BILL ANALYSIS

Senate Research Center 79R13277 JTS-F C.S.S.B. 410 By: Whitmire Government Organization 4/27/2005 Committee Report (Substituted)

AUTHOR'S/SPONSOR'S STATEMENT OF INTENT

The Texas State Board of Pharmacy (board) is subject to the Sunset Act and will be abolished on September 1, 2005, unless continued in existence by the legislature. However, the board's authority to regulate out-of-state pharmacies has not kept pace with changing technology, and the Texas Pharmacy Act does not give the board adequate authority to fully protect the public. The board also does not have access to sales and pricing information needed to prosecute illegal activity, and key elements of the board's licensing and regulatory functions do not conform to commonly applied licensing practices.

C.S.S.B. 410 strengthens the board's ability to regulate out-of-state pharmacies; updates the board's enforcement authority over in-state pharmacists and pharmacies, as well as pharmacy technicians; authorizes the board to gain access to financial, sales, and pricing data during investigations; authorizes the board to register and discipline pharmacy technician trainees; and continues the agency for another 12 years.

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the Texas State Board of Pharmacy in SECTION 8 (Section 554.001, Occupations Code), SECTION 14 (Section 558.058, Occupations Code), and SECTION 30 (Section 566.002, Occupations Code) of this bill.

Rulemaking authority previously granted to the Texas State Board of Pharmacy is modified in SECTION 19 (Section 561.003, Occupations Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Section 551.005, Occupations Code, as follows:

Sec. 551.005. APPLICATION OF SUNSET ACT. Provides that the Texas State Board of Pharmacy (board) is subject to Chapter 325 (Texas Sunset Act), Government Code. Provides that the board is abolished and this subtitle expires September 1, 2017, rather than 2005, unless continued in existence as provided by that chapter.

SECTION 2. Amends Section 551.003(42), Occupations Code, to redefine "Texas trade association."

SECTION 3. Amends Section 552.004, Occupations Code, as follows:

Sec. 552.004. MEMBERSHIP RESTRICTIONS. (a) Prohibits a person from being a member of the board if the person is required to register as a lobbyist under Chapter 305 (Registration of Lobbyists), Government Code, because of the person's activities for compensation on behalf of a profession related to the operation of the board. Makes a nonsubstantive change.

(b) Prohibits a person, rather than a pharmacist, from being a member of the board if the person is a certain representative of Texas trade association in the field of health care; or the person's spouse is a certain representative of the Texas trade association in the field of health care. Deletes existing text relating to the prohibition on allowing certain persons membership on the board. Makes nonsubstantive changes. SECTION 4. Amends Section 552.006, Occupations Code, as follows:

Sec. 552.006. BOARD MEMBER TRAINING. (a) Prohibits a person who is appointed to and qualifies for office as a member of the board from voting, deliberating, or being counted as a member in attendance at a meeting of the board until the person completes a training program.

(b) Requires the training program to provide the person with certain information.

(c) Provides that a person appointed to the board is entitled to reimbursement, as provided by the General Appropriations Act, for travel expenses incurred in attending the training program regardless of whether the attendance at the program occurs before or after the person qualifies for office. Deletes existing text relating to the compliance with member training requirements.

SECTION 5. Amends Section 552.007(a) Occupations Code, to require the governor to designate a member of the board as the president of the board to serve in that capacity at the pleasure of the governor. Makes a conforming change.

SECTION 6. Amends Section 552.009(b), Occupations Code, to provide that a member is entitled to reimbursement for travel expenses as prescribed by the General Appropriations Act. Deletes existing text relating to the prohibition against a member receiving reimbursement for travel, meals, or lodging expenses. Makes a nonsubstantive change.

SECTION 7. Amends Section 553.005, Occupations Code, as follows:

Sec. 553.005. EMPLOYEE RESTRICTIONS. (a) Prohibits a person from being an employee of the board employed in a "bona fide executive administrative, or professional capacity," as that phrases is used for purposes of establishing an exemption to the overtime provisions of the federal Fair Labor Standards Act of 1938 (29 U.S.C. Section 201 et seq.), if the person is a certain representative of a Texas trade association in the field of health care; or the person's spouse is a certain representative of a Texas trade association in the filed of health care. Deletes existing text prohibiting certain persons from serving as an employee of the board. Redesignates text of existing Subsection (c) as Subsection (b). Makes a conforming change.

SECTION 8. Amends Section 554.001, Occupations Code, by adding Subsection (e), to require the board to develop formal policies outlining the structure, role, and responsibilities of each committee established under Subsection (b)(2) that contains board members. Requires the board to adopt rules to implement this subsection.

SECTION 9. Amends Section 554.007, Occupations Code, as follows:

Sec. 554.007. New heading: FUNDS. (a) Requires the board to deposit revenue collected under this subtitle to the credit of the general revenue fund. Deletes existing text relating to administrative penalty revenue and the state pharmacy account. Makes nonsubstantive changes.

(b) Makes no change to this subsection. Deletes Subsection (c) relating to requiring the board to pay the expense of administrating this subtitle.

SECTION 10. Amends Section 555.001, Occupations Code, by adding Subsections (c) and (d), as follows:

(c) Requires the board to provide on its website a list of all Internet pharmacies licensed by the board and to provide information about each pharmacy, including the pharmacy's name, license number, and state of physical location. Provides that an Internet pharmacy is a pharmacy physically located in this state or another state that dispenses drugs or devices in a particular manner. (d) Provides that information regarding the home address or home telephone number of a person licensed or registered under this subtitle, including a pharmacy owner, is confidential and not subject to disclosure under Chapter 552 (Public Information), Government Code, but each person licensed or registered is required to provide the board with a business address or address of record that is subject to disclosure under Chapter 552, Government Code, and that may be posted on the board's Internet site or in the board's licensure verification database.

SECTION 11. Amends Section 555.005, Occupations Code, to read as follows:

Sec. 555.005. RECORDS OF COMPLAINTS. Requires the board, for each complaint received by the board, to maintain information about parties to the complaint, the subject matter of the complaint, a summary of the results of the review or investigation of the complaint, and its disposition. Deletes existing text relating to requiring the board to keep an information file about each complaint filed with the board and certain procedures for the information file.

SECTION 12. Amends Section 555.007, Occupations Code, by amending Subsection (a) and adding Subsection (c), as follows:

(a) Requires the board's policies and procedures to allow appropriate employees of the board to dismiss a complaint if an investigation shows that no violation occurred or the subject of the complaint is out of the board's jurisdiction. Makes conforming changes.

(c) Requires the executive director, at each meeting of the board, to report to the board each complaint dismissed under Subsection (a)(6) since the board's last public meeting.

SECTION 13. Amends Section 558.057(a), Occupations Code, to redefine "preceptor."

SECTION 14. Amends Subchapter B, Chapter 558, Occupations Code, by adding Section 558.058, as follows:

Sec. 558.058. ACCESSIBILITY OF EXAMINATION. Requires the board by rule to ensure that an examination is administered to applicants with disabilities in compliance with the Americans with Disabilities Act of 1990 (42 U.S.C. Section 12101 et seq.).

SECTION 15. Amends Subchapter B, Chapter 558, Occupations Code, by adding Section 558.059, as follows:

Sec. 558.059. EXAMINATION FEE REFUND. (a) Authorizes the board to retain all or part of an examination fee paid by an applicant who is unable to take the pharmacy licensure examination.

(b) Requires the board to adopt policies allowing the board to refund the examination fee paid by an applicant who provides advance notice of inability to take the examination or is unable to take the examination because of an emergency.

(c) Requires the board's policy to establish the required notification period and the emergencies that warrant a refund.

(d) Requires the board to make efforts to ensure that the policy does not conflict with the policy of a national testing body involved in administering the examination.

SECTION 16. Amends Section 558.101, Occupations Code, as follows:

Sec. 558.101. QUALIFICATIONS FOR LICENSE BY RECIPROCITY. Deletes existing text requiring an applicant for licensing by reciprocity to have possessed, at the time of initial licensing, certain qualifications. Makes conforming and nonsubstantive changes.

SECTION 17. Amends Sections 559.003(b), (c), and (d), Occupations Code, as follows:

(b) Authorizes a person whose license has been expired for 90 days or less to renew the expired license by paying the board a renewal fee, rather than the required renewal fee, that is equal to one and one-half times the normal required renewal fee for the license. Deletes existing text relating to the examination fee for the license.

(c) Authorizes a person whose license has been expired for more than 90 days but less than one year to renew the expired license by paying the board a renewal fee that is equal two times the normally required renewal fee for the license. Makes conforming changes.

(d) Prohibits a person whose license has been expired for one year or more from renewing the license. Authorizes the person to obtain a new license by complying with the requirements and procedures for obtaining an original license, including the examination requirement. Deletes existing text relating to license cancellation or investigation.

SECTION 18. Amends Section 560.052, Occupations Code, by amending Subsection (c) and adding Subsection (f), as follows:

(c) Requires an applicant, to qualify for a Class E pharmacy license, to provide certain evidence and information including proof of creditworthiness and an inspection report issued not more than two years before the date the license application is received and requires that the report have been issued by the pharmacy licensing board in the state of the pharmacy's physical location, except as provide by Subsection (f). Makes a nonsubstantive change.

(f) Authorizes a Class E pharmacy to submit an inspection report issued by an entity other than the pharmacy licensing board of the state in which the pharmacy is physically located if certain procedures are followed.

SECTION 19. Amends Section 561.003, Occupations Code, by amending Subsection (a) and adding Subsection (c), (d), and (e), as follows:

(a) Requires the board by rule to establish certain procedures and fees. Deletes existing text relating to establishing penalties for late renewal of a pharmacy license. Makes nonsubstantive changes.

(c) Authorizes a pharmacy whose license has been expired for 90 days or less to renew the expired license by paying to the board a renewal fee that is equal to one and one-half timers the normal required renewal fee for the license.

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

(e) Prohibits the pharmacy, if a pharmacy's license has been expired for one year or more, from renewing the license. Authorizes the pharmacy to obtain a new license by complying with the requirements and procedures for obtaining an original license.

SECTION 20. Amends Chapter 561, Occupations Code, by adding Section 561.0031, as follows:

Sec. 561.0031. ADDITIONAL RENEWAL REQUIREMENT FOR CLASS E PHARMACY. (a) Requires the board, in addition to the renewal requirements in Section 561.003 (Requirements for Renewal), to require that a Class E pharmacy have on file with the board an inspection report issued not more than three years before the date the renewal application is received and issued by the pharmacy licensing board in the state of the pharmacy's physical location, except as provided by Subsection (b).

(b) Authorizes a Class E pharmacy to have on file with the board an inspection report issued by an entity other than the pharmacy licensing board of the state in which the pharmacy is physically located if the requirements of Section 560.052(f) are met.

SECTION 21. Amends Subchapter B, Chapter 562, Occupations Code, by adding Section 562.056, as follows:

Sec. 562.056. PRACTITIONER-PATIENT RELATIONSHIP REQUIRED. (a) Requires a pharmacist, before dispensing a prescription, to determine, in the exercise of sound professional judgment, that the prescription is a valid prescription. Prohibits a pharmacist from dispensing a prescription drug if the pharmacist knows or should know that the prescription was issued on the basis of an Internet-based or telephonic consultation without a valid practitioner-patient relationship.

(b) Provides that Subsection (a) does not prohibit a pharmacist from dispensing a prescription when a valid practitioner-patient relationship is not present in an emergency.

SECTION 22. Amends Subchapter C, Chapter 562, Occupations Code, by adding Section 562.111, as follows:

Sec. 562.111. PRACTITIONER-PATIENT RELATIONSHIP REQUIRED. (a) Requires a pharmacy to ensure that its agents and employees, before dispensing a prescription, determine in the exercise of sound professional judgment that the prescription is a valid prescription. Prohibits a pharmacy from dispensing a prescription drug if an agent or employee of the pharmacy knows or should know that the prescription was issued on the basis of an Internet-based or telephonic consultation without a valid practitioner-patient relationship.

(b) Provides that Subsection (a) does not prohibit a pharmacy from dispensing a prescription when a valid practitioner-patient relationship is not present in an emergency.

SECTION 23. Amends Section 562.1045, Occupations Code, by adding Subsections (c) and (d), as follows:

(c) Requires an Internet pharmacy to post certain information on its initial home page.

(d) Requires the information under Subsection (c) to include the board's telephone number, mailing address, and Internet website address.

SECTION 24. Amends Section 564.051(c), Occupations Code, to require funds and surcharges under this chapter collected to be deposited in the general revenue fund, rather than an account created under Section 554.007 (Funds; State Pharmacy Account), and provide that they may only be used by the board to administer the program.

SECTION 25. Amends Section 565.001(a), Occupations Code, to authorize the board to discipline an applicant for or the holder of a current or expired license to practice pharmacy if the board finds that the applicant or license holder has been convicted of or placed on deferred adjudication community supervision or deferred disposition or the applicable federal equivalent for certain offenses; or been disciplined by the regulatory board of another state for conduct substantially equivalent to conduct described under this subsection; violated a disciplinary order, including a confidential order or contract under the program to aid impaired pharmacists and pharmacy students under Chapter 564 (Program to Aid Impaired Pharmacists and Pharmacy Students; Pharmacy Peer Review); failed to adequately supervise a task delegated to a pharmacy technician; inappropriately delegated a task delegated to a pharmacy technician; or been responsible for a drug audit shortage. Deletes existing text relating to a license to practice pharmacy issued by another state that is canceled, revoked, surrendered, or suspended. Makes nonsubstantive changes.

SECTION 26. Amends Section 565.002, Occupations Code, as follows:

Sec. 565.002. APPLICANT FOR OR HOLDER OF PHARMACY LICENSE. (a) Authorizes the board to discipline an applicant for or the holder of a pharmacy license, including a Class E pharmacy license subject to Section 565.003(b), if the board finds that the applicant or license holder has been convicted of or placed on deferred adjudication community supervision or deferred disposition or the applicable federal equivalent for certain offenses; violated a disciplinary order; been responsible for a drug audit shortage; or been disciplined by the regulatory board of another state for conduct substantially equivalent to conduct described under this subsection. Deletes existing text relating to an applicant or license holder who has been convicted of a misdemeanor involving moral turpitude or a felony. Makes nonsubstantive changes.

(b) Provides that this subsection applies only to an applicant or license holder that is a legal business entity. Authorizes the board to discipline an applicant for or the holder of a pharmacy license, including a Class E pharmacy license, if the board finds that a managing officer of the applicant or license holder has been convicted of or placed on deferred adjudication community supervision or deferred disposition or the applicable federal equivalent for certain offenses.

(c) Provides that a certified copy of the record of the state taking action is conclusive evidence of the action taken by the state.

SECTION 27. Amends Section 565.051, Occupations Code, as follows:

Sec. 565.051. DISCIPLINE AUTHORIZED. Deletes existing text relating to determining that a ground for discipline exists to the extent authorized by Subsection (b). Deletes Subsection (b) relating to a determination that a rule of the board has been violated and authorizing the imposition of certain sanctions.

SECTION 28. Amends Section 565.053, Occupations Code, as follows:

Sec. 565.053. New heading: DISCIPLINE OF CLASS E PHARMACY; NOTICE TO RESIDENT STATE. Requires the board to give notice of a disciplinary action by the board against the holder of a Class E pharmacy license to the regulatory or licensing agency of the state in which the pharmacy is located. Deletes existing text relating to board notification in case of an emergency that creates an immediate danger to the public health or safety, before initiating a disciplinary action. Deletes existing text requiring the board to file a complaint against a Icense holder. Deletes existing text relating to the authorization to initiate the board's action to discipline a holder of a Class E pharmacy license.

SECTION 29. Amends Section 565.059, Occupations Code, as follows:

Sec. 565.059. New heading: TEMPORARY SUSPENSION OF LICENSE OR REGISTRATION. (a) Requires the president of the board to appoint a three-member disciplinary panel consisting of board members to determine whether a license or registration under this subtitle should be temporarily suspended or restricted. Provides that if a majority of the disciplinary panel, rather than board, determines from evidence or information presented to the panel that the holder of a license or registration by continuation in practice would constitute a continuing threat to the public welfare, the panel is required to temporarily suspend the license or registration. Makes a conforming change.

(b) Makes conforming changes.

(c) Makes conforming changes.

(d) Authorizes the disciplinary panel to hold a meeting by telephone conference call if immediate action is required and convening of the panel at one location is

inconvenient for any member of the disciplinary panel, notwithstanding Chapter 551 (Open Meetings), Government Code.

SECTION 30. Amends Section 566.002, Occupations Code, by amending Subsection (a) and adding Subsection (d), as follows:

(a) Prohibits the amount of the administrative penalty from exceeding \$5,000, rather than \$2,500, for each violation, including a violation involving the diversion of a controlled substance. Deletes existing text relating to an exception provided by this subsection, the amount of the administrative penalty, and the limit of administrative penalty.

(d) Requires the board by rule to adopt an administrative penalty schedule for violations of this subtitle or board rules to ensure that the amounts of the penalties imposed are appropriate to the violation.

SECTION 31. Amends Section 566.051(a), Occupations Code, to authorize the attorney general at the request of the board to petition a district court for an injunction to prohibit a person who is violating this subtitle from continuing the violation.

SECTION 32. Amends Subchapter B, Chapter 566, Occupations Code, by adding Section 566.052, as follows:

Sec. 566.052. CEASE AND DESIST ORDER. (a) Authorizes the board to issue a cease and desist order prohibiting the person from engaging in the activity, if it appears to the board that a person is engaging in an act or practice that constitutes the practice of pharmacy without a license or registration under this subtitle, after notice and opportunity for a hearing.

(b) Provides that a violation of an order constitutes grounds for imposing an administrative penalty under Subchapter A.

SECTION 33. Amends Section 568.003, Occupations Code, as follows:

Sec. 568.003. New heading: GROUNDS FOR DISCIPLINARY ACTION. (a) Authorizes the board to take disciplinary action under Section 568.0035 (Discipline Authorized), if the board determines that the applicant or registrant has committed certain offenses. Deletes existing text relating to the board refusing to issue or renew a registration.

SECTION 34. Amends Chapter 568, Occupations Code, by adding Section 568.0035, as follows:

Sec. 568.0035. DISCIPLINE AUTHORIZED. Authorizes the board, on determination that a ground for discipline exists under Section 568.003 (Grounds for Refusal to Issue or Renew Registration; Disciplinary Action), to take certain disciplinary actions.

SECTION 35. Amends Chapter 568, Occupations Code, by adding Section 568.007, as follows:

Sec. 568.007. REGISTRATION OF PHARMACY TECHNICIAN TRAINEE. (a) Requires a person to register with the board before beginning work in a pharmacy in this state as a pharmacy technician trainee.

(b) Requires an application for registration as a pharmacy technician trainee to be on a form prescribed by the board.

(c) Provides that a person's registration as a pharmacy technician trainee remains in effect as long as the person meets the qualifications specified by board rule.

(d) Authorizes the board, on a determination that a ground for discipline exists under Section 568.003, to take disciplinary action against a pharmacy technician trainee under Section 568.0035.

SECTION 36. Repealer: Section 565.003(a) (Additional Grounds For Discipline Regarding Applicant for or Holder of Class E Pharmacy License) and Section 565.060 (Applicant for or Holder of License: Certain Felony Drug Convictions), Occupations Code.

SECTION 37. Provides that on the effective date of this Act, the state pharmacy account is abolished and the comptroller is required to transfer money in the account to the general revenue fund.

SECTION 38. (a) Provides that the changes in law made by this Act to Section 552.004 (Membership Restrictions), Occupations Code, does not affect the entitlement of a member serving on the Texas State Board of Pharmacy immediately before September 1, 2005, to continue to serve and function as a member of the Texas State Board of Pharmacy for the remainder of the term the member is serving on the date. Makes application of this Act prospective to a member appointed on or after September 1, 2005.

(b) Makes application of Chapter 558 or 560, Occupations Code, as amended by this Act prospective.

(c) Makes application of Sections 559.003 and 561.003, Occupations Code, as amended by this Act, and Section 561.0031, as added by this Act prospective.

(d) Makes application of Chapter 565, Occupations Code, as amended by this Act prospective.

SECTION 39. Effective date: September 1, 2005.