BILL ANALYSIS

Senate Research Center
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C.S.H.B. 1672
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Health & Human Services
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Committee Report (Substituted)

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

The newborn screening program conducts ongoing tests to improve the identification of genetic newborn disorders that can cause physical and cognitive disabilities or death. Once those disorders are identified, negative outcomes for families can often be averted through proper medical care and nutrition.

All states have newborn screening programs and most are able to share de-identified data on an ongoing basis to facilitate research, enhance quality, and improve the program overall. Currently, Chapter 58 (Use of Genetic Information), Occupations Code, prohibits the sharing of de-identified "genetic information," including newborn screening test results, except in very limited circumstances. Section 58.103 (Exceptions to Confidentiality), Occupations Code, and Section 33.014, Health and Safety Code, provide narrow exemptions from the prohibition on sharing identified genetic information to certain individuals and entities.

As a result of these restrictions, the Department of State Health Services (DSHS) cannot reveal information about the test results to anyone outside of DSHS except the submitter or to a person or company that DSHS has a contract with. Chapter 58, Occupations Code, also prohibits the release of specimens that would inherently disclose test results, but it does not prohibit the release of de-identified random specimens that do not involve an inherent disclosure of any test results. It is impractical to obtain and track written consent for each de-identified piece of information that could help with quality assurance and program improvement because of the volume of newborn screening results (nearly 800,000 per year).

This bill authorizes DSHS to take similar steps to other states and to continue its quality assurance and program improvement activities that requires sharing of de-identified information with other states while continuing to protect the privacy and identity of all newborns.

C.S.H.B. 1672 amends current law relating to newborn screening.

[**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 Subchapter A, Chapter 33, Health and Safety Code, by adding Section 33.0021, as follows:

> Sec. 33.0021. SICKLE-CELL TRAIT. Requires the Texas Department of Health (TDH), notwithstanding any provision of this chapter, to include sickle-cell trait in the detection and treatment program established under this chapter, in the screening for heritable diseases conducted under Subchapter B (Newborn Screening), and the newborn screening services provided under Subchapter C (Newborn Screening Program Services).

SECTION 2. Amends Subchapter B, Chapter 33, Health and Safety Code, by adding Sections 33.0111 and 33.0112, as follows:

Sec. 33.0111. DISCLOSURE. (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); that TDH or a laboratory established or approved by TDH under Section 33.016 (Approval of Laboratories) 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 and that the parent, managing conservator, or guardian is authorized to limit the use of genetic material by providing to TDH in accordance with Section 33.0112 a written statement prohibiting TDH or the laboratory from retaining the genetic material or using the genetic material for any purpose other than the conduct of newborn screening tests authorized under this chapter.

(b) Requires that the disclosure statement required by Subsection (a) be included on the form developed by TDH to inform parents about newborn screening. Requires that the disclosure statement be on a separate sheet of the form; be presented together with the written statement described by Subsection (a)(2) (relating to a written statement prohibiting TDH or laboratory from retaining genetic material) in a format that allows a parent, managing conservator, or guardian of a newborn child to make certain decisions regarding the destruction of genetic material on completion of certain tests; include instructions on how to complete the portions of the form described by Subdivisions (2)(A) (relating to a box or sign indicating a requirement for the department or laboratory to destroy the genetic material on completion of certain tests) and (B) (relating to a box or sign indicating a requirement for the department or laboratory to destroy the genetic material on completion of certain tests); include TDH's mailing address; and be made available to a parent, managing conservator, or guardian of a newborn child through alternative sources.

(c) Requires the physician attending a newborn child or the person attending the delivery of a newborn child that is not attended by a physician, at the time a newborn child is subjected to screening tests under Section 33.011, to provide the parent, managing conservator, or guardian of a newborn child a copy of the written disclosure statement developed by TDH under this section.

(d) Requires TDH to establish procedures for a physician attending a newborn child or the person attending the delivery of a newborn child to provide verification to TDH that the physician or person has provided the parent, managing conservator, or guardian of the newborn child the disclosure required under this section.

Sec. 33.0112. STATEMENT PROHIBITING RETENTION OF GENETIC MATERIAL. (a) Authorizes a parent, managing conservator, or guardian of a newborn child to file with TDH a signed written statement prohibiting TDH or a laboratory established or approved by TDH from retaining any genetic material related to the newborn screening tests conducted under this chapter or using the genetic material for any purpose other than the conduct of the newborn screening tests. Authorizes a parent, managing conservator, or guardian to file the written statement on a form provided by TDH.

(b) Requires TDH or the laboratory, not later than the 60th day after TDH receives the written statement, to destroy the genetic material used in the screening tests.

(c) Authorizes an adult individual to file with TDH a written statement instructing TDH or a laboratory established or approved by TDH to destroy any genetic material of the individual that is retained and used under this chapter.

SECTION 3. Amends Subchapter B, Chapter 33, Health and Safety Code, by adding Section 33.017, as follows:

Sec. 33.017. CONFIDENTIALITY. (a) Provides that reports, records, and information obtained or developed by TDH under this chapter are confidential and are not subject to disclosure under Chapter 552 (Public Information), Government Code, are not subject to subpoena, and are prohibited from otherwise being released or made public except as provided by this section.

(b) Authorizes reports, records, and information obtained or developed by TDH under this chapter, notwithstanding other law, to be disclosed for purposes of diagnosis or follow-up authorized under Section 33.014; with the consent of each identified individual or an individual authorized to consent on behalf of an identified child; as authorized by court order; to a medical examiner authorized to conduct an autopsy on a child or an inquest on the death of a child; or to public health programs of TDH for public health research purposes provided that the disclosure is approved by an institutional review board or privacy board of TDH as authorized by the federal privacy requirements adopted under the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191) contained in 45 C.F.R. Part 160 and 45 C.F.R. Part 164, Subparts A and E.

(c) Authorizes reports, records, and information that do not identify a child or the family of a child, notwithstanding other law, to be released without consent if the disclosure is for statistical purposes; purposes related to obtaining or maintaining certification, approval, or quality assurance for TDH's laboratory or a public or private laboratory to perform newborn screening tests; purposes relating to review, quality assurance, or improvement of TDH's newborn screening under this subchapter or TDH's newborn screening program services under Subchapter C; research purposes, provided that the disclosure is approved by an institutional review board or privacy board of TDH; or quality assurance related to equipment and supplies, provided that certain qualifications are met.

(d) Prohibits a state officer or employee, a TDH contractor, or TDH contractor's employee, officer, director, or subcontractor from being examined in a civil, criminal, special, or other judicial or administrative proceeding as to the existence or contents of records, reports, or information made confidential by this section unless disclosure is authorized by this section.

SECTION 4. (a) Requires the speaker of the house of representatives to charge a committee of members selected by the speaker or a house standing committee to conduct an interim study on newborn screening in this state.

(b) Requires the committee designated under Subsection (a) of this section to study the time frame and procedures for the disclosure required by Chapter 33 (Phenylketonuria, Other Heritable Diseases, Hypothyrodism, and Certain Other Disorders), Health and Safety Code, to the parent, managing conservator, or guardian of a newborn child; analyze whether procedures should be developed by the Department of State Health Services (DSHS) to provide confirmation to a parent, managing conservator or guardian of a newborn child that a stored specimen has been destroyed as required by a written statement submitted by the parent, managing conservator, or guardian; and study standardization of the disclosure process for health care facilities in this state.

(c) Requires the committee designated under Subsection (a) of this section, not later than December 15, 2010, to file a report on the results of the interim study conducted under this section with both houses of the legislature.

SECTION 5. Requires DSHS, as soon as practicable after the effective date of this Act, to implement Section 33.0021, Health and Safety Code, as added by this Act.

SECTION 6. Requires DSHS, as soon as practicable after the effective date of this Act, to develop the disclosure statement required by Section 33.0111, Health and Safety Code, as added by this Act. Requires DSHS to modify an existing form for use for purposes of that section.

SECTION 7. Effective date: upon passage or September 1, 2009.