

BILL ANALYSIS

Senate Research Center

S.B. 609
By: Madla
Health & Human Services
3-24-97
As Filed

DIGEST

Currently, the pharmacy profession is regulated by provisions contained in the Texas Pharmacy Act, many of which are inadequate to address the challenges facing the pharmacy profession today. Problems have arisen regarding businesses illegally posing as mail-order pharmacists, lack of standards for pharmacy technician training programs, outdated pharmacist-intern registration guidelines and professional degree requirements, and an archaic license fee system, among other issues. This legislation updates existing law, while tightening regulations, to redefine "pharmacy" and "confidential record"; establish that a person operating a pharmacy without a license is subject to a civil penalty; require the Texas State Board of Pharmacy (board) to provide certain information to its members; authorize the board to determine standards for pharmacy technician training programs; authorize the board to restrict a pharmacist intern's registration and to request the intern to submit to a mental or physical examination; allow the board to specify the professional degree required for licensure; and allow the board to assess a probation fee as part of a disciplinary order to defer certain costs.

PURPOSE

As proposed, S.B. 609 establishes the regulation of pharmacies and pharmacists, and provides a penalty.

RULEMAKING AUTHORITY

Rulemaking authority is granted to the Texas State Board of Pharmacy in SECTIONS 6, 7, and 18 (Sections 17(o), 17D(a), and 29(e), Article 4542a-1, V.T.C.S.) and in SECTION 24 (Section 483.042(e), Health and Safety Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Section 5, Article 4542a-1, V.T.C.S. (Texas Pharmacy Act), to redefine "Administrative Procedure Act," "confidential record," "pharmacy," and "preceptor." Defines "pharmacy technician" and "Texas trade association." Deletes the definition of "supportive personnel." Makes conforming changes.

SECTION 2. Amends Section 8(a), Article 4542a-1, V.T.C.S., to prohibit a licensed pharmacist member of the Texas State Board of Pharmacy (board) from being a salaried faculty member at a college of pharmacy; or an officer, employee, or paid consultant of a Texas trade association in the field of health care or a spouse of an officer, employee, or paid consultant. Makes conforming changes.

SECTION 3. Amends Section 8, Article 4542a-1, V.T.C.S., by adding Subsection (f), to set forth the terms by which the board is required to provide to its members information regarding their qualifications for office or employment and their responsibilities.

SECTION 4. Amends Section 14(c), Article 4542a-1, V.T.C.S., to make standard recodification changes.

SECTION 5. Amends Sections 15(c), (d), and (f), Article 4542a-1, V.T.C.S., to make conforming changes.

SECTION 6. Amends Sections 17(a), (o), and (q), Article 4542a-1, V.T.C.S., to set forth the terms by which the board is required to establish rules for the use and duties of pharmacy technicians, rather than supportive personnel, provided that the board may not adopt rules or regulations establishing certain ratios; and is authorized to issue standards for recognition and approval of training programs for pharmacy technicians. Makes conforming and standard recodification changes.

SECTION 7. Amends Section 17D(a), Article 4542a-1, V.T.C.S., to require the board, by rule, to adopt procedures governing informal disposition of a contested case under, and informal proceedings held in compliance with, Chapter 2001, Government Code. Makes conforming changes.

SECTION 8. Amends Sections 19(a), (f), and (g), Article 4542a-1, V.T.C.S., to prohibit a person from operating a pharmacy unless the person first obtains a license to operate a pharmacy. Deletes the provision which prohibits this Act from applying to a pharmacist intern. Establishes that any person found by the board to have unlawfully engaged in the practice of pharmacy or unlawfully operated a pharmacy is subject to a civil penalty under Section 37A, rather than being subject to a fine not to exceed \$1,000 for each offense. Makes conforming changes.

SECTION 9. Amends Section 20, Article 4542a-1, V.T.C.S., to require pharmacist-intern registration to remain in effect as long as the person meets the qualifications for internship as specified by rules adopted by the board, rather than during internship training and thereafter until either the failure of the pharmacist to take or pass the next regularly scheduled examination, whichever happens first. Authorizes the board to restrict registration for any violation of this Act. Sets forth the terms by which the board is required, in enforcing Section 26(a)(4) and on probable cause, to request a pharmacist-intern or pharmacist-intern applicant to submit to a mental or physical examination. Establishes the protocol regarding the refusal of an intern or intern applicant to submit to the examination.

SECTION 10. Amends Sections 21(a) and (e), Article 4542a-1, V.T.C.S., to require an applicant for licensing by examination, in order to qualify for a license to practice pharmacy, to submit evidence that the person has graduated and received a professional practice degree, as defined by the rules adopted by the board, rather than the first professional undergraduate or advanced professional degree from an accredited pharmacy degree program. Requires the board to notify each examinee of the results of the examination within 30 days after the date the board receives the results from a national testing service. Deletes the existing provisions regarding notification of examination results.

SECTION 11. Amends Section 22(a), Article 4542a-1, V.T.C.S., to require an applicant for a license to practice pharmacy by reciprocity to pass the Texas Pharmacy Jurisprudence, rather than the Drug and Pharmacy Jurisprudence, examination. Makes a conforming change.

SECTION 12. Amends Section 26(b), Article 4542a-1, V.T.C.S., to set forth the terms by which the board is authorized to refuse to issue or renew a license; assess a penalty; restrict, cancel, or suspend any license; and probate any license suspension if the board finds that the applicant or licensee has engaged in any fraud, deceit, or misrepresentation. Makes a nonsubstantive change.

SECTION 13. Amends Section 26A(c), Article 4542a-1, V.T.C.S., to make a conforming change.

SECTION 14. Amends Section 27, Article 4542a-1, V.T.C.S., to make a conforming change.

SECTION 15. Amends Section 27A(d), Article 4542a-1, V.T.C.S., to make a conforming change.

SECTION 16. Amends Section 27B(c), Article 4542a-1, V.T.C.S., to make a conforming change.

SECTION 17. Amends Section 28(a), Article 4542a-1, V.T.C.S., to authorize the board, on the finding of grounds for discipline of a license holder or license renewer, to place the offender's license on probation and supervision and impose a probation fee to defer the costs of monitoring a licensee during the probation period, rather than imposing a civil penalty not to exceed a certain amount. Makes conforming changes.

SECTION 18. Amends Section 29(e), Article 4542a-1, V.T.C.S., to authorize the board, with respect to Class C pharmacies, to establish rules for the use and duties of pharmacy technicians, provided certain conditions exist. Prohibits the board from adopting any rule setting ratios with respect to, or limiting the number of pharmacy technicians. Makes conforming changes.

SECTION 19. Amends Section 35, Article 4542a-1, V.T.C.S., to prohibit a person from advertising any store or place of business as a pharmacy or providing pharmacy services unless the facility is a pharmacy licensed under this Act. Makes a conforming change.

SECTION 20. Amends Article 4542a-1, V.T.C.S., by adding Section 37A, as follows:

Sec. 37A. CIVIL PENALTY. Provides that a person who violates the license requirements of this Act is liable to the state for a civil penalty of \$1,000 for each day the violation continues. Authorizes the attorney general, district attorney, county attorney, or city attorney to sue in a district court of Travis County to collect the penalty.

SECTION 21. Amends Section 40(h), Article 4542a-1, V.T.C.S., to authorize a pharmacist to dispense a generically equivalent drug if the practitioner does not write by hand on the face of his or her written prescription the words "brand medically necessary" or analogous words. Deletes the existing provisions regarding written prescription dispensing instructions.

SECTION 22. Amends Sections 483.001(10) and (11), Health and Safety Code, to redefine "pharmacy" and "practice of pharmacy." Makes a conforming change.

SECTION 23. Amends Section 483.003(b), Health and Safety Code, to authorize the Texas Board of Health, rather than the board, to limit the availability of the abused drug by permitting its dispensing only on the prescription of certain practitioners.

SECTION 24. Amends Section 483.042(e), Health and Safety Code, to provide that the labeling provisions of Subsection (a) do not apply to a dangerous drug prescribed or dispensed for administration to a patient who is institutionalized. Requires the board to adopt rules for the labeling of such a drug. Deletes the provision regarding the application of labeling guidelines to food production animals in an agricultural operation.

SECTION 25. Repealer: Article 4542a, V.T.C.S. (State Board of Pharmacy to regulate practice of pharmacy).

SECTION 26. Repealer: Section 26A(b), Article 4542a-1, V.T.C.S., as amended by Section 7, Chapter 789, Acts of the 73rd Legislature, Regular Session, 1993 (Felony Drug Convictions; Suspension and Revocation of License).

SECTION 27. Effective date: September 1, 1997.

SECTION 28. Makes application of this Act prospective.

SECTION 29. Emergency clause.