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Area	Laboratory-Blood Bank
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Supplier Notification of Product Recall, Market Withdrawals, and Lookbacks

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This document will establish a standardized, consistent process for Blood Bank staff to follow-up on supplier notification of a non-conforming product. The process is intended to ensure prompt removal and quarantine of the product from available inventory, to act as a guide for suitable follow-up activities such as return or discard of a product as indicated by the supplier, and to initiate prompt notification of appropriate persons in the case of transfusion of an affected product that may involve risk of infectious disease transmission.

II. CLINICAL SIGNIFICANCE:

A. There are numerous situations in which blood or blood components that meet all established criteria at the time of distribution, are subsequently determined unsuitable. A number of these situations may prompt notification of consignees. Among these situations are recall, market withdrawal, and lookback. The Blood Bank is alerted of supplier notifications by phone call, fax, and/or US Mail. The blood supplier should follow-up a phone call notification with a faxed product information document. Depending on the specific blood supplier and the type of notification, the notification documents may be titled in various ways (e.g., “Product Action Request”, “Recall”, “Withdrawal”, or “Product Retrieval”).

III. DEFINITIONS / ACRONYMS:

A. **Designee**: A Blood Bank Medical technologist assigned to assisting with the compilation and completion of documentation steps on the *Blood Supplier Notification Form*.

B. **Blood Supplier**: Facility that supplies the hospital Blood Bank with blood products. (i.e., Versiti, American Red Cross, LifeSouth Community Blood Center, South Texas).

C. **Medical Record Number (MRN)**: A specific number assigned to each patient that is used for identification purposes and access to their medical chart.

D. **Consignee**: Anyone who received, purchased, or used the product being withdrawn or recalled.

E. **Recall**: A firm's removal or correction of a marketed product that the Food and Drug Administration (FDA) considers to be in violation of the laws it administers and against which the agency would initiate legal action (recall does not include a market withdrawal).

F. **Market Withdrawal**: A firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the Food and Drug Administration (FDA) or which involves no violation.

G. **Lookback**: The process of identifying the current location and/or final disposition of blood and blood components from a particular donor, removing any potentially infective components from inventory or, in the case of transfused products, identification of the recipient if indicated, so that appropriate treatment and counseling can be provided. (Lookback is usually initiated by detection of a confirmed reactive viral marker result on a donor who previously tested negative or who last donated prior to inclusion of that test in the routine screening protocol).

H. **Transfusion Recipient Notification**: The actions taken by a hospital, Blood Bank, or patient's physician of record to notify patients that they have received transfusion of a blood product that is at increased risk of disease transmission.

I. **Low Risk (Class III)**: Situation in which use of, or exposure to, a violative product is not likely to cause adverse consequences.

J. **Moderate Risk (Class II)**: Situation in which use of, or exposure to, a violative product may cause temporary or medically reversible health consequences or where the probability of serious adverse health consequences is remote.

K. **High Risk (Class I)**: Situation in which there is a reasonable probability that the use of, or exposure to, a violative blood product will cause serious adverse health consequences or death.

L. **Non-Transfused**: For the purpose of this document, a blood product is deemed non-transfused if the product is not transfused and is physically located in the Blood Bank.

M. **Transfused**: For the purpose of this document, a blood product is deemed transfused if the product was transfused specifically at a Beaumont Health facility.

N. **Expired/Discarded**: For the purpose of this document, a blood product is deemed expired/discarded if the product has expired or been discarded specifically at Beaumont Health.

O. **Transferred to Another Facility**: For this document, a blood product is deemed transferred to another facility if the product has been physically transferred to another facility and is no longer located in the Blood Bank. This applies even if the blood product has been transferred to another Blood Bank within the Beaumont Health.

IV. POLICY

The following outline responsibility for removal of a non-conforming product from available

inventory, subsequent handling of the affected product, and prompt notification of the recipient as indicated.

A. The Blood Bank (BB) has developed agreements with suppliers to notify us if it supplied our facility with potentially infectious blood or blood components.

B. A Blood Bank Medical Technologist (Tech), or Supervisor will handle all verbal, fax, or US mail supplier notifications to determine the availability/transfusion status of the product. They will immediately place any available product into quarantine status in the Blood Bank computer system, and physically remove and quarantine any affected product from available inventory. The *Blood Supplier Notification Form* will be documented to include notification information, product information, and identify recipients of any transfused product, if indicated.

C. Products subsequently determined unsuitable for use shall be returned or discarded as instructed by the supplier.

D. For information regarding the quarantine or discard of blood products, refer to Transfusion Medicine policy, Blood Product - Quarantine or Discard.

E. If the Blood Bank receives a blood supplier notification for a product that was transferred to another facility, a Blood Bank Tech will call the receiving facility to inform them of the blood supplier recall/withdrawal/lookback and also fax the site a copy of the notification. The department supervisor or designee will contact the blood supplier to communicate the location of the product.

F. Disposition and notification information requested by the supplier will be submitted to the supplier as soon as possible.

G. The Medical Director/Blood Bank System/Associate Directors will assess risk to recipients and the likelihood of infectious disease transmission to determine appropriate physician and/or patient notification.

H. Reasonable attempts to notify a recipient that received a blood product from a donor who is later determined at risk for transmission of infectious disease, will be completed in a timely manner as indicated in Food and Drug Administration (FDA) rules and regulations.

I. Notification and/or efforts to notify the recipient will be documented on the *Blood Supplier Notification Form*.

J. Lookback cases will be presented if appropriate to the Laboratory Quality and/or Transfusion Committees.

K. Records of the source and disposition of all units of blood and blood components will be maintained for a minimum of ten years from the date of disposition in a manner that permits prompt retrieval.

V. PROCEDURE:

A. Notification and Product Information

Supplier notification is received by phone call, fax, and/or US mail. If the notification is received by phone call, then request the supplier follow-up with a faxed document to the Blood Bank fax machine.

1. Upon receiving a notification from a blood supplier for the recall, market withdrawal, or

lookback of a blood product, a Blood Bank Technologist or Supervisor should complete the attached *Blood Supplier Notification Form*.

2. Document the following:
    a. The name of the employee documenting the form.
    b. The date and time of notification.
    c. The method in which the Blood Bank was notified. If the notification was made by phone, document the caller's name and request a follow-up fax with the information.
    d. The blood supplier that provided the blood product notification.
    e. The type of supplier notification (i.e., recall, market withdrawal, lookback, etc.).
    f. The reason for the blood supplier notification.
3. Document the type of blood product being investigated as well as the blood product's unit number and product code.
4. Look up the product history report from the Blood Bank computer system.
    a. If the product is transfused, expired/discarded, or transferred to another facility, print the product history report.
    b. If the product is still physically located in the Blood Bank (i.e., non-transfused), do not print the product history report.
5. Document the current status of the blood product.
    a. Non-Transfused: If the product is not transfused and is physically located in the Blood Bank, access the Blood Bank computer system to change the status of the product to discard, quarantine, or return as instructed by the supplier and physically discard, quarantine, or package/return the product. Refer to Transfusion Medicine policy, Blood Product - Quarantine or Discard
        i. The product history report should be printed after the product status has been changed to discard, quarantine, or returned to supplier.
        ii. Document as appropriate:
            I. Discard: Document the discard date/time.
            II. Quarantine: Document the quarantine storage location.
                a. Attach a copy of the Supplier Notification to the quarantine product.
                b. Document quarantine product on communication logs/board.
            III. Return to Supplier: Document the return date/time.
    b. Transfused: If the product was transfused at Beaumont Health, document the recipients Medical Record Number (MRN) and name.
    c. Expired/Discarded: If the product has expired or been discarded at Beaumont Health, document the day in which the product expired or was discarded.
    d. Transferred to another facility: If the product was transferred to another facility,

contact the receiving facility that the product was transferred to and inform them that the product is involved in a supplier notification event. Fax the receiving facility a copy of the supplier notification. Document the facility's name, the person notified, and the date/time of notification.

B. Notifying Blood Supplier of Final Disposition

1. Upon completing Section A of the *Blood Supplier Notification Form*, the Blood Bank Tech or Supervisor will complete the product disposition section of the supplier notification document to indicate the status of the blood product.
2. Fax the disposition form to the blood supplier using the fax number provided on the notification document.
3. Obtain the fax confirmation that prints as confirmation that the fax went through as expected.
4. Document the name of the Blood Bank Tech or Supervisor under Section B of the *Blood Supplier Notification Form* to indicate which employee completed this section.
5. Clip the following documents together and place them in the appropriate area for Supervisor/ Lead Technologist follow up:
    a. Supplier notification document(s)
    b. Blood Supplier Notification Form
    c. Product history report
    d. Fax confirmation

C. Quality Assurance (QA) Follow Up

1. The Supervisor or designee will review Section A and Section B of the *Blood Supplier Notification Form* for completeness and make any necessary corrections.
2. The Supervisor or designee will proceed as follows:
    a. If the blood product is in quarantine status, proceed to Section C step 3.
    b. If the blood product has been transfused, discarded, or returned to the supplier, proceed to Section C step 4.
    c. If the blood product has been transferred to another facility, proceed to Section C step 5.
3. If the product is in quarantine status, place all documents in the appropriate area for Supervisor/Lead Technologist follow up.
    a. The Blood Bank leadership staff will monitor the product in quarantine status and, if necessary, contact the supplier to receive a product status update. Any updates from the blood supplier will be documented on the Comment field within Section C of the *Blood Supplier Notification Form*.
    b. Once the final disposition instructions have been received from the blood supplier, the Supervisor or Blood Bank Tech will make the appropriate status change in the Blood Bank computer system and physically move the product as instructed by the supplier.

c. Complete the final supplier disposition form and fax it to the supplier using the fax number provided on the form.

d. Proceed to Section C step 5.

4. If the blood product has been transfused, discarded, or returned to the supplier, recall the product in the Blood Bank computer system using Blood Bank CDM - Unit Recall. Print the recall report and attach it to *Blood Supplier Notification Form* or write "Recalled in computer" on the product history report.
   Note: Don't perform the recall step for products that are in quarantine, available, or transferred status.
5. Document the final status of the product on *Blood Supplier Notification Form*.
6. Staple the forms in the following order and deliver to Medical Director office or place in the Medical Director mail slot/binder:
   a. Supplier notification document (s)
   b. *Blood Supplier Notification Form*
   c. Product history report
   d. SoftBank Recall report (if applicable)
   e. Fax confirmation
7. Provide the notification to the Medical Director and/or Blood Bank System Director for review. If necessary, send an email stating:
   a. Supplier notification placed in the MD mail slot
   b. Donor number of the involved product
   c. Status of the product (i.e., transfused, discarded)
   d. The reason for the notification

D. Medical Director Assessment

1. Upon completion of Section A – Section C, the Blood Bank Medical Director or Associate Medical Director will assess the risk for the recipient and determine if any additional action or notification is required.
   a. If the blood product was transferred to another facility, proceed to Section D step 8. Any risk assessments and notifications to physicians or patients are the responsibility of the facility in which the product was transferred to.
2. Assign a risk category (e.g., low, moderate, or high risk) based upon the potential for infectious disease transmission and patient notification recommendation by supplier. Refer to the *Definitions* section of this document for the risk category definitions. Document the risk category on the *Blood Supplier Notification Form*.
3. Assess the risk to the recipient and determine the extent of notification required based upon the status of the patient.
   a. If it is determined that notification is clinically indicated, proceed to Section D step 4.

b. If it is determined that notification is not clinically indicated, then document the *Blood Supplier Notification Form* accordingly and proceed to Section D step 8.

4. Notify the attending physician or the physician who ordered the blood that potentially infectious blood products were transfused and that the patient may need additional testing and/or counseling.
    a. Contact the attending physician by telephone for high risk or lookback patients.
        i. Document each attempt to contact the attending physician in the record with the outcome of the contact.
        ii. Make a reasonable number of attempts to notify the attending physician or the physician who ordered the blood, within 12 weeks after being notified by the supplier and/or after receiving the supplemental (additional, more specific) test results.
        iii. Document the notification on the *Blood Supplier Notification Form*.
    b. Confirm with the physician the requirement for notification of the patient if indicated (or legal representative or relative if the patient is a minor, or adjudged incompetent by a State court).
        i. Patient and/or next of kin notification is required for cases of Human Immunodeficiency Virus (HIV) or Hepatitis C Virus (HCV) lookbacks.
        ii. If the patient is deceased, the requirement to notify the legal guardian or relative of possible exposure applies only to HIV infection and not HCV infection.
5. If notification of the patient is required, determine whether the patient's physician will notify the patient.
    a. If the patient's physician agrees to notify the patient, document the *Blood Supplier Notification Form* with the physician's name, the date and time of the agreement, and the name of the person obtaining agreement. Proceed to Section D step 8.
    b. If the patient's physician is unavailable or declines to notify the patient, proceed to Section D step 6.
6. Make a reasonable number of attempts to notify the patient (relative or legal representative) by telephone within 12 weeks after being notified by the supplier and/or after receiving the supplemental (additional, more specific) test results. Patient information can be obtained from the hospital information system. Document the date and time of each attempt to notify.
7. If contact with the patient (relative or legal representative) is made by telephone, provide a basic explanation of the risk for disease transmission, need for additional testing, referral for counseling and documentation of each.
    a. It may be beneficial to invite the patient (relative or legal representative) to come in to discuss the laboratory test result relative to the transfusion that the patient received.
    b. If contact with the patient (relative or legal representative) cannot be made by telephone, send a notification letter marked "Confidential, for addressee only, please forward". In the letter, explain the risk of disease transmission and offer to discuss

the results and refer for counseling. Attach a copy of the letter and return receipts to the *Blood Supplier Notification Form.*

8. Once all necessary assessments and notifications have been made with proper documentation, the Medical Director, Associate Medical Director, or Blood Bank Fellow should sign and date the *Blood Supplier Notification Form*. Note: If a Blood Bank Fellow performed the assessment and notification, the *Blood Supplier Notification Form* must also be signed by the Medical Director or Associate Medical Director.
9. Place the *Blood Supplier Notification Form* and any blood supplier documents in the appropriate appropriate area for Supervisor/Lead Technologist follow up when completed.

E. Final Review and Storage

1. Upon completion of Section A – Section D, the supervisor or designee will review the *Blood Supplier Notification Form* and blood supplier documents for completeness.
2. The Supervisor will staple all documents together and file them in a designated file.
3. All documents will be kept onsite for a minimum of 2 years and then transported to the hospital-designated offsite storage for 10 years.

VI. REFERENCES:

1. 48799: Federal Register/Vol. 72 No.164: 21 CFR Parts 606 and 610 Current Good Manufacturing Practice for Blood and Blood Components; Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting Hepatitis C Virus Infection (“Lookback”); Final Rule (Friday August 24,2007), accessed March 2022
2. FDA: 21 CFR 600.12 Records
3. FDA: 21 CFR 7.3 Definitions
4. FDA:21 CFR 7.49 (d) Responsibility of recipient
5. FDA Guidance for Industry: Adequate and Appropriate Donor Screening Tests for Hepatitis B; Hepatitis B Surface Antigen (HBsAg)Assays Used to Test Donors of Whole Blood and Blood Components, Including source Plasma and Source Leukocytes (July 2007), accessed March 2022
6. FDA Guidance for Industry; Lookback for HCV (2010)
7. FDA: 21 CFR 610.47(b) and 610.48 (c)
8. College of American Pathologists, Transfusion Medicine Checklist, current edition.

Attachments

Blood Supplier Notification Form

Approval Signatures

Step Description	Approver	Date
	Ann Marie Blenc: System Med Dir, Hematopath	5/27/2022
	Muhammad Arshad: Physician	5/27/2022
	Ryan Johnson: OUWB Clinical Faculty	5/25/2022
	Jeremy Powers: Chief, Pathology	5/23/2022
	John Pui: Chief, Pathology	5/19/2022
	Vaishali Pansare: Chief, Pathology	5/19/2022
Policy and Forms Steering Committe (if needed)	Kelly Sartor: Supv, Laboratory	5/19/2022
Policy and Forms Steering Committe (if needed)	Gail Juleff: Project Mgr Policy	5/18/2022
	Craig Fletcher: System Med Dir, Blood Bank	5/18/2022
	Rebecca Thompson: Medical Technologist Lead	5/13/2022
	Anji Miri: Supv, Laboratory	5/12/2022
	Michael Rasmussen: Supv, Laboratory	5/9/2022
	Teresa Lovins: Supv, Laboratory	5/9/2022
	Karrie Torgerson: Supv, Laboratory	5/6/2022
	Kelly Sartor: Supv, Laboratory	5/6/2022
	Brooke Klapatch: Medical Technologist Lead	5/6/2022
	Kelly Sartor: Supv, Laboratory	5/6/2022