

RULE ANALYSIS

Introduction: THESE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS ADOPTED RULES

Short Title: Storage of Drugs

Rule Numbers: §§291.15, 291.133

Statutory Authority: Texas Pharmacy Act, Chapter 551-566 and 568-569, Occupations Code:

- (1) Section 551.002 specifies that the purpose of the Act is to protect the public through the effective control and regulation of the practice of pharmacy; and
- (2) Section 554.051 gives the Board the authority to adopt rules for the proper administration and enforcement of the Act.

Purpose: The new rule and amendments, if adopted, place the requirements for the storage of drugs in one section.

Background: Board staff presents the new rule and amendments to place the requirements for storage of drugs in one section to prevent the rules from being inconsistent.

The Board reviewed and voted to propose the amendments during their May 6-7, 2008, meeting. The proposed amendments were published in the June 20, 2008, issue of the *Texas Register* at 33 TexReg 4789.

1 **CHAPTER 291. PHARMACIES**

2 **SUBCHAPTER A. ALL CLASSES OF PHARMACIES**

3 **22 TAC §291.15**

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

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

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

15 Comments on the proposed new rule may be submitted to Allison Benz, R.Ph., M.S., Director of
16 Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600,
17 Austin, Texas 78701, FAX (512) 305-8082. Comments must be received by 5:00 p.m., July 21,
18 2008.

19 The new rule is proposed under §551.002, and §554.051 of the Texas Pharmacy Act (Chapters
20 551 - 566 and 568 - 569, Texas Occupations Code). The Board interprets §551.002 as
21 authorizing the agency to protect the public through the effective control and regulation of the
22 practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules
23 for the proper administration and enforcement of the Act.

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

26 §291.15.Storage of Drugs.

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

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

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

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

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

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

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

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

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

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

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

18 Filed with the Office of the Secretary of State on June 9, 2008.

19 TRD-200802977

20 Gay Dodson, R.Ph.

21 Executive Director/Secretary

22 Texas State Board of Pharmacy

23 Earliest possible date of adoption: July 20, 2008

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

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1 **SUBCHAPTER G. SERVICES PROVIDED BY PHARMACIES**

2 **22 TAC §291.133**

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

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

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

15 Comments on the proposed amendments may be submitted to Allison Benz, R.Ph., M.S.,
16 Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite
17 3-600, Austin, Texas 78701, FAX (512) 305-8082. Comments must be received by 5:00 p.m.,
18 July 21, 2008.

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

24 The statutes affected by the amendments: Texas Pharmacy Act, Chapters 551 - 566 and 568 -
25 569, Texas Occupations Code.

26 §291.133 *Pharmacies Compounding Sterile Preparations.*

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

28 (d) Operational Standards.

29 (1) - (4) (No change.)

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

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

33 (H) Storage requirements and beyond-use dating.

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

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

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

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

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

14 (ii) Beyond-use dating.

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

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

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

24 (6) - (13) (No change.)

25 (e) - (g) (No change.)

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

28 Filed with the Office of the Secretary of State on June 9, 2008.

29 TRD-200802980

30 Gay Dodson, R.Ph.

31 Executive Director/Secretary

32 Texas State Board of Pharmacy

- 1 Earliest possible date of adoption: July 20, 2008
- 2 For further information, please call: (512) 305-8028
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