

MARYLAND REGISTER

**Proposed Action on Regulations**

<b>Transmittal Sheet</b>  <b>PROPOSED OR REPROPOSED</b>  <b>Actions on Regulations</b>	<b>Date Filed with AELR Committee</b>	<b>TO BE COMPLETED BY DSD</b>
		Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

**1. Desired date of publication in Maryland Register: 10/17/2014**

**2. COMAR Codification**

**Title Subtitle Chapter Regulation**

10 11 02 01-.09

**3. Name of Promulgating Authority**

Department of Health and Mental Hygiene

**4. Name of Regulations Coordinator**

Michele Phinney

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410-767-5623

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**5. Name of Person to Call About this Document**

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**6. Check applicable items:**

- New Regulations

Amendments to Existing Regulations

    Date when existing text was downloaded from COMAR online: .

- Repeal of Existing Regulations

Recodification

Incorporation by Reference of Documents Requiring DSD Approval

Reproposal of Substantively Different Text:

:                      Md. R  
(vol.)    (issue)                      (page nos)                      (date)

Under Maryland Register docket no.: --P.

**7. Is there emergency text which is identical to this proposal:**

Yes - No

**8. Incorporation by Reference**

Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

**9. Public Body - Open Meeting**

OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to State Government Article, §10-506(c), Annotated Code of Maryland.

OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

**10. Children's Environmental Health and Protection**

Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

**11. Certificate of Authorized Officer**

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Claire Pierson, Assistant Attorney General, (telephone #410-767-6526) on September 16, 2014. A written copy of the approval is on file at this agency.

**Name of Authorized Officer**

Joshua M. Sharfstein, M.D.

**Title**

Secretary

**Telephone No.**

410-767-6500

**Date**

September 19, 2014

**Title 10**  
**DEPARTMENT OF HEALTH AND MENTAL HYGIENE**

**Subtitle 11 MATERNAL AND CHILD HEALTH**

**10.11.02 [Program for Hearing-Impaired Infants] Early Hearing Detection and Intervention Program**

Authority: Health-General Article, §§13-601—13-605, Annotated Code of Maryland

**Notice of Proposed Action**

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The Secretary of Health and Mental Hygiene proposes to repeal and adopt new Regulations .01—.09 under COMAR 10.11.02 Early Hearing Detection and Intervention Program.

**Statement of Purpose**

The purpose of this action is to update what is now considered to be archaic language and to bring this chapter into alignment with changes to the enabling statute. Certain procedures are being updated to reflect current practices, including screening and diagnostic practices as recommended in the latest Joint Committee on Infant Hearing position statement, and reporting procedures need to be upgraded. This upgrade includes a new requirement for audiologists to report results of hearing screening and diagnostic evaluations to the Program for Hearing Impaired Infants. Further, high-risk questionnaires are no longer used, and therefore language referring to the High Risk Questionnaire in Regulation .05 and references which follow, were deleted. Additionally, the regulations regarding the Advisory Council for Hearing Impaired Infants are being modernized.

**Comparison to Federal Standards**

There is no corresponding federal standard to this proposed action.

**Estimate of Economic Impact**

The proposed action has no economic impact.

**Economic Impact on Small Businesses**

The proposed action has minimal or no economic impact on small businesses.

**Impact on Individuals with Disabilities**

The proposed action has an impact on individuals with disabilities as follows:  
The proposed action has an impact on infants who miss or do not pass the birth hearing screen or are determined to have a risk factor for delayed onset or progressive hearing

loss as outlined in the most current Joint Committee on Infant Hearing Position Statement. Early hearing detection and intervention is essential to ensuring that appropriate audiological, educational, and medical care is provided.

### **Opportunity for Public Comment**

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to [dhmh.regs@maryland.gov](mailto:dhmh.regs@maryland.gov), or fax to 410-767-6483. Comments will be accepted through November 17, 2014. A public hearing has not been scheduled.

### **Economic Impact Statement Part C**

A. Fiscal Year in which regulations will become effective: FY 2015

B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

C. If 'yes', state whether general, special (exact name), or federal funds will be used:

D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly:

The revisions contained in this proposal will not change the overall administration of the Program nor the amount of funding available through the Program.

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

These regulations have no impact or affect on small businesses as the delivery of services under the Program will remain unchanged.

G. Small Business Worksheet:

Attached Document:

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**Title 10**

# DEPARTMENT OF HEALTH AND MENTAL HYGIENE

## Subtitle 11 MATERNAL AND CHILD HEALTH

### 10.11.02 [Program for Hearing-Impaired Infants] *Early Hearing Detection and Intervention Program*

Authority: Health-General Article, §§13-601—13-605, Annotated Code of Maryland

#### **.01 Purpose.**

*The Early Hearing Detection and Intervention Program shall provide for the universal hearing screening of newborns and early identification and follow-up of newborns and infants who have, or are at risk for developing, a permanent hearing status that affects speech-language skills. The Program shall identify newborns and infants who have a permanent hearing status that affects speech-language skills as early as possible.*

#### **.02 Scope.**

*This chapter requires the screening of all newborns and infants born in Maryland and follow-up for those who have, or are at risk for developing, a permanent hearing status that affects speech-language skills.*

#### **.03 Definitions.**

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Alternative birthing site" means any site of birth other than a hospital.

(2) "Appropriate services" mean any necessary audiological, medical, developmental, speech-language, psychosocial, educational, or intervention services required in the follow-up of newborns and infants who have or at risk for developing a permanent hearing status that affects speech-language skills.

(3) "At risk for developing a permanent hearing status that affects speech-language skills" means an infant identified as having any risk factor listed in Regulation .04 of this chapter.

(4) "Audiological assessment" means testing to determine status of the auditory mechanism.

(5) "Audiologist" means an individual licensed to practice audiology by the Maryland Board of Examiners for Audiologists, Hearing Aid Dispensers, and Speech-Language Pathologists.

(7) "Birthing hospital" means a medical facility licensed by the Department which provides obstetrical services.

(8) "Department" means the Department of Health and Mental Hygiene.

(9) "Department database" means the computer data management system used to gather and maintain program data.

(10) "Early Hearing Detection and Intervention Advisory Council (Advisory Council)" means the 12-member Advisory Council appointed by the Secretary to provide advice and consultation to the Department concerning the Early Hearing Detection and Intervention Program.

(11) "Early intervention system" means the total effort in the State, for children from birth to 5 years of age, to meet the needs of eligible children and the children's families, including the efforts of the Maryland Early Hearing Detection and Intervention Program.

(12) "Hearing screening" means behavioral, electrophysiological, or other procedures used to identify newborns and infants in need of diagnostic audiological assessment.

(13) "Hearing status" means the state of an individual's ability to perceive sound, based on audiological assessment.

(14) "Infant" means a Maryland resident who is younger than 1 year old.

(15) "Infant with a permanent change in hearing status that affects speech-language skills" means an infant who has a loss that is a dysfunction of the auditory system or any non-transient hearing status of any type or degree which is sufficient to interfere with the acquisition and development of speech-language skills with or without the use of sound amplification.

(16) "Local education agency" means a public board of education and public school system legally constituted to administer and direct education and programs of education in the public elementary or secondary schools, including early childhood from birth through the end of high school or their equivalent, in Baltimore City and the 23 counties in Maryland.

(17) "Local health department" means the official public health agency of the local political subdivision affiliated with the Department.

(18) "Maryland Infants and Toddlers Program" means the program within the Maryland State Department of Education's Division of Special Education/Early Intervention Services that provides early intervention services for children under Part C of the Individuals with Disabilities Education Act.

(19) "Newborn" means a child up to 29 days old who is born in the State.

(20) "Parent" means a biological or adoptive parent, a legal guardian, another individual responsible for a child's welfare, or a person appointed as the surrogate parent as defined in COMAR 13A.05.01.

(21) "Primary care provider" means a licensed practitioner who is the primary coordinator of care for the individual, whose responsibility it is to provide accessible, continuous, comprehensive, and coordinated health care services.

(22) "Program" means the Early Hearing Detection and Intervention Program established by the Secretary that provides for the universal screening of newborns and early identification and follow-up of newborns and infants who have, or are at risk for developing, a permanent hearing status that affects speech-language skills.

(23) "Referral" means directing the newborn or infant at risk for developing a permanent hearing status that affects speech-language skills and the newborn or infant's parent or guardian to a professional for diagnostic audiological assessment or other appropriate services, or both.

(24) "Risk factors" means indicators that are associated with permanent congenital, delayed-onset, or progression to a hearing status that affects speech-language skills in childhood.

(25) "Secretary" means the Secretary of the Department of Health and Mental Hygiene.

(26) "Telephone resource line" means toll-free telephone access to the Program inside Maryland through live voice or recorded message including coverage for individuals who have a permanent hearing status that affects speech-language skills.

(27) "TTY" means telecommunication device for individuals with disabilities.

#### **.04 High Risk Factors.**

Any of the following high risk factors are considered relevant in determining the possibility of a newborn or infant developing a permanent hearing status that affects speech-language skills under this chapter:

A. Caregiver concern regarding hearing, speech, language, or developmental delay;

B. Family history of a permanent hearing status that affects speech-language skills occurring during childhood;

C. Medical risk factors:

(1) Neonatal intensive care for more than 5 days;

(2) Extracorporeal membrane oxygenation;

(3) Assisted ventilation;

(4) Hyperbilirubinemia that requires exchange transfusion of the blood;

(5) Exposure to ototoxic medications, such as gentimycin and tobramycin; and

(6) Exposure to loop diuretic medications, such as furosemide and lasix;

D. In utero infections, such as cytomegalovirus, herpes, rubella, syphilis, and toxoplasmosis;

E. Craniofacial anomalies;

F. Physical findings associated with a permanent hearing status that affects speech-language skills;

G. Diagnosis of a syndrome associated with a congenital or progressive change in hearing status that affects speech-language skills;

H. Neurodegenerative disorders, including:

(1) Hunter syndrome; and

(2) Sensory motor neuropathies, such as Friedrich's Ataxia and Charcot-Marie-Tooth disease;

I. Culture-positive postnatal infections associated with a permanent change in hearing status that affects speech-language skills, including bacterial and viral meningitis;

J. Head trauma, including basal skull and temporal bone fracture, that require hospitalization; and

K. Chemotherapy.

#### **.05 Model System.**

The Department shall establish and maintain a model system to provide for the implementation of an early identification program and follow-up of newborns and infants who have or are at risk for developing a permanent hearing status that affects speech-language skills and includes the following components:

A. Educational materials;

B. Telephone resource line with TTY capabilities;

C. Department database to gather and maintain program data;

D. A service referral directory;

E. In-service training of hospitals, local health departments, and local education agencies;

F. Referral to appropriate agency or professional for services;

G. Program monitoring and review;

H. Confidentiality of records and information in accordance with Health-General Article, §4-101 and 4-301 – 4-309, Annotated Code of Maryland; and

I. Continuum of follow-up which includes:

(1) Contacting the primary care provider in writing or by telephone to verify the status of the infant;

(2) Contacting parents or guardians in writing or by telephone to facilitate referral for diagnostic audiological assessment and referral for appropriate services; and

(3) Interfacing with the single point of entry for the early intervention system.

**.06 Early Hearing Detection and Intervention Advisory Council.**

The Advisory Council shall:

A. Advise the Department on:

(1) The implementation of an early identification program and follow-up of newborns and infants who have, or are at risk for developing, a permanent hearing status that affects speech-language skills;

(2) Setting of standards for the Program including procedures for hearing screening;

(3) Monitoring and reviewing of the Program; and

(4) Provision of quality assurance for the Program;

B. Provide consultation to the Department in the development of the Program;

C. Make recommendations for operation of the Program;

D. Provide consultation to the Department in the maintenance of an educational program for families, professionals, and the public integrated with the Maryland Infants and Toddlers Program and local early intervention systems, including existing State and local education agency programs;

E. Review any materials the Department may distribute to the public concerning newborns and infants who have a permanent hearing status that affects speech-language skills;

F. Meet annually with the Secretary or the Secretary's designee; and

G. Provide consultation to the Department in the adoption of rules and regulations necessary to implement the Program.

**.07 Procedures for Birthing Hospitals and Alternative Birthing Sites.**

For each infant delivered at the facility or site, birthing hospital staff and, in the cases of alternative birthing sites, the licensed professional attending the birth, shall:

A. Within 48 hours of delivery, enter demographic and birth event data into the Department database;

B. Within 48 hours of discharge from care in the Department database:

(1) Document:

(a) The hearing screening test results; and

(b) Any known risk factors; and

(2) Identify and document:

(a) The infant's primary care provider; and

(b) Any referrals made; and

C. Provide to the family:

(1) Written documentation of the birth hearing screening results;

(2) Any identified risk factors; and

(3) Instructions for any recommended follow-up.

**.08 Procedures for Audiologists and Licensed Professionals Conducting Audiological Screening or Evaluations.**

A. An audiologist or a licensed professional who performs a hearing screening or audiological diagnostic evaluation on a child younger than 5 years old due to the presence of a risk factor as listed in Regulation .04 of this chapter or in follow-up to the birth hearing screening of a newborn or infant who did not receive or did not pass the birth hearing screening, shall:

(1) Within 2 business days:

(a) Report the results of the screening or audiological diagnostic evaluation to the Program in the Department database;

(b) Document recommendations and referrals provided in the Department database; and

(c) Confirm or update the demographic information of the child or infant in the Department database; and

(2) Within 7 business days, notify the appropriate early intervention program at the Maryland State Department of Education of any child younger than 5 years old confirmed to have or strongly suspected of having a permanent hearing status of any type or degree as described in §B of this regulation which is sufficient to interfere with the acquisition and development of speech-language skills with or without the use of sound amplification.

B. A child younger than 5 years old is strongly suspected of having a permanent hearing status if evidence or clinical judgment exists which indicates that there is a high probability of a permanent hearing status of any type or degree which is sufficient to interfere with the acquisition and development of speech-language skills.

**.09 Department Procedures.**

A. The Program shall:

(1) Implement the model system;

(2) Perform duties and responsibilities in accordance with the advice and consultation of the Advisory Council;

(3) Exercise independent judgment in the day-to-day operations of the Program;

(4) Develop Program processes in consultation with the Advisory Council;

(5) Conduct in-service training on Program procedures;

(6) Maintain a Department database to monitor infants at risk for developing a hearing status that affects speech-language skills;

- (7) Track infants identified as at risk for developing a permanent hearing status that affects speech-language skills for a period of 5 years;*
  - (8) Maintain a service directory within the Department database;*
  - (9) Assure operation of the telephone resource line;*
  - (10) Facilitate referral for diagnostic audiological assessment and early intervention for infants who are at risk for developing a permanent hearing status that affects speech-language skills;*
  - (11) Maintain records of the audiological assessment reports for infants at risk for developing a permanent hearing status that affects speech-language skills; and*
  - (12) Interface with the single point of entry of the early intervention system.*
- B. The Secretary shall establish guidelines for the operation of the Advisory Council.*

**JOSHUA M. SHARFSTEIN, M.D.**

**Secretary of Health and Mental Hygiene**