



GOVERNOR GREG ABBOTT

To: Julie Spier, Chair
Allison Benz, Executive Director
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Texas State Board of Pharmacy

From: Erin Bennett, Director
Regulatory Compliance Division, Office of the Governor

Date: January 29, 2021

Subject: Proposed Title 22 Texas Administrative Code Sections 291.1 and 291.3 (RCD Rule Review #2020-021) and Proposed Title 22 Texas Administrative Code Section 291.14 (RCD Rule Review #2020-022)

I. Syllabus

The Texas State Board of Pharmacy (“board”) proposed amended 22 TAC §§291.1, 291.3, and 291.14, which incorporate a new requirement for certain non-pharmacist owners and managing officers to take a pharmacy ownership training course.¹ The Regulatory Compliance Division (“division”) initiated a review of proposed §§291.1 and 291.3 pursuant to Section 57.106(g), Texas Occupations Code. The board identified proposed §291.14, which appeared in a subsequent issue of the *Texas Register*, as a related rule enacting substantively the same change. The board submitted all three proposed rules to the division for review on December 22, 2020. The division invited public comments on the proposed rules for a 30-day period ending January 22, 2021, but received no comments. The division has determined that requiring a mandatory course for non-pharmacist owners and managing officers as a condition of pharmacy licensure is inconsistent with state policy and, thus, the proposed rules are disapproved for final adoption.

II. Analysis

Through its informal settlement conferences for contested cases, board members have recently observed a lack of knowledge regarding the administrative and operational functions of Class A (or community) pharmacies.² As a result, the board has developed a training course to improve

¹ Rule Submission Memorandum from the Texas State Board of Pharmacy (Dec. 22, 2020), at 1, 5, and 8 (on file with the Regulatory Compliance Division of the Office of the Governor); 45 Tex. Reg. 6875 (2020) (to be codified at 22 TAC §§291.1 and 291.3) (proposed Oct. 2, 2020) (Tex. State Bd. Pharmacy); and 45 Tex. Reg. 8821 (2020) (to be codified at 22 TAC §291.14) (proposed Dec. 11, 2020) (Tex. State Bd. Pharmacy).

² Rule Submission Memorandum from the Texas State Board of Pharmacy (Dec. 22, 2020), at 1-3, 6, and 8-10.

awareness of the roles and responsibilities of pharmacy ownership for non-pharmacist owners and managing officers of certain Class A pharmacies.³ The course would be a one-time requirement for an initial pharmacy license in proposed §291.1(g). And, under proposed §§291.3(c)(3) and 291.14(a)(4), those same pharmacies would be required to provide notice to the board that any subsequent non-pharmacist owners and managing officers took the course as part of the required notifications to the board and as a condition of renewal of a pharmacy license. Because the course would be a prerequisite to the issuance, maintenance, and renewal of a pharmacy license, the proposed rules create a barrier to market participation and, thus, affect competition pursuant to Section 57.105(d)(1), Texas Occupations Code.

A. Requiring a pharmacy ownership training course as a prerequisite to pharmacy licensure and renewal in proposed 22 TAC §§291.1 and 291.14 is not consistent with state policy.

Proposed §291.1(g) adds to the prerequisites for a Class A pharmacy license the requirement that each non-pharmacist owner and managing officer submit proof of attendance for a pharmacy ownership training course approved by the board. Similarly, proposed §291.14(a)(4) adds to the prerequisites for renewal of a Class A pharmacy license the requirement that, within 90 days of notifying the board of a change in managing officer, each non-pharmacist owner and managing officer submit proof of attendance for a pharmacy ownership training course approved by the board.

Section 551.002, Texas Occupations Code, directs the board to liberally construe the Texas Pharmacy Act (“Act”) and identifies effectively regulating the practice of pharmacy and licensing pharmacies as the primary means through which the board accomplishes the purpose of the Act. Section 554.051, Texas Occupations Code, provides the board with general rulemaking authority to regulate the practice of pharmacy and to administer and enforce the Act. Although the board relies on Sections 551.002 and 554.051 as its general authority for requiring the pharmacy ownership training course in proposed §§291.1 and 291.14, Chapters 560 and 561, Texas Occupations Code, comprise the board’s more specific authority to establish prerequisites for the initial issuance and renewal of a pharmacy license.⁴

Section 560.052(a) requires the board to set standards that a pharmacy, and employees involved in the practice of pharmacy, must meet to qualify for an initial pharmacy license. However, the board’s authority under Section 560.052 only allows it to set standards for pharmacies and pharmacy employees *involved in the practice of pharmacy*. The practice of pharmacy is defined in Section 551.003(33), and, pursuant to Section 558.001, Texas

³ *Id.* As proposed, the course would not be required for Class A pharmacies that are operated by a publicly traded company or that are wholly owned by a retail grocery store chain. Hereinafter, references to pharmacies or administrative actions to pharmacy licenses or applications apply only to those pharmacies affected by the proposed rules.

⁴ Rule Submission Memorandum from the Texas State Board of Pharmacy (Dec. 22, 2020), at 2, 6, and 9.

Occupations Code, only a pharmacist may be engaged in the practice of pharmacy. Pharmacy-interns, pharmacy technicians, and pharmacy technician-trainees may also provide limited services related to the practice of pharmacy under the supervision of a pharmacist.⁵ However, neither ownership nor management of a pharmacy are included in the practice of pharmacy as defined; while non-pharmacist owners and managing officers may decide policies and procedures followed by pharmacy staff, they do so in a business capacity and are not involved in the actual practice of pharmacy as a result. Applicants for a pharmacy license must pay a fee, submit a completed application and a disclosure statement, and provide other information specific to unique classes of pharmacy, as well as undergo an inspection and submit criminal history record information.⁶ No clearly articulated statutory basis exists for the board to require non-pharmacist owners and managing officers to fulfill training requirements as a prerequisite to pharmacy licensure. Thus, proposed §291.1(g) is inconsistent with state policy.

The corresponding requirement of the pharmacy ownership training course for renewal of a pharmacy license in proposed §291.14(a)(4) suffers from the same shortcomings. Section 561.003(a)(3) requires the board to set standards that a pharmacy, and the pharmacy's employees involved in the practice of pharmacy, must meet to qualify for renewal of a pharmacy license. As explained above, non-pharmacist owners and managing officers are not involved in the practice of pharmacy. Thus, the board cannot rely on that section to require non-pharmacist owners and managing officers to fulfill training requirements as a prerequisite to renewal of a pharmacy license. Further, the board lacks the statutory grounds to require training for non-pharmacist owners and managing officers as a condition for ongoing competence, such as it may for other license holders. For example, and in contrast, Section 559.003(a)(2), Texas Occupations Code, directs the board to prescribe continuing education requirements for a pharmacist to renew their license. As a result, proposed §291.14(a)(4) is also inconsistent with state policy.⁷

⁵ See Sections 551.003(30), (32), and (32-a); 554.053(a); and 568.001(b), Texas Occupations Code. A licensed pharmacist-in-charge must be designated and is responsible for supervising and ensuring the pharmacy's compliance with statute and rules relating to the practice of pharmacy. Sections 551.003(29), 560.052(b)(2)(E)(iv), and 562.101, Texas Occupations Code.

⁶ Section 560.052(b)-(h), Texas Occupations Code; 22 TAC §291.1 (2020) (Tex. State Bd. Pharmacy). Sections 554.001(c)(2) and 556.051(a), Texas Occupations Code, authorize the board to require pre-licensure inspections of facilities. Section 411.122, Texas Government Code, and Section 565.002, Texas Occupations Code, provide authority to obtain criminal history information and take disciplinary actions for certain convictions, for which the board obtains fingerprint-based criminal background checks.

⁷ The board asserts that owners and managing officers may contribute to "a dispensing error due to a failure to set proper operational procedures or the diversion of controlled substances from the pharmacy due to a failure to establish proper safeguards." Rule Submission Memorandum from the Texas State Board of Pharmacy (Dec. 22, 2020), at 3, 6, and 9-10. The board has clear authority to set and enforce standards of professional responsibility for pharmacies in Sections 554.051(d) and 565.002, Texas Occupations Code, for which owners and managing officers may be held to account in certain circumstances. However, the authority to set and enforce standards does not imbue the board with authority to require training for unlicensed individuals as a prerequisite to licensure for the pharmacy, even if doing so is intended to reduce potential future violations.

B. Requiring notification that non-pharmacist owners and managing officers have completed a mandatory pharmacy ownership training course in proposed 22 TAC §291.3 is not consistent with state policy.

Proposed §291.1(g) requires, within 90 days of notifying the board of a change in managing officer, each non-pharmacist owner and managing officer to submit proof of attendance for a pharmacy ownership training course approved by the board. Section 562.106, Texas Occupations Code, requires pharmacies to notify the board of certain information, including changes in ownership and, in Subsection (a)(5), “any matter or occurrence that the board requires by rule to be reported.” Therefore, the board has sufficient authority to require pharmacies to report on the training of pharmacy owners and managing officers insofar as it supports the board’s regulatory purposes. However, Section 562.106 only requires reporting and cannot be the sole basis for conditioning pharmacy licensure on training requirements for non-pharmacist owners and managing officers. Because the board’s governing statute does not support such a prerequisite, proposed §291.3(c)(3) is also inconsistent with state policy.

III. Determination

The division commends the board for being proactive in identifying trends and developing a training course in pharmacy ownership, as educating licensees, owners, managing officers, employees, and the public is an important component to ensuring the health and safety of Texans through the safe practice of pharmacy. Further, the division appreciates that the course would be free and offered online — although those features do not appear in the proposed rules — with the intention of minimizing the barrier to affected individuals and pharmacies.⁸ However, as explained above, the board lacks authority to require specific training for non-pharmacist owners and managing officers, and even a minimized burden on licensure must first be consistent with state policy as expressed in the board’s governing statute. Consequently, proposed §§291.1, 291.3, and 291.14 are disapproved by the division as written.

Consistent with the above analysis, the board could provide for an optional course to be taken by non-pharmacist owners and managing officers and other non-pharmacist employees to improve their awareness of responsibilities under the Act. However, if the board decides to provide such a course, it cannot be made a prerequisite to the issuance, maintenance, or renewal of a pharmacy license.

⁸ Rule Submission Memorandum from the Texas State Board of Pharmacy (Dec. 22, 2020), at 2 and 9.