

NEW JERSEY ADMINISTRATIVE CODE
Copyright (c) 2005 by the New Jersey Office of Administrative Law

*** THIS FILE INCLUDES ALL REGULATIONS ADOPTED AND PUBLISHED THROUGH
THE ***

*** NEW JERSEY REGISTER, VOL. 37. NO. 24, DECEMBER 19, 2005 ***

TITLE 8. DEPARTMENT OF HEALTH AND SENIOR SERVICES
CHAPTER 19. NEWBORN HEARING SCREENING PROGRAM
SUBCHAPTER 1. NEWBORN HEARING SCREENING
N.J.A.C. (2005)

Adopted Repeal and New Rules: N.J.A.C.8:19-1

Proposed: November 15, 2004 at 36 N.J.R 5058(a) (see also 36 N.J.R.5639(a))

Adopted: November 1, 2005 by Fred M. Jacobs, M.D., J.D, Commissioner, Department of Health and Senior Services.

Filed: November 14, 2005 as R.2005 d.432, with substantive and technical changes not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 26:2-103.1 et seq., particularly 26:2-103.9.

Effective Date: December 19, 2005.

Expiration Date: December 19, 2010.

8:19-1.1 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings unless the context clearly indicates otherwise:

"Audiologic evaluation" means audiologic evaluation as that term is described in the JCIH Position Statement.

"Auditory Brainstem Response" or "ABR" means a physiologic measure used for detecting unilateral or bilateral hearing loss by measuring the activity of the cochlea, auditory nerve, and auditory brainstem pathways.

"Birth attendant" means a person who attends and assists during the birth of a child.

"Birthing center" means an ambulatory care facility or a distinct part of a facility that is separately licensed as an ambulatory care facility and provides routine prenatal and intrapartal care. These facilities provide care to low-risk maternity patients who are expected to deliver neonates of a weight greater than 2,499 grams and at least 37 weeks gestational age and who require a stay of less than 24 hours after birth.

"Birthing facility" means a health care facility that provides birthing and newborn care services and includes birthing centers.

"Commissioner" means the Commissioner of Health and Senior Services.

"Decibel" or "dB" means a unit of sound intensity, based on a logarithmic relationship of one intensity to a reference intensity.

"Decibels hearing level" or "dBHL" means decibel notation used on the audiogram that is referenced to audiometric zero.

"Decibels normalized hearing level" or "dBnHL" means decibel notation referenced to behavioral thresholds of a sample of normal hearing persons, used most often to describe the intensity level of click stimuli used in evoked potential audiometry.

"Department" means the Department of Health and Senior Services.

"Distortion product otoacoustic emissions" or "DPOAE" means responses generated in response to two continuous pure-tones, referred to as "primaries," and occurring at frequencies that relate mathematically to the frequency of the primaries.

"EBC" means the Electronic Birth Certificate or the Electronic Birth Certificate Registration System.

"Hearing loss" means a hearing loss of 30dB or greater in the frequency region important for speech recognition and comprehension in one or both ears, which is approximately 500 through 4,000 hertz (Hz).

"JCIH Position Statement" means the "Year 2000 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs," of the Joint Committee on Infant Hearing (JCIH), incorporated herein by reference, as amended and supplemented, published in Pediatrics, Vol. 106, No. 4, at 798 (October 2000), available by writing to the JCIH c/o American Academy of Pediatrics, 141 Northwest Point Blvd., Elk Grove Village, IL 60007-1098, telephone: (800) 433-9016, ext. 4917, e-mail: screening@aap.org, and available for download in Adobe Acrobat format at <http://www.jcih.org/jcih2000.pdf>, and at <http://www.jcih.org/posstatemts.htm>, and available upon request to the Division of Family Health Services of the Department.

"Medical home" means an approach to providing healthcare that is defined by care that is accessible, family-centered, continuous, comprehensive, coordinated, compassionate, and culturally competent.

"Midwife" means a person trained to assist a woman during childbirth.

"Newborn" means a child up to 28 days old.

"Newborn Hearing Follow-up Report" means Department form number SCH-2 with this title, used for reporting outpatient newborn hearing screening and audiologic exam results, which appears at chapter Appendix A, incorporated herein by reference. The form is available upon request from the EHDI, and can be downloaded from the Department website as a Word document at <http://www.state.nj.us/health/forms/sch-2.dot> or as an Adobe Acrobat file at <http://www.state.nj.us/health/forms/sch-2.pdf>.

"Newborn Hearing Lost to Follow-up form" means Department form number SCH-3 with this title that requires the submission of the child and parent names, date of birth, address, phone number, pediatrician name, and the reason the child is lost to follow-up. The form is available upon request from the EHDI, and can be downloaded from the Department website as a Word document at <http://www.state.nj.us/health/forms/sch-3.dot> or as an Adobe Acrobat file at <http://www.state.nj.us/health/forms/sch-3.pdf>.

"New Jersey Early Hearing Detection and Intervention Program" or "EHDI" means the program within the Department that implements the Universal Newborn Hearing Screening program

pursuant to P.L. 2001, c.373. The EHDI program may be contacted by mail at PO Box 364, Trenton, NJ 08625-0364, or by telephone at (609) 292-5676.

"Otoacoustic emissions" (OAE) means a physiologic measure used for detecting unilateral or bilateral hearing loss by measuring the responses generated within the cochlea by the outer hair cells, by means of either DPOAE or TEOAE. OAE evaluation does not detect neural dysfunction.

"Ototoxic drug monitoring procedures" means the procedures for monitoring patients who are treated with ototoxic medications.

"Ototoxic medication" means a medication that has a toxic action upon the ear resulting in possible hearing loss.

"Parent" means a biological parent, stepparent, adoptive parent, legal guardian or other legal custodian of the child.

"Physiologic hearing screening measure" means the electrical result of the application of physiologic agents by means of either ABR or OAE, and is also known as electrophysiologic hearing screening measure, as used in N.J.S.A. 26:2-103.2.

"Responsible physician" means the infant's medical home or the physician that will be providing well child care for the infant.

"Special Child Health Services Registration" means Department form number SCH-0 with this title, used for reporting children with special health care needs, which appears at subchapter Appendix B, incorporated herein by reference. The form is also available upon request from the EHDI. The form can be downloaded from the Department website as a Word document at <http://www.state.nj.us/health/forms/sch-0.dot> or as an Adobe Acrobat file at <http://www.state.nj.us/health/forms/sch-0.pdf>.

"Transient Evoked Otoacoustic Emissions" or "TEOAE" means frequency-specific responses evoked by brief acoustic stimuli, such as clicks or tone bursts, that generally appear up to 20 milliseconds after stimuli are delivered to the ear.

8:19-1.2 Hearing development literature supplied to parents

(a) Upon or prior to the admission of a newborn to a birthing facility in the State, the birthing facility shall provide all parents of the newborn with literature provided by the Department describing the normal development of auditory function and the New Jersey Early Hearing Detection and Intervention Program.

(b) The literature will be designed to provide parents with an understanding of the implications of hearing loss on the development of speech and language and provide information regarding normal auditory response behaviors.

(c) The Department shall furnish the literature to birthing facilities in languages that are most representative of the New Jersey population.

8:19-1.3 Universal newborn hearing screening

(a) All newborns shall have a physiologic hearing screening measure performed prior to discharge from a birthing facility or no later than one month of age. The birthing facility, audiologist, or physician, as applicable, shall have discretion to determine the type of physiologic hearing screening measure to be used.

(b) If a birth occurs outside a birthing facility, such as at home, and the newborn is not transferred to a birthing facility, then the midwife or responsible physician shall advise the parent of the availability of newborn hearing screening, and take such action as needed so as to facilitate the provision of such screening to the newborn prior to one month of age.

(c) Each birthing facility shall file a plan with the Department in a manner prescribed by the Commissioner detailing how the birthing facility will implement the newborn hearing screening requirements by January 31st of each year. The plan shall include, at a minimum:

1. The physiologic hearing screening measure to be performed;
2. The time frame after birth that the initial screening is to be performed;
3. The qualifications of and training received by personnel designated to perform the physiologic hearing screening measure;
4. The establishment of quality assurance protocols to determine and evaluate the effectiveness of the program in ensuring that all newborns are screened for hearing loss;
5. The month designated for annual calibration of hearing screening equipment;
6. The name of the licensed audiologist or physician designated pursuant to N.J.A.C. 8:19-1.5(a);
7. Guidelines for the provision of follow-up services for newborns who do not pass initial audiologic screening, who are not screened prior to nursery discharge and/or who are at risk for developing late-onset hearing loss;
8. The educational and counseling services to be provided to the parents of newborns identified as having, or being at risk for developing, hearing loss;
9. The guidelines for entering hearing screening results and risk indicators for late-onset hearing loss into the EBC system;
10. The protocol to be followed to ensure the confidentiality of any patient-specific information to be reported to the Department pursuant to this chapter; and
11. Ototoxic drug screening procedures for infants and children under the age of three who are admitted to the hospital for medical conditions that require administration of ototoxic medication.

(d) Infants who are too medically unstable to undergo screening by one month of age shall be screened when medically cleared and before discharge to home.

8:19-1.4 Transferred infants

(a) If a newborn is transferred to another in-State birthing facility, the receiving facility shall conduct newborn hearing screening in accordance with this subchapter.

(b) If a newborn is transferred to another in-State non-birthing facility, the birthing facility of birth shall conduct newborn hearing screening in accordance with this subchapter prior to transfer, or to ensure that a hearing screening is performed by one month of age or as soon as the newborn is medically cleared.

(c) Birthing facilities shall include Newborn Hearing Follow-up Reports in medical records of infants transferred to out-of-State health care facilities prior to transfer to encourage these out-of-State health care facilities to forward hearing screening and/or audiologic evaluation results to the New Jersey Early Hearing Detection and Intervention Program.

8:19-1.5 Screening/testing personnel

(a) Each birthing facility shall designate a licensed audiologist or physician who shall oversee the birthing facility's newborn hearing screening program, and who shall ensure the implementation of the following:

1. Training and supervision of the individuals performing the screening in accordance with (b) and (c) below;
2. Recording of screening results;
3. Reporting EBC data;
4. Educating and counseling parents;
5. Developing effective strategies for communicating the hearing screening results to parents and responsible physicians;
6. Coordinating follow-up services including referrals for re-screening or audiologic evaluation as appropriate; and
7. Annually reviewing policies and procedures.

(b) Only licensed audiologists or physicians, or other examiners under the direction and supervision of either licensed audiologists or physicians, shall conduct newborn hearing screening in accordance with the requirements of this subchapter.

1. All personnel who conduct newborn hearing screening shall undergo an annual competency evaluation on their screening administration and documentation skills as well as adherence to infection control procedures.

(c) All personnel performing newborn hearing screening shall be supervised and trained in the performance of newborn hearing screening. Training shall include the following:

1. The performance of newborn hearing screening;
2. Infection control practices;
3. The general care and handling of newborns in hospital settings according to established hospital policies and procedures;
4. The documentation of screening results as directed; and
5. Maintenance confidentiality of records.

(d) If after the conduct of screening, an infant or child is identified as being in need of audiologic evaluation, as defined in N.J.A.C. 8:19-1.1, these infants or children shall be referred for such evaluation by individuals who are licensed and trained to perform audiologic evaluations.

(e) The facility shall notify the Department when personnel providing oversight of the newborn hearing screening program change.

8:19-1.6 Reporting by means of the Electronic Birth Certificate

(a) For each live newborn born at, or transferred to a birthing facility that has elected to participate in the submission of birth certificates electronically by means of the Electronic Birth Certificate Registration System, the birthing facility shall report, within one week of the newborn's discharge or transfer, the EBC fields or information identified below to the Department by means of the Electronic Birth Certificate Registration System in the manner prescribed by the State Registrar of Vital Statistics for the submission of EBCs:

1. The mother's first name;
2. The mother's last name;
3. The child's first name;
4. The child's last name;
5. Sex;
6. Race;
7. Primary language;
8. Hearing screening results for each ear;
9. The screening methodology used for each ear;

10. The date of screening for each ear;
11. Initial screening vs. rescreening indicator;
12. Indicator if referral was made for audiologic follow-up;
13. The name of the provider to whom referral was made, if applicable; and
14. Specific neonatal conditions and procedures (family history of hearing loss, TORCH, congenital syphilis, persistent pulmonary hypertension, stigmata/syndromes associated with hearing loss, hyperbilirubinemia, meningitis, exchange transfusion, ECMO, ototoxic medication, days of mechanical ventilation, one and five minute Apgar scores, birthweight, NICU admission and discharge dates).

(b) For each live newborn born outside a birthing facility, such as at home, who subsequently is transferred to a birthing facility, the receiving facility shall ensure that the report required in (a) above is made, if the receiving facility has elected to participate in the submission of birth certificates electronically by means of the Electronic Birth Certificate Registration System.

(c) For each newborn transferred to another in-State birthing facility, the sending facility shall complete an EBC transfer abstract within one week of the transfer and shall send the abstract to the receiving facility, if the sending facility has elected to participate in the submission of birth certificates electronically by means of the Electronic Birth Certificate Registration System.

8:19-1.7 Exemption from screening

(a) This subchapter shall not apply in the case of any newborn whose parent objects to the hearing screening on the grounds that screening would conflict with the parents' bona fide religious tenets or practices.

(b) In case of refusal to screening pursuant to (a) above, the birthing facility, or in the event of a home birth, the physician or attending midwife, shall ensure that documentation of refusal to have the newborn's hearing screened is signed by the parent, becomes part of the infant's permanent medical record, and, if the birth occurs at a birth facility that has elected to participate in the submission of birth certificates electronically by means of the Electronic Birth Certificate Registration System, is documented in the EBC.

8:19-1.8 High-risk indicators

(a) The JCIH Position Statement identifies risk indicators that require periodic audiologic monitoring to detect progressive or late-onset hearing loss. Upon receipt of the notice required in N.J.A.C. 8:19-1.9(f)1 of the presence of these risk indicators, the infant's responsible physician shall ensure the monitoring of these infants in accordance with the time intervals and other protocols identified in the JCIH Position Statement.

(b) Birthing facilities that treat infants and children up to the age of three with ototoxic medications shall implement ototoxic drug screening procedures, established pursuant to N.J.A.C. 8:19-1.3(c)11.

(c) If risk indicators for late-onset hearing loss are identified after discharge from the birthing facility and at any time up to the age of three, the responsible physician and any audiologist who may have seen the child, who have identified the presence of the risk indicators shall report the risk indicators to the Department by means of the Newborn Hearing Follow-up Report, and advise the parents of the need to have an audiologic evaluation, as well as audiologic monitoring at intervals as defined by the JCIH Position Statement.

1. Audiologists who identify the presence of a risk indicator for late-onset hearing loss shall inform the child's medical home of this condition and the need for follow-up.

2. Once informed of the newly identified risk indicator for late-onset hearing loss, the medical home shall be responsible for advising parents of the importance of children under the age of three receiving audiologic monitoring in accordance with the JCIH Position Statement.

8:19-1.9 Hearing screening follow-up

(a) If a physiological hearing screening measure is performed on both ears of an infant prior to discharge, then, prior to the infant's discharge home, the birthing facility shall:

1. Notify the responsible physician of the results by written documentation, and
2. Notify the parent of the results via face-to-face communication along with written documentation.

(b) If a physiological hearing screening measure is not performed on one or both ears of an infant prior to discharge, then, prior to the infant's discharge home, the birthing facility shall:

1. Notify the responsible physician by written documentation; and
2. Notify and counsel the parent via face-to-face communication along with written documentation of the need for a follow-up hearing screening by a licensed audiologist, licensed physician, or other examiners under their direction and/or supervision.

(c) If an infant does not pass the physiologic hearing screening measure on one or both ears prior to discharge, then, prior to the infant's discharge home, the birthing facility shall:

1. Notify the responsible physician by written documentation; and
2. Notify and counsel the parent via face-to-face communication along with written documentation of the need for follow-up hearing screening or diagnostic testing in accordance with N.J.A.C. 8:19-1.5(b) and (d).

(d) If additional outpatient screening is required, the parent shall be advised of the need for screening to be performed by one month of age.

(e) If outpatient audiologic evaluations are required, the parent shall be advised of the need for audiologic evaluations to be performed by three months of age.

(f) If an infant presents with risk indicators associated with hearing loss as identified in the JCIH Position Statement, then, prior to the infant's discharge home, the birthing facility shall:

1. Notify the responsible physician by written documentation;
2. Notify the parents via face-to-face communication along with written documentation of the risk indicator(s) present; and
3. Counsel parents to monitor their infant's hearing according to the time intervals specified in the JCIH Position Statement.

(g) The birthing facility shall provide parents with information for referrals to centers that perform pediatric audiologic testing.

(h) If an infant does not pass or receive a physiological hearing screening measure on one or both ears prior to discharge, the birthing facility shall ensure that the infant receives follow-up services by making at least one documented attempt to remind parents of children who are in need of follow-up either by United States Postal Service or by telephone, excluding busy signals or no answer.

(i) Audiologic evaluation must yield ear-specific information, a statement regarding the type and degree of hearing loss in each affected ear, and recommendation for medical and habilitative services.

(j) When follow-up is required in accordance with (b) or (c) above, the birthing facility shall provide parents with a Newborn Hearing Follow-up Report form with the demographic information completed either prior to discharge or by one month of age.

8:19-1.10 Reporting newborn hearing follow-up

(a) The individuals who conduct outpatient screening or audiologic testing for the reasons identified in N.J.A.C. 8:19-1.9 shall complete the Newborn Hearing Follow-up Report form, submit the completed form to the Department, and report the results to the infant's medical home within 10 days of conduct of the outpatient screening or audiologic testing.

(b) The requirements of (a) above for submission of a Newborn Hearing Follow-up Report form to the Department and the report to the medical home apply for each screening or testing as may be administered in accordance with the JCIH Position Statement protocols for re-examination at regular intervals.

(c) Newborn Hearing Follow-up Report forms shall be completed with ear specific results for all children receiving outpatient screening or audiologic evaluation. Documentation of a "Pass" result in the Recommendations section of the Newborn Hearing Follow-up Report form can only be considered if screening or audiologic measures indicate:

1. A pass result on either DPOAE or TEOAE screening for each ear;
2. A pass ABR screening (with intensity levels at or below 35 dBnHL); or
3. Ear-specific behavioral responses better than 30 dBnHL in the speech frequency range (500 to 4000 hertz).

(d) Confirmation of hearing status shall be obtained within one month but no later than three months after initial screening.

(e) If a newborn is not screened due to birth outside a birthing facility, such as at home, and is not transferred to a birthing facility, the newborn shall be screened with physiologic measures prior to one month of age.

1. The physician or midwife shall advise the parents of the importance of newborn hearing screening .

2. If the physician or midwife performs screening and/or testing on the newborn, the physician or midwife shall complete and transmit to the Department a Newborn Hearing Follow-up Report form within 10 business days of the screening and/or testing.

(f) The following procedures are considered inappropriate for children undergoing initial or repeat screening:

1. Non-calibrated signals, such as rattles, music boxes, noisemakers;
2. Non-conditioned behavioral procedures, such as behavioral observation audiometry;
3. Signals that lack frequency specificity, such as music, broadband noise;
4. Speech stimuli in lieu of frequency specific stimuli;
5. Use of soundfield studies in isolation (without inclusion of ear specific data); or
6. Use of "age-appropriate" response criteria, unless the screener uses intensity levels at or below 30 dBHL in each ear in the frequency region important for speech recognition and comprehension (500 to 4000 hertz) to enable the practitioner to articulate whether the screening results in minimal response levels at, better than, or worse than, 30 dBHL.

(g) In the following situations, a birthing facility, audiologist, physician, or other examiner under the direction and/or supervision of an audiologist or physician, with follow-up responsibilities under this subchapter, shall submit a Newborn Hearing Lost to Follow-up form (form SCH-3) to the Department and to the medical home:

1. Missed outpatient follow-up appointment;
2. Unable to make reminder contact (disconnected phone or returned mail);
3. Infant who is known to have moved out of State;

4. To report the name and address of the facility where newborn is being treated when treated out of State;
5. Documentation of one unsuccessful attempt to contact parents for follow-up;
6. Family refusal to return for follow-up; or
7. Determination that a previously identified risk indicator has been ruled out at follow-up visit.

8:19-1.11 Documenting and reporting a diagnosed hearing loss

(a) When a permanent hearing loss is confirmed, the forms identified in 1 and 2 below shall be completed and submitted to the Department as soon as possible after diagnosis:

1. For children from birth to 36 months of age, a Newborn Hearing Follow-up Report form and a Special Child Health Services Registration form shall be completed and submitted to the Department as soon as possible after diagnosis. The Special Child Health Services Registration form shall include specification, in the "diagnosis" section of the form, of the type and degree of hearing loss, the affected ear(s), and, if applicable and known, the syndrome related to the child's hearing loss.

2. For children from birth through 21 years of age, a Special Child Health Services Registration form shall be completed and submitted to the Department as soon as possible after diagnosis, which shall include specification, in the "diagnosis" section of the form, of the type and degree of hearing loss, the affected ear(s), and, if applicable and known, the syndrome related to the child's hearing loss.

(b) When a permanent hearing loss is confirmed, the audiologist shall inform the responsible physician by written documentation and parents via face-to-face communication and written documentation of the type and degree of hearing loss.

(c) Infants born with external auditory canal atresia shall be registered as such, prior to discharge from the birthing facility. By definition, these children present with hearing loss and should be afforded the opportunity to engage in Early Intervention Services. Bone conduction ABR studies should be performed prior to three months of age to determine the cochlear status of the affected ear(s).

(d) When a diagnosis of permanent hearing loss is made, the responsible physician shall advise the parents of the importance of medical and audiologic evaluations consistent with the recommendations of the JCIH Position Statement, and shall make appropriate referrals, as necessary, for appropriate follow-up consultations to be completed by three months post-diagnosis.

1. In addition, the responsible physician shall advise the parents of the importance of ongoing audiologic reevaluation to monitor hearing status and the performance of prescribed devices such as hearing aids or cochlear implants.

2. To the extent a hearing aid is indicated, responsible physicians should refer to N.J.S.A. 45:9A-25, pertaining to the requirement of otolaryngologic referral as a condition of the dispensing of hearing aids to minors.

3. Responsible physicians shall also register children diagnosed with hearing loss (through 21 years of age) with the Special Child Health Services Registry.

(e) Updated Special Child Health Services Registration forms shall be submitted to the Department if new information is available during follow-up audiologic visits regarding hearing status; diagnosis of a syndromic condition; documented physical disabilities, and/or change in name, address or parent.

8:19-1.12 Central newborn hearing registry

Special Child Health and Early Intervention Services shall establish and maintain a central registry of newborns identified as having or being at risk of developing a hearing loss. The information in the central registry shall be used for the purposes of compiling statistical information and providing follow-up counseling, intervention and educational services to the parents of the newborns listed in the registry.

8:19-1.13 Confidentiality of reports

The reports made are to be used only by the Department and such other agencies as may be designated by the Commissioner and shall not otherwise be divulged or made public so as to disclose the identity of any person to whom they relate; and to that end, such reports shall be deemed "information relating to medical history, diagnosis, treatment or evaluation" within the meaning of Executive Order No. 26, § 4b1 (McGreevey 2002), and, therefore, not "government records" subject to public access or inspection within the meaning of N.J.S.A. 47:1A-1 et seq., particularly 1A-1.1.

8:19-1.14 Non-liability for divulging confidential information

No individual or organization providing information to the Department for the purpose of the Newborn Hearing Screening Program shall be deemed to be, or held liable for, divulging confidential information."