AHRMM
Advancing Health Care through Supply Chain Excellence

CQO: The Health Care Supply Chain

Recall Management – Delayed Recalls Percentage Rate

Purpose:

Measure the percentage rate of open recalls received from the manufacturer and the U.S. Food and Drug Administration (FDA) that are at least 7 days past the notice date.

Value:

Allows hospitals/systems to assess their effectiveness in acknowledging and responding to recall product notifications. The implementation of such effective processes affects patient safety and care, and liability (both financial and risk) to the health care organization.

Equation:

Number of product recall alerts remaining open after 7 days

÷

Total number of product recall alerts received

=

Delayed Recalls Percentage Rate

Note: it is favorable to have a lower value for this Key. The lower the value the better.

Example:

- A hospital's number of product recall alerts remaining open after 7 days is 5.
- The hospital's total number of product recall alerts received is 10

5 ÷ 10 = **50% Delayed Recalls Percentage Rate**

Example Response Rates:

- Closure of Class III recalls within 21 days
- Class II recalls within 14 days
- Class I recalls within 7 days

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Input Descriptions and Sources:

Input Name	Includes	Excludes
Total number of product recall alerts received	The number of active recalls received for the month for products the facility has purchased, or currently has in-stock. These recalls could be notified by a third-party recall management system, or, mailed into the facility from sources including the FDA and manufacturers (Field notices, etc). Include recalls that are notified, and closed immediately because an item was not purchased, and if consignment or vendor "trunk stock", the product must be tracked through facility tracking processes. Only include the volume found within the facility, as well as implants that will have a record on the patient chart.	Product recalls received for products the facility does not have in stock.
Number of product recall alerts remaining open after 7 days	The number of active recalls, remaining open for more than 7 days after the recall notice was received, for products the facility has purchased, or currently has in-stock.	Recalls received for commodity products that may have been utilized before notification due to a lack of usage tracking.

Points of Clarification:

- This KPI assumes that an automated alert system and/or a centralized process exists within the health care organization. If your organization does not have either you should first establish a third-party alert/internal organizational process for recall management.
- This KPI uses the FDA classification rankings for recall management (as follows); however, there are no federal mandates for recalls. AHRMM proposes these recommendations as guidelines for practice.
- 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.
    - Example: A situation in which a catheter may kink or rupture during use leaving remnants behind in the patient that will cause serious injuries 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.
    - Example: A package defect in which sterility has been compromised and could lead to contamination of the medical device and result in patient complications.

- Class III recall: A situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.
    - Example: Labeling defect where the expiration date does not appear on the product label. A mislabeled package that contains one size of a particular medical device but is labeled as another size.
- By tracking the delayed recall rate, health care organizations can determine the effectiveness of their recall management processes and how to set best practices/notable practices towards better management.