By: Zaffirini

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A BILL TO BE ENTITLED

AN ACT

2 relating to the immunization data included in and excluded from the 3 immunization registry.

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BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

5 SECTION 1. Section 161.007, Health and Safety Code, is 6 amended by amending Subsections (a), (a-2), (b), (b-1), (c), (d), 7 and (e) and adding Subsections (e-1), (l), and (m) to read as 8 follows:

9 (a) The department, for the primary purpose of establishing 10 and maintaining a single repository of accurate, complete, and 11 current immunization records to be used in aiding, coordinating, 12 and promoting efficient and cost-effective communicable disease 13 prevention and control efforts, shall establish and maintain an 14 immunization registry. The executive commissioner by rule shall 15 develop guidelines to:

16 (1) protect the confidentiality of patients in
 17 accordance with Section 159.002, Occupations Code;

18 (2) inform the individual or the individual's legally
19 authorized representative about the registry and that registry
20 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;

1 [(4)] permit the individual or the individual's 2 legally authorized representative to request that the individual's information be excluded from [withdraw consent for the individual 3 4 to be included in] the registry; 5 (4) provide opportunities for the individual or the individual's legally authorized representative to 6 request 7 exclusion at any time, including: 8 (A) at the time of the individual's birth if 9 attended by a health care provider who administers immunizations; 10 (B) each time the individual receives any 11 immunization administered by a health care provider in this state; 12 (C) through electronic submission of a request 13 for exclusion using a request for exclusion procedure available on 14 the department's Internet website; 15 (D) through submission to the department of a 16 written request for exclusion; and 17 (E) following a natural or man-made disaster; 18 [and] (5) ensure that an individual or the individual's 19 20 legally authorized representative is not required to request exclusion from the registry more than one time and that, after a 21 request for exclusion is made, the individual's immunization 22 information will not be included in the registry unless the 23 individual or the individual's legally authorized representative 24 submits to the department a written request for inclusion of the 25 individual's information in the registry; and 26 27 (6) include on each immunization record generated by

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1 the registry the procedures for requesting exclusion from the 2 registry [determine the process by which consent is verified, 3 including affirmation by a health care provider, birth registrar, 4 regional health information exchange, or local immunization 5 registry that consent has been obtained].

6 (a-2) [The written or electronic consent required by 7 Subsection (a)(3) for an individual who is 18 years of age or older is required to be obtained only one time and must be received from 8 9 the individual before the information may be released.] An individual's legally authorized representative or the individual, 10 11 after the individual has attained 18 years of age, may submit a request [consent] in writing or electronically for the individual's 12 13 information to be excluded from [remain in] the registry. [The consent of the representative or individual is valid until the 14 15 individual or the individual's legally authorized representative 16 withdraws consent in writing or electronically. The department may not include in the registry the immunization information of an 17 individual who is 26 years of age or older until written or 18 electronic consent has been obtained as provided by this 19 20 subsection.] The department shall coordinate with the Texas Education Agency to distribute materials described in Section 21 22 161.0095(a)(2) to students and parents through local school districts. 23

(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:

27 (1) this section of each individual for whom

immunization information [consent] has been obtained, unless the 1 individual or the individual's legally authorized representative 2 has requested that the individual's information be excluded from 3 4 the registry in accordance with guidelines adopted under Subsection (a); 5 (2) Section 161.00705 of persons immunized to prepare 6 7 for or in response to a declared disaster, public health emergency, terrorist attack, hostile military or paramilitary action, or 8 9 extraordinary law enforcement emergency; 10 (3) Section 161.00706 of first responders or their 11 immediate family members; and (4) Section 161.00735 of persons 12 evacuated or relocated to this state because of a disaster. 13 14 (b-1) The department shall exclude [remove] from the registry information for any individual for whom [consent has been 15 16 withdrawn. The department may not retain individually identifiable information about any individual: 17 [(1) for whom consent has been withdrawn; 18 [(2) for whom a consent for continued inclusion in the 19 20 registry following the end of the declared disaster, public health emergency, terrorist attack, hostile military or paramilitary 21 action, or extraordinary law enforcement emergency has not been 22 received under Section 161.00705(f); 23 24 [(3) for whom a request to be removed from the registry 25 has been received under Section 161.00706(e); [(4) for whom consent for continued inclusion 26 27 registry following the end of a disaster has not been received under

1 Section 161.00735(f); or

2 [(5) for whom] a request to <u>exclude</u> [remove]
3 information from the registry has been received under <u>this</u>
4 <u>subchapter</u> [Section 161.00735(g)].

5 (c) A payor that receives data elements from a health care provider who administers an immunization to an individual younger 6 7 than 18 years of age shall provide the data elements to the department. A payor is required to provide the department with only 8 9 the data elements the payor receives from a health care provider. A payor that receives data elements from a health care provider who 10 administers an immunization to an individual 18 years of age or 11 older may provide the data elements to the department. The data 12 13 elements shall be submitted in a format prescribed by the department. [The department shall verify consent before including 14 15 the reported information in the immunization registry. 16 department may not retain individually identifiable information about an individual for whom consent cannot be verified.] 17

18 (d) A health care provider who administers an immunization to an individual younger than 18 years of age shall provide data 19 20 elements regarding an immunization to the department. A health care provider who administers an immunization to an individual 18 21 years of age or older may submit data elements regarding an 22 immunization to the department. At the request and with the 23 authorization of the health care provider, the data elements may be 24 25 submitted through a health information exchange as defined by Section 182.151. The data elements shall be submitted in a format 26 27 prescribed by the department. A health care provider who

administers an immunization to any individual and provides data 1 2 elements to the department shall notify the individual or the individual's legally authorized representative of: 3 4 (1) the inclusion in the registry of the individual's immunization information unless exclusion from the registry is 5 requested in accordance with the guidelines adopted under 6 7 Subsection (a); and (2) the procedures for requesting exclusion from the 8 9 registry. [The department shall verify consent before including the information in the immunization registry. The department may 10 11 retain individually identifiable information about not an individual for whom consent cannot be verified. 12 13 (e) The department shall: (1) make available on the department's Internet 14 website a printable form that states an individual's immunization 15 16 information will be included in the registry unless exclusion from the registry is requested and that details the procedures for 17 submitting an electronic or written request for exclusion from the 18 registry [provide notice to a health care provider that submits an 19 20 immunization history for an individual for whom consent cannot be verified. The notice shall contain instructions for obtaining 21 22 consent] in accordance with guidelines adopted under Subsection 23 (a); and 24 (2) make the form described by Subdivision (1) 25 available for distribution to health care providers [and resubmitting the immunization history to the department]. 26 27 (e-1) A health care provider may use the printable form

1 described by Subsection (e) to provide the notification required
2 under Subsection (d).

3 <u>(1) Registry information may not be used to exclude any</u> 4 <u>individual from the receipt of any service during a natural or</u> 5 <u>man-made disaster unless the service is withheld because of a</u> 6 medical contraindication.

7 (m) The department may not sell registry information to any
8 public or private entity.

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

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

SECTION 3. Sections 161.00706(e) and (f), Health and Safety
Code, are amended to read as follows:

(e) A person whose immunization records are included in the immunization registry as authorized by this section may request in writing or electronically that the department <u>exclude</u> [remove] that information from the registry. Not later than the 10th day after receiving a request under this subsection, the department shall <u>exclude</u> [remove] the person's immunization records from the registry.

27 (f) The report required under Section 161.0074 must also

1 include the number of complaints received by the department related 2 to the department's failure to comply with requests for <u>exclusion</u> 3 [<u>removal</u>] of information from the registry under Subsection (e).

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4 SECTION 4. Sections 161.0071(a) and (b), Health and Safety 5 Code, are amended to read as follows:

6 (a) The first time the department receives registry data for 7 an individual [for whom the department has received consent] to be 8 included in the registry, the department shall send notice to the 9 individual or the individual's legally authorized representative 10 disclosing:

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

13 (2) the information that is included in the registry; 14 (3) the persons to whom the information may be 15 released under Sections 161.00735(b) and 161.008(d);

16 (4) the purpose and use of the registry;

17 (5) the procedure to <u>request exclusion of an</u> 18 <u>individual's information</u> [exclude an individual] from the 19 registry; and

(6) the procedure to report a violation if an
21 individual's information is included in the registry after
22 exclusion has been requested [or consent has been withdrawn].

(b) <u>The</u> [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

1 record of any individual from whom a request for exclusion has been 2 received by the department.

3 SECTION 5. Section 161.0073, Health and Safety Code, is 4 amended by amending Subsection (a) and adding Subsections (e), (f), 5 (g), and (h) to read as follows:

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

11 (e) The department may use registry information for 12 internal public health research on approval of the department's 13 institutional review board.

14 (f) The department may release registry information for 15 external public health research if:

16 (1) the individual or the individual's legally 17 <u>authorized representative submits a written authorization to the</u> 18 department for release of the individual's registry data;

19 (2) the department does not disclose individually 20 identifiable information; or

21 (3) the department's institutional review board 22 approves the release of individually identifiable information 23 subject to Subsection (g).

24 (g) The department's institutional review board may not 25 approve the release of individually identifiable information for a 26 research proposal unless the proposal includes a provision 27 requiring the proposal's researchers to obtain informed consent

from each individual or the individual's legally authorized 1 2 representative before the department releases the individual's 3 registry data to the researchers. 4 (h) The executive commissioner shall adopt rules to ensure that the use or release of registry information under this 5 subchapter complies with all state and federal laws relating to the 6 privacy, protection, confidentiality, and transmission of health 7 information, including the Health Insurance Portability and 8 Accountability Act of 1996 (Pub. L. No. 104-191) and rules adopted 9 under that Act. 10

SECTION 6. Sections 161.00735(c), (g), and (h), Health and Safety Code, are amended to read as follows:

13 (c) The department may receive immunization information from a health authority of another state or from a local health 14 15 authority in another state if the department determines that 16 residents of that state have evacuated or relocated to this state in response to a disaster. The department shall include information 17 received under this subsection in the registry. [Notwithstanding 18 Section 161.007, the department is not required to obtain written 19 consent for the inclusion in the registry of information received 20 under this subsection.] 21

(g) If an individual or, if a child, the child's parent, managing conservator, or guardian requests in writing that the individual's or child's information obtained under Subsection (c) be <u>excluded</u> [removed] from the registry, the department shall <u>exclude</u> [remove] that information from the registry.

27 (h) The executive commissioner shall make every effort to

1 enter into a memorandum of agreement with each state to which 2 residents of this state are likely to evacuate in a disaster on:

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3 (1) the release <u>to</u> and use <u>by</u> [of registry information 4 <u>under this section to</u>] the appropriate health authority or local 5 health authority of that state <u>of registry information under this</u> 6 <u>section</u>[, <u>including the length of time the information may be</u> 7 <u>retained by that state</u>]; and

8 (2) the receipt and use of information submitted by 9 the health authority or local health authority of that state for 10 inclusion in the registry under this section.

SECTION 7. Sections 161.008(c) and (e), Health and Safety
Code, are amended to read as follows:

13 (C) The department may obtain the data constituting an immunization record for an individual from a public health 14 15 district, a local health department, the individual or the 16 individual's legally authorized representative, a physician to the individual, a payor, or any health care provider licensed or 17 otherwise authorized to administer vaccines. [The department shall 18 verify consent before including the reported information in the 19 20 immunization registry. The department may not retain individually identifiable information about an individual for whom consent 21 cannot be verified.] 22

(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 <u>and information on the</u> <u>procedure for requesting exclusion from the registry</u>.

SECTION 8. Section 161.009(a), Health and Safety Code, is
amended to read as follows:

(a) A person commits an offense if the person:

4 (1) negligently releases or discloses immunization
5 registry information in violation of Section 161.007, 161.0071,
6 161.0073, or 161.008;

7 (2) fails to exclude an individual's immunization
8 information in violation of Section 161.0071;

9 (3) fails to <u>exclude</u> [remove] a person's immunization 10 information in violation of Section 161.00705, 161.00706, or 11 161.00735; or

12 (4) negligently uses information in the immunization 13 registry to solicit new patients or clients or for other purposes 14 that are not associated with immunization or quality-of-care 15 purposes, unless authorized under this section.

SECTION 9. Section 161.0095(a), Health and Safety Code, is amended to read as follows:

18 (a) The department shall develop:

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(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 <u>or the individual's legally authorized representative</u>

to request exclusion [who is 18 years of age or older to consent to 1 2 submission and retention] of the individual's information from [in] the immunization registry. 3 4 SECTION 10. Section 161.0107(c), Health and Safety Code, is amended to read as follows: 5 (c) The executive commissioner by rule shall specify: 6 7 (1) the fields necessary to populate the immunization registry[, including a field that indicates the patient's consent 8 9 to be listed in the immunization registry has been obtained]; and the 10 (2) data standards that must be used for electronic submission of immunization information. 11 SECTION 11. The following provisions of the Health and 12 13 Safety Code are repealed: Sections 161.007(a-1), (a-3), (a-4), (a-5), and 14 (1) 15 (a-6); 16 (2) Sections 161.00705(e) and (h); and 17 Sections 161.00735(e) and (f). (3) 18 SECTION 12. (a) The changes in law made by this Act to Subchapter A, Chapter 161, Health and Safety Code, apply to 19 20 immunization information received by the Department of State Health Services before, on, or after January 1, 2021. An individual whose 21 22 immunization information was included immediately before January 1, 2021, in the immunization registry established under Subchapter 23 24 A, Chapter 161, Health and Safety Code, is subject to the changes in 25 law made by this Act to that subchapter, including the procedures established by that subchapter as amended by this Act. 26 27 (b) The changes in law made by this Act do not authorize the

Department of State Health Services to include in the immunization registry established under Subchapter A, Chapter 161, Health and Safety Code, immunization information of an individual who is 18 years of age or older and whose immunization information was not included in the registry on or before January 1, 2021, unless the department receives immunization data from a health care provider who:

8 (1) administers an immunization to the individual 9 after that date and elects to provide the individual's immunization 10 information to the department; and

11 (2) notifies the individual before submission of the 12 information to the department:

13 (A) that the health care provider is providing14 the information to the department for inclusion in the registry;

(B) that the information will remain in the registry until exclusion is requested by the individual or the individual's legally authorized representative; and

18 (C) of the procedures for requesting exclusion
19 from the registry under Subchapter A, Chapter 161, Health and
20 Safety Code, as amended by this Act.

The changes in law made by this Act apply only to an 21 (c) 22 offense committed on or after the effective date of this Act. An offense committed before the effective date of this Act is governed 23 24 by the law in effect on the date the offense was committed, and the 25 former law is continued in effect for that purpose. For purposes of this section, an offense was committed before the effective date of 26 27 this Act if any element of the offense occurred before that date.

1 SECTION 13. (a) As soon as practicable after the effective 2 date of this section, the Department of State Health Services shall 3 conduct a public awareness campaign to educate health care 4 providers, parents, payors, schools, and the public about the 5 changes in law made by this Act.

6 (b) As soon as practicable after the effective date of this 7 section, the executive commissioner of the Health and Human 8 Services Commission shall adopt the rules required by Section 9 161.0073(h), Health and Safety Code, as added by this Act.

SECTION 14. (a) Except as provided by Subsection (b) of this section, this Act takes effect January 1, 2021.

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(b) Section 13 of this Act takes effect September 1, 2019.