

Pharmacies Compounding Sterile Preparations (Class E-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 nonresident pharmacies engaged in the compounding of sterile preparations (Class E-S) to comply with certain license renewal requirements. Specifically, board rule [291.106\(4\)](#) states that a Class E-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 291.106(4) to obtain an inspection within the last renewal period in order to renew a Class E-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.

§291.106 Pharmacies Compounding Sterile Preparations (Class E-S)

Licensing requirements. A non-resident pharmacy engaged in the compounding of sterile preparations shall be licensed as a Class E-S pharmacy.

(1) A Class E-S pharmacy shall register 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).

(2) A Class E-S license may not be issued unless the pharmacy has been inspected by the board or its designee to ensure the pharmacy meets the requirements as specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations). A Class E-S pharmacy shall reimburse the board for all expenses, including travel, related to the inspection of the Class E-S pharmacy.

(3) On initial application, the pharmacy shall follow the procedures specified in §291.1 of this title and then provide the following additional information specified in §560.052(c) and (f) of the Act (relating to Qualifications):

(A) evidence that the applicant holds a pharmacy license, registration, or permit issued by the state in which the pharmacy is located;

(B) the name of the owner and pharmacist-in-charge of the pharmacy for service of process;

(C) evidence of the applicant's ability to provide to the board a record of a prescription drug order dispensed by the applicant to a resident of this state not later than 72 hours after the time the board requests the record;

(D) an affidavit by the pharmacist-in-charge which states that the pharmacist has read and understands the laws and rules relating to a Class E pharmacy; and

(E) proof of creditworthiness.

~~(4) A Class E-S pharmacy may not renew a pharmacy license unless the pharmacy has been inspected by the board or its designee within the last renewal period.~~

(5) A Class E-S pharmacy which changes ownership shall notify the board within ten 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).

(6) A Class E-S pharmacy which changes location and/or name shall notify the board as specified in §291.3 of this title.

(7) A Class E-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 ten days of the change, as specified in §291.3 of this title.

(8) A Class E-S pharmacy shall notify the board in writing within ten days of closing.

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

(10) 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.

(11) The board may grant an exemption from the licensing requirements of this Act on the application of a pharmacy located in a state of the United States other than this state that restricts its dispensing of prescription drugs or devices to residents of this state to isolated transactions.

(12) A Class E-S pharmacy engaged in the centralized dispensing of prescription drug or medication orders shall comply with the provisions of §291.125 of this title (relating to Centralized Prescription Dispensing).

(13) A Class E-S pharmacy engaged in central processing of prescription drug or medication orders shall comply with the provisions of §291.123 of this title (relating to Central Prescription or Medication Order Processing).

(14) A Class E-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).

(15) A Class E-S pharmacy engaged in the compounding of sterile preparations shall comply with the provisions of §291.133 of this title.

(16) A Class E-S pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(5) concerning Non-Resident Pharmacy (Class E) is required to comply with the provisions of §291.101 of this title (relating to Purpose), §291.102 of this title (relating to Definitions), §291.103 of this title (relating to Personnel), §291.104 of this title (relating to Operational Standards) and §291.105 of this title (relating to Records).