Chapter 485

H.B. No. 2561

AN ACT

relating to the continuation and functions of the Texas State Board of Pharmacy and the regulation of certain prescription drugs, prescription drug prescribers and dispensers, and colleges of pharmacy; authorizing a reduction in fees.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Section 481.003(a), Health and Safety Code, is amended to read as follows:

(a) The director may adopt rules to administer and enforce this chapter, other than Sections 481.073, 481.074, 481.075, 481.076, [~~and~~] 481.0761, 481.0762, 481.0763, 481.0764, 481.0765, and 481.0766. The board may adopt rules to administer Sections 481.073, 481.074, 481.075, 481.076, [~~and~~] 481.0761, 481.0762, 481.0763, 481.0764, 481.0765, and 481.0766.

SECTION 2. Section 481.074(q), Health and Safety Code, is amended to read as follows:

(q) Each dispensing pharmacist shall send all required information, including any information required to complete the Schedule III through V prescription forms, to the board by electronic transfer or another form approved by the board not later than the next business [~~seventh~~] day after the date the prescription is completely filled.

SECTION 3. Section 481.075(i), Health and Safety Code, is amended to read as follows:

(i) Each dispensing pharmacist shall:

(1) fill in on the official prescription form or note in the electronic prescription record each item of information given orally to the dispensing pharmacy under Subsection (h) and the date the prescription is filled, and:

(A) for a written prescription, fill in the dispensing pharmacist's signature; or

(B) for an electronic prescription, appropriately record the identity of the dispensing pharmacist in the electronic prescription record;

(2) retain with the records of the pharmacy for at least two years:

(A) the official prescription form or the electronic prescription record, as applicable; and

(B) the name or other patient identification required by Section 481.074(m) or (n); and

(3) send all required information, including any information required to complete an official prescription form or electronic prescription record, to the board by electronic transfer or another form approved by the board not later than the next business [~~seventh~~] day after the date the prescription is completely filled.

SECTION 4. Sections 481.076(a) and (d), Health and Safety Code, are amended to read as follows:

(a) The board may not permit any person to have access to information submitted to the board under Section 481.074(q) or 481.075 except:

(1) [~~an investigator for~~] the board, the Texas Medical Board, the Texas State Board of Podiatric Medical Examiners, the State Board of Dental Examiners, the State Board of Veterinary Medical Examiners, the Texas Board of Nursing, or the Texas Optometry Board for the purpose of:

(A) investigating a specific license holder; or

(B) monitoring for potentially harmful prescribing or dispensing patterns or practices under Section 481.0762;

(2) an authorized officer or member of the department or authorized employee of the board engaged in the administration, investigation, or enforcement of this chapter or another law governing illicit drugs in this state or another state;

(3) the department on behalf of a law enforcement or prosecutorial official engaged in the administration, investigation, or enforcement of this chapter or another law governing illicit drugs in this state or another state;

(4) a medical examiner conducting an investigation;

(5) provided that accessing the information is authorized under the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191) and regulations adopted under that Act:

(A) a pharmacist or a pharmacy technician, as defined by Section 551.003, Occupations Code, acting at the direction of a pharmacist; or

(B) a practitioner who:

(i) is a physician, dentist, veterinarian,

podiatrist, optometrist, or advanced practice nurse or is a physician assistant described by Section 481.002(39)(D) or an employee or other agent of a practitioner acting at the direction of a practitioner; and

(ii) is inquiring about a recent Schedule II, III, IV, or V prescription history of a particular patient of the practitioner[~~, provided that the person accessing the information is authorized to do so under the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191) and rules adopted under that Act~~];

(6) a pharmacist or practitioner who is inquiring about the person's own dispensing or prescribing activity; or

(7) one or more states or an association of states with which the board has an interoperability agreement, as provided by Subsection (j).

(d) Information submitted to the board under this section may be used only for:

(1) the administration, investigation, or enforcement of this chapter or another law governing illicit drugs in this state or another state;

(2) investigatory, [~~or~~] evidentiary, or monitoring purposes in connection with the functions of an agency listed in Subsection (a)(1);

(3) the prescribing and dispensing of controlled substances by a person listed in Subsection (a)(5); or

(4) [~~(3)~~] dissemination by the board to the public in the form of a statistical tabulation or report if all information

reasonably likely to reveal the identity of each patient, practitioner, or other person who is a subject of the information has been removed.

SECTION 5. Section 481.0761, Health and Safety Code, is amended by adding Subsections (h), (i), (j), and (k) to read as follows:

(h) The board, in consultation with the department and the regulatory agencies listed in Section 481.076(a)(1), shall identify prescribing practices that may be potentially harmful and patient prescription patterns that may suggest drug diversion or drug abuse. The board shall determine the conduct that constitutes a potentially harmful prescribing pattern or practice and develop indicators for levels of prescriber or patient activity that suggest a potentially harmful prescribing pattern or practice may be occurring or drug diversion or drug abuse may be occurring.

(i) The board, based on the indicators developed under Subsection (h), may send an electronic notification to a dispenser or prescriber if the information submitted under Section 481.074(g) or 481.075 indicates a potentially harmful prescribing pattern or practice may be occurring or drug diversion or drug abuse may be occurring.

(j) The board by rule may develop guidelines identifying behavior suggesting a patient is obtaining controlled substances that indicate drug diversion or drug abuse is occurring. A pharmacist who observes behavior described by this subsection by a person who is to receive a controlled substance shall access the information under Section 481.076(a)(5) regarding the patient for

whom the substance is to be dispensed.

(k) The board by rule may develop guidelines identifying patterns that may indicate that a particular patient to whom a controlled substance is prescribed or dispensed is engaging in drug abuse or drug diversion. These guidelines may be based on the frequency of prescriptions issued to and filled by the patient, the types of controlled substances prescribed, and the number of prescribers who prescribe controlled substances to the patient. The board may, based on the guidelines developed under this subsection, send a prescriber or dispenser an electronic notification if there is reason to believe that a particular patient is engaging in drug abuse or drug diversion.

SECTION 6. Subchapter C, Chapter 481, Health and Safety Code, is amended by adding Sections 481.0762, 481.0763, 481.0764, 481.0765, and 481.0766 to read as follows:

Sec. 481.0762. MONITORING BY REGULATORY AGENCY. (a) Each regulatory agency that issues a license, certification, or registration to a prescriber shall promulgate specific guidelines for prescribers regulated by that agency for the responsible prescribing of opioids, benzodiazepines, barbiturates, or carisoprodol.

(b) A regulatory agency that issues a license, certification, or registration to a prescriber shall periodically access the information submitted to the board under Sections 481.074(q) and 481.075 to determine whether a prescriber is engaging in potentially harmful prescribing patterns or practices.

(c) If the board sends a prescriber an electronic

notification authorized under Section 481.0761(i), the board shall immediately send an electronic notification to the appropriate regulatory agency.

(d) In determining whether a potentially harmful prescribing pattern or practice is occurring, the appropriate regulatory agency, at a minimum, shall consider:

(1) the number of times a prescriber prescribes opioids, benzodiazepines, barbiturates, or carisoprodol; and

(2) for prescriptions described by Subdivision (1), patterns of prescribing combinations of those drugs and other dangerous combinations of drugs identified by the board.

(e) If, during a periodic check under this section, the regulatory agency finds evidence that a prescriber may be engaging in potentially harmful prescribing patterns or practices, the regulatory agency may notify that prescriber.

(f) A regulatory agency may open a complaint against a prescriber if the agency finds evidence during a periodic check under this section that the prescriber is engaging in conduct that violates this subchapter or any other statute or rule.

Sec. 481.0763. REGISTRATION BY REGULATORY AGENCY. A regulatory agency that issues a license, certification, or registration to a prescriber or dispenser shall provide the board with any necessary information for each prescriber or dispenser, including contact information for the notifications described by Sections 481.0761(i) and (k), to register the prescriber or dispenser with the system by which the prescriber or dispenser receives information as authorized under Section 481.076(a)(5).

Sec. 481.0764. DUTIES OF PRESCRIBERS, PHARMACISTS, AND RELATED HEALTH CARE PRACTITIONERS. (a) A person authorized to receive information under Section 481.076(a)(5), other than a veterinarian, shall access that information with respect to the patient before prescribing or dispensing opioids, benzodiazepines, barbiturates, or carisoprodol.

(b) A person authorized to receive information under Section 481.076(a)(5) may access that information with respect to the patient before prescribing or dispensing any controlled substance.

(c) A veterinarian authorized to access information under Subsection (b) regarding a controlled substance may access the information for prescriptions dispensed only for the animals of an owner and may not consider the personal prescription history of the owner.

(d) A violation of Subsection (a) is grounds for disciplinary action by the regulatory agency that issued a license, certification, or registration to the person who committed the violation.

(e) This section does not grant a person the authority to issue prescriptions for or dispense controlled substances.

Sec. 481.0765. EXCEPTIONS. (a) A prescriber is not subject to the requirements of Section 481.0764(a) if:

(1) the patient has been diagnosed with cancer or the patient is receiving hospice care; and

(2) the prescriber clearly notes in the prescription record that the patient was diagnosed with cancer or is receiving

hospice care, as applicable.

(b) A dispenser is not subject to the requirements of Section 481.0764(a) if it is clearly noted in the prescription record that the patient has been diagnosed with cancer or is receiving hospice care.

(c) A prescriber or dispenser is not subject to the requirements of Section 481.0764(a) and a dispenser is not subject to a rule adopted under Section 481.0761(j) if the prescriber or dispenser makes a good faith attempt to comply but is unable to access the information under Section 481.076(a)(5) because of circumstances outside the control of the prescriber or dispenser.

Sec. 481.0766. 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 the Federal Drug Enforcement 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 7. (a) Subtitle A, Title 6, Health and Safety Code, is amended by adding Chapter 442 to read as follows:

CHAPTER 442. DONATION OF PRESCRIPTION DRUGS

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 442.001. DEFINITIONS. In this chapter:

(1) "Donor" means an individual who donates unused prescription drugs under this chapter to a participating provider.

(2) "Health care facility" means a facility that provides health care services to patients and maintains a pharmacy in the facility. The term includes the following facilities if a pharmacy is maintained in the facility:

(A) a general or special hospital as defined by Chapter 241;

(B) an ambulatory surgical center licensed under Chapter 243; and

(C) an institution licensed under Chapter 242.

(3) "Health care professional" means an individual licensed, certified, or otherwise authorized to administer health care and prescribe prescription drugs, for profit or otherwise, in the ordinary course of business or professional practice. The term does not include a health care facility.

(4) "Participating provider" means a health care facility or pharmacy, or a pharmacist who is an employee of the facility or pharmacy, that elects to participate in the collection and redistribution of donated prescription drugs under this chapter.

(5) "Pharmacist" means a person licensed under Chapter 558, Occupations Code.

(6) "Pharmacy" means an entity licensed under Chapter

560, Occupations Code.

(7) "Prescription drug" has the meaning assigned by Section 551.003, Occupations Code.

(8) "Recipient" means an individual who voluntarily receives donated prescription drugs under this chapter.

(9) "Tamper-evident" means packaging that allows for detection of unauthorized access to a prescription drug.

Sec. 442.002. RULEMAKING AUTHORITY. The executive commissioner may adopt rules to implement this chapter.

Sec. 442.003. CONSTRUCTION WITH OTHER LAW. This chapter does not limit the authority of this state or a political subdivision of this state to regulate or prohibit a prescription drug.

SUBCHAPTER B. DONATION AND REDISTRIBUTION OF UNUSED PRESCRIPTION DRUGS

Sec. 442.051. DONATION AND REDISTRIBUTION OF PRESCRIPTION DRUGS. (a) A donor may donate unused prescription drugs to a participating provider in accordance with this chapter and rules adopted under this chapter.

(b) A participating provider may dispense donated prescription drugs to a recipient in accordance with this chapter and rules adopted under this chapter.

Sec. 442.052. STANDARDS FOR DONATION AND REDISTRIBUTION. (a) The executive commissioner by rule shall adopt standards and procedures for:

(1) accepting, storing, labeling, and dispensing donated prescription drugs; and

(2) inspecting donated prescription drugs to determine whether the drugs are adulterated and whether the drugs are safe and suitable for redistribution.

(b) In adopting standards and procedures under this section, the executive commissioner shall ensure that the donation and redistribution process is consistent with public health and safety standards.

Sec. 442.053. REQUIREMENTS FOR DONATED PRESCRIPTION DRUGS. (a) A donated prescription drug may be accepted or dispensed under this chapter only if the drug is in its original, unopened, sealed, and tamper-evident unit-dose packaging. A drug packaged in single unit doses may be accepted and dispensed if the outside packaging is opened but the single unit-dose packaging is unopened.

(b) A donated prescription drug may not be accepted or dispensed under this chapter if:

(1) the drug is a controlled substance;

(2) the drug is adulterated or misbranded;

(3) the drug is not stored in compliance with the drug's product label; or

(4) the United States Food and Drug Administration requires the drug to have a risk evaluation or mitigation strategy.

(c) A participating provider shall comply with all applicable provisions of state and federal law relating to the inspection, storage, labeling, and dispensing of prescription drugs.

Sec. 442.054. DONATION PROCESS. (a) Before being dispensed to a recipient, a prescription drug donated under this

chapter must be inspected by the participating provider in accordance with federal law, laws of this state, and department rule to determine whether the drug is adulterated or misbranded and whether the drug has been stored in compliance with the requirements of the product label.

(b) A donated prescription drug dispensed to a recipient under this chapter must be prescribed by a health care professional for use by the recipient.

(c) A participating provider may charge a handling fee not to exceed $20 to a recipient to cover the costs of inspecting, storing, labeling, and dispensing the donated prescription drug. A participating provider may not resell a prescription drug donated under this chapter. A donor may not sell a prescription drug to a participating provider.

(d) A participating provider may not submit a claim or otherwise seek reimbursement from any public or private third-party payor for donated prescription drugs dispensed to a recipient under this chapter. A public or private third-party payor is not required to provide reimbursement for donated drugs dispensed to a recipient under this chapter.

Sec. 442.055. DONOR FORM. Before donating a prescription drug under this chapter, a donor shall sign a form prescribed by the department stating that:

(1) the donor is the owner of the donated prescription drug;

(2) the donated prescription drug has been properly stored and the container has not been opened or tampered with;

(3) the donated prescription drug has not been adulterated or misbranded; and

(4) the donor is voluntarily donating the prescription drug.

Sec. 442.056. RECIPIENT FORM. Before accepting a donated prescription drug under this chapter, a recipient shall sign a form prescribed by the department stating that:

(1) the recipient acknowledges that the donor is not a pharmacist and the donor took ordinary care of the prescription drug;

(2) the recipient acknowledges that the donor is known to the participating provider and that there is no reason to believe that the prescription drug was improperly handled or stored;

(3) by accepting the prescription drug, the recipient accepts any risk that an accidental mishandling could create; and

(4) the recipient releases the donor, participating provider, and manufacturer of the drug from liability related to the prescription drug.

Sec. 442.057. LIMITATION OF LIABILITY. (a) A donor or participating provider who acts in good faith in donating, accepting, storing, labeling, distributing, or dispensing prescription drugs under this chapter:

(1) is not criminally liable and is not subject to professional disciplinary action for those activities; and

(2) is not civilly liable for damages for bodily injury, death, or property damage that arises from those activities unless the injury, death, or damage arises from the donor or

participating provider's recklessness or intentional conduct.

(b) A manufacturer of a prescription drug that donates a drug under this chapter is not, in the absence of bad faith, criminally or civilly liable for bodily injury, death, or property damage arising from the donation, acceptance, or dispensing of the drug, including the manufacturer's failure to communicate to a donor or other person:

(1) product or consumer information about the donated prescription drug; or

(2) the expiration date of the donated prescription drug.

Sec. 442.058. DATABASE OF PARTICIPATING PROVIDERS. The department shall establish and maintain an electronic database that lists each participating provider. The department shall post the database on its Internet website.

(b) If before implementing any provision of this section a state agency determines that a waiver or authorization from a federal agency is necessary for implementation of that provision, the agency affected by the provision shall request the waiver or authorization and may delay implementing that provision until the waiver or authorization is granted.

SECTION 8. Section 551.005, Occupations Code, is amended to read as follows:

Sec. 551.005. APPLICATION OF SUNSET ACT. The Texas State Board of Pharmacy is subject to Chapter 325, Government Code (Texas Sunset Act). Unless continued in existence as provided by that chapter, the board is abolished and this subtitle expires September

1, 2029 [~~2017~~].

SECTION 9. Chapter 551, Occupations Code, is amended by adding Sections 551.006 and 551.008 to read as follows:

Sec. 551.006. EXCLUSIVE AUTHORITY. Notwithstanding any other law, a pharmacist has the exclusive authority to determine whether or not to dispense a drug.

Sec. 551.008. PROHIBITION ON RULE VIOLATING SINCERELY HELD RELIGIOUS BELIEF. (a) All rules, regulations, or policies adopted by the board may not violate Chapter 110, Civil Practice and Remedies Code.

(b) A person may assert a violation of Subsection (a) as an affirmative defense in an administrative hearing or as a claim or defense in a judicial proceeding under Chapter 37, Civil Practice and Remedies Code.

SECTION 10. Section 552.006, Occupations Code, is amended by amending Subsection (b) and adding Subsection (d) to read as follows:

(b) The training program must provide the person with information regarding:

(1) the law governing the board's operations;

(2) [~~this subtitle and~~] the programs, functions, rules, and budget of the board;

(3) the scope of and limitations on the rulemaking authority of the board;

(4) the types of board rules, interpretations, and enforcement actions that may implicate federal antitrust law by limiting competition or impacting prices charged by persons engaged

in a profession or business the board regulates, including rules, interpretations, and enforcement actions that:

(A) regulate the scope of practice of persons in a profession or business the board regulates;

(B) restrict advertising by persons in a profession or business the board regulates;

(C) affect the price of goods or services provided by persons in a profession or business the board regulates; and

(D) restrict participation in a profession or business the board regulates;

(5) [~~(2)~~] the results of the most recent formal audit of the board;

(6) [~~(3)~~] the requirements of:

(A) laws relating to open meetings, public information, administrative procedure, and disclosing conflicts of interest; and

(B) other laws applicable to members of the board in performing their duties; and

(7) [~~(4)~~] any applicable ethics policies adopted by the board or the Texas Ethics Commission.

(d) The executive director shall create a training manual that includes the information required by Subsection (b). The executive director shall distribute a copy of the training manual annually to each board member. On receipt of the training manual, each board member shall sign and submit to the executive director a statement acknowledging receipt of the training manual. The board

shall publish a copy of each signed statement on the board's Internet website.

SECTION 11. Section 553.003(b), Occupations Code, is amended to read as follows:

(b) The executive director is a full-time employee of the board and shall:

(1) serve as secretary to the board; [~~and~~]

(2) perform the regular administrative functions of the board and any other duty as the board directs; and

(3) under the direction of the board, perform the duties required by this subtitle or designated by the board.

SECTION 12. Subchapter A, Chapter 554, Occupations Code, is amended by adding Section 554.0011 to read as follows:

Sec. 554.0011. USE OF ALTERNATIVE RULEMAKING AND DISPUTE RESOLUTION. (a) The board shall develop a policy to encourage the use of:

(1) negotiated rulemaking procedures under Chapter 2008, Government Code, for the adoption of board rules; and

(2) appropriate alternative dispute resolution procedures under Chapter 2009, Government Code, to assist in the resolution of internal and external disputes under the board's jurisdiction.

(b) The board's procedures relating to alternative dispute resolution must conform, to the extent possible, to any model guidelines issued by the State Office of Administrative Hearings for the use of alternative dispute resolution by state agencies.

(c) The board shall:

(1) coordinate the implementation of the policy adopted under Subsection (a);

(2) provide training as needed to implement the procedures for negotiated rulemaking or alternative dispute resolution; and

(3) collect data concerning the effectiveness of those procedures.

SECTION 13. Section 554.051(a-1), Occupations Code, is amended to read as follows:

(a-1) The board may adopt rules to administer Sections 481.073, 481.074, 481.075, 481.076, [~~and~~] 481.0761, 481.0762, 481.0763, 481.0764, 481.0765, and 481.0766, Health and Safety Code.

SECTION 14. Section 558.051(a), Occupations Code, is amended to read as follows:

(a) To qualify for a license to practice pharmacy, an applicant for licensing by examination must submit to the board:

(1) a license fee set by the board; and

(2) a completed application on a form prescribed by the board with satisfactory sworn evidence that the applicant:

(A) is at least 18 years of age;

(B) [~~is of good moral character;~~

[~~(C)~~] has completed a minimum of a 1,000-hour internship or other program that has been approved by the board or has demonstrated, to the board's satisfaction, experience in the practice of pharmacy that meets or exceeds the board's minimum internship requirements;

(C) [~~(D)~~] has graduated and received a

professional practice degree, as defined by board rule, from an accredited pharmacy degree program approved by the board;

(D) [~~(E)~~] has passed the examination required by the board; and

(E) [~~(F)~~] has not had a pharmacist license granted by another state restricted, suspended, revoked, or surrendered, for any reason.

SECTION 15. Section 558.101(a), Occupations Code, is amended to read as follows:

(a) To qualify for a license to practice pharmacy, an applicant for licensing by reciprocity must:

(1) submit to the board:

(A) a reciprocity fee set by the board; and

(B) a completed application in the form prescribed by the board, given under oath;

(2) [~~be of good moral character;~~

[~~(3)~~] have graduated and received a professional practice degree, as defined by board rule, from an accredited pharmacy degree program approved by the board;

(3) [~~(4)~~] have presented to the board:

(A) proof of current or initial licensing by examination; and

(B) proof that the current license and any other license granted to the applicant by another state has not been restricted, suspended, revoked, or surrendered for any reason; and

(4) [~~(5)~~] pass the Texas Pharmacy Jurisprudence examination.

SECTION 16. Section 559.003, Occupations Code, is amended by adding Subsection (f) to read as follows:

(f) The board may refuse to renew a license to practice pharmacy for a license holder who is in violation of a board order.

SECTION 17. Section 562.110, Occupations Code, is amended by amending Subsections (a), (b), (d), (e), and (f) and adding Subsections (g), (h), and (i) to read as follows:

(a) In this section:

(1) "Provider pharmacy" means a Class A pharmacy that provides pharmacy services through a telepharmacy system at a remote dispensing site.

(2) "Remote dispensing site" means a location licensed as a telepharmacy that is authorized by a provider pharmacy through a telepharmacy system to store and dispense prescription drugs and devices, including dangerous drugs and controlled substances.

(3) "Telepharmacy[~~, "telepharmacy~~] system" means a system that monitors the dispensing of prescription drugs and provides for related drug use review and patient counseling services by an electronic method, including the use of the following types of technology:

(A) [~~(1)~~] audio and video;

(B) [~~(2)~~] still image capture; and

(C) [~~(3)~~] store and forward.

(b) A Class A or Class C pharmacy located in this state may provide pharmacy services, including the dispensing of drugs, through a telepharmacy system at locations separate from [~~in a facility that is not at the same location as~~] the Class A or Class C

pharmacy.

(d) A telepharmacy system may be located only at:

(1) a health care facility in this state that is regulated by this state or the United States; or

(2) a remote dispensing site.

(e) The board shall adopt rules regarding the use of a telepharmacy system under this section, including:

(1) the types of health care facilities at which a telepharmacy system may be located under Subsection (d)(1), which must include the following facilities:

(A) a clinic designated as a rural health clinic regulated under 42 U.S.C. Section 1395x(aa)[~~, as amended~~]; and

(B) a health center as defined by 42 U.S.C. Section 254b[~~, as amended~~];

(2) the locations eligible to be licensed as remote dispensing sites, which must include locations in medically underserved areas, areas with a medically underserved population, and health professional shortage areas determined by the United States Department of Health and Human Services;

(3) licensing and operating requirements for remote dispensing sites, including:

(A) a requirement that a remote dispensing site license identify the provider pharmacy that will provide pharmacy services at the remote dispensing site;

(B) a requirement that a provider pharmacy be allowed to provide pharmacy services at not more than two remote dispensing sites;

(C) a requirement that a pharmacist employed by a provider pharmacy make at least monthly on-site visits to a remote dispensing site or more frequent visits if specified by board rule;

(D) a requirement that each month the perpetual inventory of controlled substances at the remote dispensing site be reconciled to the on-hand count of those controlled substances at the site by a pharmacist employed by the provider pharmacy;

(E) a requirement that a pharmacist employed by a provider pharmacy be physically present at a remote dispensing site when the pharmacist is providing services requiring the physical presence of the pharmacist, including immunizations;

(F) a requirement that a remote dispensing site be staffed by an on-site pharmacy technician who is under the continuous supervision of a pharmacist employed by the provider pharmacy;

(G) a requirement that all pharmacy technicians at a remote dispensing site be counted for the purpose of establishing the pharmacist-pharmacy technician ratio of the provider pharmacy, which, notwithstanding Section 568.006, may not exceed three pharmacy technicians for each pharmacist providing supervision;

(H) a requirement that, before working at a remote dispensing site, a pharmacy technician must:

(i) have worked at least one year at a retail pharmacy during the three years preceding the date the pharmacy technician begins working at the remote dispensing site; and

(ii) have completed a board-approved training program on the proper use of a telepharmacy system;

(I) a requirement that pharmacy technicians at a remote dispensing site may not perform extemporaneous sterile or nonsterile compounding but may prepare commercially available medications for dispensing, including the reconstitution of orally administered powder antibiotics; and

(J) any additional training or practice experience requirements for pharmacy technicians at a remote dispensing site;

(4) the areas that qualify under Subsection (f);

(5) [~~(3)~~] recordkeeping requirements; and

(6) [~~(4)~~] security requirements.

(f) A telepharmacy system located at a health care facility under Subsection (d)(1) may not be located in a community in which a Class A or Class C pharmacy is located as determined by board rule. If a Class A or Class C pharmacy is established in a community in which a telepharmacy system has been located under this section, the telepharmacy system may continue to operate in that community.

(g) A telepharmacy system located at a remote dispensing site under Subsection (d)(2) may not dispense a controlled substance listed in Schedule II as established by the commissioner of state health services under Chapter 481, Health and Safety Code, and may not be located within 22 miles by road of a Class A pharmacy.

(h) If a Class A pharmacy is established within 22 miles by road of a remote dispensing site that is currently operating, the remote dispensing site may continue to operate at that location.

(i) The board by rule shall require and develop a process for a remote dispensing site to apply for classification as a Class A pharmacy if the average number of prescriptions dispensed each day the remote dispensing site is open for business is more than 125, as calculated each calendar year.

SECTION 18. Section 568.002(c), Occupations Code, is amended to read as follows:

(c) An applicant for registration as a pharmacy technician or a pharmacy technician trainee must[~~:~~

[~~(1) be of good moral character; and~~

[~~(2)~~] submit an application on a form prescribed by the board.

SECTION 19. Section 568.004, Occupations Code, is amended to read as follows:

Sec. 568.004. RENEWAL OF REGISTRATION. (a) The board may adopt a system in which the registrations of pharmacy technicians and pharmacy technician trainees expire on various dates during the year.

(b) To renew a pharmacy technician registration, the registrant must, before the expiration date of the registration:

(1) pay a renewal fee as determined by the board under Section 568.005; and

(2) comply with the continuing education requirements prescribed by the board in accordance with Section 568.0045.

(c) A person whose pharmacy technician registration has been expired for 90 days or less may renew the expired registration by paying to the board a renewal fee that is equal to one and

one-half times the normally required renewal fee for the registration.

(d) A person whose pharmacy technician registration has been expired for more than 90 days but less than one year may renew the expired registration by paying to the board a renewal fee that is equal to two times the normally required renewal fee for the registration.

(e) A person whose pharmacy technician registration has been expired for one year or more may not renew the registration. The person may register by complying with the requirements and procedures for initially registering, including the examination requirement.

(f) The board may refuse to renew a pharmacy technician registration for a registrant who is in violation of a board order.

SECTION 20. Chapter 568, Occupations Code, is amended by adding Section 568.0045 to read as follows:

Sec. 568.0045. RULES RELATING TO CONTINUING EDUCATION. The board shall adopt rules relating to the continuing education required for pharmacy technicians. The rules must include requirements for:

(1) the number of hours of continuing education;

(2) the methods for meeting the continuing education requirements;

(3) the approval of continuing education programs;

(4) reporting completion of continuing education;

(5) records of completion of continuing education; and

(6) board audits to ensure compliance with the

continuing education requirements.

SECTION 21. Section 89.051(b), Education Code, is amended to read as follows:

(b) The college shall be known as The Texas A&M University System Health Science Center Irma Lerma Rangel College of Pharmacy, and the primary building in which the school is operated shall be located in Kleberg County and must include "Irma Rangel" in its official name.

SECTION 22. (a) A joint interim committee is created to conduct an interim study on the monitoring of the prescribing and dispensing of controlled substances in this state.

(b) The joint interim committee shall be composed of three senators appointed by the lieutenant governor and three members of the house of representatives appointed by the speaker of the house of representatives.

(c) The lieutenant governor and speaker of the house of representatives shall each designate a co-chair from among the joint interim committee members.

(d) The joint interim committee shall convene at the joint call of the co-chairs.

(e) The joint interim committee has all other powers and duties provided to a special or select committee by the rules of the senate and house of representatives, by Subchapter B, Chapter 301, Government Code, and by policies of the senate and house committees on administration.

(f) The interim study conducted by the joint interim committee must:

(1) include the number of prescribers and dispensers registered to receive information electronically under Section 481.076, Health and Safety Code, as amended by this Act;

(2) evaluate the accessing of information under Section 481.076, Health and Safety Code, as amended by this Act, by regulatory agencies to monitor persons issued a license, certification, or registration by those agencies;

(3) address any complaints, technical difficulties, or other issues with electronically accessing and receiving information under Section 481.076, Health and Safety Code, as amended by this Act;

(4) examine controlled substance prescribing and dispensing trends that may be affected by the passage and implementation of this Act;

(5) evaluate the use and effectiveness of electronic notifications sent to prescribers and dispensers under Sections 481.0761(i) and (k), Health and Safety Code, as added by this Act;

(6) evaluate the use and effectiveness of identifying geographic anomalies in comparing delivery and dispensing data;

(7) evaluate the integration of any new data elements required to be reported under this Act;

(8) evaluate the existence and scope of diversion of controlled substances by animal owners to whom the substances are dispensed by veterinarians;

(9) explore the best methods for preventing the diversion of controlled substances by animal owners; and

(10) determine how any future reporting by dispensing

veterinarians might best be tailored to fit the practice of veterinary medicine.

(g) The committee shall solicit feedback from regulatory agencies, prescribers, dispensers, and patients affected by the passage of this Act.

(h) The committee shall submit a report to the legislature on the results of the interim study, including any legislative recommendations for improvements to information access and controlled substance prescription monitoring, not later than January 1, 2019.

(i) Subject to available resources, the Texas Legislative Council shall provide legal and policy research, drafts of proposed legislation, and statistical analysis services to the joint interim committee for the purpose of the study required under this section.

(j) Notwithstanding Section 481.076, Health and Safety Code, as amended by this Act, or any other law relating to access to or disclosure of prescription drug information maintained by the Texas State Board of Pharmacy, the Texas State Board of Pharmacy shall disclose any information maintained by the board under Section 481.076, Health and Safety Code, to the Texas Legislative Council on request of the council for the purpose of assisting with the study required under this section.

(k) Not later than November 1, 2017, the lieutenant governor and speaker of the house of representatives shall appoint the members of the joint interim committee in accordance with this section.

(l) The joint interim committee created under this section

is abolished and this section expires January 2, 2019.

SECTION 23. 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 24. Section 481.0764(a), Health and Safety Code, as added by this Act, applies only to:

(1) a prescriber other than a veterinarian who issues a prescription for a controlled substance on or after September 1, 2019; or

(2) a person authorized by law to dispense a controlled substance other than a veterinarian who dispenses a controlled substance on or after September 1, 2019.

SECTION 25. Not later than December 1, 2017, the executive commissioner of the Health and Human Services Commission shall adopt the rules necessary for the implementation of Chapter 442, Health and Safety Code, as added by this Act.

SECTION 26. (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 27. 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 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 28. 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 29. The Texas State Board of Pharmacy shall adopt rules under Section 562.110, Occupations Code, as amended by this Act, not later than January 1, 2018.

SECTION 30. 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 31. This Act takes effect September 1, 2017.

President of the Senate

Speaker of the House

I certify that H.B. No. 2561 was passed by the House on May 2, 2017, by the following vote: Yeas 145, Nays 0, 1 present, not voting; and that the House concurred in Senate amendments to H.B. No. 2561 on May 26, 2017, by the following vote: Yeas 131, Nays 15, 1 present, not voting.

Chief Clerk of the House

I certify that H.B. No. 2561 was passed by the Senate, with amendments, on May 24, 2017, by the following vote: Yeas 25, Nays 6.

Secretary of the Senate

APPROVED: 6 - 7 - 2017

Date

Governor

FILED IN THE OFFICE OF THE SECRETARY OF STATE
7:00 PM O'CLOCK
JUN 09 2017
Secretary of State

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 85TH LEGISLATIVE REGULAR SESSION

May 25, 2017

TO: Honorable Joe Straus, Speaker of the House, House of Representatives

FROM: Ursula Parks, Director, Legislative Budget Board

IN RE: **HB2561** by Thompson, Senfronia (Relating to the continuation and functions of the Texas State Board of Pharmacy; authorizing a reduction in fees.), **As Passed 2nd House**

Estimated Two-year Net Impact to General Revenue Related Funds for HB2561, As Passed 2nd House: an impact of $0 through the biennium ending August 31, 2019.

The bill would make no appropriation but could provide the legal basis for an appropriation of funds to implement the provisions of the bill.

General Revenue-Related Funds, Five-Year Impact:

Fiscal Year	Probable Net Positive/(Negative) Impact to General Revenue Related Funds
2018	$0
2019	$0
2020	$0
2021	$0
2022	$0

All Funds, Five-Year Impact:

Fiscal Year	Probable Savings/(Cost) from *General Revenue Fund* 1	Probable Revenue Gain/(Loss) from *General Revenue Fund* 1	Change in Number of State Employees from FY 2017
2018	($307,990)	$307,990	2.0
2019	($241,400)	$241,400	2.0
2020	($241,400)	$241,400	2.0
2021	($241,400)	$241,400	2.0
2022	($241,400)	$241,400	2.0

Fiscal Analysis

The bill would amend the Health and Safety Code relating to the continuation and functions of the Texas State Board of Pharmacy (TSBP); authorizing a reduction in fees. The bill would continue TSBP for twelve years until September 1, 2029.

The bill would require the TSBP, in consultation with the Optometry Board, Texas Medical Board, Texas State Board of Podiatric Medical Examiners, State Board of Dental Examiners, State Board of Veterinary Medical Examiners, and the Texas Board of Nursing, to determine conduct that constitutes abusive prescribing patterns or practices by applicable licensees. Under the provisions of the bill, TSBP would be permitted to send electronic notification to a dispenser or a prescriber if the information submitted to the Prescription Monitoring Program (PMP) indicates harmful prescribing patterns. The bill would require a wholesale distributor to report the same information that is reported to the Automation of Reports and Consolidated Orders System of the Federal Drug Enforcement Administration to TSBP.

The bill would require TSBP to develop a policy to encourage the use of certain negotiated rulemaking and appropriate alternative dispute resolution procedures. Under the provisions of the bill, TSBP would be required to coordinate the implementation of the policy, provide training for implementation of the policy, and collect data on the effectiveness of the procedures.

The bill would permit an applicant or a licensee to assert as an affirmative defense in an administrative hearing or as a claim of defense in a judicial proceeding that a rule, regulation, policy or a penalty imposed by TSBP limits an applicant's exercise of religion or membership in an religious organization. The bill would provide exemptions to certain rules, regulations, policies, or penalties imposed by TSBP. Under the provisions of the bill, a licensee or applicant could bring an action for injunctive relief against a violation.

The bill would modify the renewal fee of a pharmacy technician based on the amount of time from the expiration of the licensee's former license. The bill would require TSBP to adopt rules relating to the continuing education requirements for pharmacy technicians.

The bill would require regulatory agencies, including the Texas State Board of Dental Examiners, Optometry Board, Board of Veterinary Medical Examiners, Texas Medical Board, Texas Board of Nursing and the Board of Podiatric Medical Examiners to periodically access and monitor the Prescription Monitoring Program for prescribing behavior and dispensing patterns of licensees. The bill would allow a regulatory agency to notify a prescriber of potentially harmful behavior and allow for the opening of a complaint by the agency under certain requirements. The bill would require a regulatory agency to provide contact information for applicable licensees to the TSBP and the TSBP would be required to notify the regulatory agency when TSBP notifies a licensee that a potentially harmful prescribing pattern has been indicated. The bill would permit TSBP to send electronic notifications to prescribers and dispensers meeting harmful patterns. The bill would require certain licensees to access prescription history prior to prescribing or dispensing certain substances. The bill provides exceptions.

The bill would specify that a pharmacist has the exclusive authority to determine whether or not to dispense a drug. The bill would require the Texas State Board of Pharmacy (TSBP) to develop a process for a remote dispensing site to apply for classification as a Class A pharmacy.

The bill would authorize, in certain circumstances, the donation of unused prescription drugs and the dispensing of donated drugs. The bill would require the Department of State Health Services (DSHS) to develop a form for donors and recipients participating in the program and establish and

maintain an electronic database of participating providers. Additionally, the bill would require the executive commissioner of the Health and Human Services Commission (HHSC) to adopt rules to implement the program.

The bill would amend the Education Code to require the primary building in which the Texas A&M University System Health Science Center Irma Lerma Rangel College of Pharmacy is operated to be located in Kleberg County.

The bill would take effect on September 1, 2017.

Methodology

The provisions of the bill would result in a cost of $307,990 in General Revenue in fiscal year 2018 and a cost of $241,400 in General Revenue in fiscal year 2019 and following fiscal years. This analysis assumes that TSBP would input and track wholesale pharmaceutical distributor reporting in a database.

Based on the analysis of the TBSP, it is assumed the TSBP would require two additional full-time-equivalents (FTEs) to implement provisions of the bill relating to TSBP inputting and tracking wholesale pharmaceutical distributor reporting in a database and monitoring requirements by searching PMP data and providing the information to the other regulatory agencies, including the Texas State Board of Dental Examiners, Optometry Board, Board of Veterinary Medical Examiners, Texas Medical Board, Texas Board of Nursing and the Board of Podiatric Medical Examiners. The additional two FTEs would have an estimated cost to General Revenue of $149,594 in fiscal year 2018 and $141,404 each year thereafter. TSBP estimates one-time start up costs of $8,190 for the additional FTEs and annual costs of $100,224 in salaries and wages for a Program Specialist III, $36,701 in employee benefits and other payroll contribution costs, and $4,480 for other operating expenses.

TSBP also estimates a one-time cost of $58,400 in General Revenue in fiscal year 2018 for a database to track the additional required information from wholesale pharmaceutical distributors and a PMP upgrade to include contact information for notifications of potentially harmful prescribing or dispensing habits to licensees. In addition to the one-time costs in fiscal year 2018, TSBP estimates an ongoing operating cost of $99,996 for the database in each fiscal year due to ongoing hosting and data support for the wholesale pharmaceutical distribution information.

This analysis assumes that any increased database cost to the TSBP, which is statutorily required to generate sufficient revenue to cover its costs of operation, would be offset by an increase in fee generated revenue by the agency.

This analysis assumes that any increased Prescription Monitoring Program cost to the TSBP, which is statutorily required to generate sufficient revenue to cover its costs of operation, would be offset by an increase in fee generated revenue by the agency and other regulatory agencies whose licensees are required to access the PMP, including the Board of Veterinary Medical Examiners, Texas State Board of Dental Examiners, Optometry Board, Texas Medical Board, Texas Board of Nursing and the Board of Podiatric Medical Examiners.

The Comptroller of Public Accounts estimates the modification to the renewal fee of a pharmacy technician based on time elapsed since the expiration of the licensee's former license would result in a decrease of approximately $36,000 in revenue to the General Revenue Fund per fiscal year.

The Department of Public Safety, Department of State Health Services, Health and Human Services Commission, Office of the Attorney General, State Office of Administrative Hearings, Office of Court Administration, Texas A&M University System Administration, Texas State Board of Dental Examiners, Optometry Board, Board of Veterinary Medical Examiners, Texas Medical Board, Texas Board of Nursing, and Texas Board of Podiatric Medical Examiners anticipate any additional work resulting from the passage of the bill could be reasonably absorbed within current resources.

Technology

The costs identified above include estimated one-time information technology costs of $58,400 in fiscal year 2018 and ongoing costs of $99,996 for database development to accompany the wholesale distributor reporting requirements and $2,308 for one-time equipment for the additional FTE at TSBP.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 116 Sunset Advisory Commission, 212 Office of Court Administration, Texas Judicial Council, 304 Comptroller of Public Accounts, 360 State Office of Administrative Hearings, 515 Board of Pharmacy, 302 Office of the Attorney General, 405 Department of Public Safety, 503 Texas Medical Board, 504 Texas State Board of Dental Examiners, 507 Texas Board of Nursing, 512 Board of Podiatric Medical Examiners, 514 Optometry Board, 578 Board of Veterinary Medical Examiners

LBB Staff: UP, EK, KCA, EH, BRi

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 85TH LEGISLATIVE REGULAR SESSION

May 16, 2017

TO: Honorable Charles Schwertner, Chair, Senate Committee on Health & Human Services

FROM: Ursula Parks, Director, Legislative Budget Board

IN RE: **HB2561** by Thompson, Senfronia (Relating to the continuation and functions of the Texas State Board of Pharmacy; authorizing a reduction in fees.), **Committee Report 2nd House, Substituted**

Estimated Two-year Net Impact to General Revenue Related Funds for HB2561, Committee Report 2nd House, Substituted: an impact of $0 through the biennium ending August 31, 2019.

The bill would make no appropriation but could provide the legal basis for an appropriation of funds to implement the provisions of the bill.

General Revenue-Related Funds, Five-Year Impact:

Fiscal Year	Probable Net Positive/(Negative) Impact to General Revenue Related Funds
2018	$0
2019	$0
2020	$0
2021	$0
2022	$0

All Funds, Five-Year Impact:

Fiscal Year	Probable Savings/(Cost) from *General Revenue Fund* 1	Probable Revenue Gain/(Loss) from *General Revenue Fund* 1	Change in Number of State Employees from FY 2017
2018	($224,793)	$224,793	1.0
2019	($170,698)	$170,698	1.0
2020	($170,698)	$170,698	1.0
2021	($170,698)	$170,698	1.0
2022	($170,698)	$170,698	1.0

Fiscal Analysis

The bill would amend the Health and Safety Code relating to the continuation and functions of the Texas State Board of Pharmacy (TSBP); authorizing a reduction in fees. The bill would continue TSBP for twelve years until September 1, 2029.

The bill would require the TSBP, in consultation with the Optometry Board, Texas Medical Board, Texas State Board of Podiatric Medical Examiners, State Board of Dental Examiners, State Board of Veterinary Medical Examiners, and the Texas Board of Nursing, to determine conduct that constitutes abusive prescribing patterns or practices by applicable licensees. Under the provisions of the bill, TSBP would be permitted to send electronic notification to a dispenser or a prescriber if the information submitted to the Prescription Monitoring Program (PMP) indicates harmful prescribing patterns. The bill would require a wholesale distributor to report the same information that is reported to the Automation of Reports and Consolidated Orders System of the Federal Drug Enforcement Administration to TSBP.

The bill would require TSBP to develop a policy to encourage the use of certain negotiated rulemaking and appropriate alternative dispute resolution procedures. Under the provisions of the bill, TSBP would be required to coordinate the implementation of the policy, provide training for implementation of the policy, and collect data on the effectiveness of the procedures.

The bill would permit an applicant or a licensee to assert as an affirmative defense in an administrative hearing or as a claim of defense in a judicial proceeding that a rule, regulation, policy or a penalty imposed by TSBP limits an applicant's exercise of religion or membership in an religious organization. The bill would provide exemptions to certain rules, regulations, policies, or penalties imposed by TSBP. Under the provisions of the bill, a licensee or applicant could bring an action for injunctive relief against a violation.

The bill would modify the renewal fee of a pharmacy technician based on the amount of time from the expiration of the licensee's former license. The bill would require TSBP to adopt rules relating to the continuing education requirements for pharmacy technicians.

The bill would take effect on September 1, 2017.

Methodology

This analysis assumes that TSBP would input and track wholesale pharmaceutical distributor reporting in a database. The provisions of the bill would result in a cost of $224,793 in General Revenue in fiscal year 2018 and a cost of $170,698 in General Revenue in fiscal year 2019 and following fiscal years. Based on the analysis of the TSBP, it is assumed the TSBP would require one additional full-time-equivalent (FTE) to implement provisions of the bill relating to reporting requirements of wholesale pharmaceutical distribution information. This would have an estimated cost to General Revenue of $74,797 in fiscal year 2018 and $70,702 each year thereafter. TSBP estimates one-time start up costs of $4,095 for the additional FTE and annual costs of $50,111 in salaries and wages for a Program Specialist III, $18,351 in employee benefits and other payroll contribution costs, and $2,240 for other operating expenses.

TSBP also estimates a one-time cost of $50,000 in General Revenue in fiscal year 2018 for a database to track the additional required information from wholesale pharmaceutical distributors. In addition to the one-time costs in fiscal year 2018, TSBP estimates an ongoing operating cost of $99,996 for the database in each fiscal year due to ongoing hosting and data support for the

wholesale pharmaceutical distribution information.

This analysis assumes that any increased cost to the TSBP, which is statutorily required to generate sufficient revenue to cover its costs of operation, would be offset by a corresponding increase in fee generated revenue by the agency.

The Comptroller of Public Accounts estimates the modification to the renewal fee of a pharmacy technician based on time elapsed since the expiration of the licensee's former license would result in a decrease of approximately $36,000 in revenue to the General Revenue Fund per fiscal year.

The Department of Public Safety, Office of the Attorney General, State Office of Administrative Hearings, Office of Court Administration, Texas State Board of Dental Examiners, Optometry Board, Board of Veterinary Medical Examiners, Texas Medical Board, Texas Board of Nursing, and Texas Board of Podiatric Medical Examiners anticipate any additional work resulting from the passage of the bill could be reasonably absorbed within current resources.

Technology

The costs identified above include estimated one-time information technology costs of $50,000 in fiscal year 2018 and ongoing costs of $99,996 for database development to accompany the wholesale distributor reporting requirements and $1,154 for one-time equipment for the additional FTE at TSBP.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 116 Sunset Advisory Commission, 212 Office of Court Administration, Texas Judicial Council, 304 Comptroller of Public Accounts, 360 State Office of Administrative Hearings, 515 Board of Pharmacy, 302 Office of the Attorney General, 405 Department of Public Safety, 503 Texas Medical Board, 504 Texas State Board of Dental Examiners, 507 Texas Board of Nursing, 512 Board of Podiatric Medical Examiners, 514 Optometry Board, 578 Board of Veterinary Medical Examiners

LBB Staff: UP, EK, KCA, EH, BRi

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 85TH LEGISLATIVE REGULAR SESSION

May 9, 2017

TO: Honorable Charles Schwertner, Chair, Senate Committee on Health & Human Services

FROM: Ursula Parks, Director, Legislative Budget Board

IN RE: **HB2561** by Thompson, Senfronia (Relating to the continuation and functions of the Texas State Board of Pharmacy; authorizing a reduction in fees.), **As Engrossed**

Estimated Two-year Net Impact to General Revenue Related Funds for HB2561, As Engrossed: an impact of $0 through the biennium ending August 31, 2019.

The bill would make no appropriation but could provide the legal basis for an appropriation of funds to implement the provisions of the bill.

General Revenue-Related Funds, Five-Year Impact:

Fiscal Year	Probable Net Positive/(Negative) Impact to General Revenue Related Funds
2018	$0
2019	$0
2020	$0
2021	$0
2022	$0

All Funds, Five-Year Impact:

Fiscal Year	Probable Savings/(Cost) from *General Revenue Fund* 1	Probable Revenue Gain/(Loss) from *General Revenue Fund* 1	Change in Number of State Employees from FY 2017
2018	($224,793)	$224,793	1 0
2019	($170,698)	$170,698	1 0
2020	($170,698)	$170,698	1.0
2021	($170,698)	$170,698	1 0
2022	($170,698)	$170,698	1 0

Fiscal Analysis

The bill would amend the Health and Safety Code relating to the continuation and functions of the Texas State Board of Pharmacy (TSBP); authorizing a reduction in fees. The bill would continue TSBP for twelve years until September 1, 2029.

The bill would require the TSBP, in consultation with the Optometry Board, Texas Medical Board, Texas State Board of Podiatric Medical Examiners, State Board of Dental Examiners, State Board of Veterinary Medical Examiners, and the Texas Board of Nursing, to determine conduct that constitutes abusive prescribing patterns or practices by applicable licensees. Under the provisions of the bill, TSBP would be permitted to send electronic notification to a dispenser or a prescriber if the information submitted to the Prescription Monitoring Program (PMP) indicates harmful prescribing patterns. The bill would require a wholesale distributor to report the same information that is reported to the Automation of Reports and Consolidated Orders System of the Federal Drug Enforcement Administration to TSBP.

The bill would require TSBP to develop a policy to encourage the use of certain negotiated rulemaking and appropriate alternative dispute resolution procedures. Under the provisions of the bill, TSBP would be required to coordinate the implementation of the policy, provide training for implementation of the policy, and collect data on the effectiveness of the procedures.

The bill would permit an applicant or a licensee to assert as an affirmative defense in an administrative hearing or as a claim of defense in a judicial proceeding that a rule, regulation, policy or a penalty imposed by TSBP limits an applicant's exercise of religion or membership in an religious organization. The bill would provide exemptions to certain rules, regulations, policies, or penalties imposed by TSBP. Under the provisions of the bill, a licensee or applicant could bring an action for injunctive relief against a violation.

The bill would modify the renewal fee of a pharmacy technician based on the amount of time from the expiration of the licensee's former license. The bill would require TSBP to adopt rules relating to the continuing education requirements for pharmacy technicians.

The bill would take effect on September 1, 2017.

Methodology

This analysis assumes that TSBP would input and track wholesale pharmaceutical distributor reporting in a database. The provisions of the bill would result in a cost of $224,793 in General Revenue in fiscal year 2018 and a cost of $170,698 in General Revenue in fiscal year 2019 and following fiscal years. Based on the analysis of the TSBP, it is assumed the TSBP would require one additional full-time-equivalent (FTE) to implement provisions of the bill relating to reporting requirements of wholesale pharmaceutical distribution information. This would have an estimated cost to General Revenue of $74,797 in fiscal year 2018 and $70,702 each year thereafter. TSBP estimates one-time start up costs of $4,095 for the additional FTE and annual costs of $50,111 in salaries and wages for a Program Specialist III, $18,351 in employee benefits and other payroll contribution costs, and $2,240 for other operating expenses.

TSBP also estimates a one-time cost of $50,000 in General Revenue in fiscal year 2018 for a database to track the additional required information from wholesale pharmaceutical distributors. In addition to the one-time costs in fiscal year 2018, TSBP estimates an ongoing operating cost of $99,996 for the database in each fiscal year due to ongoing hosting and data support for the

wholesale pharmaceutical distribution information.

This analysis assumes that any increased cost to the TSBP, which is statutorily required to generate sufficient revenue to cover its costs of operation, would be offset by a corresponding increase in fee generated revenue by the agency.

The Comptroller of Public Accounts estimates the modification to the renewal fee of a pharmacy technician based on time elapsed since the expiration of the licensee's former license would result in a decrease of approximately $36,000 in revenue to the General Revenue Fund per fiscal year.

The Department of Public Safety, Office of the Attorney General, State Office of Administrative Hearings, Office of Court Administration, Texas State Board of Dental Examiners, Optometry Board, Board of Veterinary Medical Examiners, Texas Medical Board, Texas Board of Nursing, and Texas Board of Podiatric Medical Examiners anticipate any additional work resulting from the passage of the bill could be reasonably absorbed within current resources.

Technology

The costs identified above include estimated one-time information technology costs of $50,000 in fiscal year 2018 and ongoing costs of $99,996 for database development to accompany the wholesale distributor reporting requirements and $1,154 for one-time equipment for the additional FTE at TSBP.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 212 Office of Court Administration, Texas Judicial Council, 304 Comptroller of Public Accounts, 360 State Office of Administrative Hearings, 116 Sunset Advisory Commission, 515 Board of Pharmacy, 302 Office of the Attorney General, 405 Department of Public Safety, 503 Texas Medical Board, 504 Texas State Board of Dental Examiners, 507 Texas Board of Nursing, 512 Board of Podiatric Medical Examiners, 514 Optometry Board, 578 Board of Veterinary Medical Examiners

LBB Staff: UP, EK, KCA, EH, BRi

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 85TH LEGISLATIVE REGULAR SESSION

April 20, 2017

TO: Honorable Four Price, Chair, House Committee on Public Health

FROM: Ursula Parks, Director, Legislative Budget Board

IN RE: **HB2561** by Thompson, Senfronia (Relating to the continuation and functions of the Texas State Board of Pharmacy; authorizing a reduction in fees.), **Committee Report 1st House, Substituted**

Estimated Two-year Net Impact to General Revenue Related Funds for HB2561, Committee Report 1st House, Substituted: an impact of $0 through the biennium ending August 31, 2019.

The bill would make no appropriation but could provide the legal basis for an appropriation of funds to implement the provisions of the bill.

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2021	$0
2022	$0

All Funds, Five-Year Impact:

Fiscal Year	Probable Savings/(Cost) from *General Revenue Fund* 1	Probable Revenue Gain/(Loss) from *General Revenue Fund* 1	Change in Number of State Employees from FY 2017
2018	($224,793)	$224,793	1.0
2019	($170,698)	$170,698	1.0
2020	($170,698)	$170,698	1.0
2021	($170,698)	$170,698	1.0
2022	($170,698)	$170,698	1.0

Fiscal Analysis

The bill would amend the Health and Safety Code relating to the continuation and functions of the Texas State Board of Pharmacy (TSBP); authorizing a reduction in fees. The bill would continue TSBP for twelve years until September 1, 2029.

The bill would require the TSBP, in consultation with the Optometry Board, Texas Medical Board, Texas State Board of Podiatric Medical Examiners, State Board of Dental Examiners, State Board of Veterinary Medical Examiners, and the Texas Board of Nursing, to determine conduct that constitutes abusive prescribing patterns or practices by applicable licensees. Under the provisions of the bill, TSBP would be permitted to send electronic notification to a dispenser or a prescriber if the information submitted to the Prescription Monitoring Program (PMP) indicates harmful prescribing patterns. The bill would require a wholesale distributor to report the same information that is reported to the Automation of Reports and Consolidated Orders System of the Federal Drug Enforcement Administration to TSBP.

The bill would require TSBP to develop a policy to encourage the use of certain negotiated rulemaking and appropriate alternative dispute resolution procedures. Under the provisions of the bill, TSBP would be required to coordinate the implementation of the policy, provide training for implementation of the policy, and collect data on the effectiveness of the procedures.

The bill would modify the renewal fee of a pharmacy technician based on the amount of time from the expiration of the licensee's former license. The bill would require TSBP to adopt rules relating to the continuing education requirements for pharmacy technicians.

The bill would take effect on September 1, 2017.

Methodology

This analysis assumes that TSBP would input and track wholesale pharmaceutical distributor reporting in a database. The provisions of the bill would result in a cost of $224,793 in General Revenue in fiscal year 2018 and a cost of $170,698 in General Revenue in fiscal year 2019 and following fiscal years. Based on the analysis of the TSBP, it is assumed the TSBP would require one additional full-time-equivalent (FTE) to implement provisions of the bill relating to reporting requirements of wholesale pharmaceutical distribution information. This would have an estimated cost to General Revenue of $74,797 in fiscal year 2018 and $70,702 each year thereafter. TSBP estimates one-time start up costs of $4,095 for the additional FTE and annual costs of $50,111 in salaries and wages for a Program Specialist III, $18,351 in employee benefits and other payroll contribution costs, and $2,240 for other operating expenses.

TSBP also estimates a one-time cost of $50,000 in General Revenue in fiscal year 2018 for a database to track the additional required information from wholesale pharmaceutical distributors. In addition to the one-time costs in fiscal year 2018, TSBP estimates an ongoing operating cost of $99,996 for the database in each fiscal year due to ongoing hosting and data support for the wholesale pharmaceutical distribution information.

This analysis assumes that any increased cost to the TSBP, which is statutorily required to generate sufficient revenue to cover its costs of operation, would be offset by a corresponding increase in fee generated revenue by the agency.

The Comptroller of Public Accounts estimates the modification to the renewal fee of a pharmacy technician based on time elapsed since the expiration of the licensee's former license would result

in a decrease of approximately $36,000 in revenue to the General Revenue Fund per fiscal year.

The Department of Public Safety, Office of the Attorney General, State Office of Administrative Hearings, Texas State Board of Dental Examiners, Optometry Board, Board of Veterinary Medical Examiners, Texas Medical Board, Texas Board of Nursing, and Texas Board of Podiatric Medical Examiners anticipate any additional work resulting from the passage of the bill could be reasonably absorbed within current resources.

Technology

The costs identified above include estimated one-time information technology costs of $50,000 in fiscal year 2018 and ongoing costs of $99,996 for database development to accompany the wholesale distributor reporting requirements and $1,154 for one-time equipment for the additional FTE at TSBP.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 116 Sunset Advisory Commission, 515 Board of Pharmacy, 302 Office of the Attorney General, 304 Comptroller of Public Accounts, 360 State Office of Administrative Hearings, 405 Department of Public Safety, 503 Texas Medical Board, 504 Texas State Board of Dental Examiners, 507 Texas Board of Nursing, 512 Board of Podiatric Medical Examiners, 514 Optometry Board, 578 Board of Veterinary Medical Examiners

LBB Staff: UP, EK, KCA, EH, BRi

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 85TH LEGISLATIVE REGULAR SESSION

April 2, 2017

TO: Honorable Four Price, Chair, House Committee on Public Health

FROM: Ursula Parks, Director, Legislative Budget Board

IN RE: **HB2561** by Thompson, Senfronia (Relating to the continuation and functions of the Texas State Board of Pharmacy; authorizing a reduction in fees.), **As Introduced**

Estimated Two-year Net Impact to General Revenue Related Funds for HB2561, As Introduced: an impact of $0 through the biennium ending August 31, 2019.

The bill would make no appropriation but could provide the legal basis for an appropriation of funds to implement the provisions of the bill.

General Revenue-Related Funds, Five-Year Impact:

Fiscal Year	Probable Net Positive/(Negative) Impact to General Revenue Related Funds
2018	$0
2019	$0
2020	$0
2021	$0
2022	$0

All Funds, Five-Year Impact:

Fiscal Year	Probable Savings/(Cost) from *General Revenue Fund* 1	Probable Revenue Gain/(Loss) from *General Revenue Fund* 1	Change in Number of State Employees from FY 2017
2018	($224,793)	$224,793	1.0
2019	($170,698)	$170,698	1.0
2020	($170,698)	$170,698	1.0
2021	($170,698)	$170,698	1.0
2022	($170,698)	$170,698	1.0

Fiscal Analysis

The bill would amend the Health and Safety Code relating to the continuation and functions of the Texas State Board of Pharmacy (TSBP); authorizing a reduction in fees. The bill would continue TSBP for twelve years until September 1, 2029.

The bill would require the TSBP, in consultation with the Optometry Board, Texas Medical Board, Texas State Board of Podiatric Medical Examiners, State Board of Dental Examiners, State Board of Veterinary Medical Examiners, and the Texas Board of Nursing, to determine conduct that constitutes abusive prescribing patterns or practices by applicable licensees. Under the provisions of the bill, TSBP would be permitted to send electronic notification to a dispenser or a prescriber if the information submitted to the Prescription Monitoring Program (PMP) indicates harmful prescribing patterns. The bill would require a wholesale pharmaceutical distributor to report to TSBP the sale of a controlled substance made by the distributor to a person in the state. TSBP would be required to include this information in the PMP.

The bill would require TSBP to develop a policy to encourage the use of certain negotiated rulemaking and appropriate alternative dispute resolution procedures. Under the provisions of the bill, TSBP would be required to coordinate the implementation of the policy, provide training for implementation of the policy, and collect data on the effectiveness of the procedures.

The bill would modify the renewal fee of a pharmacy technician based on the amount of time from the expiration of the licensee's former license. The bill would require TSBP to adopt rules relating to the continuing education requirements for pharmacy technicians.

The bill would take effect on September 1, 2017.

Methodology

The provisions of the bill would result in a cost of $224,793 in General Revenue in fiscal year 2018 and a cost of $170,698 in General Revenue in fiscal year 2019 and following fiscal years. Based on the analysis of the TSBP, it is assumed the TSBP would require one additional full-time-equivalent (FTE) to implement provisions of the bill relating to reporting requirements of wholesale pharmaceutical distribution information to the PMP. This would have an estimated cost to General Revenue of $74,797 in fiscal year 2018 and $70,702 each year thereafter. TSBP estimates one-time start up costs of $4,095 for the additional FTE and annual costs of $50,111 in salaries and wages for a Program Specialist III, $18,351 in employee benefits and other payroll contribution costs, and $2,240 for other operating expenses.

TSBP also estimates a one-time cost of $50,000 in General Revenue in fiscal year 2018 for modifications to the PMP to accommodate the additional required information for wholesale pharmaceutical distributors. In addition to the one-time costs in fiscal year 2018, TSBP estimates an ongoing operating cost of $99,996 for the PMP in each fiscal year due to ongoing hosting and data support for the wholesale pharmaceutical distribution information.

This analysis assumes that any increased cost to the TSBP, which is statutorily required to generate sufficient revenue to cover its costs of operation, would be offset by a corresponding increase in fee generated revenue by the agency and other regulatory agencies whose licensees are required to access the PMP, including the Texas State Board of Dental Examiners, Optometry Board, Board of Veterinary Medical Examiners, Texas Medical Board, Texas Board of Nursing and the Board of Podiatric Medical Examiners.

The Comptroller of Public Accounts estimates the modification to the renewal fee of a pharmacy technician based on time elapsed since the expiration of the licensee's former license would result in a decrease of approximately $36,000 in revenue to the General Revenue Fund per fiscal year.

The Department of Public Safety, Office of the Attorney General, State Office of Administrative Hearings, Texas State Board of Dental Examiners, Optometry Board, Board of Veterinary Medical Examiners, Texas Medical Board, Texas Board of Nursing, and Texas Board of Podiatric Medical Examiners anticipate any additional work resulting from the passage of the bill could be reasonably absorbed within current resources.

Technology

The costs identified above include estimated one-time information technology costs of $50,000 in fiscal year 2018 and ongoing costs of $99,996 for PMP database changes to accompany the wholesale distributor reporting requirements and $1,154 for one-time equipment for the additional FTE at TSBP.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 116 Sunset Advisory Commission, 302 Office of the Attorney General, 304 Comptroller of Public Accounts, 360 State Office of Administrative Hearings, 405 Department of Public Safety, 503 Texas Medical Board, 504 Texas State Board of Dental Examiners, 507 Texas Board of Nursing, 512 Board of Podiatric Medical Examiners, 514 Optometry Board, 515 Board of Pharmacy, 578 Board of Veterinary Medical Examiners

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