

RULE ANALYSIS

Introduction: THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS AN ADOPTED 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 **SUBCHAPTER H. OTHER CLASSES OF PHARMACY**

2 **22 TAC §291.155**

3 The Texas State Board of Pharmacy proposes amendments to §291.155, concerning Limited
4 Prescription Delivery Pharmacy (Class H).

5 The proposed amendments, if adopted, correct grammar and clarify that a licensed Class H
6 pharmacy may continue to operate after a Class A or Class C pharmacy obtains a license in the
7 county.

8 Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year
9 period the rule is in effect, there will be no fiscal implications for state or local government as a
10 result of enforcing or administering the rule.

11 Ms. Dodson has determined that, for each year of the first five-year period the rule will be in
12 effect, the public benefit anticipated as a result of enforcing the amendments will be ensuring
13 that pharmacies are properly licensed.

14 Written comments on the amendments and new rule may be submitted to Allison Vordenbaumen
15 Benz, R.Ph., M.S., Director of Professional Services, Texas State Board of Pharmacy, 333
16 Guadalupe Street, Suite 3-600, Austin, Texas 78701, FAX (512) 305-6778. Comments must be
17 received by 5:00 p.m., October 25, 2016.

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

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

25 ***§291.155.Limited Prescription Delivery Pharmacy (Class H).***

26 (a) Purpose.

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

29 (2) Any facility established for the primary purpose of limited prescription delivery by a Class A
30 pharmacy shall be licensed as a Class H pharmacy under the Act. A Class H pharmacy shall not
31 store bulk drugs[;] or dispense a prescription drug order.

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

34 (b) Definitions. Any term not defined in this chapter shall have the definition set out in the Act,
35 §551.003.

36 (c) Personnel.

37 (1) Pharmacist-in-charge.

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

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

46 (i) educating [~~education~~] and training [~~of~~] pharmacy technicians and pharmacy technician
47 trainees;

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

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

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

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

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

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

62 (3) Pharmacists.

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

- 66 (B) All pharmacists shall assist the pharmacist-in-charge in meeting his or her responsibilities.
- 67 (C) Pharmacists shall be responsible for any delegated act performed by the pharmacy
68 technicians under his or her supervision.
- 69 (4) Pharmacy Technicians and Pharmacy Technician Trainees.
- 70 (A) General. All pharmacy technicians and pharmacy technician trainees shall meet the training
71 requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy
72 Technician Trainee Training).
- 73 (B) Duties. Duties include:
- 74 (i) delivering [~~delivery of~~] previously verified prescription drug orders to a patient or patient's
75 agent provided a record of prescriptions delivered is maintained; and
- 76 (ii) maintaining pharmacy records.
- 77 (5) Identification of pharmacy personnel. All pharmacy personnel shall be identified as
78 follows: [-]
- 79 (A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge
80 that bears the person's name and identifies him or her as a pharmacy technician, or a certified
81 pharmacy technician, if the technician maintains current certification with the Pharmacy
82 Technician Certification Board or any other entity providing an examination approved by the
83 board.
- 84 (B) Pharmacy technician trainees. All pharmacy technician trainees shall wear an identification
85 tag or badge that bears the person's name and identifies him or her as a pharmacy technician
86 trainee.
- 87 (C) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that bears
88 the person's name and identifies him or her as a pharmacist intern.
- 89 (D) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the person's
90 name and identifies him or her as a pharmacist.
- 91 (d) Operational Standards.
- 92 (1) General requirements. A Class A or Class E Pharmacy may outsource limited prescription
93 delivery to a Class H pharmacy provided the pharmacies have entered into a written contract or
94 agreement which outlines the services to be provided and the responsibilities and accountabilities
95 of each pharmacy in compliance with federal and state laws and regulations.
- 96 (2) Licensing requirements.

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

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

104 (C) A Class H pharmacy that [~~which~~] changes ownership shall notify the board within 10 days of
105 the change of ownership and apply for a new and separate license as specified in §291.3 of this
106 title (relating to Required Notifications).

107 (D) A Class H pharmacy that [~~which~~] changes location and/or name shall notify the board of the
108 change [~~within 10 days~~] and file for an amended license as specified in §291.3 of this title.

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

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

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

117 (3) Environment.

118 (A) General requirements.

119 (i) The pharmacy shall have a designated area for the storage of previously verified prescription
120 drug orders.

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

122 (iii) A sink with hot and cold running water shall be available to all pharmacy personnel and
123 shall be maintained in a sanitary condition at all times.

124 (B) Security.

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

126 (ii) When a pharmacist, pharmacy technician or pharmacy technician trainee is not present all
127 storage areas for dangerous drugs devices shall be locked by key, combination, or other
128 mechanical or electronic means, so as to prohibit access by unauthorized individuals.

- 129 (iii) The pharmacist-in-charge shall be responsible for the security of all storage areas for
130 dangerous drugs including provisions for adequate safeguards against theft or diversion of
131 dangerous drugs, and records for such drugs.
- 132 (iv) Housekeeping and maintenance duties shall be carried out in the pharmacy, while the
133 pharmacist-in-charge, consultant pharmacist, staff pharmacist, or pharmacy technician/trainee is
134 on the premises.
- 135 (4) Library. A reference library shall be maintained that [~~which~~] includes current copies of the
136 following in hard copy or electronic format:
- 137 (A) Texas Pharmacy Act and rules;
- 138 (B) Texas Dangerous Drug Act;
- 139 (C) at least one current or updated patient information reference such as:
- 140 (i) United States Pharmacopeia Dispensing Information, Volume II (Advice to the Patient); or
141 (ii) a reference text or information leaflets which provide patient information; and
- 142 (D) basic antidote information and the telephone number of the nearest Regional Poison Control
143 Center.
- 144 (5) Delivery of Drugs.
- 145 (A) The pharmacist-in-charge, consultant pharmacist, staff pharmacist, pharmacy technician, or
146 pharmacy technician trainee must be present at the pharmacy to deliver prescriptions.
- 147 (B) Prescriptions for controlled substances may not be stored or delivered by the pharmacy.
- 148 (C) Prescriptions may be stored at the pharmacy for no more than 15 days. If prescriptions are
149 not picked up by the patient, the medications are to be destroyed utilizing a reverse distribution
150 service.
- 151 (D) The pharmacist-in-charge, consultant pharmacist, or staff pharmacist shall personally visit
152 the pharmacy on at least a weekly basis and conduct monthly audits of prescriptions received and
153 delivered by the pharmacy.
- 154 (e) Records.
- 155 (1) Every record required to be kept under the provisions this section shall be:
- 156 (A) kept by the pharmacy and be available, for at least two years from the date of such inventory
157 or record, for inspecting and copying by the board or its representative and to other authorized
158 local, state, or federal law enforcement agencies; and

159 (B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas
160 State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the
161 requested records must be provided in a mutually agreeable electronic format if specifically
162 requested by the board or its representative. Failure to provide the records set out in this section,
163 either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain
164 records in violation of the Act.

165 (2) A record of on-site visits by the pharmacist-in-charge, consultant pharmacist, or staff
166 pharmacist shall be maintained and include the following information:

167 (A) date of the visit;

168 (B) pharmacist's evaluation of findings; and

169 (C) signature of the visiting pharmacist.

170 (3) Records of prescription drug orders delivered to the Class H pharmacy shall include:

171 (A) patient name;

172 (B) name and quantity of drug delivered;

173 (C) name of pharmacy and address delivering the prescription drug order; and

174 (D) date received at the Class H pharmacy.

175 (4) Records of drugs delivered to a patient or patient's agent shall include:

176 (A) patient name;

177 (B) name, signature, or electronic signature of the person who picks up the prescription drug;

178 (C) date delivered; and

179 (D) the name of the drug and quantity delivered.

180 (5) Ownership of pharmacy records. For the purposes of these sections, a pharmacy licensed
181 under the Act is the only entity that [~~which~~] may legally own and maintain prescription drug
182 records.

183 The agency certifies that legal counsel has reviewed the proposal and found it to be within the
184 state agency's legal authority to adopt.

185 Filed with the Office of the Secretary of State on September 12, 2016.

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- 187 Gay Dodson, R.Ph.
- 188 Executive Director
- 189 Texas State Board of Pharmacy
- 190 Earliest possible date of adoption: October 23, 2016
- 191 For further information, please call: (512) 305-8028