BILL ANALYSIS

C.S.H.B. 2561 By: Thompson, Senfronia Public Health Committee Report (Substituted)

BACKGROUND AND PURPOSE

The Texas State Board of Pharmacy, which regulates the practice of pharmacy in the state, is subject to the Texas Sunset Act and will be abolished on September 1, 2017, unless continued by the legislature. C.S.H.B. 2561 seeks to continue the board with several statutory modifications.

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 rulemaking authority is expressly granted to the Texas State Board of Pharmacy in SECTIONS 3 and 14 of this bill.

ANALYSIS

C.S.H.B. 2561 amends the Occupations Code to postpone from September 1, 2017, to September 1, 2029, the date on which the Texas State Board of Pharmacy is abolished and the Texas Pharmacy Act expires unless continued in existence as provided by the Texas Sunset Act. The bill revises the training program for board members and requires the executive director of the board to create a training manual that includes required training information and to distribute a copy of the training manual annually to each board member. The bill requires each board member, on receipt of the training manual, to sign and submit to the executive director a statement acknowledging receipt of the training manual and requires the board to publish a copy of each signed statement on the board's website. The bill's provisions relating to board member training and the training manual apply to a board member appointed before, on, or after the bill's effective date. The bill requires a board member who, before the bill's effective date, completed the training program under the law as it existed before the bill's effective date to complete additional training only on subjects added by the bill to the training program and prohibits such a board member from voting, deliberating, or being counted as a member in attendance at a meeting of the board held on or after December 1, 2017, until the member completes the additional training.

C.S.H.B. 2561 includes among the executive director's duties the duty to perform, under the direction of the board, the duties required by the Texas Pharmacy Act or designated by the board. The bill sets out provisions relating to the board's use of negotiated rulemaking and alternative dispute resolution.

C.S.H.B. 2561 removes the requirement that an applicant for a license to practice pharmacy obtained through examination or reciprocity or for registration as a pharmacy technician or pharmacy technician trainee be of good moral character and, if applicable, provide evidence of such character. The bill authorizes the board to refuse to renew a license to practice pharmacy for a license holder who is in violation of a board order. The bill requires a registrant who seeks to

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renew a pharmacy technician registration, before the expiration date of the registration, to pay a renewal fee determined by the board and to comply with the continuing education requirements prescribed by the board in accordance with the bill's provisions. The bill sets out the amount a person must pay to renew an expired pharmacy technician registration. The bill requires the board to adopt rules to reduce the amount of the fees imposed by the board for the renewal of an expired pharmacy technician registration to reflect the amounts provided for by the bill and requires a pharmacy technician who renews an expired registration certificate on or after the bill's effective date to pay the amount provided for by the bill instead of the amount provided for under board rules adopted before that date. The bill prohibits a person whose pharmacy technician registration but authorizes the person to register by complying with the requirements and procedures for initially registering. The bill authorizes the board to refuse to renew a pharmacy technician registration of a board order. The bill requires the board to adopt rules relating to the continuing education required for pharmacy technicians and sets out requirements for those rules.

C.S.H.B. 2561 amends the Health and Safety Code to change the deadline by which each dispensing pharmacist subject to statutory provisions relating to prescriptions for controlled substances or the official prescription program is required to send all required information to the Texas State Board of Pharmacy from not later than the seventh day after the date the prescription is completely filled to not later than the next business day after that date. The bill requires the board, in consultation with the Department of Public Safety and certain regulatory agencies, to identify prescribing practices that may be potentially harmful and patient prescription patterns that may suggest drug diversion or drug abuse. The bill requires the board to determine the conduct that constitutes a potentially harmful prescribing pattern or practice and develop indicators for levels of prescriber or patient activity that suggest such a pattern or practice may be occurring or drug diversion or drug abuse may be occurring. The bill authorizes the board, based on such indicators, to send an electronic notification to a dispenser or prescriber if the information submitted under statutory provisions relating to prescriptions for controlled substances or the official prescription program indicates a potentially harmful prescribing pattern or practice may be occurring or drug diversion or drug abuse may be occurring. The bill authorizes the board by rule to develop guidelines identifying behavior suggesting a patient is obtaining controlled substances that indicate drug diversion or drug abuse is occurring and requires a pharmacist who observes this behavior by a person who is to receive a controlled substance to access information regarding the controlled substance prescription history of the patient for whom the substance is to be dispensed, but a pharmacist is not required to comply with such a rule adopted by the board before January 1, 2018.

C.S.H.B. 2561 requires a pharmacist to access controlled substance prescription history information with respect to a patient before dispensing opioids, benzodiazepines, barbiturates, or carisoprodol for the patient and makes this requirement applicable only to a pharmacist who dispenses a controlled substance on or after January 1, 2018. The bill requires a wholesale distributor to report to the board the information that the distributor is required to report to the Automation of Reports and Consolidated Orders System (ARCOS) of the Federal Drug Enforcement Administration for the distributor to report the information to the board in the same format and with the same frequency as the information is reported to ARCOS. The bill makes such information reported by a distributor confidential and exempt from disclosure under state public information law.

EFFECTIVE DATE

September 1, 2017.

COMPARISON OF ORIGINAL AND SUBSTITUTE

While C.S.H.B. 2561 may differ from the original in minor or nonsubstantive ways, the

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following comparison is organized and formatted in a manner that indicates the substantial differences between the introduced and committee substitute versions of the bill.

INTRODUCED

SECTION 1. Section 481.074(q), Health and Safety Code, is amended.

SECTION 2. Section 481.075(i), Health and Safety Code, is amended.

SECTION 3. Section 481.0761, Health and Safety Code, is amended.

SECTION 4. Subchapter C, Chapter 481, Health and Safety Code, is amended by adding Sections 481.0763 and 481.0764 to read as follows:

Sec. 481.0763. DUTY OF PHARMACISTS.

Sec. 481.0764. REPORTS OF WHOLESALE PHARMACEUTICAL DISTRIBUTORS. (a) A wholesale pharmaceutical distributor shall report to the board the sale of a controlled substance made by the distributor to a person in this state.

The distributor shall report the information to the board in a similar manner as the distributor reports information to the Federal Drug Enforcement Administration. (b) The board shall ensure that information reported to the board under Subsection (a) is included in the state's prescription monitoring program database.

SECTION 5. Section 551.005, Occupations Code, is amended.

SECTION 6. Section 552.006, Occupations Code, is amended.

SECTION 7. Section 553.003(b), Occupations Code, is amended.

SECTION 8. Subchapter A, Chapter 554, Occupations Code, is amended.

SECTION 9. Section 558.051(a), Occupations Code, is amended.

HOUSE COMMITTEE SUBSTITUTE

SECTION 1. Same as introduced version.

SECTION 2. Same as introduced version.

SECTION 3. Same as introduced version.

SECTION 4. Subchapter C, Chapter 481, Health and Safety Code, is amended by adding Sections 481.0763 and 481.0764 to read as follows:

Sec. 481.0763. DUTY OF PHARMACISTS.

Sec. 481.0764. REPORTS OF WHOLESALE DISTRIBUTORS.

(a) A wholesale distributor shall report to the board the information that the distributor is required to report to the Automation of Reports and Consolidated Orders System (ARCOS) of Federal Drug Enforcement the Administration for the distribution of a controlled substance by the distributor to a person in this state. The distributor shall report the information to the board in the same format and with the same frequency as the information is reported to ARCOS. (b) Information reported to the board under Subsection (a) is confidential and not subject to disclosure under Chapter 552, Government Code.

SECTION 5. Same as introduced version.

SECTION 6. Same as introduced version.

SECTION 7. Same as introduced version.

SECTION 8. Same as introduced version.

SECTION 9. Same as introduced version.

SECTION 10. Section 558.101(a), Occupations Code, is amended.

SECTION 11. Section 559.003, Occupations Code, is amended.

SECTION 12. Section 568.002(c), Occupations Code, is amended.

SECTION 13. Section 568.004, Occupations Code, is amended.

SECTION 14. Chapter 568, Occupations Code, is amended.

SECTION 15. A pharmacist is not required to comply with a rule adopted under Section 481.0761(j), Health and Safety Code, as added by this Act, before January 1, 2018.

SECTION 16. Section 481.0763, Health and Safety Code, as added by this Act, applies only to a pharmacist who dispenses a controlled substance on or after January 1, 2018.

SECTION 17. (a) Except as provided by Subsection (b) of this section, Section 552.006, Occupations Code, as amended by this Act, applies to a member of the Texas State Board of Pharmacy appointed before, on, or after the effective date of this Act.

(b) A member of the Texas State Board of Pharmacy who, before the effective date of this Act, completed the training program required by Section 552.006, Occupations Code, as that law existed before the effective date of this Act, is required to complete additional training only on subjects added by this Act to the training program as required by Section 552.006, Occupations Code, as amended by this Act. A board member described by this subsection may not vote, deliberate, or be counted as a member in attendance at a meeting of the board held on or after December 1, 2017, until the member completes the additional training.

SECTION 18. Sections 558.051, 558.101, and 568.002, Occupations Code, as amended by this Act, apply only to an application for a license to practice pharmacy or for registration as a pharmacy technician or pharmacy technician trainee filed on or after the effective date of this SECTION 10. Same as introduced version.

SECTION 11. Same as introduced version.

SECTION 12. Same as introduced version.

SECTION 13. Same as introduced version.

SECTION 14. Same as introduced version.

SECTION 15. Same as introduced version.

SECTION 16. Same as introduced version.

SECTION 17. Same as introduced version.

SECTION 18. Same as introduced version.

Act. An application for a license or registration filed before the effective date of this Act is governed by the law in effect on the date the application was filed, and the former law is continued in effect for that purpose.

SECTION 19. Section 559.003. Occupations Code, as amended by this Act, and Sections 568.004(b), (e), and (f), Occupations Code, as added by this Act, apply only to the renewal of a license to practice pharmacy or of a pharmacy technician registration on or after the effective date of this Act. The renewal of a license or registration before that date is governed by the law in effect immediately before the effective date of this Act, and the former law is continued in effect for that purpose.

SECTION 20. As soon as practicable after the effective date of this Act, the Texas State Board of Pharmacy shall adopt rules to reduce the amount of the fees imposed by the board for the renewal of an expired pharmacy technician registration to reflect the amounts provided for by Sections 568.004(c) and (d), Occupations Code, as added by this Act. A pharmacy technician who renews an expired registration certificate on or after the effective date of this Act shall pay the amount provided for by Section 568.004(c) or (d), Occupations Code, as added by this Act, instead of the amount provided for under board rules adopted before that date.

SECTION 21. This Act takes effect September 1, 2017.

SECTION 19. Same as introduced version.

SECTION 20. Same as introduced version.

SECTION 21. Same as introduced version.

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