PROCEDURE
Corewell Health East - Blood Product Deviation (BPD) Reporting - Blood Bank

This Procedure is Applicable to the following Corewell Health sites:
Corewell Health Beaumont Grosse Pointe Hospital, Corewell Health Beaumont Troy Hospital, Corewell Health Dearborn Hospital, Corewell Health Farmington Hills Hospital, Corewell Health Taylor Hospital, Corewell Health Trenton Hospital, Corewell Health Wayne Hospital, Corewell Health William Beaumont University Hospital (Royal Oak)

Applicability Limited to: N/A

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Functional Area: Clinical Operations, Laboratory

Lab Department Area: Lab - Blood Bank

1. Principle

A. This document will provide the Blood Bank (BB) staff with guidance and policies for a timely reporting of an event/occurrence to the Food and Drug Administration (FDA) once it has been determined that the event has affected the safety, purity or potency of a biologic product which was under the control of a Corewell Health Blood Bank facility, and the product was released for transfusion or shipped to another facility within Corewell Health.

B. The FDA requires that any event/occurrence associated with the manufacturing of a blood component be reported if the safety, purity, or potency of the product may be affected. This includes testing, processing, packing, labeling, or storage of a blood component.

C. The Blood Bank department is required to submit a Blood Product Deviation (BPD) report to the Center for Biologics Evaluation and Research (CBER), Office of Compliance and Biologics Quality (OCBQ) as soon as possible, but not to exceed 45 calendar days from the date of discovery.

2. Responsibility

Personnel who have completed the competency requirements will perform these tasks.

3. Definitions

A. Deviation: An unexpected event; departure from a standard or norm.

4. Procedure

A. To facilitate reporting, the FDA has developed a standardized reporting format that may be used to submit electronically or in paper form by mail and has provided key resources to assist with the submission of the BPD reports. The BPD report is primarily submitted electronically, password required and protected.

B. Once it has been determined that an unexpected event/occurrence is reportable to the FDA the report will be submitted by using the following:

1. The BPD report can be found on the FDA website at:

fda.gov > Vaccines, Blood & Biologics > Safety & Availability (Biologics) > Report a Problem to the Center for Biologics Evaluation & Research > Biological Product Deviations > Electronic Submission of Biological Product Deviation Reports (eBPDR)

C. Start a submission by clicking on the CBER eBPDR FIS login screen link from the Key Resources section.
   1. Enter the account name and password provided by the Blood Bank Manager/Supervisor.
   2. Click on CBER Biological Product Deviation Reporting (CBER eBPDR) from the Other FDA Systems section.
   3. For general instructions click on 3. View the instructions and deviation codes. There are additional links under the Forms & Instructions and Deviation Codes sections to provide additional assistance.

D. Select My Reports from the drop-down menu and enter all required information as prompted and self-guided by the system.

E. Print a hard copy of the completed electronic BPD report receipt confirmation, attach all supporting documents and file in the designated file/binder located in the Blood Bank Supervisor/ Manager office.

F. If for any reason, on rare occasion, the online system cannot be utilized, the form FDA 3486 may be submitted manually.
   1. Download the form: Blood Product Deviations.
   2. Complete the form by following the General Instructions for Completing the BPDR Form FDA 3486, save it, print it out and return it to the following address:

Director, Office of Compliance and Biologics Quality
Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
Building 71, Room G112
Silver Spring, MD 20993-0002

G. Notes:
   1. For any other assistance contact CBER at 240-402-9160 or by email at: bp_deviations@fda.hhs.gov
   2. Do NOT include donor, patient, or employee personal identification information or other confidential information when submitting a report to the FDA.
   3. Hard copies of the documents and/or forms below can be accessed on the FDA website; fda.gov:
      a. Guidance for Industry (BPD Reporting)
      b. BPD Codes
      c. FDA Blood Product Codes
      d. Downtime BPDR Form FDA 3486
      e. General Instructions for Completing the BPDR Form FDA 3486

5. Revisions

Corewell Health reserves the right to alter, amend, modify, or eliminate this document at any time without prior written notice.

6. References

A. AABB, Standards for Blood Banks and Transfusion Services, Current Edition.
B. College of American Pathologists (CAP) Standards, Current Edition.
C. FDA: 21 Code of Federal Regulations (CFR) Part 600.14 or 606.171.

7. Procedure Development and Approval

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8. Keywords
Not Set