

- SUBJECT:** Disclosure about and retention of newborns' genetic material
- COMMITTEE:** Public Health — committee substitute recommended
- VOTE:** 8 ayes — Kolkhorst, Naishtat, Coleman, J. Davis, Gonzales, Hopson, McReynolds, Zerwas
- 0 nays
- 3 absent — S. King, Laubenberg, Truitt
- WITNESSES:** For — Charleta Guillory, March of Dimes, Texas Pediatric Society, Texas Medical Association, Texas Academy of Family Physicians; (*Registered, but did not testify*: Kristen Doyle, Leukemia and Lymphoma Society; Merrylynn Gerstenschlager, Texas Eagle Forum)
- Against — None
- On — Susan Tanksley, Texas Department of State Health Services
- BACKGROUND:** Texas requires all newborns to be screened, via a heel-prick collection of a blood sample, for 26 inherited diseases and hypothyroidism within 48 hours of birth and a second time at the two-week newborn check-up. Parents with a religious objection to the testing may decline it. The physician or other person attending the delivery of a child collects and submits the newborn's blood for screening.
- The Department of State Health Services (DSHS) has retained the genetic material from newborn screenings since 2002 for agency-authorized purposes, including lab quality-control testing and approved health research. Each retained specimen is "de-identified" by assigning a number to that specimen, and any personally identifiable information about the newborn from whom the specimen was obtained is included in a database – accessible only by DSHS employees – that links this information to the specimen identification number.
- Requests to conduct research using the retained genetic material are reviewed by a DSHS employee, and, if approved, are forwarded to a

DSHS Internal Review Board, which follows federal guidelines to determine if the research may be conducted.

DIGEST:

CSHB 1672 would direct DSHS to develop a disclosure statement to be distributed to the newborn's parent, guardian, or managing conservator. The disclosure statement would have to state that DSHS, or a lab that conducts newborn screening on behalf of the agency, could retain the genetic material obtained from the newborn screening. It also would have to inform the parent, guardian, or managing conservator that he or she could submit a written request to DSHS prohibiting the department from retaining the child's genetic material. This disclosure would be provided to the parent by the physician or other person attending a child's birth.

DSHS would be required to destroy a child's genetic material by the 60th day after DSHS received a request to prohibit the retention of this material.

Reports, records, and information related to genetic material collected for a newborn screening would not be subject to disclosure under public records provisions and would not be subject to subpoena. This information could be released only under the following circumstances:

- for diagnosis if a newborn screening indicated the child could have one of the disorders for which the screening was run;
- with consent of an individual authorized to consent on behalf of the child;
- when authorized by court order;
- when needed by a medical examiner authorized to conduct an autopsy or inquest on the death of a child; or
- as dictated by DSHS for use in public health research if the research has been approved by an institutional review or privacy board as authorized by federal privacy requirements.

Reports, records, and information that did not identify the child or the child's family could be released, without consent, for:

- statistical purposes;
- quality control and other review of the newborn screening program;

- purposes related to maintaining operations, conducting quality control, or performing other review functions at labs conducting newborn screenings;
- research purposes, provided that the disclosure was approved by a DSHS institutional review or privacy board; or
- certain authorized quality assurance measures related to lab equipment and supplies.

Officers or employees of the state or a DSHS contractor or subcontractor could not be examined in judicial or administrative proceedings about the existence or contents of records, reports, or other information made confidential by CSHB 1672 unless otherwise authorized by the bill.

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, 2009. DSHS would have to develop the disclosure statement as soon as practicable after the effective date of the bill.

**SUPPORTERS
SAY:**

CSHB 1672 would require disclosure to parents that genetic material collected for health-critical newborn screenings will be retained by DSHS following testing. It also would provide a straightforward method by which parents could direct DSHS to destroy their child's genetic material so it could not be used for future research. The bill would put in statute the stringent confidentiality standards that DSHS already applies to the use of retained genetic material.

Research on the "de-identified" genetic material retained following newborn screenings can lead to breakthroughs in the treatment and prevention of conditions such as autism and premature birth and can assist in other disease research such as cancer. The material retained by DSHS is uniquely critical for such research because DSHS maintains the largest sample of de-identified newborn genetic material in the nation.

While research using this genetic material, which DSHS already retains, may serve an invaluable public health purpose, CSHB 1672 would acknowledge that some parents have personal concerns about the retention of their child's genetic material and would make the retention and use of this material more transparent. Even if parents did not have immediate concerns prompting them to request destruction of their child's genetic material, CSHB 1672 would allow a parent to submit such a request if concerns arose at a future date.

The disclosure process required in CSHB 1672 would not cost the state anything and would be the most efficient method of disclosing the genetic material retention policy. The disclosure could be developed this summer in conjunction with DSHS's planned development of other forms, and it could be distributed with the other materials already provided to newborns' parents.

Proposals requiring an informed consent process – disclosing information to parents directly, requiring parents to sign a consent form, and then sending signed consent forms to DSHS – would be unnecessarily burdensome and very costly to the state and health providers. DSHS would have to carry out an extensive process to develop the consent form, a system for consent form submission, and a system to store the forms and track whether a parent had granted consent. The associated costs would be particularly unnecessary in light of current privacy safeguards as well as those included in CSHB 1672. Not only is all personally identifiable information removed from the specimens, but only DSHS staff has access to the personal information database, and the research request process is structured to protect confidentiality.

In addition, the elaborate nature of a consent process could cause alarm among parents who previously would not have been concerned about retention of the genetic material. Such alarm could cause a disproportionate number of parents to decline consent, which could negatively impact the amount of data collected.

The genetic material legally obtained through the newborn screening program meets the definition of a state record as machine-readable information received on behalf of a state agency. As such, this material may be retained for an appropriate amount of time as dictated by state records retention statutes. Despite this fact, some have expressed concerns that the retention constitutes an unlawful search and seizure in violation of the Fourth Amendment of the U.S. Constitution. Such concerns are unfounded because passive consent to retention of the materials would be implicit when parents knew that they could request that the genetic material be destroyed, but did not.

DSHS's retention policies for the genetic material obtained from newborn screenings are in line with other states. A study by the Centers for Disease Control issued in 2006 found that about half of states store genetic material from newborn screenings for over six months, and only

16 percent inform parents that the genetic material might be retained. The requirements of this bill would place Texas in the minority of states that take the extra step to inform parents about retention of genetic material.

OPPONENTS
SAY:

Although CS HB 1672 would improve existing law by requiring DSHS to inform parents about retention of newborn genetic material, it would not ensure that all parents were aware of the retention process and how to prohibit use of their child's genetic material. Because CS HB 1672 would not require parents to sign a form acknowledging that they understood and submitted to DSHS's retention of genetic materials, there would be no way to verify that all parents were provided the disclosure and made aware of the policy.

Though a parent may feel comfortable with the permitted uses of retained genetic material in CS HB 1672, the Legislature could expand the permissible use of this material in future years in ways that a parent would not deem acceptable. The "opt-out" disclosure policy in this bill would afford no way to confirm that a parent received a copy of the disclosure statement. Some providers could fail to give the disclosure, and parents would not learn that their child's genetic material was subject to uses of which they may not approve.

By using an informed consent or "opt-in" process, there would be no question about whether a parent was aware that genetic material was retained. With a consent form, parents could indicate through signed acknowledgment that they understood and consented to the retention policies and possible uses of genetic materials.

Further, a lawsuit recently was filed against DSHS in the U.S. district court in San Antonio in which the plaintiffs — five parents of newborns whose genetic material was collected and retained — alleged that DSHS's retention of newborn genetic material violated the Fourth Amendment's prohibition against unlawful search and seizure when their children's confidential genetic information was taken and stored without their consent.

In enacting the CS HB 1672 approach of "opting-out" of genetic material retention, with no way to verify that a parent received the disclosure statement, as opposed to the "opt-in" approach of informed consent, the Legislature would be affirming in statute a contestable moral judgment that the potential for some measure of public good supersedes the privacy

concerns of an individual. If the public health outcomes of the research conducted on retained genetic material are considered valuable, then it should be worth the cost and extra administrative process to ensure that privacy concerns are protected.

NOTES:

The bill as filed did not include the committee substitute's requirement that DSHS develop and health professionals provide to new parents and guardians a disclosure statement about the retention of the genetic material obtained in newborn screening nor the provision for parents to request that their child's retained genetic material be destroyed.

The companion bill, SB 2421 by Deuell, has been referred to the Senate Health and Human Services Committee.