



**PRISONS**  
**Health and Wellness Services**  
**Policies and Procedures**

<b>Title</b>	<b>Recall of a Drug, Product, or Device</b>			
<b>Section</b>	TX II-15	<b>Issue Date</b> December 3, 2020	<b>Supersedes Date</b> January 2017	<b>Next Review Date</b> December 2021

**References**

**Performance-Based Standards and  
 Expected Practices for Adult Correctional  
 Institutions, 5<sup>th</sup> Edition 5-ACI-6A-43 (M)**

**I. PURPOSE**

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

**II. POLICY**

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

**III. PROCEDURE**

- (a) 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 Medical Director, Deputy Medical Director, Chief of Psychiatry, Director of Nursing, and Director of Quality Assurance.
- (b) Health and Wellness 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 generated.
    - (A) 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,




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the facility shall immediately report the names and the OPUS numbers of the offenders affected to the DPS Pharmacy.

- (B) If the product(s) was not dispensed in the original container, the DPS Pharmacy shall identify the product(s) included in the recall by offender name.
  - (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.
  - (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.
- (c) Nursing supervisors or their designees shall be responsible for ensuring that all of the product(s) targeted in the recall are returned to their DPS Pharmacy within the established time frame.

  
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Todd E. Ishee  
Commissioner of Prisons

12/03/20  
Date