

SUBJECT: Revising consent for inclusion in the state immunization registry

COMMITTEE: Public Health — committee substitute recommended

VOTE: 8 ayes — Capelo, Laubenberg, Dawson, McReynolds, Naishtat, Taylor, Truitt, Zedler

0 nays

1 absent — Coleman

WITNESSES: For — Julie Boom, M.D., Texas Pediatric Society; Jamie Fergie, Texas Medical Association; Frankie Lynn Milley; Mike Pollard, Texas Association of Life and Health Insurers; (*Registered, but did not testify:*) Tom Banning, Texas Academy of Family Physicians; Melody Chatelle, Children's Hospitals and Related Institutions of Texas; Carrie Coleman, Texas Association of Health Plans; Robert Feather, Cook Children's Health Care System; Aron Head, Amerigroup Texas, Inc, Greg Hoke, Wyeth Vaccines; Susan Craven, Texans Care for Children; Holly Jacques, Merck & Co.; Mazie Jamison, Children's Medical Center of Dallas; Carrie Kroll, Texas Pediatric Society; Gaspar, Laca, GlaxoSmithKline; Laurie Reece, Texas Transplantation Society; Bryan Sperry, Children's Hospital Association of Texas; Rosie Valadez McStay, Texas Children's Hospital; James Willmann, Texas Nurses Association; Lynda Woolbert, Coalition for Nurses in Advanced Practice; Ana Yanez-Correa, LULAC Texas; and three private citizens.

Against — Dawn Richardson, PROVE; and three private citizens; (*Registered, but did not testify:*) Merry Lynn Gerstenschlager, Texas Eagle Forum; and Ken Clark.

On — Sharilyn Stanley, M.D., Texas Department of Health.

BACKGROUND: ImmTrac is the statewide immunization registry for children from birth to age 18 established under Health and Safety Code, sec. 161.007. This section outlines reporting requirements for providers and insurance companies and stipulates that the Texas Department of Health (TDH) is required to protect the confidentiality of patients in the registry, to disclose information only with

the written consent of the child's parent, and permit a parent to withdraw consent for a child to be included in the registry. TDH can use the immunization registry to control and prevent communicable diseases, including sending reminder notices to parents or guardians about future shots. Anyone, including a health care provider, who submits or obtains a good faith immunization history is not liable for any civil damages.

Health and Safety Code, sec. 161.008 permits TDH to obtain an immunization record from a public health district, local health department, or the child's physician, with the consent of a child's parent or guardian, and release the record to one of those groups, or a school or child care facility. Under sec. 161.009, a person can be held criminally liable for negligently releasing or disclosing information in the database for an unauthorized use or using the information to solicit new patients or clients.

DIGEST:

CSHB 1921 would amend the regulation of the immunization registry, requiring consent only once, adding additional protection for the information, permitting providers to use the registry for reminders, and requiring a new report on immunizations and the registry.

It would amend ch. 161.007 of the Health and Safety Code to require written consent for the immunization registry only once. It would make consent valid until the child turned 18 years old, unless withdrawn in writing. It also would permit the parent or guardian to consent to the registry by an electronic signature on the child's birth certificate. Upon receipt of initial consent, TDH would be required to send a disclosure to the parent or guardian informing them that the immunization record could be included in the registry, as well as information about the registry, including who could access the information and how to have records removed.

The bill specifically would prohibit TDH from retaining individually identifiable information about a person for whom consent was withdrawn or for whom consent could not be verified. The information would be required to be deleted within 30 days of notice that consent was withdrawn. Once the information was deleted, TDH would send a confirmation to the parent or guardian.

Instead of requiring an immunization record from a health care provider, the bill would require data elements about the immunization. Also, it would require that the insurer send the data elements it received from the provider to the registry. TDH would be required to verify consent before including the data in the registry. TDH could alert an insurer that submitted an immunization history for which consent could not be verified and establish a way for consent to be obtained and the information resubmitted. If a parent or guardian believed that the child's health care provider or insurer failed to submit the information and wanted the information included, the parent or guardian could submit the information directly to TDH.

The bill would permit health care providers to use the registry to send reminder notices to parents or guardians about future shots. Immunity from civil liability for submitting or obtaining a good faith immunization history would be extended specifically to include an insurer or an employee of TDH. The bill would add confidentiality provisions regarding the information in the registry and requirements for consent for disclosure. The registry information would not be subject to legal compulsion for release or admission in a legal proceeding. It would permit TDH to release non-identifying summary statistics about the registry.

The bill would require TDH to report by September 30 each even numbered year certain measures about immunization rates to the Legislative Budget Board, governor, lieutenant governor, House speaker, and relevant committees of the Legislature. Some of the reported measures would include the number and types of exemptions from immunization used, complaints about the registry, and incidents of discrimination related to requesting exclusion from the registry. TDH would use the report to develop ways to increase immunization rates.

TDH would be required to adopt rules about these changes by September 1, 2004. The changes about data elements from providers and insurers would take effect September 1, 2004. 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, 2003.

**SUPPORTERS
SAY:**

CSHB 1921 would improve TDH's registry by permitting one-time consent. Instead of requiring providers to obtain consent each and every time a child

was immunized, a single consent would apply until the child turned 18 unless consent were withdrawn. This would permit providers and insurers to send immunization information to TDH and require the department to verify consent, rather than providers or insurers being responsible for verification. Under current law some providers do not send in the information because they have to verify consent before sending it. This change would put the responsibility in TDH's hands, where consent easily can be verified based on whether or not there was a record in the registry. If there were no record, consent could not be verified and the information would be sent back to the provider. In addition, the bill clearly would state that TDH could not keep any data on individuals for whom consent had been withdrawn. Consent could be withdrawn at any time. This would ensure that the information got in the registry when parents wanted it stored there and prevent erroneous reporting of non-consented information.

From a public health standpoint, Texas has a compelling interest in raising rates of immunization, and data from the immunization registry should be part of this effort. Diseases such as polio once were commonplace, but they have been virtually eradicated due to widespread programs of immunization. Clinical evidence linking immunizations to autism is extremely thin, and any risks associated with immunization are infinitely smaller than the proven risk of not immunizing children against preventable killer diseases. Therefore, it is very appropriate that providers use registry data to send immunization reminders, particularly since parents who had opted out of the registry would not receive them.

CSHB 1921 would be the fifth part of the improvements Texas needs to make to improve immunization rates. Texas consistently ranks near the bottom in rates of immunization for children under two years of age — 42nd among states according to 2001 National Immunization Survey (NIS) data. So far the House has passed three bills on immunizations: HB 1920 by Capelo, regarding provider education programs, SB 43 by Zaffirini, regarding a best practice pilot program to boost immunization rates, and SB 40 by Zaffirini, regarding a unified statewide vaccination education campaign; and soon will consider a fourth, HB 1926 by Capelo/SB 486 by Zaffirini, regarding public-private partnerships to increase public awareness about immunizations. This suite of legislation would help Texas educate parents and providers about immunizations, and CSHB 1921 would round out the improvements by

shoring up the record-keeping both for the state and for parents of immunized kids.

Current law allows parents to opt their children out of the registry and allows disclosure of confidential information only following a parent's written consent. It also establishes criminal liability for the negligent release or disclosure of immunization registry information for commercial or other unauthorized purposes, so fears that this bill would contribute to the abuse of immunization data are unfounded. On the contrary, this bill spells out all of the protection of data and disclosure requirements. In addition, the bill would require TDH to inform parents when consent is obtained, so if a parent inadvertently signed consent on the birth certificate, the notification would give the parent an opportunity to rectify the situation. Parents who did not wish their children's information to be part of the registry should feel at greater ease with the additional protections in CSHB 1921.

**OPPONENTS
SAY:**

CSHB 1921 would undermine a parent's right to refuse consent to the registry. By permitting consent on the child's birth certificate, the state would be asking parents to make a very important decision at a time of great stress. There are so many forms to sign and activities to perform just after the arrival of a baby, new parents should not be asked to give consent to disclose personal medical information at that time.

Vaccines are potentially harmful to kids, and there is evidence linking them to autism. Whether or not to vaccinate should be a choice between parents and doctors, and parents should not feel pressure from the state to vaccinate their kids. Some parents elect not to vaccinate their children for religious or health reasons. Immunizations are not for everyone, and it would be inappropriate for the state to use registry information to send reminders that encourage parents to have their children vaccinated.

The registry also might pose confidentiality concerns. Even with the protections offered in this bill, too many organizations would have access to private health information, and people that have declined immunizations might worry that their decision could one day be held against them by an insurer or some other group. For this reason, efforts to expand access to the immunization registry should be discouraged.

**OTHER
OPPONENTS
SAY:**

Texas should make its registry easier to use. If the state wants the benefit of the public health data and disease protection offered by higher statewide immunization rates, then it should invest in a system that makes it easier for providers to report immunization encounter data. The registry database is difficult to use and requires a lot of data entry, which is just one more reason why already overworked providers likely would not flock to this program.

NOTES:

The bill as introduced would have made the immunization registry an opt-out database, whereas the committee substitute would make changes to the regulation of the immunization registry while keeping it an opt-in database.

The companion bill, SB 39 by Zaffirini, was referred to the Senate Health and Human Services Committee.

HB 1920 by Capelo, which would establish provider education programs relating to immunizations and the Vaccines For Children program, passed the House on May 5. HB 1926 by Capelo/SB 486 by Zaffirini would require TDH to develop and maintain partnerships with public and private entities to increase public awareness and support around early childhood immunizations. The Senate bill passed the Senate by voice vote on March 20 and was reported favorably, without amendment, by the House Public Health Committee on April 30, making it eligible to be considered in lieu of HB 1926, which was postponed until today.

SB 43 by Zaffirini, which passed the Senate by voice vote on February 27, would require TDH to report to the Legislature the results of a best practice pilot program to boost immunization rates. SB 40 by Zaffirini, which passed the Senate by voice vote on March 12, would require TDH to partner with other public and private entities to coordinate a unified statewide vaccination education campaign. Both bills passed the House on May 2.