SUBJECT: Revising confidentiality requirements for newborn blood screening

COMMITTEE: Public Health — committee substitute recommended

VOTE: 7 ayes — Kolkhorst, Alvarado, S. Davis, V. Gonzales, Laubenberg, Schwertner, Truitt

0 nays

4 absent — Naishtat, Coleman, S. King, Zerwas

WITNESSES: For — (*Registered, but did not testify:* Troy Alexander, Texas Medical Association; Ann Hettinger, Tonja Michelle Smith, Concerned Women for America of Texas; Jonathan Saenz, Liberty Institute)

Against — James Harrington, Texas Civil Rights Project; Deborah Peel, Patient Privacy Rights; (*Registered, but did not testify:* Katherine Johnson, Patient Privacy Rights)

On — Susan Tanksley, Department of State Health Services

BACKGROUND: The Health and Safety Code, sec. 33.011 requires a physician to perform newborn screening tests to detect specific medical disorders. Parents may opt out of the screening tests for religious reasons. The Department of State Health Services (DSHS) has retained blood samples from newborn screenings since 2002 for agency-authorized purposes, including laboratory quality-control testing and approved public health research. In 2009, the 81st Legislature enacted legislation requiring DSHS to develop a disclosure form to inform parents about the agency's retention and use of the blood samples. The disclosure statement must provide parents with information about how they could order the destruction of their child's genetic materials when samples no longer were needed for screening.

DIGEST: CSHB 411 would require the approval of the DSHS commissioner or the commissioner's designee before a newborn's screening information could be disclosed for public health research purposes. A public health research purpose would be defined as a research purpose relating to cancer, an infectious disease, or a newborn screening disease.

Information that did not identify the child or family could be released for public health research purposes if the parent consented and the disclosure was approved by the commissioner and the institutional review board (IRB) or privacy board. The IRB or privacy board would have to include at least three individuals who were not affiliated with a health agency, including one member of the general public.

The DSHS could disclose information that did not identify a child without the parent's consent if the disclosure was used to:

- obtain or maintain federal certification, including related quality assurance, for a DSHS laboratory;
- obtain or maintain federal certification, including related quality assurance, for a public or private laboratory to perform tests that were not part of inter-laboratory exchanges required for federal certification, if approved by the commissioner;
- review or assure the quality of the newborn screening program;
- improve the quality of the newborn screening program services, if approved by the commissioner; or
- perform other quality assurance functions related to public health testing equipment and supplies, if approved by the commissioner and the IRB or privacy board.

The commissioner could approve disclosure of the information only for a public health purpose and not for purposes related to forensic science or health insurance underwriting. If the commissioner approved the disclosure, DSHS would have to post notice of this on its website.

The changes made to the Health and Safety Code through CSHB 411 would only affect the disclosure of the information collected through the newborn screening program, and would not change the testing requirements of the program.

The bill would take immediate effect if finally passed by a two-thirds record vote of the membership of each house. Otherwise, it would take effect September 1, 2011.

SUPPORTERS SAY:

CSHB 411 would establish an informed consent or "opt-in" process for parents before an infant's blood sample could be retained for any purpose other than screening. Research suggests that most parents would like to promote public health research, but many parents have no idea that their child's genetic material is being retained or how the material is being used. The bill would strengthen the statutory confidentiality and transparency standards required by DSHS to protect parents who are concerned about the storage and use of genetic material.

The bill would protect families' privacy by placing tight restrictions on how the blood samples could be used. The data obtained from the blood spots are incredibly valuable to individuals or companies who could misuse the information for monetary gain. CSHB 411 would permit only external use of the blood samples for public health research and would ban the use of these blood samples for purposes related to forensics or health insurance underwriting.

The privacy concerns expressed by parents have resulted in lawsuits against DSHS. The agency has worked hard to address many of these concerns and increase stakeholder participation by establishing the Newborn Screening Advisory Committee and revamping policies pertaining to the newborn screening data. CSHB 411 would increase public participation and transparency by requiring DSHS to post a notice on the agency's website for the newborn screening program with details about the date of approval and intended use of samples. The bill also would require the agency to restructure the IRB to include at least three individuals who were unaffiliated with a health agency, one of whom would have to be a member of the general public. These efforts should help to reduce the risk of future lawsuits against DSHS.

Ultimately, CSHB 411 would help to balance the need for greater transparency and parental involvement in deciding how DSHS should manage genetic material with preserving the critical benefits to individuals and society that are provided through the newborn screening program.

OPPONENTS SAY:

The "opt-in" provision for the storage and use of de-identified data under CSHB 411 would jeopardize the nation's largest sample of de-identified newborn genetic material in the country. Current law permits DSHS to store and use the genetic material from the newborn screening tests for limited purposes, but parents may opt out of this storage process if they object. These samples are critical to the future of our health care system

because the research conducted with the data has made invaluable breakthroughs in public health and biomedical research. The newborn screening data already have tremendously impacted how we understand and combat devastating diseases like cancer, childhood leukemia, and HIV. Parents may become alarmed by the disclosure form and opt out of the storage and use provision of the program, which could negatively impact the amount of data collected and limit future research.

The extensive process to develop, collect, and track consent forms that would be required by CSHB 411 would increase DSHS's workload and costs as the agency struggles with fewer staff and resources. With the budgetary challenges facing this state, asking an overstretched agency to do more with less would be unfair.

OTHER OPPONENTS SAY:

The "opt-in" disclosure requirement would help to improve privacy protections, but the language in CSHB 411 would not clearly define whether or not informed consent must be obtained each time information from the blood sample would be used. Parents and individuals have a right to know how the genetic information is being used, and the bill in its current form would not provide this assurance.

CSHB 411 would not address key concerns regarding how data could be handled after disclosure. Many parents who provide informed consent believe that their child's genetic material could only be used for internal use or public health research, but there is no guarantee that the information would not be sold or redistributed by a third party. To fully protect the child's confidentiality, the bill should include stronger language that would restrict the resale or reuse of newborn screening samples or datasets.

The bill would make no attempt to define "de-identification" or place restrictions on the type of information that could remain in a dataset. Individuals who provide informed consent believe that the genetic material collected will be stripped of the identifiable information and combined in a larger dataset, protecting their anonymity. Yet advancements in technology and modeling techniques could permit bad actors to "re-identify" an individual's blood sample and reveal that information.

While CSHB 411 would require DSHS to post information about disclosures on their Web site, the information that would be required represents a fraction of how the blood samples would be used. To achieve

real transparency, DSHS would have to require the public notice of all blood sample disclosures, even for internal use. CSHB 411 could be improved by requiring more statutory guidance on how the newborn screening page should look and by specifying the type of information that should be posted.

While the bill would help to improve the composition of the IRB by requiring involvement from outside the agency, DSHS still would continue to control more positions on the board. This would allow the agency to ignore any potential opposition to the disclosure of blood samples in the future.

NOTES:

The committee substitute differs from the original version of the bill n defining "public health research purpose" as research relating to cancer, an infectious disease, or a newborn screening disease.

The committee substitute added language specifying that DSHS could release de-identified data for public health research only if the agency received informed consent of a parent, rather than permitting the release of the information for public health research without informed consent. The original bill did not include provisions requiring the approval of the agency's commissioner or designee.

The committee substitute added a requirement to change the composition of the IRB and added language to maintain the current testing requirements for the newborn screening program.

The Senate companion, SB 507 by Deuell, has been referred to the Senate Health and Human Services Committee.