

1-1 By: Crownover, et al. (Senate Sponsor - Deuell) H.B. No. 740
1-2 (In the Senate - Received from the House April 25, 2013;
1-3 April 29, 2013, read first time and referred to Committee on Health
1-4 and Human Services; May 9, 2013, reported favorably by the
1-5 following vote: Yeas 7, Nays 0; May 9, 2013, sent to printer.)

1-6 COMMITTEE VOTE

| | Yea | Nay | Absent | PNV |
|------|------------|-----|--------|-----|
| 1-7 | | | | |
| 1-8 | Nelson | X | | |
| 1-9 | Deuell | X | | |
| 1-10 | Huffman | X | | |
| 1-11 | Nichols | X | | |
| 1-12 | Schwertner | X | | |
| 1-13 | Taylor | | X | |
| 1-14 | Uresti | | X | |
| 1-15 | West | X | | |
| 1-16 | Zaffirini | X | | |

1-17 A BILL TO BE ENTITLED
1-18 AN ACT

1-19 relating to newborn screening for critical congenital heart disease
1-20 and other disorders.

1-21 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

1-22 SECTION 1. Section 33.001, Health and Safety Code, is
1-23 amended by amending Subdivision (1) and adding Subdivisions (1-a)
1-24 and (1-b) to read as follows:

1-25 (1) "Birthing facility" means an inpatient or
1-26 ambulatory health care facility that offers obstetrical or newborn
1-27 care services. The term includes:

1-28 (A) a hospital licensed under Chapter 241 that
1-29 offers obstetrical services;

1-30 (B) a birthing center licensed under Chapter 244;

1-31 (C) a children's hospital; or

1-32 (D) a facility that provides obstetrical
1-33 services and is maintained and operated by this state or an agency
1-34 of this state.

1-35 (1-a) "Critical congenital heart disease" means an
1-36 abnormality in the structure or function of the heart that exists at
1-37 birth, causes severe, life-threatening symptoms, and requires
1-38 medical intervention within the first few hours, days, or months of
1-39 life.

1-40 (1-b) "Heritable disease" means an inherited disease
1-41 that may result in mental or physical retardation or death.

1-42 SECTION 2. Section 33.011, Health and Safety Code, is
1-43 amended by amending Subsections (a), (a-1), and (c) and adding
1-44 Subsections (d), (e), and (f) to read as follows:

1-45 (a) The physician attending a newborn child or the person
1-46 attending the delivery of a newborn child that is not attended by a
1-47 physician shall cause the child to be subjected [~~subject the child~~]
1-48 to screening tests approved by the department for phenylketonuria,
1-49 other heritable diseases, hypothyroidism, and other disorders for
1-50 which screening is required by the department.

1-51 (a-1) Except as provided by this subsection and to the
1-52 extent funding is available for the screening, the department shall
1-53 require newborn screening tests to screen for disorders listed as
1-54 core and secondary conditions in the December 2011 Recommended
1-55 Uniform Screening Panel of the Secretary's Advisory Committee on
1-56 Heritable Disorders in Newborns and Children [~~core panel and in the~~
1-57 ~~secondary targets of the uniform newborn screening panel~~
1-58 ~~recommended in the 2005 report by the American College of Medical~~
1-59 ~~Genetics entitled "Newborn Screening: Toward a Uniform Screening~~
1-60 ~~Panel and System"~~] or another report determined by the department
1-61 to provide more stringent newborn screening guidelines to protect

2-1 the health and welfare of this state's newborns. The department,
 2-2 with the advice of the Newborn Screening Advisory Committee, may
 2-3 require additional newborn screening tests under this subsection to
 2-4 screen for other disorders or conditions. The department may
 2-5 exclude from the newborn screening tests required under this
 2-6 subsection screenings for galactose epimerase and galactokinase.

2-7 (c) Except as provided by Subsection (d), the [The]
 2-8 screening tests required by this section must be performed by the
 2-9 laboratory established by the department or by a laboratory
 2-10 approved by the department under Section 33.016.

2-11 (d) The department, with the advice of the Newborn Screening
 2-12 Advisory Committee, shall authorize a screening test for critical
 2-13 congenital heart disease to be performed at a birthing facility
 2-14 that provides care to newborn patients and that complies with the
 2-15 test procedures and the standards of accuracy and precision
 2-16 required by the department for each screening test.

2-17 (e) If the department under Subsection (d) authorizes the
 2-18 performance at a birthing facility of a screening test for critical
 2-19 congenital heart disease, a birthing facility must perform the
 2-20 screening test on each newborn who is a patient of the facility
 2-21 before the newborn is discharged from the facility unless:

2-22 (1) the parent declines the screening;

2-23 (2) the newborn is transferred to another facility
 2-24 before the screening test is performed;

2-25 (3) the screening test has previously been completed;

2-26 or

2-27 (4) the newborn is discharged from the birthing
 2-28 facility not more than 10 hours after birth and a referral for the
 2-29 newborn was made to another birthing facility, physician, or health
 2-30 care provider.

2-31 (f) Before requiring any additional screening test for
 2-32 critical congenital heart disease, the department must review the
 2-33 necessity of the additional screening test, including an assessment
 2-34 of the test implementation costs to the department, birthing
 2-35 facilities, and other health care providers.

2-36 SECTION 3. Section 33.0111, Health and Safety Code, is
 2-37 amended by amending Subsections (a), (b), and (f) and adding
 2-38 Subsection (h) to read as follows:

2-39 (a) The department shall develop a disclosure statement
 2-40 that clearly discloses to the parent, managing conservator, or
 2-41 guardian of a newborn child subjected to screening tests under
 2-42 Section 33.011:

2-43 (1) that the department or a laboratory established or
 2-44 approved by the department under Section 33.016 may retain for use
 2-45 by the department or laboratory genetic material used to conduct
 2-46 the newborn screening tests and discloses how the material is
 2-47 managed and used subject to this section and Sections 33.0112 and
 2-48 33.018 [33.017]; [and]

2-49 (2) that reports, records, and information obtained by
 2-50 the department under this chapter that do not identify a child or
 2-51 the family of a child will not be released for public health
 2-52 research purposes under Section 33.018(c-1) [33.017(c-1)] unless a
 2-53 parent, managing conservator, or guardian of the child consents to
 2-54 disclosure; and

2-55 (3) that newborn screening blood spots and associated
 2-56 data are confidential under law and may only be used as described by
 2-57 Section 33.018 [33.017].

2-58 (b) The disclosure statement required by Subsection (a)
 2-59 must be included on the form developed by the department to inform
 2-60 parents about newborn screening. The disclosure statement must:

2-61 (1) be in a format that allows a parent, managing
 2-62 conservator, or guardian of a newborn child to consent to
 2-63 disclosure under Section 33.018(c-1) [33.017(c-1)];

2-64 (2) include instructions on how to complete the
 2-65 portions of the form described by Subdivision (1);

2-66 (3) include the department's mailing address; and

2-67 (4) describe how a parent, managing conservator, or
 2-68 guardian of a newborn child may obtain information regarding
 2-69 consent through alternative sources.

3-1 (f) This section does not supersede the requirements
3-2 imposed by Section 33.018 [~~33.017~~].

3-3 (h) Nothing in this section prohibits a physician attending
3-4 a newborn child from delegating the physician's responsibilities
3-5 under this section to any qualified and properly trained person
3-6 acting under the physician's supervision.

3-7 SECTION 4. Section 33.015(a), Health and Safety Code, is
3-8 amended to read as follows:

3-9 (a) Each physician, health authority, birthing facility, or
3-10 other individual who has the information of a confirmed case of a
3-11 disorder for which a screening test is required that has been
3-12 detected by a mechanism other than identification through a
3-13 screening of a specimen by the department's diagnostic laboratory
3-14 shall report the confirmed case to the department.

3-15 SECTION 5. Sections 33.017(b) and (c), Health and Safety
3-16 Code, are amended to read as follows:

3-17 (b) The advisory committee consists of members appointed by
3-18 the commissioner of state health services. The advisory committee
3-19 must include the following members:

3-20 (1) at least four physicians licensed to practice
3-21 medicine in this state, including at least two physicians
3-22 specializing in neonatal-perinatal medicine [~~health care~~
3-23 ~~providers~~];

3-24 (2) at least two [~~a~~] hospital representatives
3-25 [~~representative~~];

3-26 (3) at least two persons who have family members
3-27 affected by a condition for which newborn screening is or may be
3-28 required under this subchapter; and

3-29 (4) at least two health care providers [~~persons~~] who
3-30 are involved in the delivery of newborn screening services,
3-31 follow-up, or treatment in this state.

3-32 (c) The advisory committee shall:

3-33 (1) advise the department regarding strategic
3-34 planning, policy, rules, and services related to newborn screening
3-35 and additional newborn screening tests for each disorder included
3-36 in the list described by Section 33.011(a-1); and

3-37 (2) review the necessity of requiring additional
3-38 screening tests, including an assessment of the test implementation
3-39 costs to the department, birthing facilities, and other health care
3-40 providers.

3-41 SECTION 6. Section 33.0111(g), Health and Safety Code, is
3-42 repealed.

3-43 SECTION 7. As soon as practicable after the effective date
3-44 of this Act, the Department of State Health Services shall
3-45 implement the changes in law made by this Act to the newborn
3-46 screening program under Chapter 33, Health and Safety Code.

3-47 SECTION 8. (a) The change in law made by this Act in
3-48 amending Section 33.017, Health and Safety Code, regarding the
3-49 qualifications of members of the Newborn Screening Advisory
3-50 Committee does not affect the entitlement of a member serving on the
3-51 committee immediately before the effective date of this Act to
3-52 continue to serve as a member of the committee for the remainder of
3-53 the member's term. The change in law applies only to a member
3-54 appointed on or after the effective date of this Act.

3-55 (b) As soon as practicable after the effective date of this
3-56 Act, the commissioner of state health services shall appoint the
3-57 additional committee members required by Section 33.017, Health and
3-58 Safety Code, as amended by this Act.

3-59 SECTION 9. This Act takes effect September 1, 2013.

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