

## RULE ANALYSIS

**Introduction:** THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS A PROPOSED RULE

**Short Title:** Delivery of Prescription Drugs.

**Rule Number:** §291.12

**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 new rule, if adopted, specifies requirements for the delivery of prescription drugs to a patient or patient's agent.

1 TITLE 22 EXAMINING BOARDS  
2 PART 15 TEXAS STATE BOARD OF PHARMACY  
3 CHAPTER 291 PHARMACIES  
4 SUBCHAPTER A ALL CLASSES OF PHARMACIES

5 **§291.12. Delivery of Prescription Drugs.**

6 **(a) Applicability. This section applies to the delivery of prescription drugs by a pharmacy**  
7 **licensed by the board as a Class A, Class A-S, Class E, or Class E-S pharmacy.**

8 **(b) Delivery by common carrier. A pharmacy may deliver prescription drugs by use of a**  
9 **common carrier (e.g., U.S. Mail) as provided in §291.9 of this title (relating to Prescription**  
10 **Pick Up Locations) on request of the patient or patient's agent. For purposes of this**  
11 **section, common carrier means a person or entity who holds out to the general public a**  
12 **willingness to provide transportation of property from place to place for compensation in**  
13 **the normal course of business, with the exception of a same-day courier service.**

14 **(1) Standards. The pharmacy shall ensure that all prescription drugs are delivered to the**  
15 **patient or patient's agent in accordance with nationally recognized standards, such as**  
16 **those of the manufacturer or the United States Pharmacopeia.**

17 **(2) Packaging. The pharmacy shall ensure that prescription drugs are packaged in**  
18 **commercially available tamper evident packaging.**

19 **(3) Temperature. The pharmacy shall ensure that any prescription drug delivered by**  
20 **common carrier is packaged in a manner that maintains a temperature range appropriate**  
21 **for the drug. This may include, without limitation, use of temperature tags, time**  
22 **temperature strips, insulated packaging, gel ice packs, or a combination of these as**  
23 **necessary.**

24 **(4) Irregularity in delivery. The pharmacy shall provide a method by which a patient or**  
25 **patient's agent can notify the pharmacy as to any irregularity in the delivery of the**  
26 **patient's prescription, to include but not be limited to:**

27 **(A) timeliness of delivery;**

28 **(B) condition of the prescription drug upon delivery; and**

29 **(C) failure to receive the proper prescription drug.**

30 **(5) Refusal to deliver. The pharmacy shall refuse to deliver by common carrier a**  
31 **prescription drug which in the professional opinion of the dispensing pharmacist may be**  
32 **clinically compromised by delivery by common carrier.**

33 **(c) Delivery by pharmacy employee or same-day courier service. A pharmacy may deliver**  
34 **prescription drugs by means of its employee or a same-day courier service as provided**  
35 **in §291.9 of this title on request of the patient or patient's agent.**

36 **(1) Standards. The pharmacy is responsible for any problems in the delivery of the**  
37 **prescription drug.**

38 (2) Temperature. The prescription drug shall be maintained within the temperature  
39 range allowed by the United States Pharmacopeia or recommended by the manufacturer  
40 until the delivery has been received by the patient or patient's agent.

41 (d) All deliveries. A pharmacy that delivers prescription drugs by common carrier or by  
42 pharmacy employee or same-day courier service shall also comply with the following:

43 (1) Counseling information. The pharmacy shall comply with the requirements of  
44 §291.33(c)(1)(F) of this title (relating to Operational Standards).

45 (2) Notification of delivery. The pharmacy shall notify the patient or patient's agent of  
46 the delivery of a prescription drug. The notification shall provide information to the  
47 patient or patient's agent about the timeliness in addressing the proper storage of the  
48 prescription drug. The pharmacy shall document and maintain a record of the  
49 notification.

50 (3) Compromised delivery. If a prescription drug is in any way compromised during  
51 delivery, the pharmacy shall replace the drug or arrange for the drug to be replaced,  
52 either by promptly delivering a replacement to the patient or by promptly contacting the  
53 prescriber to arrange for the drug to be dispensed to the patient by a pharmacy of the  
54 patient's or patient's agent's choice.

55 (4) Records. The pharmacy shall maintain records for two years on the following events:

56 (A) when a prescription drug was sent to the patient or patient's agent;

57 (B) patient complaints and audits regarding the timeliness of deliveries;

58 (C) prescription drugs that were compromised in delivery; and

59 (D) the failure of a patient to receive a prescription drug delivery.

60 (5) Controlled substances. A pharmacy shall comply with all state and federal laws and  
61 rules relating to the delivery of controlled substances.