GOVERNOR GREG ABBOTT

To: Julie Spier, Chair
Daniel Carroll, Executive Director
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Texas State Board of Pharmacy

From: Caleb Gunnels, Assistant General Counsel
Office of the Governor

Date: May 2, 2025

Subject: Proposed Title 22 Texas Administrative Code Section 291.133 (RCD Rule Review #2025-002)

I. Syllabus

The Texas State Board of Pharmacy ("board") proposed amended 22 TAC §291.133, to update the personnel, environment, compounding process, cleaning and disinfecting, beyond-use dating, cleansing and garbing, environmental testing, sterility testing, recall procedure, and recordkeeping requirements for pharmacies compounding sterile preparations, and submitted the rule to the Regulatory Compliance Division ("division") for review, as published in the December 27, 2024, issue of the *Texas Register*.[1] Proposed amended §291.133 is primarily intended to ensure the safety and efficacy of compounded sterile preparations, that sterile compounding is conducted in a safe and sanitary environment, improve the health, safety, and welfare of patients, and provide clearer regulatory language informed by and in line with recently updated guidance in the United States Pharmacopeia-National Formulary.[2] The board submitted the proposed rule to the division for review on February 4, 2025.[3] The division invited public comments on the proposed rule for a 30-day period ending on March 12, 2025, and the division received no comments.

Based on the following analysis, the division has determined that the proposed rule is consistent with state policy, and thus, proposed amended 22 TAC §291.133 is approved by the division and may be finally adopted and implemented.

[1] 49 Tex. Reg. 10463 (2024) (to be codified at 22 TAC §291.133) (proposed Dec. 27, 2024) (Tex. State Bd. Pharmacy); Rule Submission Memorandum from the Texas State Board of Pharmacy (Feb. 4, 2025), at 1 (on file with the Regulatory Compliance Division of the Office of the Governor).
[2] Rule Submission Memorandum from the Texas State Board of Pharmacy (Feb. 4, 2025), at 1.
[3] *Id.*

II. Analysis

In 2022, the United States Pharmacopeia-National Formulary was updated to revise General Chapter 797 regarding Pharmaceutical Compounding and Sterile Preparations, and those revisions became effective on November 1, 2023.[4] During that time, the board voted to create a Compounding Rules Advisory Group Sterile Subcommittee ("subcommittee") to review the proposed revisions to Chapter 797 and any effects on current board rules.[5] The subcommittee met on five separate occasions in 2023, and subsequently proposed its recommendations to the board in two public meetings held in 2024.[6] On August 6, 2024, the board convened and heard oral comments from the subcommittee and voted to propose amendments to 22 TAC §291.133.[7] On November 5, 2024, the board convened once again and considered written and oral comments from the public before voting to propose additional changes to the previously proposed amendments.[8]

The purpose of the proposed amendments is to align board standards regarding compounded sterile preparations with the updated guidelines in the United States Pharmacopeia-National Formulary, which reflect advances in science and pharmacy practices that have created new techniques to reduce the risk of contamination, infection, or incorrect dosing when compounding drugs.[9] Specifically, the amended rule generally updates proper garbing requirements to ensure sterile work environments, specifies sampling and testing procedures to identify and reduce contamination both in the work space and in compounded preparations, details proper sterilization techniques and air exchange requirements to reduce contamination of tools and air quality, and updates beyond-use dates to identify the date and time by which a preparation must be used before the preparation becomes a risk to patient safety.[10]

In reviewing the updated guidelines in General Chapter 797, the subcommittee considered various methods of compliance to reduce burdensome impacts on industry participants while ensuring the health, safety, and welfare of the public.[11] The subcommittee ultimately recommended limiting or not adopting several provisions from the updated United States Pharmacopeia-National Formulary, and the board asserts that many of the proposed amendments to §291.133 are less restrictive than the guidelines in current General Chapter 797.[12] However, given that updated practice requirements could potentially result in higher prices or reduced

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[4] U.S. Pharmacopeia, *<797> FAQs*, GENERAL CHAPTER <797> (Dec. 11, 2023), https://go.usp.org/USP_GC_797_FAQs?_gl=1*17d5q2u*_gcl_au*MjkxMzYzODQ1LjE3MzU1OTIyNDk.*_ga*MTEzNDcyNDE1NC4xNzM1NTkyMjQ5*_ga_DTGQ04CR27*MTczNjYzNjEzNC40LjEuMTczNjYzNjkxOC4wLjAuMA.
[5] Rule Submission Memorandum from the Texas State Board of Pharmacy (Feb. 4, 2025), at 1-2.
[6] *Id*. at 2.
[7] *Id*.
[8] *Id*.
[9] *Id*. at 3.
[10] *Id*. at 3-4.
[11] *Id*. at 4.
[12] *Id*.

competition for a product or service provided by or to a license holder in the state, proposed amended §291.133 may affect competition pursuant to Section 57.105(d)(2), Texas Occupations Code.

Section 551.002, Texas Occupations Code, directs the board to liberally construe the Texas Pharmacy Act ("Act"), including to protect public health, safety, and welfare, 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 broad rulemaking authority to regulate the practice of pharmacy and to administer and enforce the Act. The practice of pharmacy as defined by Section 551.003(33), includes the compounding of drugs, which Section 551.003(9), in part, defines as the preparation, mixing, assembling, packaging, or labeling of a drug or device. And, Section 560.052(g), Texas Occupations Code, generally prohibits the board from issuing a license to a pharmacy that compounds sterile preparations unless the pharmacy has been inspected by the board to ensure the pharmacy meets any safety standards imposed by state law or board rules.

The board's regulatory authority to prescribe pharmacy requirements for recordkeeping and compounding, labeling, dispensing, storing, and packaging of drugs by pharmacies is broad. However, proposed amended 22 TAC §291.133 is the result of an effort that began in May 2023, when the board created an advisory subcommittee to specifically review newly enacted national standards related to sterile compounding, and the board requested nominations for licensees to serve as subcommittee members.[13] As discussed, the board and the subcommittee met on a number of occasions to develop the least restrictive methods of ensuring the safety and efficacy of compounded sterile preparations, and ultimately proposed rule amendments that were less restrictive than those published in the United States Pharmacopeia-National Formulary.[14] After the board first proposed amendments to the rule in September 2024, the board considered public comments and once again, in December, proposed new amendments in response to those comments.[15]

Ultimately, proposed amended 22 TAC §291.133, informed by national guidance, is a reasonable exercise of the board's regulatory authority to protect public health, safety, and welfare by ensuring that pharmacies engaged in sterile compounding operate in a safe and sanitary environment. Thus, proposed amended 22 TAC §291.133 is consistent with state policy.

III. Determination

Based on the above analysis, the proposed amended rule is approved by the division and may proceed to final adoption and implementation.

[13] *Id*. at 2 and 4.
[14] *Id*.
[15] *Id*.