Olive View-UCLA MEDICAL CENTER

COUNTY OF LOS ANGELES
DEPARTMENT OF HEALTH SERVICES

Policy Title:	**DRUG RECALLS AND DRUG DEFECT REPORTING**		
Category:	10 - Medication Management	**Policy No.:**	1008
Originally Issued:	12/14/2012	**Update (U)/Revised (R):**	12/22/19
Distribution:	**Hospital-Wide** ☒	**If not Hospital-Wide, Other:**	

PURPOSE:

To establish a uniform policy to handle drug recalls and drug defects throughout the organization.

To maximize patient safety by ensuring that recalled/defective drugs are removed from pharmacy and nursing medication areas and are not dispensed to patients.

DEFINITION(S):

Recall Classifications:

Class I: Dangerous or defective products that predictably could cause serious health problems or death.

Class II: Products that might cause a temporary health problem, or pose only a slight threat of a serious nature.

Class III: Products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing laws.

Market Withdrawals: The removal or correction of a distributed product due to a minor violation that would not be subject to legal action by the FDA or which involves no violation.

Drug Defect: A problem with a drug that may include a suspected counterfeit product, product contamination, poor packaging or product mix-up, questionable stability and/or labeling concerns.

POLICY:

The Pharmacy Procurement Department will monitor all drug recalls, disseminate drug recall information to the appropriate departments/services, remove recall/defective drugs from pharmacy and nursing unit medication areas, and suspend distribution of all drugs affected by recalls.

The Pharmacy Department will document and maintain appropriate filing systems for all drug recalls as well as the actions taken.

The Pharmacy Department shall report all drug product defects to the manufacturer and to the USP-FDA-ASHP Drug Product Defect
Reporting Program.

PROCEDURE:

DRUG RECALL PROCEDURES

1. The Pharmacy Director, or a designee, reviews all drug recall notices that are sent from DHS Pharmacy Affairs, vendors, wholesalers, or the FDA.

2. If the recalled drug is not on the DHS formulary, not stocked in the pharmacy, and/or no drug of that lot was found on pharmacy shelves, the vendor is so notified, and our action is documented on the Drug Recall Master Log.

3. If the recalled drug is stocked in the pharmacy, Pyxis MedStation and/or patient care area, a pharmacy technician or pharmacist will remove the drug from inventory. The recalled drug will be stored temporarily in a segregated, clearly labeled area away from pharmacy stock.

4. Recalled drugs are sent to the vendor, manufacturer or other designated site in accordance with the instructions outlined in the drug recall notice.

5. Schedule II drugs: Each pharmacy shall obtain a DEA 222 form from the manufacturer or vendor for the amount of recalled drug returned. The DEA 222 form is issued to each pharmacy with an individual DEA number. The supplier's copy is filed in the 222 form binder, and the DEA copy is forwarded to DEA office.

6. Pharmacy action is documented on the Drug Recall Master Log. In addition, a summary of actions taken will be forwarded to DHS Pharmacy Director within 7 days of recall notice.

7. The Pharmacy & Therapeutics Committee members are notified of all drug recalls monthly at the next scheduled meeting.

PATIENT NOTIFICATION

1. If a drug recall/market withdrawal requires patient notification, DHS Pharmacy Affairs will collaborate with County Counsel and the DHS Chief Medical Officer to review and recommend appropriate actions to DHS institutions.

DEFECTIVE DRUG PRODUCTS REPORTING

1. All drug defects shall be reported in accordance with the Food and Drug Administration Drug Quality Reporting System or the United States Pharmacopoeia Convention Drug Reporting Program.

2. The FDA MedWatch Form 3500 shall be completed and sent to the FDA.

3. A copy of the report shall be filed in a Drug Product Defect Reporting file in the Pharmacy.

4. All drug defects identified will be recalled from the pharmacy and patient care areas as per the above "Drug Recalls Procedures".

RECORDS DOCUMENTATION AND RETENTION

1. All recall documents, memos, and notices are stored in designated files.

2. Pharmacy shall document every urgent drug recall or drug product defect memo on a Drug Recall Master Log.

3. The Drug Recall Master Log documents
   a. Recall date;
   b. Manufacturer;
   c. Drug name, dosage form, strength, and lot number;
   d. Quantity of recalled drug in stock
   e. The action taken.
   f. Initials of pharmacy technician/helper

4. Above records shall be maintained for three years.

ATTACHMENTS/FORMS:

None

REFERENCE(S)/AUTHORITY:

FDA Drug Recalls and Drug Defect Reporting, Background and Definitions, 2009.
The Joint Commission E-dition (accessed January 7, 2016)

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