

Advanced Heart and Vascular Center			
Policies and Procedures			
Policy Code: MM.006		Medication Recalls	
Approved By: Sandra Germany, Administrator	Effective Date: 06/18	Review Date: 5/26	Revision Date:

POLICY

- Selected Advanced Heart and Vascular Center (“AHVC”) employees shall be notified and action shall be taken when a product warning or recall has been issued by the manufacturer.
- In the event of a medication recall, AHVC will remove all quantities of the medications involved that are in distribution throughout the facility.
- Medications that have been discontinued by the manufacturer (but not recalled) are not affected by this policy and may be stocked, dispensed, and administered until the supply is exhausted.
- Manufacturer’s Name and Lot Number: All medications shall be labeled so that recalls can be affected as necessary and proper controls established. Labels shall contain:
 - Lot number or control number.
 - Manufacturer’s name (if not evident from the proprietary name or from packaging records).

PROCEDURE

- Upon receipt of a recall or notice, immediately ensure that all recalled products are removed from all areas of the facility and returned for proper disposition.
- Review dispensing records to identify patients taking/using the recalled product.
- Check all medication storage areas.

Routine Inspections

- Routine inspections shall include a check for recalled drugs.

Storage of Recalled Products

- Stocks of recalled products shall be labeled, “RECALLED—AWAITING DISPOSITION. DO NOT USE” (or similar label). Recalled products shall be quarantined in a designated area while awaiting disposition.

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Disposal of Recalled Products

- Recalled products shall be disposed of in accordance with the recall notice.

Documentation

- Action taken shall be documented. Recall notices shall be dated and initialed when the procedure is completed. An indication of the action taken shall be entered on the notice. AHVC will maintain records of notices.

Informing Administration and Nursing

- If the recall has an effect on the availability of medications or the safe use of medications, AHVC shall inform the nursing staff through the Director of Nursing.

Reports to Medical Staff

- If the recall has an effect on the availability of medications or the safe use of medications, AHVC shall inform the medical staff through the Medical Director. When necessary, the medical staff, individual practitioners, or other professionals shall be notified immediately.