

## **BILL ANALYSIS**

Senate Research Center  
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C.S.S.B. 265  
By: Perry  
Health & Human Services  
4/13/2023  
Committee Report (Substituted)

### **AUTHOR'S / SPONSOR'S STATEMENT OF INTENT**

According to the United States Department of Health and Human Services VAERS website:

The Vaccine Adverse Event Reporting System (VAERS) is a passive reporting system, meaning it relies on individuals to send in reports of their experiences. Anyone can submit a report to VAERS, including parents and patients.

MedWatch is a medical product safety reporting program operating by the FDA. This program is similar to VAERS but applies to drugs, biologics, medical devices, combination products, special nutritional products, cosmetics, and food. The program also relies on voluntary reporting.

S.B. 265 requires by statute, a physician to report any adverse reaction that is caused by or potentially caused by an experimental or investigational, or administered under emergency use authorization by the United States Food and Drug Administration.

The substitute version exempts clinical trials. The substitute also limits the reporting requirements to a physician who diagnosed a patient with a serious adverse event and knew the patient had received a vaccine within the previous 12 months.

Requiring this reporting would help identify possible side effects or reactions, which would help better inform the patient while helping health care workers and policymakers work toward solutions in preventing or treating diseases.

C.S.S.B. 265 amends current law relating to required reports of certain vaccine-related or drug-related adverse events.

### **RULEMAKING AUTHORITY**

Rulemaking authority is expressly granted to executive commissioner of the Health and Human Services Commission in SECTION 1 (Section 161.0103, Health and Safety Code) and SECTION 2 (Section 431.1145, Health and Safety Code) of this bill.

### **SECTION BY SECTION ANALYSIS**

SECTION 1. Amends Subchapter A, Chapter 161, Health and Safety Code, by adding Section 161.0103, as follows:

Sec. 161.0103. REQUIRED REPORT OF CERTAIN VACCINE-RELATED ADVERSE EVENTS. (a) Defines "serious adverse event."

(b) Provides that this section applies only to a vaccine that is experimental or investigational or is approved or authorized for emergency use by the United States Food and Drug Administration.

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

(d) Requires a physician, notwithstanding any other law, to 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) Provides that a physician who violates this section is subject to:

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

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

(f) Prohibits a violation of this section, for purposes of non-disciplinary corrective action or disciplinary action imposed under Subsection (e), from being considered after the third anniversary of the date of the violation. Requires TMB, however, to retain information on each violation in the physician's permanent record.

(g) Requires the executive commissioner of the Health and Human Services Commission (executive commissioner) to adopt rules necessary to implement this section.

SECTION 2. Amends Subchapter E, Chapter 431, Health and Safety Code, by adding Section 431.1145, as follows:

Sec. 431.1145. REQUIRED REPORT OF CERTAIN DRUG-RELATED ADVERSE EVENTS. (a) Defines "serious adverse event."

(b) Provides that this section applies only to a drug that is experimental or investigational or is approved or authorized for emergency use by the United States Food and Drug Administration.

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

(d) Requires a physician, notwithstanding any other law, to 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) Provides that a physician who violates this section is subject to:

(1) for an initial violation, non-disciplinary corrective action by TMB; and

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

(f) Provides that a violation, for purposes of non-disciplinary corrective action or disciplinary action imposed under Subsection (e), is not considered after the third anniversary of the date of the violation. Requires TMB, however, to retain information on each violation in the physician's permanent record.

(g) Requires the executive commissioner to adopt rules necessary to implement this section.

SECTION 3. Requires the executive commissioner, as soon as practicable after the effective date of this Act, to adopt rules necessary to implement the changes in law made by this Act.

SECTION 4. Effective date: September 1, 2023.