

## 15.12 PHARMACY DRUG RECALL

**Policy:** Title X clinics must comply with all manufacturers and/or Food and Drug Administration (FDA) drug recalls. As part of its activities, the FDA initiates drug recalls of drugs or devices that are found to be in violation of federal law relating to these products. The recalls are classified according to the potential adverse impact of the drug or device upon the health of exposed individuals.

### **Definitions:**

#### *Class I Recalls*

Situations wherein the use of or exposure to the violative product can cause serious adverse health consequences or death.

#### *Class II Recalls*

Situations wherein the use of or exposure to the violative product may cause temporary or medically reversible adverse health consequences of where the probability of serious adverse health consequences is remote.

#### *Class III Recalls*

Situations wherein the use of or exposure to the violative product is not likely to cause adverse health consequences.

### **Procedure:**

Clinics may handle recalls in the following manner:

#### *Class I Recalls:*

1. All products of the named violative substance must be quarantined, and none shall be provided to any client until such time that a physician on duty or the pharmacist-in-charge verifies that none of the specific lot numbers are found in stock.
2. Any of the violative products found in stock must be removed and packaged for return to the manufacturer unless otherwise directed in the recall information.
3. Purchase logs will be scanned by the Medical/Nursing/Pharmacy personnel for a period of not less than two (2) years prior to the date of the recall. The clinic director shall be kept informed.
4. If, upon inspection of the stock and purchase records, it is determined that none of the violative lots have been received by the clinic, then no further action is required other than verifying that none of the involved lots are shipped to the clinic during the following two (2) months.
5. If, upon inspection of the stock and/or purchase records, it is shown that the violative substances have been provided to clients within the past two (2) years, the following action will be taken:
  - a. Daily logs will be reviewed to determine the names of clients who may have received the violative products.
  - b. Identified clients will be contacted by telephone by a physician or a nurse
    - i. If it can be determined that the client has received the named violative product and the violative lot, or if the lot cannot be determined, the client will be instructed to discontinue the medication and bring it back to the clinic immediately for replacement with a non-involved lot of the same medication, if available. If a non-involved lot cannot be obtained for the client, the client shall be seen by the clinician and changed to an alternate medication.

- ii. If it is determined that the client received the named medication, but not the involved lot, they should be reassured that continuation with their prescribed regimen is safe. If the client wishes, an appointment can be made to have the medication changed as soon as possible.
- c. If an identified client cannot be contacted, a letter will be sent to her/him, informing of the nature of the recall and requesting that the clinic be contacted. The letter should be sent "return receipt requested."
- d. If the client has been exposed to an item subject to a Class I recall, the foregoing procedure will be implemented immediately. As time permits, the following will be notified if not already involved: Pharmacist in charge; Medical Director; Chair Medical Committee; Clinic Nurse Director; Clinic Director; and The Montana Family Planning Program.

*Class II Recalls:*

1. All affected lots of the named products shall be removed from stock by either the Medical Director or the Clinic Nurse Supervisor. These lots will be prepared for return to the supplier.
2. Purchase logs for the past year will be checked to determine if any of the violative lots have been received.
3. Same as Class I recalls, Section 3, except that the Medical Director or the Clinic Director may review the purchase logs.
4. If, upon examination of the stock and/or purchase records, it is shown that the violative substances have been provided to a client within the last six (6) months, the following action will be taken:
  - a. Same as Class I Recalls, 5, a
  - b. Same as Class I Recalls, 5, b
    - i. The nature of the recall will be explained, and the client will be requested to return any outstanding supplies of the violative products to the clinic.
    - ii. Same as Class I Recalls, 5, b, 2
  - c. If the client cannot be contacted by telephone, a letter with "return receipt requested" will be sent informing of the recall and requesting the return of any outstanding violative products
  - d. Same as Class I Recalls, 5, d, but "Class I" will read "Class II"

*Class III Recalls:*

1. No product lot listed in a Class III recall shall be provided to a client.
2. The violative substance shall be removed from inventory and returned to the supplier.

**Notification:**

The manufacturer or supplier should notify all customers in the event of drug recalls.