

CHAPTER 291. PHARMACIES

SUBCHAPTER A. ALL CLASSES OF PHARMACIES

22 TAC §291.15

The Texas State Board of Pharmacy proposes new §291.15, concerning Storage of Drugs. The proposed new rule, if adopted, provides the storage requirements for drugs in all classes of pharmacies.

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 between the different 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 new rule 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., July 21, 2008.

The new rule is 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.

§291.15.Storage of Drugs.

All drugs shall be stored at the proper temperature and conditions as defined by the following terms:

(1) Freezer--A place in which the temperature is maintained thermostatically between minus 25 degrees Celsius and minus 10 degrees Celsius (minus 13 degrees Fahrenheit and 14 degrees Fahrenheit).

(2) Cold--Any temperature not exceeding 8 degrees Celsius (46 degrees Fahrenheit). A refrigerator is a cold place in which the temperature is maintained thermostatically between 2 degrees Celsius and 8 degrees Celsius (36 degrees Fahrenheit and 46 degrees Fahrenheit).

(3) Cool--Any temperature between 8 degrees Celsius and 15 degrees Celsius (46 degrees Fahrenheit and 59 degrees Fahrenheit). An article for which storage in a cool place is directed may, alternatively, be stored and distributed in a refrigerator, unless otherwise specified by the individual monograph.

(4) Room temperature--The temperature prevailing in a working area.

(5) Controlled room temperature--A temperature maintained thermostatically between 15 degrees Celsius and 30 degrees Celsius (59 degrees Fahrenheit and 86 degrees Fahrenheit).

(6) Warm--Any temperature between 30 degrees Celsius and 40 degrees Celsius (86 degrees Fahrenheit and 104 degrees Fahrenheit).

(7) Excessive heat--Any temperature above 40 degrees Celsius (104 degrees Fahrenheit).

(8) Protection from freezing--Where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency, or to destructive alteration of the dosage form, the container label bears an appropriate instruction to protect the product from freezing.

(9) Dry place--A place that does not exceed 40% average relative humidity at controlled room temperature or the equivalent water vapor pressure at other temperatures.

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 June 9, 2008.

TRD-200802977

Gay Dodson, R.Ph.

Executive Director/Secretary

Texas State Board of Pharmacy

Earliest possible date of adoption: July 20, 2008

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