed:
 - “Congenital cytomegalovirus (cCMV)” - this definition was added to define what congenital cytomegalovirus means in these rules.
 - “Congenital Cytomegalovirus (cCMV) Diagnostic Testing and Care Protocol” - this definition was added to reference the diagnostic testing and care protocol that the Oregon Health Authority was required to develop as part of HB 2685 (2025).
 - “Congenital cytomegalovirus (cCMV) screening” - this definition was added to define what congenital cytomegalovirus screening means in these rules.
 - “Congenital Cytomegalovirus (cCMV) Screening Protocol” - this definition was added to reference the congenital cytomegalovirus screening protocol that the Oregon Health Authority was required to develop as part of HB 2685 (2025).
 - “Cytomegalovirus (CMV)” - this definition was added to define what cytomegalovirus means in these rules.
 - “Health maintenance organization” - this definition was added to reference the statute where this term was defined.
 - “Newborn hearing screening test registry” - this definition was added to reference the statute where this term is defined.
 - “Non-mandated facility” - this definition was added to define what non-mandated facility means in these rules.
 - “Prenatal healthcare provider” - this definition was added to define what prenatal healthcare provider means in these rules.

- o "Prenatal healthcare services"- this definition was added to define what prenatal healthcare services means in these rules.
- o "These Rules" - this definition was added to define Oregon administrative rules these definitions apply to.
- The following definitions have significant changes:
- o "Birthing facility" - clarifies that birthing facility means hospital or birthing center where the child was born to align with language referenced in statute.
- o "Early intervention services" or "EI services" - adds language to align with statute.
- o "Early intervention facility" - removes "public or private" from language to align with statute.
- o "Hearing screening" - remove language that references test being "performed on both ears using technologies approved" to avoid confusion with different testing scenarios and align recommendations outlined in the "Hearing Screening Protocol".
- o "Hearing Screening Protocol" – this definition has been updated to provide a dated version of the protocol incorporated by reference. The protocol has been updated to a newer format and contact information was updated, but no other substantive changes were made.
- o "Hospital" - this definition now references ORS 442.015 to align with statute.
- o "Mandated facility"- this definition now includes how the authority determines this facility type.
- o "Refer" - redefined to align with meaning with other types of hearing screening results defined in these rules.
- o "Risk factor" - removed reference to outside entities to ensure alignment with best practice guidelines determined by the Oregon Health Authority.
- The following definitions were removed from these rules:
- o "Tracking and recall system" - this definition was removed as under it is covered under the "Newborn hearing screening test registry" definition.
- o "Public education institution" - this definition was removed as it is covered under the overarching definition of "early intervention facility".
- o "Private educational institution" - this definition was removed as it is covered under the overarching definition of "early intervention facility".
- o "Hearing screening registry" - this definition was removed as under it is covered under the "Newborn hearing screening test registry" definition.
- o "EI" - this was removed as it was duplicative and is covered under the "early intervention services" definition.

CHANGES TO RULE:

333-020-0125

Definitions ¶

As used in ~~these rules~~OAR 333-020-0125 through 333-020-0187:¶

- (1) "Advisory committee" means the Early Hearing Detection and Intervention (EHDI) Advisory Committee.¶
- (2) "Authority" means the Oregon Health Authority.¶
- (3) "Birthing center" has the same meaning as "freestanding birthing center" in ORS 442.015.¶
- (4) "Birthing facility" means the ~~location of~~hospital or birthing center where a child is birth, including hospital or birthing center. Oregon.¶
- (5) "Child" means any individual who is under 36 months of age.¶
- (6) "Congenital" means present at birth.¶
- (7) "Congenital cytomegalovirus (cCMV)" means the transmission of a cytomegalovirus (CMV) infection from a pregnant person to their fetus during pregnancy and the infection is confirmed in the newborn through congenital cytomegalovirus screening.¶
- (8) "Child" means any individual who is under 36 months and congenital Cytomegalovirus (cCMV) Diagnostic Testing and Care Protocol means the evidence-based protocol for infant and early childhood diagnostic testing and care following a positive screening result for congenital cytomegalovirus, established by the Authority, dated January 1, 2026, incorporated herein by this reference.¶
- (6) "Congenital" means present at birth.¶

~~(7) reference.~~¶

(9) "Congenital cytomegalovirus (cCMV) screening" means an evidence-based assessment including testing using a newborn's bodily fluids to determine the need for additional diagnostic testing, as described in the Authority's Congenital Cytomegalovirus (cCMV) Screening Protocol.¶

(10) "Congenital Cytomegalovirus (cCMV) Screening Protocol" means the evidence-based protocol, established by the Authority, to conduct congenital cytomegalovirus (cCMV) screenings on newborns, dated January 1, 2026, incorporated herein by this reference.¶

(11) "Cytomegalovirus (CMV)" means a virus that can infect people of all ages and may cause congenital infections in newborns that may result in symptoms including hearing loss, developmental delays, and vision loss.¶

(12) "Diagnostic facility" means any facility that conducts pediatric diagnostic hearing evaluations.¶

(813) "Diagnostic testing" means physiologic and behavioral testing on children to determine the presence or absence, type and degree of a hearing loss, using procedures specified by the Authority, for the purposes of establishing a diagnosis and serving as a basis for initiating early intervention.¶

~~(9) services.~~¶

(14) "Director" means the Director of the Public Health Division within the Oregon Health Authority: or their designee.¶

(105) "Early Hearing Detection and Intervention Program" or "EHDI" means the program, within the Public Health Division of the Oregon Health Authority, responsible for the implementation of ORS 433.298 and 433.321-433.327.¶

(116) "Early intervention services" or "EI services" means services for children with disabilities from birth until three years of age that are designed to meet the developmental needs of children with disabilities and the needs of the family related to enhancing supporting the child's development, and that are selected in collaboration with the parents and caregivers.¶

(12) "Early intervention facility" is any public or private educational institution providing early intervention services.¶

(13) "EI" (or, alternately, "EI/ECSE") means the Early Intervention/Early Childhood Special Education Program of the Office of Student Services of the Oregon Department of Education. EI/ECSE provides early intervention services, and provided under public supervision by personnel qualified in accordance with criteria established by rules of the State Board the Oregon Department of Education and in conformity with an individualized family service plan, as defined in ORS 343.035.¶

(147) "Hearing screening" means a physiologically based test procedure performed on both ears using technologies approved by the Early intervention facility means any educational institution providing early intervention services.¶

(18) "Health maintenance organization" has the same meaning given that term in ORS 750.005.¶

(19) "Hearing screening" means a physiologically based hearing test established by the Authority, as described in the Hearing Screening Protocol.¶

(1520) "Hearing Screening Protocol" means an Oregon specific protocol based on evidence the evidence-based protocol for newborn hearing screening and best practice for newborn hearing screening, to be implemented by all hearing screening facilities, and available from the Oregon Health Authority established by the Authority, dated January 1, 2026, incorporated herein by this reference.¶

(21) "Hospital" has the meaning given that term in ORS 442.015.¶

(22) "Mandated facility" means any hospital or birthing center with more than 200 live births per calendar year, as determined by information provided by the Oregon Health Authority's Center for Health Statistics.¶

(1623) "Newborn" means a child less than one month of age.¶

(24) "Newborn hearing screening test registry" (or, alternately, "EHDI Early Hearing Detection and Intervention Information System") means a database of newborn children and information related to their hearing status, as defined in ORS 433.323, including but not limited to results of hearing screenings, diagnostic testing, and early intervention referrals, designed for the purpose of contacting families and health care providers.¶

(1725) "Hospital" means any health care facility licensed by the State of Oregon and meeting the definition of "hospital" in ORS 442.015.¶

(18) "Non-mandated facility" means any hospital or birthing center with more than 200 live births per calendar year.¶

(19) "Newborn" means a child less than one month of age, as determined by information provided by the Oregon Health Authority's Center for Health Statistics.¶

(206) "Pass" means a hearing screening result that indicates that a child's hearing meets the pass criteria identified in the Hearing Screening Protocol, provided by the Oregon Health Authority EHDI program, or as determined by national best practice guidelines.¶

(247) "Private educational institution" means any private institution providing early intervention services as defined in ORS 343.035 or the equivalent and which have been accepted for the Office of Student Services of the

Oregon Department of Education's "Approved Private Schools" list. antenatal healthcare provider" means any medical care provider providing prenatal healthcare services, including but not limited to physicians, physician associates, nurse practitioners, certified nurse midwives, and direct entry midwives.¶

(228) "Public educational institution" means any public educational institution providing early intervention services, as defined in ORS 343.035. antenatal healthcare services" means the medical care and other services provided to a pregnant person during pregnancy.¶

(239) "Refer" means a child hearing screening result that indicates that a child's hearing did not meet the pass criteria identified in these rules Hearing Screening Protocol as determined by best practice guidelines, and needs more testing to determine the presence or absence of a hearing loss.¶

(2430) "Risk factor" means any one of the risk indicators determined by the Joint Committee for Infant Hearing best practice guidelines as being associated with either congenital or delayed-onset hearing loss.¶

(2531) "Screening facility" means any facility that conducts hearing screenings, as defined in these rules.¶

(26) "Tracking and recall system" (or, alternately, "EHDI Information System") means a database of children and information related to their hearing status designed to identify and contact the parent or guardian of a child for the purposes of assisting in testing and in enrollment of the child in early intervention services for a child.¶

(32) "These rules" means OAR 333-020-0125 through 333-020-0187.

Statutory/Other Authority: ORS 433.323

Statutes/Other Implemented: ORS 433.321-433.327, ORS 433.298

RULE ATTACHMENTS MAY NOT SHOW CHANGES. PLEASE CONTACT AGENCY REGARDING CHANGES.

Congenital Cytomegalovirus (cCMV) Diagnostic Testing and Care Protocol

Guidance for primary care providers caring for children diagnosed with congenital cytomegalovirus (cCMV)

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Purpose

To provide diagnostic testing and care recommendations for primary care providers caring for newborns diagnosed with congenital cytomegalovirus (cCMV) in Oregon.

Congenital Cytomegalovirus (cCMV) Overview

Cytomegalovirus (CMV) is a common infection in newborns with an estimated 1 in 200 babies infected at birth. CMV spreads easily, especially in settings with children such as childcare, and often has no symptoms. Babies born with CMV and diagnosed within 21 days of age are considered to have congenital cytomegalovirus (cCMV) which can cause long-term health impacts. Of newborns infected with cCMV, around 10% are symptomatic at birth while around 90% are asymptomatic. While most babies with cCMV will grow and develop typically, some may experience serious and permanent health issues, including problems with their brain, eyes, and inner ears that can be present at birth or develop later in childhood. In rare cases, cCMV may cause death.

Hearing loss is among the most frequent long-term impacts of cCMV. It is the most common non-hereditary cause of sensorineural hearing loss in children, accounting for 20% of diagnoses at birth and 25% by age four. Hearing loss from cCMV can be progressive or late-onset, making ongoing monitoring by a child's primary care provider and audiologist essential to support communication, language acquisition, and developmental outcomes.

Screening newborns for cCMV risk factors and clinical signs within 21 days of age helps with early detection, access to care, and enrollment in early intervention services to support long-term health outcomes for these infants. This timing helps determine whether the infection was acquired congenitally (present at birth) or postnatally (acquired after birth). Postnatal infections are generally not associated with serious health concerns, whereas congenital infections can impact long-term development.

Following a positive test result from cCMV screening, newborns should complete additional diagnostic lab-based testing and imaging as well as further evaluation by various health care professionals for possible treatment and ongoing monitoring.

Oregon Congenital Cytomegalovirus (cCMV) Screening Rules

Oregon licensed hospitals and birthing centers must screen newborns for cCMV pursuant to Oregon Administrative Rules 333-020-0125 through 333-020-0187. The hospital or birthing center must conduct cCMV screening based on the Congenital Cytomegalovirus (cCMV) Screening Protocol developed by the Oregon Health Authority (OHA), which includes:

- assessing each newborn for known risk factors and clinical signs of cCMV, and
- as necessary, based on the presence of one or more of the risk factors or clinical signs, conduct CMV testing.

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 shall occur within 14 days of age.

Below are the list of risk factors and clinical signs associated with cCMV that all newborns must be assessed for:

- Birth parent diagnosed with primary CMV infection during pregnancy
- Did not pass the newborn hearing screening (one or both ears)
- Symmetric small for gestational age: birth weight <10th percentile
- Microcephaly: head circumference <3rd percentile based on gestational age, recommend remeasuring 24 hours after delivery
- Unexplained petechial rash or blueberry muffin rash
- Unexplained abnormal red reflex, retinitis, or cataracts
- Unexplained fetal hydrops or ascites, abdominal calcifications, or thickened bowel on prenatal ultrasound
- Unexplained or persistent hepatomegaly, splenomegaly, or elevated liver function tests (AST or ALT >100 U/L or direct bilirubin >1.0 mg/dL)
- Unexplained abnormal brain imaging including ventriculomegaly, intracerebral calcifications, white matter changes, periventricular echogenicity, cortical or cerebellar malformations, or migration abnormalities
- Unexplained thrombocytopenia (platelets <100,000/mm³)

Following a positive test result, hospital and birthing center staff must inform the newborn's parent or guardian and primary care provider or their designated staff through direct personal communication. Document all interactions in the newborn's medical record.

Congenital Cytomegalovirus (cCMV) Diagnostic Testing and Care Recommendations

Around 10% of infants diagnosed with cCMV are symptomatic at birth and early access to treatment and care may improve their long-term health outcomes.

Asymptomatic infants with cCMV may develop symptoms later. All children diagnosed with cCMV should be closely monitored for ongoing development and care.

Diagnostic Testing, Imaging, Exams, and Referrals

Following receipt of positive urine CMV PCR results, primary care providers caring for a newly diagnosed infant are encouraged to complete additional diagnostic lab-based testing, imaging, and referrals. If a saliva sample was used, cCMV diagnosis should be confirmed by a positive urine PCR test within 21 days of age.

Following a positive urine PCR test result, the following are recommended to evaluate for further evidence and extent of cCMV disease:

- Complete Blood Count (CBC) with differential
- Complete Metabolic Panel (CMP)
- Head Ultrasound (HUS)
- Physical exam with height, weight, and head circumference measurements
- Referral to audiology for diagnostic audiology evaluation
- Referral to Early Intervention services

The following referrals are recommended to support ongoing continuity of care and evaluation:

- Pediatric Infectious Disease
 - When possible, it is preferred that results from CBC with differential, CMP, HUS (or other brain imaging), physical exam, and diagnostic audiology

evaluation be available prior to being seen by Pediatric Infectious Disease specialist for clinical management.

- Pediatric Otolaryngology (ENT) if hearing loss is identified by audiology
- Pediatric Neurology if abnormal imaging, microcephaly, hearing loss, or abnormal neurological exam
- Pediatric Ophthalmology or Pediatric Optometry
 - When possible, indicate any abnormal eye findings, hearing loss, or abnormal neurological exam on referral.

Types of Referrals

Pediatric Infectious Disease (ID)

A pediatric infectious disease specialist can assess appropriate treatment and guide families through available options. For some infants, antiviral medication may improve hearing and speech development. If eligible, treatment is most effective when started early and should be considered before 13 weeks of age.

Pediatric Audiology

An audiologist measures hearing ability in infants. Newborns should be referred to an audiologist as soon as possible to complete diagnostic audiology evaluations, regardless of newborn hearing screening results. Results from audiology evaluation should be obtained no later than 12 weeks of age to allow for consideration of treatment options by Pediatric Infectious Disease specialist. Children with cCMV are at high risk for progressive or late-onset sensorineural hearing loss so ongoing audiology monitoring is essential.

Few audiologists throughout the state have the skills and equipment to test infants under 6 months of age. Please refer to the OHA EHDI website (healthoregon.org/ehdi) for a list of available providers. Referring to audiologists not on this list may result in incomplete or inaccurate testing.

Recommended follow-up schedule for children with a cCMV diagnosis:

- Every 3 months until 1 year of age
- Every 6 months from 1 to 3 years of age

- Annually until 6 years of age

More frequent evaluations may be needed based on audiologist recommendation.

Pediatric Otolaryngology (ENT)

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.

Pediatric Neurology

A pediatric neurologist can assess for neurological disorders. Infants with cCMV may develop neurological conditions that require ongoing monitoring. If a newborn has abnormal brain imaging, microcephaly, hearing loss, or an abnormal neurological exam, they should be referred to a pediatric neurologist for additional evaluation.

Pediatric Ophthalmology or Pediatric Optometry

A pediatric ophthalmologist or pediatric optometrist can assess for eye conditions and discuss need for assistive technology such as glasses. Children with cCMV are at risk for progressive or late-onset vision loss so ongoing vision monitoring is essential. Newborns should be referred to a pediatric ophthalmologist or pediatric optometrist and should indicate if abnormal eye findings, hearing loss, or abnormal neurological exam were identified.

More frequent evaluations may be needed based on provider recommendation.

Early Intervention Services

Children diagnosed with cCMV are eligible for Early Intervention services through the Oregon Department of Education to monitor and support ongoing development. Early Intervention services provide free, timely, and individualized services that enhance learning and development through everyday opportunities for all infants, toddlers, and young children with disabilities. All children with cCMV should be referred to Early Intervention Services as soon as possible following a confirmed diagnosis.

More information on the Oregon Department of Education Early Intervention and Early Childhood Special Education (EI/ECSE) can be found on this webpage:
<https://www.oregon.gov/ode/students-and-family/specialeducation/earlyintervention/Pages/default.aspx>

Ongoing Monitoring

PCPs should consider frequent monitoring of child's growth and development due to progressive symptoms. Children with cCMV may have difficulties with hearing, vision, communication, growth, cognition, learning, and motor coordination.

All children with cCMV are recommended to be monitored by an audiologist, even if they pass the newborn hearing screening, because they are at risk of progressive hearing loss. For children with cCMV, families should plan for audiology visits every 3 months until 1 year of age, then every 6 months until 3 years of age, then yearly until 6 years of age. More frequent evaluations may be needed based on audiologist recommendation.

Congenital Cytomegalovirus (cCMV) Diagnostic Testing and Care Process Map

To view the Congenital Cytomegalovirus (cCMV) Diagnostic Testing and Care Process Map, please refer to the attachment at the end of this document or visit Oregon.gov/CMV.

Reporting Requirements

cCMV is not a reportable condition in Oregon.

Additional Resources

To find more information and resources about Cytomegalovirus (CMV) prevention, testing, and care in Oregon, visit Oregon.gov/CMV.

American Academy of Audiology on Congenital Cytomegalovirus:

<https://www.audiology.org/consumers-and-patients/hearing-and-balance/congenital-cytomegalovirus-cmv-infection/>

American Academy of Pediatrics on Cytomegalovirus: <https://www.aap.org/en/patient-care/congenital-cytomegalovirus-ccmv>

American College of Obstetricians and Gynecologists on Cytomegalovirus in Pregnancy: <https://www.acog.org/clinical-information/physician-faqs/cytomegalovirus-in-pregnancy>

Center for Disease Control (CDC) on CMV in Newborns:

<https://www.cdc.gov/cytomegalovirus/congenital-infection/index.html>

National CMV Foundation: <https://www.nationalcmv.org/>

Acknowledgements and Contributors

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You can get this document in other languages, large print, braille or a format you prefer free of charge. Contact the Early Hearing Detection and Intervention (EHDI) Program at Oregon.EHDI@odhsoha.oregon.gov or 888-917-4327. We accept all relay calls.

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Congenital Cytomegalovirus (cCMV) Diagnostic Testing and Care Process Map

Primary Care Provider Recommendations



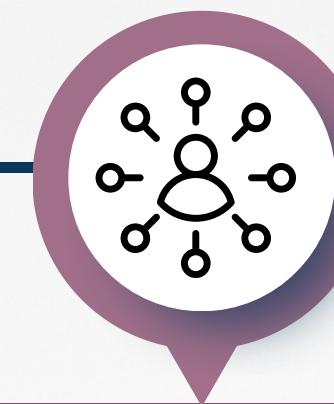
Oregon.gov/CMV



Review and Order

Following receipt of positive urine CMV test results within 21 days of age, the newborn's primary care provider is encouraged to complete the following to evaluate for further evidence and extent of cCMV disease as soon as possible:

- Complete Blood Count (CBC) with differential
- Complete Metabolic Panel (CMP)
- Head Ultrasound (HUS)
- Physical exam with height, weight, and head circumference measurements
- Referral to audiology for diagnostic audiology evaluation
- Referral to Early Intervention services



Refer

The primary care provider may consider the following referrals:

- Pediatric Infectious Disease
 - When possible, it is preferred that results from CBC with differential, CMP, HUS (or other brain imaging), physical exam, and diagnostic audiology evaluation be available prior to being seen by Pediatric Infectious Disease specialist for clinical management.
- Pediatric Otolaryngology (ENT) if hearing loss is identified by audiology
- Pediatric Neurology if abnormal imaging, microcephaly, hearing loss, or abnormal neurological exam
- Pediatric Ophthalmology or Pediatric Optometry
 - When possible, indicate any abnormal eye findings, hearing loss, or abnormal neurological exam on referral.



Monitor

Primary care providers are encouraged to consider frequent monitoring of a child's growth and development due to progressive symptoms. Children with cCMV may have difficulties with hearing, vision, and cognition leading to possible developmental delays.

All children with cCMV are recommended to be monitored by an audiologist, even if they pass the newborn hearing screening, because they are at risk of progressive hearing loss. For children with cCMV, the American Academy of Audiology recommends audiology visits every 3 months until 1 year of age, then every 6 months until 3 years of age, then yearly until 6 years of age. More frequent evaluations may be needed based on audiologist recommendation.

Step 1

Step 2

Step 3

Congenital Cytomegalovirus (cCMV) Screening Protocol

Guidance for Oregon Licensed Hospitals and Birthing Centers

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Purpose

To provide a standard protocol for expanded targeted congenital cytomegalovirus (cCMV) screening at licensed hospitals and birthing centers to support the health and wellbeing of newborns in Oregon.

Congenital Cytomegalovirus (cCMV) Overview

Cytomegalovirus (CMV) is a common infection in newborns with an estimated 1 in 200 babies infected at birth. CMV spreads easily, especially in settings with children such as childcare, and often has no symptoms. Babies born with CMV and diagnosed within 21 days of age are considered to have congenital cytomegalovirus (cCMV) which can cause long-term health impacts. Of newborns infected with cCMV, around 10% are symptomatic at birth while around 90% are asymptomatic. While most babies with cCMV will grow and develop typically, some may experience serious and permanent health issues, including problems with their brain, eyes, and inner ears that can be present at birth or develop later in childhood. In rare cases, cCMV may cause death.

Hearing loss is among the most frequent long-term impacts of cCMV. It is the most common non-hereditary cause of sensorineural hearing loss in children, accounting for 20% of diagnoses at birth and 25% by age four. Hearing loss from cCMV can be progressive or late-onset, making ongoing monitoring by a child's primary care provider and audiologist essential to support communication, language acquisition, and developmental outcomes.

Screening newborns for cCMV risk factors and clinical signs within 21 days of age helps with early detection, access to care, and enrollment in early intervention services to support long-term health outcomes for these infants. This timing helps determine whether the infection was acquired congenitally (present at birth) or postnatally (acquired after birth). Postnatal infections are generally not associated with serious health concerns, whereas congenital infections can impact long-term development.

Following a positive test result from cCMV screening, newborns should complete additional diagnostic lab-based testing and imaging as well as further evaluation by various health care professionals for possible treatment and ongoing monitoring.

Congenital Cytomegalovirus (cCMV) Screening Rules

Oregon licensed hospitals and birthing centers must screen newborns for cCMV pursuant to Oregon Administrative Rules 333-020-0125 through 333-020-0187. The hospital or birthing center must conduct cCMV screening based on this protocol, which includes:

- assessing each newborn for known risk factors and clinical signs of cCMV, and
- as necessary, based on the presence of one or more of the risk factors or clinical signs, conduct CMV testing.

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.

cCMV Screening and Testing Overview

Hospitals and birthing center must assess a newborn for the following risk factors and clinical signs:

- Birth parent diagnosed with primary CMV infection during pregnancy
- Did not pass the newborn hearing screening (one or both ears)
- Symmetric small for gestational age: birth weight <10th percentile
- Microcephaly: head circumference <3rd percentile based on gestational age, recommend remeasuring 24 hours after delivery
- Unexplained petechial rash or blueberry muffin rash
- Unexplained abnormal red reflex, retinitis, or cataracts
- Unexplained fetal hydrops or ascites, abdominal calcifications, or thickened bowel on prenatal ultrasound
- Unexplained or persistent hepatomegaly, splenomegaly, or elevated liver function tests (AST or ALT >100 U/L or direct bilirubin >1.0 mg/dL)

- Unexplained abnormal brain imaging including ventriculomegaly, intracerebral calcifications, white matter changes, periventricular echogenicity, cortical or cerebellar malformations, or migration abnormalities
- Unexplained thrombocytopenia (platelets <100,000/mm³)

For newborns transferred from one facility to another or admitted to the neonatal intensive care unit (NICU), please see the section on [Special Populations](#).

If any of the risk factors or clinical signs above are present, the hospital or birthing center must conduct CMV testing using Polymerase Chain Reaction (PCR) testing of urine or saliva specimens, with urine being the preferred specimen due to its higher diagnostic reliability. All specimens for CMV testing shall be collected prior to discharge. If saliva PCR testing is used and returns a positive result, a confirmatory urine PCR test should be performed within 21 days of age to confirm diagnosis.

Hospitals and birthing centers are encouraged to inform parents or guardians at the time of discharge about the status of the newborn's CMV testing (e.g., results pending, test not completed). If results are not yet available at discharge, facilities are encouraged to provide information on recommended follow-up steps should the test return positive.

Parents or guardians of the newborn must be informed of positive PCR test results through direct personal communication as specified in OAR 333-020-0175, prior to discharge. Additionally, the newborn's primary care provider (PCP) on record must be informed of a positive CMV test result through direct personal communication to PCP or their designated staff as specified in OAR 333-020-0175. All communications must be documented in the newborn's medical record.

Following receipt of results, hospital and birthing center staff are encouraged to:

- document all CMV test results in the newborn's medical record,
- inform PCP that confirmatory urine PCR testing is needed following a positive saliva PCR test to confirm diagnosis,
- inform PCP of inconclusive CMV test results through direct personal communication to PCP or their designated staff and document all interactions in the newborn's medical record, and

- add the diagnosis “Congenital CMV Infection” (ICD-10 code is P35.1) to the problem list in the newborn’s medical record if positive results are received prior to the newborn’s discharge.

Expanded Targeted Congenital Cytomegalovirus (cCMV) Screening Process Map

To view the Expanded Targeted Congenital Cytomegalovirus (cCMV) Screening Process Map, please refer to the attachment at the end of this document or visit Oregon.gov/CMV.

Additional Health Professional Recommendations

Hospital and Birthing Center Recommendations

Hospital and birthing centers are encouraged to:

- Establish protocols for data collection and recording of CMV testing results.
- Ensure adequate training for all testing personnel to conduct CMV testing effectively using recommended methods and procedures and ensure the maintenance of comprehensive training records.
- Develop facility processes for placing the order for CMV testing following a newborn meeting the screening criteria for cCMV. Facilities may consider adopting a standing order policy to reduce delays and improve compliance.

Primary Care Provider Recommendations

For detailed recommendations on cCMV diagnostic testing and care, review OHA’s Congenital Cytomegalovirus (cCMV) Diagnostic Testing and Care Protocol listed on Oregon.gov/CMV. For brief overview, see the information below.

Following receipt of positive urine CMV test results within 21 days of age, the newborn’s primary care provider is encouraged to complete the following to evaluate for further evidence and extent of cCMV disease as soon as possible:

- Complete Blood Count (CBC) with differential
- Complete Metabolic Panel (CMP)
- Head Ultrasound (HUS)

- Physical exam with height, weight, and head circumference measurements
- Referral to audiology for diagnostic audiology evaluation
- Referral to Early Intervention services

Referrals

The primary care provider may consider the following referrals:

- Pediatric Infectious Disease
 - When possible, it is preferred that results from CBC with differential, CMP, HUS (or other brain imaging), physical exam, and diagnostic audiology evaluation be available prior to being seen by Pediatric Infectious Disease specialist for clinical management.
- Pediatric Otolaryngology (ENT) if hearing loss is identified by audiology
- Pediatric Neurology if abnormal imaging, microcephaly, hearing loss, or abnormal neurological exam
- Pediatric Ophthalmology or Pediatric Optometry
 - When possible, indicate any abnormal eye findings, hearing loss, or abnormal neurological exam on referral.

Ongoing Monitoring

PCPs should consider frequent monitoring of child's growth and development due to progressive symptoms. Children with cCMV may have difficulties with hearing, vision, communication, growth, cognition, learning, and motor coordination.

All children with cCMV are recommended to be monitored by an audiologist, even if they pass the newborn hearing screening, because they are at risk of progressive hearing loss. For children with cCMV, families should plan for audiology visits every 3 months until 1 year of age, then every 6 months until 3 years of age, then yearly until 6 years of age. More frequent evaluations may be needed based on audiologist recommendation.

Reporting Requirements

cCMV is not a reportable condition in Oregon.

Special Populations

Hospital Transfers and Neonatal Intensive Care Unit (NICU) Patients

If a newborn is transferred from one facility to another prior to cCMV screening occurring, then it is the responsibility of the receiving facility to ensure that cCMV screening is completed. If the newborn was screened for cCMV prior to transfer, the transferring facility must provide the status of cCMV screening to the receiving facility upon transfer.

For newborns where a hearing screening cannot be accomplished prior to 14 days of age due to gestational age or other medical reasons, the newborn shall be screened for the other risk factors and clinical signs, as listed in this protocol, to determine if CMV testing is recommended.

For newborns that have one or more risk factors and clinical signs of cCMV and CMV testing cannot be accomplished prior to 14 days of age for medical reasons, testing for CMV is left to the discretion of the medical practitioner caring for the newborn and should be considered up to 21 days of age.

If a newborn tests positive for CMV and remains in care, the hospital is encouraged to order additional diagnostic testing and follow care recommendations outlined in the Congenital Cytomegalovirus (cCMV) Diagnostic Testing and Care Protocol.

Multiple Births

In cases where a pregnant individual gives birth to multiple infants (e.g., twins, triplets), it is possible for one or more infants to be infected with CMV, while others may not be. If any one infant in a multiple birth presents with risk factors or clinical signs that meet the criteria for CMV testing outlined in this protocol, then all other infants from the same pregnancy must also be tested, regardless of whether they individually meet the screening criteria.

Testing Refusal

Parents or guardians of a newborn may refuse cCMV screening. Hospital and birthing center staff must obtain a signed refusal form at the time of the screening, and it

should be retained in the child's medical record for the period of time defined by the hospital or birthing center policy.

Additional Resources

To find more information and resources about Cytomegalovirus (CMV) prevention, testing, and care in Oregon, visit Oregon.gov/CMV.

American Academy of Audiology on Congenital Cytomegalovirus:

<https://www.audiology.org/consumers-and-patients/hearing-and-balance/congenital-cytomegalovirus-cmv-infection/>

American Academy of Pediatrics on Congenital Cytomegalovirus:

<https://www.aap.org/en/patient-care/congenital-cytomegalovirus-ccmv>

American College of Obstetricians and Gynecologists on Cytomegalovirus in Pregnancy: <https://www.acog.org/clinical-information/physician-faqs/cytomegalovirus-in-pregnancy>

Center for Disease Control (CDC) on Congenital Cytomegalovirus in Newborns:

<https://www.cdc.gov/cytomegalovirus/congenital-infection/index.html>

National CMV Foundation: <https://www.nationalcmv.org/>

Acknowledgements and Contributors

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You can get this document in other languages, large print, braille or a format you prefer free of charge. Contact the Early Hearing Detection and Intervention (EHDI) Program at Oregon.EHDI@odhsoha.oregon.gov or 888-917-4327. We accept all relay calls.

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Oregon.gov/CMV

Expanded Targeted Congenital Cytomegalovirus (cCMV) Screening Process Map

Hospital and Birthing Center Responsibilities



Oregon.gov/CMV



Screen

All newborns must be screened for the following risk factors and clinical signs associated with congenital cytomegalovirus (cCMV) within 14 days of age and prior to discharge, whichever occurs earlier:

- Birth parent diagnosed with primary CMV infection during pregnancy
- Did not pass the newborn hearing screening (one or both ears)
- Symmetric small for gestational age: birth weight <10th percentile
- Microcephaly: head circumference <3rd percentile based on gestational age, recommend remeasuring 24 hours after delivery
- Unexplained petechial rash or blueberry muffin rash
- Unexplained abnormal red reflex, retinitis, or cataracts
- Unexplained fetal hydrops or ascites, abdominal calcifications, or thickened bowel on prenatal ultrasound
- Unexplained or persistent hepatomegaly, splenomegaly, or elevated liver function tests (AST or ALT >100 U/L or direct bilirubin >1.0 mg/dL)
- Unexplained abnormal brain imaging including ventriculomegaly, intracerebral calcifications, white matter changes, periventricular echogenicity, cortical or cerebellar malformations, or migration abnormalities
- Unexplained thrombocytopenia (platelets <100,000/mm³)



Test

Any newborns presenting with one or more of the risk factors and clinical signs must receive CMV testing within 14 days of age and prior to discharge, whichever occurs earlier, unless the parents or guardians refuse in writing.

Collect urine for CMV PCR test. Urine is the preferred specimen for testing due to its higher diagnostic reliability. If unable to collect urine, saliva CMV PCR test may be used. If saliva is used, wait at least 1 hour after consumption of breastmilk to avoid false positives. Saliva CMV PCR tests that return a positive result should follow up with urine CMV PCR testing within 21 days of age to confirm diagnosis.



Inform

It is encouraged to inform parents or guardians of newborn at discharge of the status of CMV testing (e.g. pending results, not completed, etc.). If results have not been received prior to discharge, it is encouraged to include follow up steps in the event of a positive results.



Document and Alert

Requirements upon receipt of positive PCR test results:

- Inform the newborn's primary care provider (PCP) on record of any positive CMV test results through direct personal communication to PCP or their designated staff. Document all interactions in the newborn's medical record.
- Inform the newborn's parent or guardians of newborn of any positive CMV test result, through direct personal communication if possible. Document all interactions in the newborn's medical record.

Recommendations upon receipt of results:

- All results (e.g. positive, negative, contaminated, etc.) should be included in the newborn's medical record.
- Inform PCP that confirmatory urine PCR testing is needed following a positive saliva PCR test to confirm diagnosis.
- Inform PCP of inconclusive CMV test results through direct personal communication to PCP or their designated staff. Document all interactions in the newborn's medical record.
- If a positive PCR test result is received prior to newborn's discharge, add the diagnosis "Congenital CMV Infection" (ICD-10 code is P35.1) to the problem list in the newborn's medical record.

Step 1

Step 2

Step 3

Step 4

Newborn Hearing Screening Protocol

National recommendations indicate that each infant should receive a hearing screening within **one** month of age, complete diagnostic hearing evaluations by **three** months of age, and for any children identified as deaf or hard of hearing, enroll in early intervention services by **six** months of age.

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Policy

Oregon Revised Statute 433.321 Hearing screening tests for newborns:

1. In all Oregon hospitals and birthing centers with more than 200 live births per year, each newborn child shall receive a newborn hearing screening test within one month of the date of birth. A hospital or birthing center shall attempt to conduct the test required under this subsection prior to the discharge of the child from the facility.
2. All Oregon hospitals and birthing centers with fewer than 200 live births per year shall provide the parent or guardian of a newborn child with the appropriate information furnished by the Oregon Health Authority concerning the importance of newborn hearing screening tests.

Personnel

Newborn Hearing Screening Program Coordinator: Every birth hospital or birth center shall designate an employee to be their Newborn Hearing Screening Program Coordinator. It is recommended that this employee be an audiologist. If the coordinator is not an audiologist, then each birth hospital or birth center should have access to an audiologist for consultation. Each coordinator shall act as liaison between their facility and the Oregon State EHDI Program.

Newborn Hearing Screeners: Only those individuals who undergo comprehensive newborn hearing screening training on protocol, equipment and communication of results shall perform hearing screens. These individuals include but are not limited to audiologists, audiology assistants, nurses, midwives, entry-level employees or volunteers.

Equipment

All newborns shall receive a hearing screen using at least one of the following:

- Automated auditory brainstem response (AABR)

- Otoacoustic emissions (OAE)

Neither method is perfect; each will miss some forms of hearing loss (i.e. mild hearing loss, neural hearing loss, or a specific frequency region loss). Both tests should be performed while the baby is asleep or quiet and does not require the infant's participation. Both tests are quick, painless, and non-invasive. Equipment shall be calibrated in accordance with manufacturer's recommendation. Disposable components of equipment shall not be re-used.

Otoacoustic Emissions (OAE): A soft tip containing a miniature earphone and microphone is placed into the baby's ear. Sounds (tones or clicks) are presented through the tip, and, in most normal-hearing ears, the cochlea generates a response to the sounds that are recorded by the microphone automatically. OAE technology reflects the status of the peripheral auditory system extending to the outer hair cells in the cochlea.

Automated Auditory Brainstem Response (AABR): A few electrodes will be placed on the baby's head to measure the brainstem's response to soft clicking or chirping sounds presented through earphones. The electrodes record neural activity generated in the cochlea, auditory nerve and brainstem in response to the sounds. AABR technology reflects the status of the peripheral auditory system, the eighth nerve, and the brainstem auditory pathway.

Screening Parameters and Pass Criteria

Screening parameters and pass criteria should be pre-set into the hearing screening equipment by the manufacturer or an audiologist. When the hearing screens are administered, a "pass" or "refer" result should automatically appear. There should be no interpretation of results by the hearing screener at time of screen.

Transient Evoked Otoacoustic Emissions (TEOAE)

- **Parameters:**
 - Stimulus type: click
 - Click rate: 50-80 per second
 - Stimulus intensity: 78-82 dB SPL
 - Frequency Region: 1500-5000 Hz

- **Pass Criteria:**

- 70% reproducibility
- At least 3 to 6 dB SNR (signal-to-noise ratio) for the majority of responses
- Emission amplitudes within the normal range for a given age (Prieve, 1997)

Distortion Product Otoacoustic Emissions (DPOAE)

- **Parameters:**

- Stimulus type: two primary pure tones, response measured at $2f_1-f_2$ for each tone pair
- Frequency ratio (f_2/f_1): 1.22
- Stimulus intensity: L_1 65 dB SPL, L_2 55 dB SPL
- F_2 Frequency region: 2000-5000 Hz

- **Pass Criteria:**

- At least 3 to 6 dB between the noise floor and distortion product (DP-NF)
- Emission amplitudes within the normal range for a given age (Gorga et al, 2000)
- The majority of emissions within the 1500-8000 Hz region must meet the criteria above

Automated Auditory Brainstem Response (AABR)

- **Parameters:**

- Stimulus type: 0.1 msec click
- Intensity: 35 dB nHL

- **Pass Criteria:**

- Baby's response matched to template to determine "pass" or "refer" status.

Ideal Screening Conditions

- Baby is at least 8-12 hours old, recently fed, and sleeping or quiet with very little muscle movement
- Baby has been cleaned/washed

- Room is quiet, with no electrical interference (for AABR screening)

Factors Affecting Screening Result

- Hearing sensitivity of the baby
- Screener skill and experience
- Equipment type and functionality
- Room noise (acoustic and/or electrical)
- State of the baby
- Health of the baby
- Age of the baby

A refer may occur for **one or more** of the above reasons. Without ideal screening conditions, accurate results cannot be obtained, and require additional testing.

Recommended Protocol for the Well-Baby Nursery

Both OAE and AABR technology are sufficient technologies for testing peripheral hearing loss of 40 dB or greater in the well-baby nursery.

The initial screening should be performed at least 8-12 hours after birth. This allows the infant's ears to clear of any fluid or birthing debris. If a second screen is required, an ear canal massage between screens is recommended.

Not all babies pass, so make only two valid attempts. Excessive re-screening can increase the false negative rate (passing babies with hearing loss). Even if only one ear refers, rescreen both ears. A true pass is indicated only when both ears pass during the same screening session. Wait at least 4 hours between initial screening and rescreening unless baby will be discharged before the 4 hours between screenings can elapse. Initial screening should not be completed so close to discharge that a second screening is not possible.

OAE screening in the well-baby nursery

1. Initial Screening **at least 8 hours after birth:**

- **Pass** both ears: Testing complete

- **Refer** either ear: Repeat screening of both ears **as close to discharge as possible**

2. Inpatient Rescreening of both ears **as close to discharge as possible**:
 - **Pass** both ears: Testing complete
 - **Refer** either ear: Schedule outpatient rescreening of both ears **within one month**
3. Outpatient Rescreening of both ears **within one month**:
 - **Pass** both ears: Testing complete
 - **Refer** either ear: Schedule comprehensive audiologic evaluation of both ears **as soon as possible**

AABR screening in the well-baby nursery

1. Initial Screening with AABR **at least 8 hours after birth**:
 - **Pass** both ears: Testing complete
 - **Refer** either ear: Repeat screening of both ears **as close to discharge as possible**
2. Inpatient Rescreening of both ears:
 - **Pass** both ears: Testing is complete
 - **Refer** either ear: Schedule outpatient rescreening of both ears **within one month**
3. Outpatient Rescreening of both ears:
 - **Pass** both ears: Testing is complete
 - **Refer** either ear: Schedule comprehensive audiologic evaluation of both ears **as soon as possible**

NOTE: AABR screening resulting in a “refer” should NOT be followed by an OAE screen.

OAE/AABR two-step screening in well-baby nursery

1. Initial Screening with **OAE at least 8 hours after birth**:
 - **Pass** both ears: Testing complete

- **Refer** either ear: Repeat screening with AABR at each ear before discharge

2. Inpatient Rescreening of both ears with **AABR**:

- **Pass** both ears: Testing complete
- **Refer** either ear: Schedule outpatient rescreening **within one month**

3. Outpatient Rescreening of both ears with **AABR**:

- **Pass** both ears: Testing complete
- **Refer** either ear: Schedule comprehensive audiologic evaluation **as soon as possible**

Recommended Protocol for the Neonatal Intensive Care Unit (NICU)

A NICU is defined as a facility in which a Neonatologist provides primary care for the infant. Infants cared for in the NICU are at higher risk of having neural hearing loss (Auditory Neuropathy Spectrum Disorder). Therefore, the AABR is the only appropriate screening technology to use in the NICU, as the OAE does not evaluate the status of the auditory nerve or brainstem.

In the NICU, the preferred age at screening is at least 34 weeks gestational age AND at least five days of age in the NICU (if length of stay permits).

AABR screening in the NICU

1. Initial Screening with AABR:

- **Pass** both ears: Testing complete
- **Refer** either ear: Repeat screening of both ears as close to discharge as possible

2. Inpatient Rescreening of both ears with AABR:

- **Pass** both ears: Testing complete
- **Refer** either ear: Schedule comprehensive audiologic evaluation **as soon as possible**

NOTE: OAE is NOT permitted for use in the NICU; the only screening method allowed is the AABR.

Explanation of Results to Parents

Screening results should be communicated to the families immediately by the hearing screener, or by the charge nurse or newborn hearing screening coordinator, according to hospital protocol.

Whoever communicates the results must not downplay the results of the testing, nor cause undue anxiety for the family. Screeners should be provided a script to ensure consistent information is being provided to each family, and should be coached on answering frequently asked questions, as well as who to refer the family to for more information.

A written results report shall also be given to the families and entered into the medical record. Screening should not be completed so close to discharge that discussion of results is rushed or without time to answer parent questions.

What Happens When...

Both Ears Pass the Hearing Screening: Give the baby's family a form indicating the infant has passed their newborn hearing screen, with a list of developmental milestones related to hearing.

Either Ear Refers on the Hearing Screening: Review a form containing the screening results and next steps with the family. Have them sign the form and provide them with a copy. Alert the baby's primary care doctor of these results. The baby should be referred for follow-up testing: either an outpatient hearing screening or a comprehensive audiology evaluation. If possible, the follow-up appointment should be scheduled prior to the baby discharging from the hospital.

Baby's Hearing Screening is Missed: Contact the family to make an appointment for the hearing screen before 30 days of age, and preferably within two weeks of discharge.

Baby's Hearing Screening is Incomplete (rescreening not performed before discharge): An appointment should be made at discharge for the baby to return to

complete the hearing screen before 30 days of age, and preferably within two weeks of discharge.

Family Refuses the Hearing Screening: Have parent sign a waiver form indicating they understand the risks of declining the screening. Maintain the original copy in the infant's medical record.

Required Reporting of the Hearing Screening Results

The following information shall be reported to the Oregon EHDI Program **within 10 days** of the hearing screening, utilizing the designated reporting system (in most cases, OVERS):

1. Newborn's name, date of the birth, sex, and hospital medical identification number
2. Parent/Guardian's name, address, telephone number, and email (if available)
3. Birth facility
4. Name of the newborn's primary care provider (PCP)
5. Screening facility, test date, equipment type, results for each ear separately
6. Presence of any risk factors for hearing loss

If a hearing screening is not performed, a reason/status must be reported to the Oregon EHDI program within 10 days of the event or discharge, whichever is sooner. For example, if the family refuses the hearing screening, this information must be reported to the Oregon EHDI program within 10 days of the refusal.

If the baby is not accessible in OVERS, complete and fax the [Hearing Screening Report form](#).

Confidentiality

Reports, records, and other information collected by or provided to the Oregon EHDI program relating to a child's newborn hearing screening and diagnostic audiologic assessment are confidential records.

Oregon EHDI Program personnel shall maintain the confidentiality of all the information and records used in its review.

No individual or organization providing information to the department in accordance with its rules shall be deemed to be or held liable for divulging confidential information.

Liability

To reduce liability, each facility's equipment must be functional and calibrated. All screeners must be trained to perform the screen and counsel families appropriately. The screening equipment provides an objective result that screening staff will share with each family. No interpretation is required nor should any interpretation be provided, including suspected reason for non-pass result.

Passing the newborn hearing screening does not guarantee that a child will never have a hearing loss, nor does it guarantee that the child has normal hearing, as it is not a diagnostic test. The screening is intended to identify those infants most likely to have or be at risk for hearing loss that would contribute to developmental, educational, and/or social deficits, if not discovered and treated early in life.

Resources

Oregon EHDI Program Website: healthoregon.org/ehdi

Joint Committee on Infant Hearing (JCIH) 2007:

<http://pediatrics.aappublications.org/content/120/4/898.full?ijkey=oj9BAeq21OIA&keytype=ref&siteid=aapjournals>

American Academy of Audiology (AAA) Pediatric Assessment Guidelines 2012:

http://www.audiology.org/resources/documentlibrary/Documents/201208_AudGuideAssessHear_youth.pdf

American Academy of Audiology (AAA) Pediatric Amplification Guidelines 2013:

<http://www.audiology.org/resources/documentlibrary/Documents/PediatricAmplificationGuidelines.pdf>

American Speech-Language Hearing Association (ASHA) Guidelines for Audiologic Assessment of Children 2004: <http://www.asha.org/policy/GL2004-00002/>

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ADOPT: 333-020-0128

NOTICE FILED DATE: 11/13/2025

RULE SUMMARY: 333-020-0128 Determining Facility Requirements to Provide Hearing Screenings in Newborns: This rule is added to describe and clarify what facilities are required to provide hearing screenings in newborns. This rule consists of text that was in previously in OAR 333-020-0130.

CHANGES TO RULE:

333-020-0128

Determining Facility Requirements to Provide Hearing Screenings in Newborns

(1) A non-mandated facility whose reports of live births increases to more than 200 following the end of a calendar year shall be required to begin providing newborn hearing screening on or before July 1 of the following calendar year.¶

(2) A mandated facility whose reports of live births decreases to 200 or less following the end of a calendar year may choose to discontinue providing newborn hearing screening on or after July 1 of the following year.

Statutory/Other Authority: ORS 433.321

Statutes/Other Implemented: ORS 433.321

This rule describes the facility requirements to provide hearing screening in newborns. The rule is updated to remove and separate rule language to improve clarity and specification of rule text.

CHANGES TO RULE:

333-020-0130

Facility Requirements to Provide Hearing Screenings in Children Newborns ¶

(1) In all mandated facilities, each newborn child shall receive a hearing screening, consistent with the Hearing Screening Protocol, prior to discharge of the child from the facility.¶

(2) ~~No newborn child~~ A mandated facility may be not refused to conduct a hearing screening from a mandated facility because of ~~due to~~ an inability of the parent or guardian to pay for the procedure.¶

(3) ~~The Authority will determine the number of live births per year by information provided by the Center for Health Statistics in all non-mandated facilities of the Authority.¶~~

(4) Hospitals or birthing centers which in the past have not had more than 200 births per year and which then report to the Authority more than 200 live births in a calendar year, shall be required to begin providing newborn hearing screening by July 1 of the following calendar year.¶

(5) Hospitals or birthing centers which in the past have had more than 200 live births per year and which then report to the Authority fewer than 200 live births in a calendar year may choose to discontinue providing newborn hearing screening on or after July 1 of the following calendar year.¶

(6) Hospitals or birthing centers with fewer than 200 live births where a hearing screening is not performed, each newborn's parent or guardian shall be provided with information furnished by the Oregon Health Authority (Authority) including, but not limited to: ¶

(a) A statement indicating that newborn hearing screening is important to determine the presence or absence of hearing loss and is considered standard of care; and ¶

(b) A list of Authority recommended screening facility locations and contact information, and a statement indicating that newborn.¶

(4) A non-mandated facility that chooses to conduct hearing screening is important to determine the presence or absence of hearing loss and is considered standard of care must follow guidelines and follow-up requirements established for a mandated facility identified in these rules.

Statutory/Other Authority: ORS 433.321

Statutes/Other Implemented: ORS 433.321

AMEND: 333-020-0132

NOTICE FILED DATE: 11/13/2025

RULE SUMMARY: 333-020-0132 Follow Up Requirements for Facilities Conducting Hearing Screenings:

This rule describes the facility follow up requirements upon conducting hearing screenings in newborns. The rule is updated to align with health care interpreter services statute and clarify what information must be shared with parents or guardians and the primary care provider of a child who received a hearing screening as mentioned in statute.

CHANGES TO RULE:

333-020-0132

Follow Up Requirements for Screening Facilities Conducting Hearing Screenings

~~S~~All screening facilities shall:

(1) Provide ~~the ho~~ the parent or guardian of the child, the following:

~~(a) Hearing screening results verbally and in writing within 10 days of the screening to the parent or guardian and the health care provider of the child. This notifie.~~

~~(A) This information shall include a description of the meaning of a "Pass" result and a "Refer" result, as defined in these rules.~~

~~(2B) Provide the names and contact information for diagnostic facilities and a description of the importance of timely diagnosis and intervention to the parent or guardian and the health. For parents or guardians who have limited English proficiency or who prefer to communicate in a language other than English or who communicates in signed language, health care interpreter services shall be provided in accordance with ORS 413.559 and OAR 950-050-0160.~~

~~(C) Written information shall be provided in the parent or guardian's language of choice.~~

~~(b) Names and contact information for diagnostic facilities and a description of the importance of timely diagnosis and intervention for any child who needs additional testing.~~

~~(c) Information on congenital cytomegalovirus (cCMV), furnished by the Oregon Health Authority.~~

~~(2) Provide the primary care provider of any the child who needs additional testing.~~

~~(3) Provide the information described in ORS 433.321 to the parent or guardian of the child, the hearing screening results in writing within 10 days of the screening. This notification shall include a description of the meaning of a "Pass" result and a "Refer" result, as defined in these rules.~~

~~(43) Identify a point of contact for the facility and provide the designated staff name and contact information to the Early Hearing Detection and Intervention pProgram to aid in the follow up and care coordination of children screened at their facility.~~

Statutory/Other Authority: ORS 433.321, ORS 433.323

Statutes/Other Implemented: ORS 433.321, ORS 433.323, ORS 433.298

AMEND: 333-020-0135

NOTICE FILED DATE: 11/13/2025

RULE SUMMARY: 333-020-0135 Facility Responsibility if Hearing Screening is Not Conducted Timely:

This rule describes facility requirements in situations where a hearing screening is not conducted timely. The rule is updated to improve clarity.

CHANGES TO RULE:

333-020-0135

Facility Responsible for Performing the Newborn Hearing Screening if Hearing Screening is Not Conducted Timely ¶

~~Should~~(1) If a newborn child ~~be~~is discharged from a mandated facility before the newborn hearing screening is performed or completed, it shall be the responsibility of the mandated facility to arrange for the provision of screening.¶

~~(1)~~ The timing of the screening may be delayed, if medically indicated. If delayed, the mandated facility shall be responsible for performing the hearing screening prior to the child's discharge to home.¶

~~(2)~~ For purposes of this rule, in the case ~~op~~prior to completion of a newborn hearing screening, the mandated facility shall arrange for the provision of screening.¶

(2) If a newborn child ~~be~~is admitted to a hospital as a result of transfer from another hospital or birthing center, the receiving hospital from which the child is discharged to home shall be responsible for ~~a~~sensuring that a hearing screening is performed, according to the Hearing Screening Protocol.

Statutory/Other Authority: ORS 433.321

Statutes/Other Implemented: ORS 433.321

AMEND: 333-020-0150

NOTICE FILED DATE: 11/13/2025

RULE SUMMARY: 333-020-0150 Reporting Responsibility for Facilities Conducting Hearing Screenings:

This rule describes facility reporting requirements following a hearing screening being conducted. The rule is updated to improve clarity and alignment with definitions outlined in OAR 333-020-0125.

CHANGES TO RULE:

333-020-0150

Collecting and Submitting Information Related to Reporting Responsibility for Facilities Conducting Hearing Screenings ¶

(1) Within 10 days of screening a child, a screening facility shall report, at a minimum, the following information to the AuthorityOregon Health Authority (Authority) via the confidential reporting mechanism(s) established by the Authority:¶

- (a) Full name of the child;¶
- (b) Child's date of birth;¶
- (c) Parent or guardian's name, address and contact information;¶
- (d) Name of birthing facility;¶
- (e) Name of screening facility, if different than birthing facility;¶
- (f) Identification number from newborn blood spot screening kit, for matching purposes;¶
- (g) Medical record number, for matching purposes;¶
- (h) Left and right ear specific results of the hearing screening or status of the newborn hearing screening, if not completed;¶
- (i) Type of screening performed;¶
- (j) Date that screening was performed;¶
- (k) Name of child's primary health care provider, for any child who does not pass the has a "Refer" result on a hearing screening, does not receive a complete hearing screening, or has a risk factor for hearing loss; and¶
- (l) Name of secondary point of contact for any child who does not pass the has a "Refer" result on a hearing screening, does not receive a complete hearing screening, or has a risk factor for hearing loss.¶

(2) The Authority may request that screening facilities report additional information deemed necessary to:¶

- (a) Match the hearing screening result or status with the appropriate child in the Early Hearing Detection and Intervention Information System;¶
- (b) Assist in tracking and follow up for children needing additional testing; and¶
- (c) Identify children with risk factors for hearing loss.

Statutory/Other Authority: ORS 433.323

Statutes/Other Implemented: ORS 433.321-433.327

AMEND: 333-020-0151

NOTICE FILED DATE: 11/13/2025

RULE SUMMARY: 333-020-0151 Reporting Responsibility for Facilities Conducting Diagnostic Testing for Hearing Loss in Children:

This rule describes reporting requirements following a hearing testing being conducted at a diagnostic facility. The rule is updated to improve clarity and alignment with definitions outlined in OAR 333-020-0125.

CHANGES TO RULE:

333-020-0151

Collecting and Submitting Information Related to Reporting Responsibility for Facilities Conducting Diagnostic Testing for Hearing Loss in Children ¶

(1) Within 10 days of testing of a child who has a "REFER" result on the hearing screening, or who presents for an initial or completion of a hearing screening, or who is diagnosed with a permanent hearing loss, the diagnostic facility conducting the testing shall report, at a minimum, the following information to the AuthorityOregon Health Authority (Authority) via the confidential reporting mechanism(s) established by the Authority:¶

- (a) Full name of the child;¶
- (b) Child's date of birth;¶
- (c) Name of birthing facility, if known;¶
- (d) Parent or guardian's name, address, and contact information;¶
- (e) Name of child's primary health care provider;¶
- (f) Newborn hearing screening results, if not already known;¶
- (g) Name of diagnostic facility;¶
- (h) Type of diagnostic tests performed;¶
- (i) Date that diagnostic testing was performed;¶
- (j) ~~Left and right~~ ear specific results, including type and degree of hearing loss, if applicable;¶
- (k) Disposition, including referrals indicated for early intervention or other services;¶
- (l) Name and contact information for person completing diagnostic hearing evaluation; and¶
- (m) For those diagnosed with permanent hearing loss, the complete evaluation report.¶

(2) The Authority may request that diagnostic facilities report additional information deemed necessary to:¶

- (a) Match the follow-up test result or status with the appropriate child in the Early Hearing Detection and Intervention Information System; and¶
- (b) Provide or offer follow-up services to children identified with hearing loss or at-risk of hearing loss.

Statutory/Other Authority: ORS 433.323

Statutes/Other Implemented: ORS 433.321-433.327

AMEND: 333-020-0155

NOTICE FILED DATE: 11/13/2025

RULE SUMMARY: 333-020-0155 Responsibility for Issuing Reports:

This rule describes requirement for the Oregon Health Authority to issue an annual report. The rule is updated to describe the data sources being used to generate the annual report.

CHANGES TO RULE:

333-020-0155

Responsibility for Issuing Reports ¶

The Oregon Health Authority shall issue an annual report and analysis of aggregated data submitted by all screening facilities, diagnostic facilities, and early intervention facilities.

Statutory/Other Authority: ORS 433.323

Statutes/Other Implemented: ORS 433.321-433.327

RULE SUMMARY: 333-020-0160 Appointment of an Advisory Committee:

This rule describes requirements for convening an advisory committee. The rule is updated to remove outdated language and add new language outlining purpose, appointment of new members, expectations of members, term limits, alignment with public meeting laws, and convening discretion.

CHANGES TO RULE:

333-020-0160

Appointment of an Advisory Committee ¶

(1) The Director ~~shall~~may appoint an advisory committee.¶

(21) At a minimum, the ~~Individuals eligible to serve on an~~ advisory committee ~~shall~~ include but are not limited to representatives from ~~each of the~~ the following categories:¶

(a) Parent or guardian of a ~~child with~~ deaf or hard of hearing ~~less~~ child;¶

(b) ~~Adult with childhood hearing loss~~ Deaf or hard of hearing adult identified in childhood;¶

(c) Pediatric health care provider;¶

(d) Clinical audiologist representing a diagnostic facility;¶

(e) Hospital newborn hearing screening program representative;¶

(f) Early intervention program representative;¶

(h) Local public health agency representative; and¶

(i) Speech-language pathologist.¶

(2) The purpose of the advisory committee is to gather its members' collective knowledge, experience, expertise, and insight to assist the Oregon Health Authority (Authority) in meeting its responsibilities including advising on issues and topics related to the identification of deaf and hard of hearing (D/HH) children through a universal hearing screening program, follow up diagnostic testing appointments, and referrals to early intervention services.¶

(3) The Authority will solicit members for an advisory committee by public announcement; Individuals interested in serving on the committee are required to complete an application. From the applications received, the Director will appoint, at a minimum, 10 members who are willing to undertake the duties of an advisory committee member and adhere to the committee bylaws adopted and established by the Authority. The Authority will notify each applicant in writing whether they have been appointed to the committee.¶

(4) An advisory committee member must: ¶

(a) Attend meetings. If there are more than two unexcused absences in a two-year period, membership is terminated at the following meeting and the position is declared vacant.¶

(b) Comply with any confidentiality requirements established by the Authority.¶

(5) Members shall serve for a two-year term, beginning and ending with the annual meeting in January, and may reapply for membership.¶

(6) All advisory committee meetings are subject to Oregon's Public Meetings Law (ORS 192.610 to 192.705).¶

(7) Advisory committee meetings are convened at the discretion of the Authority.

Statutory/Other Authority: ORS 433.323~~1~~.250

Statutes/Other Implemented: ORS 433.321-433.327

AMEND: 333-020-0165

NOTICE FILED DATE: 11/13/2025

RULE SUMMARY: 333-020-0165 Exemptions from Hearing Screening:

This rule describes exemptions to hearing screenings. The rule is updated to align language with statute.

CHANGES TO RULE:

333-020-0165

~~Religious~~ Exemptions from Hearing Screening ¶

(1) A ~~hospital or birthing center~~~~mandated facility~~ directed to provide hearing screening ~~under these administrative rules is exempt from providing such services~~ is exempt from the requirements specified in these rules if the parent or guardian of the newborn child objects to the screening procedure on the grounds that ~~it~~ the procedure conflicts with the religious tenets and practices of the parent or guardian.¶

(2) The parent or guardian must sign a statement that the ~~child is being reared with religious tenets and practices that conflict with the screening and that~~ the hearing screening is waived for religious reasons.

Statutory/Other Authority: ORS 433.323, ORS 433.321

Statutes/Other Implemented: ORS 433.321-433.327

ADOPT: 333-020-0170

NOTICE FILED DATE: 11/13/2025

RULE SUMMARY: 333-020-0170 Facility Requirements to Provide Congenital Cytomegalovirus (cCMV) Screening to Newborns:

This rule is added to describe the birthing facility requirements to provide congenital cytomegalovirus screening to newborns as outlined in ORS 433.321 and sets a date for when birthing facilities must begin screening.

CHANGES TO RULE:

333-020-0170

Facility Requirements to Provide Congenital Cytomegalovirus (cCMV) Screening to Newborns

(1) No later than April 1, 2026, all birthing facilities must conduct congenital cytomegalovirus (cCMV) screening on every newborn within 14 days of birth and prior to discharge of the newborn from the facility.

(2) If a birthing facility is part of a Health Maintenance Organization, the facility must conduct congenital cytomegalovirus (cCMV) screening on every newborn within 14 days of birth.

Statutory/Other Authority: ORS 433.321

Statutes/Other Implemented: ORS 433.321

ADOPT: 333-020-0175

NOTICE FILED DATE: 11/13/2025

RULE SUMMARY: 333-020-0175 Follow Up Requirements for Facilities Conducting Congenital Cytomegalovirus (cCMV) Screenings:

This rule is added to describe the birthing facility requirements to follow up with parents or guardians and primary care providers as outlined in ORS 433.321. It includes alignment with health care interpreter services statute and clarifies what information must be shared with parents or guardians and the primary care provider of a child who received a positive screening result for congenital cytomegalovirus.

CHANGES TO RULE:

333-020-0175

Follow Up Requirements for Facilities Conducting Congenital Cytomegalovirus (cCMV) Screenings

If a newborn has a positive screening result for congenital cytomegalovirus (cCMV), the birthing facility:

(1) Shall notify the parent or guardian and the primary care provider of the newborn of the result through direct personal communication.

(a) For parents or guardians who have limited English proficiency or who prefer to communicate in a language other than English or who communicates in signed language, health care interpreter services shall be provided in accordance with ORS 413.559 and OAR 950-050-0160.

(b) Written information shall be provided in the parent or guardian's language of choice.

(2) Is encouraged to provide the parent or guardian and primary care provider of the newborn with information on congenital cytomegalovirus (cCMV) diagnostic testing and care, consistent with Congenital Cytomegalovirus (cCMV) Diagnostic Testing and Care Protocol.

Statutory/Other Authority: ORS 433.321

Statutes/Other Implemented: ORS 433.321

ADOPT: 333-020-0180

NOTICE FILED DATE: 11/13/2025

RULE SUMMARY: 333-020-0180 Facility Responsibility if Transfer Occurs Prior to Congenital Cytomegalovirus (cCMV) Screening:

This rule is added to describe the facility responsible for conducting congenital cytomegalovirus screening following hospital admission as a result of a transfer from another birthing facility.

CHANGES TO RULE:

333-020-0180

Facility Responsibility if Transfer Occurs Prior to Congenital Cytomegalovirus (cCMV) Screening

If a newborn is admitted to a hospital as a result of transfer from another hospital or birthing center, the receiving hospital from which the child is discharged to home shall be responsible for ensuring that a congenital cytomegalovirus (cCMV) screening is performed.

Statutory/Other Authority: ORS 433.321

Statutes/Other Implemented: ORS 433.321

ADOPT: 333-020-0185

NOTICE FILED DATE: 11/13/2025

RULE SUMMARY: 333-020-0185 Exemptions from Congenital Cytomegalovirus (cCMV) Screening

This rule is added to describe exemptions for congenital cytomegalovirus screenings.

CHANGES TO RULE:

333-020-0185

Exemptions from Congenital Cytomegalovirus (cCMV) Screening

A hospital or birthing center is exempt from conducting congenital cytomegalovirus (cCMV) screening if the parent or guardian of the newborn objects in writing.

Statutory/Other Authority: ORS 433.321, ORS 433.323

Statutes/Other Implemented: ORS 433.321 - 433.327

ADOPT: 333-020-0187

NOTICE FILED DATE: 11/13/2025

RULE SUMMARY: 333-020-0187 Dissemination of Cytomegalovirus Information:

This rule is added to describe the Oregon Health Authority's responsibility to disseminate information on congenital cytomegalovirus to various entities.

CHANGES TO RULE:

333-020-0187

Dissemination of Cytomegalovirus Information

(1)(a) The Oregon Health Authority (Authority) shall disseminate information about congenital cytomegalovirus (cCMV), as described in ORS 433.298, to the following entities:¶

(A) Prenatal healthcare providers;¶

(B) Hospitals;¶

(C) Birthing centers;¶

(D) Screening facilities;¶

(E) The Department of Early Learning and Care;¶

(F) The public; and¶

(G) Certified or registered childcare facilities, as defined in ORS 329A.263, for the purpose of educating employees about the risk of contracting cytomegalovirus during pregnancy.¶

(b) Information may be disseminated by print, electronic mail, video, or other cost-effective methods, as determined by the Authority.¶

(2) Hospitals, birthing centers, screening facilities, and prenatal healthcare providers shall, at a minimum, provide the information about congenital cytomegalovirus (cCMV) developed by the Authority to the parent or guardian of the newborn in print within 48 hours after birth.¶

(3) Prenatal healthcare providers are encouraged to provide information to pregnant individuals as early as possible during pregnancy for the purpose of educating individuals on prevention measures and risks associated with contracting congenital cytomegalovirus (cCMV) infection during pregnancy.

Statutory/Other Authority: ORS 433.323

Statutes/Other Implemented: ORS 433.323, ORS 433.298, ORS 433.321

RULE SUMMARY: 333-077-0130 Medical Records

This rule describes information that is required to be retained in medical records for each client receiving care and each newborn birthed at birthing centers. The rule text was updated to include documentation requirements following congenital cytomegalovirus screening for newborns outlined in OAR chapter 333, division 20. Additional formatting changes were made for clarity.

CHANGES TO RULE:

333-077-0130
Medical Records ¶

(1) A medical record shall be maintained for each client and newborn admitted for care.¶

(2) Medical records must be completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information. Each client and newborn medical record must contain sufficient information to clearly identify the client.¶

(3) A legible, reproducible medical record shall include at least the following (if applicable):¶

(a) For the client: ¶

(A) Race, ethnicity, preferred spoken and written language, disability status, sexual orientation, and gender identity that meets the requirements of ORS 413.164 and OAR chapter 950, division 30; ¶

(B) Initial prenatal physical exam; ¶

(C) Laboratory tests and results; ¶

(D) Regular periodic prenatal and intrapartum examinations and assessments of risk status in accordance with OAR 333-077-0100 and OAR 333-077-0125; ¶

(E) A signed disclosure in accordance with OAR 333-077-0100; ¶

(F) Client history, physical exam and risk assessment on admission to the birthing center in labor (including assessment of fetus); ¶

(G) Regular periodic assessment (including assessment of the fetus) during labor and delivery in accordance with OAR 333-077-0100; ¶

(H) Labor summary; ¶

(I) The emergency transport plan (including the emergency transport plan for the newborn client); ¶

(J) Postpartum evaluation; ¶

(K) Discharge summary; ¶

(L) Documentation of assessments, consultation, referral, or transfer; ¶

(M) Documentation of disclosures pursuant to ORS 441.098; ¶

(N) Signed documents as may be required by law; and ¶

(b) For the newborn or stillborn delivery: ¶

(A) Date and hour of birth; ¶

(B) Birth weight; ¶

(C) Length of infant; ¶

(D) Period of gestation; ¶

(E) Sex assigned at birth; ¶

(F) Initial physical assessment and condition on delivery, including Apgar scores and vital signs; ¶

(G) Client's name; ¶

(H) Record of ophthalmic prophylaxis and Vitamin K administration or refusal of same; ¶

(I) Record of newborn hearing and ~~newborn metabolic screening and~~ cytomegalovirus screening, or record of referral to screenings if ~~screenings are~~ is not provided by the birthing center; ¶

(J) Record of newborn metabolic screening or record of referral to screening if not provided by the birthing center; ¶

(JK) Progress notes including: ¶

(i) Temperature, weight and feeding data; ¶

(ii) Stool output; ¶

(iii) Urinary output; ¶

(iv) Condition of eyes and umbilical cord; ¶

(v) Condition and color of skin; and ¶

(vi) Motor behavior; and ¶

(KL) Discharge summary.¶

(4) All entries in a client's labor record must be promptly dated, timed, and authenticated: ¶

(a) Entries made 48 hours after the care has been provided must be identified as an addendum or an amended entry and must include the date and time of entry and the clinical providers initials.¶

(b) Verification of an entry requires use of a unique identifier, for example, signature, code, or other means, that allows identification of the individual responsible for the entry.¶

(c) A single signature or authentication of the responsible clinical provider or other individual authorized within the scope of their professional license on the medical record does not suffice to cover the entire content of the record.¶

(5) The completion of the medical record is the responsibility of the attending clinical provider.¶

(6)(a) The birthing center will ensure that the prenatal and intrapartal records are available at the time of admission and, in the event of transfer, the birthing center must ensure the following information accompanies the client or newborn client to the care of another clinician or hospital-based care: medical history, prenatal flow sheet, diagnostic studies, laboratory findings, and client and newborn care notes through time of transfer.¶

(b) In cases of emergency, at the time of transfer, the birthing center must provide the information specified in subsection (6)(a) of this rule to the hospital-based care or another clinician, including notes for care provided during the emergency. If notes are not available, an oral summary of care during the emergency must be made available to the hospital-based care or responding EMS provider(s).¶

(7) Medical records will be stored in such a way as to comply with state and federal privacy laws and minimize the chance of their destruction by fire or other source of loss or damage and to ensure prevention of access by unauthorized persons.¶

(8) Medical records are the property of the birthing center, and will be kept confidential unless released by the permission of the client. The medical record, either in original or electronic form, shall not be removed from the birthing center except where necessary for a judicial or administrative proceeding. Authorized personnel of the Oregon Health Authority (Authority) shall be permitted to review medical records. If a birthing center uses off-site storage for medical records, arrangements must be made for prompt delivery of these records to the birthing center when needed for client care or other activities.¶

(9) All clinical records must be kept for a period of at least seven years after the date of discharge for the birthing client and 21 years after the date of last discharge for the newborn client. Original medical records may be retained on paper, electronic, or other media.¶

(10) If a birthing center changes ownership, all medical records in original, electronic, or other form must remain in the birthing center or off-site storage, and it must be the responsibility of the new owner to protect and maintain these records.¶

(11) If a birthing center is permanently closed, its medical records may be delivered and turned over to any other health care facility in the vicinity willing to accept and retain the same as provided in section (9) of this rule. A birthing center which permanently closes shall follow the procedures for notifying the Authority and public notice requirements regarding disposal of medical records under OAR 333-077-0045.¶

(12) A current written policy on the release of medical record information including client access to the medical record shall be maintained in the facility.¶

(13) As part of its quality assessment and performance improvement program, a birthing center shall measure and evaluate its medical record documentation of care including timeliness of documentation. The following factors shall be considered during an evaluation:¶

(a) Confidentiality of the record;¶

(b) Records are easily retrievable;¶

(c) Quality, legibility and accuracy of the information in the record;¶

(d) Documentation of all requirements specified in these rules;¶

(e) All entries are dated and timed; and¶

(f) The timeliness of the entry.¶

(14) A birthing center shall implement performance improvement activities based on its medical record evaluation.¶

(15) A birthing center is encouraged to consult with a qualified clinical record practitioner to conduct its review.¶

(16) As used in this rule, "qualified clinical record practitioner" means a Registered Health Information Administrator (RHIA) or Registered Health Information Technician (RHIT).

Statutory/Other Authority: ORS 441.025

Statutes/Other Implemented: ORS 441.025, ORS 433.321

RULE SUMMARY: 333-077-0170 Newborn Care and Screening

This rule describes the newborn care services that are required to be provided at a birthing center. The rule text was updated to include congenital cytomegalovirus screening requirements outlined in OAR chapter 333, division 20, and as prescribed in statute.

CHANGES TO RULE:

333-077-0170

Newborn Care and Screening

(1) A birthing center shall ensure that all newborns are given Vitamin K at birth in accordance with OAR 333-021-0800, the purpose of which is to protect newborns against Vitamin K deficiency bleeding. ¶

(2) A birthing center shall ensure that every newborn delivered in the birthing center is tested for metabolic diseases as required by OAR 333-024-1020. ¶

(3) A birthing center shall ensure that every newborn delivered in the birthing center receives a newborn hearing screening test or referral, and cytomegalovirus screening, as required by OAR chapter 333, division 20 and ORS 433.321. ¶

(4) The birthing center must ensure that a newborn is evaluated and treated who is at risk for gonococcal ophthalmia neonatorum in accordance with OAR 333-019-0036. ¶

(5) A birthing center must perform pulse oximetry screening on every newborn delivered at the birthing center before discharging the newborn in conformance with the following requirements: ¶

(a) The pulse oximetry screening must be performed using evidence-based guidelines such as those recommended by Strategies for Implementing Screening for Critical Congenital Heart Disease, AR Kemper et al., Pediatrics 2011;128(5): e1259-1267. ¶

(b) The birthing center must have policies and procedures based on the guidelines required by subsection (a) of this section for: ¶

(A) Determining what is considered a positive screening result; and ¶

(B) Determining what follow-up services, treatment or referrals must be provided if a newborn has a positive screening result. ¶

(c) A Federal Drug Administration (FDA) approved motion tolerant pulse oximeter must be used. ¶

(d) The pulse oximetry screening must be performed no sooner than 24 hours after birth or as close to discharge of the newborn as possible. ¶

(e) Before performing pulse oximetry screening on a newborn, birthing center staff must have received training on how to correctly operate the pulse oximeter and the policies and procedures associated with the screening. The birthing center must document this training. ¶

(f) If a newborn is admitted to hospital-based care as the result of a transfer from the birthing center before a pulse oximetry screening is performed, the hospital-based care from which the newborn is discharged to home is responsible for performing the screening. ¶

(g) The birthing center must provide the following notifications and document them in the newborn's medical record: ¶

(A) Prior to the pulse oximetry screening, notify a client or legal representative of the newborn about the reasons for the screening and the risks and consequences of not screening. ¶

(B) Following the pulse oximetry screening, notify the health care provider responsible for the newborn and the newborn's primary care provider of the results of the screening. ¶

(C) Following the pulse oximetry screening and prior to discharge, notify a client or legal representative of the newborn of the screening result, an explanation of its meaning and, if it is a positive screening result, provide information about the importance of timely diagnosis and intervention. ¶

(h) A client or legal representative of a newborn may decline pulse oximetry screening and, if screening is declined, the birthing center must document the declination in the newborn's medical record. ¶

(i) Following the pulse oximetry screening, the birthing center, in accordance with the applicable standard of care, must provide any appropriate follow-up services or treatment for the newborn if necessary or provide a referral to a client or legal representative of the newborn for follow-up services or treatment if necessary. ¶

(j) The birthing center must document in the newborn's medical record that the screening was performed, the screening result, the names of the health care providers who were notified of the screening result, and any follow-up services or treatment or referral for services or treatment. ¶

(k) No newborn may be refused screening because of the inability of a client or legal representative to pay for the

screening. ¶

NOTE: The document referenced in section (5) of this rule is available upon request by contacting the Health Care Regulation and Quality Improvement section at mailbox.hclc@odhsoha.oregon.gov

Statutory/Other Authority: ORS 441.025, ORS 433.285, ORS 433.318, ORS 433.323

Statutes/Other Implemented: ORS 441.025, ORS 433.285, ORS 433.306, ORS 433.318, ORS 433.321

RULE SUMMARY: 333-505-0050 Medical Records

This rule describes information that is required to be retained in medical records at hospitals. The rule text was updated to include documentation requirements following congenital cytomegalovirus screening outlined in OAR chapter 333, division 20.

CHANGES TO RULE:

333-505-0050

Medical Records ¶

(1) A medical record shall be maintained for every patient admitted for care in a hospital.¶

(2) A legible reproducible medical record shall include, but is not limited to (as applicable):¶

(a) Admitting identification data including date of admission.¶

(b) Chief complaint.¶

(c) Pertinent family and personal history.¶

(d) Medical history, physical examination report and provisional diagnosis as required by OAR 333-510-0010.¶

(e) Admission notes outlining information crucial to patient care.¶

(f) All patient admission, treatment, and discharge orders:¶

(A) All patient orders shall be initiated, dated, timed and authenticated by a licensed health care practitioner in accordance with section (7) of this rule.¶

(B) Documentation of verbal orders shall include:¶

(i) The date and time the order was received;¶

(ii) The name and title of the health care practitioner who gave the order; and¶

(iii) Authentication by the authorized individual who accepted the order, including the individual's title.¶

(C) Verbal orders shall be dated, timed, and authenticated promptly by the ordering health care practitioner or another health care practitioner who is responsible for the care of the patient.¶

(D) For purposes of this rule, a verbal order includes but is not limited to an order given over the telephone.¶

(g) Clinical laboratory reports as well as reports on any special examinations. The original report shall be recorded in the patient's medical record.¶

(h) X-ray reports bearing the identification of the originator of the interpretation.¶

(i) Consultation reports when such services have been obtained.¶

(j) Records of assessment and intervention, including graphic charts and medication records and appropriate personnel notes.¶

(k) Discharge planning documentation in accordance with OAR 333-505-0055.¶

(l) Discharge summary including final diagnosis.¶

(m) Autopsy report if applicable.¶

(n) Such signed documents as may be required by law.¶

(o) Informed consent forms that document:¶

(A) The name of the hospital where the procedure or treatment was undertaken;¶

(B) The specific procedure or treatment for which consent was given;¶

(C) The name of the health care practitioner performing the procedure or administering the treatment;¶

(D) That the procedure or treatment, including the anticipated benefits, material risks, and alternatives was explained to the patient or the patient's representative or why it would have been materially detrimental to the patient to do so, giving due consideration to the appropriate standards of practice of reasonable health care practitioners in the same or a similar community under the same or similar circumstances;¶

(E) The manner in which care will be provided in the event that complications occur that require health services beyond what the hospital has the capability to provide;¶

(F) The signature of the patient or the patient's legal representative; and¶

(G) The date and time the informed consent was signed by the patient or the patient's legal representative;¶

(p) Documentation of the disclosures required in ORS 441.098; and¶

(q) Documentation of support persons designated by a patient, or a patient's legal representative, in collaboration with the patient, pursuant to OAR 333-505-0033. The following information shall be documented:¶

(A) The name and contact information for each designated support person;¶

(B) The date and time the patient was informed of their rights in OAR 333-505-0033(3) to designate support persons and have one support person present at all times to assist the patient when the patient is receiving

hospital services; and¶

(C) Any conditions imposed on the support person(s).¶

(3) A medical record of a surgical patient shall include, in addition to other record requirements, but is not limited to:¶

(a) Preoperative history, physical examination and diagnosis documented prior to operation.¶

(b) Anesthesia record including preanesthesia assessment and plan for anesthesia, records of anesthesia, analgesia and medications given in the course of the operation and postanesthetic condition.¶

(c) A record of operation dictated or written immediately following surgery and including a complete description of the operation procedures and findings, postoperative diagnostic impression, and a description of the tissues and appliances, if any, removed. When the dictated operative report is not placed in the medical record immediately after surgery, an operative progress note shall be entered in the medical record after surgery to provide pertinent information for any individual required to provide care to the patient.¶

(d) Postanesthesia recovery progress notes.¶

(e) Pathology report on tissues and appliances, if any, removed at the operation.¶

(4) An obstetrical record for a patient, in addition to the requirements for medical records, shall include but is not limited to:¶

(a) The prenatal care record containing at least a serologic test result for syphilis, Rh factor determination, and past obstetrical history and physical examination.¶

(b) The labor and delivery record, including reasons for induction and operative procedures, if any.¶

(c) Records of anesthesia, analgesia, and medications given in the course of delivery.¶

(5) A medical record of a newborn or stillborn infant, in addition to the requirement for medical records, shall include but is not limited to:¶

(a) Date and hour of birth; birth weight and length; period of gestation; sex; and condition of infant on delivery (Apgar rating is recommended).¶

(b) ~~Mother~~Birth parent's name and hospital number.¶

(c) Record of ophthalmic prophylaxis or refusal of same.¶

(d) Physical examination at birth and at discharge.¶

(e) Progress and nurse's notes including temperature; weight and feeding data; number, consistency and color of stools; urinary output; condition of eyes and umbilical cord; condition and color of skin; and motor behavior.¶

(f) Type of identification placed on infant in delivery room.¶

(g) Newborn hearing screening tests and cytomegalovirus screening conducted in accordance with OAR chapter 333, division 20.¶

(6) A patient's emergency room, outpatient and clinic records, in addition to the requirements for medical records, shall be maintained and available to the other professional services of the hospital and shall include but are not limited to:¶

(a) Patient identification.¶

(b) Admitting diagnosis, chief complaint and brief history of the disease or injury.¶

(c) Physical findings.¶

(d) Laboratory and X-ray reports (if performed), as well as reports on any special examinations. The original report shall be authenticated and recorded in the patient's medical record.¶

(e) Diagnosis.¶

(f) Record of treatment, including medications.¶

(g) Disposition of case with instructions to the patient.¶

(h) Signature or authentication of attending physician.¶

(i) A record of the pre-hospital report form (when patient is brought in by ambulance) shall be attached to the emergency room record.¶

(7) All entries in a patient's medical record shall be dated, timed and authenticated.¶

(a) Authentication of an entry requires the use of a unique identifier, including but not limited to a written signature or initials, code, password, or by other computer or electronic means that allows identification of the individual responsible for the entry.¶

(b) Systems for authentication of dictated, computer, or electronically generated documents must ensure that the author of the entry has verified the accuracy of the document after it has been transcribed or generated.¶

(8) The following records shall be maintained in written or computerized form for the time period specified:¶

(a) Permanent:¶

(A) Patient's register, containing admissions and discharges;¶

(B) Patient's master index;¶

(C) Register of all deliveries, including live births and stillbirths;¶

(D) Register of all deaths; and¶

(E) Register of operations.¶

(b) Seven years:¶

(A) Register of outpatients; and¶

(B) Emergency room register.¶

(c) Blood banking register shall be retained for 20 years.¶

(9) The completion of the medical record shall be the responsibility of the attending qualified member of the medical staff. Any licensed health care practitioner responsible for providing or evaluating the service provided shall complete and authenticate those portions of the record that pertain to their portion of the patient's care. The appropriate individual shall authenticate the history and physical examination, operative report, progress notes, orders and the summary. In a hospital using interns, such orders must be according to policies and protocols established and approved by the medical staff. An authentication of a licensed health care practitioner on the face sheet of the medical record does not suffice to cover the entire content of the record.¶

(a) Medical records shall be completed by a licensed health care practitioner and closed within four weeks following the patient's discharge.¶

(b) If a patient is transferred to another health care facility, transfer information shall accompany the patient. Transfer information shall include but is not limited to:¶

(A) The name of the hospital from which they were transferred;¶

(B) The name of physician or other health care practitioner to assume care at the receiving facility;¶

(C) The date and time of discharge;¶

(D) The current medical findings;¶

(E) The current nursing assessment;¶

(F) Current medical history and physical information;¶

(G) Current diagnosis;¶

(H) Orders from a physician or other licensed health care practitioner for immediate care of the patient;¶

(I) Operative report, if applicable;¶

(J) TB test, if applicable; and¶

(K) Other information germane to patient's condition.¶

(c) If the discharge summary is not available at time of transfer, it shall be transmitted to the new facility as soon as it is available.¶

(10) Diagnoses and operations shall be expressed in standard terminology. Only abbreviations approved by the medical staff may be used in the medical records.¶

(11) Medical records shall be filed and indexed. Filing shall consist of an alphabetical master file with a number cross-file. Indexing is to be done according to diagnosis, operation, and qualified member of the medical staff, using a system such as the International or Standard nomenclature systems.¶

(12) Medical records are the property of the hospital. The medical record, either in original, electronic or microfilm form, shall not be removed from the hospital except where necessary for a judicial or administrative proceeding. Treating and attending physicians shall have access to medical records. When a hospital uses off-site storage for medical records, arrangements must be made for delivery of these records to the hospital when needed for patient care or other hospital activities. Precautions must be taken to protect patient confidentiality.¶

(13) Authorized personnel of the Oregon Health Authority (Authority) shall be permitted to review medical records and patient registers as necessary to determine compliance with health care facility licensing laws.¶

(14) Medical records shall be kept for a period of at least 10 years after discharge. Original medical records may be retained on paper, microfilm, electronic or other media.¶

(15) Medical records shall be protected against unauthorized access, fire, water and theft.¶

(16) If a hospital changes ownership, all medical records in original, electronic or microfilm form shall remain in the hospital and it shall be the responsibility of the new owner to protect and maintain these records.¶

(17) If a hospital closes, its medical records and the registers required under section (8) of this rule may be delivered and turned over to any other hospital in the vicinity willing to accept and retain the same as provided in section (12) of this rule. A hospital which closes permanently shall follow the procedure for Authority and public notice regarding disposal of medical records under OAR 333-500-0060.¶

(18) All original clinical records or photographic or electronic facsimile thereof, not otherwise incorporated in the medical record, such as X-rays, electrocardiograms, electroencephalograms, and radiological isotope scans shall be retained for seven years after a patient's last exam date if professional interpretations of such graphics are included in the medical records. Mammography images shall be retained for 10 years after a patient's last exam date.¶

(19) If a qualified medical record practitioner, RHIT (Registered Health Information Technician) or RHIA (Registered Health Information Administrator) is not the Director of the Medical Records Department, periodic and at least annual consultation must be provided by a qualified medical records consultant, RHIT or RHIA. The visits of the medical records consultant shall be of sufficient duration and frequency to review medical record systems and assure quality records of the patients. The contract for such services shall be made available to the

Authority.¶

(20) A current written policy on the release of medical record information including a patient's access to his or her medical record shall be maintained in the medical records department.¶

(21) A hospital is not required to keep a medical record in accordance with this rule for a person referred to a hospital ancillary department for a diagnostic procedure or health screening by a private physician, dentist, or other licensed health care practitioner acting within his or her scope of practice.¶

(22) Pursuant to ORS 441.059, the rules of a hospital that govern patient access to previously performed X-rays or diagnostic laboratory reports shall not discriminate between patients of chiropractic physicians and patients of other licensed health care practitioners permitted access to such X-rays and diagnostic laboratory reports.¶

(23) Nothing in this rule is meant to prohibit or discourage a hospital from maintaining its records in electronic form.

Statutory/Other Authority: ORS 441.025

Statutes/Other Implemented: ORS 441.025, ORS 433.321, ORS 441.049

RULE SUMMARY: 333-520-0060 Maternity Services

This rule describes the types of maternity services that are required to be provided by general hospitals and at low occupancy acute care hospitals if offering maternity services. The rule text was updated to include congenital cytomegalovirus screening requirements outlined in OAR chapter 333, division 20.

CHANGES TO RULE:

333-520-0060

Maternity Services ¶

(1) General hospitals are required to comply with this rule. A low occupancy acute care hospital shall comply with this rule if it offers maternity services. ¶

(2) A hospital that provides maternity services shall have separate maternity facilities and a maternity care department that: ¶

- (a) Has labor, delivery, recovery, postpartum, and nursery rooms that conform to the applicable requirements of OAR chapter 333, division 535; ¶
- (b) Requires every person in the delivery room during a delivery to be appropriately attired according to the hospital's Infection Control Policy; ¶
- (c) Has appropriate resuscitation equipment immediately available to rooms where deliveries are planned and where newborn infants are kept; ¶
- (d) Has a warmed blanket or incubator for newborns to prevent thermal loss; ¶
- (e) Has incubators for premature infants equipped with a governor to control the flow of oxygen at 40 percent or under, and an oxygen analyzer; ¶
- (f) Has an accurate scale for weighing of infants; and ¶
- (g) Includes a nursery and a separate bassinet for each infant with a clean mattress covered with suitable sheeting, washable pads, and bed linen that is kept clean at all times. ¶

(3) A health care practitioner attending the birth of a newborn shall evaluate and treat a newborn at risk for chlamydial or gonococcal ophthalmia neonatorum in accordance with OAR 333-019-0036. ¶

(4) A parent or legal representative that refuses to allow prophylaxis for an infant shall be informed by the attending health care practitioner of the risks of the refusal and must sign a witnessed affidavit that attests they have been so informed and nonetheless refuse to allow prophylaxis. ¶

(5) A hospital shall ensure that all newborns are given Vitamin K at birth as required by ORS 433.303 through 433.314 and in accordance with OAR chapter 333, division 021. ¶

(6) A hospital shall ensure that every newborn infant born in the hospital is tested for Metabolic Diseases as required by OAR 333-024-1000 through 333-024-1050 and instructions to the parents or legal representative regarding the testing that be documented in the medical record. ¶

(7) A hospital shall ensure that every newborn infant born in the hospital receives a newborn hearing screening test and cytomegalovirus screening as required by ORS 433.321 and OAR chapter 333, division 20. ¶

(8) A hospital must perform pulse oximetry screening on every newborn infant delivered at the hospital before discharging the newborn infant in conformance with the following requirements: ¶

- (a) The pulse oximetry screening must be performed using evidence-based guidelines such as those recommended by Strategies for Implementing Screening for Critical Congenital Heart Disease, AR Kemper et al., Pediatrics 2011;128(5): e1259-1267. ¶
- (b) The hospital must have policies and procedures based on the guidelines required by subsection (a) of this section for: ¶
 - (A) Determining what is considered a positive screening result; and ¶
 - (B) Determining what follow-up services, treatment, or referrals must be provided if a newborn infant has a positive screening result. ¶
- (c) A Federal Drug Administration (FDA) approved motion tolerant pulse oximeter must be used. ¶
- (d) The pulse oximetry screening must be performed no sooner than 24 hours after birth or as close to discharge of the newborn infant as possible. ¶
- (e) If a newborn infant is admitted to a hospital as the result of a transfer from another hospital or Birthing Center before a pulse oximetry screening is performed, the hospital from which the newborn infant is discharged to home is responsible for performing the screening. ¶
- (f) The hospital must provide the following notifications and document them in the newborn infant's medical

record: ¶

- (A) Prior to the pulse oximetry screening, notify a parent or legal representative of the newborn about the reasons for the screening and the risks and consequences of not screening. ¶
- (B) Following the pulse oximetry screening, notify the health care provider responsible for the newborn infant and the infant's primary care provider of the results of the screening. ¶
- (C) Following the pulse oximetry screening and prior to discharge, notify a parent or legal representative of the newborn infant of the screening result, an explanation of its meaning and, if it is a positive screening result, provide information about the importance of timely diagnosis and intervention. ¶
- (g) A parent or legal representative of a newborn infant may decline pulse oximetry screening and, if screening is declined, the hospital must document the declination in the newborn infant's medical record. ¶
- (h) Following the pulse oximetry screening, the hospital, in accordance with the applicable standard of care, must provide any appropriate follow-up services or treatment for the newborn infant if necessary or provide a referral to a parent or legal representative of the newborn for follow-up services or treatment if necessary. ¶
- (i) The hospital must document in the newborn infant's medical record that the screening was performed, the screening result, the names of the health care providers who were notified of the screening result, and any follow-up services or treatment or referral for services or treatment. ¶
- (j) No newborn infant may be refused screening because of the inability of a parent or legal representative to pay for the screening. ¶

(9) Every infant born in a hospital shall be marked for identification before the infant is removed from the place of delivery and such identification shall not be removed from the infant until the infant is discharged. ¶

(10) A hospital shall not admit visitors to a delivery room, maternity rooms, wards, units, or the nursery except in accordance with the hospital's visiting policy. ¶

(11) A hospital shall ensure that persons entering the nursery are attired according to the hospital infection control policy and that hands are washed before touching an infant. ¶

(12) A hospital shall follow its infection control policy when handling and storing linens. ¶

(13) Formula feedings and any other feedings shall be given only as prescribed in writing by the physician or certified nurse midwife. ¶

(14) A hospital shall maintain and preserve a log of births giving date of birth, name of newborn, and mother/birth parent's name and chart number, in addition to complying with the requirements of the Oregon Health Authority's Center for Health Statistics. ¶

(15) A hospital may use a part of the maternity department for selected, non-communicable non-obstetrical patients as defined by hospital policy and approved by the hospital's infection control program under the following conditions: ¶

- (a) Patients admitted or transferred to the maternity department shall be instructed by appropriate maternity service personnel as to their responsibilities regarding use of the facility. ¶
- (b) Patients admitted to the maternity department shall be limited to obstetrical patients admitted for delivery, patients with obstetric complications, and selected non-communicable, non-obstetrical patients. ¶
- (c) Obstetrical patients and medical/surgical patients shall not occupy the same room. ¶
- (d) If necessary, one or more medical/surgical patients shall be transferred to another service in order to admit obstetrical patients. ¶

(16) A hospital shall adhere strictly to the guidelines for standard precautions developed by the Hospital Infection Control Practices Advisory Committee (HICPAC) when caring for obstetrical patients with infectious conditions. Patients with infectious conditions requiring strict isolation according to the above guidelines shall be transferred out of the maternity department following delivery, and given care in an area of the hospital where that isolation can be provided. If a maternity patient is found to have an infectious condition during surgery or delivery, the patient shall be returned to the maternity department and isolated according to hospital infection control policy. ¶

(17) A delivery room suite may be used for surgical procedures on non-obstetrical patients if approved by the Chief of Obstetrics in accordance with medical staff rules and regulations. ¶

(18) A hospital with maternity services may place stable postpartum patients and stable newborns, as those terms are defined in OAR 333-500-0010, on another acute care unit on a periodic basis under the following conditions: ¶

- (a) When a postpartum patient or newborn to be transferred out of the obstetrics (OB) unit meet the hospital's criteria for care on another unit as described in this rule; ¶
- (b) Where the decision to place a postpartum patient or newborn on another unit is based on currently accepted postpartum and newborn care standards and the ability of that unit to meet the needs of the patient; and ¶
- (c) When nursing staff on the non-OB unit have received training required by this rule and have demonstrated continuing competence. ¶

(19) A hospital that provides care to postpartum patients and newborns on non-OB units shall: ¶

(a) Develop and implement policies and procedures that include but are not limited to: ¶

(A) The transfer of postpartum patients and newborns to non-OB units including a delineation of the authority for medical, clinical and administrative nursing staff, and, when applicable, nurse practitioner staff to make the decision; ¶

(B) Staffing guidelines for the nursing care of postpartum patients and newborns on the non-OB unit; ¶

(C) Provision of information to maternity patients of possible or intended placement on a non-OB unit; ¶

(D) Provision of consumer information related to the availability and location of specialty maternity services; ¶

(E) Infection control practices including the use of standard precautions; ¶

(F) Procedures for patient placement, privacy, and safety that prohibit postpartum patients and newborns from occupying the same room as non-obstetrical patients; ¶

(G) Protocols for the placement of newborns without ~~mother~~birth parents; ¶

(H) Procedures to assure the inclusion of the care of postpartum patients and newborns on non-OB units in the hospital's quality assurance program; and ¶

(I) Delineation of hospital protocols for the return of postpartum patients and newborns to the OB unit, including addressing situations when safe care can no longer be provided on the non-OB unit. ¶

(b) Develop and implement staff training, continuing education, and continuing competency program that includes but is not limited to: ¶

(A) Postpartum nursing care; ¶

(B) Nursing care of the newborn; ¶

(C) Newborn resuscitation; ¶

(D) Newborn feeding; ¶

(E) Maternal and family education; ¶

(F) Infection control practices including the use of standard precautions; and ¶

(G) Maternity services policies and procedures including those required in subsection (19)(a) of this rule.

Statutory/Other Authority: ORS 441.025

Statutes/Other Implemented: ORS 441.025, ORS 433.306, ORS 433.321