

By: Perry, Hall

S.B. No. 265

A BILL TO BE ENTITLED

AN ACT

relating to required reports of certain vaccine-related or drug-related adverse events.

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

SECTION 1. Subchapter A, Chapter 161, Health and Safety Code, is amended by adding Section 161.0103 to read as follows:

Sec. 161.0103. REQUIRED REPORT OF CERTAIN VACCINE-RELATED ADVERSE EVENTS. (a) In this section, "serious adverse event" means an event that:

(1) results in death;

(2) is considered life-threatening;

(3) results in inpatient hospitalization or an extension of the duration of an existing hospitalization;

(4) results in a persistent or significant incapacity or substantial disruption of a person's ability to perform normal life functions;

(5) results in a congenital anomaly or birth defect;

or

(6) results in a medically important condition that, based on the physician's reasonable medical judgment, may require medical or surgical intervention to prevent an outcome described by Subdivisions (1) through (5).

(b) This section applies only to a vaccine that is:

(1) experimental or investigational; or

1 (2) approved or authorized for emergency use by the
2 United States Food and Drug Administration.

3 (c) Notwithstanding Subsection (b), this section does not
4 apply to a vaccine administered as part of a clinical trial.

5 (d) Notwithstanding any other law, a physician shall report
6 to the federal Vaccine Adverse Event Reporting System any serious
7 adverse event the physician's patient suffers if:

8 (1) the physician:

9 (A) diagnoses the patient with a condition
10 related to the serious adverse event; and

11 (B) knows the patient received a vaccination to
12 which this section applies; and

13 (2) the patient suffers the serious adverse event
14 before the first anniversary of the date the patient was
15 vaccinated.

16 (e) A physician who violates this section is subject to:

17 (1) for an initial violation, non-disciplinary
18 corrective action by the Texas Medical Board; and

19 (2) for each subsequent violation, disciplinary
20 action by the Texas Medical Board as if the physician violated
21 Subtitle B, Title 3, Occupations Code.

22 (f) For purposes of non-disciplinary corrective action or
23 disciplinary action imposed under Subsection (e), a violation of
24 this section may not be considered after the third anniversary of
25 the date of the violation. However, the Texas Medical Board must
26 retain information on each violation in the physician's permanent
27 record.

1 (g) The executive commissioner shall adopt rules necessary
2 to implement this section.

3 SECTION 2. Subchapter E, Chapter 431, Health and Safety
4 Code, is amended by adding Section 431.1145 to read as follows:

5 Sec. 431.1145. REQUIRED REPORT OF CERTAIN DRUG-RELATED
6 ADVERSE EVENTS. (a) In this section, "serious adverse event" means
7 an event that:

8 (1) results in death;

9 (2) is considered life-threatening;

10 (3) results in inpatient hospitalization or an
11 extension of the duration of an existing hospitalization;

12 (4) results in a persistent or significant incapacity
13 or substantial disruption of the person's ability to perform normal
14 life functions;

15 (5) results in a congenital anomaly or birth defect;
16 or

17 (6) results in a medically important medical condition
18 that, based on the physician's reasonable medical judgment, may
19 require medical or surgical intervention to prevent an outcome
20 described by Subdivisions (1) through (5).

21 (b) This section applies only to a drug that is:

22 (1) experimental or investigational; or

23 (2) approved or authorized for emergency use by the
24 United States Food and Drug Administration.

25 (c) Notwithstanding Subsection (b), this section does not
26 apply to a drug that is administered or used as part of a clinical
27 trial.

1 (d) Notwithstanding any other law, a physician shall report
2 to the United States Food and Drug Administration through the
3 MedWatch Reporting System any serious adverse event the physician's
4 patient suffers if:

5 (1) the physician:

6 (A) diagnoses the patient with a condition
7 related to the serious adverse event; and

8 (B) knows the patient was administered or used a
9 drug to which this section applies; and

10 (2) the patient suffers the serious adverse event
11 before the first anniversary of the date the patient was
12 administered or used the drug.

13 (e) A physician who violates this section is subject to:

14 (1) for an initial violation, non-disciplinary
15 corrective action by the Texas Medical Board; and

16 (2) for each subsequent violation, disciplinary
17 action by the Texas Medical Board as if the physician violated
18 Subtitle B, Title 3, Occupations Code.

19 (f) For purposes of non-disciplinary corrective action or
20 disciplinary action imposed under Subsection (e), a violation is
21 not considered after the third anniversary of the date of the
22 violation. However, the Texas Medical Board must retain
23 information on each violation in the physician's permanent record.

24 (g) The executive commissioner shall adopt rules necessary
25 to implement this section.

26 SECTION 3. As soon as practicable after the effective date
27 of this Act, the executive commissioner of the Health and Human

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1 Services Commission shall adopt rules necessary to implement the
2 changes in law made by this Act.

3 SECTION 4. This Act takes effect September 1, 2023.