

Massachusetts Department of Public Health Universal Newborn Hearing Screening Program 2012 Birth Facility Guidelines

The Universal Newborn Hearing Screening Guidelines will assist hospitals and birth centers in writing protocols for newborn hearing screening programs. These guidelines define the topics that shall be covered in protocols and the criteria the Massachusetts Department of Public Health (MDPH) will use to assess their effectiveness. Hospital groups with multiple sites may submit one protocol that includes specific information about each site. Please refer to the guidelines when writing or changing a protocol for universal newborn hearing screening.

***Important:** Protocols shall be written using the sequence and categories on the checklist provided in these guidelines (see Appendix I-Protocol Checklist).*

I. Staffing and Roles

1. Program Director

The birth hospital or birth center shall designate a program director who is responsible for the provision of newborn hearing screening services. The program director shall be an audiologist, neonatologist, pediatric otolaryngologist, neonatal or perinatal nurse, or pediatrician. The program director may delegate duties related to the oversight of the hearing screening service to appropriately trained staff. The program director shall establish effective communication with perinatal staff, understand the hearing screening procedure used at the hospital or birth center, and be responsible for the success of the hearing screening program. At least one person in a leadership position (Program Director or Audiologist) shall work on site and be available for newborn hearing screening data inquiries from the Universal Newborn Hearing Screening Program (UNHSP).

MDPH Responsibilities of the Program Director shall include:

- Submitting newborn hearing screening protocols to MDPH at the request of the Department (every five years, MDPH will send a letter requesting the protocol and a new copy of the guidelines will be sent to birth facilities).
- Submitting a separate newborn hearing screening protocol for the Neonatal Intensive Care Unit (NICU) or Level II Special Care Nursery (SCN) when this level of care is provided at a facility (this shall be submitted to MDPH as part of the overall facility newborn hearing screening protocol).
- Submitting any major changes that occur to the protocol in writing to MDPH.
- Submitting a form identifying the program director, audiologist, physician available for medical consultation for the hearing screening program, MDPH on-site contact, birth certificate data entry person, and MDPH quality assurance reports contact(s) to the MDPH. The type of hearing screening performed [otoacoustic emissions (OAE) or auditory brainstem response (ABR)] and the policy of the birth hospital or birth center regarding

outpatient hearing screens will also be on the form (Appendix 2-facility staffing and technology form).

- Ensuring that the hearing screening program complies with MA Chapter 243 of the Acts of 1998, An Act Providing for Hearing Screening of Newborns (see Appendix 3-state statute), and hospital licensure and birth center regulations (see Appendix 4-regulations).
- Assuring that an initial hearing screen is performed on every newborn and only one hearing rescreen is performed on infants that do not pass the screen.
- Developing, in consultation with the audiologist, a written quality assurance/improvement plan that addresses all aspects of the hearing screening process and follow-up, including: 1) developing measures to assess family satisfaction, and 2) measures to assure adherence to the hospital's or birth center's protocols and these guidelines.
- Overseeing all aspects of program operation including: 1) staffing, 2) structure, 3) implementation, 4) procurement of hearing screening equipment, including Auditory Brainstem Response (ABR) equipment to be used in a NICU or Level II SCN when a facility offers this level of care, 5) communication of hearing screening results, including identifying systems to ensure families receive hearing screening results and other information in a culturally sensitive manner and in a language they understand, 6) maintenance of equipment, 7) procurement of supplies, 8) infection control, 9) data collection and analysis, 10) monitoring of referral rates, 11) quality assurance/improvement, and 12) communication with internal birth registrar(s) and MDPH.
- Identifying a licensed clinical professional(s) responsible for answering questions, discussing hearing screening results, or addressing other concerns in the event that the hearing screener is not a licensed clinical professional (e.g., nurse, audiologist). This clinical professional shall be available to the trained hearing screening personnel who may be responsible to provide parent(s)/guardian(s) with the newborn hearing screening results.
- Oversee the protocol in collaboration with the audiologist for hearing screening personnel and licensed clinical professionals responsible for communication of hearing screening results to parent(s)/guardian(s)/infant's primary care provider, including a plan to ensure parent(s)/guardian(s) receive the results in a language they understand.
- Identifying staff who will be responsible for entering data in the newborn record (see Appendix 5-newborn hearing screening birth certificate criteria), discharge plan or summary, electronic health record, and birth certificate, including Newborn Hearing Screening Transmittal form data for infants transferred into a facility other than the one they were born in.
- Ensuring that data are reported through the MDPH Registry of Vital Records and Statistics, Vitals Information Partnership (VIP) birth certificate system or such mechanism as specified by the MDPH.
- Identifying staff responsible for reviewing MDPH quality assurance reports and communicating updates to the MDPH UNHSP and hospital birth certificate registrar.
- Identifying and overseeing the duties of the audiologist assigned to the universal newborn hearing screening program.
- Ensuring that hearing screening personnel receive training and oversight of duties related to newborn hearing screening from a licensed audiologist.
- Reviewing and implementing program guidelines written by the audiologist.
- Designating an acting director to cover extended absence of the program director.
- Serving as the MDPH contact person or designating an alternate for this function.

- Presenting annual hearing screening data to the birth facility's perinatal advisory committee.
- Identifying a physician for medical consultation for the newborn hearing screening program if the Program Director is not a physician.
- Identify a contact person and telephone number of a designated staff person in the nursery that the MDPH may contact for questions if the Program Director and Audiologist are not regularly in the nursery. This person shall have the authority to address questions about hearing screening results. The UNHSP has direct contact with parent(s)/guardian(s) and may have to verify screening results with the birth facility for the family.

Important: *The role of the program director and the audiologist can be performed by the same person if the person chosen as the program director is an audiologist and meets the requirements listed in these guidelines.*

2. Audiologist

The audiologist shall be licensed by the Commonwealth of Massachusetts pursuant to the Board of Registration of Speech-Language Pathology and Audiology Regulations at 260 CMR 1.00 et seq. The designated newborn hearing screening audiologist shall have *at least six months of* documented professional experience in performing hearing screenings and/or diagnostic evaluations on infants in a clinical setting.

Responsibilities of the Audiologist shall include:

- Working in collaboration with the Program Director to develop the newborn hearing screening protocol, including the protocol for NICU and Level II SCN when applicable.
- Providing guidance to hearing screening personnel and licensed clinical professionals responsible for communication of hearing screening results to parent(s)/guardian(s)/infant's primary care provider in collaboration with the Program Director, including a plan to ensure the parent(s)/guardian(s) receive the results in a language they understand.
- Assuring in collaboration with the Program Director that an initial screen is performed on every newborn and only one rescreen is performed on infants that do not pass the screen.
- Working with the program director to implement a quality assurance/quality improvement plan.
- Providing written procedures explaining how to: 1) perform the newborn hearing screening, 2) secure supplies necessary for accurate hearing screening, 3) ensure results are documented in the newborn record, electronic health record, discharge plan or summary, and birth certificate system, 4) make referrals, 5) provide information to parent(s) or guardian(s), 6) communicate hearing screening results to parent(s)/guardian(s) and primary care provider, and 7) obtain interpreters for languages other than English as needed, including American Sign Language (ASL).
- Providing on-going oversight of hearing screening personnel in relation to hearing screening duties, to assure competent performance of hearing screening and related activities and to identify training and technical assistance needs.
- Providing comprehensive initial and on-going training to hearing screening personnel, covering, at a minimum, how to 1) perform the newborn hearing screen, 2) document results in the newborn record, discharge plan or summary, electronic health record, and birth

certificate system, 3) make referrals, 4) provide information to parent(s)/guardian(s), and 5) communicate hearing screening results to parent(s)/guardian(s) and primary care providers.

- Developing a competency form, which includes a line for the audiologist's signature, indicating that each hearing screener is competent to perform newborn hearing screening.
- Outlining a process for periodic review, annually at a minimum, of the competency of hearing screening personnel to continue to perform hearing screenings.
- Reviewing data to monitor the performance of the hearing screening program and provide additional training and assistance when necessary.
- Obtaining normative data for the hearing screening instruments and protocols that are used, including understanding facility specific typical refer rates, acceptable manufacturer and state refer rates, NICU/Level II SCN refer rates when applicable, and identifying deviations in the data.
- Providing information and technical assistance to parent(s)/guardian(s), the program director, primary care providers, hearing screening personnel, and others.
- Communicating results to parent(s)/guardian(s) when deemed appropriate according to protocols and procedures.
- Recommending hearing screening equipment to the program director based upon current equipment availability and performance.
- Ensuring ABR hearing screening equipment is used to perform hearing screenings in the NICU or Level II SCN when a facility offers this level of care.
- Ensuring ABR hearing screening is performed when infants are readmitted and have defined risk indicators for hearing loss (See Appendix 6-risk indicators).
- Ensuring accurate operation, calibration, and maintenance of hearing screening equipment.
- Developing a back-up plan for hearing screening to ensure continuation of service when hearing screening equipment malfunctions.
- Ensuring that appropriate supplies are used in hearing screening procedures.
- Training and monitoring personnel for appropriate infection control procedures in coordination with the program director and the facility's infection control policy.
- Assisting physicians, other medical staff and hearing screening personnel in making appropriate referrals.
- Staying informed about advances in procedures, equipment, and other issues relevant to newborn hearing screening and providing this information to the hearing screeners.
- Assisting Program Director in preparing annual presentation for Perinatal Advisory Committee.

Important: *The Universal Newborn Hearing Screening Program has developed a video called "Loss and Found, What to do if your baby didn't pass the newborn hearing screening". The video can be used for training screeners or other personnel involved in newborn hearing screening, shown to parents to help them understand hearing screening and the importance of follow-up, or used on the hospital television system for general educational viewing. The DVD is available by calling 1-800-882-1435 and is on the Newborn Hearing Screening website at <http://www.mass.gov/eohhs/streaming/dph/loss-and-found.mp4> A copy has been included in the pocket of this binder.*

3. Hearing Screening Personnel

In Massachusetts and other parts of the country, newborn hearing screening is performed by a wide variety of people. Nurses, audiologists, therapists, technicians, students, and volunteers have been trained to perform newborn hearing screening in hospitals or birth centers. The Universal Newborn Hearing Screening Law mandates that whatever the background of the hearing screening personnel at a given hospital or birth center, they shall be trained and supervised in all areas related to newborn hearing screening by a licensed audiologist. If the audiologist is not the direct supervisor of hearing screening personnel, the audiologist shall ensure that the supervisor(s) is aware of and adheres to policies and protocols related to newborn hearing screening.

Responsibilities of hearing screening personnel shall include :

- Working under the supervision of an audiologist licensed by the Commonwealth of Massachusetts in all areas related to newborn hearing screening.
- Following procedures written by the audiologist with regard to newborn hearing screening, documenting hearing screening results, making referrals, providing information to parent(s)/guardian(s), communicating hearing screening results to parent(s)/guardian(s) in a language they understand, and communicating hearing screening results to the infant's primary care provider.
- Participating fully in initial and on-going training.
- Using equipment and supplies approved by the audiologist.
- Following infection control procedures established by the facility.
- Working with the identified licensed clinical professional (s) responsible for answering questions or concerns when the screener is not a licensed clinical professional.

II. Training and Supervision

The Universal Newborn Hearing Screening Law mandates that training and supervision of hearing screening personnel be performed by an audiologist licensed by the Commonwealth of Massachusetts.

1. Training

Training shall include at a minimum:

- A written training curriculum developed by the audiologist which outlines : 1) the benefits of early detection of hearing loss, 2) information on equipment, 3) procedures for ordering necessary supplies, 4) where and when the hearing screening will take place, 5) communication of results, 6) how the hearing screeners follow the facility's infection control procedures, 7) procedures for recording results of hearing screening in the newborn record, discharge plan or summary, electronic health record, and birth certificate, 8) information on risk indicators for hearing loss (see Appendix 6-risk indicators for hearing loss algorithm), and 9) training on NICU and Level II SCN newborn hearing screening protocol when applicable.
- Training of hearing screeners by the audiologist on how to use the hearing screening equipment and plans for measuring hearing screeners competency annually.

- A plan for the audiologist to train and observe annually hearing screening personnel/licensed clinical professional staff who communicate results to parent(s)/guardian(s) (see Appendix 7 - hearing screening trainer tool).
- A plan for hearing screening staff to observe the audiologist screening at least two infants during initial training and when new hearing screening equipment is being implemented.
- A plan for the audiologist to observe each new screener performing at least three newborn hearing screenings during initial training and when new hearing screening equipment is being implemented.
- A plan for the audiologist to train licensed clinical professionals identified to be a support for communication with parent(s)/guardian(s) regarding newborn hearing screening when the hearing screening personnel are not licensed clinical professionals.

2. Oversight of Hearing Screening

Oversight shall include at a minimum:

- Involvement of the audiologist in the identification of appropriate staff or volunteers for the newborn hearing screening program, including those who communicate the hearing screening results.
- Review of hearing screening data (e.g., number inconclusive, number did not pass, number missed, etc.) by the audiologist to determine the effectiveness of each screener.
- Initial and ongoing periodic observation of hearing screening staff by the audiologist.
- Monitoring and supervision of the hearing screening process by the audiologist to prevent delayed discharges.
- Oversight of the procedures for communication to parent(s)/guardian(s) by the audiologist.
- Annual monitoring including direct observation of staff who communicate results to parent(s)/guardian(s) to ensure results are communicated effectively, if someone other than the audiologist is communicating the results.

Please Note: It is not a requirement of these Guidelines that all nursery personnel shall be trained to perform newborn hearing screening. Each birth facility may determine appropriate staff to carry out the hearing screening and related duties.

III. Information to Parent(s)/Guardian(s) Prior to the Newborn Hearing Screening

Prior to the hearing screening of a newborn, the birth center or hospital, including hospitals with pediatric services but without a nursery, shall provide written information regarding newborn hearing screening to parent(s)/guardian(s). A hospital without maternal newborn services, but with pediatric services, shall provide information about newborn hearing screening to parent(s)/guardian(s) of a newborn admitted or transferred to the hospital when a hearing screening was not performed in the birth hospital or birth center. Information shall also be provided when an infant is readmitted in the first month of life and a hearing screening is performed (see section V. Screening Process and Appendix 8-Joint Committee on Infant Hearing Position Statement). This information shall be readily available in the major languages as identified through the acute hospital's language needs assessment required under 105 CMR 130.1103 (A) and appropriate literacy levels shall be used. Translation of the information to

languages used by a smaller percentage of the obstetrical population shall be provided prior to the hearing screening to the maximum extent possible, but in no event later than discharge.

1. Information to be distributed prior to hearing screening

- MDPH, Universal Newborn Hearing Screening brochure “Can your baby hear this nursery rhyme?” (see Appendix 9-brochure available in 13 languages)
- MDPH Fact Sheet/Questions and Answers document (see Appendix 10- Information for Parents about Newborn Hearing Screening). Facilities may choose to include the information from the Fact Sheet in their hospital educational materials instead of providing the Fact Sheet.

2. Other important information to include

- Brief description of the hearing screening process (i.e., how the hearing screening is conducted, when and where the hearing screening takes place)
- Amount of time needed for the hearing screening process
- Reassurance to parent(s)/guardian(s) that the hearing screening is safe and non-invasive
- Definitions of possible hearing screening results (pass and did not pass/refer)
- Steps involved in religious exemption from hearing screening

***Important:** It is recommended that the term "did not pass" rather than "failed" be used when communicating to the parent(s)/guardian(s) that the infant did not pass the hearing screening . Hearing screening results and required follow-up shall be explained clearly to parent(s)/guardian(s) (see Appendix 8-hearing screener training tool).*

IV. Religious Exemption

1. Documentation of Religious Exemption

Parent(s) or guardian(s) may refuse a hearing screening *only* if the parent(s) or guardian(s) of the infant object to the hearing screening based upon sincerely held religious beliefs. In order to relieve hospitals and birth centers of any liability from not doing the hearing screening, it is recommended that hospitals and birth centers develop a waiver form documenting that the parent or guardian has refused hearing screening based on sincerely held religious beliefs (see Appendix 11-sample religious exemption). The form shall be in a language that the parent(s)/guardian(s) understand. This signed form shall be included in the infant’s medical record.

V. Hearing Screening Process

1. Newborn Hearing Screening Procedure

Hospitals and birth centers shall outline procedures for performing hearing screenings for all infants prior to discharge to home. Components of the procedure for performing hearing screenings which must be defined include, but are not limited to, the following:

- The site within the hospital or birth center at which the hearing screening will be performed

- When the hearing screening will be performed, target age of the infant (e.g., between 12-24 hours of birth)
- Specific instructions for moving an infant to the hearing screening site, if applicable
- Specific instructions for introduction of hearing screening and relaying results when the infant is screened in the presence of parent(s)/guardian(s)
- Specific instructions for preparing the infant for hearing screening.

Important: *The protocol shall include information on performing repeat hearing screenings on readmissions in the first month of life (this includes NICU /Level II SCN and well baby infants) when there are conditions associated with potential hearing loss. A repeat hearing screening on such readmissions shall be done using ABR hearing screening technology even if the infant passed the hearing screening prior to discharge to home after birth (see Appendix 12 – readmission tool).*

2. Equipment

The MDPH does not recommend a particular technique or type of equipment for performing newborn hearing screening. The Joint Committee on Infant Hearing (JCIH) Year 2007 Position Statement, Principles and Guidelines for Early Hearing Detection and Intervention Programs (EHDI) (see Appendix 8–position statement), provides information on hearing screening (*JCIH Hearing Screening section, Pediatrics, Volume 120 Number 4, 10/2007, page 903 -905*). Physiological measures shall be used to screen newborns and infants for hearing loss. Such measures include 1) otoacoustic emissions (OAEs) either transient -evoked (TEOAE) or distortion-product (DPOAE), and/or 2) auditory brainstem response (ABR) . Interpretive criteria for pass/did not pass or refer outcomes shall reflect clear scientific rationale and shall be evidence based. The audiologist working with the hearing screening program shall obtain normative data for the instruments and protocols that are used. Hospitals that have a NICU or Level II SCN are required to provide ABR hearing screening for infants that receive this level of care.

Once a technique(s) is chosen, the birth facility shall provide the following information in the protocols:

- Type of hearing screening equipment used, including model and year of manufacture.
- Specific instructions for setting up the hearing screening equipment prior to screening.
- Specific instructions for using the hearing screening equipment.
- Specific instructions for equipment calibration, if applicable.
- Back-up instructions in case of equipment malfunction.

3. Supplies

Hospitals or birth centers shall outline procedures for ensuring that adequate supplies are available at all times. In particular, hospitals and birth centers shall:

- Designate a person in charge of monitoring inventory, ordering, and stocking supplies.

Important: *Hospitals or birth centers shall only use supplies that are recommended by the manufacturer of the hearing screening equipment they use.*

4. Infection Control

Hospitals and birth centers shall explain how the hearing screeners meet the facility's infection control procedures. The protocol shall describe how the hearing screeners will carry out the following:

- Cleaning hands before and after hearing screening
- Wearing gloves during hearing screening when medically indicated
- Cleaning equipment between patients
- Disposing of materials
- Controlling infants' exposure to communicable diseases, active infections, or acute illnesses from hearing screening personnel
- Procedures for screening infants in need of contact precautions as identified by medical staff

5. Missed Hearing Screenings

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 a newborn may be missed for one of a number of reasons. If a hospital fails to screen a newborn prior to discharge, the hospital shall carry out the following:

- Schedule an appointment for the newborn at the birth facility or a MDPH approved hearing screening center to have a hearing screening performed within ten business days from the infant's date of discharge.
- Notify the person making the appointment that an interpreter is needed if the family's preferred language is other than English.
- Provide verbal and written notice to parent(s)/guardian(s) about the missed hearing screening prior to discharge whenever possible, but in any case no later than ten days following discharge, and in a language understood by the parent(s)/guardian(s).
- Identify resources within the birth facility to assist parent(s)/guardian(s) with information to select a primary care provider for the infant when necessary.
- Notify the infant's primary care provider about the missed hearing screening by telephone and in writing prior to discharge whenever possible, but in any case no later than ten days following discharge.
- Include in both verbal and written notice to parents, at a minimum: 1) the time/day and location/address of the hearing screening appointment that has been scheduled, 2) the telephone number of the hearing screening site, 3) a list of MDPH Approved Audiological Diagnostic Centers (See Appendix 13-MDPH Approved Audiological Centers), 4) information about the importance of hearing screening, and 5) information about ABR screening if the infant meets NICU/Level II SCN or other criteria that calls for ABR screening.
- Provide the written notice and information about the importance of hearing screening in a language understood by the parent(s)/guardian(s).
- Remind parent(s)/guardian(s) of the hearing screening appointment prior to discharge or by telephone.
- Provide the MDPH 800 telephone number (1-800-882-1435) for more information on universal newborn hearing screening.

- Indicate through the birth certificate system that the infant missed the newborn hearing screening.

Important: *When an infant is scheduled for an outpatient screen, the birth certificate newborn hearing screening field shall be marked as missed until the hearing screening appointment occurs. The facility shall replace the missed results with new information when the family returns for the screen.*

6. Inconclusive/Unsuccessful Hearing Screenings

An inconclusive/unsuccessful newborn hearing screening occurs when an infant receives a hearing screening, but the results are inconclusive or the equipment does not produce any results in one or both ears. Hospitals or birth centers are responsible for obtaining results from a hearing screening in both ears. The following are options of what to do in the event of an inconclusive hearing screening:

<u>Scenario</u>	<u>Action Steps</u>
a. Child passes hearing screening in one ear, but hearing screening is inconclusive in the other ear.	⇒ Repeat the hearing screening in both ears prior to discharge from hospital or birth center. If hearing screening cannot occur prior to discharge, follow procedure for a missed hearing screening.
b. Child does not pass the hearing screening in one ear, and hearing screening is inconclusive in the other ear.	⇒ Repeat the hearing screening in both ears prior to discharge from hospital or birth center. If hearing screening cannot occur prior to discharge, follow procedure for a did not pass screen.
c. Hearing screening is inconclusive in both ears.	⇒ Repeat the hearing screening in both ears prior to discharge from hospital or birth center. If hearing screening cannot occur prior to discharge, follow procedure for a missed hearing screening.

Important: *If the hearing screener is unsuccessful in achieving results for one or both ears, the result of “screened, results inconclusive” shall be recorded in the birth certificate system.*

7. Rescreens

Hospitals or birth centers that perform newborn hearing screenings may perform one confirmatory rescreen if the infant does not pass an initial hearing screening in one or both ears. When performing a rescreen, both ears must be rescreened even if only one ear did not pass the first hearing screening. An inpatient rescreen shall be considered the final screen (*no more than one rescreen shall be performed*).

7.1 Inpatient rescreens

A number of newborns receive a hearing rescreening prior to discharge. If the facility is planning on performing a hearing rescreening prior to discharge, only the final results of the hearing screening shall be entered into the birth certificate system. Therefore, please hold the results until the final results are determined and then forward to the birth registrar at your facility. To reduce the number of infants that become lost to follow-up in the newborn hearing screening process, the rescreen shall be performed prior to discharge whenever possible.

7.2 Outpatient rescreens

Birthing facilities may choose to include in their protocol the allowance for an outpatient rescreen (instead of an inpatient rescreen), if a newborn did not pass the initial hearing screening. Outpatient rescreens have several additional requirements prior to and post discharge (see bullets below). Birthing facilities shall follow these procedures in the event of an outpatient rescreen:

- Schedule an appointment for the infant to return for the rescreen at the birthing facility. All outpatient rescreens must be performed within ten business days following the infant's discharge date.
- Provide verbal and written notice to parent(s)/guardian(s) regarding the following: 1) date, 2) time, 3) address and location of the appointment, and 4) telephone number of the hearing screening site.
- When performing a rescreen, both ears must be rescreened even if only one ear did not pass the first hearing screening.
- Upon performance of the rescreen, document the hearing rescreen results in the infant's medical record.
- Follow Section VII of these Guidelines, Communication of Results, including making an appointment at an approved audiological assessment/diagnostic center if the newborn did not pass the rescreen in one or both ears.
- Document hearing screening results in the birth certificate system.
- If the rescreen appointment is not kept by the parent(s)/guardian(s), the birthing facility shall ensure that procedures for a "did not pass" hearing screening result are followed. This includes making an appointment at an approved audiological assessment/diagnostic center, notifying the parent(s)/guardian(s) in writing and in a language understood by the parent(s)/guardian and alerting the infant's primary care provider by telephone and in writing.

Important: Outpatient rescreens are not a requirement of these Guidelines and most facilities complete the hearing screening process while the infant is in the hospital.

VI. Special Circumstances Relating to New born Hearing Screening

1. Performing Hearing Screening in the Neonatal Intensive Care Units (NICUs) and Level II Special Care Nursery (SCN)

Hospitals with NICU or Level II SCN services shall develop separate hearing screening protocols that specifically address the following: 1) hearing screening for infants transferred from a community birth hospital to a NICU or Level II SCN, and 2) infants born at a hospital with a NICU or Level II SCN who are transferred directly from the delivery room or well infant nursery to the NICU or Level II SCN and 3) infants born at home or enroute to hospital who are admitted to the NICU or Level II SCN.

Important: It is not necessary to repeat the entire birth hospital's hearing screening protocol in the NICU/Level II SCN section. Please provide a section on NICU/Level II SCN when indicated and provide references to the hospital's newborn hearing screening protocol sections as necessary.

The protocol shall describe the following:

- How the infant is identified/selected for hearing screening at admission or other time.
- Description of how medical status and age criteria for hearing screening of infants in the NICU or Level II SCN are determined (e.g., premature infants) to ensure these infants receive hearing screening as early as physiological development or stability will permit reliable screening and no later than discharge.
- How the NICU or Level II SCN meets the protocol established for the hospital's newborn hearing screening program (e.g., information provided to parent(s)/guardian(s), notification of results to the parent(s)/guardian(s)/infant's primary care provider and results entered into the birth certificate/medical record/electronic health record).
- How the facility will perform hearing screening using Auditory Brainstem Response (ABR) for infants admitted to the NICU or Level II SCN for medical reasons and/or for greater than five days (OAE alone is not acceptable to screen these high risk infants). OAE may be combined with ABR hearing screening if the birth facility has a two-stage hearing screening protocol for high risk infants, but infants shall be referred directly to a MDPH Approved Audiological Diagnostic Center if they do not pass either OAE or ABR hearing screening.
- Details on how infants who did not pass automated ABR in the NICU or Level II SCN shall be referred directly to a MDPH Approved Audiological Diagnostic Center.
- Description of how instructions will be given to transfer/receiving facilities that admits newborns that an infant who did not pass in the NICU or Level II SCN shall not be rescreened and specific details on follow-up (e.g., audiological appointment that was made and other instructions).
- A description of the hospital's policy on rescreening infants admitted to the NICU or Level II SCN, including infants who may have been screened previously, shall be provided.

- A description of how families are educated about potential risk indicators for hearing loss prior to discharge (including identified risk indicators) and how identified risk indicators for hearing loss are provided in detail to any transfer/receiving facility.
- A description of how families are provided information on obtaining follow-up audiological evaluation for their infants who pass newborn hearing screening, but who are at risk for developing hearing loss at a later time (See Appendix 6-risk indicators).
- A description of how the newborn hearing screening, including rescreening results, are entered into the birth certificate system or faxed on a transmittal form to the MDPH, Universal Newborn Hearing Screening Program (See Appendix 14-hearing screening transmittal form)

2. Physiologically Unstable Infants

By the age of three months, an infant shall receive a hearing screening unless the infant has delayed physiological development or physiological instability as a result of illness or premature birth. In any circumstance, the infant shall be screened *prior to discharge to home* and as early as physiological development or stability will permit reliable hearing screening.

3. Transferred Infants

If an infant is transferred directly to a hospital from a birth hospital, birth center, or from home subsequent to a home birth, the responsibility for hearing screening lies with the hospital from which the infant is discharged to home, unless the newborn patient record clearly documents that the hearing screening and communication of results were performed by the birth hospital. If the hearing screening was not performed by the birth facility, the birth certificate system shall indicate that the newborn missed his/her hearing screening because he/she was transferred.

If the record shows an infant did not pass a hearing screening at the birth hospital/birth center, and no follow-up information was provided during the transfer, then the receiving hospital shall set up a follow-up appointment and follow all other procedures detailed in the receiving hospital's hearing screening protocols. If a rescreen is performed, both ears must be rescreened even if only one ear did not pass the first hearing screening at the birth facility.

Facilities accepting transferred newborns who did not receive a hearing screening at the birth facility are responsible for performing the hearing screening prior to discharge in accordance with its MDPH approved hearing screening protocol. Results of the hearing screening shall be filled out on the MA Department of Public Health, Newborn Hearing Screening Transmittal form (see Appendix 14-hearing screening transmittal form) and faxed into the UNHSP's confidential fax line (617-994-9822) within 3 days of performing the hearing screening. The Program Director will identify staff who are responsible for submitting Newborn Hearing Screening Transmittal forms to the MDPH within the specified time period.

A written procedure shall be developed for updating the transferred infant's birth certificate with hearing screening information received on the Newborn Hearing Screening Transmittal form. Specific information shall include but not be limited to:

- Identification of all persons involved in the process, including the birth certificate contact person(s).
- Clearly defined procedures for how New born Hearing Screening Transmittal forms are received by the person(s) responsible for entering and reporting results on the birth certificate.
- Specified timeframe for delivery of Newborn Hearing Screening Transmittal forms to the person(s) responsible for entering and reporting results on the birth certificate.
- Specified timeframe for the person(s) responsible for entering and reporting results on the birth certificate to update the hearing screening information.

3.1 Providing Screening Information to the Receiving Hospital or Birth Center

The birth hospital/birth center shall provide hearing screening information to the receiving hospital/birth center. Information which shall be included in the patient record and discharge summary shall include, but is not limited to, the following:

- Results of the hearing screening
- If child was not screened, a notation to that effect
- Hearing screening results were given to parent(s)/guardian(s) in writing
- A copy of any date, time, and place of the diagnostic appointment if one was scheduled.
- Explicit instruction not to rescreen the infant if the infant did not pass in the NICU/Level II SCN and meet described high risk criteria. The receiving facility shall include in the discharge instructions any information about the follow -up appointment at a MDPH approved audiological diagnostic center or assist the family in scheduling/rescheduling the follow -up audiological appointment as necessary.

4. Change of Hearing Screening Results During a Rescreen Procedure

It is possible for the hearing screening results to change during a rescreen procedure (only one rescreen shall be performed). The results of the first screen and rescreen should never be combined to make a pass result when the “did not pass” result changed from one ear to the other. The outcome of the rescreen shall be the final result of the hearing screening and should be communicated and recorded accordingly.

5. Outpatient Hearing Screens for Children Born Outside of the Birthing Facility

Almost all infants born in birth facilities in Massachusetts receive newborn hearing screening. Only an estimated 20% of the >200 infants who are born at home in Massachusetts receive hearing screening. Birth facilities can assist in addressing this health concern by offering newborn hearing screening services to families with infants born at home and partnering with midwives practicing in the community.

Outpatient hearing screens may be provided to newborns who are born in a birth center, home, or outside of Massachusetts in accordance with birth facility newborn hearing screening protocols. Results of the screens shall be filled out on the MA Department of Public Health, Newborn Hearing Screening Transmittal form (see Appendix 14) and faxed into the UNHSP’s confidential

fax line (617-994-9822) within 3 days of performing the hearing screening. The family shall be informed that their health insurance will be billed and the MDPH is the payer of last resort.

VII. Communication of Results

1. Oral Communication

The birth hospital or birth center shall inform the parent(s)/guardian(s) of results in person when an infant did not pass, missed a hearing screening, or the hearing screening result was inconclusive. The hospital or birth center shall designate staff who are responsible for communicating the hearing screening results in person to the parent(s)/guardian(s). Protocols for communication shall ensure that communication is confidential, culturally sensitive, understandable, presented in a caring and sensitive manner and in a language the parent(s)/guardian(s) understand. This person shall document in the infant's medical record that the conversation took place with the parent(s)/guardian(s). Whenever possible, it is helpful to provide the results and any related follow-up information when there is another person present to support the parent(s)/guardian(s) receiving the results.

***Important:** Parents with children diagnosed with hearing loss express intense frustration when the hearing screening results were provided in a way that led them to believe there probably was not a hearing loss and the screening result was really not that important. Hearing screening results shall be communicated plainly to the parent(s)/guardian(s) without downplaying the results (e.g., there may be fluid in the ears or many infants do not pass). This might lead parent(s)/guardian(s) to believe that follow-up might not be necessary. According to the American Academy of Pediatrics, hearing loss is the most common congenital condition in the United States. Children with hearing loss can experience delayed speech, language and development if the hearing loss is not identified early and timely intervention is provided (see Appendix 7-screener training tool).*

2. Written Communication

2.1 Parent(s)/Guardian(s)

Form letters shall be developed to inform parent(s)/guardian(s) whether their newborn passed the hearing screening, the results were inconclusive, missed a hearing screening, or did not pass the hearing screening. All form letters must express the results of the hearing screening specifically for *each* ear.

- This information shall be readily available in the major languages as identified through the acute hospital's language needs assessment required under 105 CMR 130.1103 (A) and appropriate literacy levels should be used.
- Translation of the information to languages used by a smaller percentage of the obstetrical population shall be provided no later than discharge.

If an infant passed a hearing screening, the form letter shall include at a minimum:

- Explanation of newborn hearing screening.
- Results of the hearing screening.

- Links to available resources should the parent(s)/guardian(s) have concerns about newborn hearing screening or desire additional information on hearing loss (e.g., babyhearing.org)
- MDPH 800 telephone number (1-800-882-1435) for information about universal newborn hearing screening.
- Information about major milestones in typical early language and communication development (see Appendix 15-language and communication milestones)

If an infant passed a hearing screening but has any known risk factors for hearing loss (see Appendix 6-risk indicators), the form letter shall include at a minimum:

- Explanation of newborn hearing screening
- Results of the hearing screening
- Explanation or description of known risk indicator
- Recommendation for diagnostic evaluation when deemed appropriate and in accordance with the attached risk indicator algorithm (Appendix 6-risk indicators).
- Information about major milestones in typical early language and communication development (see Appendix 15-Language and Communication Milestones)
- Links to available resources should the parent(s)/guardian(s) have concerns about newborn hearing screening or desire additional information on hearing loss (e.g., babyhearing.org)
- MDPH 800 number (1-800-882-1435) for information about universal newborn hearing screening.

If the infant was screened and the results were inconclusive, missed a hearing screening, or did not pass the hearing screening, the form letter shall also provide appropriate follow-up information. These letters shall include, but are not limited to, the following:

- Explanation of newborn hearing screening
- Importance of hearing screening
- Results of hearing screening for each ear
- Importance of follow-up
- Time, date, and address of the follow-up appointment (*it is recommended that this appointment be made in collaboration with the parent(s)/guardian(s).*)
- Telephone number of hearing screening site or audiological diagnostic center
- List of MDPH Approved Audiological Diagnostic Centers
- Information about major milestones in typical early language and communication development (see Appendix 15-Language and Communication Milestones)
- Links to available resources should the parent(s)/guardian(s) have concerns about newborn hearing screening or desire additional information on hearing loss (e.g., babyhearing.org)
- MDPH 800 telephone number (1-800-882-1435) for information about universal newborn hearing screening.

Important: For those infants that did not pass the hearing screen, please provide the parent(s)/guardian(s) with “Things to know if your baby did not pass the hearing screening” (see Appendix 16 Things to know if your baby did not pass the hearing screen)

2.2 Infant’s Primary Care Provider

The infant’s primary care provider shall be notified in writing of the results of the hearing screening for every infant, including infants that passed the hearing screening . This notice shall include information on any known risk indicator for hearing loss (See Appendix 6).

The infant’s primary care provider shall be notified by *telephone* and in writing if an infant was screened and results were inconclusive, did not pass, or missed a hearing screening. Such notices shall include, but is not limited to:

- Results of hearing screening for each ear and the importance of follow-up
- Information on missed or inconclusive hearing screening results when hearing screening results were not achieved
- Type of equipment used to perform the screening (e.g., ABR or OAE)
- Time, date and location of the follow-up appointment
- Telephone number for the hearing screening or audiological diagnostic center where the appointment was made
- List of MDPH Approved Audiological Diagnostic Centers
- Importance of follow-up for known risk indicators for hearing loss . Please include instructions on follow-up based on the risk indicator algorithm provided. (see Appendix 6-risk indicators)

Important: In the event that the parent(s)/guardian(s) have not identified a primary care provider for their infant, the birth facility shall identify internal resources to assist the family in selecting a primary care provider for their infant.

VIII. Newborn Hearing Screening Follow-up

1. Follow-up Procedures

Hospitals or birth centers shall develop procedures for follow-up in order to ensure that an infant who missed a hearing screening, or the hearing screening results were inconclusive, receives a hearing screening and that the parent(s)/guardian(s) of an infant who did not pass the hearing screening will receive information about follow-up and an appointment for diagnostic testing. Activities shall include, but are not limited to, the following:

- Identify and document in the hearing screening program protocol the person(s) responsible for making appointments at MDPH Approved Audiological Diagnostic Centers for infants who did not pass the hearing screening.
- Provide the results of the hearing screening to the MDPH Approved Audiological Diagnostic Center when the appointment is made and it is important to include the type of hearing screening equipment used when an infant did not pass the screen (e.g., ABR/OAE) .

- When the family's preferred language is other than English, the birth facility shall notify the MDPH Approved Audiological Diagnostic Center that an interpreter is needed and provide the language spoken by the parent.
- Identify and document in the hearing screening program protocol the person(s) responsible for making appointments at the hospital or birth center for infants who missed a hearing screening or hearing screening results were inconclusive.
- Identify and document in protocol the person(s) responsible for informing parent(s)/guardian(s) of the follow-up appointments.
- Identify and document in the hearing screening program protocol the person(s) responsible for documenting the hearing screening result, appointment date, time, place, and telephone number on the following: 1) the data collection form, 2) the written letters informing parent(s)/guardian(s) of the hearing screening results, and 3) the discharge plan/summary, newborn patient record and electronic health record.
- Identify the process to make appointments on weekends, holidays, or hours when MDPH Approved Diagnostic Centers are not open for business.

Important: For an infant who did not pass the hearing screening it is very important that the diagnostic appointment occur soon after discharge. The appointment shall be made at a MDPH Approved Audiological Diagnostic center, and the date of the appointment shall be no later than three weeks after the infant is discharged. This includes infants who did not pass the hearing screen in one or both ears. The appointment should be made with input from the parent(s)/guardian(s).

Important: For an infant who missed the screen or who was inconclusively screened, follow-up hearing screening must occur within 10 business days of discharge.

2. Infants at Risk for Hearing Loss

Hospitals and birth centers shall follow the same protocol for infants identified to be at -risk for hearing loss as for infants with no known risk factors for hearing loss with one exception. If an infant with known risk passes a hearing screening, MDPH recommends that the hospital or birth center uses the attached algorithm (see Appendix 6-risk indicators) and ensure the following:

- Inform parent(s)/guardian(s) of the need for a follow-up diagnostic evaluation, including making follow-up appointment at a MDPH Approved Audiological Diagnostic Center when the risk indicator algorithm indicates the need for this.
- When an appointment is made, provide family with written information on date, time and location of the follow-up audiological appointment.
- Inform the infant's primary care provider of the infant's risk for hearing loss and recommend follow-up.
- Describe how appointments will be made at a MDPH Approved Audiological Diagnostic Center when indicated and how instructions will be given to the parent(s)/guardian(s)/infant's primary care provider about follow-up. This includes instructions on advice to families to consult with their infant's primary care provider and provide a list of the MDPH Approved Audiological Diagnostic Centers.

Important: Please see the Joint Committee on Infant Hearing Position Statement for additional information on risk indicators for hearing loss.

IX. Documentation of Screening Results

1. Data Management System

Provide a description of the hospital based data management system (manual, computer based, commercial product, electronic health record, etc.) used to record newborn hearing screening results. Examples include nursery logs, databases, and other tracking mechanisms. Such information includes but is not limited to the following:

- Name of the system (if using a commercial product)
- Data fields collected
- System backups

2. Medical Record, Electronic Health Record, and Discharge Plan or Summary

The person performing the hearing screening shall document newborn hearing screening information, including hearing screening results for all infants screened in the medical record/electronic health record/discharge plan or summary. Appropriate follow-up information shall be documented in these systems when an infant misses a hearing screening, results were inconclusive, or does not pass the hearing screening. Such information includes but is not limited to the following:

- Infant's hearing screening status
- Results of hearing screening
- Follow-up information (appointment date, time, place, phone number of the follow-up facility), if applicable
- Transfer information, if applicable

3. Birth Certificate

All hearing screening information shall be entered into the birth certificate system or manually documented on the birth certificate by the facility birth registrar or a person(s) indicated by the program director. The hearing screening results must be received by the person in charge of the birth certificate within two days of the infant's discharge and entered on the birth certificate no later than ten days following discharge. Results are sent to the Massachusetts Department of Public Health as part of the newborn's statistical birth certificate.

Important: The hearing screening results and related demographic data from the birth certificate are used as soon as they are received by the Universal Newborn Hearing Screening Program Outreach Staff to call families to ensure infants receive necessary and timely audiological services when an infant missed or did not pass a hearing screen. This data is also submitted by MDPH annually in aggregate format to the Centers for Disease Control and Prevention to measure hearing screening performance in Massachusetts and across the country. Your hospital/birth center will receive an annual report with your facility specific performance data each year from the MDPH.

The required information to be reported to MDPH can be found on the Newborn Hearing Screening Transmittal Form (Appendix 14—hearing screening transmittal form). The Newborn Hearing Screening Transmittal Form was developed to assist facilities in data collection and only needs to be submitted to the Universal Newborn Hearing Screening Program if the results cannot be entered into the birth certificate. It may be used as permanent documentation in the child’s medical record. A written procedure shall be developed for the flow of hearing screening information and results to the birth certificate system. Specific information shall include but not be limited to the following:

- Identification of all persons involved in the process, including the birth certificate contact person(s).
- Clearly defined procedures for how hearing screening information is received by the person(s) responsible for entering and reporting results on the birth certificate.
- Clearly defined procedures for how hearing screening information is received by the person(s) responsible for entering and reporting results on the birth certificate on infants who are screened in the NICU or Level II SCN.
- Clearly defined procedures for how hearing screening information is received by the person(s) responsible for entering and reporting results on the birth certificate on infants who are rescreened in an outpatient setting.
- Specified timeframe for delivery of hearing screening information and results to the person(s) responsible for entering and reporting results on the birth certificate.

Important: For all infants born at your facility and rescreened in an outpatient setting at your facility, results of the hearing screening must be recorded on the birth certificate and documented in the medical record. For all infants transferred into your facility, please fax the transmittal form to MDPH. Please do not send results back to birth facilities.

X. Quality Assurance/Quality Improvement

1. MDPH Quality Assurance Data Reports

MDPH quality assurance reports are sent by the MDPH to each hospital and birth center. These reports include child-specific data on: 1) infants that did not pass or missed the hearing screen, 2) infants with missing or questionable hearing screen data, 3) infants who were transferred without confirmed hearing screen results, and 4) other outstanding data issues. Birth hospitals will develop a written protocol for: 1) timely review of MDPH quality assurance reports, 2) updating hearing screening information in the birth certificate, and 3) communicating data updates to MDPH. The written protocol shall include, but not be limited to:

- Identification of all persons involved in the process, including the birth certificate contact person(s).
- Clearly defined procedures for review of the MDPH quality assurance reports including the person responsible for communicating updates to the MDPH through the UNHSP confidential fax (617-994-9822) or through secure electronic method specified by the Department.
- Clearly defined procedures for how updated hearing screening information is communicated to and entered by the person(s) responsible for birth certificate data.

- Specified timeframe for delivery and entry of updated hearing screening information to/by the person(s) responsible for birth certificate data.
- Specified timeframe for the person(s) responsible to communicate updated or new data to MDPH based on quality assurance reports.

2. Birth Facility Quality Assurance and Quality Improvement Plan

Hospitals and birth center protocols shall also contain detailed information for quality assurance and quality improvement plans. Specific information shall include:

- Methods for monitoring referral rates to assure:
 - Refer rates range approximately 1-3% for well baby nurseries*
 - Refer rates range approximately 2-8% for intensive care nurseries*

(The target refer rates were established by the Massachusetts Department of Public Health Universal Newborn Hearing Screening Advisory Committee. The overall statewide hearing screening refer rate in Massachusetts has been consistent at 1.8% for several years. It is expected that refer rates shall not be below 1 %).

 - Hospitals and birth centers shall define target refer rates specific to their facility based on their own historical data.
 - Number/percent of follow-up appointments scheduled for newborns that did not pass or missed a hearing screen. Protocols shall define methods used to: 1) ascertain that follow-up appointments are scheduled, 2) ascertain that follow-up appointment information is recorded accurately in the birth certificate.
 - Monitoring of parent(s)/guardian(s) satisfaction with hearing screening process. Protocols shall define methods used to measure parent(s)/guardian(s) satisfaction with hearing screening process and copies of the instrument shall be included in the protocol.
 - Protocols shall define methods to monitor the timeliness and accuracy of hearing screening results documented in the birth certificate for all infants in the following categories: 1) passed the hearing screen, 2) did not pass or missed a hearing screen, 3) transferred without a hearing screen (transfer facility shall be recorded in the birth certificate), 4) deceased or refused consent.
 - Protocols shall describe other quality assurance/quality improvement activities a birth facility uses or participates in.
 - Birth facilities shall have the capacity to analyze and report well baby newborn hearing screening data, including NICU/Level II SCN newborn hearing screening data separately when applicable, and report it back to the Perinatal Advisory Committee at their facility.
 - The quality assurance protocol shall also include an annual evaluation of critical performance data including, but not limited to: total number of live births, number of infants screened, number of infants who passed the hearing screening, number of infants who did not pass the hearing screening (results by right ear, left ear and both ears), number of infants referred for diagnostic testing, number of infants who missed hearing screening or hearing screening results were inconclusive, total number of infants transferred in/out of the facility, number of infants screened who were transferred in/out of the facility, number of deceased infants, and number of parents or guardians who refused consent.

***Important:** It is recommended that each hospital or birth center identify a mechanism to assess satisfaction with the communication of newborn hearing screening results to parent(s)/guardian(s) and overall satisfaction with newborn hearing screening services received at the facility.*

XI. Billing

1. Responsibility of Health Insurance and the Massachusetts Department of Public Health

The cost of providing the newborn hearing screening shall be covered by all health insurers except for supplemental policies which only provide coverage for specific diseases, hospital indemnity, Medicare supplement, or other limited services. If a family does not have health insurance that covers the newborn hearing screen, please contact the Universal Newborn Hearing Screening Program at 1-800-882-1435 for information. Families whose infant requires further hearing testing after not passing a newborn hearing screening shall receive information that health insurers provide coverage for follow-up audiological testing and the Commonwealth is available as the payer of last resort when insurance does not cover the cost for follow-up hearing test.

XII. Signatures

1. Program Director and Audiologist Signatures

Both the program director and the audiologist of the Newborn Hearing Screening Program are required to sign the facility protocol upon submitting the document to the Department of Public Health, UNHSP. This may be in the form of a cover letter.