Manifest Pharmacy
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PRODUCT RECALL POLICY AND PROCEDURE

1. DEFINITIONS

A. Drug & Market Recall: A drug recall is a situation where a drug product that has been distributed is found to be possibly unsafe and must be pulled from stock and returned to a supplier. Usually, a recall is associated with a defective or contaminated product. Recalls may be conducted on a firm's own initiative, by Federal Drug Administration (FDA) request, or by FDA order under statutory authority. Drugs that are removed from the market because the drug itself is potentially harmful to extent that the risks outweigh the benefits. Unlike recalls that may involve specific lots of a drug, a withdrawal involves a drug being completely taken off the market. Withdrawals, like recalls, can be either voluntary or mandated by the (FDA).

B. Recall Classifications: As defined by the FDA.

- Class I Recall: A situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

- Class II Recall: A situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

- Class III Recall: A situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

- Medical Device Safety Alert: Issued by FDA in situations where a medical device may present an unreasonable risk of substantial harm. In some cases, these situations also are considered recalls.

2. POLICY

A. This procedure describes the actions Manifest pharmacy shall take upon being notified of a Drug Recall or a Market Withdrawal. The recall or market withdrawal may come from the drug manufacturer or wholesaler upon advice from an advisory committee or from information received from a regulatory agency.

B. This procedure applies to all drug products in inventory, staged for dispensing, or dispensed to patients. The Pharmacist-in-Charge is responsible for taking immediate action to isolate recalled or market withdrawn drugs or products upon notification.

3. PROCEDURE

A. Safety Requirements: Recalled or market withdrawn drug products will be separated according to the notification instructions. If disposal is required, the proper safety handling and disposal practices will be followed in compliance with all applicable regulations. If the notification requires return of the drug product to the wholesaler and/ or drug manufacturer, documentation is required for accurate accounting of what was returned.

B. Notification and Required Action:

- The wholesaler or other notifying entity/organization will inform Manifest pharmacy directly via electronic or written communication when there is a Recall or Market Withdrawal for a drug product.

- The communication shall contain the requirements for the specific lot or other relevant drug product information.

- Upon immediate notification, it is the responsibility of the Pharmacist-in-Charge to immediately check Manifest pharmacy inventory. All identified recalled or market withdrawn drug products shall be removed, separated, and labeled to prevent use.

- If there is no drug product in inventory stock, the Pharmacist-in-Charge will sign the printed notification with "None in Stock" and sign/ date and file the notification.

- As needed Management, Quality, Legal or other Operational Departments may be involved in research of dispensed prescription records of the recalled or withdrawn drug product to identify all patients who may have received the drug or specific lots.

- Patient communication shall include the proper steps for returning the medication or the proper disposal procedure and product credit information.

- The Recall/ Withdrawal process will not be terminated until such a time as all impacted drug products are accounted for, all attempts have been made to retrieve, separate and isolate recalled or withdrawn medications, and disposal or returns are complete.

- Recalled or Market Withdrawn product information such as identified inventory quantity, patient return quantity or other applicable information shall be fully tracked, documented, and filed as part of Pharmacy control records by the pharmacist with support from the Quality Assurance Department. As needed, this information may be provided to the notifying entity/organization.