

Pursuant to the authority vested in the New York State Department of Health by Section 2500-g of the Public Health Law and Chapter 585 of the Laws of 1999, Part 69 of Subchapter H of Chapter II of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended by the addition of a new Subpart 69-8 to be effective upon filing with the Secretary of State and publication in the State Register.

## Part 69

### Testing for Phenylketonuria and Other Diseases and Conditions/Early Intervention

#### Program/Newborn Hearing Screening

A new Subpart 69-8 is added as follows:

### Subpart 69-8

#### Newborn Hearing Screening

(Statutory authority: Public Health Law Section 2500-g)

#### Section 69-8.1 Definitions

#### Section 69-8.2 General Requirements for Infant Hearing Screening Programs and Responsibilities of the Administrative Officers or Designees of Facilities

#### Section 69-8.3 General Requirements for Administration of the Infant Hearing Screening Program

#### Section 69-8.4 Procedures for Infant Hearing Screening

#### Section 69-8.5 General Requirements for Institutions Caring for Infants that Provide a Referral for Infants to Obtain Hearing Screening

#### Section 69-8.6 Responsibilities of Institutions Caring for Infants in Special Circumstances

Section 69-8.1 *Definitions*

(a) Administrative officer means the chief executive officer of the hospital, as defined in section 405.3 of this title.

(b) Audiologic evaluation means the use of physiologic and behavioral procedures to evaluate and diagnose hearing loss.

(c) Hearing problems (hearing loss) shall mean a permanent unilateral or bilateral hearing loss of mild (30 to 40 dB HL) or greater degree in the frequency region (500-4000 Hz) important for speech recognition and comprehension.

(d) Institution caring for infants (facility) means all general hospitals having maternity and infant services or premature infant services as defined in section 405.21 of this title and primary care hospitals and critical access hospitals as defined in section 407.1 of this title and birthing centers as defined in section 754.1 of this title.

(e) Newborn infant (infant) means a minor child who is less than ninety days of age.

(f) Newborn infant hearing screening (infant hearing screening) means the use of an objective electrophysiologic or otoacoustic measurement of the auditory system using equipment approved by the United States Department of Health and Human Services, Food and Drug Administration (FDA), to identify infants at risk for hearing loss.

(g) Parent means a parent by birth or adoption, legal guardian, or any other person legally authorized to consent to medical services for the infant.

(h) Article 28 facility shall mean a health care facility established under article 28 of the Public Health Law.

#### Section 69-8.2 General Requirements for Infant Hearing Screening Programs and Responsibilities of the Administrative Officers or Designees of Facilities

(a) Each facility shall administer an infant hearing screening program, directly or by contract pursuant to section 400.4 of this title, as required by this part and as generally described in subdivision (b) of this section, except for those facilities identified in subdivision (c) of this section.

(1) Facilities that establish a contract(s) with providers of infant hearing screening shall designate a staff member responsible for contract management and general oversight of the program.

(2) Contracts may be established for the conduct of inpatient and/or outpatient infant hearing screening.

(3) Contractors must be article 28 facilities or health care providers licensed under state education law and authorized under such law to perform infant hearing screening.

(4) Contractors shall have the capacity to meet general requirements for infant hearing screening programs as set forth in subdivision (b) of this section.

(b) General requirements of an infant hearing screening program are:

(1) The conduct of inpatient infant hearing screening prior to discharge from the facility.

(2) Communication of results of infant hearing screenings to parents by designated personnel, including provision of written materials supplied by the Department.

(3) The conduct of follow-up infant hearing screening or provision of referrals to obtain follow-up screening on an outpatient basis for those infants who fail or do not receive infant hearing screening prior to discharge from the facility. On an annual basis, facilities shall notify the Department whether the facility will conduct follow-up infant hearing screening or provide referrals for infants to obtain such screening from another facility or provider licensed under State Education Law and authorized to provide infant hearing screening.

(4) Referral of infants who are suspected of having a hearing loss as defined in this part to the Early Intervention Program for appropriate evaluation and early intervention services pursuant to section 69-4.3 of this title including, but not limited to:

(i) providing a general explanation of the Early Intervention Program and the purpose of referral and the parents' right to object to the referral;

(ii) ensuring confidentiality of referral information transmitted; and

(iii) transmitting of personally identifying information as necessary to ensure follow-up.

(5) The reporting of aggregate data on infant hearing screenings to the Department upon Department request, in a format and frequency prescribed by the commissioner.

(6) The establishment of facility quality assurance protocols as necessary pursuant to section 405.6 of this title to determine and evaluate the effectiveness of the program in ensuring all infants are screened for hearing loss.

(c) Facilities with 400 or fewer births annually, based on a three year rolling average, may provide referrals for infants to receive hearing screening from an article 28 facility or a provider licensed under State Education Law and authorized under such law to perform infant hearing screening.

(1) Such referrals shall include a prescription issued by the facility, including a request for results of the screening to be returned to that facility, for infants to receive hearing screening from an article 28 facility or a provider licensed under State Education Law and authorized under such law to provide infant hearing screening.

(2) Such facilities shall submit screening results returned to the facility by the outpatient provider as required by the Department to determine the effectiveness of referral procedures in ensuring infants are screened for hearing loss.

#### Section 69-8.3 General Requirements for Administration of the Infant Hearing Screening Program

(a) The administrative officer of each facility caring for infants or their contractor(s) shall designate a program manager responsible for management and oversight of the infant hearing screening program.

(1) The program manager shall be a licensed audiologist, physician, physician's assistant, registered nurse or nurse practitioner.

(2) If the program manager is not an audiologist, infant hearing screening procedures and training shall be established and monitored in consultation with an audiologist.

(b) The program manager shall be responsible for ensuring:

(1) training and supervision of the individuals performing the screening;

(2) review, recording and documentation of screening results;

(3) data reporting;

(4) staff and parent education; and,

(5) coordination of services and follow-up including referrals for re-screening or diagnostic audiologic evaluation as appropriate.

(c) All personnel performing infant hearing screening must be supervised and trained in the performance of infant hearing screening.

(d) Training shall include the following:

(1) the performance of infant hearing screening;

(2) the risks including psychological stress for the parent;

(3) infection control practices;

(4) the general care and handling of infants in hospital settings according to established hospital policies and procedures;

(5) the recording and documentation of screening results as directed; and,

(6) procedures for communicating screening results to parents.

(e) Personnel other than licensed audiologists may perform infant hearing screening provided that:

(1) the screening equipment and protocol used are fully automated;

(2) equipment parameters are not accessible for alteration or adjustment by such personnel;  
and,

(3) the results of the screening are determined without clinical decision-making and are reported as pass or fail.

(f) Equipment that requires clinical decision-making shall be used to conduct infant hearing screenings only by personnel licensed under State Education Law and authorized to perform infant hearing screening.

(g) Equipment used for infant hearing screening shall be maintained and calibrated in accordance with section 405.24 (c)(2) of this title.

(h) The facility shall provide adequate physical space for equipment and supplies and an environment suitable to obtain reliable infant hearing screening results.

#### Section 69-8.4 Procedures for Infant Hearing Screening

(a) All infants born in the facility shall receive an initial hearing screening prior to discharge from the facility except as provided in section 69-8.2(c) of this Part.

(b) Prior to the hearing screening, parents shall be provided educational materials, supplied by the Department to the facility, or consistent in content with Department-supplied materials, regarding infant hearing screening.

(c) If the infant passes the hearing screening, the results shall be documented in the infant's record by the individual who performed the screening and documented in the discharge summary.

(1) The parent shall be informed of the screening results prior to the infant's discharge from the facility.

(d) The parent shall be provided educational materials, supplied by the Department to the facility, on developmental milestones for communication and signs of hearing loss in young children.

(e) In the event that an infant is not screened for hearing loss prior to discharge from the facility, the program manager shall ensure that:

(1) The parent is offered the opportunity to schedule an appointment for the infant to be screened for hearing loss on an outpatient basis within four weeks from the infant's discharge from the facility. Whenever practicable, the parent shall be afforded such opportunity to schedule an outpatient screening prior to the infant's discharge from the facility.

(2) If the parent is not provided the opportunity to schedule an appointment for an outpatient screening prior to the infant's discharge from the facility following birth, a minimum of two documented attempts, either by United States mail or by telephone, excluding busy signals or no answer, shall be made to contact the parent post-discharge to schedule an appointment for an outpatient screening for the infant.

(3) If the parent agrees to schedule an appointment for an outpatient hearing screening by the facility or a provider under contract with the facility, the appointment shall be scheduled and documented in the infant's record.

(4) If the parent returns to the facility or provider under contract with the facility for an outpatient screening, the screening results shall be documented in the infant's record and reported to the Department as prescribed by the commissioner.



(5) If the parent declines to schedule an appointment for an outpatient hearing screening for the infant by the facility or by a provider under contract with the facility, such declination shall be documented in the infant's record and discharge summary.

(i) The parent shall be provided instead with a prescription for the infant to obtain an outpatient hearing screening from an article 28 facility or provider licensed by and authorized under State Education Law to perform infant hearing screening.

(ii) The prescription shall specify that the results of the hearing screening shall be returned to the facility.

(f) If the infant fails the inpatient hearing screening, a repeat screening shall be conducted whenever possible prior to the infant's discharge from the facility to minimize the likelihood of false positive results and need for a follow-up outpatient screening.

(g) If the infant fails the inpatient screening and any repeat screening, if performed, an outpatient follow-up screening shall be performed to confirm the results of the inpatient screens.

(h) If the facility has elected to conduct follow-up hearing screening either directly or through a contractual agreement, the following procedures shall be followed:

(1) The parent shall be informed of the infant's screening results by an individual trained as required in subdivisions (c) and (d) of section 69-8.3 to counsel the parent(s) on the importance of a follow-up screening.

(2) The parent shall be provided with educational materials on the importance of early detection of hearing loss, supplied by or consistent with Department materials.

(3) The parent shall be provided, prior to the infant's discharge, a prescription to obtain follow-up infant hearing screening post-discharge to be performed at the facility or by a provider under contract with the facility.

(4) If the parent agrees, an appointment shall be scheduled prior to the infant's discharge from the facility except under circumstances where such scheduling is not practicable, such as on weekends, or within ten days post-discharge.

(5) The appointment shall be documented in the infant's record and discharge summary to facilitate follow-up by the infant's primary health care provider.

(6) If an infant does not present for a scheduled appointment for a follow-up screening based on the infant's failure of an in-patient screen, the facility or provider under contract with the facility shall make at least two documented attempts either by United States mail or by telephone, excluding a busy signal or no answer, to contact the parent and reschedule the appointment.

(7) If the facility or provider under contract with the facility cannot reach the family or for any other reason cannot schedule and complete a follow-up screening within seventy-five days from discharge, the infant shall be referred to the Early Intervention Official in his or her county of residence as an at-risk child in accordance with section 69-4.3 of this title, unless the parent objected to the referral at the time of the inpatient hearing screening.

(8) If the parent declines to schedule a follow-up screening with the facility or provider under contract with the facility for an infant who has failed the inpatient infant hearing screening, the following procedures shall be used:

(i) The parent(s) shall be provided with a prescription issued by the facility for the infant to obtain a follow-up screening from a provider licensed under State Education Law and authorized under such law to perform infant hearing screening.

(a) The prescription shall include a request that results of the screening be submitted back to the facility.

(ii) The parent shall be provided with a list of qualified providers of infant hearing screening, which shall consist of providers licensed under state education law and authorized under such law to perform infant hearing screening and article 28 facilities.

(iii) The individual counseling the parent shall document in the infant's record and discharge summary the parent(s)' decision not to schedule an appointment with the facility and the issuance of a prescription to obtain follow-up screening from another qualified provider.

(iv) The infant's primary health care provider, when such provider is known, shall be notified of the parents' decision to obtain a follow-up outpatient screening.

(v) If the prescription is filled and the results of the follow-up screening are returned to the facility, such results shall be documented in the infant's record.

(i) If the facility elects to refer infants who fail the inpatient hearing screening to other facilities or providers licensed under the State Education Law and authorized by such law to perform infant hearing screening on an outpatient basis, the following procedures shall be used:

(1) The parent shall be informed that the screening should be completed within four weeks from the infant's discharge from the facility if possible and not later than twelve weeks following birth.

(2) The parent shall be provided with educational materials on the importance of early detection of hearing loss, supplied by the Department to the facility, or consistent in content with Department-supplied materials, and a list of licensed providers and/or article 28 facilities where infant hearing screening may be obtained.

(3) The parent shall receive a prescription for an outpatient screening by a provider licensed under the State Education Law and authorized under such law to perform infant hearing screening, or by an article 28 facility. Such prescription shall state that results shall be returned to the facility.

(4) The parent shall be informed that if results of a follow-up outpatient screening are not returned to the facility, the infant will be referred as an at risk child to the Early Intervention Official in their county of residence for follow-up purposes unless the parent(s) object to such a referral, in accordance with section 69-4.3 of this part.

(5) The referral, including issuance of a prescription, shall be documented in the infant's record and discharge summary to facilitate follow-up by the infant's primary health care provider.

(6) The infant's primary health care provider, when such provider is known, shall be notified of the inpatient results and need for a follow-up outpatient screening.

(7) If results of a follow-up outpatient screening are not returned to the facility within seventy-five days, the infant shall be referred as an at-risk child to the Early Intervention Official in his/her county of residence for follow-up purposes, in accordance with section 69-4.3 of this part, unless the parent has objected to such a referral.

Section 69-8.5 General Requirements for Institutions Caring for Infants that Provide a Referral for Infants to Obtain Hearing Screening.

(a) This section shall apply to those exempt from direct administration of the infant hearing screening program. The administrative officer of a facility as described in subdivision (c) of section 69-8.2 of this Part shall designate a program manager responsible for infant hearing screening who shall ensure infants are referred for an outpatient screening for hearing loss.

(b) The program manager for infant hearing screening shall ensure that infants are referred, prior to discharge from the facility, to a provider licensed under State Education Law and authorized under such law to perform infant hearing screening or an article 28 facility.

(1) The parent shall be informed that the screening should be completed within four weeks of the infant's discharge from the facility if possible and not later than twelve weeks following birth.

(2) The parent shall be provided with educational materials on the importance of early detection of hearing loss, supplied by or consistent with department materials; and, a list of licensed providers and/or article 28 facilities where infant hearing screening may be obtained.

(3) The parent shall receive a prescription for an outpatient screening by an article 28 provider or a provider licensed under the State Education Law and authorized by such law to perform infant hearing screening. The prescription shall require that results be returned to the facility issuing the prescription.

(4) The referral, including issuance of a prescription, shall be documented in the infant's record and discharge summary to facilitate follow-up by the infant's primary health care provider.

(c) The program manager shall be responsible for ensuring that results of infant hearing screening reported to the facility are documented in the infant's record and reported to the Department as prescribed by the commissioner.

(d) The Department may seek corrective action as necessary to ensure infants are screened for hearing loss under the referral process provided for in this section.

#### Section 69-8.6 Responsibilities of Institutions Caring for Infants in Special Circumstances

(a) In the event that an infant is transferred from one facility to another such facility, the facility discharging the infant to home shall be responsible for ensuring that infant hearing screening services are provided to the infant in a manner consistent with the applicable provisions set forth in this part.

If the infant fails both an initial and follow-up screening, the infant shall be referred for an evaluation to the Early Intervention Official in his or her county of residence, according to the procedures set forth in Section 69-4.3 of this part unless the parent objects.

(b) Medically unstable infants shall receive infant hearing screening prior to discharge to home and as early as development or medical stability will permit such screening. In instances where the medical condition of the infant contraindicates infant hearing screening, a decision to forego such screening may be made and documented in the medical record.