

RULE ANALYSIS

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

Short Title: Storage of Drugs

Rule Numbers: §291.33

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.

1 TITLE 22. EXAMINING BOARDS
2 PART 15. TEXAS STATE BOARD OF PHARMACY
3 CHAPTER 291. PHARMACIES
4 SUBCHAPTER B. COMMUNITY PHARMACY (CLASS A)

5
6 §291.33 Operational Standards

7
8 (a) – (e) (No change.)

9
10 (f) Drugs.

11
12 (1) Procurement and storage.

13
14 (A) The pharmacist-in-charge shall have the responsibility for the procurement and
15 storage of drugs, but may receive input from other appropriate staff relative to such
16 responsibility.

17
18 (B) Prescription drugs and devices and nonprescription Schedule V controlled substances
19 shall be stored within the prescription department or a locked storage area.

20
21 (C) All drugs shall be stored at the proper temperature, as defined **in the USP/NF and**
22 **§291.15 of this title (relating to Storage of Drugs).** [by the following terms:]

23
24 — ~~[(i) controlled room temperature—temperature maintained thermostatically between 15~~
25 ~~degrees and 30 degrees Celsius (59 degrees and 86 degrees Fahrenheit);]~~

26
27 — ~~[(ii) cool—temperature between 8 degrees and 15 degrees Celsius (46 degrees and 59~~
28 ~~degrees Fahrenheit) which may, alternatively, be stored in a refrigerator unless otherwise~~
29 ~~specified on the labeling;]~~

30
31 — ~~[(iii) refrigerate—temperature maintained thermostatically between 2 degrees and 8~~
32 ~~degrees Celsius (36 degrees and 46 degrees Fahrenheit); and]~~

33
34 — ~~[(iv) freeze—temperature maintained thermostatically between -20 degrees and -10~~
35 ~~degrees Celsius (-4 degrees and 14 degrees Fahrenheit).]~~

36
37 (2) – (4) (No change.)

38
39 (g) – (i) (No change.)