

## RULE ANALYSIS

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

**Short Title:** Prescriptions.

**Rule Number:** §315.3

**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, 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 2168.**

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

4 **§315.3. Prescriptions.**

5 The Texas State Board of Pharmacy proposes amendments to §315.3 concerning  
6 Prescriptions. The amendments, if adopted, extend the time period for Schedule II prescriptions  
7 to be valid to no longer than 30 days to be consistent with federal law.

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

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

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

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

34 The amendments are proposed under §§551.002 and 554.051 of the Texas Pharmacy Act  
35 (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing

36 the agency to protect the public through the effective control and regulation of the practice of  
37 pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the  
38 proper administration and enforcement of the Act.

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

41 *§315.3. Prescriptions.*

42 (a) Schedule II Prescriptions.

43 (1) Except as provided by subsection (e) of this section, a practitioner, as defined in  
44 §481.002(39)(A) of the TCSA, must issue a written prescription for a Schedule II controlled  
45 substance only on an official Texas prescription form or through an electronic prescription that  
46 meets all requirements of the TCSA. This subsection also applies to a prescription issued in an  
47 emergency situation.

48 (2) A practitioner who issues a written prescription for any quantity of a Schedule II controlled  
49 substance must complete an official prescription form.

50 (3) Except as provided by subsection (f) of this section, a practitioner may issue multiple written  
51 prescriptions authorizing a patient to receive up to a 90-day supply of a Schedule II controlled  
52 substance provided:

53 (A) each prescription is issued for a legitimate medical purpose by a practitioner acting in the  
54 usual course of professional practice;

55 (B) the practitioner provides written instructions on each prescription, other than the first  
56 prescription if the practitioner intends for that prescription to be filled immediately, indicating the  
57 earliest date on which a pharmacy may dispense each prescription; and

58 (C) the practitioner concludes that providing the patient with multiple prescriptions in this  
59 manner does not create an undue risk of diversion or abuse.

60 (4) A schedule II prescription must be dispensed no later than **30 [24]** days after the date of  
61 issuance or, if the prescription is part of a multiple set of prescriptions, issued on the same day,  
62 no later than **30 [24]** days after the earliest date on which a pharmacy may dispense the  
63 prescription as indicated on each prescription.

64 (5) A person dispensing a Schedule II controlled substance prescription shall provide written  
65 notice on the safe disposal of controlled substance prescription drugs that includes information  
66 on locations at which Schedule II controlled substance prescription drugs are accepted for safe  
67 disposal. In lieu of listing those locations, the notice may alternatively provide the address of an  
68 Internet website specified by the board that provides a searchable database of locations at  
69 which Schedule II controlled substance prescription drugs are accepted for safe disposal. The  
70 written notice may be provided to the patient in an electronic format, such as by e-mail, if the  
71 patient or patient's agent requests the notice in an electronic format and the request is  
72 documented. Such written notice is not required if:

- 73 (A) the Schedule II controlled substance prescription drug is dispensed at a pharmacy or other  
74 location that:
- 75 (i) is authorized to take back those drugs for safe disposal; and
- 76 (ii) regularly accepts those drugs for safe disposal; or
- 77 (B) the dispenser provides to the person to whom the Schedule II controlled substance  
78 prescription drug is dispensed, at the time of dispensation and at no cost to the person:
- 79 (i) a mail-in pouch for surrendering unused controlled substance prescription drugs; or
- 80 (ii) chemicals to render any unused drugs unusable or non-retrievable.
- 81 (b) Schedules III through V Prescriptions.
- 82 (1) A practitioner, as defined in §§481.002(39)(A), (C), (D) of the TCSA, may use prescription  
83 forms and order forms through individual sources. A practitioner may issue, or allow to be  
84 issued by a person under the practitioner's direction or supervision, a Schedule III through V  
85 controlled substance on a prescription form for a valid medical purpose and in the course of  
86 medical practice.
- 87 (2) Except as provided in subsection (f) of this section, Schedule III through V prescriptions may  
88 be refilled up to five times within six months after date of issuance.
- 89 (c) Electronic prescribing.
- 90 (1) A practitioner is permitted to issue and to dispense an electronic controlled substance  
91 prescription only in accordance with the requirements of the Code of Federal Regulations, Title  
92 21, Part 1311.
- 93 (2) Effective January 1, 2021, a prescription for a controlled substance is not required to be  
94 issued electronically and may be issued in writing if the prescription is issued:
- 95 (A) in circumstances in which electronic prescribing is not available due to temporary  
96 technological or electronic failure;
- 97 (B) by a practitioner to be dispensed by a pharmacy located outside this state; or
- 98 (C) in any other circumstance described in §481.0755(a) of the TCSA.
- 99 (3) A prescriber may apply for a waiver from the electronic prescribing requirement by:
- 100 (A) submitting a waiver request form to the agency that issued the license, certification, or  
101 registration to the prescriber, including any information requested on the form; and
- 102 (B) demonstrating circumstances necessitating a waiver from the requirement, including:

- 103 (i) economic hardship, as determined by the agency that issued the license, registration, or  
104 certification to the prescriber on a prescriber/by prescriber basis, taking into account factors  
105 including:
- 106 (I) any special situational factors affecting either the cost of compliance or ability to comply;
  - 107 (II) the likely impact of compliance on profitability or viability; and
  - 108 (III) the availability of measures that would mitigate the economic impact of compliance;
- 109 (ii) technological limitations not reasonably within the control of the prescriber; or
- 110 (iii) other exceptional circumstances demonstrated by the prescriber.
- 111 (C) A waiver may be issued to a prescriber for a period of one year as specified in Chapter 481  
112 of the Texas Controlled Substances Act. A prescriber may reapply for a subsequent waiver not  
113 earlier than the 30th day before the date the waiver expires if the circumstances that  
114 necessitated the waiver continue.
- 115 (d) Controlled substance prescriptions may not be postdated.
- 116 (e) Advanced practice registered nurses or physician assistants may only use the official  
117 prescription forms issued with their name, address, phone number, and DEA numbers, and the  
118 delegating physician's name and DEA number.
- 119 (f) Opioids for the treatment of acute pain.
- 120 (1) For the treatment of acute pain, as defined in §481.07636 of the TCSA, a practitioner may  
121 not:
- 122 (A) issue a prescription for an opioid in an amount that exceeds a 10-day supply; or
  - 123 (B) provide for a refill of the opioid prescription.
- 124 (2) Paragraph (1) of this subsection does not apply to a prescription for an opioid approved by  
125 the U.S. Food and Drug Administration for the treatment of substance addiction that is issued by  
126 a practitioner for the treatment of substance addiction.
- 127 (3) A dispenser is not subject to criminal, civil, or administrative penalties for dispensing or  
128 refusing to dispense a controlled substance under a prescription that exceed the limits provided  
129 by paragraph (1) of this subsection.