

HEALTH SERVICES POLICY & PROCEDURE MANUAL

North Carolina Department Of Correction
Division Of Prisons

SECTION: Care and Treatment of Patient -
Medication Administration

POLICY # TX II-15

Page 1 of 1

SUBJECT: Drug Recall

EFFECTIVE DATE: March 2010

SUPERCEDES DATE: February 2009

References

Related ACA Standards

**4th Edition Standards for adult Correctional
Institutions 4-4378**

PURPOSE

To provide a procedure that Central Pharmacy will use in the event of the recall of a drug, product, or device.

POLICY

The Department of Correction shall maintain a safe and effective supply of drugs, products, and devices.

PROCEDURE

Upon receiving notice of a drug recall, Central Pharmacy will assess the current stock at the pharmacy to ascertain if any of the affected drugs named in the recall are in the inventory. Central Pharmacy will then assess the severity of the recall and send the appropriate information to the Chief of Health Services, Deputy Medical Director, Mental Health Director Regional Health Treatment Administrators, the DOC Director of Nursing, and the Risk Manager. The DOC Director of Nursing or designee will be responsible for disseminating the information to the Regional Assistant Directors of Nursing and the Directors of Nursing at Central Prison and NCCIW. The information will include, but not be limited to the following.

1. If, after assessing the severity of the recall, Central Pharmacy deems that the drug is not safe and/or effective for use, Central Pharmacy will prepare a facility-specific list of the inmates likely to be affected by the recall. This list will be issued electronically to facilitate the recall process.
 - If the product(s) was dispensed in the manufacturer's original container, Central Pharmacy will identify the product(s) included in the recall by product name, manufacturer, National Drug Code (NDC), and lot number. If the drug product issued to the identified inmates matches these identifiers, the facility will immediately report the names and the OPUS numbers of the inmates affected to Central Pharmacy.
 - If the product(s) was not dispensed in the original container, Central Pharmacy will identify the product(s) included in the recall by name.
2. Central Pharmacy will issue clear instructions detailing the action that the correctional facilities will take to retrieve the product(s) named in the recall. The instructions will include a time frame in which the retrieval and return to Central Pharmacy must be accomplished. If the product(s) are not to be returned to Central Pharmacy, then the instructions will be clear as to how the facilities will dispose of the product(s).
3. Central Pharmacy will replace the recalled product with a like product which is safe and effective or recommend an alternative product if like product is not available.
4. If the recall is related to a device or product other than a drug, the process for retrieval and return to the pharmacy is the same.

Nursing supervisors or their designees will be responsible for ensuring that all of the product(s) targeted in the recall is returned to Central Pharmacy or disposed of in accordance with the instructions promulgated by Central Pharmacy within the established time frame.

Paula Y. Smith, M.D.

3/30/10

Paula Y. Smith, MD, Director of Health Services

Date

SOR: Director of Pharmacy