

2025 Rules Advisory Committee House Bill 2685 (2025)

RAC Meeting 2 October 1, 2025

Time	Agenda
9:00 am – 9:10am	Introductions and Housekeeping
9:10am – 9:30am	Review of Draft Statement of Fiscal Need and Impact
9:30 am – 10:45 am	Review Example Protocols
10:45am – 10:55am	Public Comment
10:55 am – 11:00 am	Next Steps

2025 Rules Advisory Committee House Bill 2685 (2025) Membership Roster

Name	Key Category	Organization	Occupation/Title	Email Address
Members				
Anna Agnew, MD	Pediatric healthcare providers	Legacy Health Systems	Pediatric Hospitalist	
Justine Clark, MS, RN	Healthcare professionals	Providence Health System	Perinatal Clinical Program Manager	
Annette Cole, RN	Coordinated Cascade Health Care Organizations (CCO) Cascade Health Alliance/ Cascade Comprehensive Care Care Comprehensive Care			
Kate Dillon, MS	Parent or guardian of a Deaf or Hard of Hearing Child	Oregon CMV Project	Special Education Teacher	
Heather Durham, Au.D.	Clinical audiologist	OHSU	Pediatric Audiologist	
Laura Erickson, CPM	Birthing center staff	Alma Midwifery Birth Center	Clinical Director, CPM	
Michael Gilbert, MD	Healthcare professionals	Randall Children's Hospital / Legacy Health Systems	Pediatric Hospitalist	

Sheevaun Khaki, MD	Pediatric healthcare providers	OHSU	Pediatrician	
Chad Ludwig, MSW	Communities of persons with a disability	Bridges Oregon	Founder and Executive Director	
Cynthia Luxford, CPM	Birthing center staff	Nova Vida Midwives, LLC	Licensed Direct Entry Midwife	
Leonard Machado	Healthcare professionals	Halo Unlimited, Inc. dba Infant Hearing Screening Specialists	CEO Halo Unlimited, Inc., RRT	
Zilmillia Pittman, LPN	Birthing center staff	Corvallis Birth Center/ Midvalley Birthing Services	LPN/ Office Manager	
Emilia Smith, CPM	Healthcare professionals	Oregon Midwifery Council	Executive Director, Licensed Midwife	
David Stein	Parent or guardian of a Deaf or Hard of Hearing Child	Oregon CMV Project	Government Finance Manager	
Louise Vaz, MD	Pediatric healthcare providers	Oregon Health & Science University	Professor, Pediatric Infectious Disease	
Shelley Weise, BSN, RN	Birthing center staff	Salem Hospital	Nurse Manager Mother Baby Unit	
Mariah Wharton, CPM	Birthing center staff	Astoria Birth Center & Family Medicine	Certified Nurse Midwife	

Willa Woodard Ervin, CPM	Birthing center staff	Rogue Birth Center LLC	Midwife, Birth Center Owner, Academic Faculty, Perinatal Mental Health Professional	
		Oregon Hea	alth Authority (OHA) Staff	
Catalina Aragón, MS	Staff	ОНА	Maternal & Child Health Policy & Programs Manager	catalina.aragon@oha.oregon.gov
Gianna Bortoli	Staff	ОНА	EHDI Program Lead, Public Health Division	gianna.a.bortoli@oho.oregon.gov
Sarah Kowalski, MS	Staff	ОНА	Operations & Policy Analyst, Public Health Division	sarah.e.kowalski@oha.oregon.gov
Mellony Bernal	Staff	ОНА	Health Care Regulation & Quality Improvement	mellony.c.bernal@oha.oregon.gov
Sadie Morrissey	Staff	ОНА	HCRQI Section Operations Coordinator	sadie.morrissey@oha.oregon.gov



DRAFT Rulemaking Process

The Oregon Health Authority, Public Health Division has policies and procedures that guide the rulemaking process. In order to have the rules effective in January 2026, we will be following the timeline below.

Date	Activity
August 2025	Notify stakeholders of RAC application process
September 2025	Select RAC members from applications Draft proposed rules and Statement of Need and Fiscal Impact form
September – October 2025	Convene RAC and hold meetings to seek input on proposed rules and required forms
No later than November 6, 2025	OHA Rules Coordinator needs final proposed rules and rulemaking forms
No later than November 6, 2025	OHA Rules Coordinator will review forms and seek approval to file
November 13, 2025	OHA Rules Coordinator will file the notice of proposed rulemaking with the Oregon Secretary of State
November 13-14, 2025	Rulemaking documents will be posted to our website and interested parties will be notified
December 1, 2025	Notice appears in the Oregon Bulletin
December 15, 2025 or later	Hold public hearing to seek public comments
December 21, 2025 or later	Public comment period closes
After Public Comment Period Closes	Respond to comments from the public comment period
No later than December 26, 2025	Final rule text showing changes and responses to public comment period due to the OHA Rules Coordinator OHA Rules Coordinator will file the final rules with the Oregon Secretary of State
January 1, 2026	Rules effective date

I. PURPOSE AND ROLES

Rules Advisory Committees (RACs) provide an opportunity for subject matter experts, individuals, entity representatives, community representatives, and advocates to provide input to the Oregon Health Authority (OHA) about proposed rulemaking. RAC members will have the opportunity to review and comment on proposed rules, the agency's Statement of Need and Fiscal Impact and the rulemaking notice. The RAC's role is advisory and therefore consensus is not necessary.

A. Duties and Responsibilities

An individual that commits to serving on the RAC agrees to fulfill their responsibilities through attending and participating in meetings, studying available information, and providing recommendations and information to OHA.

Members will provide feedback and input on the draft rules, as well as review the Statement of Fiscal Impact, Racial Equity Impact and Cost of Compliance, including impact to small businesses.

Members acknowledge that the group's role is to provide information and recommendations to OHA, and that rulemaking authority rests with OHA. RAC members provide information and advice to OHA, but do not make final decisions on rules.

B. Membership

OHA seeks members who bring a broad range of expertise, skills, and perspectives to the committee. By including voices from different professional backgrounds and lived experiences, OHA aims to ensure that policies and decisions are informed, balanced, and responsive to the needs of all Oregonians.

C. OHA's Role

In addition to facilitating meetings, OHA staff will provide technical support, subject-matter expertise, and administrative assistance. Staff will strive to conduct meetings in a manner that fosters collaboration and consensus building, and to ensure that all opinions are heard and considered by the group. Staff will also seek to identify policy options that OHA has authority to implement.

Members are strongly encouraged to speak with staff about concerns about the process, as well as any recommendations OHA can implement to improve the rulemaking process.

II. OPERATING PROCEDURES

A. Protocols

All members agree to act in good faith in all aspects of the RAC process. This includes being honest and refraining from undertaking actions that will undermine the process, as well as behavior and communication outside of meetings.

Expectations include:

- Members should try to attend all meetings. If a meeting is missed, the member is encouraged to contact OHA staff for a briefing. Members may be represented by alternates with a minimum of 24-hours' notice to OHA staff contact. Members are expected to ensure that the alternate is up to speed on information and any previous conversations, so that they can fully participate. Members should minimize the use of alternates.
- Members will participate fully in letting the group know their perspective on issues, their concerns, and their differing points of view. At the same time, members will respect time constraints and will share the speaking time with others.
- Members agree to be respectful at all times of other representatives, staff, and audience members. They agree to listen to each other to seek to understand the perspectives of others, even if they disagree, and help to find ways to address concerns.
- Members agree that, while sharing opinions is welcomed, the intent is to listen to a variety of viewpoints that they may or may not agree with.
- Members agree to refrain from personal attacks, intentionally undermining the process, or publicly criticizing or misrepresenting positions taken by other participants during the process. Any reporting to constituents, the media, or other parties will focus on issues and not individuals. While not precluded from communicating with the media, participants should defer to OHA for all media communications related to the process and recommendations.
- Any written communications, including e-mails, blogs, and other social networking media, must be mindful of these procedural ground rules, and must maintain a respectful tone even if highlighting different perspectives.
- E-mails and other electronic communications, such as social networking messages, meant for the entire group should be sent to OHA staff for distribution to the group.
- Requests for information made outside of meetings must be directed to the staff contact.
- All participation in the process is voluntary and may be withdrawn. However, members agree that before withdrawing they will discuss the reason for their withdrawal with the staff and, if appropriate, the other members to provide an opportunity to understand the reasons for withdrawal and to encourage continued participation.

B. Meetings and Records

Meetings are open to the public. Meetings may be recorded.

OHA considers RACs public meetings, and any individual is welcome to attend, observe and listen. However, only those specifically invited to be a member of the committee may participate fully in the meeting. RACs may include time for the public to comment.

RAC records are public records. Communications of the RAC are not confidential.

"Communications" refers to all statements made during meetings, memoranda, work projects, records, documents, or materials developed, including social media and electronic mail correspondence (ORS 192.410(4)).

A-Engrossed House Bill 2685

Ordered by the House April 7 Including House Amendments dated April 7

Sponsored by Representatives PHAM H, LEVY B, DIEHL, MUNOZ; Representatives BOWMAN, ELMER, GOMBERG, GRAYBER, HARBICK, HUDSON, ISADORE, JAVADI, NELSON, OWENS, WALTERS, WRIGHT, Senators FREDERICK, SOLLMAN (Presession filed.)

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure. The statement includes a measure digest written in compliance with applicable readability standards.

Digest: The Act updates the law concerning a disease that affects newborns. (Flesch Readability Score: 64.9).

Directs the Oregon Health Authority to provide information on the screening protocol for cytomegalovirus to hospitals and birthing centers. Requires the authority to establish by rule a newborn screening protocol for cytomegalovirus. Eliminates the requirement if cytomegalovirus is added to the newborn bloodspot screening panel.

Takes effect on the 91st day following adjournment sine die.

A BILL FOR AN ACT

Relating to cytomegalovirus; creating new provisions; amending ORS 433.298 and 433.321; and prescribing an effective date.

Be It Enacted by the People of the State of Oregon:

SECTION 1. ORS 433.321 is amended to read:

433.321. (1) In all Oregon hospitals and birthing centers where more than 200 live births occur per year, each newborn child must receive a newborn hearing screening test. A hospital or birthing center shall attempt to conduct the test required under this subsection prior to the discharge of the newborn child from the facility.

- (2) All Oregon hospitals and birthing centers where fewer than 200 live births occur 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.
- (3) All Oregon hospitals and birthing centers conducting newborn hearing screening tests, within 10 days of conducting a newborn hearing screening test, shall:
- (a) Notify the parent or guardian and the health care provider of the newborn child of the test results;
- (b) Provide the parent or guardian with names and contact information for diagnostic facilities that conduct newborn hearing screening tests in the community and with materials developed pursuant to ORS 433.298; and
- (c) Report to the authority the results of the test for the newborn child and information identifying the newborn child.
- (4) A diagnostic facility conducting newborn hearing screening tests, within 10 days of conducting a newborn hearing screening test, shall report to the authority the results of the test for the newborn child and information identifying the newborn child. If a diagnostic facility conducting

NOTE: Matter in **boldfaced** type in an amended section is new; matter [italic and bracketed] is existing law to be omitted. New sections are in **boldfaced** type.

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- newborn hearing screening tests detects hearing loss in a newborn child, the diagnostic facility shall provide to the parent or guardian materials developed pursuant to ORS 433.298.
- (5) Each public and private educational institution that provides early intervention services as defined in ORS 343.035 shall disclose to the authority information identifying the children referred to the educational institution with diagnosed hearing loss and the enrollment status of the children. The institution may disclose to the authority additional information regarding children with hearing loss who are receiving early intervention services if the educational institution has obtained consent to disclose the information.
- (6) The authority[, in collaboration with the Child Development and Rehabilitation Center of the Oregon Health and Science University,] shall, on an annual basis, provide to all Oregon hospitals and birthing centers the following information:
 - (a) A description of the responsibilities created by this section;

- (b) A list of appropriate screening devices and descriptions of training protocols to ensure that staff members are adequately trained in the use of hearing screening equipment;
 - (c) A list of diagnostic facilities that conduct newborn hearing screening tests;
- (d) Using evidence-based best practice standards, a recommended schedule for conducting newborn hearing screening tests[, and for referring parents and guardians to health care providers for the purpose of diagnosing whether the newborn child has congenital cytomegalovirus, within 21 days of the newborn child's date of birth];
- (e) An expanded targeted screening protocol to identify newborns that should receive testing for cytomegalovirus within 14 days of birth and prior to discharge from the hospital or birthing center;
- (f) A recommended protocol for infant and early childhood diagnostic testing and care following a positive screening result for cytomegalovirus;
- [(e)] (g) A list of public and private educational institutions that provide early intervention services and a description of the geographic area served by each institution; and
- [(f)] (h) Other information related to newborn hearing screening tests or cytomegalovirus that the authority deems appropriate.
- (7)(a) If a newborn has a positive screening result for cytomegalovirus, the hospital or birthing center shall notify the parent or guardian and the health care provider of the newborn.
- (b) A health benefit plan, as defined in ORS 743B.005, shall provide payment, coverage or reimbursement for the cost of cytomegalovirus testing conducted in accordance with the expanded targeted screening protocol adopted by the authority under this section.
- (c) The authority shall adopt rules to establish the expanded targeted screening protocol for cytomegalovirus described in this section based on symptoms that could be attributed to cytomegalovirus, using evidence-based best practices and standards.
- (8)(a) Except as provided in paragraph (b) or (c) of this subsection, all hospitals and birthing centers shall comply with the screening protocol established by the department under subsection (7) of this section.
- (b) A hospital or birthing center is exempt from conducting newborn screening for cytomegalovirus under this section if the parent or guardian of the newborn objects to the testing in writing.
- (c) A hospital or birthing center in a health maintenance organization, as defined in ORS 750.005, shall conduct newborn screening for cytomegalovirus under this section within 14

days of birth.

- [(7)] (9) A hospital or birthing center described in subsection (1) of this section is exempt from providing newborn hearing screening tests if the parent or guardian of the newborn child objects to the testing procedure on the grounds that the procedure conflicts with the religious tenets and practices of the parent or guardian. The parent or guardian must sign a statement that the newborn child is being reared in accordance with those religious tenets and practices.
- [(8)] (10) A newborn child may not be refused the procedure described in subsection (1) of this section because of an inability of the parent or guardian to pay for the procedure.

SECTION 2. ORS 433.321, as amended by section 1 of this 2025 Act, is amended to read:

- 433.321. (1) In all Oregon hospitals and birthing centers where more than 200 live births occur per year, each newborn child must receive a newborn hearing screening test. A hospital or birthing center shall attempt to conduct the test required under this subsection prior to the discharge of the newborn child from the facility.
- (2) All Oregon hospitals and birthing centers where fewer than 200 live births occur 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.
- (3) All Oregon hospitals and birthing centers conducting newborn hearing screening tests, within 10 days of conducting a newborn hearing screening test, shall:
- (a) Notify the parent or guardian and the health care provider of the newborn child of the test results;
- (b) Provide the parent or guardian with names and contact information for diagnostic facilities that conduct newborn hearing screening tests in the community and with materials developed pursuant to ORS 433.298; and
- (c) Report to the authority the results of the test for the newborn child and information identifying the newborn child.
- (4) A diagnostic facility conducting newborn hearing screening tests, within 10 days of conducting a newborn hearing screening test, shall report to the authority the results of the test for the newborn child and information identifying the newborn child. If a diagnostic facility conducting newborn hearing screening tests detects hearing loss in a newborn child, the diagnostic facility shall provide to the parent or guardian materials developed pursuant to ORS 433.298.
- (5) Each public and private educational institution that provides early intervention services as defined in ORS 343.035 shall disclose to the authority information identifying the children referred to the educational institution with diagnosed hearing loss and the enrollment status of the children. The institution may disclose to the authority additional information regarding children with hearing loss who are receiving early intervention services if the educational institution has obtained consent to disclose the information.
- (6) The authority shall, on an annual basis, provide to all Oregon hospitals and birthing centers the following information:
 - (a) A description of the responsibilities created by this section;
- (b) A list of appropriate screening devices and descriptions of training protocols to ensure that staff members are adequately trained in the use of hearing screening equipment;
 - (c) A list of diagnostic facilities that conduct newborn hearing screening tests;
- 43 (d) Using evidence-based best practice standards, a recommended schedule for conducting new-44 born hearing screening tests;
 - [(e) An expanded targeted screening protocol to identify newborns that should receive testing for

- 1 cytomegalovirus within 14 days of birth and prior to discharge from the hospital or birthing center;]
 - [(f)] (e) A recommended protocol for infant and early childhood diagnostic testing and care following a positive screening result for cytomegalovirus;
 - [(g)] (f) A list of public and private educational institutions that provide early intervention services and a description of the geographic area served by each institution; and
 - [(h)] (g) Other information related to newborn hearing screening tests or cytomegalovirus that the authority deems appropriate.
 - [(7)(a) If a newborn has a positive screening result for cytomegalovirus, the hospital or birthing center shall notify the parent or guardian and the health care provider of the newborn.]
 - [(b) A health benefit plan, as defined in ORS 743B.005, shall provide payment, coverage or reimbursement for the cost of cytomegalovirus testing conducted in accordance with the expanded targeted screening protocol adopted by the authority under this section.]
 - [(c) The authority shall adopt rules to establish the expanded targeted screening protocol for cytomegalovirus described in this section based on symptoms that could be attributed to cytomegalovirus, using evidence-based best practices and standards.]
 - [(8)(a) Except as provided in paragraph (b) or (c) of this subsection, all hospitals and birthing centers shall comply with the screening protocol established by the department under subsection (7) of this section.]
 - [(b) A hospital or birthing center is exempt from conducting newborn screening for cytomegalovirus under this section if the parent or guardian of the newborn objects to the testing in writing.]
 - [(c) A hospital or birthing center in a health maintenance organization, as defined in ORS 750.005, shall conduct newborn screening for cytomegalovirus under this section within 14 days of birth.]
 - [(9)] (7) A hospital or birthing center described in subsection (1) of this section is exempt from providing newborn hearing screening tests if the parent or guardian of the newborn child objects to the testing procedure on the grounds that the procedure conflicts with the religious tenets and practices of the parent or guardian. The parent or guardian must sign a statement that the newborn child is being reared in accordance with those religious tenets and practices.
 - [(10)] (8) A newborn child may not be refused the procedure described in subsection (1) of this section because of an inability of the parent or guardian to pay for the procedure.
 - SECTION 3. The amendments to ORS 433.321 by section 2 of this 2025 Act become operative on the date the Oregon Health Authority adds cytomegalovirus to the newborn bloodspot screening panel.

SECTION 4. ORS 433.298 is amended to read:

- 433.298. (1) The Oregon Health Authority shall compile information on the following:
- (a) The transmission of congenital cytomegalovirus and methods to reduce the risk of infection during pregnancy;
 - (b) The signs and symptoms of and methods of diagnosing congenital cytomegalovirus;
 - (c) The potential complications associated with congenital cytomegalovirus; and
 - (d) Treating and managing congenital cytomegalovirus.
- [(2) The authority shall disseminate the information described in subsection (1) of this section to hospitals, birthing centers, diagnostic facilities that conduct newborn hearing screening tests, health care providers and the public. The authority must disseminate the information through print publications. The authority also may disseminate the information through electronic publications, video productions or any other method determined to be cost-effective by the authority.]
 - (2)(a) The authority shall disseminate the information described in subsection (1) of this

1 section to:

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- (A) Hospitals.
- 3 (B) Birthing centers.
- (C) Diagnostic facilities that conduct newborn hearing screening tests.
- 5 (D) Prenatal health care providers, including gynecologists and obstetricians.
- (E) The Department of Early Learning and Care.
 - (F) The public.
 - (b) The department shall disseminate the information to all certified or registered child care facilities, as defined in ORS 329A.263, for the facilities to educate employees about the risk of contracting cytomegalovirus during pregnancy.
 - (c) Except as provided in paragraph (d) of this subsection, the information disseminated under this section may be disseminated by print publication, electronic publication, video publication or any other cost-effective method.
 - (d) Hospitals, birthing centers, diagnostic facilities that conduct newborn hearing screening tests and prenatal health care providers shall at a minimum provide information to patients in print publications under this section no later than 48 hours after birth.
 - SECTION 5. No later than January 1, 2026, the Oregon Health Authority shall establish by rule the expanded targeted screening protocol for cytomegalovirus described in ORS 433.321 (7)(c), as amended by section 1 of this 2025 Act.
 - SECTION 6. Section 5 of this 2025 Act is repealed on January 2, 2027.
- SECTION 7. This 2025 Act takes effect on the 91st day after the date on which the 2025 regular session of the Eighty-third Legislative Assembly adjourns sine die.

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Oregon Health Authority Public Health Division - Chapter 333 Division 20 EARLY HEARING DETECTION AND INTERVENTION 333-020-0125 Definitions As used in these rules OARs 333-020-0125 through 333-020-0165: Commented [A1]: Clarifying rules referenced in definitions. (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 a child's birth, including hospital or birthing center. (5) "Child" means any individual who is under 36 months of age. (6) "Congenital" means present at birth. (7) "Congenital Cytomegalovirus (CMV) Diagnostic Testing and Care Protocol" means the evidence-based protocol for infant and early childhood diagnostic testing and care following a positive test result for congenital cytomegalovirus, provided by the Authority. Commented [A2]: Refers to the protocol following a positive test result for CMV. (8) "Congenital cytomegalovirus screening" means an evidence-based assessment approved by the Authority, as described in the Congenital Cytomegalovirus Screening Protocol. Commented [A3]: Refers to the assessment conducted to determine congenital CMV testing. (9) "Congenital Cytomegalovirus Screening Protocol" means the evidence-based protocol to identify newborns that should receive testing for cytomegalovirus (CMV) within 14 days of birth and prior to discharge from the hospital or birthing center, to be implemented by all birthing facilities, and provided by the Authority. Commented [A4]: Refers to the protocol to determine if initial CMV testing is warranted.

RAC Meeting #2 10-1-2025

Level 3 - Restricted

(10) "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/or vision loss. (7911) "Diagnostic facility" means any facility that conducts pediatric diagnostic hearing evaluations. (8)12)0 "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 intervention. (911) "Director" means the Director of the Public Health Division within the Oregon Health Authority. Commented [A5]: Clarifying language based on grant expectations - will be appointed by the section manager of Family and Child Health. (1013) "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 433.321-433.327. (4114) "Early intervention services" or "EI" 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 Commented [A6]: Clarifying language. in collaboration with the parents and caregivers. (1215) "Early intervention facility" is any public or private educational institution providing early Commented [A7]: Not applicable based on rules defined in ORS 343.035 intervention services. (1316) "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 under public supervision by personnel qualified in accordance with criteria established by rules of the State Board of Education and in conformity with an individualized family service plan, as defined in ORS 343.035. (1417) "Hearing screening" means a physiologically-based test procedure performed on both ears using Commented [A8]: Clarifying comment. technologies approved by the Authority, as described in the Hearing Screening Protocol. Level 3 - Restricted

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(2326) "Refer" means a child did not meet the pass criteria defined in these rules and needs more testing to determine the presence or absence of a hearing loss.

(2427) "Risk factor" means any one of the risk indicators determined by the Joint Committee for Infant Hearing Authority as being associated with either congenital or delayed-onset hearing loss.

(2528) "Screening facility" means any a mandated and a non-mandated birthing facility that chooses to conducts hearing screenings, as defined in these rules.

(29) "Section Manager" means the Section Manager of the Oregon Health Authority's Family and Child Health Section within the Public Health Division.

Commented [A16]: Removing this to ensure clarity in the event that this committee is no longer in existence, we will still be following this as long as it is aligned with the Authority's recommendations and national best practices.

Commented [A17]: Clarifying language.

(2630) "These Rules" means OAR 333-020-0125 through 333-020-0165.

(31) "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.

Statutory/Other Authority: ORS 433.323

Statutes/Other Implemented: ORS <u>433.298</u>, 433.321–433.327

History:

PH 26-2017, amend filed 12/21/2017, effective 01/01/2018

PH 11-2011, f. & cert. ef. 10-27-11

PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11

PH 21-2003, f. & cert. ef. 12-16-03

OHD 8-2000, f. & cert. ef. 7-20-00

Commented [A18]: Clarifying definition.

Commented [A19]: Added in statute for CMV dissemination of information.

333-020-01xx Determining Facility Requirements to Provide Hearing Screenings

- (1) A non-mandated facility whose reports of live births increases to more than 200 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 may choose to discontinue providing newborn hearing screening on or after July 1 of the following year.

Commented [A20]: Rules are already established, moved from rule 333-020-0130 into its own rule and reworded to clarification.

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Statutory/Other Authority: ORS 433.321

Statutes/Other Implemented: ORS 433.321

333-020-0130

<u>Facility</u> Requirements for Hearing Screening in <u>ChildrenNewborns</u>

(1) In all mandated facilities, each newborn:

- a) Shall receive a hearing screening, consistent with the Hearing Screening Protocol, prior to discharge from the facility.
- b) May not be refused a hearing screening due to an inability of the parent or guardian to pay for the procedure.

(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 may be refused a hearing screening from a mandated facility because of 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 of the Authority.

(2) In a non-mandated facilities where a hearing screening is not performed, each newborn's parent or guardian shall be provided with information furnished by the 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

(3) A non-mandated facility that chooses to conduct hearing screenings must follow guidelines and follow-up requirements established for a mandated facility identified in OARs 333-020-0132 and 333-020-0150.

(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.

Commented [A21]: Clarifying language.

Commented [A22]: Moved into the definitions of mandated and non-mandated facilitates above.

Commented [A23]: Moved to a new OAR above.

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(6) Hospitals or birthing centers with fewer than 200 live births per year, and which are not providing newborn hearing screening, shall provide the parent or guardian of a newborn child born in their facility with information furnished by the Authority including, but not limited to, a list of Authority recommended screening facility locations and contact information, and a statement indicating that newborn hearing screening is important to determine the presence or absence of hearing loss and is considered standard of care.

Commented [A24]: Moved above to separate rule regarding determining facility requirements.

Statutory/Other Authority: ORS 433.321

Statutes/Other Implemented: ORS 433.321

History:

PH 26-2017, amend filed 12/21/2017, effective 01/01/2018

PH 21-2003, f. & cert. ef. 12-16-03

OHD 8-2000, f. & cert. ef. 7-20-00

333-020-01xx Facility Requirements to Provide Congenital Cytomegalovirus Testing in Newborns

(1) In all birthing facilities, each newborn shall be assessed for the need for congenital cytomegalovirus (CMV) testing, consistent with the Congenital Cytomegalovirus Screening Protocol, within 14 days of birth and prior to discharge of the child from the facility.

(2) If a newborn has a positive screening result for congenital cytomegalovirus (CMV) based on the assessment in section (1) of this rule, the birthing facility shall:

(a) Notify the parent or guardian and the health care provider of the newborn; and

(b) Provide the parent or guardian with information on congenital cytomegalovirus diagnostic testing and care, according to the Congenital Cytomegalovirus (CMV) Diagnostic Testing and Care Protocol

Statutory/Other Authority: ORS 433.321

Statutes/Other Implemented: ORS 433.321

333-020-01xx Dissemination of Cytomegalovirus Information

(1)(a) The Authority shall develop and disseminate information about cytomegalovirus (CMV), as described, in ORS 433.298 to the following entities:

(A) Hospitals.

(B) Birthing centers.

(C) Diagnostic facilities that conduct newborn hearing screening.

(D) Prenatal healthcare providers, including gynecologists and obstetricians.

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Commented [A25]: Information about diagnostic testing and care following a positive result would be in the Diagnostic Testing and Care Protocol.

Commented [A26]: New requirements establishing rule according to HB 2685 (2025).

(E) The Department of Early Learning and Care.

(F) The public.

(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, diagnostic facilities, and prenatal healthcare providers shall, at a minimum, provide the information developed by the Authority to the parent or guardian of the newborn in print within 48 hours after birth.

(3) Screening facilities shall provide to the parent or guardian information about congenital cytomegalovirus, as furnished by the Authority, in print publications no later than 48 hours after birth.

Statutory/Other Authority: ORS 433.323

Statutes/Other Implemented: ORS 433.298, 433.321 & 433.323

333-020-0132

Requirements for Screening Facilities

All Screening facilities shall:

- **Commented [A27]:** Per "(29) "Screening facility" means any facility that conducts hearing screenings."
- (1) Provide the 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 notification shall include a description of the meaning of a Pass result and a Refer result, as defined in these rules.
- (2) 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 care provider of any child who needs additional testing.

(3) (3) Provide to the parent or guardian of a child, information on congenital cytomegalovirus (CMV), furnished by the Authority.

the information described in ORS 433.321 to the parent or guardian of the child-

Commented [A28]: Clarifying language on requirement to provide CMV information.

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(4) Identify a point of contact for the facility and provide the designated staff name and contact information to the Early Hearing Detection and Intervention program.

Statutory/Other Authority: ORS 433.321 and 433.323

Statutes/Other Implemented: ORS 433.321, and 433.323

History:

PH 26-2017, adopt filed 12/21/2017, effective 01/01/2018

333-020-0135

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

(1) If a newborn is discharged from a mandated facility prior to completion of a newborn hearing screening, the mandated facility shall arrange for the provision of screening.

(2) 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 hearing screening is performed, according to the Hearing Screening Protocol.

Should a newborn child be 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.

Commented [A29]: Reworded above for consistency.

(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.

Commented [A30]: Removed - language was captured in (1) above.

(2) For purposes of this rule, in the case of a newborn child 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 assuring that a hearing screening is performed, according to the Hearing Screening Protocol.

Commented [A31]: Reworded above for consistency.

Statutory/Other Authority: ORS 433.321 Statutes/Other Implemented: ORS 433.321

History:

Level 3 - Restricted

PH 21-2003, f. & cert. ef. 12-16-03
OHD 8-2000, f. & cert. ef. 7-20-00
333-020-0150
Collecting and Submitting Information Related to Hearing Screening
(1) Within 10 days of screening a child, a screening facility shall report, at a minimum, the following information to the Authority via the confidential reporting mechanism(s) established by the Authority:
(a) Full name of the child;
(a) Fall Halle of the child,
(b) Child's date of birth;
(4) 2 3 3 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4
(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) Ear specific results of the hearing screening or status of the newborn hearing screening, if not
completed;
(i) Type of screening performed;

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PH 26-2017, amend filed 12/21/2017, effective 01/01/2018

Commented [A32]: No statutory authority to track or report CMV testing, only required for hearing screenings.

(i)	Date that	screening	was	nerform	ed.

(k) Name of child's primary health care provider, for any child who does not pass the screeninghas a "Refer" results on a hearing screening, does not receive a complete hearing screening, or has a risk factor for hearing loss; and

Commented [A33]: To make consistent with language and definitions.

- (I) Name of secondary point of contact for any child who does not pass the 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

History:

PH 26-2017, amend filed 12/21/2017, effective 01/01/2018

PH 21-2003, f. & cert. ef. 12-16-03

OHD 8-2000, f. & cert. ef. 7-20-00

333-020-0151

Collecting and Submitting Information Related to Diagnostic Testing for Hearing Loss in Children

Level 3 - Restricted

(1) Within 10 days of testing of a child who has a "REFERRefer" 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 Authority via the confidential reporting mechanism(s) established by the Authority:	 Commented [A34]: Consistent with language used in definitions.
(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) Ear specific results, including type and degree of hearing loss, if applicable;	
(k) Disposition, including referrals indicated for early intervention or other services;	
(I) Name and contact information for person completing diagnostic hearing evaluation; and	
(m) For those diagnosed with permanent hearing loss, the complete evaluation report.	

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- (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

History:

PH 26-2017, amend filed 12/21/2017, effective 01/01/2018

PH 21-2003, f. & cert. ef. 12-16-03

333-020-0155

Responsibility for Issuing Reports

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

Statutory/Other Authority: ORS 433.323

Statutes/Other Implemented: ORS 433.321–433.327

History:

PH 26-2017, amend filed 12/21/2017, effective 01/01/2018

PH 21-2003, f. & cert. ef. 12-16-03 OHD 8-2000, f. & cert. ef. 7-20-00

Level 3 - Restricted

333-020-0160 Appointment of an Advisory Committee (1) The Director Section Manager shall may appoint an advisory committee. **Commented [A35]:** Aligns with appointments for federal grants. (a2) At a minimum, the advisory committee shall include representatives from each of the following categories: Individuals eligible to serve on an advisory committee include but are not limited to: (A) Representatives from the following categories: (a) Parent or guardian of a child with hearing loss; deaf or hard of hearing child; (b) Deaf or hard of hearing a Adult with identified in childhood hearing loss; Commented [A36]: Updates to language. (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 viii. (i)-Speech-language pathologist. (b) The purpose of the advisory committee is to gather its members' collective knowledge, experience, expertise, and insight to assist the 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.

RAC Meeting #2 10-1-2025 26

Level 3 - Restricted

(c) 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 Authority 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.

(d) An advisory committee member must:

(A) Attend meetings;

(i) If there are more than 2 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.

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

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

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

Statutory/Other Authority: ORS 433.323431.250

Statutes/Other Implemented: ORS 433.321-433.327

History:

PH 26-2017, amend filed 12/21/2017, effective 01/01/2018

PH 21-2003, f. & cert. ef. 12-16-03

OHD 8-2000, f. & cert. ef. 7-20-00

333-020-0165

Religious-Exemptions from Hearing Screening

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

Commented [A37]: Added definition for "these rules".

Level 3 - Restricted

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

Commented [A38]: Language listed in statute.

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

Statutory/Other Authority: ORS 433.321 and 433.323

Statutes/Other Implemented: ORS 433.321–433.327

History:

PH 26-2017, amend filed 12/21/2017, effective 01/01/2018

PH 21-2003, f. & cert. ef. 12-16-03 OHD 8-2000, f. & cert. ef. 7-20-00



OREGON ADMINISTRATIVE RULES

OREGON HEALTH AUTHORITY, PUBLIC HEALTH DIVISION

CHAPTER 333

Division 505 HOSPITAL ORGANIZATION AND MANAGEMENT

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.
- (I) 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'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 <u>and cytomegalovirus testing</u> 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

Division 520

HOSPITAL SERVICES

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 <u>and cytomegalovirus testing</u> 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's name and chart number, in addition to complying with the requirements of the 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 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 mothers;
- (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 & 433.306

Division 77

BIRTHING CENTERS

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 screening and cytomegalovirus testing, and newborn metabolic screening, or record of referral to screenings if screenings is are 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;
- (K₄) 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
- (LK) 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

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 testing, as required by OAR chapter 333, division 20.
- (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 followup 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





How to Screen for Congenital CMV

Colorado Congenital CMV Testing Protocol

ASSESS for Risk Factors:

- 1. Mother diagnosed with CMV infection during pregnancy
- 2. Small for gestational age: birth weight <10th percentile
- 3. Microcephaly: head circumference <10th percentile
- 4. Low birth weight or preterm: birth weight <2000 grams
- 5. Did not pass the newborn hearing screen (one or both ears)
- Fetal hydrops or ascites, abdominal calcifications, or thickened bowel on prenatal ultrasound
- 7. Hepatomegaly, splenomegaly, or elevated liver function tests (AST or ALT >100 U/L or direct bilirubin >1.0 mg/dL)
- 8. Abnormal brain imaging
- 9. Persistent thrombocytopenia (platelets <100,000/mm3)
- 10. Petechial or "blueberry muffin" rash
- 11. Retinitis or other eye finding



SCREEN if any risk factors are identified:

- 1. Order Qualitative CMV PCR on urine or saliva, with a diagnosis code indicating the risk factor
- 2. If saliva CMV PCR is positive, order urine CMV PCR to confirm
- 3. Give the family the handout: Why Is My Baby Being Tested for CMV? (English link, Spanish link).
- 4. Add the diagnosis **Screening for CMV** to the Problem List



If urine CMV PCR is POSITIVE:

- 1. Add the diagnosis **Congenital CMV Infection** to the Problem List
- Give the family the handout We invite you and your child with cCMV to join the Colorado cCMV Family Network (English link, Spanish link)
- 3. Discuss the case with a Pediatric Infectious Disease specialist
- 4. Order a CBC with differential and liver function tests
- 5. Order brain imaging, either head ultrasound or brain MRI
- 6. Refer to a pediatric ophthalmologist, to look for CMV retinitis
- 7. Refer to Early Intervention, to monitor for developmental delays
- 8. Refer to Pediatric Audiology and Pediatric ENT
- 9. For more information, go to aapcolorado.org

A clinical guideline from the Colorado Chapter, American Academy of Pediatrics

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abnormal, seizures, microcephaly)

Evaluation of Suspected Congenital Cytomegalovirus Infection (cCMV)

If any of the following present:

- Mother positive for CMV infection during pregnancy
- Abnormal head size (OFC <10th %ile <u>OR</u> >90th %ile at birth) 2)
- Intrauterine growth restriction (weight <10th %ile for gestational 3)
- 4) Unexplained hydrops
- 5) Intracranial OR intraabdominal calcifications on first imaging
- Unexplained hepatomegaly OR splenomegaly (>1 cm below the right or left costal margin)
- AST or ALT >100 U/L OR unexplained direct bilirubin >1.0 mg/dL
- Petechial rash or blueberry muffin rash at any time
- Leukomalacia, polymicrogyria, lissencephaly, pachygyria, schizencephaly
- Unexplained persistent thrombocytopenia (platelets < 100k/mm³)
- 11) Failed hearing screen

Send urine CMV PCR

(obtain by 21 days of life when possible)

If CMV + , perform the following tests: (If in WBN/SCN, consider neonatology consult)

- CBC with differential
- Ophthalmology (inpatient or
- Head Ultrasound
- Hearing: Diagnostic ABR, OAE

(Tympanometry and Bone if indicated)

- Refer to Early Intervention
- EMAIL Utah Dept Health
- CMV@Utah.gov

ASYMPTOMATIC if all of the following:

- Normal Ophthalmology Exam
 Normal Platelet Count
- Normal ABR *
- Normal Head US
- No hepatosplenomegaly
- Normal Liver Function
- * Normal ABR = 25 dBeHL or less at all test frequencies (500, 1k, 2k and 4k whenever possible) with present OAE

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Isolated Sensorineural **Hearing Loss**

SYMPTOMATIC if one or more of the following:

- Thrombocytopenia
- Hepatomegaly
- Splenomegaly
- IUGR/SGA
- Abnormal HUS

Microcephaly

• Sensorineural hearing loss (if also one or more of the above)

At 3mos of age:

Follow up with Audiology & ENT

By 4 weeks of age:

- Consult **Pediatric ID** to discuss antiviral treatment
- Consult **Pediatric Neurology** if abnormal **HUS** or microcephaly

Evaluation in Multidisciplinary Congenital CMV Clinic Call (801) 662-1740 to schedule:

- Infectious Disease
- Neurology



Congenital cytomegalovirus

Congenital cytomegalovirus (cCMV) is the most common viral infection that infants are born with in the U.S. and can result in brain damage, hearing and/or vision loss, developmental delays, and on rare occasion, death.

According to <u>Utah's CMV legislation</u>, if a newborn fails their initial and follow-up hearing screen, or just their initial hearing screen after 14 days of age, they need to be tested for cCMV.

In addition to testing based on hearing screening results, most Utah hospitals also test for cCMV if the infant has certain risk factors, such as petechiae, microcephaly or low birthweight. For more information, contact cmv@utah.gov or 801-273-6600.

What to do with a positive case

Infected infants should receive follow-up care as soon as possible. Infected infants could have immediate, delayed, or progressive concerns and may benefit from anti-viral treatment.

Follow-up includes:

- Diagnostic audiological evaluation;
- Referral to an infectious disease specialist;
- Referral to an otolaryngologist (ENT);
- Referral to a pediatric ophthalmologist;
- Referral to a neurologist:
- Referral to early intervention (familyhealth.utah.gov/oec/baby-watchearly-intervention/)

cCMV clinic

The cCMV clinic at Primary Children's Hospital offers an integrated follow-up process. This clinic provides consultation, evaluation, treatment as needed, specialist coordination for babies and families affected by cCMV, and support to their providers. When you receive notice of a positive case, please reach out to the cCMV clinic at 801-662-1705.

Resources

Utah CMV public health initiative: cmv@utah.gov, 801-273-6600, 51

Congenital CMV (cCMV) Infection Colorado Clinical Care Worksheet

Colorado Chapter

OF THE AMERICAN ACADEMY OF PEDIATRICS
INCORPORATED IN COLORADO



Did this child have a **positive** <u>urine</u> **CMV PCR before 21 days of age**? If so, this confirms the diagnosis of congenital CMV infection. Positive CMV tests on saliva or dried blood spot must be confirmed by urine PCR.

Infant's Name: DOB:
Aliases (mother's maiden name, etc):
Birth location: MRN:
Birth weight:grams / Pounds-ounces%ile Gestational age: weeks
Head circumference (OFC): cm%ile Length: cm / inches%ile
Physical exam findings:
Prenatal history (for example: US findings, maternal illness):
☐ Provide a family handout about cCMV in Colorado: English or Spanish
About Cytomegalovirus Cytomegalovirus (CMV) and Congenital CMV Infection CDC
National CMV Foundation—Cytomegalovirus (CMV) National CMV Foundation
□ Add the diagnosis Congenital CMV to the problem list (ICD-10 code: P35.1)
☐ As soon as possible, perform the following testing :
□ CBC with differential
☐ Liver and kidney function tests ALT AST Total protein
Total bilirubin Direct bilirubin Alkaline Phosphatase
BUN Creatinine
☐ Cranial imaging : MRI brain without contrast¹ or Head US Result:
 ☐ Hearing screen should be completed ASAP Result: Lear: ☐ pass ☐ did not pass Rear: ☐ pass ☐ did not pass
 If the infant did not pass the hearing screen in one or both ears: Refer to Pediatric Audiology for evaluation ASAP, no later than 3 months of age
 Refer to Pediatric Otolaryngology (ENT)
☐ Plan for Pediatric 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 ² . ALL children with cCMV require monitoring by Pediatric Audiology,
even if they pass the infant hearing screen, because they are at risk of progressive hearing loss.

^{1.} Note that Pediatric Neurology at Children's Hospital Colorado (CHCO) recommends MRI without contrast for all children with cCMV. If such imaging is not available in the child's home location, Pediatric Neurology at CHCO can be contacted through OneCall 720-777-3999 to discuss options and recommendations.

^{2.} For exampte Ather Mediatric Applie (1964), 2019 the for a child with normal hearing at birth is at 3 months, 6 mo, 9 mo, 12 mo, 18 mo, 24 mo, 30 mo, 3 years, 4 years, 5 years, and 50 years.

Congenital CMV Infection Colorado Clinical Care Worksheet

Refer to Pediatric Infectious Disease if the child has significant abnormalities on testing (CBC, LFTs, brain imaging, retinitis, hearing loss) and/or clinical findings (microcephaly, hepatosplenomegaly, SGA/IUGR, petechiae/purpura), then they may be eligible for treatment with antiviral medication. Referrals may also be sent for patients with asymptomatic cCMV if the caregiver has questions. Referrals may be faxed to 720-777-7295 or placed in EPIC. Pediatric ID at Children's Hospital Colorado can be requested through One Call at 720-777-3999 for questions about specific patients.
cCMV is a reportable disease in Colorado. Report this case at https://cdphe.colorado.gov/report-a-disease or call 303-692-2700.
Refer to Early Intervention (EI) in the county where the family lives: Early Intervention Colorado Referral
Refer to Ophthalmology to evaluate for CMV retinitis
Refer to Pediatric Neurology if the child has microcephaly (head circumference below 3rd %ile), abnormal brain imaging, suspected seizure, or abnormal neurologic exam.
Refer for testing for Vestibular Dysfunction at 1 year of age. Vestibular testing is available at Children's Hospital Colorado, 720-777-8501 and recommended at 1 year of age, 3 years, and 7 years.
Consider more frequent monitoring of growth than the well child visit schedule. Children with cCMV may have problems with feeding and growth.
Refer for Developmental Evaluation if concerns for autism, which is more common in children with cCMV.

Resources:

- AAP Red Book Cytomegalovirus Chapter
- Congenital CMV Consensus Guidelines 2017 Lancet Infectious Disease Rawlinson et al
- American Academy of Audiology CMV Position Statement

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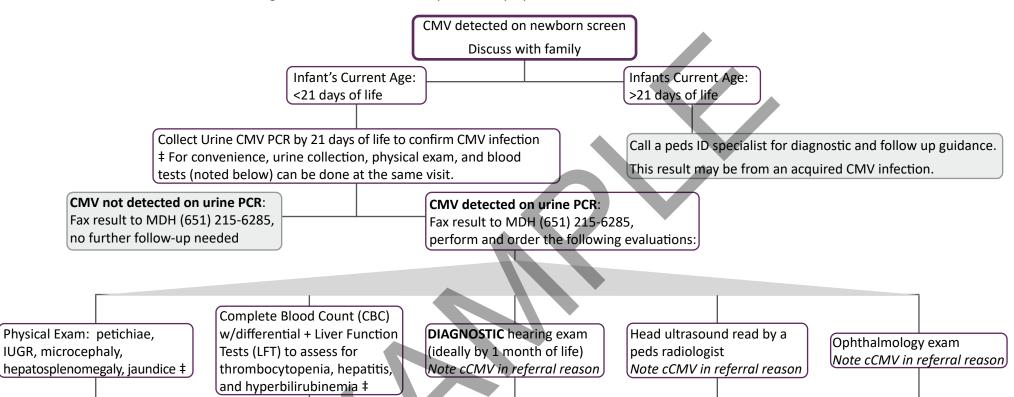




Colorado Chapter

Steps for cCMV Follow-up

Primary care providers of cCMV patients can manage most cCMV follow-up. All infants and children should be offered a referral to early intervention, although those services will likely benefit symptomatic children with cCMV the most.



YES: Call and consult with peds ID for referral and treatment recommendations

Specialist contact list can be found on MDH website



MDH Cytomegalovirus webpage

https://www.health.state.mn.us/diseases/cytomegalovirus/index.html

Were ANY signs or symptoms of cCMV disease detected through evaluations?

QUESTIONS?

Call the MDH on-call genetic counselor line at 651-201-3548.

NO: Continue to follow with developmental checks and audiology monitoring based on guidelines.



MDH EHDI Audiologic Guidelines for Infants with Congenital Cytomegalovirus

https://www.health.state.mn.us/docs/people/childrenyouth/improveehdi/audiogdlnccmv.pdf

Minnesota Newborn Screening 601 Robert St. N., St. Paul, MN 55155

Phone: (800) 664-7772* or (651) 201-5466* Fax: (651) 215-6285

*translators available



REV: 06/2023



Steps for cCMV Follow-up

OUTLINE VERSION

Primary care providers of cCMV patients can manage most cCMV follow-up. All infants and children should be offered a referral to early intervention, although those services will likely benefit symptomatic children with cCMV the most.

CMV detected on newborn screen, infant is older than 21 days of life:

- Discuss newborn screening result with the family
- Call a pediatric Infectious Disease specialist for diagnostics and follow-up guidance.
- This result may be from an acquired CMV infection.

CMV detected on newborn screening, infant is younger than 21 days of life:

- Collect Urine CMV PCR by 21 days of life to confirm CMV infection.
- For convenience, urine collection, physical exam, and blood tests (noted below) can be done at the same visit. ‡
 - Physical Exam: petechiae, IUGR, microcephaly, hepatosplenomegaly, jaundice ‡
 - Complete Blood Count (CBC) w/differential + Liver Function Tests (LFT) to assess for thrombocytopenia, hepatitis, and hyperbilirubinemia ‡

CMV not detected on diagnostic urine PCR:

• Fax result to MDH (651) 215-6285, no further follow-up needed.

CMV detected on diagnostic urine PCR:

- Fax result to MDH (651) 215-6285, perform and order the following evaluations:
- Physical Exam: petechiae, IUGR, microcephaly, hepatosplenomegaly, jaundice ‡
- Complete Blood Count (CBC) w/differential + Liver Function Tests (LFT) to assess for thrombocytopenia, hepatitis, and hyperbilirubinemia ‡
- **DIAGNOSTIC** hearing exam (ideally by 1 month of life). *Note cCMV in referral reason.*
- Head ultrasound read by a peds radiologist. Note cCMV in referral reason.
- Ophthalmology exam. Note cCMV in referral reason.

No signs or symptoms of cCMV disease were detected through evaluations:

- Continue to follow with developmental checks and audiology monitoring based on guidelines.
- Section 4: Audiology Guidelines For Infants With Congenital Cytomegalovirus (state.mn.us)

Signs or symptoms of cCMV disease were detected through evaluations:

- Call and consult with pediatric Infectious Disease Specialist for referral and treatment recommendations.
- Specialist contact list can be found on MDH website: <u>Cytomegalovirus (CMV) and Congenital</u> <u>CMV - MN Dept. of Health (state.mn.us)</u>

Questions?

If you have any questions, please call the MDH on-call genetic counselor line at 651-201-3548.

Minnesota Department of Health Minnesota Newborn Screening 601 Robert St. N.,P St. Paul, MN #55155

Phone: (800) 664-7772 or (651) 201-5466

Fax: (651) 215-6285

health.newbornscreening@state.mn.us

www.health.state.mn.us

06/2023

To obtain this information in a different format, call: (651) 201-5466

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