

By: Perry

S.B. No. 269

A BILL TO BE ENTITLED

1 AN ACT  
2 relating to required reports of certain vaccine-related or  
3 drug-related adverse events.

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

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

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

- 10 (1) results in death;  
11 (2) is considered life-threatening;  
12 (3) results in inpatient hospitalization or an  
13 extension of the duration of an existing hospitalization;  
14 (4) results in a persistent or significant incapacity  
15 or substantial disruption of an individual's ability to perform  
16 normal life functions;  
17 (5) results in a congenital anomaly or birth defect;  
18 or  
19 (6) results in a medically important condition that,  
20 based on the physician's reasonable medical judgment, may require  
21 medical or surgical intervention to prevent an outcome described by  
22 Subdivisions (1) through (5).

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

- 24 (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), the Texas Medical  
24 Board may not consider a violation of this section after the third  
25 anniversary of the date of the violation. The Texas Medical Board  
26 shall retain information on each violation of this section in the  
27 physician's permanent 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 an individual's ability to perform  
14 normal 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 program any serious adverse event the  
4 physician's 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), the Texas Medical  
21 Board may not consider a violation of this section after the third  
22 anniversary of the date of the violation. The Texas Medical Board  
23 shall retain information on each violation of this section in the  
24 physician's permanent record.

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

27        SECTION 3. As soon as practicable after the effective date

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1 of this Act, the executive commissioner of the Health and Human  
2 Services Commission shall adopt rules necessary to implement the  
3 changes in law made by this Act.

4 SECTION 4. This Act takes effect September 1, 2025.