

BILL ANALYSIS

Senate Research Center

C.S.H.B. 411
By: Laubenberg, Crownover (Deuell)
Health & Human Services
5/17/2011
Committee Report (Substituted)

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

This legislation clarifies issues relating to the Newborn Screening Program by providing for increased management approval on handling records, notifying the public of the use of these records via the Internet, and preventing these records from being used in forensic science or insurance underwriting.

H.B. 1672, enacted by the 81st Legislature and authored by Representative Crownover, provides parents with an opportunity to have the newborn screening samples destroyed and used for no other purpose than screening. If the parents do not ask for the sample to be destroyed the laboratory may keep it for other uses, but must report how the sample is used. Current law allows for disclosing records for statistical purposes, laboratory maintenance, and other research projects with the approval of the institutional review board.

This bill requires that the commissioner of the Department of State Health Services (commissioner; DSHS) as well as the institutional review board to approve a sample's use in public health programs and any other public health testing procedures. The approved uses must be documented on the newborn screening page of DSHS's website. When the records are used directly in maintaining the Newborn Screening Program, or when they will stay in DSHS's laboratory, approval is not required. The sample can be used for quality assurance purposes related to public health testing equipment as long as it is approved by the commissioner and an institutional review board. Records that do not identify a child may be released as long as parents, the commissioner, and the institutional review board approve. The commissioner can approve of disclosure only for public health purposes and not for the use of screening information in forensic science cases or health insurance underwriting. The institutional review board must include three people not affiliated with a health agency and one must be a member of the public.

C.S.H.B. 411 amends current law relating to the confidentiality of newborn screening information.

[**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 33.017, Health and Safety Code, as added by Chapter 179 (H.B. 1672), Acts of the 81st Legislature, Regular Session, 2009, by amending Subsections (a), (b), and (c) and adding Subsections (a-1), (c-1), (e), (f), (g), (h), and (i), as follows:

(a) Defines, in this section, "affiliated with a health agency," "commission," "commissioner," "health agency," and "public health purpose."

(a-1) Creates this subsection from existing text. Makes no further changes to this subsection.

(b) Authorizes reports, records, and information obtained or developed by the Texas Department of Health (TDH) under this chapter, notwithstanding other law, to be disclosed, under certain conditions, including to public health programs of TDH for public health research purposes, provided that the disclosure is approved by the commissioner of state health services (commissioner) or the commissioner's designee, and 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:

(1) statistical purposes;

(2) purposes related to obtaining or maintaining federal certification, including related quality assurance for TDH's laboratory, or a public or private laboratory to perform newborn screening tests that are not part of inter-laboratory exchanges required for federal certification of TDH's laboratory, provided that the disclosure is approved by the commissioner or the commissioner's designee;

(3) purposes relating to review or quality assurance of TDH's newborn screening under this chapter or TDH's newborn screening program services under Subchapter C (Newborn Screening Program Services); or improvement of TDH's newborn screening under this chapter or TDH's newborn screening program services under Subchapter C, provided that the disclosure is approved by the commissioner or the commissioner's designee; or

(4) other quality assurance purposes related to public health testing equipment and supplies, provided that the disclosure is approved by the commissioner or the commissioner's designee; and an institutional review board or privacy board of TDH or quality assurance related to equipment and supplies, provided that the assessment is performed by a person who is not a laboratory, only newborn screening specimens are disclosed, and the disclosure is approved by an institutional review board or privacy board of TDH.

Deletes existing text providing that reports, records, and information that do not identify a child or the family of a child, notwithstanding other law, 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 chapter or the department'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 the department; or quality assurance related to equipment and supplies, provided that the assessment is performed by a person who is not a laboratory and only newborn screening specimens are disclosed, and the disclosure is approved by an institutional review board or privacy board of TDH.

(c-1) Authorizes reports, records, and information that do not identify a child or the family of a child, notwithstanding other law, to be released for public health research purposes if:

(1) a parent of the child consents to the disclosure; and

(2) the disclosure is approved by an institutional review board or privacy board of TDH, and the commissioner or the commissioner's designee.

(e) Requires TDH, if disclosure is approved by the commissioner or the commissioner's designee under Subsection (c)(4) or (c-1), to post notice on the newborn screening web page on TDH's Internet website that disclosure has been approved. Requires the commissioner to determine the form and content of the notice.

(f) Provides that in accordance with this section, the commissioner or the commissioner's designee is authorized to approve disclosure of reports, records, or information obtained or developed under this chapter only for a public health purpose; and is prohibited from approving disclosure of reports, records, or information obtained or developed under this chapter for purposes related to forensic science or health insurance underwriting.

(g) Requires an institutional review board or privacy board of TDH that approves disclosure under this section to include at least three persons who are not affiliated with a health agency, one of whom must be a member of the public.

(h) Authorizes the requirement that consent be obtained before certain disclosures of reports, records, or information to be made under this section does not affect the requirement that screening tests be performed under Section 33.011 (Test Requirement).

(i) Provides that if a parent of a child consents to disclosure under this section a parent of the child is authorized to revoke the consent, in whole or in part, at any time, and the child is authorized to revoke the consent, in whole or in part, at any time on or after the date the child attains the age of majority.

SECTION 2. (a) Effective date, except as provided by Subsection (b) of this section: upon passage or September 1, 2011.

(b) Effective date, Section 33.017(c-1), Health and Safety Code, as added by this Act: June 1, 2012.