

ADMINISTRATIVE POLICY AND PROCEDURE

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Subject: PRODUCT RECALL OR ALERT RESPONSE TRACKING

Policy No.: A427.1

Supersedes: February 1, 2016

Review Date: May 22, 2023

Origin Date: July 14, 2006

Revision Date: May 22, 2023

PURPOSE:

To ensure that appropriate actions are taken whenever a product recall or alert is received. To identify if the product is in inventory, stock, or use at Rancho, and the actions required. To ensure that necessary actions are taken to protect the health and safety of patients, employees, and visitors whenever the rehabilitation center is notified of a product recall or alert.

POLICY:

Rancho Los Amigos National Rehabilitation Center will maintain a process to ensure awareness of and response to all product recalls or alerts.

PROCEDURE:

1. The Pharmacy Department, Supply Chain Operations, BioMed, and Risk Management will provide a quarterly summary to the Safety Officer of all recall or alert notices received, and any actions required.
2. Any pharmaceutical related recalls or alerts will also be addressed at the Pharmacy and Therapeutics Committee monthly.
3. Any other employee who receives a recall or alert notice is to contact the Safety Officer, and inform them of the recall or alert, and any actions required.
4. Affected departments or individuals will be required to document any corrective or preventive actions taken, date taken, sign and date the form and maintain records.
5. The Safety Officer will maintain a log with copies of the reports on file.
6. The Safety Officer, as Chair of the Environment of Care Committee, will provide a report to the Environment of Care Committee, at least quarterly, addressing all recalls or alerts received and any actions required.

Severity Classification:

CLASS I:

A situation in which there is reasonable probability that the use of, or exposure to, or a violation of the product will cause serious adverse health consequences, or death.

CLASS II:

A situation in which the use or exposure to a product may cause temporary or medically reversible health consequences, or where the probability of serious adverse health consequences is remote.

Revised: 2/16, 5/23

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Approved By:

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CLASS III:

A situation in which the use of, or exposure to, a product is not likely to cause adverse health consequences.