SUBCHAPTER G. SERVICES PROVIDED BY PHARMACIES

22 TAC §291.133

The Texas State Board of Pharmacy proposes amendments to §291.133, concerning Pharmacies Compounding Sterile Preparations. The amendments, if adopted, remove the storage of drugs requirements from this section and locate the requirements in new §291.15 proposed elsewhere in this issue of the *Texas Register*.

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., July 21, 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 the amendments: Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

§291.133Pharmacies Compounding Sterile Preparations.

(a) - (c) (No change.)

(d) Operational Standards.

(1) - (4) (No change.)

(5) Environment. Compounding facilities shall be physically designed and environmentally controlled to minimize airborne contamination of critical sites.

(A) - (G) (No change.)

(H) Storage requirements and beyond-use dating.

(i) Storage requirements. All drugs shall be stored at the proper temperature and conditions, as defined in the USP/NF and in §291.15 of this title (relating to Storage of Drugs). [~~The most commonly used definitions are as follows:~~]

~~[(I) freezer--A place where the temperature is maintained thermostatically between minus 25 degrees and minus 10 degrees Celsius (minus 13 degrees Fahrenheit and 14 degrees Fahrenheit).]~~

~~[(II) cold temperature--A temperature not exceeding 8 degrees Celsius (46 degrees Fahrenheit). A refrigerator is a cold place in which the temperature maintained thermostatically between 2 degrees and 8 degrees Celsius (36 degrees and 46 degrees Fahrenheit);]~~

~~[(III) cool--A temperature between 8 degrees and 15 degrees Celsius (46 degrees and 59 degrees Fahrenheit). An article for which storage in a cool place is directed may, alternatively, be stored in a refrigerator unless otherwise specified on the labeling; and]~~

~~[(IV) controlled room temperature--A temperature maintained thermostatically between 15 degrees and 30 degrees Celsius (59 degrees and 86 degrees Fahrenheit).]~~

(ii) Beyond-use dating.

(I) Beyond-use dates for compounded sterile preparations shall be assigned based on professional experience, which shall include careful interpretation of appropriate information sources for the same or similar formulations.

(II) Beyond-use dates for compounded sterile preparations that are prepared strictly in accordance with manufacturers' product labeling must be those specified in that labeling, or from appropriate literature sources or direct testing.

(III) Beyond-use dates for compounded sterile preparations that lack justification from either appropriate literature sources or by direct testing evidence must be assigned as described in Chapter 797, Pharmaceutical Compounding--Sterile Preparations of the USP/NF.

(6) - (13) (No change.)

(e) - (g) (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 June 9, 2008.

TRD-200802980

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