

# Suggested Guidelines for Newborn Hearing Screening and Evaluation Services State of Florida

## The purpose of this document is:

- To provide a description of a suggested quality hearing screening program for newborn nurseries.
- To provide a description of recommended procedures to audiologists performing follow up hearing screening or audiological assessment of infants identified during universal newborn hearing screening.

### I. Description

Newborn Hearing Screening services are provided to identify newborns at risk of hearing impairment and to assure that follow-up audiometric screening, diagnosis, and referral to intervention is provided as indicated in accordance with Florida Statutes [391.301-304](#), [383.14](#) and [383.145](#).

### II. Legislative Intent

To provide a statewide comprehensive and coordinated interdisciplinary program of early hearing screening and follow-up care for newborns identified as referring from the hearing screening process. The goal is to screen all newborns for hearing impairment in order to alleviate the adverse effects of hearing loss to speech and language development, academic performance, and cognitive development.

### III. Definition of Targeted Hearing Loss

Congenital permanent bilateral, unilateral sensory or permanent conductive hearing loss of newborns in well-infant nurseries to include neural hearing loss (e.g., auditory neuropathy / auditory dyssynchrony) in infants admitted to the Newborn Intensive Care Unit (NICU) for more than 5 days. Identification of risk factors associated with delayed onset or progressive hearing loss.

### IV. Suggested Inpatient Community Hospital Guidelines

#### A. Definition

An inpatient newborn hearing-screening program will be capable of providing newborn hearing screening testing to all newborns and infants during their birth admission or neonatal intensive care unit admission.

#### B. Standards for Hearing Screening

It is recommended that:

1. **The hospital designates one individual** (preferably an audiologist) to serve as the contact person for the newborn hearing screening program. The designated person is responsible for ensuring that persons who perform hearing screening are sufficiently trained, coordinating follow-up services, and managing all correspondence. This person will also serve as the liaison between the hospital, family, and Children's Medical Services.

2. **The hospital demonstrate training** criteria and competencies for newborn hearing screeners as determined by the hospital and document dates of training for each person who performs hearing screening. A CD/DVD called *Universal Newborn Hearing Screening Training Program* on screening techniques and necessary competencies is available to hospital newborn hearing screening programs from the Children's Medical Services Newborn Screening Program by calling (850) 245-4201.
3. **The hospital have protocols, policies, and procedures** available for inspection that provide operational details of the facility's newborn hearing screening program including:
  - a. the staff training criteria,
  - b. staff roles and responsibilities, including supervision of screening outcomes
  - c. referral and follow-up procedures;
  - d. protocols for follow-up testing of babies who were discharged before receiving a hearing screening Follow-up protocols may include return to the hospital for outpatient screening or referral to an audiologist.
  - e. procedure for reporting screening results in each individual child's medical record,
  - f. culturally and linguistically appropriate information for distribution to parents,
  - g. documentation of final screening prior to discharge including:
    - i. screening outcome (pass or refer)
    - ii. if a child is discharged from the hospital in "refer" status, the discharge documents will include a referral for follow up hearing testing
    - iii. if a child is discharged from the hospital in "refer" status,, an appointment will either be scheduled for follow up hearing testing as a hospital outpatient or the mother will be given information and resource materials to make an appointment for follow up hearing testing. If there is no payer source for follow up hearing testing contact (850) 245-4201 for information on potential funding sources.
    - iv. the follow up appointment is to occur within 30 days of referral from hearing screening and diagnostic procedures are to be completed no later than 3 months of age.
4. **Each hospital provides that all newborns receive a hearing screening prior to discharge.**
  - a. Each ear will be screened at each stage of screening.
  - b. In the well-baby nursery, newborns may be screened by either ABR or OAE techniques. If the child does not pass the initial screening and is available for re-test at a later time, then the child should be retested prior to discharge using either ABR or OAE. Hospitals are cautioned not to allow excessive rescreening on each test encounter (e.g., 8-10 attempts in a single encounter) to try to obtain a pass result after a valid refer has been recorded.
  - c. Newborn Intensive Care Unit: Infants admitted to Level II and/or Level III NICUs for more than 5 days will receive a screening of both ears with ABR. If the child does not pass the initial screening and is available for retest prior to discharge, then the retest should be completed using ABR.
5. **Newborn hearing screening will be conducted by** a licensed audiologist, physician, or other appropriately supervised individual who has completed documented training specifically for newborn hearing screening.

6. **The following risk factors should be considered for each newborn.** If present, the appropriate risk factor(s) should be checked on the Newborn Screening Specimen Card:
  - a. Family history of permanent childhood hearing loss (blood relative with permanent hearing loss in early childhood, e.g. grandparent, parent, aunt, uncle, first cousin, siblings)
  - b. Hyperbilirubinemia at a serum level requiring exchange transfusion
  - c. Persistent pulmonary hypertension of the newborn associated with mechanical ventilation (PPHN)
  - d. Conditions requiring the use of extracorporeal membrane oxygenation (ECMO).
  - e. Birth weight < 1500 Grams
7. **As specified by law ([F.S. 383.145](#)), parents will sign a waiver only** if a hearing screening is refused. The signed document must be placed in the newborn's medical record. The hospital should give the parents who refuse information on appropriate developmental auditory, speech and language milestones such as what is included in the Children's Medical Services Newborn Screening Program brochure.
8. **The hospital should inform parents**, in writing, of the results of the hearing screening, prior to hospital discharge. Screening results should be conveyed immediately to families so they understand the outcome and importance of follow-up when indicated. The parents should be given information on appropriate developmental auditory, speech and language milestones such as what is included in the Children's Medical Services Newborn Screening Program brochure. For infants who are referred, a brochure offering information for the parents is available at no charge from the Children's Medical Services Newborn Screening Program. To request the *Does your baby need another hearing test?* brochure complete a [request form](#).
9. **As specified by law ([F.S. 383.145](#)),** the hospital shall ensure documentation of the hearing screening results in the newborn's medical record. It is recommended that the result of the final hearing screening prior to discharge and the presence of any hearing loss risk factors be recorded in a prominent place on the discharge summary.
10. **The hospital should document the need for a hearing screening referral** as part of the discharge summary for the newborns that leave the hospital in a "refer" status (e.g., newborns who failed the in-hospital hearing screening or who were not screened prior to discharge), including the appointment time and place scheduled for hearing follow-up testing. The *Does your baby need another hearing test?* brochure has been designed to cite the follow up hearing test appointment information. The brochures can be obtained at no cost by completing a [request form](#).
11. **The newborn's hearing results shall be recorded** on the HEARING SCREENING INFORMATION section of the Newborn Screening Specimen Cards and subsequently submitted to the Department of Health Bureau of Laboratories at 1217 Pearl Street, Jacksonville, Florida 32202. If genetic screening is performed before the hearing screening has been completed, the appropriate box should be marked signifying that the hearing screening had not yet been done. If the hearing screening is completed at a time separate from the genetic screening, only the hearing section of the Specimen Card should be completed and submitted to the Department of Health Bureau of Laboratories. Hospitals with access to the electronic birth registration system should enter hearing screening results into this system.

**12. Infants readmitted within the first month of life** should receive a repeat hearing screening prior to discharge if there are conditions present that are associated with potential hearing loss (i.e., hyperbilirubinemia requiring exchange transfusion, culture results indicating sepsis or meningitis, and/or ototoxic medication exposure).

### **C. Audiological Screening Guidelines**

#### **It is recommended that:**

Determination of presence or absence of an Auditory Evoked Potential (e.g. ABR) and/or Otoacoustic Emissions (OAE) at a predetermined screening level to assess the need for further audiological evaluation.

1. Newborn hearing screening services should be performed using FDA approved otoacoustic emissions or evoked potential testing that detects mild to profound hearing loss in newborns (ABR is to be used to screen infants with NICU stays of more than 5 days).
2. Use of screening equipment should be in accordance with manufacturer's protocols and stated norms for newborn hearing screening purposes.
3. The equipment should be calibrated in accordance with the manufacturer's recommendation and a log should be kept documenting the dates of calibration, repair or replacement of parts.
4. For rescreening or a complete evaluation it is necessary to test both ears, even if only one ear caused a referral from newborn hearing screening.

### **D. Quality Indicators of appropriate referral rate**

#### **It is recommended that:**

1. A minimum of 96% of newborns born in the hospital should receive a hearing screening prior to discharge.
2. A maximum outpatient referral rate of 4% of all newborns screened prior to discharge should be achieved.
3. Following a two-stage screening, a minimum outpatient referral rate of 1% for ABR screening and 2% for OAE screening should be observed for all newborns screened prior to discharge (if the refer rate is worse than these percentages the hospital should train screening personnel on the importance of the two-stage (or repeat) screening process while avoiding excessive rescreening during an single encounter).

## **V. Suggested Practice Guidelines for Follow-up of Newborn Hearing Screening Referrals**

### **A. Definition: Referral and outpatient follow-up will be necessary for:**

1. Any newborn who did not receive a hearing screening prior to discharge, including home births.
2. Any newborn that was discharged with a "refer" result during the inpatient stay.
3. If conditions associated with delayed onset hearing loss are documented (refer to Appendix A for hearing loss risk factors).
4. All infants with a risk factor for hearing loss (Appendix A), regardless of status on developmental milestones, should be referred for an audiological assessment at least once by 24 to 30 months of age. Children with risk factors that are highly associated with delayed-onset hearing loss, such as ECMO or CMV infection, should have more frequent audiological assessments.

### **B. Standards for follow-up of newborn hearing screening results for all referrals**

**A pediatric audiologist or hospital based screening program** will provide follow-up outpatient hearing testing. It is preferable when referring to an audiologist that an appointment be scheduled with a [CMS Approved Pediatric Audiologist](#). It is standard care for the follow-up

screening or audiological evaluation to be completed within the first 30 days following discharge and for all diagnostic procedures to be completed prior to age 3 months.

1. **At the time of discharge for newborns who are referred from newborn hearing screening** (including those who are discharged before hospital screening was completed):
  - a. The physician completing the discharge process will prepare a written referral for follow up hearing testing.
  - b. When possible, the appointment for follow up testing (hearing screening or audiological evaluation) will be scheduled prior to discharge and the appointment time and place included on the discharge summary to be given to parents.
  - c. The referral for follow-up screening should be to a pediatric audiologist or outpatient hospital program with FDA approved equipment for newborn hearing screening that uses a protocol instituting 30-35 dB HL newborn hearing screening criteria.
  - d. The state metabolic laboratory will prepare reports newborn screening results, including hearing, that are delivered to all birth hospitals to file in the medical record of all newborns. If a physician of record is known, hospitals will send this information to the newborn's physician (medical home) of record.
2. **Newborns failing a subsequent screening procedure require audiological evaluation**, preferably by a [CMS Approved Pediatric Audiologist](#). It is standard of care for this evaluation to follow a protocol that renders information regarding the infant's auditory thresholds, status of auditory nerve and brainstem pathway, and determination of locus of hearing impairment if abnormal results are found. Refer to Appendix B for the recommended audiological evaluation and reporting protocols.

### C. Standards for reporting hearing screening and follow-up results

1. **For newborns who (1) were discharged prior to screening completion, or (2) were readmitted in the first 30 days of life and rescreening is warranted** the hearing (re)screening results shall be recorded on:
  - a. The Department of Health [Repeat Hearing Screen Form](#) and faxed to the Newborn Screening Program (850) 245-4049 or
  - b. The Newborn Screening Specimen Cards and submitted to the Department of Health Bureau of Laboratories at 1217 Pearl Street, Jacksonville, Florida 32202.
2. **For newborns who failed the in-hospital screening:**
  - a. The hearing (re)screening performed in the hospital shall be recorded on either (i) or (ii) below.
    - i. The Department of Health [Repeat Hearing Screen Form](#) and faxed to the Newborn Screening Program (850) 245-4049 or
    - ii. The Newborn Screening Specimen Cards and submitted to the Department of Health Bureau of Laboratories at 1217 Pearl Street, Jacksonville, Florida 32202.
  - b. The hearing (re)screening performed by an audiologist shall be recorded on either (i) or (ii) below:
    - i. The Department of Health [Repeat Hearing Screen Form](#) and faxed to the Newborn Screening Program (850) 245-4049 or
    - ii. [Diagnostic Hearing Evaluation Form](#) and faxed to the Newborn Screening Program (850) 245-4049
  - c. **Test results that confirm the presence of a hearing loss** for newborns or infants who receive a diagnostic audiological evaluation shall be recorded on:
    1. [Diagnostic Hearing Evaluation Form](#)

### 3. Evaluation tools for outpatient screening of “refer” status follow-up

- a. Refer to Appendix B for information on the rescreen/evaluation protocol to be used.
- b. Results / recommendation:
  - i. Parents should receive information about hearing, speech and language milestones and information regarding risk factors for progressive hearing loss.
  - ii. For infants that exhibit a “pass” result after follow up hearing testing, the hearing test results shall be:
    1. Sent in writing to the primary care physician (medical home)
    2. Reported to the Children’s Medical Services Newborn Screening Program via:
      - a. The Department of Health [Repeat Hearing Screen Form](#) and faxed to the Newborn Screening Program (850) 245-4049 or
      - b. The Newborn Screening Specimen Cards and submitted to the Department of Health Bureau of Laboratories at 1217 Pearl Street, Jacksonville, Florida 32202.
  - iii. For infants that continue to exhibit a “refer” result:
    1. A referral will be made to an audiologist for a complete audiological evaluation.
    2. The results of hearing testing should be sent in writing to the primary care physician (medical home) for further audiological and medical evaluations and referrals, as appropriate.
    3. The hearing results indicating a continuation of “refer” status shall be reported to the Children’s Medical Services Newborn Screening Program via:
      - a. The Department of Health [Repeat Hearing Screen Form](#) and faxed to the Newborn Screening Program at (850) 245-4049 or
      - b. The Newborn Screening Specimen Cards and submitted to the Department of Health Bureau of Laboratories at 1217 Pearl Street, Jacksonville, Florida 32202.

### 4. Quality Indicators for rescreening rate:

#### It is recommended that:

- a. Achieve 95% attendance for infants rescheduled for outpatient re-screening.
- b. Achieve 100% reporting of newborn hearing rescreen results to the Department of Health.

## VI. Considerations for Audiological Assessment of Infants (0-12 months) with Hearing Loss

**A. Definition:** A licensed [CMS Approved Pediatric Audiologist](#) with experience in assessing hearing in infants should conduct a diagnostic audiological evaluation. The audiologist must have the equipment necessary to complete all described evaluation procedures. The goal is to determine the presence or absence of a hearing loss through the application of a battery of audiological tests culminating in the referral of children diagnosed with hearing loss to local Children's Medical Services Part C Early Steps for intervention services.

**B. Audiologic Assessment Guidelines for Infants and Toddlers in Florida:** Appendix B is a summary of the recommended audiological evaluation and reporting protocols. Consult the [Guidelines for Infant Hearing Screening, Referral, Audiologic Assessment, Hearing Loss Management and Early Intervention document](#) for detail on recommended assessment and management procedures.

## **C. Criteria for significant hearing loss for eligibility for local Children's Medical Services**

### **Part C Early Steps**

1. Evidence of a documented permanent hearing threshold level of (Re: ANSI 1996):
  - a. 25 dB or greater based on pure tone average of 500, 1000, and 2000 Hz unaided in the better ear (Air-bone gap not to exceed 10 dB HL)
  - b. Air conduction thresholds, unaided in the better ear, 25 dB or greater HL at two or more frequencies in the high frequency range (2000, 3000, 4000, 6000 Hz) in both ears with air-bone gaps no greater than 10 dB HL.
2. Evidence of auditory dys-synchrony (auditory neuropathy) in both ears characterized by a unique constellation of behavioral and physiologic auditory test results.

### **D. Quality Indicators for referral to early intervention**

1. Achieve 100% referral rate to the local Early Steps within two business days of diagnosis of infants with permanent or long term conductive hearing loss. Reporting of infants and toddlers with diagnosed hearing loss to the local Children's Medical Services Part C Early Steps is required by [Federal Law 34 CFR, § 303.321 d.2.](#)
2. For infants that are confirmed to have hearing loss, parents should receive information about support services available in the form of:
  - a. "Serving Hearing Impaired Newborns Effectively (SHINE)" brochure (available free of charge from the Children's Medical Services Newborn Screening Program at (850) 245-4201)
  - b. "Florida's Resource Guide for Families of Young Children with Hearing Loss " (available free of charge from the Children's Medical Services Newborn Screening Program at (850) 245-4201)
3. The outcome of the objective test measurements should be in agreement with parental report of sound awareness and alertness to environmental acoustic stimulation.
4. Achieve a diagnosis with initiation of amplification fitting as appropriate by 4 months of age for 95% of infants with significant hearing loss.
5. Completion of early intervention evaluation and initiation of family-centered early intervention services no later than 6 months of age.

## RISK INDICATORS ASSOCIATED WITH PERMANENT CONGENITAL, DELAYED-ONSET, OR PROGRESSIVE HEARING LOSS IN CHILDHOOD

Risk indicators that are marked with a “\*\*\*” are of greater concern for delayed-onset hearing loss.

1. Caregiver concern\*\* regarding hearing, speech, language, or developmental delay
2. Family history\*\* of permanent childhood hearing loss
3. Neonatal intensive care of more than 5 days or any of the following regardless of length of stay:
  - a. ECMO\*\* assisted ventilation
  - b. Exposure to ototoxic medications (gentimycin and tobramycin)
  - c. Exposure to loop diuretics (furosemide/Lasix)
  - d. Hyperbilirubinemia that requires exchange transfusion
4. In utero infections, such as CMV\*\*, herpes, rubella, syphilis, and toxoplasmosis
5. Craniofacial anomalies, including those that involve the pinna, ear canal, ear tags, ear pits, and temporal bone anomalies
6. Physical findings, such as white forelock, that are associated with a syndrome known to include a sensorineural or permanent conductive hearing loss
7. Syndromes associated with hearing loss or progressive or late-onset hearing loss\*\*, such as neurofibromatosis, osteopetrosis, and Usher syndrome, other frequently identified syndromes include Waardenburg, Alport, Pendred, and Jervell and Lange-Nielson.
8. Neurodegenerative disorders\*\*, such as Hunter syndrome, or sensory motor neuropathies, such as Friedreich ataxia and Charcot-Marie-Tooth syndrome.
9. Culture-positive postnatal infections associated with sensorineural hearing loss\*\*, including confirmed bacterial and viral (especially herpes viruses and varicella) meningitis.
10. Head trauma, especially basal skull/temporal bone fracture that requires hospitalization.
11. Chemotherapy\*\*

Source: Year 2007 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs, Joint Committee on Infant Hearing.

**Evaluation and Practice Protocols**

It is necessary for pediatric audiologists to abide by the evaluation and practice protocol below for infants referred from newborn hearing screening (per [Guidelines for Infant Hearing Screening, Referral, Audiologic Assessment, Hearing Loss Management and Early Intervention](#)). NOTE: It is recognized that there may be some situations in which professional judgment should supersede the below practice protocols.

**IF** failed one hospital screening test:

**THEN:** screening or diagnostic OAE **OR** screening click AER

**IF** failed two hospital screening tests:

**THEN:** diagnostic OAE testing (2000 Hz – 6000 Hz) **OR** air conduction click AER

**IF** diagnostic OAE results are abnormal or inconclusive **OR** air conduction click AER was not performed

**THEN:** high frequency tympanometry (600 Hz or 1000 Hz probe tone)

**AND:** air conduction click AER

**IF** air conduction click AER is abnormal:

**THEN:** bone conduction click AER

**AND:** frequency specific tone bursts (500 Hz, 2000 Hz, 4000 Hz)

**AND/OR:** Auditory Steady State Response (ASSR)

**IF** there is a suspicion of auditory dyssynchrony, confirm by observing **more than one** of the following:

- a. AER wave 1 is present with the absence of later waveforms
- b. Cochlear microphonic is verified in the complete absence of all waveforms
- c. Middle ear muscle reflex is absent
- d. AER response indicates moderate hearing loss but there is no observable response to sound stimulation in combination with absent middle ear muscle reflex
- e. Presence of fluctuating hearing thresholds in the absence of any detectable middle ear abnormalities
- f. Presence of normal OAEs and abnormal ABR results.

**IF** the child is an audiological candidate for amplification:

**THEN:** obtain medical clearance for amplification fitting

**AND:** use probe microphone measures as a part of appropriate hearing aid fitting

**Timelines and Reporting**

It is intended that children referred from newborn hearing screening have their hearing status confirmed by 3 months of age. Therefore, the following activities must occur within the specified timelines, including reporting hearing results to the Department of Health, Children’s Medical Services Newborn Screening Program:

- A. Every effort shall be made to schedule infants referred from newborn hearing screening so that follow up screening or diagnostic procedures will be completed within 15 working days following the day of referral.
- B. Every effort shall be made to re-schedule missed appointments within 10 working days of the missed appointment.
- C. Any no-show family will be contacted and rescheduled within 15 working days of the missed appointment. Fax the [Repeat Hearing Screen Form](#) (for missed screenings) or [Diagnostic Hearing Evaluation Form](#) (for missed diagnostic evaluations) to the CMS Newborn Screening Unit, indicating that the family did not show for the appointment so that follow up with the family can occur.
- D. Follow up evaluation of well babies with abnormal diagnostic OAE and/or click AER results should occur as soon as possible, preferably within the same appointment or as soon as possible after medical approval for continued evaluation is obtained as necessary.
- E. Completion of the diagnostic test battery shall not be delayed beyond 3 months of age for treatment of middle ear effusion. Bone conduction AER procedures should be used as a means to confirm hearing status if a continuing middle ear condition is present.
- F. Fax or otherwise transmit the confirmation of hearing status including diagnosis within 2 days of determination to the Children’s Medical Services Newborn Screening Program using (a) the [Repeat Hearing Screen Form](#) if screening tools were used or (b) the [Diagnostic Hearing Evaluation Form](#) if diagnostic tests were used.
- G. Children up to age 36 months with apparent late onset or late diagnosed hearing loss shall be referred to the Children’s Medical Services Newborn Screening Program the [Diagnostic Hearing Evaluation Form](#) if the child was identified with hearing loss.
- H. Refer children under age 36 months who have confirmed hearing loss to the local Early Steps office within 2 days of confirmation. The audiologist shall not wait until complete audiometric information (frequency specific responses) has been obtained to refer the child to Early Steps.
- I. Strive to ensure that amplification (loaner or purchased) is fit to children with hearing loss within 30 calendar days of confirmation of hearing loss as appropriate to meet the needs of the child and family.