

BILL ANALYSIS

Senate Research Center
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H.B. 740
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Health & Human Services
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Engrossed

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Several years ago, the legislature expanded the scope of newborn screening in Texas to protect the health and welfare of Texas newborns. According to interested parties, the legislation passed at that time was designed to give the Department of State Health Services (DSHS) the flexibility to update the list of disorders for which Texas provides newborn screening as technology improves and the need for additional testing becomes more apparent, noting that DSHS was able to add Severe Combined Immunodeficiency Disorder, or SCID, to the list of disorders in 2012 without the need for additional legislation.

These parties contend that, while critical congenital heart disease (CCHD) was recently added to the Recommended Uniform Screening Panel of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, screening for CCHD involves a type of screening best performed at the hospital or birthing facility where the newborn is delivered. The parties further contend that current law does not give DSHS adequate authority to mandate testing for disorders if that testing occurs outside DSHS's laboratory. H.B. 740 seeks to ensure that DSHS has the flexibility and authority needed to add new disorders to newborn screening requirements in Texas.

H.B. 740 amends current law relating to newborn screening for critical congenital heart disease and other disorders.

[**Note:** While the statutory reference in this bill is to the Texas Department of Health (TDH), the following amendments affect the Department of State Health Services, as the successor agency to TDH.]

RULEMAKING AUTHORITY

This bill does not expressly grant any additional rulemaking authority to a state officer, institution, or agency.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Section 33.001, Health and Safety Code, by amending Subdivision (1) and adding Subdivisions (1-a) and (1-b), to define "birthing facility" and "critical congenital heart disease," and to make a nonsubstantive change.

SECTION 2. Amends Section 33.011, Health and Safety Code, by amending Subsections (a), (a-1), and (c) and adding Subsections (d), (e), and (f), as follows:

(a) Requires the physician attending a newborn child or the person attending the delivery of a newborn child that is not attended by a physician to cause the child to be subjected to screening tests approved by the Texas Department of Health (TDH) for phenylketonuria, other heritable diseases, hypothyroidism, and other disorders for which screening is required by TDH.

(a-1) Requires TDH, except as provided by this subsection and to the extent funding is available for the screening, to require newborn screening tests to screen for disorders listed as core and secondary conditions in the December 2011 Recommended Uniform

Screening Panel of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children or another report determined by TDH to provide more stringent newborn screening guidelines to protect the health and welfare of this state's newborns, rather than to screen for disorders listed in the core panel and in the secondary targets of the uniform newborn screening panel recommended in the 2005 report by the American College of Medical Genetics entitled "Newborn Screening: Toward a Uniform Screening Panel and System" or another report determined by TDH to provide more stringent newborn screening guidelines to protect the health and welfare of this state's newborns.

(c) Requires that the screening tests required by this section, except as provided by Subsection (d), be performed by the laboratory established by TDH or by a laboratory approved by TDH under Section 33.016 (Approval of Laboratories).

(d) Requires TDH, with the advice of the Newborn Screening Advisory Committee (advisory committee), to authorize a screening test for critical congenital heart disease to be performed at a birthing facility that provides care to newborn patients and that complies with the test procedures and the standards of accuracy and precision required by TDH for each screening test.

(e) Requires a birthing facility, if TDH under Subsection (d) authorizes the performance at a birthing facility of a screening test for critical congenital heart disease, to perform the screening test on each newborn who is a patient of the facility before the newborn is discharged from the facility unless:

(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.

(f) Requires TDH, before requiring any additional screening test for critical congenital heart disease, to review the necessity of the additional screening test, including an assessment of the test implementation costs to TDH, birthing facilities, and other health care providers.

SECTION 3. Amends Section 33.0111, Health and Safety Code, by amending Subsections (a), (b), and (f) and adding Subsection (h), as follows:

(a) Requires TDH to develop a disclosure statement that clearly discloses to the parent, managing conservator, or guardian of a newborn child subjected to screening tests under Section 33.011 (Test Requirement):

(1) that TDH or a laboratory established or approved by TDH under Section 33.016 is authorized to retain for use by TDH or laboratory genetic material used to conduct the newborn screening tests and discloses how the material is managed and used subject to this section and Sections 33.0112 (Destruction of Genetic Material) and 33.018 (Confidentiality), rather than subject to this section and Sections 33.0112 and 33.017 (Confidentiality);

(2) that reports, records, and information obtained by TDH under this chapter that do not identify a child or the family of a child will not be released for public health research purposes under Section 33.018(c-1) (relating to authorizing the release of certain information that does not identify a child or the family for public health research purposes under certain circumstances), rather than under Section 33.017(c-1) (relating to authorizing the release of certain information that

does not identify a child or the family for statistical purposes), unless a parent, managing conservator, or guardian of the child consents to disclosure; and

(3) that newborn screening blood spots and associated data are confidential under law and may only be used as described by Section 33.018, rather than as described by Section 33.017.

(b) Requires that the disclosure statement required by Subsection (a), among other requirements, be in a format that allows a parent, managing conservator, or guardian of a newborn child to consent to disclosure under Section 33.018(c-1), rather than under Section 33.017(c-1);

(f) Provides that this section does not supersede the requirements imposed by Section 33.018, rather than by Section 33.017.

(h) Provides that nothing in this section prohibits a physician attending a newborn child from delegating the physician's responsibilities under this section to any qualified and properly trained person acting under the physician's supervision.

SECTION 4. Amends Section 33.015(a), Health and Safety Code, to require each physician, 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 that has been detected by a mechanism other than identification through a screening of a specimen by the TDH's diagnostic laboratory to report the confirmed case to TDH.

SECTION 5. Amends Sections 33.017(b) and (c), Health and Safety Code, as follows:

(b) Requires the advisory committee to include:

(1) at least four physicians licensed to practice medicine in this state, including at least two physicians specializing in neonatal-perinatal medicine, rather than health care providers;

(2) at least two hospital representatives, rather than a hospital representative;

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

(4) at least two health care providers who are involved in the delivery of newborn screening services, follow-up, or treatment in this state, rather than persons who are involved in the delivery of newborn screening services, follow-up, or treatment in this state.

(c) Requires the advisory committee to:

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

(2) review the necessity of requiring additional screening tests, including an assessment of the test implementation costs to TDH, birthing facilities, and other health care providers.

SECTION 6. Repealer: Section 33.0111(g) (providing that a reference in this section to Section 33.017 means Section 33.017, as added by Chapter 179 (H.B. 1672), Acts of the 81st Legislature, Regular Session, 2009), Health and Safety Code.

SECTION 7. Requires the Department of State Health Services, as soon as practicable after the effective date of this Act, to implement the changes in law made by this Act to the newborn screening program under Chapter 33 (Phenylketonuria, Other Heritable Diseases, Hypothyroidism, and Certain Other Disorders), Health and Safety Code.

SECTION 8. (a) Provides that the change in law made by this Act in amending Section 33.017, Health and Safety Code, regarding the qualifications of members of the advisory committee does not affect the entitlement of a member serving on the committee immediately before the effective date of this Act to continue to serve as a member of the committee for the remainder of the member's term. Provides that the change in law applies only to a member appointed on or after the effective date of this Act.

(b) Requires the commissioner of state health services, as soon as practicable after the effective date of this Act, to appoint the additional committee members required by Section 33.017, Health and Safety Code, as amended by this Act.

SECTION 9. Effective date: September 1, 2013.