

RULE ANALYSIS

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

Short Title: Registration Requirements

Rule Numbers: §291.1

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, eliminate the provisions allowing individuals who are unable to obtain a social security number, to provide an individual taxpayer identification number in lieu of a social security number because a social security number is required in order to process criminal background checks.

The Board reviewed and voted to propose the amendments during the May 3, 2016, meeting. The proposed amendments were published in the March 11, 2016, issue of the *Texas Register* at 41 TexReg 4593.

1 **CHAPTER 291. PHARMACIES**

2 **SUBCHAPTER A. ALL CLASSES OF PHARMACIES**

3 **22 TAC §291.1, §291.17**

4 The Texas State Board of Pharmacy proposes amendments to §291.1 concerning Pharmacy
5 License Application and §291.17 concerning Inventory Requirements. The amendments to
6 §291.1, if adopted, eliminate the provisions allowing individuals who are unable to obtain a
7 social security number to provide an individual taxpayer identification number in lieu of a social
8 security number because a social security number is required in order to process criminal
9 background checks. The amendments to §291.17, if adopted, require Class A and Class A-S
10 pharmacies to maintain perpetual inventories for all Schedule II controlled substances; and
11 perpetual inventories will be required to be reconciled monthly.

12 Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year
13 period the rules are in effect, there will be no fiscal implications for state or local government as
14 a result of enforcing or administering the rules.

15 Ms. Dodson has determined that, for each year of the first five-year period the rules will be in
16 effect, the public benefit anticipated as a result of enforcing the amendments will ensure
17 individuals applying for a pharmacist license meet the requirements in order to conduct criminal
18 background checks and pharmacies have accurate inventories for Schedule II controlled
19 substances. There is no fiscal impact for individuals, small or large businesses, or to other
20 entities which are required to comply with these sections.

21 Written comments on the amendments may be submitted to Allison Vordenbaumen Benz, R.Ph.,
22 M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street,
23 Suite 3-600, Austin, Texas 78701, FAX (512) 305-6778. Comments must be received by 5:00
24 p.m., August 1, 2016.

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

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

32 ***§291.1. Pharmacy License Application.***

33 (a) To qualify for a pharmacy license, the applicant must submit an application including the
34 following information:

35 (1) name and address of pharmacy;

- 36 (2) type of ownership;
- 37 (3) names, addresses, phone numbers, dates of birth, copies of social security cards or other
38 official documents showing the social security numbers as approved by the board, and copies of
39 current driver's licenses, state issued photo identification cards, or passports of all owners, or of
40 all managing officers if the pharmacy is owned by a partnership or corporation~~[-If an individual
41 is unable to obtain a social security number, an individual taxpayer identification number may be
42 provided in lieu of a social security number along with documentation indicating why the
43 individual is unable to obtain a social security number];~~
- 44 (4) name and license number of the pharmacist-in-charge;
- 45 (5) name(s) and license number(s) of other pharmacists employed by the pharmacy;
- 46 (6) anticipated date of opening and hours of operation;
- 47 (7) copy of lease agreement or if the location of the pharmacy is owned by the applicant, a
48 notarized statement certifying such location ownership;
- 49 (8) the signature of the pharmacist-in-charge;
- 50 (9) the notarized signature of the owner, or if the pharmacy is owned by a partnership or
51 corporation, the notarized signature of an owner or managing officer;
- 52 (10) federal tax ID number of the owner;
- 53 (11) description of business services that will be offered;
- 54 (12) name and address of malpractice insurance carrier or statement that the business will be
55 self-insured;
- 56 (13) documents from a primary wholesaler showing credit worthiness or other documents
57 showing credit worthiness as approved by the board;
- 58 (14) official copy of the business formation documents filed with the Secretary of State;
- 59 (15) current certificate of Good Standing for the business structure from the state where the
60 business structure is located; and
- 61 (16) any other information requested on the application.
- 62 (b) The applicant may be required to meet all requirements necessary in order for the Board to
63 access the criminal history record information, including submitting fingerprint information and
64 being responsible for all associated costs. The criminal history information may be required for
65 each individual owner, or if the pharmacy is owned by a partnership or a closely held corporation
66 for each managing officer.

67 (c) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged
68 for the issuance of a pharmacy license.

69 (d) For purpose of this section, managing officers are defined as the top four executive officers,
70 including the corporate officer in charge of pharmacy operations, who are designated by the
71 partnership or corporation to be jointly responsible for the legal operation of the pharmacy.

72 (e) Prior to the issuance of a license for a pharmacy located in Texas, the board shall conduct an
73 on-site inspection of the pharmacy in the presence of the pharmacist-in-charge and owner or
74 representative of the owner, to ensure that the pharmacist-in-charge and owner can meet the
75 requirements of the Texas Pharmacy Act and Board Rules.

76 (f) If the applicant holds an active pharmacy license in Texas on the date of application for a new
77 pharmacy license or for other good cause shown as specified by the board, the board may waive
78 the pre-inspection as set forth in subsection (e) of this section.

79 *§291.17.Inventory Requirements.*

80 (a) General requirements.

81 (1) The pharmacist-in-charge shall be responsible for taking all required inventories, but may
82 delegate the performance of the inventory to another person(s).

83 (2) The inventory shall be maintained in a written, typewritten, or printed form. An inventory
84 taken by use of an oral recording device must be promptly transcribed.

85 (3) The inventory shall be kept in the pharmacy and shall be available for inspection for two
86 years.

87 (4) The inventory shall be filed separately from all other records.

88 (5) The inventory shall be in a written, typewritten, or printed form and include all stocks of all
89 controlled substances on hand on the date of the inventory (including any which are out-of-date).

90 (6) The inventory may be taken either as of the opening of business or as of the close of business
91 on the inventory date.

92 (7) The inventory record shall indicate whether the inventory is taken as of the opening of
93 business or as of the close of business on the inventory date. If the pharmacy is open 24 hours a
94 day, the inventory record shall indicate the time that the inventory was taken.

95 (8) The person(s) taking the inventory shall make an exact count or measure of all substances
96 listed in Schedule II.

97 (9) The person(s) taking the inventory shall make an estimated count or measure of all controlled
98 substances listed in Schedule III, IV, and V, unless the container holds more than 1,000 tablets or
99 capsules in which case, an exact count of the contents must be made.

100 (10) The inventory of Schedule II controlled substances shall be listed separately from the
101 inventory of Schedule III, IV, and V controlled substances.

102 (11) If the pharmacy maintains a perpetual inventory of any of the drugs required to be
103 inventoried, the perpetual inventory shall be reconciled on the date of the inventory.

104 (b) Initial inventory.

105 (1) A new Class A, Class A-S, Class C, Class C-S, or Class F pharmacy shall take an inventory
106 on the opening day of business. Such inventory shall include all stocks of all controlled
107 substances (including any out-of-date drugs).

108 (2) In the event the Class A, Class A-S, Class C, Class C-S, or Class F pharmacy commences
109 business with no controlled substances on hand, the pharmacy shall record this fact as the initial
110 inventory.

111 (3) The initial inventory shall serve as the pharmacy's inventory until the next May 1, or until the
112 pharmacy's regular general physical inventory date, at which time the Class A, Class A-S, Class
113 C, Class C-S, or Class F pharmacy shall take an annual inventory as specified in subsection (c)
114 of this section.

115 (c) Annual inventory.

116 (1) A Class A, Class A-S, Class C, Class C-S, or Class F pharmacy shall take an inventory on
117 May 1 of each year, or on the pharmacy's regular general physical inventory date. Such inventory
118 may be taken within four days of the specified inventory date and shall include all stocks of all
119 controlled substances (including out-of-date drugs).

120 (2) A Class A, Class A-S, Class C, Class C-S, or Class F pharmacy applying for renewal of a
121 pharmacy license shall include as a part of the pharmacy license renewal application a statement
122 attesting that an annual inventory has been conducted, the date of the inventory, and the name of
123 the person taking the inventory.

124 (3) The person(s) taking the annual inventory and the pharmacist-in-charge shall indicate the
125 time the inventory was taken (as specified in subsection (a)(7) of this section) and shall sign and
126 date the inventory with the date the inventory was taken. The signature of the pharmacist-in-
127 charge and the date of the inventory shall be notarized within three days after the day the
128 inventory is completed, excluding Saturdays, Sundays, and federal holidays.

129 (4) The annual inventory of a Class C or Class C-S pharmacy shall be maintained in the
130 pharmacy; if an inventory is conducted in other departments within the institution, the inventory
131 of the pharmacy shall be listed separately, as follows:

132 (A) the inventory of drugs on hand in the pharmacy shall be listed separately from the inventory
133 of drugs on hand in the other areas of the institution; and

134 (B) the inventory of drugs on hand in all other departments shall be identified by department.

135 (d) Perpetual inventory.

136 (1) Effective May 1, 2017, a Class A or Class A-S pharmacy shall maintain a perpetual inventory
137 of all Schedule II controlled substances.

138 (2) A Class C or Class C-S pharmacy shall maintain a perpetual inventory of all Schedule II
139 controlled substances.

140 (3) Prior to May 1, 2017, the perpetual inventory shall be reconciled on the date of the annual
141 inventory. Effective May 1, 2017, the perpetual inventory shall be reconciled monthly.

142 (e) [~~d~~] Change of ownership.

143 (1) A Class A, Class A-S, Class C, Class C-S, or Class F pharmacy that changes ownership shall
144 take an inventory of all of the following drugs on the date of the change of ownership. Such
145 inventory shall include all stocks of all controlled substances (including any out-of-date drugs).

146 (2) Such inventory shall constitute, for the purpose of this section, the closing inventory for the
147 seller and the initial inventory for the buyer.

148 (3) Transfer of any controlled substances listed in Schedule II shall require the use of official
149 DEA order forms (Form 222).

150 (4) The person(s) taking the annual inventory and the pharmacist-in-charge shall indicate the
151 time the inventory was taken (as specified in subsection (a)(7) of this section) and shall sign and
152 date the inventory with the date the inventory was taken. The signature of the pharmacist-in-
153 charge and the date of the inventory shall be notarized within three days after the day the
154 inventory is completed, excluding Saturdays, Sundays, and federal holidays.

155 (f) [~~e~~] Closed pharmacies.

156 (1) The pharmacist-in-charge of a Class A, Class A-S, Class C, Class C-S, or Class F pharmacy
157 that ceases to operate as a pharmacy shall forward to the board, within 10 days of the cessation
158 of operation, a statement attesting that an inventory of all controlled substances on hand has been
159 conducted, the date of closing, and a statement attesting the manner by which the dangerous
160 drugs and controlled substances possessed by such pharmacy were transferred or disposed.

161 (2) The person(s) taking the annual inventory and the pharmacist-in-charge shall indicate the
162 time the inventory was taken (as specified in subsection (a)(7) of this section) and shall sign and
163 date the inventory with the date the inventory was taken. The signature of the pharmacist-in-

164 charge and the date of the inventory shall be notarized within three days after the day the
165 inventory is completed, excluding Saturdays, Sundays, and federal holidays.

166 ~~[(f) Additional requirements for Class C and Class C-S pharmacies.]~~

167 ~~[(1) Perpetual inventory.]~~

168 ~~[(A) A Class C or Class C-S pharmacy shall maintain a perpetual inventory of all Schedule II
169 controlled substances.]~~

170 ~~[(B) The perpetual inventory shall be reconciled on the date of the annual inventory.]~~

171 ~~[(2) Annual inventory. The inventory of the Class C or Class C-S pharmacy shall be maintained
172 in the pharmacy; if an inventory is conducted in other departments within the institution, the
173 inventory of the pharmacy shall be listed separately, as follows:]~~

174 ~~[(A) the inventory of drugs on hand in the pharmacy shall be listed separately from the inventory
175 of drugs on hand in the other areas of the institution; and]~~

176 ~~[(B) the inventory of drugs on hand in all other departments shall be identified by department.]~~

177 (g) Change of pharmacist-in-charge of a pharmacy.

178 (1) On the date of the change of the pharmacist-in-charge of a Class A, Class A-S, Class C, Class
179 C-S, or Class F pharmacy, an inventory shall be taken. Such inventory shall include all stocks of
180 all controlled substances (including any out-of-date drugs).

181 (2) This inventory shall constitute, for the purpose of this section, the closing inventory of the
182 departing pharmacist-in-charge and the beginning inventory of the incoming pharmacist-in-
183 charge.

184 (3) If the departing and the incoming pharmacists-in-charge are unable to conduct the inventory
185 together, a closing inventory shall be conducted by the departing pharmacist-in-charge and a new
186 and separate beginning inventory shall be conducted by the incoming pharmacist-in-charge.

187 (4) The incoming pharmacist-in-charge shall be responsible for notifying the board within 10
188 days, as specified in §291.3 of this title (relating to Notifications), that a change of pharmacist-
189 in-charge has occurred.