# Rules of

## Department of Health and Senior Services

### Division 40—Division of Maternal, Child and Family Health

#### Chapter 9—Universal Newborn Hearing Screening Program

<table>
<thead>
<tr>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>19 CSR 40-9.010 Definitions</td>
<td>3</td>
</tr>
<tr>
<td>19 CSR 40-9.020 Screening Methodologies and Procedures</td>
<td>3</td>
</tr>
<tr>
<td>19 CSR 40-9.040 Information to be Reported to the Department of Health</td>
<td>4</td>
</tr>
</tbody>
</table>
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 depart-
ment has determined the facility’s percentage
of newborns referred for rescreening or diag-
nostic evaluation is acceptable, based on fac-
tors including but not limited to type of equip-
ment; 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 equip-
ment used for newborn hearing screening
which automatically provides a pass/refer outcome.

(4) Automated pass/refer criteria is the inter-
pretive criteria incorporated into hearing
screening equipment that automatically pro-
vides a pass/refer outcome.

(5) Birth admission is the hospitalization dur-
ing which the newborn is delivered.

(6) Diagnostic audiological assessment is the
required audiometric testing used to deter-
mine the presence, type and severity of hear-
ing 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 surgi-
cal 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 audi-
tory system of any type or degree that is suf-
ficient 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 iden-
tify 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 hear-
ing screening performed on a newborn preferably prior to discharge from the facili-
ty where the birth occurred.

(15) Lost to follow-up is a newborn who can-
not 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 assess-
ment.

(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 designat-
ed as being responsible for the newborn hear-
ing 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 ration-
ale, that requires further screening or con-
firmatory testing.

(26) Referral is the process of sending a new-
born that receives a “refer” screening result
for additional audiological, educational,
medical, or social assessment or evaluation.

(27) Rescreening is a repeat hearing screen-
ing performed on a newborn or infant, typi-
cally in an outpatient setting and preferably
within thirty (30) days of the initial hearing
screening.

(28) Third party payer is any person, corpo-
ration, trust, association, the state of Mis-
souri, any governmental subdivision or agen-
cy 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 per-
son for health care services in conformance
to a contract, plan, employee benefit or mem-
ber benefit.

(29) Tracking is the process of reviewing
information concerning the newborn’s hear-
ing 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 new-
born 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


19 CSR 40-9.020 Screening Methodologies
and Procedures

PURPOSE: This rule establishes the screen-
ing 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 hear-
ing screening program and/or perform diag-
nostic 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) 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.

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

(10) 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.

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

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

(13) 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.

(14) 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).

(15) 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. *


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.*