

Pharmacies Compounding Sterile Preparations (Class C-S)

Governor Greg Abbott has [declared a state of disaster](#) in Texas due to COVID-19 (coronavirus).

The laws and rules governing the practice of pharmacy in Texas require institutional pharmacies engaged in the compounding of sterile preparations (Class C-S) to comply with certain license renewal requirements. Specifically, board rule [291.77\(2\)](#) states that a Class C-S pharmacy may not renew a pharmacy license unless the pharmacy has been inspected by the board within the last renewal period.

The Texas State Board of Pharmacy has determined that strict compliance with these laws could prevent, hinder, or delay the delivery of pharmaceutical services in relation to efforts to cope with the declared disaster.

Accordingly, the Office of the Governor has temporarily suspended the requirement in board rule 291.77(2) to obtain an inspection within the last renewal period in order to renew a Class C-S pharmacy license. This suspension is in effect until terminated by the Office of the Governor or until the March 13, 2020, disaster declaration is lifted or expires.

§291.77 Pharmacies Compounding Sterile Preparations (Class C-S)

Licensing requirements. An institutional or ASC pharmacy engaged in the compounding of sterile preparations shall be designated as a Class C-S pharmacy.

(1) A Class C-S pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application). A Class C-S license may not be issued unless the pharmacy has been inspected by the board to ensure the pharmacy meets the requirements as specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

~~(2) A Class C-S pharmacy may not renew a pharmacy license unless the pharmacy has been inspected by the board within the last renewal period.~~

(3) A Class C-S pharmacy which changes ownership shall notify the board within 10 days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications).

(4) A Class C-S pharmacy which changes location and/or name shall notify the board within 10 days of the change and file for an amended license as specified in §291.3 of this title.

(5) A Class C-S pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within 10 days of the change following the procedures in §291.3 of this title.

(6) A Class C-S pharmacy shall notify the board in writing within 10 days of closing, following the procedures in §291.5 of this title (relating to Closing a Pharmacy).

(7) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for the issuance and renewal of a license and the issuance of an amended license.

(8) A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location.

(9) A Class C-S pharmacy, licensed under the Act, §560.051(a)(3), which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1) (Community Pharmacy (Class A)) or the Act, §560.051(a)(2) (Nuclear Pharmacy (Class B)), is not required to secure a license for the such other type of pharmacy; provided, however, such licensee is required to comply with the provisions of §291.31 of this title (relating to Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of this title (relating to Records), and §291.35 of this title (relating to Official Prescription Requirements), contained in Community Pharmacy (Class A), or §291.51 of this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title (relating to Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such sections are applicable to the operation of the pharmacy.

(10) A Class C-S pharmacy engaged in the compounding of non-sterile preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(11) A Class C-S pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title (relating to Remote Pharmacy Services).

(12) A Class C-S pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.123 of this title (relating to Central

Prescription Drug or Medication Order Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing).

(13) A Class C-S pharmacy with an ongoing clinical pharmacy program that proposes to allow a pharmacy technician to verify the accuracy of work performed by another pharmacy technician relating to the filling of floor stock and unit dose distribution systems for a patient admitted to the hospital if the patient's orders have previously been reviewed and approved by a pharmacist shall make application to the board as follows.

(A) The pharmacist-in-charge must submit an application on a form provided by the board, containing the following information:

- (i) name, address, and pharmacy license number;
- (ii) name and license number of the pharmacist-in-charge;
- (iii) name and registration numbers of the pharmacy technicians;
- (iv) anticipated date the pharmacy plans to begin allowing a pharmacy technician to verify the accuracy of work performed by another pharmacy technician;
- (v) documentation that the pharmacy has an ongoing clinical pharmacy program; and
- (vi) any other information specified on the application.

(B) The pharmacy may not allow a pharmacy technician to check the work of another pharmacy technician until the board has reviewed and approved the application and issued an amended license to the pharmacy.

(C) Every two years, in connection with the application for renewal of the pharmacy license, the pharmacy shall provide updated documentation that the pharmacy continues to have an ongoing clinical pharmacy program as specified in subparagraph (A)(v) of this paragraph.

(14) A rural hospital that wishes to allow a pharmacy technician to perform the duties specified in §291.73(e)(2)(D) of this title (relating to Personnel) shall make application to the board as follows.

(A) Prior to allowing a pharmacy technician to perform the duties specified in §291.73(e)(2)(D) of this title, the pharmacist-in-charge must submit an application on a form provided by the board, containing the following information:

- (i) name, address, and pharmacy license number;
- (ii) name and license number of the pharmacist-in-charge;
- (iii) name and registration number of the pharmacy technicians;
- (iv) proposed date the pharmacy wishes to start allowing pharmacy technicians to perform the duties specified in §291.73(e)(2)(D) of this title;
- (v) documentation that the hospital is a rural hospital with 75 or fewer beds and that the rural hospital is either:
 - (I) located in a county with a population of 50,000 or less as defined by the United States Census Bureau in the most recent U.S. census; or
 - (II) designated by the Centers for Medicare and Medicaid Services as a critical access hospital, rural referral center, or sole community hospital; and
- (vi) any other information specified on the application.

(B) A rural hospital may not allow a pharmacy technician to perform the duties specified in §291.73(e)(2)(D) of this title until the board has reviewed and approved the application and issued an amended license to the pharmacy.

(C) Every two years in conjunction with the application for renewal of the pharmacy license, the pharmacist-in-charge shall update the application for pharmacy technicians to perform the duties specified in §291.73(e)(2)(D) of this title.