Department of Pharmacy POLICY AND PROCEDURE

POLICY NUMBER: 891
VERSION: 2

SUBJECT: Medication Recalls

PURPOSE:

To provide standardized system drug recall guidelines to be followed at High Desert Regional Health Center, 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 Recalls are defined below:

A. **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 lifesaving drug.

B. **Class II Recalls** are for products that might cause 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.

C. **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 incorrect dye.

D. **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 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 websites
http://www.fda.gov/opacom/7alerts.html.

PROCEDURE:

1. The Chief Pharmacist or his/her designee shall review all Drug Recall Notices received from vendors, the Federal Drug Administration (FDA) and /or DHS Pharmacy Affairs. All recalls will be recorded on the Drug Recall Log.

2. If the recalled drug is not routinely stocked in High Desert Regional Health Center Clinics, as verified by procurement records or manual verification of pharmacy shelves, it shall be documented on the Drug Recall Log and other appropriate forms.

3. If the recall drug has been received by the Pharmacy, a Drug Recall Notice shall be sent to the High Desert Health System to the Pharmacy and Therapeutics Committee Chair, the Medical Director, the Chief Nursing Officer and to the Nurse Managers.

4. Upon receipt of the Drug Recall Notice, the charge nurse in each clinic shall check the clinic stock, remove recalled drugs, and return them to the pharmacy. Even if no recalled drugs are found, the Drug Recall Notice shall be filled out, signed, and returned to the pharmacy for filing.

5. The Chief Pharmacist or his/her designee shall immediately pull all recalled stock from the shelves and return to the manufacturer. If necessary, the Chief Pharmacist will assess impact and provide recommendations for alternative therapy.

6. In the event of a Class I recall, a computer audit trail or all patients receiving the recalled product shall be generated by DHS Pharmacy Affairs using the current DHS Pharmacy System.

7. If a drug recall/market withdrawal requires patient notification, DHS Pharmacy Affairs will collaborate with County Counsel and the DHS Medical Officer to review and recommend appropriate actions to High Desert Regional Health Center.

8. Copies of all Drug Recall Notices shall be retained on file for a period of at least three years.

Drug Recalls Involving Sterile Compounded Products

The Pharmacy shall contact the recipient patient, the prescribing physician, and the board as soon as possible within 12 hours of the recall notice (class 1) if the exposure to the recalled drug may cause serious adverse health consequences or death.

REFERENCE:

DHS Drug Recall Process, Policy 329.004, August 15, 2008 (attached)

Approved By: Romina Panoussi (PHARMACY SERVICES CHIEF II)	
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