

## **BILL ANALYSIS**

C.S.H.B. 411  
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Public Health  
Committee Report (Substituted)

### **BACKGROUND AND PURPOSE**

Currently, there is a process for parents to have a child's blood spots, which were collected in the newborn screening process, destroyed. However, the state still may keep blood spots when parents have not denied permission for retention. C.S.H.B. 411 attempts to increase oversight of disclosure of newborn screening information and the use of certain newborn screening information.

### **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. 411 amends Section 33.017, Health and Safety Code, as added by Chapter 179 (H.B. 1672), Acts of the 81st Legislature, Regular Session, 2009, to include approval by the commissioner of state health services or the commissioner's designee as a condition required for the disclosure of newborn screening information to public health programs of the Department of State Health Services (DSHS) for public health research purposes. The bill clarifies that the authorization to disclose nonidentifying newborn screening information without consent, for purposes relating to obtaining or maintaining federal certification, because the disclosure is for newborn screening tests performed by a public or private laboratory, applies to tests that are not part of inter-laboratory exchanges required for federal certification of the department's laboratory if the disclosure is approved by the commissioner of state health services or the commissioner's designee.

C.S.H.B. 411 removes obtaining or maintaining approval for certain laboratories from the purposes for which nonidentifying newborn screening information is authorized to be disclosed without consent. The bill adds to the purposes of such disclosure improvement of the department's newborn screening tests or the department's newborn screening program services, if the disclosure is approved by the commissioner or the commissioner's designee. The bill clarifies that the disclosure of nonidentifying newborn screening information authorized for quality assurance purposes applies to public health testing equipment and supplies. The bill revises the conditions under which a disclosure for quality assurance purposes is allowed to remove a condition allowing the disclosure if an assessment is performed by a person who is not a laboratory and the condition limiting that disclosure to newborn screening specimens. The bill requires approval by the commissioner or the commissioner's designee, in addition to an institutional review board or privacy board of DSHS, as a condition of disclosure for quality assurance purposes. The bill removes a provision including research purposes approved by an institutional review board or privacy board of DSHS among the purposes for which nonidentifying newborn screening information may be disclosed without consent and authorizes such information to be released for public health research purposes if a parent of the child consents to the disclosure and the disclosure is approved by such a review or privacy board and the commissioner or the commissioner's designee.

C.S.H.B. 411 requires DSHS to post notice on the newborn screening web page on the department's Internet website of a disclosure for public health research purposes or certain quality assurance purposes that has been approved by the commissioner or the commissioner's designee and requires the commissioner to determine the form and content of the notice. The bill authorizes the commissioner or the commissioner's designee to approve disclosure of newborn screening reports, records, or information only for a public health purpose and prohibits the commissioner or designee from approving disclosure of such newborn screening information for purposes related to forensic science or health insurance underwriting.

C.S.H.B. 411 requires an institutional review board or privacy board of DSHS that approves disclosure of newborn screening information to include at least three persons who are not affiliated with a state health agency, one of whom must be a member of the public. The bill specifies that the requirement for consent to be obtained before certain disclosures of reports, records, or information relating to newborn screening may be made does not affect the requirement that newborn screening tests be performed.

C.S.H.B. 411 defines "affiliated with a health agency," "commission," "commissioner," and "health agency" and defines "public health research purpose" to mean a research purpose that relates to cancer, an infectious disease, or a newborn screening disease. The bill makes conforming changes.

#### **EFFECTIVE DATE**

On passage, or, if the bill does not receive the necessary vote, September 1, 2011.

#### **COMPARISON OF ORIGINAL AND SUBSTITUTE**

C.S.H.B. 411 includes provisions not included in the original defining "affiliated with a health agency," "commission," "health agency," and "public health research purpose." The substitute differs from the original by removing a provision of law including research purposes among the purposes for which nonidentifying newborn screening information may be disclosed without consent, whereas the original amends that provision to limit the research purposes for which such information may be disclosed without consent to public health research purposes and adds approval by the commissioner of state health services as a condition of such a disclosure. The substitute differs from the original, in the bill provision requiring approval by the commissioner as a condition of disclosure of nonidentifying newborn screening information for quality assurance purposes, by including the commissioner's designee as a person authorized to approve the disclosure. The substitute contains a provision not included in the original authorizing nonidentifying information to be disclosed for public health research purposes if a parent of the child consents to the disclosure and the disclosure is approved by certain persons and entities.

C.S.H.B. 411 contains a provision not included in the original requiring an institutional review board or privacy board of the Department of State Health Services that approves disclosure to include certain unaffiliated persons. The substitute contains a provision not included in the original specifying that the requirement that consent be obtained before certain disclosures of reports, records, or information may be made does not affect the requirement that newborn screening tests be performed. The substitute differs from the original by making conforming and nonsubstantive changes.