



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: January 26, 2026

Subject: Proposed Title 22 Texas Administrative Code Section 291.133 (RCD Rule Review #2025-006)

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, as published in the December 27, 2024, issue of the *Texas Register*.¹ On February 4, 2025, the Board submitted the proposed amended rule to the Regulatory Compliance Division (“Division”) for review, and on May 2, 2025, the Division approved the rule and instructed the Board that it may act to adopt and implement it.²

However, before taking formal action to adopt the amended rule, the Board voted to propose additional changes, as published in the October 3, 2025, issue of the *Texas Register*.³ Similar to its prior proposal, 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, to 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.⁴ On October 26, 2025, the Board submitted the proposed

¹ 49 Tex. Reg. 10463 (2024) (to be codified at 22 TAC §291.133) (proposed Dec. 27, 2024) (Tex. State Bd. Pharmacy);

² 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); Regulatory Compliance Division Determination Letter for Proposed Title 22 Texas Administrative Code Section 291.133 (RCD Rule Review #2025-002) (May 2, 2025) (on file with the Regulatory Compliance Division of the Office of the Governor).

³ 50 Tex. Reg. 6416 (2025) (to be codified at 22 TAC §291.133) (proposed Sept. 19, 2025) (Tex. State Bd. Pharmacy).

⁴ Rule Submission Memorandum from the Texas State Board of Pharmacy (Oct. 26, 2025), at 1 (on file with the Regulatory Compliance Division of the Office of the Governor).

amended rule to the Division for review.⁵ The Division invited public comments on the proposed rules for a 30-day period ending on December 5, 2025, and received three comments.⁶

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.

II. Analysis

By way of background, 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, 2023.⁷ On May 2, 2023, 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.⁸ The Subcommittee met on five separate occasions in 2023, and subsequently proposed its recommendations to the Board in two public meetings held in 2024.⁹ On August 6, 2024, the Board convened and heard oral comments from the Subcommittee and voted to propose amendments to 22 TAC §291.133.¹⁰ 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.¹¹ As mentioned, that version of proposed amended §291.133 was reviewed and approved by the Division on May 2, 2025.¹² The Board subsequently met on June 17, 2025, and once again received written and oral comments from the public before voting to propose additional amendments to the rule.¹³

Much of proposed amended 22 TAC §291.133 mirrors language already approved by the Division, and thus, the Division reasserts its analysis and determination from its letter issued on May 2, 2025.¹⁴ Pertinent to the scope of the Division’s review, however, the newly proposed amendments

⁵ Rule Submission Memorandum from the Texas State Board of Pharmacy (Oct. 26, 2025).

⁶ Public Comment from Edward Dominguez (Nov. 21, 2025) (on file with the Regulatory Compliance Division of the Office of the Governor); Public Comment from Empower Pharmacy (Dec. 4, 2025) (on file with the Regulatory Compliance Division of the Office of the Governor); Public Comment from Eli Lilly and Company (Dec. 5, 2025) (on file with the Regulatory Compliance Division of the Office of the Governor).

⁷ U.S. Pharmacopeia, <797> FAQs, GENERAL CHAPTER <797> (Dec. 11, 2023), https://go.usp.org/USP_GC_797_FAQs?_gl=1*17d5q2u*_gcl_au*MjkkxMzYzODQ1LjE3MzU1OTIyNDk.*_ga*MTEzNDcyNDE1NC4xNzM1NTkyMjQ5*_ga_DTGQ04CR27*MTczNjYzNjEzNC40LjEuMTczNjYzNjkkxOC4wLjAuMA.

⁸ Rule Submission Memorandum from the Texas State Board of Pharmacy (Oct. 26, 2025), at 1-2.

⁹ *Id.* at 2.

¹⁰ *Id.*

¹¹ *Id.*

¹² Regulatory Compliance Division Determination Letter for Proposed Title 22 Texas Administrative Code Section 291.133 (RCD Rule Review #2025-002) (May 2, 2025).

¹³ Rule Submission Memorandum from the Texas State Board of Pharmacy (Oct. 26, 2025), at 2.

¹⁴ Regulatory Compliance Division Determination Letter for Proposed Title 22 Texas Administrative Code Section 291.133 (RCD Rule Review #2025-002) (May 2, 2025).

update the maximum batch size for preparations requiring sterility testing, the beyond-use date limits for specific compounded sterile preparations, and clarify safe temperature and humidity requirements in areas where compounding of certain sterile preparations may occur.

The Board reasserts that the general 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 aim to reduce the risk of contamination, infection, or incorrect dosing when compounding drugs.¹⁵ Specifically, the proposed amendments under current Division review are intended to prevent harm from microbial contamination, excessive endotoxins, or other contaminants, and decrease the risk of chemical degradation.¹⁶

Similar to its original proposal on December 27, 2024, the Board's Subcommittee considered various methods of compliance with the guidelines in General Chapter 797 to reduce burdensome impacts on industry participants while seeking to protect the health, safety, and welfare of the public, and the Board ultimately recommended limiting or not adopting several provisions from the updated United States Pharmacopeia-National Formulary—making the State's regulatory scheme less restrictive.¹⁷ However, given that updated practice requirements could potentially result in higher prices or reduced 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 and safe storage of drugs, and Section 551.003(9), in part, defines compounding 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.

As the Division explained in its determination letter issued on May 2, 2025, in the interest of protecting public health and safety, the Legislature granted the Board broad regulatory authority to prescribe requirements for the practice of pharmacy, including the compounding and safe storage of drugs and devices—that reasonably includes assessing the cleanliness of the

¹⁵ Rule Submission Memorandum from the Texas State Board of Pharmacy (Feb. 4, 2025), at 3; Rule Submission Memorandum from the Texas State Board of Pharmacy (Oct. 26, 2025), at 1 and 3.

¹⁶ Rule Submission Memorandum from the Texas State Board of Pharmacy (Oct. 26, 2025), at 3-4.

¹⁷ Rule Submission Memorandum from the Texas State Board of Pharmacy (Feb. 4, 2025), at 4; Rule Submission Memorandum from the Texas State Board of Pharmacy (Oct. 26, 2025), at 4-5.

environment where the practice of pharmacy occurs, setting the duration and standards by which drugs may be stored, and assuring appropriate testing is in place to provide products that do not threaten the safety of Texas consumers.¹⁸ Likewise, the Division noted that 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.¹⁹ The Board and the Subcommittee met on a number of occasions before ultimately proposing amendments that were less restrictive than those published in the United States Pharmacopeia-National Formulary.²⁰ Prior to formally adopting those amendments, and after the Division had already approved them, the Board met once again to receive written and oral comments from the public, which formed the basis for its newly proposed amendments.²¹

Consistent with the Division's prior determination, proposed amended 22 TAC §291.133 is ultimately a reasonable exercise of the Board's broad authority, granted by statute, to regulate the practice of pharmacy, including ensuring that pharmacies engaged in sterile compounding operate in a safe and sanitary environment that best protects the health, safety, and welfare of the public.²² 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.

¹⁸ Regulatory Compliance Division Determination Letter for Proposed Title 22 Texas Administrative Code Section 291.133 (RCD Rule Review #2025-002) (May 2, 2025), at 3.

¹⁹ *Id.*

²⁰ *Id.*; Rule Submission Memorandum from the Texas State Board of Pharmacy (Oct. 26, 2025), at 1-3.

²¹ Rule Submission Memorandum from the Texas State Board of Pharmacy (Oct. 26, 2025), at 2, 3, 5, and 6.

²² Regulatory Compliance Division Determination Letter for Proposed Title 22 Texas Administrative Code Section 291.133 (RCD Rule Review #2025-002) (May 2, 2025), at 3.