BILL ANALYSIS

C.S.H.B. 1672
By: Crownover
Public Health
Committee Report (Substituted)

BACKGROUND AND PURPOSE

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 these 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, Occupations Code, prohibits the sharing of de-identified "genetic information," including newborn screening test results, except in very limited circumstances. Section 58.103, Occupations Code, and Section 33.014, Health and Safety Code, provide narrow exemptions from the prohibition on sharing de-identified genetic information to certain individuals and entities.

As a result of these restrictions, the Department of State Health Services cannot reveal information about the test results to anyone outside of the department except the submitter or to a person or company that the department 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). Parents can also decline testing for religious reasons.

C.S.H.B. 1672 authorizes the department to take similar steps as the other states and to continue its quality assurance and program improvement activities that require sharing of de-identified information with other states while continuing to protect the privacy and identity of all newborns.

RULEMAKING AUTHORITY

It is the committee's opinion that this bill does not expressly grant any additional rulemaking authority to a state officer, department, agency, or institution.

ANALYSIS

C.S.H.B. 1672 amends the Health and Safety Code to require the Department of State Health Services to develop a disclosure statement that discloses to the parent, managing conservator, or guardian of a newborn child subjected to newborn screening tests that genetic material used to conduct the newborn screening tests may be retained for use by the department or a laboratory approved by the department, and that the parent, managing conservator, or guardian is authorized to limit that use by providing to the department a written statement prohibiting the department or laboratory from retaining the genetic material. The bill 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, to provide the parent, managing conservator, or guardian of a newborn child a copy of the disclosure statement.

C.S.H.B. 1672 authorizes a parent, managing conservator, or guardian of a newborn child to file with the department a written statement prohibiting the department or a laboratory established or approved by the department from retaining any genetic material related to the newborn screening tests. The bill requires the department or laboratory to destroy the genetic material used in the screening tests not later than the 60th day after the department receives the written statement.

C.S.H.B. 1672 exempts reports, records, and information obtained or developed by the department relating to newborn screening information from disclosure under open records provisions and from being subject to subpoena and prohibits that information from otherwise being released or made public except as provided by the bill.

C.S.H.B. 1672 authorizes newborn screening information to be disclosed: for purposes of diagnosis or follow-up; 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 the department for public health research purposes provided that the disclosure is approved by an institutional review board or privacy board of the department as authorized by the privacy requirements adopted under the federal Health Insurance Portability and Accountability Act of 1996.

C.S.H.B. 1672 authorizes newborn screening information to be released without consent if the disclosure is for statistical purposes; purposes related to obtaining or maintaining certification, approval, or quality assurance for the department's laboratory or a public or private laboratory to perform newborn screening tests; purposes relating to review, quality assurance, or improvement of the department's newborn screening or the department's newborn screening program services; research purposes, provided that the disclosure is approved by an institutional review board or privacy board of the department; or quality assurance related to equipment and supplies, provided that the assessment is performed by a person who is not in a laboratory, only newborn screening specimens are disclosed, and the disclosure is approved by an institutional review board or privacy board of the department.

C.S.H.B. 1672 prohibits a state officer or employee, a department contractor, or 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 these provisions unless disclosure is authorized.

C.S.H.B. 1672 requires the department to develop the disclosure statement as soon as practicable after the effective date of the bill and authorizes the department to modify an existing form for use in developing the disclosure statement.

EFFECTIVE DATE

On passage, or, if the act does not receive the necessary vote, the act takes effect September 1, 2009.

COMPARISON OF ORIGINAL AND SUBSTITUTE

C.S.H.B. 1672 differs from the original by adding the requirement that the Department of State Health Services develop a disclosure statement about the retention by the department or a laboratory of genetic material used to conduct newborn screening tests. The substitute differs from the original by adding the authorization for a parent, managing conservator, or guardian to limit the use of the genetic material by providing to the department a written statement prohibiting the department or laboratory from retaining the genetic material and adds the

requirement that the department or laboratory destroy the genetic material within 60 days of receiving this statement. The substitute differs from the original by adding the requirement that the physician attending a newborn child or the person attending the delivery of a newborn child that is not attended by a physician provide a copy of the disclosure statement to the parent, managing conservator, or guardian of a newborn child.

C.S.H.B. 1672 differs from the original by adding the requirement that the department develop the disclosure statement as soon as practicable after the effective date of the bill and adds the authorization for the department to modify an existing form for use in developing the disclosure statement.