Los Angeles County Department of Health Services

Policy & Procedure Title:	DHS Drug Recall Process		
Category:	300-399 Operation Policy	**Policy No.:**	329.004
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Distribution: DHS-wide ☒	**If not DHS-wide, other distribution:**		

PURPOSE:

The purpose of this policy is to provide standardized system drug recall guidelines to be followed by all DHS institutions, with the purpose of maximizing patient safety and adherence to drug recalls and market withdrawals announced by the FDA or from a pharmaceutical manufacturer.

POLICY:

Recalls are actions taken by a pharmaceutical vendor to remove a specific product, medication, strength, or lot number from patient circulation. Recalls may be conducted on a manufacturer's own initiative, by FDA request, or by FDA order under statutory authority. The various types of FDA Drug Recalls are defined below[1]:

- **Class I recalls** are for dangerous or defective products that predictably could cause serious health problems or death. Examples of drugs that could fall into this category may include oversized tablets that may contain twice the active ingredient or a label mix-up on a life-saving drug.
- **Class II recalls** are for products that might cause a temporary health problem, or pose only a slight threat of a serious nature. One example is a drug that is under-strength but that is not used to treat life-threatening situations.
- **Class III recalls** are for products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing regulations. Examples might be a packaging defect (plastic material delaminating) of a drug bottle or off color tablet due to use of an incorrect dye.
- **Market Withdrawals** - Occurs when a product may have a minor violation that would not be subject to FDA legal action. The manufacturer may voluntarily remove the product from the

[1] FDA Website: http://www.fda.gov/safety/recalls/ucm165546.htm

market until they correct the violation. For example, a specific lot number of a product may be removed from the market due to suspicions of tampering, without evidence of manufacturing or distribution problems.

FDA recalls may be found on the following FDA website http://www.fda.gov/Safety/Recalls/default.htm. At this website, DHS institutions may register for automatic FDA recall email notifications.

PROCEDURE:

The following actions shall be taken by all DHS institutions (Hospitals, ACN, and MLK OC) in response to an announced FDA Class Drug Recall or Market Withdrawal. (See Appendix A: "DHS Drug Recall Process" for flowchart of this process):

1. DHS Pharmacy Affairs to notify all DHS pharmacies upon notification of a drug recall or market withdrawal. The DHS Procurement Pharmacy area will also query system purchase history of impacted product, and notify impacted facilities within 48 hours of receipt of recall/market withdrawal notice. If urgent, the purchase query will be conducted immediately. If necessary, the DHS formulary clinical pharmacists will assess impact and provide recommendations for alternative therapy.
2. DHS institutions to follow institutional policies regarding removal of drug from all inventories, notification to appropriate healthcare professionals, and documentation of actions taken. A summary of all actions taken shall be forwarded to DHS Pharmacy Affairs within 7 days of drug recall/market withdrawal. DHS Pharmacy Affairs will summarize all DHS institutional actions on the "DHS Recall Summary - Facility Action" form (see Appendix B) and forward to the DHS Chief Medical Officer and the DHS Core Pharmacy & Therapeutics (P&T) Committee. The DHS Core P&T Committee may provide formulary modifications, if necessary.
3. 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.

ATTACHMENTS/FORMS:

- Appendix A: DHS Drug Recall Process Flowchart
- Appendix B: DHS Recall Summary - Facility Action Summary Form