

Massachusetts Department of Public Health  
Audiological Assessment/Diagnostic Centers Guidelines

**I. Introduction:**

In Massachusetts, Chapter 243 of the Acts of 1998, an Act Providing for Hearing Screening of Newborns, became effective in November 1998. The Universal Newborn Hearing Screening law, as the statute is known, mandates that a hearing screening be performed on all newborns in the Commonwealth of Massachusetts prior to discharge from a hospital or birth center. (Appendix 1) In response to this law, the Department of Public Health (DPH) promulgated Amendments to the Hospital Licensure Regulations (105 CMR 130.000) and Birth Center Licensure Regulations (105 CMR 142.000) Regarding Universal Newborn Hearing Screening Programs. (Appendix 2) These regulations require birth centers and birth hospitals to refer infants exclusively to DPH approved audiological assessment/diagnostic centers.

This law also mandates the Massachusetts Department of Public Health to establish standards for audiological assessment/diagnostic centers that serve infants and young children identified by newborn hearing screening. The Department will maintain a list of approved centers categorized according to the level of testing they administer.

**II. Levels of Centers:**

**Level 1:** Serve children birth to 3 years. Offer sedated and nonsedated Auditory Brainstem Response (ABR) testing in addition to other traditional pediatric test procedures.

**Level 2:** Serve children birth to 3 years. Offer nonsedated ABR testing in addition to other traditional pediatric test procedures.

**Level 3:** Serve children 6 months corrected age (CA) to 3 years. Offer traditional pediatric test procedures including, but not limited to, sound field testing, play audiometry, tympanometry, and otoacoustic emissions (OAE). On occasion, a Level 3 center may see a child at 5 months if transportation difficulties make travelling to a Level 1 or 2 site prohibitive.

**III. Submitting Protocols:**

Each center shall develop and submit a protocol for approval to DPH. Protocols shall be written using the DPH Guidelines for Audiological Assessment/Diagnostic Centers, American Speech-Language Hearing Association Preferred Practice Patterns for the Profession of Audiology, November 1997 (Appendix 3) and the Joint Committee on Infant Hearing Year 2000 Position Statement, Principles and Guidelines for Early Detection and Intervention Programs. (Appendix 4) Once a center has received written approval from DPH,

it will be responsible to notify DPH in writing within 30 days of any significant changes to staffing or protocol. Complete protocols shall be submitted to DPH *every other year*. Annual data reports will be required. Centers currently approved by DPH shall submit protocols by March 1, 2001.

#### **IV. Staffing and Support Services:**

##### **Contact person:**

The center shall submit the name of an audiologist in a leadership position at the center as a contact person for DPH. The center shall submit the following:

- Name of contact person
- Title
- Address
- Telephone number and TTY
- Fax
- E-mail address

The contact person or a designee will be required to attend meetings facilitated by DPH approximately 3 times per year.

##### **Audiologist(s):**

Audiologist shall mean an audiologist, licensed by the Commonwealth of Massachusetts pursuant to the Board of Registration of Speech-Language Pathology and Audiology regulations at 260CMR1.00 et seq. Audiologists or centers performing diagnostic evaluations on infants and young children up to age 3 years shall have an annual pediatric caseload of at least 10% or be under the supervision of an audiologist that does. The pediatric caseload experience must be documented in the center's written protocol submitted to DPH.

##### **Audiologist in a clinical fellowship year:**

An individual in an audiological clinical fellowship year may perform hearing screenings and evaluations on infants and young children following American Speech and Hearing Association guidelines. A licensed audiologist must be on site and readily available for consultation in person when the clinical fellow performs the evaluation.

##### **Support services:**

Each center shall provide as part of their protocol the policy and procedures used to recommend referrals to related disciplines. Related disciplines shall include, but not be limited to, the following:

- Otolaryngology
- Genetics
- Speech-language pathology
- Deaf education

- Psychology
- Social services
- Early Intervention
- Commission for the Deaf and Hard of Hearing specialists

## **V. Follow-up and Documentation:**

Each center shall provide as part of their protocol a policy that will be followed when a newborn or young child identified through newborn hearing screening misses or does not keep a diagnostic appointment. The policy shall include information on rescheduling the appointment and performing outreach to the parent(s) or guardian(s).

Each center shall provide as part of their protocol information on how the results of the assessment/diagnostic results are documented in each child's medical record at the center.

## **VI. Testing Procedures:**

Each center shall provide as part of their protocol a list of the types of audiometric test procedures available at its facility when testing children under three years of age. The availability of these procedures must be verifiable through departmental records and/or on-site inspection. The level of the center will be determined based on the testing procedures made available.

### **Level 1:**

- Auditory evoked response threshold using frequency-specific signals by air and bone conduction with appropriate equipment, procedures and personnel for sedation during testing
- Testing in a calibrated soundfield
- Visual reinforcement audiometry
- Play audiometry
- Word recognition testing with materials appropriate for different language levels
- Pure-tone audiometry including air-conduction testing with circumaural and insert earphones and bone-conducting testing. The limits of air-conduction testing must meet or exceed 110dB HL.
- Acoustic immittance testing, including acoustic reflex testing
- Otoacoustic (OAE) emission testing
- Hearing instrument evaluation and minimal maintenance including real ear (probe microphone) measures, hearing aid test analyzer, hearing aids, and hearing-aid servicing supplies

**Level 2:**

- Auditory evoked response threshold testing using frequency-specific signals by air and bone conduction
- Testing in a calibrated soundfield
- Visual reinforcement audiometry
- Play audiometry
- Word recognition testing with materials appropriate for different language levels
- Pure-tone audiometry including air-conduction testing with circumaural and insert earphones and bone conduction testing. The limits of air-conduction testing must meet or exceed 110dB HL.
- Acoustic immittance testing, including acoustic reflex testing
- Otoacoustic emission (OAE) testing
- Hearing instrument evaluation and minimal maintenance including real ear (probe microphone) measures, hearing aid test analyzer, hearing aids, and hearing-aid servicing supplies

**Level 3:**

- Procedures for referral of Auditory Brainstem Response (ABR) testing
- Testing in a calibrated soundfield
- Visual reinforcement audiometry
- Play audiometry
- Word recognition testing with materials appropriate for different language levels
- Pure-tone audiometry including air-conduction testing with circumaural and insert earphones and bone conduction testing. The limits of air-conduction testing must meet or exceed 110dB HL.
- Acoustic immittance testing, including acoustic reflex testing
- Otoacoustic emission (OAE) testing
- Hearing instrument evaluation and minimal maintenance including real ear (probe microphone) measures, hearing aid test analyzer, hearing aids, and hearing-aid servicing supplies

**Exceptions to testing procedures:**

- Provisional approval will be granted to test centers without OAE equipment until October 2001.
- Level 1 and Level 2 centers must provide tone burst ABRs no later than January 2002.

**Calibration of equipment:**

All equipment (including sound field) must be calibrated in accordance with current ANSI standards, i.e., ANSI S3.39 (1987) and ANSI S3.6 (1989). Calibration records must be available on site for review by DPH.

## **VII. Pediatric Sedation:**

Each center that administers sedation shall develop and submit as part of their protocol a written policy for sedation. Centers must adhere to the American Academy of Pediatrics, Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures (RE9252). Compliance with this policy shall be documented in each patient's medical record. Centers shall include in their protocols to DPH the following:

- A statement affirming the center meets the standards set in the American Academy of Pediatrics, Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures
- A policy explicitly prohibiting administration of sedation, including chloral hydrate, at home
- Information about how staff becomes credentialed by the facility for administration of conscious sedation
- A policy on attendance of training and credentialing of staff for conscious sedation for each staff member that is involved in the administration of sedation
- A statement affirming staff are credentialed by hospital or center

Each center that does not administer sedation shall include a written statement to DPH indicating that the center does not administer sedation.

## **VIII. Americans with Disabilities Act:**

Centers shall submit as part of their protocol an assurance stating that their center will comply with the Americans with Disabilities Act. The following information must also be submitted:

- TTY number
- Policy on providing ASL/sign language interpreters, CART reporters and Oral transliterators
- List of providers used for interpreter services

## **IX. Interpreters for Languages other than English:**

Centers shall provide as part of their protocol a policy that insures interpreting services will be made available for parents whose primary language is other than English.

## **X. Management Plan for Confirmed Hearing Loss:**

Centers shall provide as part of their protocol its management plan policy for an infant or young child with newly diagnosed hearing loss. The management plan shall include, but is not limited to, the following:

- Early and ongoing communication with child's primary care clinician
- Counseling
- Referral to Otolaryngology
- Provision of information to parents regarding options for communication methods
- Information about Early Intervention
- Information about the Commission for the Deaf and Hard of Hearing
- DPH and Commission for the Deaf and Hard of Hearing Fact Sheet and Brochures
- Information about community, educational, and financial resources
- Hearing aid recommendation and follow-up
- Information on appropriate equipment i.e. hearing aids, FM system, cochlear implant
- Evaluation/support available by related disciplines
- Information about audiological monitoring and management

## **XI. Fees and Services:**

Centers shall provide as part of their protocol an assurance stating that they will bill any available health insurance prior to billing the Department of Public Health and accept as payment in full the fees as scheduled and approved by the Division of Health Care Finance and Policy or the Division of Medical Assistance.

## **XII. Data Agreement with DPH:**

For all babies referred from a universal newborn hearing screening program, each center shall agree to provide to the maximum extent possible child specific data to DPH about the initial visit and diagnosis. This shall include obtaining written consent from families in order to provide DPH with necessary data elements. Data and consent forms will be provided by DPH.

## **XIII. Quality Assurance/Quality Improvement:**

Centers shall provide as part of their protocol detailed information on quality assurance and quality improvement plans. The plan shall include information on how the center will obtain information on customer satisfaction.

#### **XIV. Annual Statistics:**

Centers approved by DPH must submit an annual summary of data collected as a result of referrals from hospital and birth center newborn hearing screening programs. This summary will be due March 2002 and each year thereafter. Summaries shall include, but not be limited to the following:

- Number of infants seen as a result of a newborn hearing screening
- Number of infants found through testing to have normal hearing
- Number of infants diagnosed with a bilateral hearing loss
- Number of infants diagnosed with a unilateral hearing loss
- Number of infants found to have a temporary hearing loss
- Number of infants that did not keep appointment and were lost to follow-up

#### **XV. Approval to Perform Newborn Hearing Screening:**

While each birth hospital or birth center is required to ensure that a hearing screening is performed on every newborn before the newborn is discharged to home, occasionally an infant may be missed. Newborns will be born at home or out-of-state and may not receive a newborn hearing screening. Because of this, diagnostic centers may wish to become approved to perform hearing screenings on these babies. Each center wishing to become approved to perform newborn hearing screenings shall submit a protocol (see Appendix 2) that includes the following:

- Staff performing the newborn hearing screening
- Responsibilities of each staff member
- Copy of training curriculum developed by a licensed audiologist
- Description of supervision of screening staff
- Describe training and supervision of individuals with responsibility to inform parents or guardians of screening results
- Copies of written information given to parents, guardians, and physicians including how and when the results are communicated
- Statement that the center will provide data required by DPH
- Mechanism to refer family to DPH for additional information
- Infection control procedures
- Screening methods and equipment to be used to conduct the screening, including provisions for readily available back-up equipment in the event of an equipment malfunction
- Outline the procedure for documenting the results of the screening
- Identify the procedure to ensure an infant who missed a screening or was unsuccessfully screened will receive a screening

- Identify the procedure to ensure the parent or guardian of an infant who did not pass the screening will receive information about follow-up and an appointment for diagnostic services
- Describe the screening program's quality assurance review process