

RULE ANALYSIS

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

Short Title: Drug Destruction

Rule Numbers: §§303.1 and 303.2

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 rules to be consistent with DEA requirements.

1 **TITLE 22 EXAMINING BOARDS**
2 **PART 15 TEXAS STATE BOARD OF PHARMACY**
3 **CHAPTER 303 DESTRUCTION OF DRUGS**

4
5 **§303.1 Destruction of Dispensed Drugs**
6

7 (a) Drugs dispensed to patients in health care facilities or institutions.

8
9 (1) Destruction by the consultant pharmacist. The consultant pharmacist, if in good standing
10 with the Texas State Board of Pharmacy, is authorized to destroy dangerous drugs dispensed to
11 patients in health care facilities or institutions. A consultant pharmacist may [~~not~~] destroy
12 controlled substances **as** [~~unless~~] allowed to do so by federal laws or rules of the Drug
13 Enforcement Administration. Dangerous drugs may be destroyed provided the following
14 conditions are met.

15
16 (A) A written agreement exists between the facility and the consultant pharmacist.

17
18 (B) The drugs are inventoried and such inventory is verified by the consultant pharmacist.
19 The following information shall be included on this inventory:

20
21 (i) name and address of the facility or institution;

22
23 (ii) name and pharmacist license number of the consultant pharmacist;

24
25 (iii) date of drug destruction;

26
27 (iv) date the prescription was dispensed;

28
29 (v) unique identification number assigned to the prescription by the pharmacy;

30
31 (vi) name of dispensing pharmacy;

32
33 (vii) name, strength, and quantity of drug;

34
35 (viii) signature of consultant pharmacist destroying drugs;

36
37 (ix) signature of the witness(es); and

38
39 (x) method of destruction.

40
41 (C) The signature of the consultant pharmacist and witness(es) to the destruction and the
42 method of destruction specified in subparagraph (B) of this paragraph may be on a cover sheet
43 attached to the inventory and not on each individual inventory sheet, provided the cover sheet
44 contains a statement indicating the number of inventory pages that are attached and each of the
45 attached pages are initialed by the consultant pharmacist and witness(es).

46
47 (D) The drugs are destroyed in a manner to render the drugs unfit for human consumption
48 and disposed of in compliance with all applicable state and federal requirements.

49
50 (E) The actual destruction of the drugs is witnessed by one of the following:
51

52 (i) a commissioned peace officer;

53
54 (ii) an agent of the Texas State Board of Pharmacy;

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56 (iii) an agent of the Texas Health and Human Services Commission, authorized by the
57 Texas State Board of Pharmacy to destroy drugs;

58
59 (iv) an agent of the Texas Department of State Health Services, authorized by the Texas
60 State Board of Pharmacy to destroy drugs; or

61
62 (v) any two individuals working in the following capacities at the facility:

63
64 (I) facility administrator;

65
66 (II) director of nursing;

67
68 (III) acting director of nursing; or

69
70 (IV) licensed nurse.

71
72 (F) If the actual destruction of the drugs is conducted at a location other than the facility or
73 institution, the consultant pharmacist and witness(es) shall retrieve the drugs from the facility or
74 institution, transport, and destroy the drugs at such other location.

75
76 (2) Destruction by a waste disposal service. A consultant pharmacist may utilize a waste
77 disposal service to destroy dangerous drugs dispensed to patients in health care facilities or
78 institutions. A consultant pharmacist may ~~[not use a waste disposal service to]~~ destroy
79 controlled substances as ~~[unless]~~ allowed to do so by federal laws or rules of the Drug
80 Enforcement Administration. Dangerous drugs may be transferred to a waste disposal service
81 for destruction provided the following conditions are met.

82
83 (A) The waste disposal service is in compliance with applicable rules of the Texas
84 Commission on Environmental Quality and United States Environmental Protection Agency
85 relating to waste disposal.

86
87 (B) The drugs are inventoried and such inventory is verified by the consultant pharmacist
88 prior to placing the drugs in an appropriate container, and sealing the container. The following
89 information must be included on this inventory:

90
91 (i) name and address of the facility or institution;

92
93 (ii) name and pharmacist license number of the consultant pharmacist;

94
95 (iii) date of packaging and sealing of the container;

96
97 (iv) date the prescription was dispensed;

98
99 (v) unique identification number assigned to the prescription by the pharmacy;

100
101 (vi) name of dispensing pharmacy;

102

103 (vii) name, strength, and quantity of drug;

104

105 (viii) signature of consultant pharmacist packaging and sealing the container; and

106

107 (ix) signature of the witness(es).

108

109 (C) The consultant pharmacist seals the container of drugs in the presence of the facility
110 administrator and the director of nursing or one of the other witnesses listed in paragraph (1)(E)
111 of this subsection as follows:

112

113 (i) tamper resistant tape is placed on the container in such a manner that any attempt to
114 reopen the container will result in the breaking of the tape; and

115

116 (ii) the signature of the consultant pharmacist is placed over this tape seal.

117

118 (D) The sealed container is maintained in a secure area at the facility or institution until
119 transferred to the waste disposal service by the consultant pharmacist, facility administrator,
120 director of nursing, or acting director of nursing.

121

122 (E) A record of the transfer to the waste disposal service is maintained and attached to the
123 inventory of drugs specified in subparagraph (B) of this paragraph. Such record shall contain the
124 following information:

125

126 (i) date of the transfer;

127

128 (ii) signature of the person who transferred the drugs to the waste disposal service;

129

130 (iii) name and address of the waste disposal service; and

131

132 (iv) signature of the employee of the waste disposal service who receives the container.

133

134 (F) The waste disposal service shall provide the facility with proof of destruction of the sealed
135 container. Such proof of destruction shall contain the date, location, and method of destruction
136 of the container and shall be attached to the inventory of drugs specified in subparagraph (B) of
137 this paragraph.

138

139 (3) Record retention. All records required in this subsection shall be maintained by the
140 consultant pharmacist at the health care facility or institution for two years from the date of
141 destruction.

142

143 (b) Dangerous drugs returned to a pharmacy. A pharmacist in a pharmacy may accept and
144 destroy dangerous drugs that have been previously dispensed to a patient and returned to a
145 pharmacy by the patient or an agent of the patient. However, a pharmacist may ~~not~~ accept
146 controlled substances that have been previously dispensed to a patient as ~~unless~~ allowed by
147 federal laws of the Drug Enforcement Administration. The following procedures shall be followed
148 in destroying dangerous drugs.

149

150 (1) The dangerous drugs shall be destroyed in a manner to render the drugs unfit for human
151 consumption and disposed of in compliance with all applicable state and federal requirements.

152

153 (2) Documentation shall be maintained that includes the following information:

- 154
155 (A) name and address of the dispensing pharmacy;
156
157 (B) unique identification number assigned to the prescription, if available;
158
159 (C) name and strength of the dangerous drug; and
160
161 (D) signature of the pharmacist.
162

163 **§303.2 Disposal of Stock Prescription Drugs**

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165
166 (a) Definition of stock. "Stock" as used in these sections means dangerous drugs or controlled
167 substances which are packaged in the original manufacturer's container.
168

169 (b) Disposal of stock dangerous drugs. A pharmacist, licensed by the board, is authorized to
170 destroy stock dangerous drugs owned by a licensed pharmacy if such dangerous drugs are
171 destroyed in a manner to render the drugs unfit for human consumption and disposed of in
172 compliance with all applicable state and federal requirements. [~~However, the following~~
173 ~~procedures shall be followed in destroying any brand or dosage form of nalbuphine (e.g.,~~
174 ~~Nubain), and carisoprodol (e.g., Soma):~~

175
176 ~~—(1) the dangerous drugs are inventoried; and~~

177
178 ~~—(2) the destruction is witnessed by another licensed pharmacist or a commissioned peace~~
179 ~~officer.]~~

180
181 (c) Disposal of stock controlled substances. A pharmacist, licensed by the board, may dispose
182 of stock controlled substances owned by a licensed pharmacy in accordance with procedures
183 authorized by the Federal and Texas Controlled Substances Acts and sections adopted
184 pursuant to such Acts. Disposal of controlled substances is deemed to be in accordance with
185 the Federal and Texas Controlled Substances Acts and sections adopted pursuant to such Acts
186 if any one of the following actions is taken:

187
188 (1) transfer to a controlled substances registrant authorized to possess controlled substances
189 is the preferred method of disposal (e.g., DEA registered disposal firm); if transferred, the stock
190 controlled substances shall be documented by appropriate invoices, federal Drug Enforcement
191 Administration (DEA) order forms, or other documents legally transferring the controlled
192 substances; or

193
194 (2) with prior DEA approval, destruction of the controlled substances according to following
195 guidelines.

196
197 (A) **Class A and Class A-S** [~~Community (Class A)~~] pharmacies. This method of drug
198 destruction may be used only one time in each calendar year.

199
200 (i) The pharmacy shall inventory the controlled substances to be destroyed and itemize the
201 inventory on DEA Form 41, making three copies.

202
203 (ii) DEA approval shall be obtained by submitting a registered or certified letter to DEA at
204 least 14 days prior to the anticipated destruction date indicating the day, time, and place of the

205 anticipated destruction, and including a copy of DEA Form 41 which lists the controlled
206 substances to be destroyed. No written or other response from DEA regarding the planned
207 destruction will constitute DEA approval of the destruction.
208

209 (iii) The controlled substances shall be destroyed beyond reclamation and disposed of in
210 compliance with all applicable state and federal requirements on the approved date/time/place
211 in the presence of one of the following witnesses:

- 212 (I) a commissioned peace officer;
- 213 (II) an agent of the Drug Enforcement Administration;
- 214 (III) an agent of the Department of Public Safety; or
- 215 (IV) an agent of the Texas Board of Pharmacy.

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220 (iv) After destruction of the drugs, DEA Form 41 shall be completed to indicate the method
221 of destruction and be signed and dated by the registrant and witness.

222
223 (v) The pharmacy shall distribute copies of the completed DEA Form 41 as follows:

- 224 (I) maintain the original in the records of the pharmacy for at least two years; and
- 225 (II) mail one copy to the appropriate DEA divisional office.

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228 (B) **Class C and Class C-S** [~~Institutional (Class C)~~] pharmacies.

229
230 (i) Written DEA approval giving authorization to destroy controlled substances must be
231 obtained from the appropriate DEA divisional office. The hospital may destroy controlled
232 substances at any time provided the written authorization is maintained in the files of the
233 hospital pharmacy.

234
235 (ii) The pharmacy shall inventory the controlled substances to be destroyed and itemize the
236 inventory on DEA Form 41, making two copies.

237
238 (iii) The controlled substances shall be destroyed beyond reclamation and disposed of in
239 compliance with all applicable state and federal requirements in the presence of one of the
240 following witnesses:

- 241 (I) a commissioned peace officer;
- 242 (II) a supervisory member of the hospital's security department;
- 243 (III) an agent of the Drug Enforcement Administration;
- 244 (IV) an agent of the Department of Public Safety; or
- 245 (V) an agent of the Texas State Board of Pharmacy.

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250 (iv) After destruction of the drugs, DEA Form 41 shall be completed to indicate the method
251 of destruction and be signed and dated by the registrant and witness.
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(v) The hospital pharmacy shall distribute copies of the completed DEA Form 41 as follows:

(I) maintain the original in the records of the pharmacy for at least two years; and

(II) mail one copy to the appropriate DEA divisional office.