

**Department of State Health Services
Council Agenda Memo for State Health Services Council
February 26-27, 2014**

Agenda Item Title: New rules concerning newborn screening for critical congenital heart disease

Agenda Number: 5.a

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background:

The Department of State Health Services (DSHS) administers the Newborn Screening Program, which is designed to screen all newborns in the state for certain genetic or heritable diseases. If disorders are identified and treated early, serious problems such as developmental delays, intellectual disability, illness, or death can be prevented or ameliorated. The Newborn Screening Unit in the Division for Family and Community Health Services provides follow-up, care coordination, and outreach education.

Newborn screening is comprised of screening performed on blood specimens (bloodspot-based newborn screening) as well as screening performed at the point-of-care. The new rules cover point-of-care newborn screening for critical congenital heart disease (CCHD).

Program funding includes state and federal funds.

Summary:

The purpose of the new rules is to establish test procedures and standards of accuracy for screening CCHD, and describe the reporting of confirmed cases of CCHD to DSHS. The new rules comply with House Bill (HB) 740, 83rd Legislature, Regular Session, 2013, which amended Chapter 33, Health and Safety Code. Unlike bloodspot-based screening, the statute does not authorize follow-up by DSHS staff for positive screens or for data collection other than confirmed cases.

The rules will:

- explain the purpose;
- provide definitions;
- outline the exemptions from screening;
- establish the test procedures and standards of accuracy for screening; and
- describe reporting and record keeping requirements on confirmed cases.

Key Health Measures:

Staff will monitor and document the number of reported confirmed cases, and establish a year-one baseline for use in subsequent reporting years. The effectiveness of these changes will also be monitored by ongoing communication with stakeholders and agency staff through regular meetings held every 2-3 months with the Newborn Screening Advisory Committee, Texas Medical Association (TMA), Texas Hospital Association (THA), Texas Pediatric Society (TPS), March of Dimes (MOD), and Texas Academy of Family Physicians.

Summary of Input from Stakeholder Groups:

Informal stakeholder input has been obtained by posting on the DSHS website, email/list serves, verbal communication, and coordination with the Newborn Screening Advisory Committee and professional associations. Informal comments were solicited from stakeholders beginning December 4, 2013, through December 16, 2013.

The Newborn Screening Program received comments from nine separate organizations and individuals, including MOD, Pediatrix Cardiology, THA, TMA, TPS, and Houston Methodist Willowbrook Hospital. In addition to these commenters, approximately 100 individual letters supporting CCHD screening were sent to DSHS via e-mail.

Stakeholders in general were supportive of the new rules. Some suggestions did not directly affect the rules; however, the program made programmatic changes, as appropriate. Other suggestions resulted in minor rule changes. DSHS was unable to incorporate all of the suggestions that include:

- Requiring reporting elements to include more than confirmatory data. The statute only authorizes the reporting of confirmed cases to DSHS; therefore, no changes were made to the rules.
- Providing education to staff performing the screening to ensure consistency and greater reliability and validity. DSHS will develop educational information on pulse oximetry screening; however, the test procedures and standards for accuracy are outlined in the proposed rules.
- Revising categories on the reporting form. DSHS incorporated some of the revisions to the form, so no changes were required to the rules.
- Including a narrative to accompany the screening algorithm diagram. DSHS will evaluate whether a narrative is beneficial to describe the algorithm diagram, so no changes required to the rules.

Proposed Motion:

Motion to recommend HHSC approval for publication of rules contained in agenda item #5.a.

Approved by Assistant Commissioner/Director: Evelyn Delgado **Date:** 2/12/14

Presenter: David Martinez **Program:** Newborn Screening Program **Phone No.:** 512/776-2216

Approved by CCEA: Carolyn Bivens **Date:** 2/11/2014

Title 25. Health Services
Part 1. Department of State Health Services
Chapter 37. Maternal and Infant Health Services
New Subchapter E. Newborn Screening for Critical Congenital Heart Disease
New §§37.75 - 37.79

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes new §§37.75 - 37.79, concerning newborn screening for critical congenital heart disease (CCHD).

BACKGROUND AND PURPOSE

The department administers the Newborn Screening Program, which is designed to screen all newborns in the state for certain genetic or heritable disorders. If identified and treated early, serious problems such as developmental delays, intellectual disability, illness, or death can be prevented or ameliorated. Newborn screening is comprised of screening performed on blood specimens (bloodspot-based newborn screening) as well as screening performed at the point-of-care, which takes place in birthing facilities or hospitals. This subchapter covers point-of-care newborn screening for CCHD.

The new rules are necessary to comply with House Bill 740, 83rd Legislature, Regular Session, 2013, which amended Health and Safety Code, Chapter 33, by adding screening for CCHD. The statute requires the department to establish test procedures and standards of accuracy for screening, and to describe the required reporting of confirmed cases of CCHD to the department. Unlike bloodspot-based screening, the statute does not authorize follow-up by department staff for positive screens or for data collection other than confirmed cases. The new rules will: (1) explain the purpose; (2) provide definitions; (3) outline the exemptions from screening; (4) establish the test procedures and standards of accuracy for screening to be established by the department; and (5) describe required reporting of confirmed cases to the department.

SECTION-BY-SECTION SUMMARY

New §37.75 provides a comprehensive summary of the contents of the subchapter which requires the department to implement newborn screening for CCHD.

New §37.76 defines birthing facility; CCHD; department; echocardiogram; health care practitioner; neonatal intensive care unit; newborn; physician; pulse oximeter; and screening algorithm.

New §37.77 describes exemptions from the requirement to conduct the newborn screening for CCHD. Qualifying exemptions are: (1) the parent declines the screening; (2) the newborn is transferred to another facility before the screening test is performed; (3) the post-natal screening test has previously been completed; (4) the newborn is discharged from the birthing facility not more than 10 hours after birth and a referral for the newborn was made to another birthing facility, physician, or health care provider; (5) the newborn has previously been diagnosed with CCHD; or (6) the newborn has had a post-natal echocardiogram.

New §37.78 sets forth test procedures and standards, and includes when, where, and how screening tests must be performed, unless exempted from the requirements by §37.77 of this title.

New §37.79 sets forth who is responsible for reporting, and how reporting to the department is to be conducted for confirmed cases of CCHD.

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.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Mr. Cooper has also determined that there should 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 EMPLOYMENT

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

PUBLIC BENEFIT

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. Public benefit anticipated as a result of enforcing or administering the sections is to define how the state administers newborn screening for CCHD for all Texas babies through the addition of test procedures and standards of accuracy, and requirements for reporting confirmed cases to the department. Early detection and timely intervention can decrease morbidity and lead to better outcomes. These proposed rules will

improve department operations, provide user-friendly rules for stakeholders, provide for greater department transparency in its processes, and make department 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 new rules are authorized by Health and Safety Code, §33.002, which requires the department to adopt rules necessary to carry out the program, and by Chapter 33 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.

The new rules affect Health and Safety Code, Chapters 33 and 1001, and Government Code, Chapter 531.

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

§37.75. Purpose.

This subchapter implements Texas Health and Safety Code, Chapter 33, administered by the Texas Department of State Health Services, associated with conducting point-of-care newborn screening for critical congenital heart disease (CCHD). Newborns delivered in the state must be screened at a birthing facility for CCHD as described in this subchapter. This subchapter also defines the test procedures and standards required by the department for each screening test and details reporting and record keeping requirements on confirmed cases.

§37.76. Definitions.

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

(1) Birthing facility--An inpatient or ambulatory health care facility that offers obstetrical or newborn care services. The term includes:

(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; or

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

(2) Critical Congenital Heart Disease (CCHD)--An abnormality in the structure or function of the heart that exists at birth, that causes severe, life-threatening symptoms, and requires medical intervention within the first few hours, days, or months of life.

(3) Department--The Texas Department of State Health Services or its successor.

(4) Echocardiogram--An ultrasound test that evaluates the structure and function of the heart.

(5) Health care practitioner--One of the following individuals who is currently licensed and in good standing as indicated:

(A) an advanced practice registered nurse licensed by the Texas Board of Nursing pursuant to Texas Occupations Code, Chapter 301;

(B) a physician assistant licensed by the Texas Physician Assistant Board pursuant to Texas Occupations Code, Chapter 204; or

(C) a midwife licensed by the Texas Midwifery Board pursuant to Texas Occupations Code, Chapter 203.

(6) Neonatal intensive care unit (NICU)--An intensive care unit specializing in the care of ill or premature newborn infants.

(7) Newborn--A child through 30 days of age.

(8) Physician--A person licensed to practice medicine by the Texas Medical Board pursuant to Texas Occupations Code, Chapter 151.

(9) Pulse Oximeter--A U.S. Food and Drug Administration approved instrument used to measure the percentage of hemoglobin in the blood that is saturated with oxygen in neonates.

(10) Screening algorithm--A standardized process and methodology used to conduct newborn screening for CCHD.

§37.77. Exemption from Screen.

The newborn screening test for CCHD referenced in §37.78 of this title (relating to Test Procedures and Standards) is not required for a newborn under the following conditions:

(1) the parent declines the screening;

(2) the newborn is transferred to another facility before the screening test is performed;

(3) the screening test has previously been completed after birth;

(4) the newborn is discharged from the birthing facility not more than 10 hours after birth and a referral for the newborn was made to another birthing facility, physician, or health care provider;

(5) the newborn has previously been diagnosed with CCHD; or

(6) the newborn has had a post-natal echocardiogram.

§37.78. Test Procedures and Standards.

(a) A screening test for CCHD using pulse oximetry must be performed at a birthing facility that provides care to newborn patients except as described in §37.77 of this title (relating to Exemption from Screen).

(b) Testing procedures must be consistent with the most current published screening algorithm and any other protocol currently posted, linked, or referenced on the department's Newborn Screening website at <http://www.dshs.state.tx.us/newborn/>.

(c) Pulse oximeters used to conduct CCHD newborn screening must meet the standards and accuracy as determined by the Food and Drug Administration for hospital use in newborns.

(d) Newborns in the NICU must receive CCHD screening prior to discharge except as described in §37.77 of this title (relating to Exemption from Screen).

§37.79. Reporting.

(a) A physician, health care practitioner, health authority, birthing facility, or other individual who has the information of a confirmed case of a disorder for which a screening test is required, shall report a confirmed case to the department.

(b) Confirmed case information must be submitted to the department's Newborn Screening Unit using the most current reporting method(s) located on the department's Newborn Screening website at <http://www.dshs.state.tx.us/newborn/>.