

HEALTH SERVICES POLICY & PROCEDURE MANUAL

North Carolina Department Of Public Safety
Prison

SECTION: Care and Treatment of Patient -
Medication Administration

POLICY # TX II-15

SUBJECT: Drug Recall

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EFFECTIVE DATE: January 2017

SUPERCEDES DATE: March 2010

References

Related ACA Standards

4th Edition Standards for adult Correctional
Institutions 4-4378

PURPOSE

To provide a procedure that the Department of Public Safety Pharmacies shall use in the event of the recall of a drug, product, or device.

POLICY

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

PROCEDURE

Upon receiving notice of a drug recall, the DPS Pharmacy shall assess the current stock at the pharmacy to ascertain if any of the affected drugs named in the recall are in the inventory. The severity of the recall shall be assessed and the appropriate information shall be sent to the Chief of Health Services, Deputy Medical Director, Mental Health Director, Regional Health Treatment Administrators, the Director of Nursing, and the Risk Manager. The Director of Nursing or designee shall 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 shall include, but not be limited to the following.

1. If, after assessing the severity of the recall, the DPS Pharmacy deems that the drug is not safe and/or effective for use, a facility-specific list of the offenders likely to be affected by the recall shall be prepared. This list shall be issued electronically to facilitate the recall process.
 - If the product(s) was dispensed in the manufacturer's original container, the DPS Pharmacy shall 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 offenders matches these identifiers, the facility shall immediately report the names and the OPUS numbers of the offenders affected to the DPS Pharmacy.
 - If the product(s) was not dispensed in the original container, the DPS Pharmacy shall identify the product(s) included in the recall by name.

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2. The DPS Pharmacy shall issue clear instructions detailing the action that the facilities shall take to retrieve the product(s) named in the recall. The instructions shall include a time frame in which the retrieval and return to the DPS Pharmacy must be accomplished. If the product(s) are not to be returned to the DPS Pharmacy, then the instructions shall be clear as to how the facilities shall dispose of the product(s).
3. The DPS Pharmacy shall 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 shall be responsible for ensuring that all of the product(s) targeted in the recall is returned to their DPS Pharmacy or disposed of in accordance with the instructions promulgated by the DPS Pharmacy within the established time frame.

Paula Y. Smith, M.D.

1/31/2017

Paula Y. Smith, MD, Chief of Health Services Date

SOR: Director of Pharmacy