

1-1 By: Perry, Hall S.B. No. 265
1-2 (In the Senate - Filed December 6, 2022; February 15, 2023,
1-3 read first time and referred to Committee on Health & Human
1-4 Services; April 17, 2023, reported adversely, with favorable
1-5 Committee Substitute by the following vote: Yeas 9, Nays 0;
1-6 April 17, 2023, sent to printer.)

1-7 COMMITTEE VOTE

	Yea	Nay	Absent	PNV
1-8				
1-9	X			
1-10	X			
1-11	X			
1-12	X			
1-13	X			
1-14	X			
1-15	X			
1-16	X			
1-17	X			

1-18 COMMITTEE SUBSTITUTE FOR S.B. No. 265 By: Perry

1-19 A BILL TO BE ENTITLED
1-20 AN ACT

1-21 relating to required reports of certain vaccine-related or
1-22 drug-related adverse events.

1-23 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

1-24 SECTION 1. Subchapter A, Chapter 161, Health and Safety
1-25 Code, is amended by adding Section 161.0103 to read as follows:

1-26 Sec. 161.0103. REQUIRED REPORT OF CERTAIN VACCINE-RELATED
1-27 ADVERSE EVENTS. (a) In this section, "serious adverse event" means
1-28 an event that:

1-29 (1) results in death;

1-30 (2) is considered life-threatening;

1-31 (3) results in inpatient hospitalization or an
1-32 extension of the duration of an existing hospitalization;

1-33 (4) results in a persistent or significant incapacity
1-34 or substantial disruption of a person's ability to perform normal
1-35 life functions;

1-36 (5) results in a congenital anomaly or birth defect;

1-37 or

1-38 (6) results in a medically important condition that,
1-39 based on the physician's reasonable medical judgment, may require
1-40 medical or surgical intervention to prevent an outcome described by
1-41 Subdivisions (1) through (5).

1-42 (b) This section applies only to a vaccine that is:

1-43 (1) experimental or investigational; or

1-44 (2) approved or authorized for emergency use by the
1-45 United States Food and Drug Administration.

1-46 (c) Notwithstanding Subsection (b), this section does not
1-47 apply to a vaccine administered as part of a clinical trial.

1-48 (d) Notwithstanding any other law, a physician shall report
1-49 to the federal Vaccine Adverse Event Reporting System any serious
1-50 adverse event the physician's patient suffers if:

1-51 (1) the physician:

1-52 (A) diagnoses the patient with a condition
1-53 related to the serious adverse event; and

1-54 (B) knows the patient received a vaccination to
1-55 which this section applies; and

1-56 (2) the patient suffers the serious adverse event
1-57 before the first anniversary of the date the patient was
1-58 vaccinated.

1-59 (e) A physician who violates this section is subject to:

1-60 (1) for an initial violation, non-disciplinary

2-1 corrective action by the Texas Medical Board; and
2-2 (2) for each subsequent violation, disciplinary
2-3 action by the Texas Medical Board as if the physician violated
2-4 Subtitle B, Title 3, Occupations Code.

2-5 (f) For purposes of non-disciplinary corrective action or
2-6 disciplinary action imposed under Subsection (e), a violation of
2-7 this section may not be considered after the third anniversary of
2-8 the date of the violation. However, the Texas Medical Board must
2-9 retain information on each violation in the physician's permanent
2-10 record.

2-11 (g) The executive commissioner shall adopt rules necessary
2-12 to implement this section.

2-13 SECTION 2. Subchapter E, Chapter 431, Health and Safety
2-14 Code, is amended by adding Section 431.1145 to read as follows:

2-15 Sec. 431.1145. REQUIRED REPORT OF CERTAIN DRUG-RELATED
2-16 ADVERSE EVENTS. (a) In this section, "serious adverse event" means
2-17 an event that:

2-18 (1) results in death;

2-19 (2) is considered life-threatening;

2-20 (3) results in inpatient hospitalization or an
2-21 extension of the duration of an existing hospitalization;

2-22 (4) results in a persistent or significant incapacity
2-23 or substantial disruption of the person's ability to perform normal
2-24 life functions;

2-25 (5) results in a congenital anomaly or birth defect;

2-26 or

2-27 (6) results in a medically important medical condition
2-28 that, based on the physician's reasonable medical judgment, may
2-29 require medical or surgical intervention to prevent an outcome
2-30 described by Subdivisions (1) through (5).

2-31 (b) This section applies only to a drug that is:

2-32 (1) experimental or investigational; or

2-33 (2) approved or authorized for emergency use by the
2-34 United States Food and Drug Administration.

2-35 (c) Notwithstanding Subsection (b), this section does not
2-36 apply to a drug that is administered or used as part of a clinical
2-37 trial.

2-38 (d) Notwithstanding any other law, a physician shall report
2-39 to the United States Food and Drug Administration through the
2-40 MedWatch Reporting System any serious adverse event the physician's
2-41 patient suffers if:

2-42 (1) the physician:

2-43 (A) diagnoses the patient with a condition
2-44 related to the serious adverse event; and

2-45 (B) knows the patient was administered or used a
2-46 drug to which this section applies; and

2-47 (2) the patient suffers the serious adverse event
2-48 before the first anniversary of the date the patient was
2-49 administered or used the drug.

2-50 (e) A physician who violates this section is subject to:

2-51 (1) for an initial violation, non-disciplinary
2-52 corrective action by the Texas Medical Board; and

2-53 (2) for each subsequent violation, disciplinary
2-54 action by the Texas Medical Board as if the physician violated
2-55 Subtitle B, Title 3, Occupations Code.

2-56 (f) For purposes of non-disciplinary corrective action or
2-57 disciplinary action imposed under Subsection (e), a violation is
2-58 not considered after the third anniversary of the date of the
2-59 violation. However, the Texas Medical Board must retain
2-60 information on each violation in the physician's permanent record.

2-61 (g) The executive commissioner shall adopt rules necessary
2-62 to implement this section.

2-63 SECTION 3. As soon as practicable after the effective date
2-64 of this Act, the executive commissioner of the Health and Human
2-65 Services Commission shall adopt rules necessary to implement the
2-66 changes in law made by this Act.

2-67 SECTION 4. This Act takes effect September 1, 2023.

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