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SUBCHAPTER E NEWBORN SCREENING FOR CRITICAL CONGENITAL HEART DISEASE (CCHD)

§37.75. Purpose.

- (a) This subchapter implements Texas Health and Safety Code, Chapter 33, administered by the Texas Department of State Health Services (department), 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 critical congenital heart disease as described in this subchapter.
- (b) This subchapter also defines the test procedures and standards required by the department for each screening test.
- (c) This subchapter also details reporting and record keeping 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 Chapter 241 that offers obstetrical services;
 - (B) a birthing center licensed under 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 is 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) Echocardiogram - an ultrasound test that evaluates the structure of the heart.
- (4) Department--The Department of State Health Services or its successor.
- (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 Approved (FDA) instrument used to measure the percentage of hemoglobin in the blood that is saturated with oxygen.

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

§37.77. Exemption from Screen

(a) The newborn screening test for CCHD referenced in §37.78 of this title (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; or
- (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.
- (6) the newborn has had a post-natal echocardiogram.

§37.78. Test Procedures and Standards

- (a) A screening test for CCHD must be performed at a birthing facility that provides care to newborn patients except as described in §37.77. (Exemption from Screen).
- (b) Testing procedures must be consistent with the screening algorithm and any other protocol currently posted, linked, or referenced on the DSHS Newborn Screening website, or any other test procedure designated by the department on its website.

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- (c) Pulse oximeters used to conduct CCHD newborn screening must meet the standards and accuracy as determined by the FDA for hospital use in newborns.
- (d) Newborns in the NICU must receive CCHD screening prior to discharge unless exempted in §37.77. (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) Diagnosed case information must be faxed to DSHS Newborn Screening Unit or sent electronically (once electronic reporting process is established by DSHS) using the most current DSHS CCHD Reporting Form located on the DSHS Newborn Screening website.