

RULE ANALYSIS

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

Short Title: Inventory Requirements

Rule Numbers: §291.17

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, update the inventory requirements; clarify the recordkeeping regarding the time inventory shall be taken; and add Class A-S and Class C-S to the inventory requirements.

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
6 **§291.17 Inventory Requirements**
7

8
9 (a) General requirements.

10
11 (1) The pharmacist-in-charge shall be responsible for taking all required inventories, but may
12 delegate the performance of the inventory to another person(s).

13
14 (2) The inventory shall be maintained in a written, typewritten, or printed form. An inventory
15 taken by use of an oral recording device must be promptly transcribed.

16
17 (3) The inventory shall be kept in the pharmacy and shall be available for inspection for two
18 years.

19
20 (4) The inventory shall be filed separately from all other records.

21
22 (5) The inventory shall be in a written, typewritten, or printed form and include all stocks of **all**
23 **controlled substances** ~~[the following drugs]~~ on hand on the date of the inventory (including any
24 which are out-of-date):

25
26 ~~—(A) all controlled substances;~~

27
28 ~~—(B) all dosage forms containing nalbuphine (e.g., Nubain); and~~

29
30 ~~—(C) for any inventory taken after January 1, 2013, all dosage forms containing tramadol (e.g.,~~
31 ~~Ultram)].~~

32
33 (6) The inventory may be taken either as of the opening of business or as of the close of
34 business on the inventory date.

35
36 (7) The inventory record shall indicate whether the inventory is taken as of the opening of
37 business or as of the close of business on the inventory date. If the pharmacy is open 24 hours
38 a day, **the inventory record shall indicate the time that the inventory was taken.** ~~[the~~
39 ~~opening of business shall be 12:01 a.m. and the close of business shall be 12 midnight. The~~
40 ~~inventory shall indicate that it is a record of drugs on hand as of the opening or closing of the~~
41 ~~business day.]~~

42
43 (8) The person(s) taking the inventory shall make an exact count or measure of all substances
44 listed in Schedule II.

45
46 (9) The person(s) taking the inventory shall make an estimated count or measure of all
47 **controlled** substances listed in Schedule III, IV, **and** ~~[or] V [and dangerous drugs]~~, unless the
48 container holds more than 1,000 tablets or capsules in which case, an exact count of the
49 contents must be made.
50

51 (10) The inventory of Schedule II controlled substances shall be listed separately from the
52 inventory of Schedule III, IV, and V controlled substances [~~which shall be listed separately from~~
53 ~~the inventory of dangerous drugs~~].

54
55 (11) If the pharmacy maintains a perpetual inventory of any of the drugs required to be
56 inventoried, the perpetual inventory shall be reconciled on the date of the inventory.

57
58 (b) Initial inventory.

59
60 (1) A new Class A [~~(Community) pharmacy~~], **Class A-S**, Class C [~~(Institutional) pharmacy~~],
61 **Class C-S**, or Class F [~~(Free Standing Emergency Medical Care Center)~~] pharmacy shall take
62 an inventory on the opening day of business. Such inventory shall include all stocks **of all**
63 **controlled substances** (including any out-of-date drugs) [~~of the drugs specified in subsection~~
64 ~~(a)(5) of this section~~].

65
66 (2) In the event the Class A, **Class A-S**, **Class C**, **Class C-S**, or **Class F** pharmacy
67 commences business with **no controlled substances** [~~none of the drugs specified in~~
68 ~~subsection (a)(5) of this section~~] on hand, the pharmacy shall record this fact as the initial
69 inventory.

70
71 (3) The initial inventory shall serve as the pharmacy's inventory until the next May 1, or until
72 the pharmacy's regular general physical inventory date, at which time the Class A, **Class A-S**,
73 **Class C**, **Class C-S**, or **Class F** pharmacy shall take an annual inventory as specified in
74 subsection (c) of this section. [~~Such inventory may be taken within four days of the specified~~
75 ~~inventory date and shall include all stocks (including out-of-date drugs)~~].

76
77 (c) Annual inventory.

78
79 (1) A Class A, **Class A-S**, **Class C**, **Class C-S**, or **Class F** pharmacy shall take an inventory
80 on May 1 of each year, or on the pharmacy's regular general physical inventory date. Such
81 inventory may be taken within four days of the specified inventory date and shall include all
82 stocks **of all controlled substances** (including out-of-date drugs) [~~of the drugs specified in~~
83 ~~subsection (a)(5) of this section~~].

84
85 (2) A Class A, **Class A-S**, **Class C**, **Class C-S**, or **Class F** pharmacy applying for renewal of a
86 pharmacy license shall include as a part of the pharmacy license renewal application a
87 statement attesting that an annual inventory has been conducted, the date of the inventory, and
88 the name of the person taking the inventory.

89
90 (3) The person(s) taking the annual inventory and the pharmacist-in-charge shall indicate the
91 time the inventory was taken (as specified in subsection (a)(7) of this section) and shall sign and
92 date the inventory with the date the inventory was taken. The signature of the pharmacist-in-
93 charge and the date of the inventory shall be notarized within three days after the day the
94 inventory is completed, excluding Saturdays, Sundays, and federal holidays.

95
96 (d) Change of ownership.

97
98 (1) A Class A, **Class A-S**, **Class C**, **Class C-S**, or **Class F** pharmacy that changes ownership
99 shall take an inventory of all of the following drugs on the date of the change of ownership. Such
100 inventory shall include all stocks **of all controlled substances** (including any out-of-date drugs)
101 [~~of the drugs specified in subsection (a)(5) of this section~~].

102
103 (2) Such inventory shall constitute, for the purpose of this section, the closing inventory for the
104 seller and the initial inventory for the buyer.

105
106 (3) Transfer of any controlled substances listed in Schedule II shall require the use of official
107 DEA order forms (Form 222[~~€~~]).

108
109 (4) The person(s) taking the annual inventory and the pharmacist-in-charge shall indicate the
110 time the inventory was taken (as specified in subsection (a)(7) of this section) and shall sign and
111 date the inventory with the date the inventory was taken. The signature of the pharmacist-in-
112 charge and the date of the inventory shall be notarized within three days after the day the
113 inventory is completed, excluding Saturdays, Sundays, and federal holidays.

114
115 (e) Closed pharmacies.

116
117 (1) The pharmacist-in-charge of a Class A, Class A-S, Class C, Class C-S, or Class F
118 pharmacy that ceases to operate as a pharmacy shall forward to the board, within 10 days of
119 the cessation of operation, a statement attesting that an inventory of all controlled substances
120 ~~[the drugs specified in subsection (a)(5) of this section]~~ on hand has been conducted, the date
121 of closing, and a statement attesting the manner by which the dangerous drugs and controlled
122 substances possessed by such pharmacy were transferred or disposed.

123
124 (2) 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
130 (f) Additional requirements for Class C and Class C-S ~~[(Institutional)]~~ pharmacies.

131
132 (1) Perpetual inventory.

133
134 (A) A Class C or Class C-S pharmacy shall maintain a perpetual inventory of all Schedule II
135 controlled substances.

136
137 (B) The perpetual inventory shall be reconciled on the date of the annual inventory.

138
139 (2) Annual inventory. The inventory of the Class C or Class C-S pharmacy ~~[institution]~~ shall
140 be maintained in the pharmacy; if an inventory is conducted in other departments within the
141 institution, the inventory of the pharmacy shall be listed separately, as follows:

142
143 (A) the inventory of drugs on hand in the pharmacy shall be listed separately from the
144 inventory of drugs on hand in the other areas of the institution; and

145
146 (B) the inventory of drugs on hand in all other departments shall be identified by department.

147
148 (g) Change of pharmacist-in-charge of a pharmacy.

149
150 (1) On ~~[For an inventory taken after June 1, 2013, on]~~ the date of the change ~~[of change]~~ of the
151 pharmacist-in-charge of a Class A ~~[(Community)]~~, Class A-S, Class C ~~[(Institutional)]~~, Class C-
152 S, or Class F ~~[(Free Standing Emergency Medical Care Center)]~~ pharmacy, an inventory shall

153 be taken. Such inventory shall include all stocks **of all controlled substances** (including any
154 out-of-date drugs) [~~of the drugs specified in subsection (a)(5) of this section. For an inventory~~
155 ~~taken prior to June 1, 2013, on the date of change of the pharmacist-in-charge of a Class A~~
156 ~~(Community), Class C (Institutional), or Class F (Free Standing Emergency Medical Care~~
157 ~~Center) pharmacy, an inventory of the following drugs shall be taken.~~

158 —(A) all Schedule II controlled substances;

160 —(B) all dosage forms containing pentazocine (e.g., Talwin);

163 —(C) all dosage forms containing phentermine (e.g., Adipex-P, etc.);

165 —(D) all dosage forms containing diazepam (e.g., Valium);

167 —(E) all dosage forms containing phendimetrazine (e.g., Bontril, Prelu-2, etc.);

169 —(F) all dosage forms containing codeine;

171 —(G) all dosage forms containing hydrocodone (e.g., Tussionex, Tussend, Vicodin, etc.);

173 —(H) all dosage forms containing alprazolam (e.g., Xanax);

175 —(I) all dosage forms containing triazolam (e.g., Halcion);

177 —(J) all dosage forms containing butorphanol (e.g., Stadol);

179 —(K) all dosage forms containing nalbuphine (e.g., Nubain);

181 —(L) all dosage forms containing carisoprodol (e.g., Soma); and

183 —(M) for any inventory taken after January 1, 2013, all dosage forms containing tramadol (e.g.,
184 Ultram)].

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

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

195 (4) The incoming pharmacist-in-charge shall be responsible for notifying the board within 10
196 days, **as specified in §291.3 of this title (relating to Notifications)**, [in writing on a form
197 provided by the board,] that a change of pharmacist-in-charge has occurred. [The notification
198 shall include the following:

200 —(A) the name and license number of the departing pharmacist-in-charge;

202 —(B) the name and license number of the incoming pharmacist-in-charge;

203

204 ~~—(C) the date the incoming pharmacist-in-charge became the pharmacist-in-charge; and~~
205
206 ~~—(D) a statement signed by the incoming pharmacist-in-charge attesting that:~~
207
208 ~~—(i) an inventory has been conducted by the departing and incoming pharmacists-in-charge; if~~
209 ~~the inventory was not taken by both pharmacists, the statement shall provide an explanation;~~
210 ~~and~~
211
212 ~~—(ii) the incoming pharmacist-in-charge has read and understands the laws and rules relating~~
213 ~~to this class of pharmacy.]~~