

**Department of State Health Services
Council Agenda Memo for State Health Services Council
August 14, 2014**

Agenda Item Title: Repeal of rules and new rules concerning the Newborn Hearing Screening Program

Agenda Number: 4.a

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background:

The Newborn Hearing Screening Program is located in the Specialized Health Services Section under the Division for Family and Community Health Services and is a point-of-care service designed to screen all newborns for hearing loss. Texas birthing facilities perform hearing screenings, either directly or through a referral, and then the results are shared with the parents, and with parental consent reported to DSHS.

When a newborn or infant does not pass a hearing screen, the rules prescribe follow-up, diagnostic, and intervention timelines and reporting requirements to follow the progress of the child in the hearing screening continuum of care to maximize linguistic competence and literacy development. Without opportunities to learn language, these children will fall behind their hearing peers in communication, cognition, reading, and social-emotional development. Such developmental delays may result in lower educational and employment levels in adulthood. With full participation of the providers in the early hearing screening continuum of care, the data reporting and use of DSHS's management information system provides a seamless transition for infants and their families through this process.

The Newborn Hearing Screening Program funding sources include state and federal funds.

Summary:

The purpose of the repeals and new rules is to update, clarify, and restructure sections to increase accessibility and understandability. The rules comply with House Bill 411 and Senate Bill 229, 82nd Legislature, Regular Session, 2011, and Senate Bill 793, 83rd Legislature, Regular Session, 2013, which amended Health and Safety Code, Chapter 47, Hearing Loss in Newborns.

The rule revisions change definitions, roles and responsibilities; clarify requirements for birthing facilities; and change reporting by health care providers, including performance, tracking, and documentation and intervention requirements. The rules also comply with the four-year review of agency rules required by Government Code, Section 2001.039.

Key Health Measures:

The new rules are expected to improve hearing screening providers' understanding of the screening protocols and program certification and increase timely follow-up and intervention. Additionally, DSHS's information management system for reporting and obtaining information is expected to decrease loss to follow-up (LTF) and loss to documentation (LTD). The fiscal year 2013 data below will be used as a baseline and data will be reviewed quarterly.

Children born in Texas that received initial hearing screening	375,447
Children that did not pass or missed initial hearing screening and required outpatient screen	11,131 (3%)
Children that received outpatient screen	5,390 (46% with 54% LTD or LTF)
Children that did not pass outpatient screen and required diagnostic evaluation	777 (14%)
Children that received diagnostic evaluation	230 (30% with 70% LTD or LTF)

Summary of Input from Stakeholder Groups:

Informal stakeholder input was obtained by posting on the DSHS website; email/list serves; verbal communication with stakeholders; and coordinating with the Newborn Screening Advisory Committee and professional associations. Stakeholder input was received from the Texas Medical Association; UT Southwestern Medical Center; Department of Assistive and Rehabilitative Services, Division for Early Childhood Intervention; Texas Hands and Voices, Guide By Your Side; National Childhood Hearing Assessment and Management; and March of Dimes. Of the informal comments received, some were applicable to the rules and others were related to program policy, which will be addressed separately outside of this rulemaking process.

Based on comments received, the following changes were made to the rules:

- Definition of intervention was modified and a new definition Part C Early Childhood Intervention was added to distinguish Part C Early Childhood Intervention from other types of intervention services.
- Definition of screen was modified to limit the number of screens to the initial and repeat test only.
- Definition of the Texas Early Hearing Detection and Intervention Management Information System (TEHDI MIS) was modified to add “audiological” to clarify the type of diagnostics required.
- Modification was made to Section 37.503(1) to clarify that it is the birthing facility, program, or provider’s responsibility to obtain parental consent before releasing individually-identifying information through TEHDI MIS.
- Modification was made to Section 37.505(a) to reiterate that it is the responsibility of the physician or other health care provider to direct, track, and coordinate the appropriate care of the infant who does not pass the hearing screening.
- Modification was made to Section 37.505(e) to reference the applicable federal statute regarding timeframes for referrals to early childhood intervention.
- Modification was made to Section 37.505(f) to separate the results of intervention from the reports on the initiation of Part C Early Childhood Intervention and to clarify that tracking activities apply to all providers in the hearing continuum of care.

Proposed Motion:

Motion to recommend HHSC approval for publication of rules contained in agenda item #4.a.

Approved by Assistant Commissioner Sam B. Cooper III for Evelyn Delgado **Date:** July 30, 2014
/Director: _____

Presenter: David Martinez **Program:** Newborn Screening Unit **Phone No.:** (512) 776-2216

Approved by CCEA: Carolyn Bivens **Date:** July 29, 2014

Title 25. Health Services
Part 1. Department of State Health Services
Chapter 37. Maternal and Infant Health Services
Subchapter S. Newborn Hearing Screening
Repeal §§37.501 - 37.512
New §§37.501 - 37.507

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes the repeal of §§37.501 - 37.512, and new §§37.501 - 37.507, concerning the Newborn Hearing Screening Program.

BACKGROUND AND PURPOSE

The department administers the Newborn Hearing Screening Program, which is a point-of-care hearing screen on all newborns in the state. Pursuant to Texas Health and Safety Code, Chapter 47, Texas birthing facilities are required to perform hearing screenings, either directly or through a referral. The results are shared with the parents and with parental consent, reported to the department. When a newborn or infant does not pass a hearing screen, the rules prescribe follow-up, diagnostic, and intervention timelines and reporting requirements to follow the progress of the child in the hearing screening continuum of care to maximize linguistic competence and literacy development. Without opportunities to learn language, these children will fall behind their hearing peers in communication, cognition, reading and social-emotional development. Such developmental delays may result in lower educational and employment levels in adulthood. With full participation of the providers in the early hearing screening continuum of care, the data reporting and use of the department's Texas Early Hearing Detection and Intervention Management Information System (TEHDI MIS) provides a seamless transition for infants and their families through this process.

The rules incorporate legislative revisions from House Bill (HB) 411 and Senate Bill (SB) 229, 82nd Legislature, Regular Session, 2011, and SB 793, 83rd Legislature, Regular Session, 2013, which amended Health and Safety Code, Chapter 47, Hearing Loss in Newborns. The revisions will reflect changes in definitions; changes in roles and responsibilities; clarification of requirements for birthing facilities; and changes to reporting by health care providers, including performance, tracking and documentation and intervention requirements. The repeal of and new rules are necessary to update, clarify, and restructure sections to improve readability and user-friendliness.

The rules also comply with the Government Code, §2001.039, requires that each state agency review and consider for re-adoption each rule adopted by that agency pursuant to Government Code, Chapter 2001 (Administrative Procedure Act). Sections 37.501 - 37.512 have been reviewed and the department has determined that reasons for adopting the sections continue to exist because rules on this subject are needed, although revisions are needed as detailed herein.

SECTION-BY-SECTION SUMMARY

New §37.501 provides a detailed summary of the contents of the subchapter. It identifies the statutory authority for the various elements of the program, emphasizes the guidelines the department will use to protect patient confidentiality, identifies the department's TEDHI MIS as the mechanism used to capture and report newborn hearing screening data, and references the online policy regarding program protocols and program certification process.

New §37.502 provides definitions for terminology used throughout the subchapter.

New §37.503 establishes the process the department will use to obtain parental consent before capturing or sharing individually-identifiable information through the department's TEDHI MIS and the guidelines used to protect patient data.

New §37.504 identifies the department's TEHDI MIS for all newborn hearing screening programs to report and share information regarding infants that do not pass hearing screenings. This information is vital to the infant's physician or health care provider to ensure follow-up and coordinate appropriate and necessary care as required by Health and Safety Code, §47.005.

New §37.505 documents the timelines required for each level of care for infants that do not pass hearing screenings and the audiological diagnostic evaluation. The section simplifies and condenses the reporting requirements for all hearing screening participants and promotes the TEDHI MIS as a shared resource to follow the progress of an infant that requires follow-up services.

New §37.506 establishes program protocols and certification. The current nationally-recognized standard for newborn hearing screening is the most recent Joint Committee on Infant Hearing (JCIH) Position Statement. The standards are incorporated into the section by reference to allow the department to stay current with national standards without having a potential contradiction in the department rules.

New §37.507 identifies statutory references for authorizing hearing screening services under Medicaid and private insurance.

FISCAL NOTE

Sam Cooper, Director, Specialized Health Services Section, has determined that for each year of the first five years that the sections will be in effect, there will be no fiscal implications to state or local governments as a result of enforcing and administering the sections as proposed, other than greater efficiencies resulting from improved organization, clarity, readability and user-friendliness.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Mr. Cooper has also determined that there will be no adverse economic impact on small businesses or micro-businesses required to comply with the sections as proposed. This was determined by interpretation of the rules that small businesses and micro-businesses will not be

required to alter their business practices, beyond what is already required by statute, in order to comply with the sections.

REGULATORY FLEXIBILITY ANALYSIS

Texas Government Code, Chapter 2006, was amended by the HB 3430, 80th Legislature, Regular Session, 2007, to require, as part of the rulemaking process, state agencies to prepare a Regulatory Flexibility Analysis that considers alternative methods of achieving the purpose of the rules. There is an exception to this requirement, however. An agency is not required to consider alternatives that, while possibly minimizing adverse impacts on small businesses would not be protective of the “health, safety and environmental and economic welfare of the state.” When the proposed rules are an implementation of legislative directives because of statutory changes, that proposed rule language becomes *per se* consistent with the health, safety, or environmental and economic welfare of the state, and therefore the department need not consider alternative methodologies as part of the preamble small business impact analysis.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL GOVERNMENT

There are no anticipated costs to persons who are required to comply with the sections as proposed. There is no fiscal impact to local employment.

PUBLIC BENEFIT

In addition, Mr. Cooper has also determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The public benefit anticipated as a result of enforcing or administering the sections is to improve how the state newborn hearing screening program screens all Texas babies for hearing loss and provides follow-up and intervention services to those infants who do not pass by ensuring that follow-up confirmatory tests and intervention are received, if needed. These proposed new rules will increase the efficiency in the hearing services continuum of care and will increase the user-friendliness of the rules for stakeholders because of improved organization, clarity and readability. The new rules would provide for greater agency transparency in its processes, and make agency actions more predictable for stakeholders. All of this would constitute a public benefit.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to David R. Martinez, Newborn Screening Unit, Specialized Health Services Section, Division of Family and Community Health Services, Department of State Health Services, Mail Code 1918, P. O. Box 149347, Austin, Texas, 78714-9347, or by email at Davidr.Martinez@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The repeals and new rules are authorized by Health and Safety Code, §47.010, which requires the department to adopt rules necessary to carry out the program, and by Chapter 47 in general; and Government Code, §531.0055(e), and the Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001. Review of the sections implements Government Code, §2001.039.

The repeals and new rules affect Health and Safety Code, Chapters 47 and 1001; and Government Code, Chapter 531.

Sections for repeal.

§37.501. Purpose.

§37.502. Definitions.

§37.503. Newborn Hearing Screening, Tracking, and Intervention Program.

§37.504. Certification of Screening Programs.

§37.505. Program Performance Standards and Goals.

§37.506. Program Certification.

§37.507. Information Concerning Screening Results and Follow-up Care.

§37.508. Training and Technical Assistance by Department.

§37.509. Information Management, Reporting, and Tracking System.

§37.510. Responsibilities of the Department of State Health Services.

§37.511. Confidentiality and General Access to Data.

§37.512. Authorized Medicaid Newborn Hearing Services.

Legend: (Proposed New Rules)
Regular Print = Proposed new language

§37.501. Purpose.

This purpose of this subchapter:

(1) describes point-of-care newborn hearing screening process administered by the Department of State Health Services (department) pursuant to Texas Health and Safety Code, Chapter 47;

(2) details confidentiality and general access to data regarding newborn hearing screening with state and federal privacy guidelines;

(3) identifies the department's Texas Early Hearing Detection and Intervention Management Information System (TEHDI MIS) used to capture and report newborn hearing screening information, and describes the requirements for follow-up, intervention, and reporting to the department by newborn hearing screening participants; and

(4) incorporates by reference the protocols for newborn hearing screening programs and the criteria used by the department to certify hearing screening programs.

§37.502. Definitions.

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Audiologist--A person licensed pursuant to Texas Occupations Code, Chapter 401.

(2) Birthing facility:

(A) a hospital licensed under Texas Health and Safety Code, Chapter 241 that offers obstetrical services;

(B) a birthing center licensed under Texas Health and Safety Code, Chapter 244;

(C) a children's hospital licensed under Texas Health and Safety Code, Chapter 241 that offers obstetrical and/or neonatal intensive care unit services; or

(D) a facility maintained or operated by this state or an agency of this state that provides obstetrical services.

(3) Consent--A written statement signed by a parent agreeing that individually identifying information may be disclosed to the department.

(4) Department--The Department of State Health Services.

(5) Follow-Up Care--Additional screening, diagnostic audiological evaluation, or treatment and services for newborns or infants who do not pass.

(6) Hearing loss--A hearing loss averaging 30 dB hearing level or greater in the frequency region important for speech recognition and comprehension in one or both ears, 500 through 4000 Hz.

(7) Individually-identifying information--Confidential and protected health information (PHI) that identifies the parent or newborn including common identifiers such as, but not limited to, names, addresses, birthdates, and social security numbers.

(8) Infant--A child who is at least 30 days but who is younger than 24 months old.

(9) Intervention--Other intervention services separate from Part C Early Childhood Intervention and include those medical and therapeutic services designed to support infants with hearing loss.

(10) Newborn--A child younger than 30 days old.

(11) Parent--A natural parent, stepparent, adoptive parent, legal guardian, or other legal custodian of a child.

(12) Part C Early Childhood Intervention--The early intervention services described in Part C, Individuals with Disabilities Education Act (20) United States Code §§1431-1445, as amended by Pub. L. No. 105-17.

(13) Program--A supervised newborn hearing screening, tracking and intervention program certified by the department.

(14) Protocol(s)--Guidelines or procedures, based on the latest Joint Committee on Infant Hearing (JCIH) position statement, used by programs to conduct newborn hearing screening.

(15) Screen--An initial or a repeat test that identifies an increased risk for hearing loss, which must be confirmed by an audiological diagnostic evaluation.

(16) State--The State of Texas.

(17) Texas Early Hearing Detection and Intervention Management Information System (TEHDI MIS)--The department's central information source of newborn hearing screens and audiological diagnostics to ensure follow-up and any type of intervention for newborns or infants identified as hard of hearing or deaf.

§37.503. Confidentiality and General Access to Data,

This section establishes the guidelines to protect the confidentiality of patients in accordance with Texas Occupations Code, Chapter 159, and Texas Health and Safety Code, §47.008

(relating to Confidentiality and General Access to Data) and §47.009 (relating to Immunity from Liability).

(1) The birthing facility, provider, or program shall ensure that the written consent of a parent is obtained before any individually-identifying information on the newborn or infant is released through the TEHDI MIS.

(2) If consent to disclose individually-identifying information to the department is obtained, the facility or provider obtaining consent shall retain the consent in the patient's medical record.

(3) At any time a parent may request the department in writing that individually-identifying information concerning his or her child be removed from the department's TEDHI MIS. The department shall act on any request in a timely manner.

(4) Sample consent forms can be found on the department's newborn hearing website at: www.dshs.state.tx.us/tehdi.

§37.504. Information Management and Tracking System.

(a) Birthing facilities, programs and providers mentioned in this subchapter that perform hearing screening, diagnosis, and provide follow-up and intervention, including Part C early childhood intervention services for newborns or infants shall have access to the department's TEHDI MIS. Information regarding access and technical assistance is located at www.dshs.state.tx.us/tedhi.

(b) Reporting is required to the department's TEHDI MIS. The TEHDI MIS shall be updated to provide the department with information and data necessary to plan, monitor, and evaluate the program, including the program's screening, follow-up, diagnostic, and intervention components. The department may also use the collected data to monitor for health events of epidemiological importance.

§37.505. Screens, Follow-up, and Reporting.

(a) After an initial or a follow-up hearing screening is performed, the birthing facility that operates the program, other programs, or other providers shall report the results to the parents. With parental consent, the results are also reported to the attending or primary care physician or other applicable healthcare provider, and to the department according to the requirements in Texas Health and Safety Code, Chapter 47. The results are reported to the department within five business days after the date of birth or the date of discharge. The physician or health care provider attending to the infant who needs follow-up care should direct, track, and coordinate appropriate and necessary care.

(b) The follow-up hearing screen must be performed within 30 days from date of discharge from the birthing facility.

(c) If the newborn or infant does not pass the follow-up hearing screen, the program or provider performing the screens shall:

(1) assist in coordinating and scheduling a diagnostic audiological evaluation with another program or licensed audiologist who performs these evaluations; and

(2) refer the newborn or infant to Early Childhood Intervention Services, Department of Assistive and Rehabilitative Services.

(d) Unless the newborn or infant has been hospitalized since birth, the diagnostic audiological evaluation must be completed:

(1) no later than the third month of birth; or

(2) upon referral by the newborn's or infant's primary care physician or other applicable health care provider.

(e) The program, person, or provider that identified or diagnosed the newborn or infant with hearing loss shall refer the family for Part C Early Childhood Intervention services, in accordance with 34 Code of Federal Regulations §303.303(a)(2)(i) (relating to Referral Procedures) as soon as possible, but in no case more than seven days after the child has been identified and not later than the sixth month after birth and through the time the child is an infant, unless the infant has been hospitalized since birth. A referral can come from a primary referral resource identified in §303.303(c) (relating to Primary Referral Sources).

(f) Audiologists, hospitals, physicians, health care providers, qualified hearing screeners, early childhood intervention specialists, educators, and others who receive referrals from programs under this subchapter shall either provide the needed services or refer the newborn or infant to appropriate services. With parental consent, these providers shall report the following information to the department's TEHDI MIS. These providers may also track the activities and progress of the infant and obtain information from the TEHDI MIS relating to:

(1) results of each hearing screening performed;

(2) results of all follow-up care and services;

(3) results of each diagnostic audiological evaluation;

(4) reports on initiation and results of intervention services;

(5) reports on the initiation of Part C Early Childhood Intervention services; and

(6) case-level information necessary to report required statistics to the:

(A) Maternal and Child Health Bureau/ Health Resources and Services Administration on an annual basis; and

(B) federal Centers for Disease Control and Prevention.

§37.506. Program Protocols and Certification.

(a) The department shall certify programs that meet and maintain the newborn hearing screening criteria and may renew certification to ensure quality services to newborns, infants and families. The department's criteria are based on the most recent JCIH position paper for newborn hearing screens. Specific requirements for program protocols and certification are established in policy located on the department's website at: www.dshs.state.tx.us/tehdi.

(b) No fees are associated with the certification or recertification of a program.

§37.507. Authorized Newborn Hearing Services.

(a) A newborn hearing screening performed by a birthing facility and any related diagnostic follow-up care, provided in accordance with Texas Health and Safety Code, Chapter 47 and the requirements of this subchapter, for a newborn who receives medical assistance or who is Medicaid-eligible is a covered service of the Texas Medical Assistance (Medicaid) Program, in accordance with Texas Human Resources Code, Chapter 32.

(b) The reimbursement rates and methodology for covered services described in this section shall be established by the Health and Human Services Commission.

(c) Screening tests for hearing loss from birth through the date the infant is 30 days of age and any diagnostic follow-up care related to the screening test from birth through the date the child is 24 months of age as provided under this subchapter shall be a covered benefit pursuant to Texas Insurance Code, §§1367.101-1367.103. Co-payments or co-insurance requirements are permitted, however; deductible requirements or dollar limits are prohibited.

Repealed Language
~~Strikethrough—Repealed Text~~

~~§37.501 Purpose~~

~~These rules implement a statewide newborn hearing screening, tracking, and intervention program.~~

~~§37.502 Definitions~~

~~The following words and terms pertain explicitly to this chapter and shall have the following meanings, unless the context clearly indicates otherwise.~~

~~(1) Birth admission—The time after birth that a newborn remains in the birthing facility before the newborn is discharged. If a newborn is transferred to an intensive care nursery, the hearing screen must be done after the newborn is medically stable, but before the newborn or infant is released from the hospital.~~

~~(2) Birthing facility—~~

~~(A) a hospital licensed under Health and Safety Code, Chapter 241 that offers obstetrical services and is located in a county with a population of more than 50,000;~~

~~(B) a birthing center licensed under Health and Safety Code, Chapter 244 that is located in a county with a population of more than 50,000 and that has 100 or more births per year; or~~

~~(C) a hospital that offers obstetrical services or a birthing center licensed under Health and Safety Code, Chapter 244:~~

~~(i) that participates in the State's medical assistance program; and~~

~~(ii) is not otherwise included in paragraphs (2)(A) or (2)(B) of this section but agrees with the department to provide hearing screening services for newborns in compliance with Health and Safety Code, Chapter 47, and accepts a one-time grant from the department for the purchase of newborn hearing screening equipment prior to August 31, 2002.~~

~~(3) Department—The Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756.~~

~~(4) Health care provider—A registered nurse recognized as an advanced practice nurse by the Board of Nurse Examiners or a physician assistant licensed by the Texas Physician Assistant Board.~~

~~(5) Hearing loss—A hearing loss averaging 30 to 40 dB HL or greater in the frequency region important for speech recognition and comprehension in one or both ears, approximately 500 through 4000 Hz.~~

~~(6) Infant—A child who is at least 30 days but who is younger than 24 months old.~~

~~(7) Newborn—A child younger than 30 days old.~~

~~(8) Parent—A natural parent, stepparent, adoptive parent, legal guardian, or other legal custodian of a child.~~

~~(9) Physician—A person licensed to practice medicine by the Texas Medical Board.~~

~~(10) Intervention or follow-up care—The early intervention services described in the Individuals with Disabilities Education Act, 20 U.S.C. §§1431–1445.~~

~~(11) Program—A newborn hearing screening, tracking, and intervention program certified by the department or the department's designee.~~

~~(12) State—The State of Texas.~~

~~(13) Consent—A statement signed by a parent, as defined in §37.502(8) of this title (relating to Definitions) agreeing that individually identified newborn information may be disclosed to the department.~~

~~(14) Individually identifying information includes:~~

~~(A) the name of the child or the child's parent;~~

~~(B) the address of the child; and~~

~~(C) a personal identifier, such as the child's social security number or Medicaid number.~~

~~(15) Protocols—The guidelines used by the birthing facility for conducting a certified newborn hearing screening program.~~

~~§37.503 Newborn Hearing Screening, Tracking, and Intervention Program~~

~~(a) A birthing facility, through a program certified by the department under this subchapter, shall offer the parents of a newborn a hearing screening for the newborn for the identification of hearing loss. A birthing facility as defined at §37.502(2)(C) of this title (relating to Definitions) may offer a hearing screening to the parents of newborns who receive medical assistance (Medicaid).~~

~~(b) The hearing screening shall be provided during the birth admission.~~

~~(c) The parents of a newborn who is transferred to another hospital for neonatal care may be offered a hearing screening prior to discharge. If the receiving facility is a birthing facility as defined in §37.502(2) of this title (relating to Definitions) and the transferring facility did not offer the newborn's parents a hearing screening, the receiving facility shall offer a hearing screening prior to discharge.~~

~~(d) The parents shall be informed that, upon their written consent, individually identifying information shall be disclosed by the birthing facility or the (receiving facility as defined in subsection (c) of this section to the department.~~

~~(e) The department or the department's designee shall approve program protocols which must include procedures concerning at least the following: newborn hearing screening records; informed consent for individually identifying information to be sent to the department; disclosure of information; newborn hearing screening staff, technology, and screening procedures; reporting and referral; and data transfer. Birthing facilities which provided hearing screening services to all newborns prior to September 1, 1999, shall provide their program protocols to the department or the department's designee for review and approval. If the department's designee declines to approve a birthing facility's program protocols, the birthing facility may request a hearing concerning the decision to be conducted according to §§1.51-1.55 of this title (relating to Fair Hearing Procedures).~~

~~(f) The department may maintain data and information on each newborn who receives services under a program.~~

~~(g) Program protocols shall require appropriate referrals to Early Childhood Intervention Services (ECI), Department of Assistive and Rehabilitative Services, as required by 40 Texas Administrative Code, §108.61 (relating to Primary Referral Requirements). Programs that offer outpatient screening or audiologic assessment services shall refer an infant with confirmed or suspected hearing loss to ECI by entering this information into the infant's record in the department's hearing screening system so that the form is electronically completed and sent to ECI. Providers outside birth facility programs may enter the information into the department's hearing screening system, mail the form, send it by facsimile, or call the local ECI office regarding referral.~~

~~(h) If a birthing facility is not required by Health and Safety Code, Chapter 47, to offer newborn hearing screening, and did not accept an equipment grant from the department to conduct newborn hearing screening, the facility must refer the parents of each newborn delivered in the facility to another birthing facility which offers newborn hearing screening, by using the data system provided by the department and entering the necessary data, including the name of the referral facility into the system.~~

~~(i) A birthing facility not required by Health and Safety Code, §47.003(a), to offer newborn hearing screening that nevertheless elects to do so must notify the department and comply with all applicable certification requirements.~~

§37.504 Certification of Screening Programs

Program certification criteria shall include the following:

(1) procedures for maintaining and reporting data electronically to the department, including assurances that confidentiality and general access to data meet state and federal guidelines;

(2) obtaining parental consent according to §37.511 of this title (relating to Confidentiality and General Access to Data);

(3) assuring that a sufficient number of screening staff, including managers and screeners, successfully complete training provided by the department or the department's designee during program implementation. Staff members who complete the department's training successfully shall be considered qualified hearing screening providers, and may train other staff members at their facilities;

(4) providing hearing screening using equipment that meets department criteria, including but not limited to the following:

(A) a demonstrated ability to link electronically to the department's newborn hearing screening information system;

(B) clearance or approval for marketing for hearing screening by the Food & Drug Administration, if applicable; and

(C) capability to identify hearing loss that meets the definition in §37.502(5) of this title;

(5) communicating with parents, physicians or health care providers, the department, and Early Childhood Intervention Services with appropriate procedures for reporting screening and follow-up results and providing information to parents regarding follow-up services;

(6) procedures for distribution by birthing facilities of standardized educational materials developed and provided by the department, as well as additional materials it may select, to parents, health care providers, and physicians;

(7) performance of program services in compliance with §37.505 of this title (relating to Program Performance Standards and Goals); and

(8) approved protocols for program operation.

§37.505 Program Performance Standards and Goals

~~(a) Minimum acceptable levels of performance include:~~

~~(1) All parents of newborns shall be offered a newborn hearing screen during the birth admission, and given the results of the screen;~~

~~(2) 95% of newborns shall be screened during the birth admission. Newborns whose parent(s) refuse the screening shall not be counted in reaching this percentage;~~

~~(3) 90% of newborns shall pass the birth admission screen; and~~

~~(4) All newborns with abnormal screening results shall be reported to the newborn's attending physician or health care provider, and the department.~~

~~(b) Goals for program performance shall include:~~

~~(1) All parents of newborns shall be offered a newborn hearing screen during the birth admission, and given the results of the screen;~~

~~(2) 98% of newborns shall be screened during the birth admission;~~

~~(3) 95% of newborns shall pass the birth admission screen. Newborns whose parent(s) refuse the screening shall not be counted in reaching this percentage; and~~

~~(4) All newborns with abnormal screening results shall be reported to the newborn's attending physician or health care provider, and the department.~~

~~§37.506 Program Certification~~

~~(a) The department shall certify programs in the following classifications.~~

~~(1) Preliminary.~~

~~(A) Preliminary certification may be awarded for a period of not more than six months to a program which has never been previously certified and has met the criteria described in §37.504 of this title (relating to Certification of Screening Programs) and §37.505(a) of this title (relating to Program Performance Standards and Goals).~~

~~(B) A program holding preliminary certification may seek recertification based on performance data for the three months immediately preceding the program certification review.~~

~~(C) A program holding preliminary certification may be awarded Provisional or Standard status, or may be decertified.~~

~~(2) Standard.~~

~~(A) Standard certification may be awarded for a period of not more than 24 months to a program that has met the criteria described in §37.504 and §37.505(a) of this title.~~

~~(B) A program holding standard certification may seek recertification based on performance data for the 24 months immediately preceding the program certification review.~~

~~(C) A program maintains its designated certification during certification review.~~

~~(D) A program holding standard certification may be awarded Provisional, Standard, or Distinguished status, or may be decertified.~~

~~(3) Distinguished.~~

~~(A) Distinguished certification may be awarded for a period of not more than 36 months to a program that has met the criteria described in §37.504 and §37.505(b) of this title.~~

~~(B) A program holding distinguished certification may seek recertification based on performance data for the 36 months immediately preceding the program certification review.~~

~~(C) A program maintains its designated certification during certification review.~~

~~(D) A program holding distinguished certification may be awarded Provisional, Standard, or Distinguished status, or may be decertified.~~

~~(4) Provisional.~~

~~(A) Provisional certification shall be valid for no more than six months.~~

~~(B) Provisional certification shall be given to a program which fails to meet one or more of the criteria described in §37.504 or §37.505(a) of this title upon recertification review.~~

~~(C) A program holding provisional certification may seek recertification review based on performance data for the six months immediately preceding the program certification review.~~

~~(D) A program holding provisional certification may be awarded Standard status, or may be decertified.~~

~~(b) Decertification.~~

~~(1) A program holding a Preliminary, Provisional, Standard, or Distinguished certification may be decertified if the department or department's designee determines that the program has knowingly submitted data that does not accurately reflect the screening results obtained from each newborn or infant tested.~~

~~(2) A program holding a Provisional certification may be decertified if it fails to meet one or more of the certification criteria or performance standards in §37.504 or §37.505(a) of this title.~~

~~(3) If the department or the department's designee proposes to decertify a program, the department or the department's designee shall notify the program in writing and shall provide the program an opportunity for a hearing in accordance with §§1.51–1.55 of this title (relating to Fair Hearing Procedures) to determine if there is evidence to support the proposed action. The program may submit a written request for a hearing to the department or the department's designee within 10 working days after receiving the notice.~~

~~(e) Recertification Following Decertification.~~

~~(1) A program may apply for recertification following decertification based on performance data for the six months immediately preceding the review.~~

~~(2) A program applying for recertification after decertification may receive Standard status or may remain decertified.~~

~~(d) Notice of Failure to Meet Performance Standards. The department or the department's designee shall notify in writing any certified program which fails to meet applicable performance standards during any two-month period.~~

~~(1) A program notified of failure to meet performance standards shall provide to the department or the department's designee within 30 days of receipt of the notice a corrective action plan and the time frame needed to return the program to compliance.~~

~~(2) Failure by the program to provide a written corrective action plan within 30 days may result in an immediate certification review.~~

~~(e) Fees. No fees shall be charged for certification or re-certification.~~

~~§37.507 Information Concerning Screening Results and Follow-up Care~~

~~(a) Birthing facilities shall provide information regarding the results of the birth admission hearing screen to the parents, attending physician or health care provider, and to the department or the department's designee. Individually identified information will be reported to the department upon written consent of the parents.~~

~~(b) Birthing facilities shall provide information recommended by the department to the parents regarding available follow-up services for newborns and infants with abnormal screening results.~~

~~§37.508 Training and Technical Assistance by Department~~

~~The department or its designee will provide training and technical assistance associated with the implementation or maintenance of a certified program upon request.~~

~~§37.509 Information Management, Reporting, and Tracking System~~

~~(a) The department shall provide appropriate information management, reporting, and tracking software to birthing facilities that provide newborn hearing screening under the State's medical assistance program provided under Human Resources Code, Chapter 32.~~

~~(b) The department shall offer birthing facilities participating in the medical assistance program software for the newborn hearing screening program. Birthing facilities must report the resulting information in a format and according to a time frame specified by the department.~~

~~(c) Audiologists, qualified hearing screening providers, intervention specialists, educators, and others who receive referrals from programs under this chapter shall either provide the needed services or refer the children to another provider of the needed services, and with consent shall provide the following information to the department or its designee:~~

~~(1) results of follow-up care;~~

~~(2) results of audiologic testing of infants identified with hearing loss;~~

~~(3) reports on initiation of intervention services; and~~

~~(4) results of follow-up and testing on children served under the state's medical assistance program under Human Resources Code, Chapter 32, who are eligible for services and hearing aids through the department's Program for Amplification for Children of Texas.~~

~~(d) Audiologists, qualified hearing screening providers, intervention specialists, educators, and others who provide services to infants who are diagnosed with hearing~~

loss shall provide the following information, with consent, to the department or its designee:

~~(1) results of follow-up services;~~

~~(2) results of audiologic testing of infants identified with hearing loss;~~

~~(3) report on initiation of intervention services; and~~

~~(4) results of follow-up and testing on children served under the state's medical assistance program under Human Resources Code, Chapter 32, who are eligible for services and hearing aids through the department's Program for Amplification for Children of Texas.~~

~~(e) Hospitals that provide services under this chapter shall use the information management, reporting and tracking software provided by the department to report, with consent, the following information to the department or its designee:~~

~~(1) results of all follow-up services for infants who do not pass the birth admission screen when the hospital provides the follow-up services; or~~

~~(2) the name of the provider or facility where the hospital refers the family for follow-up services.~~

~~§37.510 Responsibilities of the Department of State Health Services~~

~~(a) The department shall use the information provided under §37.509 of this title (relating to Information Management, Reporting, and Tracking System) to plan, monitor and evaluate programs, including the screening, follow-up, diagnostic, and intervention components.~~

~~(b) The department may use the collected information to monitor for health events of epidemiological importance.~~

~~§37.511 Confidentiality and General Access to Data~~

~~(a) The birthing facility shall obtain a statement of consent from the parent, guardian, or managing conservator if individually identifying information for newborns tested under this chapter is disclosed to the department or its designee.~~

~~(b) All primary referral sources identified in 40 Texas Administrative Code, §108.61 (relating to Primary Referral Requirements) shall provide information concerning children suspected of hearing loss to Early Childhood Intervention Services, Department of Assistive and Rehabilitative Services.~~

~~(c) The department shall prepare appropriate language for consent forms for disclosing individually identifying information and shall make samples available to birthing facilities.~~

~~(d) At any time a parent may request in writing that individually identifying information concerning his or her child be removed from the department's newborn hearing screening system by contacting the Department of State Health Services, Newborn Screening Branch, 1100 West 49th Street, Austin, Texas, 78756. The department shall act on any request in a timely manner.~~

~~(e) All information which identifies individuals shall be protected as confidential medical information in accordance with the Medical Practice Act, Occupations Code, Chapter 159.~~

~~(f) A birthing facility and any other entity or person cited in Health and Safety Code, §47.009 which discloses individually identifying information regarding newborn hearing screening results to the department in good faith pursuant to this section is not subject to civil or criminal liability, as provided by Health and Safety Code, §47.009.~~

~~(g) If consent to disclose individually identifying information to the department is obtained, the facility obtaining consent shall maintain the consent in the patient's medical record.~~

~~§37.512 Authorized Medicaid Newborn Hearing Services~~

~~(a) A newborn hearing screening test performed by a birthing facility in accordance with Health and Safety Code, Chapter 47 and the requirements of this subchapter for a newborn who receives medical assistance or who is Medicaid-eligible is a covered service of the Texas Medical Assistance (Medicaid) Program.~~

~~(b) Any necessary diagnostic follow-up care related to the newborn hearing screening test provided to a newborn who receives medical assistance or who is Medicaid-eligible is a covered service of the Texas Medical Assistance Program.~~

~~(c) The reimbursement rates and methodology for covered services described in this section shall be established by the Texas Health and Human Services Commission.~~