

Name of Policy: <u>Market Withdrawals/Recalls</u> Policy Number: 3364-100-45-20 Department: Hospital Administration Approving Officer: Chief Medical Officer Chief of Staff Responsible Agent: Chief Executive Officer Scope: The University of Toledo Medical Center and its Medical Staff	 Effective Date: 05/01/2021 Initial Effective Date: December 14, 2005
<input type="checkbox"/> New policy proposal <input type="checkbox"/> Major revision of existing policy	<input type="checkbox"/> Minor/technical revision of existing policy <input checked="" type="checkbox"/> Reaffirmation of existing policy

(A) Policy Statement

To determine if patient notification is necessary in cases of Market Withdrawal and or recall of products initiated by the American Red Cross (ARC)

(B) Purpose of Policy

Market withdrawal and/or recalls (MW/R) are initiated by the American Red Cross (ARC) for a variety of reasons, including, but not limited to, donors who provide information subsequent to donating a unit(s) of blood, such as tattoos, history of hepatitis, a positive test result for hepatitis or hepatitis exposure, travel to a malarial risk area, cold/flu, labeling errors, etc.

(C) Procedure

Upon receipt of a letter from the ARC delineating the reason for the MW/R the Medical Director of the Blood Bank evaluates the significance of the event and makes a determination as to whether notification of the physician who prescribed the unit is necessary. Notification will occur via a phone call to the physician by the Medical Director of the Blood Bank and a copy of the ARC letter will be sent to the physician. The physician determines if notification and follow-up with the patient needs to take place and follows through appropriately.

Approved by: /s/ _____ 05/13/2021 Michael Ellis, MD Chief Medical Officer Date /s/ _____ 05/18/2021 Andrew Casabianca, MD, DMD Chief of Staff Date <i>Review/Revision Completed By:</i> Blood Utilization Review Committee HAS Chief of Staff	Review/Revision Date: 3/25/2009 12/1/2011 3/5/2012 3/1/2015 4/1/2020 5/1/2021 Next Review Date: 5/1/2024
Policies Superseded by This Policy: 7-45-20 - Market Withdrawals/Recalls	

It is the responsibility of the reader to verify with the responsible agent that this is the most current version of the policy.