HIGH DESERT HEALTH SYSTEM
AMBULATORY SURGICAL CENTER

SUBJECT: XI-115 MEDICATION RECALL	**POLICY #**: 1271
	VERSION: 1
APPROVED BY: Aram. Messerlian (CHIEF PHYSICIAN I ANESTHESIOLOGY), Beryl Brooks (ADMR,COMP AMB HEALTH CARE CENTER), Leila Adriano (NURSE MANAGER)	
DATE APPROVED: 09/15/2017	

PURPOSE: To provide guidelines for management of medication recall.

POLICY: The Ambulatory Surgery Center (ASC) staff HDHS Pharmacy will comply with the following procedure, developed in compliance with the DHS Drug Recall Policy, in the event of a medication recall for medication used at the ASC.

DEFINITIONS:

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 life saving drug.

2. **Class II Recalls** are for products that might cause temporary health problems, 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.

3. **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.

4. **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.

PROCEDURE:

1. The HDHS Pharmacy Director/designee reviews all Drug Recall Notices received from vendors, the FDA and DHS Pharmacy Affairs.

2. The HDHS Pharmacy Staff will record all recalls on the Pharmacy Drug Recall Log.

HIGH DESERT HEALTH SYSTEM
AMBULATORY SURGICAL CENTER

SUBJECT: XI-115 MEDICATION RECALL	**POLICY #**: 1271
	VERSION: 1

3. If the recalled drug is not routinely stocked in the ASC, as verified by procurement records or manual verification of pharmacy shelves, it shall be documented on the Drug Recall Log.

4. If the recalled drug has been dispensed to the ASC, a Drug Recall Notice shall be sent to the ASC Nursing Director and Medical Director.

5. Upon receipt of the Drug Recall Notice, the ASC Nursing Director/designee shall check the ASC 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.

6. The Director of HDHS Pharmacy or designee shall immediately pull all recalled stock from HDHS Pharmacy and return to the manufacturer. If necessary, the Pharmacy Director will assess impact and provide recommendations for alternative therapy.

7. In the event of a Class I recall, HDHS Pharmacy using the current DHS Pharmacy System shall generate a computer audit trail for all patients who have received the recalled product.

8. If a drug recall/market withdrawal requires patient notification due to patient receiving the medication, DHS Pharmacy Affairs will collaborate with County Counsel and the DHS Medical Officer to review and recommend appropriate actions to High Desert Health System ASC.

9. Copies of all Drug Recall Notices shall be retained in the HDHS Pharmacy on file for a period of at least three years.

FDA recalls may be found on the following FDA websites
http://www.fda.gov/opacom/7alerts.html

REFERENCES:

DHS Drug Recall Process, Policy 329.004, April 28, 2015.

Original Date: 01/28/2009
Reviewed: 09/15/2017
Next Review Date: 05/15/2020
Previous Review Dates: 07/05/13
Previous Revise Dates: 07/09/13