

RULE ANALYSIS

Introduction: THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS AN ADOPTED RULE

Short Title: Pharmacy Responsibility - Generally - Effective September 1, 2016.

Rule Number: §315.5

Statutory Authority: Texas Pharmacy Act, Chapter 551-569, 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 amendments, if adopted, remove the effective date from the short title and extend the time period for Schedule II prescriptions to be valid to no longer than 30 days to be consistent with federal law.

The Board reviewed and voted to propose the amendments during the February 2, 2021 meeting. The proposed amendments were published in the April 2, 2021, issue of the *Texas Register* at 46 TexReg 2169.

1 **TITLE 22. EXAMINING BOARDS**
2 **PART 15. TEXAS STATE BOARD OF PHARMACY**
3 **CHAPTER 315. CONTROLLED SUBSTANCES**

4 **§315.5. Pharmacy Responsibility - Generally - Effective September 1, 2016.**

5 The Texas State Board of Pharmacy proposes amendments to §315.5, concerning Pharmacy
6 Responsibility - Generally - Effective September 1, 2016. The amendments, if adopted, remove
7 the effective date from the short title and extend the time period for Schedule II prescriptions to
8 be valid to no longer than 30 days to be consistent with federal law.

9 Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary, has determined that,
10 for the first five-year period the rules are in effect, there will be no fiscal implications for state or
11 local government as a result of enforcing or administering the rule. Ms. Benz has determined
12 that, for each year of the first five-year period the rule will be in effect, the public benefit
13 anticipated as a result of enforcing the amendments will be to provide clearer regulatory
14 language and consistency between Board rules and federal law. There is no anticipated
15 adverse economic impact on large, small or micro-businesses (pharmacies), rural communities,
16 or local or state employment. Therefore, an economic impact statement and regulatory flexibility
17 analysis are not required.

18 For each year of the first five years the proposed amendments will be in effect, Ms. Benz has
19 determined the following:

- 20 (1) The proposed amendments do not create or eliminate a government program;
- 21 (2) Implementation of the proposed amendments does not require the creation of new employee
22 positions or the elimination of existing employee positions;
- 23 (3) Implementation of the proposed amendments does not require an increase or decrease in
24 the future legislative appropriations to the agency;
- 25 (4) The proposed amendments do not require an increase or decrease in fees paid to the
26 agency;
- 27 (5) The proposed amendments do not create a new regulation;
- 28 (6) The proposed amendments do limit an existing regulation in order to be consistent with
29 federal law;
- 30 (7) The proposed amendments do not increase or decrease the number of individuals subject to
31 the rule's applicability; and
- 32 (8) The proposed amendments do not positively or adversely affect this state's economy.

33 Written comments on the amendments may be submitted to Megan G. Holloway, Deputy
34 General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin,
35 Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., May 4, 2021.

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

41 The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas
42 Occupations Code.

43 *§315.5. Pharmacy Responsibility - Generally* [~~Effective September 1, 2016~~].

44 (a) Upon receipt of a properly completed prescription form, a dispensing pharmacist must:

45 (1) if the prescription is for a Schedule II controlled substance, ensure the date the prescription
46 is presented is not later than **30 [24]** days after the date of issuance;

47 (2) if multiple prescriptions are issued by the prescribing practitioner allowing up to a 90-day
48 supply of Schedule II controlled substances, ensure each prescription is neither dispensed prior
49 to the earliest date intended by the practitioner nor dispensed beyond **30 [24]** days from the
50 earliest date the prescription may be dispensed;

51 (3) record the date dispensed and the pharmacy prescription number;

52 (4) indicate whether the pharmacy dispensed to the patient a quantity less than the quantity
53 prescribed; and

54 (5) if issued on an official prescription form, record the following information, if different from the
55 prescribing practitioner's information:

56 (A) the brand name or, if none, the generic name of the controlled substance dispensed; or

57 (B) the strength, quantity, and dosage form of the Schedule II controlled substance used to
58 prepare the mixture or compound.

59 (b) The prescription presented for dispensing is void, and a new prescription is required, if:

60 (1) the prescription is for a Schedule II controlled substance, **30 [24]** days after issuance,
61 or **30 [24]** days after any earliest dispense date; or

62 (2) the prescription is for a Schedule III, IV, or V controlled substance, more than six months
63 after issuance or has been dispensed five times during the six months after issuance.