

## Operational Standards

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 nuclear pharmacies (Class B) to comply with certain license renewal requirements. Specifically, board rule [291.54\(a\)\(13\)](#) states that a Class B 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 291.54(a)(13) to obtain an inspection within the last renewal period in order to renew a Class B 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.

### §291.54 Operational Standards

(a) Licensing requirements.

(1) It is unlawful for a person to provide radioactive drug services unless such provision is performed by a person licensed to act as an authorized nuclear pharmacist, as defined by the board, or is a person acting under the direct supervision of an authorized nuclear pharmacist acting in accordance with the Act and its rules, and the regulations of the Texas Department of State Health Services, Radiation Control Program. Subsection (a) of this section does not apply to:

(A) a licensed practitioner or his or her designated agent for administration to his or her patient, provided no person may receive, possess, use, transfer, own, acquire, or dispose of radiopharmaceuticals except as authorized in a specific or a general license as provided in accordance with the requirements of the Texas Department of State Health Services, Radiation Control Program, Texas Administrative Code, Title 25, Part 1, Subchapter F, §289.252 relating to Licensing of Radioactive Material, or the Act;

(B) institutions and/or facilities with nuclear medicine services operated by practitioners and who are licensed by the Texas Department of State Health Services, Radiation Control Program, to prescribe, administer, and dispense radioactive materials (drugs and/or devices).

(2) An applicant for a Class B pharmacy shall provide evidence to the board of the possession of a Texas Department of State Health Services radioactive material license or proof of application for a radioactive material license.

(3) A Class B 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).

(4) A Class B 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).

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

(6) A Class B 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, following the procedures in §291.3 of this title.

(7) A Class B pharmacy shall notify the board in writing within ten days of closing, following the procedures in §291.5 of this title (relating to Closing a Pharmacy).

(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 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.

(10) A Class B pharmacy, licensed under the provisions of the Act, §560.051(a)(2), which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1), concerning community pharmacy (Class A), is not required to secure a license for 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), to the extent such rules are applicable to the operation of the pharmacy.

(11) A Class B pharmacy engaged in the compounding of non-sterile preparations, including radioactive preparations, shall comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(12) A Class B pharmacy engaged in the compounding of sterile preparations, including radioactive preparations, shall comply with the provisions of §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations) using only radiopharmaceuticals from FDA-approved drug products.

~~(13) Effective June 1, 2016, a Class B pharmacy may not renew a pharmacy license unless the pharmacy has been inspected by the board within the last renewal period.~~