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**Rules of**  
**Department of Health and**  
**Senior Services**  
**Division 40—Division of Maternal, Child and**  
**Family Health**  
**Chapter 9—Universal Newborn Hearing Screening Program**

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**Title 19—DEPARTMENT OF  
HEALTH AND SENIOR SERVICES**  
**Division 40—Division of Maternal, Child  
and Family Health**  
**Chapter 9—Universal Newborn Hearing  
Screening Program**

**19 CSR 40-9.010 Definitions**

*PURPOSE: This section defines the terms used in this chapter.*

- (1) Acceptable refer rates means the department has determined the facility's percentage of newborns referred for rescreening or diagnostic evaluation is acceptable, based on factors including but not limited to type of equipment; methodology; population screened; and facility staff.
- (2) Audiologist is a person who is licensed in the state of Missouri according to Chapter 345, RSMo to provide audiological services.
- (3) Automated screening equipment is equipment used for newborn hearing screening which automatically provides a pass/refer outcome.
- (4) Automated pass/refer criteria is the interpretive criteria incorporated into hearing screening equipment that automatically provides a pass/refer outcome.
- (5) Birth admission is the hospitalization during which the newborn is delivered.
- (6) Diagnostic audiological assessment is the required audiometric testing used to determine the presence, type and severity of hearing loss.
- (7) Department is the Missouri Department of Health.
- (8) Department-designee is a person acting on behalf of the department in assessing, tracking and/or surveillance of hearing screening information.
- (9) Facility is a hospital or ambulatory surgical center licensed by the state of Missouri, Department of Health.
- (10) Food and Drug Administration (FDA)-approved equipment is hearing screening equipment that is designed specifically for use with newborns, and has met approved standards of operation set forth by the U.S. Food and Drug Administration.
- (11) Hearing loss is a dysfunction of the auditory system of any type or degree that is sufficient to interfere with the acquisition and development of speech and language skills.
- (12) Hearing screening is the completion of an objective, physiological test or battery of tests using recommended guidelines to identify newborns that need further audiological assessment.
- (13) Infant is any child at least thirty (30) days of age, and less than twelve (12) months of age.
- (14) Initial hearing screening is the first hearing screening performed on a newborn preferably prior to discharge from the facility where the birth occurred.
- (15) Lost to follow-up is a newborn who cannot be located through tracking, and who may not have completed the screening and/or referral process.
- (16) Missed is any newborn that did not have a hearing screening prior to discharge from the birthing facility.
- (17) Newborn is any child twenty-nine (29) days of age or less.
- (18) Non-audiologic personnel means any person that is not licensed as an audiologist in the state of Missouri according to Chapter 345, RSMo.
- (19) One-stage newborn hearing screening program is designed so that newborns who do not pass the initial hearing screening are referred for diagnostic audiological assessment.
- (20) Parent is a biological parent, stepparent, adoptive parent, legal guardian or other legal custodian of a newborn.
- (21) Pass is the result obtained by automated hearing screening equipment, with preset interpretive criteria based upon a specific scientific rationale, which requires no further screening or testing.
- (22) Primary care provider is a physician or person who professionally undertakes the pediatric care of the newborn, and is licensed in the state of Missouri as appropriate.
- (23) Program manager is the person designated as being responsible for the newborn hearing screening program at a facility.
- (24) Reasonable effort is demonstrated when the department has documentation of at least two (2) attempts to contact the newborn/infant's parent(s) by mail or phone, and at least one (1) attempt to contact the newborn/infant's primary care provider.
- (25) Refer is the result obtained by hearing screening equipment, with preset interpretive criteria based upon a specific scientific rationale, that requires further screening or confirmatory testing.
- (26) Referral is the process of sending a newborn that receives a "refer" screening result for additional audiological, educational, medical, or social assessment or evaluation.
- (27) Rescreening is a repeat hearing screening performed on a newborn or infant, typically in an outpatient setting and preferably within thirty (30) days of the initial hearing screening.
- (28) Third party payer is any person, corporation, trust, association, the state of Missouri, any governmental subdivision or agency or any other legal entity which pays directly or indirectly for health care services provided to another person or reimburses or pays a benefit to or on behalf of another person for health care services in conformance to a contract, plan, employee benefit or member benefit.
- (29) Tracking is the process of reviewing information concerning the newborn's hearing screening status, to ensure the hearing screening and referral process is completed in a timely manner.
- (30) Two-stage newborn hearing screening program is designed so that newborns who do not pass the initial hearing screening are referred for a rescreening exam. If the newborn does not pass the rescreening exam, the newborn/infant is referred for diagnostic audiological assessment.

*AUTHORITY: section 191.937, RSMo 2000.\*  
Original rule filed Aug. 1, 2001, effective  
Jan. 30, 2002.*

*\*Original authority: 191.937, RSMo 1999.*

**19 CSR 40-9.020 Screening Methodologies  
and Procedures**

*PURPOSE: This rule establishes the screening methodologies and procedures that a facility, audiologist, and/or other person that performs hearing screenings outside of a facility must use to operate a newborn hearing screening program and/or perform diagnostic audiological assessments.*



(1) Each facility shall designate a person responsible for carrying out the newborn hearing screening program at their facility, referred to as the program manager.

(2) By February 1, 2002, each facility shall notify the department, electronically or in writing, of the name, business address and telephone number of the program manager. Changes to the facility's program manager and/or changes in the business contact information shall be reported to the department within thirty (30) calendar days.

(3) Each facility operating a newborn hearing screening program shall establish written policies and procedures. These policies and procedures shall include, but are not limited to:

(A) The type of newborn hearing screening program (one or two stage) to be operated;

(B) The type of Food and Drug Administration (FDA)-approved hearing screening equipment being used, and screening methods, including the facility location(s) where the screenings will be completed;

(C) Specific duties for all persons participating in the newborn hearing screening program, including minimum training/experience requirements for persons performing the screenings;

(D) A written plan for initial training for all persons participating in the newborn hearing screening program;

(E) A method of evaluating and documenting the competency of each newborn hearing screener's performance upon completion of the initial training and at least annually thereafter;

(F) A plan for ensuring accuracy of newborn hearing screening results. The plan shall address the importance of attaining and maintaining acceptable referral rates;

(G) A plan to notify the parent(s) and primary care provider of the hearing screening results;

(H) Designation of facility personnel responsible for reporting newborn hearing screening results to the department;

(I) Distribution of the prescreening pamphlet to all families of newborns;

(J) Distribution of the audiologist resource guide;

(K) A method of referral for newborns who "missed" the birth admission hearing screening, or require rescreening and/or diagnostic audiological assessment; and

(L) Documentation of screenings refused by the family.

(4) A facility using non-audiologic personnel to perform the newborn hearing screening

shall use FDA-approved screening equipment that provides automated pass/refer criteria.

(5) A facility shall provide to the department or department-designee, a copy of their written policies and procedures upon request.

(6) The facility shall provide each newborn's parent(s) with information about newborn hearing screening in English or other language or alternate method as appropriate. The department shall provide information to facilities in other languages upon request.

(7) A facility or person(s) performing hearing screenings outside a facility shall notify parent(s) and the primary care provider of the hearing screening results within seven (7) calendar days of the screening.

(8) Any facility that transfers a newborn for further acute care prior to the completion of newborn hearing screening shall assure the receiving facility is aware of the status of the newborn hearing screening. The newborn/infant may have the hearing screening performed by the receiving facility, or be referred back to the birth facility for the hearing screening.

(9) A facility or person that performs a hearing screening outside a facility, shall give the parent(s) of a newborn receiving unilateral or bilateral "refer" result(s), a list (developed by the department) of audiological services. Parent(s) shall be instructed to contact the primary care provider and any third party payers to determine the appropriate referral process prior to obtaining audiological services.

(10) Rescreening shall be performed by an audiologist, physician, and/or facility personnel trained in the newborn hearing screening program.

(11) Rescreening shall be completed within thirty (30) calendar days of the initial newborn hearing screening. Infants requiring continuous acute care following birth shall have their rescreening completed within thirty (30) calendar days of the acute care discharge.

(12) Diagnostic audiological assessments shall be performed by audiologists.

(13) Diagnostic audiological assessments shall be completed within thirty (30) calendar days of the rescreening, or initial screening if applicable. Infants requiring continuous acute care following birth shall have their diagnos-

tic audiological assessment completed within three (3) months of the acute care discharge.

(14) The audiologist shall notify the parent(s) and primary care provider of the diagnostic audiological assessment results no later than seven (7) calendar days following the completion of the assessment.

(15) The department shall make reasonable efforts to assure that all newborns have a hearing screening by three (3) months of age (or within three (3) months of discharge from an acute facility for infants requiring continuous acute care following birth).

(16) The department shall make reasonable efforts to assure that all newborns with a confirmed hearing loss are referred to the appropriate point of contact for the Part C of the Individuals with Disabilities Education Act (IDEA) system of early intervention services (First Steps) by six (6) months of age (or within six (6) months of discharge from an acute care facility for infants requiring continuous acute care following birth).

*AUTHORITY: section 191.937, RSMo 2000.\* Original rule filed Aug. 1, 2001, effective Jan. 31, 2002.*

*\*Original authority: 191.937, RSMo 1999.*

### 19 CSR 40-9.040 Information to be Reported to the Department of Health

*PURPOSE: This rule establishes the information management, reporting and tracking system used by facilities, primary care providers, and audiologists to report newborn hearing screening data to the department. Timely reporting is necessary to assure the provision of early diagnostic and intervention services.*

(1) Each facility, physician, or primary care provider shall report all newborn hearing screening results, including missed screenings, via either the department's web-based reporting system or manually on the department's newborn hearing reporting form. This newborn hearing reporting form shall be developed and made available by the department. The results shall be reported to the department within seven (7) calendar days of completion of the hearing screening.

(2) Each facility, or person designated to perform repeat hearing screenings, shall report information for tracking newborns who receive "refer" results or missed the birth

admission hearing screening. The information shall be reported to the department via either the web-based reporting system or manually on the department's newborn hearing tracking form, within seven (7) calendar days of completion of the hearing screening.

(3) The facility or person designated to perform the missed hearing screening, the rescreening, and/or the diagnostic audiological assessment, shall notify the department if the scheduled appointment was not kept. This information shall be reported to the department via either the department's web-based reporting system or manually on the department's newborn hearing tracking form, within seven (7) calendar days of the date of discharge or scheduled appointment date.

(4) The audiologist shall report all diagnostic audiological assessment results to the department, via either the web-based reporting system or manually on the department's newborn hearing tracking form, within seven (7) calendar days of completion of the assessment.

(5) Each facility or primary care provider shall provide to the department, upon request, information from the newborn's medical record relevant to the newborn's hearing status.

(6) Each facility, physician, primary care provider, or audiologist shall document all parental refusals for newborn hearing screening, and report the refusal to the department via either the web-based reporting system or manually on the department's newborn hearing screening tracking form within seven (7) calendar days of refusal.

*AUTHORITY: section 191.937, RSMo 2000.\*  
Original rule filed Aug. 1, 2001, effective  
Jan. 30, 2002.*

*\*Original authority: 191.937, RSMo 1999.*