By: Perry, Hall S.B. No. 265

(In the Senate - Filed December 6, 2022; February 15, 2023, read first time and referred to Committee on Health & Human Services; April 17, 2023, reported adversely, with favorable Committee Substitute by the following vote: Yeas 9, Nays 0; April 17, 2023, sent to printer.)

COMMITTEE VOTE

	Yea	Nay	Absent	PNV
Kolkhorst	X			
Perry	X			
Blanco	X			
Hall	X			
Hancock	X			
Hughes	X			
LaMantia	X			
Miles	X			
Sparks	X			

COMMITTEE SUBSTITUTE FOR S.B. No. 265 By: Perry

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

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

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

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

(1) the physician:

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

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

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

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

(1) for an initial violation, non-disciplinary

corrective action by the Texas Medical Board; and

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

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

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

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

Sec. 431.1145. REQUIRED REPORT OF CERTAIN DRUG-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 the person's ability to perform normal life functions;

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

(6) results in a medically important medical 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 drug that is:

(1) experimental or investigational; or

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

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

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

(1) the physician:

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

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

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

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

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

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

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

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

SECTION 3. As soon as practicable after the effective date of this Act, the executive commissioner of the Health and Human Services Commission shall adopt rules necessary to implement the changes in law made by this Act.

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

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