

**Department of State Health Services
Agenda Item for State Health Services Council
October 5 - 6, 2005**

Agenda Item Title: Amend 25 TAC 37.501 – 37.512 Rules Relating to Newborn Hearing Screening

Agenda Number: 3e

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background: The rules became effective in May, 2000 in response to Health and Safety Code, Chapter 47. Birthing facilities subject to the rules have been operating since September 2001, and are currently screening 98 percent of all births in Texas. The newborn hearing screening program is deleting an option from the rules that authorizes nine birthing facilities out of 247 to continue to use their own tracking software rather than software provided at no cost by the department so the department can more effectively monitor data provided by these facility programs as required by statute. Two minor changes involve rural facilities that were exempt from screening. Exempt facilities that do not choose to screen must refer newborns to facilities that do perform screening, and the program is requiring these facilities to enter the names of the newborns being referred into the hearing screening information system so that their testing can be tracked. Additionally, a few referring facilities have begun screening, and the program has amended the rules to require that exempt facilities that nevertheless choose to screen must comply with the department's newborn hearing screening system. It is not expected that this requirement will create a problem for these facilities, and it will allow the department to close one of the gaps in follow-up for newborns with hearing loss. Other minor changes will clarify that facilities being reviewed for certification renewal maintain their current certification level until the review process is completed, and clarification of program certification guidelines will be made.

There is no anticipated fiscal impact from the amendment to the rules. The department already licenses rights to the application used for newborn hearing screening, and adding a few programs to the system will have no fiscal impact to either the birth facilities or the department.

Summary: The rule amendments concern changes that clarify newborn hearing screening protocols for referral, change agency and program names as appropriate, and eliminate the option that enables nine of the 247 birthing facilities to use their own newborn hearing screening tracking software. The department is requiring that all facilities use the software provided by the department so that the department can meet its statutory mandate for monitoring birthing facilities statewide.

Summary of Stakeholder Input to Date (including advisory committees): Discussed specific proposed rules changes with birthing facilities and audiologists.

Proposed Motion:

Motion to recommend HHSC approval for publication of rules contained in the agenda item # 3e.

Agenda Item Approved by: Mike Montgomery for Evelyn Delgado

Date Submitted

Presented by: _____ **Title:** _____

Program/Division: _____ **Contact Name/Phone:** _____

Title 25. HEALTH SERVICES

Part 1. Department of State Health Services
Chapter 37. Maternal and Infant Health Services
Subchapter S. Newborn Hearing Screening
Amendments §§37.501-37.512

PROPOSED PREAMBLE

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

BACKGROUND AND PURPOSE

The sections were adopted in May, 2000, to implement Health and Safety Code, Chapter 47. Birthing facilities subject to Health and Safety Code, Chapter 47 have been operating since September 2001, and are currently providing screening for 98 percent of all births in the state.

Government Code, §2001.039, requires that each state agency review and consider for readoption each rule adopted by that agency pursuant to the 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.

SECTION-BY-SECTION SUMMARY

Section 37.501 has been amended to simplify and increase the readability of the text.

Section 37.502(3) has been amended to incorporate the department's current name. Section 37.502(4) has been amended because the 79th Texas Legislature changed the name of the "Texas State Board of Physician Assistant Examiners" to the "Texas Physician Assistant Board." Section 37.502(9) has been amended because the 79th Texas Legislature changed the name of the "Texas State Board of Medical Examiners" to the "Texas Medical Board."

Section 37.503(g) has been amended to change the name of the "Interagency Council on Early Childhood Intervention" to "Early Childhood Intervention Services" and to clarify that the reference "25 TAC §621.45 of this title (relating to Primary Referral Requirements)" was transferred to 40 TAC §108.61, effective March 1, 2004. Section 37.503(g) has also been amended to require that facilities refer infants with confirmed or suspected hearing loss to Early Childhood Intervention, either directly or through the department. Section 37.503(h) has been amended to clarify how facilities that are not subject to Health and Safety Code, Chapter 47, and that did not accept an equipment grant from the department must refer newborns delivered at those facilities to other participating facilities and enter necessary data concerning the referral facility into the system. New §37.503(i) requires facilities that are not required to screen newborns for hearing loss but choose to do so, to notify the department and comply with all applicable certification requirements.

Section 37.504(5) has been amended to change the name of the "Interagency Council on Early Childhood Intervention" to "Early Childhood Intervention Services" and to clarify that follow-up as well as screening results must be reported to the department.

Section 37.505(b) has been amended to increase the clarity of the section.

New paragraphs in §37.506(a)(2)(C) and (3)(C) have been added to clarify that during both Standard and Distinguished certification review, programs will retain their then-current certifications. Existing paragraphs in §37.506(a)(2)(C) and (3)(C) have been renumbered in §37.506(a)(2)(D) and (3)(D), respectively. Section 37.506(d)

has been deleted because the option is outdated and no longer relevant to the administration of the newborn hearing screening program. Subsections in §37.506(e) and (f) have been renumbered as §37.506(d) and (e), respectively.

Section 37.507(b) has been amended to increase the clarity of the section.

Section 37.508 has been amended to clarify that birthing facilities that operate certified newborn hearing screening programs may request needed technical assistance and training.

Section 37.509(c) has been deleted, thereby requiring all birthing facilities subject to Health and Safety Code, Chapter 47, to utilize information management, reporting, and tracking software provided by the department. With the deletion of §37.509(c), §37.509(d) has been renumbered as §37.509(c) and the word “hospitals” has been deleted and added to new §37.509(e) to clarify the responsibility of hospitals for follow-up referrals. New §37.509(d) clarifies the responsibilities of hearing professionals concerning referrals of infants with late onset hearing loss.

The title of §37.510 has been amended to increase clarity and readability.

Section 37.511(b) has been amended to clarify that the Interagency Council on Early Childhood Intervention now functions as Early Childhood Intervention Services, a part of the Department of Assistive and Rehabilitative Services. Additionally, §37.511(b) has been amended because 25 TAC §621.45 of this title (relating to Primary Referral Requirements) was transferred to 40 TAC §108.61, effective March 1, 2004. Section 37.511(d) has also been amended to reflect the current name of the of the department and the program.

Section 37.512(d) has been deleted because it refers to the initiation of newborn hearing screening at certain birthing facilities as mandated by Health and Safety Code, Chapter 47, not later than 2001.

FISCAL NOTE

Jann Melton-Kissel, Section Director, Specialized Health Services, has determined that for each of the first five years the sections are in effect, there will be no fiscal implications to state or local governments as a result of administering the sections as proposed. The proposed amendments do not require state or local governments that operate birthing facilities to change their business practices in order to provide data to the department, and no birthing facilities will be required to purchase computer software or to pay for staff training in order to do so.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Melton-Kissel has determined that there will be no effect on small businesses or micro-businesses required to comply with the sections as proposed, because neither small businesses nor micro-businesses that are subject to Health and Safety Code, Chapter 47, will be required to change their business practices in order to provide data to the department, and no birthing facilities will be required to purchase computer software or to obtain staff training in order to do so. There are no anticipated economic costs to persons who are required to comply with the sections as proposed. There is no anticipated negative impact on local employment.

PUBLIC BENEFIT

Ms. Melton-Kissel has determined that the public benefit anticipated as a result of amending the sections is the ability to better ensure follow-up services for newborns and infants with hearing loss.

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 proposed sections do 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, do not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to David R. Martinez, Newborn Screening Branch, Mail Code 1918, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756. 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, Cathy Campbell, 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 proposed amendments are authorized by Health and Safety Code, §47.004(d), §47.008(c), and §1001.075; and by Government Code, §531.0055; and which authorizes 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.

The proposed amendments affect Government Code, Chapter 531, and Health and Safety, Chapters 47 and 1001. Review of the sections implements Government Code, §2001.039.

Legend: (Proposed Amendments)

Single Underline = Proposed new language

[Bold Print and Brackets] = Current language proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision

§37.501. These **[The purpose of these sections is to establish the]** rules implement **[for the implementation of]** 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)-(2) (No change.)

(3) Department - The Department of State Health Services **[Texas Department of Health]**, 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 **[Texas State Board of Physician Assistant Examiners]**.

(5)-(8) (No change.)

(9) Physician - A person licensed to practice medicine by the Texas Medical Board **[Texas State Board of Medical Examiners]**.

(10)-(15) (No change.)

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

(a)-(f) (No change.)

(g) Program protocols shall require appropriate referrals to Early Childhood Intervention Services (ECI), Department of Assistive and Rehabilitative Services, [the Interagency Council on Early Childhood Intervention] as required by 40 Texas Administrative Code, §108.61 [§621.45 of this title] (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 [has chosen] not [to] accept an equipment grant from the department to conduct newborn hearing screening, the facility must refer the parents of each

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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)-(4) (No change.)

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

(6)-(8) (No change.)

§37.505. Program Performance Standards and Goals.

(a) (No change.)

(b) Goals for program performance shall include:

(1)-(4) (No change.)

§37.506. Program Certification.

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

(1) (No change.)

(2) Standard.

(A)-(B) (No change.)

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

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

(3) Distinguished.

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(A)-(B) (No change.)

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

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

(4) (No change.)

(b)-(c) (No change.)

[(d) Certification For Operational Programs. Hospitals that were providing newborn hearing screening to all newborns on September 1,1999, may be awarded Standard or Distinguished certification based upon compliance with §37.505(a) or §37.505(b) of this title.]

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

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

(a) (No change.)

(b) Birthing facilities shall **[must]** 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)-(b) (No change.)

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[(c) Birthing facilities which, on September 1, 1999, were offering newborn hearing screening to all newborns utilizing information management, reporting, and tracking software not provided by the department, or that do not participate in the medical assistance program shall cooperate with the department's designee to report screening information to the department in a format and according to a time frame specified by the department.]

(c)~~(d)~~ Audiologists, **[Hospitals, 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 **[, where available,]** 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:

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(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. [Texas Department of Health Responsibilities].

(a)-(b) (No change.)

§37.511. Confidentiality and General Access to Data.

(a) (No change.)

(b) All primary referral sources identified in 40 Texas Administrative Code, §108.61 [**§621.45 of this title**] (relating to Primary Referral Requirements) shall provide information concerning children suspected of [**diagnosed with**] hearing loss to Early Childhood Intervention Services, Department of Assistive and Rehabilitative Services [**the Interagency Council on Early Childhood Intervention**].

(c) (No change.)

(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 [Texas Department of Health, Audiology Services Program], 1100 West 49th Street, Austin, Texas, 78756. The department shall act on any request in a timely manner.

(e)-(g) (No change.)

§37.512. Authorized Medicaid Newborn Hearing Services.

(a)-(c) (No change.)

[(d) A Medicaid birthing facility described in §37.502(2)(A) or (B) of this title (relating to Definitions) shall implement its newborn hearing screening program by the dates required by Chapter 1347, §6, Acts of the 76th Legislature, 1999 (HB 714).]