

RULE ANALYSIS

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

Short Title: Limited Prescription Delivery Pharmacy

Rule Numbers: §291.155

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, clarify that a licensed Class H pharmacy may continue to operate after a Class A or Class C pharmacy is obtains a license in the county.

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

5
6 **291.155 Limited Prescription Delivery Pharmacy (Class H)**
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9 (a) Purpose.

10 (1) The purpose of this section is to provide standards for a limited prescription delivery
11 pharmacy.

12 (2) Any facility established for the primary purpose of limited prescription delivery by a Class A
13 pharmacy shall be licensed as a Class H pharmacy under the Act. A Class H pharmacy shall
14 not store bulk drugs, or dispense a prescription drug order.

15 (3) A Class H pharmacy may deliver prescription drug orders for dangerous drugs. A Class H
16 pharmacy may not deliver prescription drug orders for controlled substances.

17 (b) Definitions. Any term not defined in this chapter shall have the definition set out in the Act,
18 §551.003.

19 (c) Personnel.

20 (1) Pharmacist-in-charge.

21 (A) General. Each Class H pharmacy shall have one pharmacist-in-charge who is employed
22 or under written agreement, at least on a part-time basis, but may be employed on a full-time
23 basis, and who may be the pharmacist-in-charge for more than one limited prescription delivery
24 pharmacy.

25 (B) Responsibilities. The pharmacist-in-charge shall have responsibility for the practice of
26 pharmacy at the pharmacy for which he or she is the pharmacist-in-charge. The pharmacist-in-
27 charge may advise the owner on administrative or operational concerns. The pharmacist-in-
28 charge shall have responsibility for, at a minimum, the following:

29 (i) **educating** [~~education~~] and training of pharmacy technicians and pharmacy technician
30 trainees;

31 (ii) maintaining records of all transactions of the Class H pharmacy required by applicable
32 state and federal laws and sections;

33 (iii) **adhering** [~~adherence~~] to policies and procedures regarding the maintenance of records;
34 and

35 (iv) **legally operating** [~~legal operation of~~] the pharmacy, including meeting all inspection
36 and other requirements of all state and federal laws or sections governing the practice of
37 pharmacy.

38 (2) Owner. The owner of a Class H pharmacy shall have responsibility for all administrative
39 and operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on
40 administrative and operational concerns. The owner shall have responsibility for, at a minimum,
41 the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with
42 the pharmacist-in-charge or another Texas licensed pharmacist:

43 (A) providing the pharmacy with the necessary equipment and resources commensurate with
44 its level and type of practice; and

45 (B) **establishing** [~~establishment of~~] policies and procedures regarding maintenance, storage,
46 and retrieval of records in compliance with state and federal requirements.

47 (3) Pharmacists.

48 (A) The pharmacist-in-charge shall be assisted by sufficient number of additional licensed
49 pharmacists as may be required to operate the Class H pharmacy competently, safely, and
50 adequately to meet the needs of the patients of the pharmacy.

51 (B) All pharmacists shall assist the pharmacist-in-charge in meeting his or her
52 responsibilities.

53 (C) Pharmacists shall be responsible for any delegated act performed by the pharmacy
54 technicians under his or her supervision.

55 (4) Pharmacy Technicians and Pharmacy Technician Trainees.

56 (A) General. All pharmacy technicians and pharmacy technician trainees shall meet the
57 training requirements specified in §297.6 of this title (relating to Pharmacy Technician and
58 Pharmacy Technician Trainee Training).

59 (B) Duties. Duties include:

60 (i) ~~delivering~~ [delivery of] previously verified prescription drug orders to a patient or patient's
61 agent provided a record of prescriptions delivered is maintained; and

62 (ii) maintaining pharmacy records.

63 (5) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows.

64 (A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge
65 that bears the person's name and identifies him or her as a pharmacy technician, or a certified
66 pharmacy technician, if the technician maintains current certification with the Pharmacy
67 Technician Certification Board or any other entity providing an examination approved by the
68 board.

69 (B) Pharmacy technician trainees. All pharmacy technician trainees shall wear an
70 identification tag or badge that bears the person's name and identifies him or her as a pharmacy
71 technician trainee.

72 (C) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that
73 bears the person's name and identifies him or her as a pharmacist intern.

74 (D) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the
75 person's name and identifies him or her as a pharmacist.

76 (d) Operational Standards.

77 (1) General requirements. A Class A or Class E Pharmacy may outsource limited prescription
78 delivery to a Class H pharmacy provided the pharmacies have entered into a written contract or
79 agreement which outlines the services to be provided and the responsibilities and
80 accountabilities of each pharmacy in compliance with federal and state laws and regulations.

81 (2) Licensing requirements.

82 (A) A Class H pharmacy shall register with the board on a pharmacy license application
83 provided by the board, following the procedures specified in §291.1 of this title (relating to
84 Pharmacy License Application).

85 (B) A Class H pharmacy must be owned by a hospital district and located in a county without
86 another pharmacy. **If a Class A or Class C pharmacy is established in a county in which a**
87 **Class H pharmacy has been located under this section, the Class H pharmacy may**
88 **continue to operate in that county.**

89 (C) A Class H pharmacy which changes ownership shall notify the board within 10 days of
90 the change of ownership and apply for a new and separate license as specified in §291.3 of this
91 title (relating to Required Notifications).

92 (D) A Class H pharmacy which changes location and/or name shall notify the board of the
93 change [~~within 40 days~~] and file for an amended license as specified in §291.3 of this title.

94 (E) A Class H pharmacy shall notify the board in writing within 10 days of closing, following
95 the procedures in §291.5 of this title (relating to Closing a Pharmacy).

96 (F) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be
97 charged for issuance and renewal of a license and the issuance of an amended license.
98 However, a pharmacy operated by the state or a political subdivision of the state that qualifies
99 for a Class H license is not required to pay a fee to obtain a license.

100 (G) A separate license is required for each principal place of business and only one
101 pharmacy license may be issued to a specific location.

102 (3) Environment.

103 (A) General requirements.

104 (i) The pharmacy shall have a designated area for the storage of previously verified

105 prescription drug orders.

106 (ii) The pharmacy shall be arranged in an orderly fashion and kept clean.

107 (iii) A sink with hot and cold running water shall be available to all pharmacy personnel and

108 shall be maintained in a sanitary condition at all times.

109 (B) Security.

110 (i) Only authorized personnel may have access to storage areas for dangerous drugs.

111 (ii) When a pharmacist, pharmacy technician or pharmacy technician trainee is not present

112 all storage areas for dangerous drugs devices shall be locked by key, combination, or other

113 mechanical or electronic means, so as to prohibit access by unauthorized individuals.

114 (iii) The pharmacist-in-charge shall be responsible for the security of all storage areas for

115 dangerous drugs including provisions for adequate safeguards against theft or diversion of

116 dangerous drugs, and records for such drugs.

117 (iv) Housekeeping and maintenance duties shall be carried out in the pharmacy, while the

118 pharmacist-in-charge, consultant pharmacist, staff pharmacist, or pharmacy technician/trainee is

119 on the premises.

120 (4) Library. A reference library shall be maintained which includes current copies of the

121 following in hard copy or electronic format:

122 (A) Texas Pharmacy Act and rules;

123 (B) Texas Dangerous Drug Act;

124 (C) at least one current or updated patient information reference such as:

125 (i) United States Pharmacopeia Dispensing Information, Volume II (Advice to the Patient); or

126 (ii) a reference text or information leaflets which provide patient information; and

127 (D) basic antidote information and the telephone number of the nearest Regional Poison

128 Control Center.

129 (5) Delivery of Drugs.

130 (A) The pharmacist-in-charge, consultant pharmacist, staff pharmacist, pharmacy technician,

131 or pharmacy technician trainee must be present at the pharmacy to deliver prescriptions.

132 (B) Prescriptions for controlled substances may not be stored or delivered by the pharmacy.

133 (C) Prescriptions may be stored at the pharmacy for no more than 15 days. If prescriptions

134 are not picked up by the patient, the medications are to be destroyed utilizing a reverse

135 distribution service.

136 (D) The pharmacist-in-charge, consultant pharmacist, or staff pharmacist shall personally

137 visit the pharmacy on at least a weekly basis and conduct monthly audits of prescriptions

138 received and delivered by the pharmacy.

139 (e) Records.

140 (1) Every record required to be kept under the provisions this section shall be:

141 (A) kept by the pharmacy and be available, for at least two years from the date of such

142 inventory or record, for inspecting and copying by the board or its representative and to other

143 authorized local, state, or federal law enforcement agencies; and

144 (B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the

145 Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format,

146 the requested records must be provided in a mutually agreeable electronic format if specifically

147 requested by the board or its representative. Failure to provide the records set out in this

148 section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and

149 maintain records in violation of the Act.

150 (2) A record of on-site visits by the pharmacist-in-charge, consultant pharmacist, or staff

151 pharmacist shall be maintained and include the following information:

152 (A) date of the visit;

- 153 (B) pharmacist's evaluation of findings; and
154 (C) signature of the visiting pharmacist.
- 155 (3) Records of prescription drug orders delivered to the Class H pharmacy shall include:
156 (A) patient name;
157 (B) name and quantity of drug delivered;
158 (C) name of pharmacy and address delivering the prescription drug order; and
159 (D) date received at the Class H pharmacy.
- 160 (4) Records of drugs delivered to a patient or patient's agent shall include:
161 (A) patient name;
162 (B) name, signature, or electronic signature of the person who picks up the prescription drug;
163 (C) date delivered; and
164 (D) the name of the drug and quantity delivered.
- 165 (5) Ownership of pharmacy records. For the purposes of these sections, a pharmacy licensed
166 under the Act is the only entity which may legally own and maintain prescription drug records.