

Institutional Handbook of Operating Procedures
Policy 09.13.11

Section: Clinical Policies	Responsible Vice President: EVP and CEO Health System
Subject: General Procedures	Responsible Entity: Quality & Healthcare Safety

I. Title

Manufacturer, Distributor, and FDA Recall Policy

II. Policy

UTMB is committed to patient safety and responds accordingly to [product](#) recall notices as required by the FDA, manufacturer, and/or distributor.

UTMB departments shall comply with the recommendations included in any [recall, alert, or safety hazard notice](#) provided by the FDA, product manufacturer, and/or distributor. Compliance efforts, or an explanation of any differences between the recall recommendations and UTMB activities, shall be communicated via the ECRI Alerts Tracker system or routed to Quality & Healthcare Management.

III. Recall Classification (fda.gov)

- A. **Class I:** A dangerous or defective product that could cause serious health problems or death.
- B. **Class II:** A product that might cause a temporary health problem or pose slight threat of a serious nature.
- C. **Class III:** A product that is unlikely to cause any adverse health reaction, but that violates FDA labeling or manufacturing laws.

IV. Notification and Departmental Actions

- A. Recalls and safety hazard notifications will be provided by the FDA, manufacturer and/or distributor, which will then be received by and distributed to the appropriate department director (or designee) by Quality & Healthcare Management. This will be distributed using vendor/manufacturer communications for recalls and/or urgent medical device corrections. Quality and Healthcare Management will forward these notifications to the appropriate department that shall:
 - 1. Review the information provided, determine applicability.
 - 2. Complete corrective action recommended by the manufacturer, distributor or the FDA.
 - 3. Document remediation efforts as directed by the Quality and Healthcare Management Department within six (6) business days.
- B. All recalls and safety hazard notices are also received by Quality & Healthcare Management via letter or e-mail delivery and are distributed electronically to the appropriate department director (or designee) for processing as described above.

- C. All recalls and safety hazard notices received by a department other than Quality & Healthcare Management shall be immediately forwarded to Quality & Healthcare Management for processing.

V. Departmental Responsibilities

A. Quarantine of Recalled Items

1. Supply Chain Management and/or affected departments will sequester any affected items or equipment safely and mark accordingly. Appropriate documentation of catalog number, quantity, lot number, serial number, equipment remediation measures and any other pertinent information should be recorded immediately and sent to Quality & Healthcare Management and Supply Chain Management.
2. Following the completion of the above steps, Supply Chain Management will work with the manufacturer and/or distributor to determine return and replacement procedure.

B. Quarantine of Recalled Drugs

1. Pharmacy will sequester any affected drugs safely and mark accordingly. Appropriate documentation of NDC number, quantity, lot number, and any other pertinent information should be recorded immediately and sent to Quality & Healthcare Management.
2. Pharmacy will work with the manufacturer to determine return and replacement procedure.

C. Identification of Substitute Items

1. Supply Chain will assist in identifying substitute products with existing substitute lists and/or in conjunction with clinical staff (as appropriate).
2. Supply Chain will send notification of substitute items to affected areas (as appropriate).
3. Pharmacy will handle drug substitutions and communicate as appropriate.

D. Record Keeping

1. A record of all recalls and safety hazard responses received will be maintained by Quality & Healthcare Management.

VI. Patient Contact

Physicians should be considered the primary liaison in concert with Quality & Healthcare Management when circumstances require that a patient be contacted by the Chief Medical Officer or designee.

VII. Dates Approved or Amended

<i>Originated:</i> 04/01/1990	
<i>Reviewed with Changes</i>	<i>Reviewed without Changes</i>
10/11/2012	02/16/2009
01/29/2020	12/22/2016
	09/07/2018

VIII. Contact Information

Quality & Healthcare Management
(409) 772-8509