

**OREGON HEALTH AUTHORITY,
PUBLIC HEALTH DIVISION**

DIVISION 20

NEWBORN HEARING SCREENING TESTS

333-020-0125

Definitions

As used in these rules:

(1) "Advisory Committee" means the Newborn Hearing Advisory Committee appointed by the Director of the Oregon Health Authority to advise the Authority and the legislature on the implementation and evaluation of universal newborn hearing screening in Oregon and the state newborn hearing screening test registry, tracking and recall system.

(2) "Authority" means the Oregon Health Authority.

(3) "Automated auditory brainstem response" means a specific test method that elicits an objective electro-physiological measurement of the brainstem's response to acoustic stimulation of the ear, obtained with equipment that automatically provides a pass/refer outcome.

(4) "Birthing Center" means any health facility licensed by the State of Oregon for the primary purpose of performing low risk deliveries, as defined in ORS 442.015(14)(f).

(5) "Birthing Facility" means the location of a child's birth, including hospital, birthing center (or) in the case of a home or out-of-facility birth, the child's birthing attendant.

(6) "Child" (or plural "children") means any individual (or individuals) who is (are) less than 36 months of age.

(7) "Diagnostic Facility" means any facility or person, including hospitals, private audiology practices, licenses health care providers and educational facilities that conduct newborn hearing diagnostic testing.

(8) "Diagnostic Testing" means the performance of physiologically-based testing on children to determine the presence or absence and extent of a hearing loss, using procedures specified by the Authority, for the purposes of establishing a diagnosis and serving as a basis for initiating therapy and/or intervention.

(9) "Director" means the Assistant Director of the Oregon Health Authority, Public Health Division.

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

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

(12) "EI" (or, alternately, "EI/ECSE") means the Early Intervention/Early Childhood Special Education Program of the Office of Special Education 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(6).

(13) "Follow-up Hearing Test" means any hearing screening or diagnostic test procedure that is conducted on a child who is enrolled in the Tracking and Recall System.

(14) "Hospital" means any health care facility licensed by the State of Oregon and meeting the definition of "hospital" in ORS 442.015(14)(a).

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

(16) "Newborn Hearing Screening Test" means a physiologically-based test procedure utilizing either otoacoustic emissions or automated auditory brainstem response technologies, or other technologies as approved by the Authority. If a newborn achieves a 'pass' on the first screening test, screening is completed. If a newborn does not pass, a second screening test is carried out immediately using a different technology or, after an interval of 12 hours, using the same technology.

(17) "Newborn hearing screening test registry" means a listing of newborn children and information related to their newborn hearing screening tests.

(18) "Otoacoustic emissions" means a specific test method that elicits a physiologic response from the cochlea, and may include Transient Evoked Otoacoustic Emissions and Distortion Product Otoacoustic Emissions.

(19) "Pass" means a newborn hearing screening result that indicates that a child's hearing is most likely within normal limits.

(20) "Private educational institution" means any private institution providing early intervention services as defined in ORS 343.035(6) or the equivalent and which have been accepted for the Office of Special Education of the Oregon Department of Education's "Approved Private Schools" list.

(21) "Public educational institution" means any public educational institution providing early intervention services, as defined in ORS 343.035(6).

(22) "Refer" means a newborn hearing screening test result that indicates that a child needs a follow-up hearing test.

(23) "Regional Program" means any one of the Low Incidence Regional Programs for the Deaf and Hard-of-Hearing.

(24) "Screening Facility" means any facility or person, including hospitals, birthing centers, private audiology practices, licensed health care providers and educational facilities that conduct newborn hearing screening tests.

(25) "Tracking and recall system" means a system attached to the newborn hearing test registry designed to identify and contact the parent or guardian of a newborn child listed in the newborn hearing screening test registry for the purposes of assisting in testing and in enrollment of the child in early intervention services in a timely manner.

Stat. Auth.: ORS 433.323

Stat. Implemented: ORS 433.321–433.327

Hist.: OHD 8-2000, f. & cert. ef. 7-20-00, PH 21-2003, f. & cert. ef. 12-16-03; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 11-2011, f. & cert. ef. 10-27-11

333-020-0127

Purpose and Intent

(1) The purpose of these rules is to implement ORS 433.321 et.seq., which:

(a) Authorizes the Authority to develop a newborn hearing screening test registry and tracking and recall system for all newborns in Oregon; and

(b) Requires the Authority to adopt rules to develop and implement the registry and recall system.

(2) In order to identify children with hearing loss as early as possible and assure timely entry into early intervention services, it is the intent that all Oregon newborns will be enrolled in the newborn hearing screening test registry using information derived from birth records and from screening facility reports to the Authority.

(3) It is the intent that all children who are identified in the newborn hearing screening test registry as not having completed a newborn hearing screening test (and) all children who received a result of "REFER" on the newborn hearing screening test shall be enrolled in the Tracking and Recall system. In addition, it is the intent that all children in the Newborn Hearing Screening Test Registry who are diagnosed with a hearing loss regardless of their initial newborn hearing screening test result shall be enrolled in the Tracking and Recall System.

(4) It is the intent that all screening facilities and diagnostic facilities that are conducting follow-up hearing tests on children enrolled in the tracking and recall system shall report child-specific information

to the Authority for the purposes of assuring that children are receiving needed services in a timely manner.

Stat. Auth.: ORS 433.323

Stat. Implemented: ORS 433.321-433.327

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

333-020-0130

Requirement for Hearing Loss Screening in Newborn Children

- (1) In all hospitals or birthing centers with more than 200 live births per year, each newborn child shall receive a Newborn Hearing Screening Test within one month of the child's date of birth.
- (2) The hospital or birthing center shall attempt to conduct the Newborn Hearing Screening Test prior to discharge of the child from the facility.
- (3) No newborn child may be refused the Newborn Hearing Screening Testing because of an inability of the parent or guardian to pay for the testing.
- (4) For hospitalized children, the timing of the Newborn Hearing Screening Test may be deferred if medically indicated.
- (5) The hospital or birthing center shall notify the parent or guardian and the health care provider of the newborn child of the Newborn Hearing Screening Test results within 10 days of the test. This notification shall include a description of the meaning of a Pass result and a Refer result.
- (6) The hospital or birthing center shall, with the results of the Newborn Hearing Screening Test, provide the parent or guardian of a child who needs follow-up testing and the health care provider with the names and contact information for diagnostic facilities and a description of the importance of timely diagnosis and intervention.
- (7) The Authority will determine the number of live births per year by information provided by the Center for Health Statistics of the Authority.
- (8) 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 Testing by July first of the following calendar year.
- (9) 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 Testing on or after April first of the following calendar year.
- (10) Hospitals or birthing centers with fewer than 200 live births per year, and which are not providing the Newborn Hearing Screening Test, 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 considered standard of care.

Stat. Auth.: ORS 433.321

Stat. Implemented: ORS 433.321

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

333-020-0135

Facility Responsible for Performing the Newborn Hearing Screening Test

(1) Should a newborn child be discharged from a hospital or birthing center with more than 200 live births in a calendar year before the Newborn Hearing Screening Test is performed or completed, it shall be the responsibility of the hospital to arrange for the provision of screening.

(2)(a) In all hospitals and birthing centers with more than 200 live births in a calendar year, the hospital or birthing center where a baby is born is responsible for assuring that the Newborn Hearing Screening Test is performed on that newborn child within one month of the child's date of birth, except that, for hospitalized children, the timing of the testing may be deferred past the one month time line, if medically indicated. If testing is deferred, the hospital shall be responsible for performing the Newborn Hearing Screening Test prior to the child's discharge to home.

(b) For purposes of this section, in the case of a newborn child admitted to a hospital as a result of transfer from another hospital or birthing center, the hospital from which the child is discharged to home shall be responsible for the performance of the Newborn Hearing Screening Test, if not done prior to transfer.

Stat. Auth.: ORS 433.321

Stat. Implemented: ORS 433.321

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

333-020-0140

Maintaining a List of Facilities Able to Perform Follow-up Diagnostic Testing

(1) The Authority shall maintain a list of licensed clinical audiologists or licensed physicians able to perform Diagnostic Testing, as follows:

(a) The Authority shall establish written criteria for placement on the list, including testing and reporting requirements.

(b) Individual audiologists or physicians may choose to be identified solely by the facility with which they are affiliated or by whom they are employed, if that facility accepts the testing requirements of 333-020-0145(1)(a).

(c) Audiologists or physicians who meet the criteria for inclusion on the list may notify the Authority that they wish to be included on the list, and upon verification of eligibility, the Authority shall immediately update the list.

(2) The list, and the criteria, shall be available at the Authority, upon request.

(3) The Authority shall provide the list, on at least an annual basis, no later than April first, to all hospitals or birthing centers.

Stat. Auth.: ORS 433.321

Stat. Implemented: ORS 433.321

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

333-020-0145

Maintaining and Distributing a List of Early Intervention Facilities

(1) The Authority shall maintain a list of early intervention facilities that provide early intervention services to infants who are deaf or hard-of-hearing, as follows:

(a) Each Regional Program.

(b) Each county office of the EI/ECSE program.

(c) Each private educational institution.

(d) The Authority may list the Regional Program in lieu of the EI county office(s) in that region, at the discretion of the Office of Special Education of the Oregon Department of Education, for the purpose of simplifying and facilitating the early intervention enrollment process for parents and guardians.

(2) The Authority shall provide this list of early intervention facilities to all individuals or facilities that are on the list of diagnostic facilities, as defined in OAR 333-20-0145, annually, no later than September first, to facilitate referrals.

Stat. Auth.: ORS 433.321

Stat. Implemented: ORS 433.321

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

333-020-0147

Newborn Hearing Screening Test Registry

Using information submitted by birthing facilities and screening facilities, including birth records and newborn hearing screening test results, the Authority shall establish a registry of all newborns and their hearing screening test results or status.

Stat. Auth.: ORS 433.323

Stat. Implemented: ORS 433.321-433.327

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

333-020-0149

Tracking and Recall System

(1) In consultation with the Advisory Committee, the Authority shall establish and implement a tracking and follow-up protocol for newborns in the Newborn Hearing Screening Test Registry identified with hearing loss or at-risk of hearing loss, including, but not limited to:

(a) Newborns who have no recorded newborn hearing screening test results and/or no recorded newborn hearing screening status in the Newborn Hearing Screening Test Registry

(b) Newborns who have newborn hearing screening test results or status of:

(A) "REFER"

(B) Unable to complete initial screen

(C) Screening deferred for medical reasons

(c) Newborns or children who have been diagnosed with hearing loss

(2) At a minimum, the tracking and follow-up protocol shall include:

(a) Responsibilities of Authority staff for identifying children in need of follow-up testing and for contacting parents/guardians, health care providers and local public health staff regarding needed follow-up services

(b) Recommended methods and time frames for contacting parents/guardians, health care providers and local public health agencies regarding needed follow-up services

(c) Procedures to document contacts made and outcomes of contacts

(d) Procedures to identify, document and comply with parent/family desire to opt-out of continued follow-up

(e) Procedures to document and address barriers to timely follow-up services, including financial and geographic barriers

(f) Procedures to document "Loss to follow-up" after reasonable attempts are made to contact family and/or health care provider

(g) Procedures to assure child-specific and family information is used only for the purposes for which it is intended and is not disclosed for other unrelated purposes.

Stat. Auth.: ORS 433.323

Stat. Implemented: ORS 433.321-433.327

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

333-020-0150

Collecting and Submitting Information Related to Newborn Hearing Screening

(1) By November 1, 2003, the Authority shall develop confidential reporting mechanisms and protocols for reporting newborn hearing screening test results to the Newborn Hearing Screening Test Registry. The reporting mechanisms and protocols shall be reviewed at least annually and modified as necessary.

(2) By November first of each year, or as necessary due to modifications, the Authority shall provide a written description of the reporting mechanisms and protocols, including reporting form templates if appropriate, to all screening facilities.

(3) Prior to the January 1, 2004 effective date of the law and as requested, the Authority shall offer training and technical assistance for screening facility staff to assure effective implementation of the newborn hearing screening reporting requirements.

(4) Beginning January 1, 2004, within 10 days of testing, each screening facility conducting newborn hearing screening tests shall report to the Authority, at a minimum, the following information about each newborn child receiving hearing screening in that facility.

(a) Name of the child;

(b) Child's date of birth;

(c) Birthing facility identifier;

(d) Screening facility identifier, if different than birthing facility;

(e) Newborn blood spot screening kit unique identification number, for matching purposes;

(f) Result of the newborn hearing screening test (or) status of the newborn hearing screening test, if not completed.

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

(a) Match the newborn hearing screening test result or status with the appropriate child in the Newborn Hearing Screening Test Registry;

(b) Identify children with risk factors for hearing loss.

Stat. Auth.: ORS 433.323

Stat. Implemented: ORS 433.321-433.327

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

333-020-0151

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

(1) By November 1, 2003, the Authority shall develop and maintain confidential reporting mechanism (s) for child-specific diagnostic hearing test information.

(2) In consultation with the Advisory Committee, the Authority shall develop and distribute reporting form templates and protocols to approved diagnostic facilities, clinical audiologists and physicians conducting diagnostic hearing tests or other follow-up hearing testing on children.

(3) Prior to the January 1, 2004 effective date of the law and as requested, the Authority shall develop and offer training sessions for diagnostic facility staff to assure effective implementation of the reporting forms and protocols.

(4) The Authority shall review reporting forms and protocols at least annually, and as necessary, for effective management of the program. In the event of a modified form or protocol, the Authority shall give the diagnostic facility at least one full calendar month to incorporate the new form or protocol into practice.

(5) Within 10 days of testing of a child who has a "REFER" result on the newborn hearing screening test (or) who presents for an initial or completion of a newborn hearing screening test (or) who is diagnosed with a 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

(a) Name of the child

(b) Child's date of birth

(c) Birthing facility identifier, if known

(d) Parent or guardian's name, address, and contact information

(e) Child's primary health care provider

(f) Newborn hearing screening results, if known

(g) Diagnostic facility identifier

(h) Diagnostic testing results, including type and degree of hearing loss and affected ear(s), if applicable

(i) Disposition, including referrals made to early intervention services

- (j) Name and contact information for person completing diagnostic hearing test
- (k) Name and contact information for person completing form, if different than (j).
- (6) 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 Newborn Hearing Screening Test Registry and Tracking and Recall System;
 - (b) Provide or offer follow-up services to children identified with hearing loss or at-risk of hearing loss and their families.

Stat. Auth.: ORS 433.323

Stat. Implemented: ORS 433.321-433.327

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

333-020-0155

Responsibility for Issuing Reports

- (1) The Authority shall analyze the information collected under OAR 333-020-160 through 333-020-0175:
 - (a) The Authority shall provide an individualized monthly report to each screening, diagnostic and early intervention facility detailing submissions from that facility from the previous month. Monthly reports to each facility shall include information about the follow-up status of individual children from that facility who are enrolled in the tracking and recall system as allowed by law.
 - (2) The Authority shall issue an annual report and analysis of aggregated data submitted by all screening, diagnostic and early intervention facilities, by July first of each year for the previous year's data.
 - (3) In consultation with the Advisory Committee, the Authority shall include in the annual report recommendations for improvement of the Early Hearing Detection and Intervention Program, including but not limited to improvement in the Newborn Hearing Screening Test Registry and Tracking and Follow-up System.

Stat. Auth.: ORS 433.323

Stat. Implemented: ORS 433.321-433.327

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

333-020-0160

Appointment of a Newborn Hearing Advisory Committee

- (1) The Director shall appoint an Advisory Committee to:

(a) Provide policy level guidance and advice to the Authority on the implementation of the Newborn Hearing Screening Test Registry and Tracking and Recall system as defined by OAR 333-020-125 through 333-025-0180.

(b) Provide assistance in the preparation of a report to the biennial Legislative Assembly on the status of early hearing detection and intervention efforts in Oregon and the implementation and evaluation of the Newborn Hearing Screening Test Registry and Tracking and Recall System. The report will include but not be limited to strategies to increase the rate of early screening for children born in hospitals and birthing centers with less than 200 live births per year or born outside of hospitals and birthing centers.

(2) At a minimum, the Advisory Committee shall include at least one representative from each of the following categories:

(a) Parent of a child with hearing loss;

(b) Adult with hearing loss;

(c) Pediatric health care provider;

(d) Clinical audiologist;

(e) Hospital newborn hearing screening program representative;

(f) Diagnostic facility representative;

(g) Early intervention facility representative;

(h) Local public health agency representative;

(i) Speech-language pathologist.

(3) The Director shall establish by-laws of the Advisory Committee, including additional committee membership categories, committee duties and terms.

Stat. Auth.: ORS 433.323

Stat. Implemented: ORS 433.321-433.327

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

333-020-0165

Religious Exemption from Testing

(1) A hospital or birthing center directed to provide Newborn Hearing Screening Tests under these Administrative Rules is exempt from providing such services 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.

(2) The parent or guardian must sign a statement that the newborn child is being so reared, using the following language: [Form not included. See ED. NOTE.]

[ED. NOTE: Forms referenced are available from the agency.]

Stat. Auth.: ORS 433.323

Stat. Implemented: ORS 433.321-433.327

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