

RULE REVIEW ANALYSIS

Introduction: **THIS RULE REVIEW IS SUBMITTED TO THE BOARD FOR CONSIDERATION AS AN ADOPTED REVIEW**

Short Title: Destruction of Dangerous Drugs and Controlled Substances

Rule Number: Chapter 303 (§§303.1-303.3)

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

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

**TITLE 22. EXAMINING BOARDS
PART 15. TEXAS STATE BOARD OF PHARMACY
CHAPTER 303. DESTRUCTION OF DANGEROUS DRUGS AND CONTROLLED
SUBSTANCES**

§303.1 Destruction of Dispensed Drugs

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

(1) Destruction by the consultant pharmacist. The consultant pharmacist, if in good standing with the Texas State Board of Pharmacy, is authorized to destroy dangerous drugs and controlled substances dispensed to patients in health care facilities or institutions, providing the following conditions are met.

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

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

- (i) name and address of the facility or institution;
- (ii) name and pharmacist license number of the consultant pharmacist;
- (iii) date of drug destruction;
- (iv) date the prescription was dispensed;
- (v) unique identification number assigned to the prescription by the pharmacy;
- (vi) name of dispensing pharmacy;
- (vii) name, strength, and quantity of drug;
- (viii) signature of consultant pharmacist destroying drugs;
- (ix) signature of the witness(es); and
- (x) method of destruction.

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

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

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

- (i) a commissioned peace officer;

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

(iii) an agent of the Texas Department of Human Services, authorized by the Texas State Board of Pharmacy to destroy drugs;

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

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

(I) facility administrator;

(II) director of nursing;

(III) acting director of nursing; or

(IV) licensed nurse.

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

(2) Destruction by a waste disposal service. A consultant pharmacist may utilize a waste disposal service to destroy dangerous drugs and controlled substances dispensed to patients in health care facilities or institutions, provided the following conditions are met.

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

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

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

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

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

(iv) date the prescription was dispensed;

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

(vi) name of dispensing pharmacy;

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

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

(ix) signature of the witness(es).

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

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

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

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

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

(i) date of the transfer;

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

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

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

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

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

(b) Drugs returned to a pharmacy. A pharmacist, licensed by the board, is authorized to destroy dangerous drugs and controlled substances which have been previously dispensed to a patient and returned to a pharmacy by the patient or an agent of the patient. The following procedures shall be followed in destroying these drugs.

(1) Dangerous drugs other than tripeleminamine (e.g., PBZ), nalbuphine (e.g., Nubain), and carisoprodol (e.g., Soma).

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

(B) Documentation shall be maintained which includes the following information:

(i) name and address of the dispensing pharmacy;

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

(iii) name and strength of the dangerous drug; and

(iv) signature of the pharmacist.

(2) Controlled substances and tripeleminamine (e.g., PBZ), nalbuphine (e.g., Nubain), and carisoprodol (e.g., Soma).

(A) Controlled substances and tripeleminamine (PBZ), nalbuphine (Nubain) , and carisoprodol (e.g., Soma) shall be destroyed in a manner to render the drugs unfit for human consumption and disposed of in compliance with all applicable state and federal requirements.

(B) The destruction shall be witnessed by one of the following individuals:

(i) the patient or patient's agent;

(ii) another licensed pharmacist;

(iii) a commissioned peace officer; or

(iv) an agent of the Texas State Board of Pharmacy, Texas Department of Public Safety, or Drug Enforcement Agency.

(C) Documentation shall be maintained which includes the following information:

(i) date of destruction;

(ii) name and address of the dispensing pharmacy;

(iii) unique identification number assigned to the prescription if available;

(iv) name of the patient;

(v) name, strength, and quantity of the drug; and

(vi) signature of the pharmacist who destroyed the drugs and signature of the witness to the destruction.

§303.2 Disposal of Stock Prescription Drugs

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

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

(1) the dangerous drugs are inventoried; and

(2) the destruction is witnessed by another licensed pharmacist or a commissioned peace officer.

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

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

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

(A) Community (Class A) pharmacies. This method of drug destruction may be used only one time in each calendar year.

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

(ii) DEA approval shall be obtained by submitting a registered or certified letter to DEA at least 14 days prior to the anticipated destruction date indicating the day, time, and place of the anticipated destruction, and including a copy of DEA Form 41 which lists the controlled substances to be destroyed. No written or other response from DEA regarding the planned destruction will constitute DEA approval of the destruction.

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

(I) a commissioned peace officer;

(II) an agent of the Drug Enforcement Administration;

(III) an agent of the Department of Public Safety; or

(IV) an agent of the Texas Board of Pharmacy.

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

(v) The 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.

(B) Institutional (Class C) pharmacies.

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

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

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

(I) a commissioned peace officer;

(II) a supervisory member of the hospital's security department;

(III) an agent of the Drug Enforcement Administration;

(IV) an agent of the Department of Public Safety; or

(V) an agent of the Texas State Board of Pharmacy.

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

(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.

§303.3 Records

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