HOUSE
RESEARCH
ORGANIZATION bill analysis 5/1/2013

HB 772
Howard, et al.
(CSHB 772 by Collier)

SUBJECT: Creating an opt-out immunization registry, replacing the opt-in system

COMMITTEE: Public Health — committee substitute recommended

VOTE: 9 ayes — Kolkhorst, Naishtat, Coleman, Collier, Cortez, S. Davis, Guerra, S. King, J.D. Sheffield

2 nays — Laubenberg, Zedler

WITNESSES: For — Georgia Armstrong, Peoples Community Clinic; Ari Brown, Texas Medical Association, Texas Pediatric Society; Anna C. Dragsbaek, The Immunization Partnership; Patsy Schanbaum, The JAMIE Group; (*Registered, but did not testify*: Keveney Avila, Children at Risk; Nora Belcher, Texas e-health Alliance; Miryam Bujanda, Methodist Healthcare Ministries; Teresa Devine, Blue Cross and Blue Shield of Texas; Marisa Finley, Scott & White Center for Healthcare Policy; Karen Johnson, United Ways of Texas; Marshall Kenderdine, Texas Academy of Family Physicians; Carrie Kroll, Texas Hospital Association; Shannon Lucas, March of Dimes; Mary Nava, Bexar County Medical Society; Carlos Rivera, Austin/Travis County Health & Human Services Department; Rebekah Schroeder, Texas Children's Hospital; Bryan Sperry, Children's Hospital Association of Texas; James Willmann, Texas Nurses Association)

Against — Read King; (*Registered, but did not testify*: Jeremy Blosser; Ben Snodgrass, Texas Home School Coalition)

On — Kevin Allen and Saroj Rai, Department of State Health Services

BACKGROUND: Health and Safety Code, ch. 161, governs immunizations and directs the Department of State Health Services to maintain an immunization registry. It is an opt-in system that requires consent from an individual or the individual's legally authorized representative.

**Consent required (opt-in).** An individual or representative must provide written or electronic consent before an individual's information is included in the immunization registry, and the executive commissioner of the Health and Human Services Commission must establish consent procedures. Consent only needs to be given once until an individual turns

18. Unless consent to remain in the registry is obtained, the department must remove an individual's information when an individual turns 18 or following a disaster or emergency in which immunizations are given. If consent is withdrawn, the department must remove the information.

**Notice and exclusion.** The first time the department receives information about an individual that has consented to the registry, the department must send a notice explaining the registry. If the department discovers that consent has not been granted or has been withdrawn, the individual's immunization information must be excluded from the registry.

**Immunization data.** If the department receives immunization data from an insurance company, other payors, health-care providers, public health districts, or local health departments, the department must verify consent before including information in the registry and may not retain individually identifiable information if consent is not verified. If consent cannot be verified, the department must direct the health-care providers to obtain consent and resubmit the data.

After an emergency or disaster, the commissioner must by rule determine how long the information remains in the registry. The department must report to the legislature any complaints about failing to remove information after an emergency or disaster.

**Confidentiality.** With a few exceptions related to an emergency or disaster, registry information that identifies individuals is confidential and can be used by the department only for registry purposes.

DIGEST:

CSHB 772 would require an individual or legally authorized representative to opt-out, rather than opt-in, to the immunization registry.

**Request for removal (opt-out).** The bill would require the executive commissioner of the Health and Human Services Commission to develop rules allowing an individual or representative to request removal of the individual's information. The commissioner would have to provide opportunities for the individual or representative to request removal:

- whenever a health-care provider administered an immunization in Texas, including at the individual's birth;
- through the DSHS website;
- through a written request to DSHS; and

- following a natural or man-made disaster.

The procedures for requesting removal would have to be included on every immunization record generated by the registry. The department, upon request, would need to provide information about requesting removal from the registry. After an individual turned 18, the individual or representative could submit a written or electronic request for removal.

Unless the individual or representative had requested removal, the registry would have to contain an immunization history for any individual about whom information had been received. If the department received a request for removal, it would be required to remove the information.

The department's website would need to have a printable form stating that individual's information would be included in the registry unless removal was requested and detailing removal procedures. This form would need to be available for distribution to health-care providers and could be used to provide the necessary notification to individuals.

**Notice and exclusion.** The first time the department received information about an individual, the department would have to send a notice explaining the registry. The department would have to remove information about any individual who had requested exclusion from the registry.

**Immunization data.** A health-care provider who administers immunizations and provides the department with the data would have to notify an individual or the individual's representative that the individual's immunization information would be included in the registry unless removal was requested and inform them of removal procedures.

The registry data could not be used to exclude an individual from any service during a natural or man-made disaster, unless the service was medically contraindicated. The department could not sell registry data to any public or private entity.

**Confidentiality.** With approval from the department's institutional review board, the registry information could be used for internal public health research. Registry information could be released for external public health research only if written authorization from individuals or representatives was obtained, individually identifiable information was not disclosed, and the release was approved by the department's institutional review board.

The department's institutional review board could not approve any proposal not requiring researchers to obtain informed consent before the release of an individual's information.

**Public awareness.** The department would have to develop educational information for health-care providers about the option to request removal from the immunization registry. The department would have to conduct a public awareness to educate health-care providers, parents, payors, schools and the public about changes to the registry.

**Conforming changes.** CSHB 772 would make additional conforming changes that would require an individual to request removal from the registry. It would remove requirements that the commissioner develop consent procedures and determine how long information remained in the registry after an emergency or disaster. The department would not need to report to Legislature any complaints about failing to remove information after an emergency or disaster.

**Effective dates.** The changes to the immunization registry would apply to information received by the department before, on, or after January 1, 2015. The changes would apply to immunization information included in the registry immediately before January 1, 2015.

The bill would take effect January 1, 2015, except the provision requiring the department to conduct a public awareness campaign would take effect September 1, 2013.

SUPPORTERS SAY:

CSHB 772 would modernize the state immunization registry. An opt-out system would increase efficiency, reduce costs, and enhance privacy protections. An immunization registry with more information would ensure more comprehensive care, improve patient outcomes, and prevent duplicative immunizations.

**Increases efficiency**. The current immunization registry system is cumbersome and inefficient. Ninety-five percent of Texans consent to have their immunization information included in ImmTrac, the state immunization registry. Currently, the department must obtain consent forms for all these individuals. By creating an opt-out system, the department would only need to obtain removal request forms for the 5 percent of individuals who wish to be excluded. This would streamline the registry process and significantly reduce administrative burdens.

**Reduces costs.** The current opt-in system is outdated and expensive. According to one estimate, an opt-out system would decrease operating costs from $2.64 per child to 29 cents per child. A modernized system also would save money by harmonizing the process with other public health databases and preventing the duplication of expensive immunizations.

**Protects privacy.** This bill would enhance data protection by specifying the purposes for which immunization information could not be used and involving the department's institution review board for any research project involving the data. It also would prevent individuals who had opted-out of the registry from receiving immunization reminders, further protecting their privacy.

OPPONENTS SAY:

CSHB 772 would be unnecessary because the current system is adequate. The opt-in process captures nearly all Texans, so there is no need to create a new system. Moreover, an opt-out system would be difficult to explain to patients and would create more work for health-care providers.

This bill would change the default immunization position, putting an additional burden on individuals who wanted to be excluded from the registry. This would create the possibility that an individual who wished to be excluded from the registry could be included without his or her knowledge.

This bill would allow the department and external entities to use immunization data for research projects, creating concerns about privacy and the protection of personal information.

NOTES:

Compared to the introduced bill, the committee substitute would:

- direct the commissioner to develop guidelines to provide specific opportunities to request removal of information;
- require the procedure for requesting removal from the registry to be included on each immunization record generated by the registry system;
- require a health-care provider to notify an individual or representative that the immunization information will be included in the registry unless removal is requested and provide the procedures for requesting removal;
- require the department's website to have a printable form with

registry information and removal procedures that could be used by providers;

- require the department, upon request, to provide information to an individual on removal procedures; and
- add schools and payors to the list of entities to be involved in the department's public awareness campaign.

The companion bill, SB 40 by Zaffirini, was referred to Senate Health and Human Services Committee on January 28.