

TEXAS STATE BOARD OF PHARMACY

CHAPTER 291. PHARMACIES

SUBCHAPTER B. COMMUNITY PHARMACY (CLASS A)

22 TAC §291.33

The Texas State Board of Pharmacy proposes amendments to §291.33, concerning Operational Standards. The amendments, if adopted, remove the storage of drugs requirements from this section and locate the requirements in new §291.15 previously adopted by the Board.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the rule is in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule.

Ms. Dodson has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the rule will be to ensure that the storage of drugs is consistent with other classes of pharmacies and USP guidelines. There is no fiscal impact for individuals, small or large businesses or to other entities which are required to comply with this section.

Comments on the proposed amendments may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, FAX (512) 305-8082. Comments must be received by 5:00 p.m., October 30, 2008.

The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act (Chapters 551 - 566 and 568 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by this rule: Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

§291.33.Operational Standards.

(a) - (e) (No change.)

(f) Drugs.

(1) Procurement and storage.

(A) - (B) (No change.)

(C) All drugs shall be stored at the proper temperature, as defined in the USP/NF and §291.15 of this title (relating to Storage of Drugs). [~~by the following terms:~~]

~~[(i) controlled room temperature—temperature maintained thermostatically between 15 degrees and 30 degrees Celsius (59 degrees and 86 degrees Fahrenheit);]~~

~~[(ii) cool—temperature between 8 degrees and 15 degrees Celsius (46 degrees and 59 degrees Fahrenheit) which may, alternatively, be stored in a refrigerator unless otherwise specified on the labeling;]~~

~~[(iii) refrigerate—temperature maintained thermostatically between 2 degrees and 8 degrees Celsius (36 degrees and 46 degrees Fahrenheit); and]~~

~~[(iv) freeze—temperature maintained thermostatically between 20 degrees and 10 degrees Celsius (-4 degrees and 14 degrees Fahrenheit).]~~

(2) - (4) (No change.)

(g) - (i) (No change.)

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on September 8, 2008.

TRD-200804802

Gay Dodson, R.Ph.

Executive Director/Secretary

Texas State Board of Pharmacy

Earliest possible date of adoption: October 19, 2008

For further information, please call: (512) 305-8028