

BILL ANALYSIS

C.S.H.B. 772
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Public Health
Committee Report (Substituted)

BACKGROUND AND PURPOSE

Immunization information contained in the state immunization registry helps streamline the delivery of health services by establishing a greater continuum of care across city, county, and state borders, especially during public health and natural disasters. Currently, in order to have an immunization record included in Texas' electronic immunization registry, an individual must provide consent, or opt in. Interested parties contend that the process to verify and maintain consent for a record is complicated, inefficient, and costly. These parties assert that Texas is one of only a handful of states that maintains an opt-in, as opposed to an opt-out, immunization registry and that approximately 95 percent of Texans provide consent to include an immunization record in the registry, so it would be more efficient and cost-effective to provide a mechanism for the smaller percentage of Texans to opt out of the registry. C.S.H.B. 772 seeks to address this issue by providing for an opt-out system.

RULEMAKING AUTHORITY

It is the committee's opinion that rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in SECTION 1 of this bill.

ANALYSIS

C.S.H.B. 772 amends the Health and Safety Code to remove statutory provisions relating to a requirement that an individual or the individual's legally authorized representative provide consent before the individual's information can be included in the immunization registry maintained by the Department of State Health Services (DSHS) and instead requires the registry to contain information on the immunization history of each individual for whom immunization information has been obtained by DSHS, unless the individual or the individual's legally authorized representative has requested that the individual's information be removed from the registry. The bill requires the executive commissioner of the Health and Human Services Commission (HHSC) by rule to develop guidelines to provide opportunities for the individual or the individual's legally authorized representative to request removal from the registry at the time of the individual's birth if attended by a health care provider who administers immunizations, at the time the individual receives any immunization administered by a health care provider in this state, through electronic submission of a request for removal using a request for removal procedure available on DSHS's Internet website, through submission to DSHS of a written request for removal, and following a natural or man-made disaster and to develop guidelines to include on each immunization record generated by the registry the procedures for requesting removal from the registry.

C.S.H.B. 772 authorizes an individual's legally authorized representative or the individual, after the individual has attained 18 years of age, to submit a request in writing or electronically for the individual's information to be removed from the registry and requires the executive commissioner by rule to develop guidelines relating to such a request. The bill requires a health care provider who administers an immunization to any individual and provides data elements regarding an immunization to DSHS to notify the individual or the individual's legally authorized representative that the individual's immunization information will be included in the

registry unless removal from the registry is requested in accordance with the adopted guidelines and to notify the individual or the representative of the procedures for requesting removal from the registry.

C.S.H.B. 772 requires DSHS to make available on DSHS's Internet website a printable form that states an individual's immunization information will be included in the registry unless removal from the registry is requested and that details the procedures for submitting an electronic or written request for removal from the registry and to make the form available for distribution to health care providers. The bill authorizes a health care provider to use the printable form to provide the required notification. The bill prohibits registry information from being used to exclude any individual from the receipt of any service during a natural or man-made disaster unless the service is withheld because of a medical contraindication. The bill prohibits DSHS from selling registry information to any public or private entity.

C.S.H.B. 772 removes the requirement that DSHS remove an immunization record from the registry of immunizations and medications administered in preparation for or in response to a disaster or emergency unless an individual or the individual's legally authorized representative consents to continued inclusion of the individual's information in the registry and instead requires DSHS to include such an immunization record in that registry unless the individual or the individual's legally authorized representative requests that the information be removed from the registry.

C.S.H.B. 772, for purposes of provisions requiring notice to be sent to an individual or an individual's legally authorized representative when DSHS receives registry data for the individual for the first time, requires DSHS to exclude from the immunization registry and any other registry-related department record that individually identifies the individual the immunization record of any individual from whom a request for exclusion has been received by DSHS.

C.S.H.B. 772 authorizes DSHS to use registry information for internal public health research on approval of DSHS's institutional review board. The bill authorizes DSHS to release registry information for external public health research if the individual or the individual's legally authorized representative submits a written authorization to DSHS for release of the individual's registry data, DSHS does not disclose individually identifiable information, or the institutional review board approves the release of individually identifiable information. The bill prohibits the institutional review board from approving the release of individually identifiable information for a research proposal unless the proposal includes a provision requiring the proposal's researchers to obtain informed consent from each individual or the individual's legally authorized representative before DSHS releases the individual's registry data to the researchers.

C.S.H.B. 772 removes the requirement that a memorandum of agreement regarding the release and use of registry information entered into by the executive commissioner with another state to which Texas residents are likely to evacuate in a disaster include the length of time the information may be retained by that state. The bill requires an individual or the individual's legally authorized representative, on request, to be provided with information on the procedure for requesting removal from the registry, in addition to all individually identifiable immunization registry information concerning the individual.

C.S.H.B. 772 requires the educational information relating to the registry developed by DSHS for health care providers, health care clinics, hospitals, and any other health care facility that provides health care to children 14 to 18 years of age to include information regarding the option for an individual or the individual's legally authorized representative to request removal of the individual's information from the registry.

C.S.H.B. 772 applies to immunization information received by DSHS before, on, or after January 1, 2015, and specifies that an individual whose immunization information was included in the immunization registry immediately before January 1, 2015, is subject to the bill's

provisions.

C.S.H.B. 772, in a provision effective September 1, 2013, requires DSHS, as soon as practicable after the bill's effective date, to conduct a public awareness campaign to educate health care providers, parents, payors, schools, and the public about the changes in law made by the bill's provisions.

C.S.H.B. 772 repeals the following provisions of the Health and Safety Code:

- Sections 161.007(a-1) and (a-3)
- Sections 161.00705(e) and (h)
- Sections 161.00735(e) and (f)

EFFECTIVE DATE

Except as otherwise provided, January 1, 2015.

COMPARISON OF ORIGINAL AND SUBSTITUTE

While C.S.H.B. 772 may differ from the original in minor or nonsubstantive ways, the following comparison is organized and highlighted in a manner that indicates the substantial differences between the introduced and committee substitute versions of the bill.

INTRODUCED

SECTION 1. Sections 161.007(a), (a-2), (b), (b-1), (c), and (d), Health and Safety Code, are amended to read as follows:

(a) The department, for the primary purpose of establishing and maintaining a single repository of accurate, complete, and current immunization records to be used in aiding, coordinating, and promoting efficient and cost-effective communicable disease prevention and control efforts, shall establish and maintain an immunization registry. The executive commissioner of the Health and Human Services Commission by rule shall develop guidelines to:

- (1) protect the confidentiality of patients in accordance with Section 159.002, Occupations Code;
 - (2) inform the individual or the individual's legally authorized representative about the registry and that registry information may be released under Section 161.00735; and
 - (3) ~~[require the written or electronic consent of the individual or the individual's legally authorized representative before any information relating to the individual is included in the registry;~~
- [4] permit the individual or the

HOUSE COMMITTEE SUBSTITUTE

SECTION 1. Section 161.007, Health and Safety Code, is amended by amending Subsections (a), (a-2), (b), (b-1), (c), (d), and (e) and adding Subsections (e-1), (l), and (m) to read as follows:

(a) The department, for the primary purpose of establishing and maintaining a single repository of accurate, complete, and current immunization records to be used in aiding, coordinating, and promoting efficient and cost-effective communicable disease prevention and control efforts, shall establish and maintain an immunization registry. The executive commissioner of the Health and Human Services Commission by rule shall develop guidelines to:

- (1) protect the confidentiality of patients in accordance with Section 159.002, Occupations Code;
 - (2) inform the individual or the individual's legally authorized representative about the registry and that registry information may be released under Section 161.00735;
 - (3) ~~[require the written or electronic consent of the individual or the individual's legally authorized representative before any information relating to the individual is included in the registry;~~
- [4] permit the individual or the

individual's legally authorized representative to request that the individual's information be removed from ~~[withdraw consent for the individual to be included in]~~ the registry; and

~~[(5) determine the process by which consent is verified, including affirmation by a health care provider, birth registrar, regional health information exchange, or local immunization registry that consent has been obtained].~~

~~(a-2) An individual's legally authorized representative or the individual, after the individual has attained 18 years of age, may submit a request ~~[consent]~~ in writing or electronically for the individual's information to be removed from ~~[remain in]~~ the registry ~~[after the individual's 18th birthday and for the individual's subsequent immunizations to be included in the registry. The written or electronic consent of the minor's legally authorized representative as described by Section 161.0001(1-c)(A) must be submitted to the department before the individual's 18th birthday. The written or electronic consent of the individual or the individual's legally authorized representative as described by Section 161.0001(1-c)(B) or (C) must be submitted to the department not later than the individual's 19th birthday. The consent of the representative or individual is valid until the individual or the individual's legally authorized representative withdraws consent in writing or electronically. The department may not include in the registry the immunization~~~~

individual's legally authorized representative to request that the individual's information be removed from ~~[withdraw consent for the individual to be included in]~~ the registry;

~~(4) provide opportunities for the individual or the individual's legally authorized representative to request removal;~~

~~(A) at the time of the individual's birth if attended by a health care provider who administers immunizations;~~

~~(B) at the time the individual receives any immunization administered by a health care provider in this state;~~

~~(C) through electronic submission of a request for removal using a request for removal procedure available on the department's Internet website;~~

~~(D) through submission to the department of a written request for removal; and~~

~~(E) following a natural or man-made disaster; and~~

~~(5) include on each immunization record generated by the registry the procedures for requesting removal from the registry~~

~~[determine the process by which consent is verified, including affirmation by a health care provider, birth registrar, regional health information exchange, or local immunization registry that consent has been obtained].~~

~~(a-2) An individual's legally authorized representative or the individual, after the individual has attained 18 years of age, may submit a request ~~[consent]~~ in writing or electronically for the individual's information to be removed from ~~[remain in]~~ the registry ~~[after the individual's 18th birthday and for the individual's subsequent immunizations to be included in the registry. The written or electronic consent of the minor's legally authorized representative as described by Section 161.0001(1-c)(A) must be submitted to the department before the individual's 18th birthday. The written or electronic consent of the individual or the individual's legally authorized representative as described by Section 161.0001(1-c)(B) or (C) must be submitted to the department not later than the individual's 19th birthday. The consent of the representative or individual is valid until the individual or the individual's legally authorized representative withdraws consent in writing or electronically. The department may not include in the registry~~~~

~~information of an individual who is 18 years of age or older until written or electronic consent has been obtained as provided by this subsection].~~ The department shall coordinate with the Texas Education Agency to distribute materials described in Section 161.0095(a)(2) to students and parents through local school districts.

(b) Except as provided by Section 161.0071, the immunization registry must contain information on the immunization history that is obtained by the department under:

(1) this section of each individual for whom immunization information [consent] has been obtained, unless the individual or the individual's legally authorized representative has requested that the individual's information be removed from the registry in accordance with guidelines adopted under Subsection (a) [or (a-3), as applicable];

(2) Section 161.00705 of persons immunized to prepare for or in response to a declared disaster, public health emergency, terrorist attack, hostile military or paramilitary action, or extraordinary law enforcement emergency;

(3) Section 161.00706 of first responders or their immediate family members; and

(4) Section 161.00735 of persons evacuated or relocated to this state because of a disaster.

(b-1) The department shall remove from the registry information for any individual for whom ~~[consent has been withdrawn. The department may not retain individually identifiable information about any individual:~~

~~[(1) for whom consent has been withdrawn;~~

~~[(2) for whom a consent for continued inclusion in the registry following the end of the declared disaster, public health emergency, terrorist attack, hostile military or paramilitary action, or extraordinary law enforcement emergency has not been received under Section 161.00705(f);~~

~~[(3) for whom a request to be removed from the registry has been received under Section 161.00706(e);~~

~~[(4) for whom consent for continued inclusion in the registry following the end of a disaster has not been received under Section 161.00735(f); or~~

~~[(5) for whom] a request to remove~~

~~the immunization information of an individual who is 18 years of age or older until written or electronic consent has been obtained as provided by this subsection].~~ The department shall coordinate with the Texas Education Agency to distribute materials described in Section 161.0095(a)(2) to students and parents through local school districts.

(b) Except as provided by Section 161.0071, the immunization registry must contain information on the immunization history that is obtained by the department under:

(1) this section of each individual for whom immunization information [consent] has been obtained, unless the individual or the individual's legally authorized representative has requested that the individual's information be removed from the registry in accordance with guidelines adopted under Subsection (a) [or (a-3), as applicable];

(2) Section 161.00705 of persons immunized to prepare for or in response to a declared disaster, public health emergency, terrorist attack, hostile military or paramilitary action, or extraordinary law enforcement emergency;

(3) Section 161.00706 of first responders or their immediate family members; and

(4) Section 161.00735 of persons evacuated or relocated to this state because of a disaster.

(b-1) The department shall remove from the registry information for any individual for whom ~~[consent has been withdrawn. The department may not retain individually identifiable information about any individual:~~

~~[(1) for whom consent has been withdrawn;~~

~~[(2) for whom a consent for continued inclusion in the registry following the end of the declared disaster, public health emergency, terrorist attack, hostile military or paramilitary action, or extraordinary law enforcement emergency has not been received under Section 161.00705(f);~~

~~[(3) for whom a request to be removed from the registry has been received under Section 161.00706(e);~~

~~[(4) for whom consent for continued inclusion in the registry following the end of a disaster has not been received under Section 161.00735(f); or~~

~~[(5) for whom] a request to remove~~

information from the registry has been received under this subchapter [Section 161.00735(g)].

(c) A payor that receives data elements from a health care provider who administers an immunization to an individual younger than 18 years of age shall provide the data elements to the department. A payor is required to provide the department with only the data elements the payor receives from a health care provider. A payor that receives data elements from a health care provider who administers an immunization to an individual 18 years of age or older may provide the data elements to the department. The data elements shall be submitted in a format prescribed by the department. [~~The department shall verify consent before including the reported information in the immunization registry. The department may not retain individually identifiable information about an individual for whom consent cannot be verified.~~]

(d) A health care provider who administers an immunization to an individual younger than 18 years of age shall provide data elements regarding an immunization to the department. A health care provider who administers an immunization to an individual 18 years of age or older may submit data elements regarding an immunization to the department. The data elements shall be submitted in a format prescribed by the department.

~~[The department shall verify consent before including the information in the immunization registry. The department may not retain individually identifiable information about an individual for whom consent cannot be verified.]~~

information from the registry has been received under this subchapter [Section 161.00735(g)].

(c) A payor that receives data elements from a health care provider who administers an immunization to an individual younger than 18 years of age shall provide the data elements to the department. A payor is required to provide the department with only the data elements the payor receives from a health care provider. A payor that receives data elements from a health care provider who administers an immunization to an individual 18 years of age or older may provide the data elements to the department. The data elements shall be submitted in a format prescribed by the department. [~~The department shall verify consent before including the reported information in the immunization registry. The department may not retain individually identifiable information about an individual for whom consent cannot be verified.~~]

(d) A health care provider who administers an immunization to an individual younger than 18 years of age shall provide data elements regarding an immunization to the department. A health care provider who administers an immunization to an individual 18 years of age or older may submit data elements regarding an immunization to the department. The data elements shall be submitted in a format prescribed by the department. A health care provider who administers an immunization to any individual and provides data elements to the department shall notify the individual or the individual's legally authorized representative:

(1) that the individual's immunization information will be included in the registry unless removal from the registry is requested in accordance with the guidelines adopted under Subsection (a); and

(2) of the procedures for requesting removal from the registry. [~~The department shall verify consent before including the information in the immunization registry. The department may not retain individually identifiable information about an individual for whom consent cannot be verified.~~]

(e) The department shall:

(1) make available on the department's Internet website a printable form that states an individual's immunization information will be included in the registry unless

removal from the registry is requested and that details the procedures for submitting an electronic or written request for removal from the registry [provide notice to a health care provider that submits an immunization history for an individual for whom consent cannot be verified. The notice shall contain instructions for obtaining consent] in accordance with guidelines adopted under Subsection [Subsections] (a); and (2) make the form described by Subdivision (1) available for distribution to health care providers [and (a 3) and resubmitting the immunization history to the department]. (e-1) A health care provider may use the printable form described by Subsection (e) to provide the notification required under Subsection (d). (l) Registry information may not be used to exclude any individual from the receipt of any service during a natural or man-made disaster unless the service is withheld because of a medical contraindication. (m) The department may not sell registry information to any public or private entity.

SECTION 2. Section 161.00705(f), Health and Safety Code, is amended to read as follows:

(f) Unless an individual or the individual's legally authorized representative [consents] in writing or electronically requests that [~~to continued inclusion of~~] the individual's information be removed from [~~in~~] the registry, the department shall include [~~remove~~] the immunization records collected under this section in [~~from~~] the registry [~~on expiration of the period prescribed under Subsection (e)~~].

SECTION 3. Sections 161.0071(a) and (b), Health and Safety Code, are amended to read as follows:

(a) The first time the department receives registry data for an individual [~~for whom the department has received consent~~] to be included in the registry, the department shall send notice to the individual or the individual's legally authorized representative disclosing:

(1) that providers and payors may be sending the individual's immunization information to the department;

SECTION 2. Same as introduced version.

SECTION 3. Same as introduced version.

- (2) the information that is included in the registry;
 - (3) the persons to whom the information may be released under Sections 161.00735(b) and 161.008(d);
 - (4) the purpose and use of the registry;
 - (5) the procedure to exclude an individual from the registry; and
 - (6) the procedure to report a violation if an individual's information is included in the registry after exclusion has been requested ~~[or consent has been withdrawn]~~.
- (b) ~~The [On discovering that consent to be included in the registry has not been granted or has been withdrawn, the]~~ department shall exclude ~~[the individual's immunization records]~~ from the registry and any other registry-related department record that individually identifies the individual the immunization record of any individual from whom a request for exclusion has been received by the department.

No equivalent provision.

SECTION 4. Section 161.0073, Health and Safety Code, is amended by amending Subsection (a) and adding Subsections (e), (f), and (g) to read as follows:

(a) Except as provided by this section and Sections 161.007, 161.00705, 161.00706, [and] 161.00735, and 161.008, information that individually identifies an individual that is received by the department for the immunization registry is confidential and may be used by the department for registry purposes only.

(e) The department may use registry information for internal public health research on approval of the department's institutional review board.

(f) The department may release registry information for external public health research if:

(1) the individual or the individual's legally authorized representative submits a written authorization to the department for release of the individual's registry data;

(2) the department does not disclose individually identifiable information; or

(3) the department's institutional review board approves the release of individually identifiable information subject to Subsection (g).

(g) The department's institutional review board may not approve the release of individually identifiable information for a

research proposal unless the proposal includes a provision requiring the proposal's researchers to obtain informed consent from each individual or the individual's legally authorized representative before the department releases the individual's registry data to the researchers.

SECTION 4. Sections 161.00735(c) and (h), Health and Safety Code, are amended to read as follows:

(c) The department may receive immunization information from a health authority of another state or from a local health authority in another state if the department determines that residents of that state have evacuated or relocated to this state in response to a disaster. The department shall include information received under this subsection in the registry. ~~[Notwithstanding Section 161.007, the department is not required to obtain written consent for the inclusion in the registry of information received under this subsection.]~~

(h) The executive commissioner of the Health and Human Services Commission shall make every effort to enter into a memorandum of agreement with each state to which residents of this state are likely to evacuate in a disaster on:

(1) the release to and use by ~~[of registry information under this section to]~~ the appropriate health authority or local health authority of that state of registry information under this section, ~~including the length of time the information may be retained by that state~~; and

(2) the receipt and use of information submitted by the health authority or local health authority of that state for inclusion in the registry under this section.

SECTION 5. Section 161.008(c), Health and Safety Code, is amended to read as follows:

(c) The department may obtain the data constituting an immunization record for an individual from a public health district, a local health department, the individual or the individual's legally authorized representative, a physician to the individual, a payor, or any health care provider licensed or otherwise authorized to administer

SECTION 5. Same as introduced version.

SECTION 6. Sections 161.008(c) and (e), Health and Safety Code, are amended to read as follows:

(c) The department may obtain the data constituting an immunization record for an individual from a public health district, a local health department, the individual or the individual's legally authorized representative, a physician to the individual, a payor, or any health care provider licensed or otherwise authorized to administer

vaccines. ~~[The department shall verify consent before including the reported information in the immunization registry. The department may not retain individually identifiable information about an individual for whom consent cannot be verified.]~~

(Repealed in SECTION 8 below.)

SECTION 6. Section 161.0095(a), Health and Safety Code, is amended to read as follows:

- (a) The department shall develop:
- (1) continuing education programs for health care providers relating to immunizations and the vaccines for children program operated by the department under authority of 42 U.S.C. Section 1396s; and
 - (2) educational information, for health care providers, health care clinics, hospitals, and any other health care facility that provides health care to children 14 to 18 years of age, relating to the immunization registry and the option for an individual or the individual's legally authorized representative to request removal ~~[who is 18 years of age or older to consent to submission and retention]~~ of the individual's information from ~~[in]~~ the immunization registry.

SECTION 7. Section 161.0107(c), Health and Safety Code, is amended to read as follows:

- (c) The executive commissioner of the Health and Human Services Commission by rule shall specify:
- (1) the fields necessary to populate the immunization registry~~[-, including a field that indicates the patient's consent to be listed in the immunization registry has been obtained];~~ and
 - (2) the data standards that must be used for electronic submission of immunization information.

SECTION 8. The following provisions of

83R 11855

Substitute Document Number: 83R 20242

vaccines. ~~[The department shall verify consent before including the reported information in the immunization registry. The department may not retain individually identifiable information about an individual for whom consent cannot be verified.]~~

(e) An individual or the individual's legally authorized representative may obtain and on request to the department shall be provided with all individually identifiable immunization registry information concerning the individual and information on the procedure for requesting removal from the registry.

SECTION 7. Same as introduced version.

SECTION 8. Same as introduced version.

SECTION 9. The following provisions of

13.103.379

the Health and Safety Code are repealed:
(1) Sections 161.007(a-1), (a-3), and (e);
(2) Sections 161.00705(e) and (h); and
(3) Sections 161.00735(e) and (f).

SECTION 9. The changes in law made by this Act to Subchapter A, Chapter 161, Health and Safety Code, apply only to immunization information received by the Department of State Health Services on or after the effective date of this Act. The information received by the department before the effective date of this Act is covered by the law in effect immediately before that date, and that law is continued in effect for that purpose.

No equivalent provision.

SECTION 10. This Act takes effect September 1, 2013.

the Health and Safety Code are repealed:
(1) Sections 161.007(a-1) and (a-3);
(2) Sections 161.00705(e) and (h); and
(3) Sections 161.00735(e) and (f).

SECTION 10. The changes in law made by this Act to Subchapter A, Chapter 161, Health and Safety Code, apply to immunization information received by the Department of State Health Services before, on, or after January 1, 2015.

An individual whose immunization information was included immediately before January 1, 2015, in the immunization registry established under Subchapter A, Chapter 161, Health and Safety Code, is subject to the changes in law made by this Act to that subchapter, including the procedures established by that subchapter as amended by this Act.

SECTION 11. As soon as practicable after the effective date of this Act, the Department of State Health Services shall conduct a public awareness campaign to educate health care providers, parents, payors, schools, and the public about the changes in law made by this Act.

SECTION 12. (a) Except as provided by Subsection (b) of this section, this Act takes effect January 1, 2015.
(b) Section 11 of this Act takes effect September 1, 2013.