

## RULE REVIEW ANALYSIS

**Introduction:** THIS RULE REVIEW IS SUBMITTED TO THE BOARD FOR CONSIDERATION AS A PROPOSED REVIEW

**Short Title:** Destruction of Dangerous Drugs & Controlled Substances

**Rule Number:** Chapter 303, §§303.1-303.3

**Statutory Authority:** Government Code, §2001.039, added by Acts 1999, 76<sup>th</sup> Legislature, Chapter 1499, Article 1, Section 1.11.

**Background:** Review of these sections follow the Board's rule review plan.

1 **TITLE 22 EXAMINING BOARDS**

2 **PART 15 TEXAS STATE BOARD OF PHARMACY**

3 **CHAPTER 303 DESTRUCTION OF DRUGS**

4 **§303.1 Destruction of Dispensed Drugs**

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

6 (1) Destruction by the consultant pharmacist. The consultant pharmacist, if in good standing with the  
7 Texas State Board of Pharmacy, is authorized to destroy dangerous drugs dispensed to patients in health  
8 care facilities or institutions. A consultant pharmacist may destroy controlled substances as allowed to do  
9 so by federal laws or rules of the Drug Enforcement Administration. Dangerous drugs may be destroyed  
10 provided the following conditions are met.

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

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

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

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

16 (iii) date of drug destruction;

17 (iv) date the prescription was dispensed;

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

19 (vi) name of dispensing pharmacy;

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

21 (viii) signature of consultant pharmacist destroying drugs;

22 (ix) signature of the witness(es); and

23 (x) method of destruction.

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

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

31 (E) The actual destruction of the drugs is witnessed by one of the following:

32 (i) a commissioned peace officer;

- 33 (ii) an agent of the Texas State Board of Pharmacy;
- 34 (iii) an agent of the Texas Health and Human Services Commission, authorized by the Texas State Board  
35 of Pharmacy to destroy drugs;
- 36 (iv) an agent of the Texas Department of State Health Services, authorized by the Texas State Board of  
37 Pharmacy to destroy drugs; or
- 38 (v) any two individuals working in the following capacities at the facility:
- 39 (I) facility administrator;
- 40 (II) director of nursing;
- 41 (III) acting director of nursing; or
- 42 (IV) licensed nurse.
- 43 (F) If the actual destruction of the drugs is conducted at a location other than the facility or institution, the  
44 consultant pharmacist and witness(es) shall retrieve the drugs from the facility or institution, transport,  
45 and destroy the drugs at such other location.
- 46 (2) Destruction by a waste disposal service. A consultant pharmacist may utilize a waste disposal service  
47 to destroy dangerous drugs dispensed to patients in health care facilities or institutions. A consultant  
48 pharmacist may destroy controlled substances as allowed to do so by federal laws or rules of the Drug  
49 Enforcement Administration. Dangerous drugs may be transferred to a waste disposal service for  
50 destruction provided the following conditions are met.
- 51 (A) The waste disposal service is in compliance with applicable rules of the Texas Commission on  
52 Environmental Quality and United States Environmental Protection Agency relating to waste disposal.
- 53 (B) The drugs are inventoried and such inventory is verified by the consultant pharmacist prior to placing  
54 the drugs in an appropriate container, and sealing the container. The following information must be  
55 included on this inventory:
- 56 (i) name and address of the facility or institution;
- 57 (ii) name and pharmacist license number of the consultant pharmacist;
- 58 (iii) date of packaging and sealing of the container;
- 59 (iv) date the prescription was dispensed;
- 60 (v) unique identification number assigned to the prescription by the pharmacy;
- 61 (vi) name of dispensing pharmacy;
- 62 (vii) name, strength, and quantity of drug;
- 63 (viii) signature of consultant pharmacist packaging and sealing the container; and
- 64 (ix) signature of the witness(es).

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

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

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

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

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

77 (i) date of the transfer;

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

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

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

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

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

86 (b) Drugs returned to a pharmacy. A pharmacist in a pharmacy may accept and destroy dangerous drugs  
87 that have been previously dispensed to a patient and returned to a pharmacy by the patient or an agent of  
88 the patient. A pharmacist may accept controlled substances that have been previously dispensed to a  
89 patient as allowed by federal laws of the Drug Enforcement Administration. The following procedures  
90 shall be followed in destroying dangerous drugs.

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

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

94 (A) name and address of the dispensing pharmacy;

95 (B) unique identification number assigned to the prescription, if available;

96 (C) name and strength of the dangerous drug; and

97 (D) signature of the pharmacist.

98 **§303.2 Disposal of Stock Prescription Drugs**

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

101 (b) Disposal of stock dangerous drugs. A pharmacist, licensed by the board, is authorized to destroy stock  
102 dangerous drugs owned by a licensed pharmacy if such dangerous drugs are destroyed in a manner to  
103 render the drugs unfit for human consumption and disposed of in compliance with all applicable state and  
104 federal requirements.

105 (c) Disposal of stock controlled substances. A pharmacist, licensed by the board, shall dispose of stock  
106 controlled substances owned by a licensed pharmacy in accordance with procedures authorized by the  
107 Federal and Texas Controlled Substances Acts and sections adopted pursuant to such Acts.

108 **§303.3 Records**

109 All inventory records and forms of disposed drugs shall be maintained for two years from the date of  
110 transfer, disposal, or destruction and be available for inspection by an agent of the board, Texas  
111 Department of Public Safety, Drug Enforcement Administration, or any other agent authorized to inspect  
112 such records.