

# 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.

## 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, the coordination of services, follow-up and management of 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** in place that define the facility's newborn hearing screening program:
  - a. the staff training criteria,
  - b. staff roles and responsibilities, including supervision of screening quality
  - c. referral and follow-up procedures;
  - d. protocols for babies who were discharged before hearing screening was offered or completed (return for outpatient screening or referral to audiology)
  - e. procedure for reporting screening results in each individual child's medical record,
  - f. the culturally sensitive materials distributed to parents,
  - g. written results of final screening prior to discharge to include:
    - i. results of screening (pass or refer)
    - ii. if a child refers, a signed physician referral for follow up hearing testing must be obtained prior to discharge
    - iii. if a child refers, an appointment will be scheduled for follow up hearing testing comprised of either an outpatient hospital rescreen or an audiological evaluation (preferably by a CMS Approved Pediatric Audiologist). 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. **The hospital offers a hearing-screening test to all newborns born in the facility.**
  - a. Each ear will be screened at each stage of screening.
  - b. Well-infant nursery infants will receive a two-stage screening of both ears (ABR-ABR; ABR-OAE; OAE-OAE). Hospitals are cautioned not to allow excessive rescreening to try to obtain a pass result after a valid refer result has been elicited during a two-stage screening process.
  - c. Newborn Intensive Care Unit: Infants admitted to Level II and/or Level III NICUs for more than 5 days will receive a two-stage screening of both ears with ABR (ABR-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 and metabolic 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, the hospital must have parents sign a waiver only** if a hearing screening is refused and place this document in the 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 contact 850-245-4201.
9. **As specified by law**, the hospital shall include the results of the hearing screening 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 for children in 'refer' status and as a part of the discharge data recorded on the face sheet of well-baby charts.
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 not cost by contacting 850-245-4201.
11. **The newborn's hearing results shall be recorded** on the HEARING SCREENING INFORMATION section of the Newborn Metabolic Screening Specimen Cards and subsequently submitted to the Department of Health Bureau of Laboratories at 1217 Pearl Street, Jacksonville, Florida 32202 (F.S. 383.14).
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 or culture and sepsis, meningitis, 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 at least 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 95% 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 less than these percentages the hospital should train screening personnel on the importance of the two-stage screening process and avoidance of excessive rescreening).

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

##### **A. Definition: Referral and 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. Any infant who is readmitted to the hospital within the first 30 days of life if there are conditions present that are associated with potential hearing loss (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 having received ECMO or having 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 hearing testing outside of the hospital's inpatient screening program. It is preferable when referring to audiology, for an appointment to be scheduled with a CMS Approved Pediatric Audiologist. It is standard of care for the appointment for follow-up screening or audiological evaluation to be completed within 30 days of life and completion of all diagnostic evaluation procedures to occur 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. A written referral from a physician for follow up hearing testing will be obtained prior to discharge.
  - b. 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.
  - 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 prepares reports describing the results of reported newborn screening results, including hearing, that are delivered to all birth hospitals to file in the medical record of all newborns. 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 presents auditory stimulations at high levels (i.e., 70-80 dB nHL) with incremental decrease in intensity until 20-30 dB nHL or until no further response is obtained, whichever comes first. 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 (Hearing 002) and faxed to the Newborn Screening Program (850) 922-5385 (Appendix C) or
- b. The Newborn Metabolic 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 (Hearing 002) and faxed to the Newborn Screening Program (850) 922-5385 (Appendix C) or
  - ii. The Newborn Metabolic 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 (Hearing 002) and faxed to the Newborn Screening Program (850) 922-5385 (Appendix C) or
  - ii. Diagnostic Hearing Evaluation Form (Hearing 003) (Appendix D)
- 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:
  - i. Diagnostic Hearing Evaluation Form (Hearing 003)(Appendix D)

- 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 Screen Form (Hearing 002) and faxed to the Newborn Screening Program (850) 922-5385 (Appendix C) or
  - b. The Newborn Metabolic 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. Obtain 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.
  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 Screen Form (Hearing 002) and faxed to the Newborn Screening Program (850) 922-5385 (Appendix B) or
    - b. The Newborn Metabolic Screening Specimen Cards and submitted to the Department of Health Bureau of Laboratories at 1217 Pearl Street, Jacksonville, Florida 32202.
    - c. Test results that confirm the presence of a permanent hearing loss shall be reported on Diagnostic Hearing Evaluation Form (Hearing 003)(Appendix C)
  4. The Children’s Medical Services Newborn Screening Program provides the document *Standard of Care Language for Newborn Hearing* and the most current list of CMS Approved Audiologists to the infant’s physician (medical home) of record (Appendix E).

**4. Quality Indicator 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 D is a summary of the recommended audiological evaluation and reporting protocols. Consult the Audiologic Assessment Guidelines for Infants and Toddlers in Florida for

detail on recommended assessment and management procedures. These guidelines can be obtained from [www.cms-kids.org](http://www.cms-kids.org), Infant Hearing Program.

### **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.
  - c. Evidence of an anatomical malformation of the outer and/or middle ear in conjunction with a hearing loss  $\geq 30$  dB HL pure tone average of 500, 1000, and 2000 Hz in the better ear (atresia, stenosis, etc; ABR: AC – BC  $\geq 25$  dB HL).
  - d. Sensorineural hearing loss in excess of 50 dB HL in the worse ear based on pure tone average of 500, 1000, and 2000 Hz. Air-bone gap not to exceed 10 dB HL.
2. Evidence of a documented unresolved or chronically recurrent conductive hearing loss resulting in a speech and language delay in combination **with at least 4** of the following:
  - a. 4 or more episodes of otitis media in 12 months; primarily occurring in both ears
  - b. single episode of otitis media lasting longer than 3 months; primarily occurring in both ears
  - c. indication of fluctuating hearing loss (audiological hearing evaluation(s) revealing average of 20 dB at 500, 1000, 2000 Hz or worse in the better-hearing ear; OR caregiver or physician report)
  - d. caregiver or physician concern over speech and/or language development (i.e., as compared to "Sequence of Development for Infants and Toddlers: Auditory, Language and Speech")
  - e. caregiver concern over behavioral response when child is given a direction or placed in new situations
  - f. chronological age of 18 months or greater
3. Evidence of auditory dys-synchrony (auditory neuropathy) in both ears characterized by a unique constellation of behavioral and physiologic auditory test results<sup>2</sup>.

### **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 CFA 303.321d.
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.

# Repeat Hearing Screen Form

Appendix B

## Department of Health, Children's Medical Services, Newborn Screening Program

### NEWBORN'S INFORMATION:

\_\_\_\_\_  
Newborn's Last Name

\_\_\_\_\_  
First Name

\_\_\_\_\_  
Birth Hospital

\_\_\_\_\_  
Date of Birth

MM--DD--YY

\_\_\_\_\_  
Newborn's Medical Record #

### MOTHER'S INFORMATION:

\_\_\_\_\_  
Mother's Last Name

\_\_\_\_\_  
Mother's First Name

\_\_\_\_\_  
Mother's Social Security Number

### HEARING SCREEN RESULTS:

\_\_\_\_\_  
Date of Hearing Screen

MM--DD--YY

#### Right Ear

\_\_\_\_ Pass  
\_\_\_\_ Refer

#### Left Ear

\_\_\_\_ Pass  
\_\_\_\_ Refer

#### Test Method(s) used. Check all that apply:

##### Right Ear

\_\_\_\_ OAE  
\_\_\_\_ ABR

##### Left Ear

\_\_\_\_ OAE  
\_\_\_\_ ABR

#### Hearing risk status – Check all that apply:

\_\_\_\_ Family history (blood relative with permanent hearing loss in early childhood,  
e.g. grandparent, parent, aunt, uncle, first cousin, siblings)

\_\_\_\_ PPHN

\_\_\_\_ ECMO

\_\_\_\_ Hyperbilirubinemia/had exchange transfusion

\_\_\_\_ Low-birth weight (less than 1500 grams)

\_\_\_\_ NICU

\_\_\_\_\_  
Person Completing Form

\_\_\_\_\_  
Phone Number

**Note: This form can also be used to report infants who referred from newborn hearing screening who passed a diagnostic audiological evaluation protocol.**

**Fax to Newborn Screening Unit (850) 922-5385**

DOH Hearing 002

**Diagnostic Hearing Evaluation Form**  
**Department of Health, Children's Medical Services (CMS), Newborn Screening Program**  
**Complete this form ONLY for infants or toddlers up to age 36 months**

Appendix C

\*Audiology Clinic \_\_\_\_\_ \*Phone Number \_\_\_\_\_ \*Date of Visit \_\_\_\_\_

**Demographic Information** (Items with an asterisk \* are required)

\*Child's Name \_\_\_\_\_ LAST NAME, FIRST NAME  
 \*Child's DOB \_\_\_\_/\_\_\_\_/\_\_\_\_ Gender: \_\_\_\_\_  
 Child's Race \_\_\_African American \_\_\_Caucasian \_\_\_Hispanic \_\_\_Haitian  
 Primary Language of Child's Family: \_\_\_English  
 \_\_\_Asian/Pacific Islander \_\_\_Native American \_\_\_Unknown  
 \_\_\_Spanish \_\_\_Creole \_\_\_Other:  
 \*Birth Mother's Name (if known) \_\_\_\_\_ \*Birth Hospital (if known) \_\_\_\_\_  
 \*Mother's Social Security Number \_\_\_\_\_ \*Mother's DOB \_\_\_\_/\_\_\_\_/\_\_\_\_  
 \*Street Address \_\_\_\_\_ \*City \_\_\_\_\_ \*Zip \_\_\_\_\_  
 County \_\_\_\_\_ \*Home Phone \_\_\_\_\_ Other Phone \_\_\_\_\_  
 Child resides with: \_\_\_\_\_ Phone # if different from mother's \_\_\_\_\_  
 Primary Care Physician \_\_\_\_\_ Physician Phone \_\_\_\_\_

**Audiological Evaluation Results**

**Level 1 - Diagnostic evaluation results from this visit (Please record Pass (P) or Fail (F):**

	01 Diagnostic ABR	02 Bone Cond ABR	03 Tone Burst ABR 500	04 Tone Burst ABR 1000	05 Steady State ASSR	06 Diagnostic OAE	07 High Freq Immittance/ Tympanogra m	08 BOA	09 VRA	10 Middle Ear Muscle Reflex
<b>Right Ear</b>	__ P __ F	__ P __ F	__ P __ F	__ P __ F	__ P __ F	__ P __ F	__ P __ F	__ P __ F	__ P __ F	__ P __ F
<b>Left Ear</b>	__ P __ F	__ P __ F	__ P __ F	__ P __ F	__ P __ F	__ P __ F	__ P __ F	__ P __ F	__ P __ F	__ P __ F

**Level 2 - Extent of hearing loss suspected (S) or confirmed (C) during this visit:**

	01 None 16-25 dB	02 Mild 26-40 dB	03 Moderate 41-55 dB	04 Moderate- Severe 56-70 dB	05 Severe 71-90 dB	06 Profound > 90 dB	07 Sensori- Neural	08 __Permanent __Temporary Conductive	09 __Permanent __Temporary Mixed	10 Auditory Dyssynchrony
<b>Right Ear</b>	__ S __ C	__ S __ C	__ S __ C	__ S __ C	__ S __ C	__ S __ C	__ S __ C	__ S __ C	__ S __ C	__ S __ C
<b>Left Ear</b>	__ S __ C	__ S __ C	__ S __ C	__ S __ C	__ S __ C	__ S __ C	__ S __ C	__ S __ C	__ S __ C	__ S __ C

**\*Referral and Follow-Up Information - At the conclusion of this visit, overall hearing status is considered**

\_\_\_ Apparent normal hearing in both ears at this time  
 \_\_\_ Apparent middle ear effusion; presence of sensorineural hearing loss is unlikely based on test battery results  
 \_\_\_ Apparent middle ear effusion; return for more hearing tests after \_\_\_ weeks  
 \_\_\_ Inconclusive or borderline results; return in \_\_\_ weeks to confirm  
 \_\_\_ Medical complications prevent hearing testing until age \_\_\_ months  
 \_\_\_ No show for \_\_\_ appointment(s) in \_\_\_ weeks  
 \_\_\_ **Permanent / long term hearing Loss has been confirmed during this visit**

\*\*Referral to your local CMS Early Steps Program for Part C Services is required by law (CFA 303.321d) within 2 working days of hearing loss confirmation (not to include children with middle ear histories under age 12 months).  
 Date of referral to CMS-Early Steps Program \_\_\_\_\_  
**Comments on findings:** (i.e., malformations, further referral, etc.)  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**Materials Requested from CMS Newborn Screening Program**

Hearing aid(s) have been recommended \_\_\_No \_\_\_Yes Anticipated Funding: \_\_\_Medicaid \_\_\_Early Steps \_\_\_Insurance \_\_\_Other  
 If no, due to  Parent refusal  Parents are considering hearing aids \_\_\_ **I request a hearing aid listening test kit for this family** (up to age 3 only).

Send  **Early Steps:** \_\_\_ English \_\_\_ Spanish \_\_\_ Creole (Write the number of brochures ordered)

\*Audiologist's name: \_\_\_\_\_ \*Audiologist's signature: \_\_\_\_\_

Please return this form by mail or by fax to the attention of Ann Filloon at the FL Dept. of Health, Children's Medical Services, EHDI/Newborn Screening Program, which is located at 4052 Bald Cypress Way Bin A-06 Tallahassee, Florida 32399-1707. Form Current as of: 2-22-08

If you need assistance completing or submitting this form, contact Ann Filloon at (850) 245-4673.

**Fax number: (850) 922-5385**  
Hearing 0003

# Children’s Medical Services (CMS) - Newborn Screening Data System

## **Please complete the Follow-Up Diagnostic Evaluation Results Form for each visit for:**

All infants and toddlers (birth to three) with CONFIRMED hearing loss of suspected or defined degree, and all Infants or toddlers with evidence of auditory neuropathy/dys-synchrony in both ears. The presence of confirmed hearing loss or auditory dys-synchrony allows the child to be eligible for early intervention services.

**This form is intended to collect the results of a single visit. Please record only the extent of loss noted during this visit, and use additional forms to record subsequent visits.**

**Release of Protected Health Information without Authorization** – Children’s Medical Services, a division of the Florida Department of Health, administers the Newborn Screening Program, which includes hearing and metabolic screening. Newborn screening is an activity described in its capacity as a public health authority as defined by the HIPAA Standards for Privacy of Individually Identifiable Health Information, Final Rule (Privacy Rule). Pursuant to 45 CFR 164.512(b) of the Privacy Rule, covered entities such as your organization may disclose protected health information (PHI) to public health authorities. Public health entities are authorized to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and for the purpose of conducting public health surveillance, public health investigations, and public health intervention. For more information, visit the Center for Disease Control and Prevention site: <http://www.cdc.gov/mmwr/preview/mmwrhtml/su5201a1.htm>.

**Required Demographic Information** – For the child’s first visit to your facility, please complete all asterisked (\*) demographic information to ensure that CMS Newborn Screening has a complete record. On subsequent visits only update the demographic information that may have changed (address, phone number, etc.).

## **Audiological Results** –

**Level 1 – Diagnostic Evaluation Results – Presence or Confirmation of Hearing Loss** - *Referral to the local Early Steps Program should occur after this point of confirmation of the hearing loss.*

**Level 2 – Extent of Suspected or Confirmed Hearing** – Please indicate whether hearing loss is SUSPECTED (S) or CONFIRMED (C) in the appropriate box(es).

**Comments** – Please indicate if this is a child who passed newborn hearing screening and is later being identified with permanent hearing loss, presence of syndromes or known etiologies, if child is already receiving Part C services, date of further confirmatory hearing testing, etcetera.

**Referral and Follow-Up Information** – **Overall Hearing Status** – Select a single option that best represents the hearing status determined at the close of this visit. Please use the comment section to provide further information as appropriate.

**Referral to CMS Early Steps Program is Required by Federal Law (CFA 303.321d)** An audiologist must refer an infant/family to the local early intervention program within 2 days of confirmation of hearing loss after audiological evaluation (presence of hearing loss, **do not wait for full threshold information**). Please indicate the date that your facility contacted the local CMS-Early Steps Center.

**How to Request a Free Hearing Aid Test Kit** – When amplification is recommended or fitted, a free hearing aid test kit for the child may be requested from CMS Newborn Screening Program by checking the appropriate box. The test kit will be mailed to your facility immediately upon receipt of this form. To receive the free kit, the “Primary language of the family” must be indicated on the form so that the appropriate instruction sheet can be included. Please note that in order to receive a free kit:

- Families must be referred to a local Early Steps Program;
- The Newborn Screening data system must have received this data form, and
- Check the box “I request a **hearing aid listening test kit** for this family “

**Request for Early Steps Program Brochures** – Indicate if you would like to receive brochures describing early intervention in Florida. Specify the number of brochures in the different languages you would like to receive.

For more information regarding Florida’s universal newborn hearing screening program, referral, or diagnostic follow up services contact Ann Filloon in the CMS Newborn Hearing Screening program at (850) 245-4673 or refer to <http://www.cms-kids.com/InfantHearing.htm>.

For more information about CMS Approved Audiologists or the SHINE component of Early Steps for families of children with hearing loss contact Karen Anderson, Early Steps Coordinator of Hearing Services at (850)245-4444 x 2269 or refer to <http://www.cms-kids.com/SHINE/index.htm>

# Florida Protocol for Follow-Up Hearing Evaluation and Reporting of Results

## 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 [http://www.cms-kids.com/SHINE/Aud\\_assmt\\_guidelines\\_8-23-04.pdf](http://www.cms-kids.com/SHINE/Aud_assmt_guidelines_8-23-04.pdf)). 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

**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 3 weeks (15 work days) following the day of referral.
- B. Every effort shall be made to schedule missed appointments within 10 working days of the missed appointment.
- C. Any no-show family will be contacted and rescheduled within 3 weeks (15 working days) of the missed appointment. Fax the Hearing Results Form 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 Screening 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.

Source: CMS Audiologist Provider Application <http://www.doh.state.fl.us/cms/NewbornScreening/CMSAudiologistProviderapplication.dot>

## Standard of Care Language for Newborn Hearing

### ALL HEARING SCREENING REFERRALS

**Action required newborns that did not pass hearing screening in one or both ears:** Completion of an audiological evaluation by 3 months of age. Immediate referral to an audiologist\* to obtain otoacoustic emissions and/or auditory evoked response evaluation. If child is under treatment for middle ear effusion an audiological evaluation must be completed within 3 months of initial newborn hearing screening referral, regardless of middle ear status, to rule out sensorineural hearing impairment. The audiologist is required to refer a child with confirmed permanent hearing loss to the local Early Intervention Program for family-centered services and to the primary care physician or otolaryngologist for medical management and medical clearance for amplification.

\*Referral for audiological evaluation should be made to an audiologist who has the capability to perform hearing evaluation on children 0-36 months of age, which could include otoacoustic emissions, auditory evoked potentials, high frequency tympanometry, and visual reinforced audiometry.

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### IDENTIFIED HEARING RISK FACTORS

**Action required for infants with identified high risk factors for hearing loss:** These risk factors are known to be associated with late onset hearing loss that will cause delays in communication development. Referral for a hearing evaluation performed by an audiologist\* specializing in children needs to be considered at every routine visit until age 3 years. Referral should be made when there is parental concern about hearing or indication of delay in communication development. Communication development monitoring using a formal screening measure (i.e., Early Language Milestones – ELM) at every growth and development check-up at intervals no greater than 6 months is recommended until age 3 years. Referral to the local Early Intervention Program is required by federal law\*\* when developmental delays are evident in infants or toddlers.

\*Referral for audiological evaluation should be made to an audiologist who has the capability to perform hearing evaluation on children 0-36 months of age, which could include otoacoustic emissions, auditory evoked potentials, high frequency tympanometry, and visual reinforced audiometry.

\*\*Physicians are required by Federal law 34 CFR§303.321d to refer children with evident or suspected developmental delays or impairments to their local early intervention program. Referrals must be made within 2 working days of when the child is identified with an evident disorder or impairment that could affect their early development. Contact information can be obtained by calling 850-245-4200.

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### CHILDREN DISCHARGED WITHOUT RECEIVING HEARING SCREENING

**No hearing screening performed:** Each licensed birth center that provides maternity and newborn care services is responsible for providing hearing screening services to all newborns within the first 30 days of life (FS 383.145). Immediate referral for hearing screening within the first 30 days of life to be performed by hearing screening personnel at the birth hospital, an audiologist\*, or appropriately performed under the supervision of a physician. Screening shall result in a conclusive pass or refer status. Children not passing screening procedures in both ears shall be referred immediately for full audiological evaluation. Parents or legal guardians may waive the right to hearing screening for their newborn.

\*Referral for audiological evaluation should be made to an audiologist who has the capability to perform hearing evaluation on children 0-36 months of age, which could include otoacoustic emissions, auditory evoked potentials, high frequency tympanometry, and visual reinforced audiometry.

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### LATE ONSET HEARING LOSS:

**About 25% of children with hearing loss by age 3 pass newborn hearing screening and have no known risk factors.** Not all hearing loss risk factors can be effectively identified in the newborn nursery, therefore, the primary medical care provider has the responsibility to identify potential risk factors and to refer to audiology for hearing evaluation if a child with one or more hearing loss risk factors are present and a concern about hearing or communication development arises. The hearing loss risk factors that are associated with late-onset hearing loss are:

- congenital infection (neonatal herpes, CMV, HIV, rubella, syphilis, toxoplasmosis)
- stigmata or other findings associated with a syndrome known to include sensorineural or conductive hearing loss or eustachian tube dysfunction
- neurodegenerative disorders such as Hunter syndrome or sensory motor neuropathies such as Friedreich's ataxia and Charcot-Marie-Tooth syndrome
- postnatal infections associated with sensorineural hearing loss including bacterial meningitis
- head trauma
- syndromes associated with progressive hearing loss such as neurofibromatosis, osteopetrosis, and Usher's syndrome
- recurrent or persistent otitis media with effusion for at least 3 months.