

BILL ANALYSIS

C.S.H.B. 3540
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Public Health
Committee Report (Substituted)

BACKGROUND AND PURPOSE

The bill author has informed the committee that, following the expiration of the federal Public Readiness and Emergency Preparedness (PREP) Act, Texas pharmacists cannot, without physicians' protocol or standing orders, administer vaccines to patients under the age of fourteen or administer flu vaccines to patients under the age of seven. The bill author has also informed the committee that the ability to obtain immunizations and vaccinations is critical, especially for rural Texans who experience an increasing lack of consistent or abundant access to a physician. C.S.H.B. 3540 seeks to expand the circumstances under which a pharmacist may administer an immunization or vaccination to a patient without an established patient-physician relationship. The bill also allows for a pharmacist's authority to administer an immunization or vaccination to be delegated to an appropriately qualified pharmacy technician and makes certain other changes regarding the conditions under which a pharmacist may order and administer an immunization or vaccination.

CRIMINAL JUSTICE IMPACT

It is the committee's opinion that this bill does not expressly create a criminal offense, increase the punishment for an existing criminal offense or category of offenses, or change the eligibility of a person for community supervision, parole, or mandatory supervision.

RULEMAKING AUTHORITY

It is the committee's opinion that this bill does not expressly grant any additional rulemaking authority to a state officer, department, agency, or institution.

ANALYSIS

C.S.H.B. 3540 amends the Occupations Code to revise certain provisions of the Texas Pharmacy Act with respect to the administration of a medication and the ordering and administration of an immunization or vaccination by a pharmacist as follows:

- replaces the requirement that the Texas State Board of Pharmacy (TSBP) specify conditions under which a pharmacist may administer medication, including an immunization and vaccination, with a requirement that the TSBP specify conditions under which a pharmacist may administer medication and order or administer an immunization or vaccination;
- retains the following as matters the conditions must ensure but makes them solely applicable to ordering or administering an immunization or vaccination and makes them inapplicable to administration of medication:
 - that the pharmacist possess the necessary skill, education, and certification as specified by the TSBP to order or administer the immunization or vaccination; and
 - that the pharmacist, after administering an immunization or vaccination, notify the licensed health care provider responsible for the patient's care that the immunization or vaccination was administered;

- changes the time frame within which the pharmacist must notify the appropriate licensed health care provider from within a reasonable time after administering an immunization or vaccination to not later than the third business day after administering an immunization or vaccination;
- removes the following as matters the conditions must ensure:
 - that a licensed health care provider authorized to administer the medication is not reasonably available to administer the medication;
 - that failure to administer the medication, other than an immunization or vaccination, might result in a significant delay or interruption of a critical phase of drug therapy;
 - that the pharmacist may not administer medication to a patient at the patient's residence, except at a licensed nursing home or hospital;
 - that the pharmacist administers an immunization or vaccination under a physician's written protocol and meets the standards established by the TSBP; and
 - that the authority of a pharmacist to administer medication may not be delegated; and
- adds as a matter the conditions must ensure that the authority of the pharmacist to administer an immunization or vaccination may be delegated to a certified pharmacy technician who possesses the necessary skill, education, and certification as specified by the TSBP to administer the immunization or vaccination.

The bill establishes that a pharmacist who administers an immunization or vaccination satisfies the requirement to notify the appropriate licensed health care provider if the immunization or vaccination is recorded in the immunization registry maintained by the state. The bill requires a pharmacist to inform a child receiving an immunization or vaccination and the adult caregiver accompanying the child of the importance of an annual well-child visit with a pediatrician or other licensed primary health care provider.

C.S.H.B. 3540 changes the deadline by which a pharmacist must notify a physician who prescribes an immunization or vaccination of its administration from within 24 hours after the pharmacist administers the immunization or vaccination to not later than the third business day after the date the pharmacist administers the immunization or vaccination. In addition, the bill does the following:

- requires a TSBP rule adopted to implement that notice requirement to provide that a pharmacist satisfies the notice requirement if the immunization or vaccination is recorded in the immunization registry maintained by the state;
- revises the requirement for the TSBP to establish minimum education and continuing education standards for a pharmacist who administers an immunization or vaccination by specifying that the standards are for a pharmacist who orders or administers an immunization or vaccination;
- removes from the conditions for supervision by a physician to be considered adequate with respect to immunizations and vaccines the condition that the delegating physician has established a physician-patient relationship with each patient under 14 years of age and referred the patient to the pharmacist; and
- replaces an authorization for a pharmacist to administer an influenza vaccination to a patient over seven years of age without an established physician-patient relationship with an authorization for a pharmacist to order or administer:
 - to a patient who is at least three years of age an influenza immunization or vaccination and SARS-CoV-2 immunization or vaccination; and
 - to a patient who is at least five years of age an immunization or vaccination if the immunization or vaccination is:
 - authorized or approved by the FDA or listed in the routine immunization schedule recommended by the federal Advisory Committee on Immunization Practices published by the CDC; and

- ordered or administered in accordance with the federal Advisory Committee on Immunization Practices vaccine-specific recommendations.

C.S.H.B. 3540 revises the definition of "practice of pharmacy" by replacing the specification that such practice includes administering an immunization or vaccination under a physician's written protocol with the specification that such practice includes the following:

- ordering or administering an immunization or vaccination that the bill expressly authorizes a pharmacist to order or administer; and
- administering other immunizations or vaccinations to a patient under a protocol or prescription from a licensed health care provider.

EFFECTIVE DATE

On passage, or, if the bill does not receive the necessary vote, September 1, 2025.

COMPARISON OF INTRODUCED AND SUBSTITUTE

While C.S.H.B. 3540 may differ from the introduced in minor or nonsubstantive ways, the following summarizes the substantial differences between the introduced and committee substitute versions of the bill.

With respect to the requirement for a pharmacist, after administering an immunization or vaccination, to notify the licensed health care provider responsible for the patient's care that the immunization or vaccination was administered, the introduced and the substitute differ as follows:

- the introduced retained the existing requirement for the pharmacist to do so within a reasonable time after administration, whereas the substitute sets a deadline for the notice of not later than the third business day after administration;
- the introduced limited the notice requirement to immunizations or vaccinations prescribed by a licensed health care provider, whereas the substitute does not; and
- the substitute includes a provision absent from the introduced establishing that a pharmacist satisfies the notice requirement if the immunization or vaccination is recorded in the immunization registry maintained by the state.

Both the introduced and the substitute require the conditions for a pharmacist's ordering or administration of an immunization or vaccination to ensure that the authority of a pharmacist to administer an immunization or vaccination may be delegated to a certified pharmacy technician. However, the substitute conditions such delegation on the technician possessing the necessary skill, education, and certification as specified by the TSBP to administer the immunization or vaccination, whereas the introduced did not include this condition.

The substitute includes a requirement absent from the introduced for a pharmacist to inform a child receiving an immunization or vaccination and the adult caregiver accompanying the child of the importance of an annual well-child visit with a pediatrician or other licensed primary health care provider.

Both the introduced and the substitute change the deadline by which a pharmacist must notify a physician who prescribes an immunization or vaccination of its administration. However, whereas the introduced changed the deadline to not later than the 14th day after the date the pharmacist administers the immunization or vaccination, the substitute changes the deadline to not later than the third business day after that date of administration. The substitute includes a requirement absent from the introduced for a rule adopted to implement that notice requirement to provide that a pharmacist satisfies the notice requirement if the immunization or vaccination is recorded in the immunization registry maintained by the state.

The introduced authorized a pharmacist to order or administer an immunization or vaccination to a patient who is at least three years of age if the immunization or vaccination meets the following criteria:

- is authorized or approved by the FDA or listed in the routine immunization schedule recommended by the federal Advisory Committee on Immunization Practices published by the CDC; and
- is ordered or administered in accordance with the federal Advisory Committee on Immunization Practices vaccine-specific recommendations.

The substitute restricts that authorization to patients who are at least five years of age and establishes a separate authorization for a pharmacist to order or administer an influenza immunization or vaccination and SARS-CoV-2 immunization or vaccination to a patient who is at least three years of age. The substitute and the introduced differ with respect to their revisions to the definition of "practice of pharmacy" as follows:

- both versions revise the definition to reflect the authorization for pharmacists to order or administer certain immunizations or vaccinations under the bill's provisions, but the substitute omits the introduced version's specification that the applicable patients are at least three years of age to conform to the substitute's changes to the authorization; and
- whereas the introduced specified that such practice includes administering an immunization or vaccination to a patient younger than three years of age under a physician's written protocol if the patient is referred to a pharmacist by a physician, the substitute specifies that such practice includes administering an immunization or vaccination, other than those expressly authorized by the substitute, to a patient under a protocol or prescription from a licensed health care provider.