

Charleston Dorchester Mental Health Center

Drug Recall Policy

**POLICY:**

To establish guidelines that will be implemented regarding the recall of products that are considered a danger to the life and/or safety of persons served by the Charleston Dorchester Mental Health Center.

**PURPOSE:**

The purpose of this document is to ensure proper identification and removal of recalled products.

**RESPONSIBILITY:**

The Mental Health Center Executive Director, all physicians and nurses are tasked with the responsibility for fulfillment of this policy and implementation of the procedures for meeting requirements, in addition to the SCDMH consulting pharmacist.

All nurses are designated to assist with coordinating the removal and accountability for the disposition of all drugs recalled by the manufacturer. All recall drugs will be segregated from the stock of medications purchased by the Mental Health Center, samples, or PAP medications, and will be locked in a designated cabinet drawer until returned or destroyed as outlined in the manufacturer's recall notification.

**RECALL DEFINITIONS:**

- |           |   |
|-----------|---|
| Class I   | Situation in which there is a reasonable probability that the use or exposure to the product will cause serious adverse health consequences.  |
| Class II  | Situation in which the use of or exposure to the product may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequence is remote. |
| Class III | Situation in which the use of or exposure to the product is not likely to cause adverse consequences.   |

**PROCEDURES:**

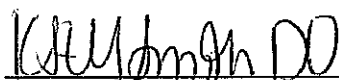
1. Upon receipt of written or verbal product recall notification from the manufacturer, wholesaler, FDA or the SCDMH Consulting Pharmacist, the individual receiving the notice will immediately notify the nursing supervisor.

The nursing supervisor will immediately notify all medical staff as well as begin coordination of the appropriate action plan to facilitate procedures and documentation for the recall.

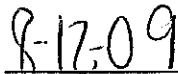
2. The nursing supervisor or designee(s) are responsible for the review and removal process for unopened or partially used containers of the involved lot(s) of the drug from stock (purchased, samples, or PAP medications). The following areas will be checked for the product recalled as applicable.
  - a. Cabinets in the medication storage room where IM medications purchased by the facility are kept.
  - b. Refrigerators
  - c. The medication clinic at Charleston and Dorchester Mental Health Centers.
  - d. Preparation trays for medication administration
  - e. Transport bag used for emergencies
  - f. Drug sample cabinet(s)
  - g. PAP medication storage cabinet
3. All recall drugs found are removed from active stocks and are secured in a cabinet until dispositioned with the SCDMH consulting pharmacist to take to Columbia for destruction, or destruction will occur as stipulated by the recall notification.
4. A Drug Recall Form will be completed to address all recalls regardless of whether medication are found in stock or not.

The Drug Recall Log shall include the following information and will be retained on file attached to each Drug Recall Notification

- A. log number
  - B. start, projected and completion date
  - C. product
  - D. lot number
  - E. location
  - F. action
  - G. name of person taking action
5. A **"Drug Recall Documentation Binder"** will be maintained in the medication storage room at Charleston Dorchester Mental Health Center. (See Drug Recall Log Form Attached)



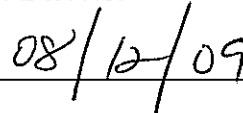
Katherine Smith, MD  
Interim Medical Director



Date



Deborah S. Blalock, M.Ed., LPCS  
Executive Director



Date

# DRUG RECALL LOG

<b>Log #.</b>	
Location (check the applicable site)	<input type="checkbox"/> Charleston MH Clinic <input type="checkbox"/> Dorchester MH Clinic

Date Notification Received: \_\_\_\_\_

<b>Product:</b>	<b>Lot #:</b>
<b>Action Taken:</b>	
Start Date:	
Projected Completion Date:	
Completion Date:	
Name of the person taking this action ( <i>print name</i> )	
Signature and title of person taking action:	