

## Texas Administrative Code

### Rules: Newborn Screening for Critical Congenital Heart Disease (CCHD)

#### §37.75. Purpose

This subchapter implements Texas Health and Safety Code, Chapter 33, administered by the 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 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;



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(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.



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### **§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). If another U.S. Federal Drug Administration approved instrument is available, it will be posted as identified in subsection (b) of this section.

(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/>.