Inspections, Compliance, Enforcement, and Criminal Investigations

Baptist Medical Center

hhsbluebirdDepartment of Health and Human Services

Public Health Service
Food and Drug Administration

Dallas District

4040 North Central Expressway

Dallas, Texas 75204-3145

May 14, 2009
2009-DAL-WL-10

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Keith Swinney, President
Baptist Medical Center
111 Dallas Street
San Antonio, Texas 78205

Dear Mr. Swinney:

The Food and Drug Administration (FDA) conducted inspections of your hospital blood bank, located at 111 Dallas Street, San Antonio, Texas 78205, from October 16, 2008 through December 12, 2008 and March 23, 2009 through April 3, 2009. During the inspections, FDA investigators documented deviations from applicable current Good Manufacturing Practice (cGMP) regulations for blood and blood components, Title 21, Code of Federal Regulations (21 CFR) Parts 600-680. These deviations caused your blood products to be adulterated within the meaning section 501 (a)(2)(B) (21 U.S.C. 351) of.the Federal Food, Drug, and Cosmetic Act (the Act)

At the close of both inspections, you were issued a Form FDA-483, Inspectional Observations, which listed a number of deviations including, but not limited to the following:

December 12, 2008 FDA 483:

1) Failure to maintain and/or follow written standard operating procedures (SOPs) that include all steps to be followed in the collection, processing, compatibility testing, storage, and distribution of blood and blood components for transfusion including all steps for pre-transfusion testing, including precautions to be taken to identify accurately the recipient blood samples and crossmatched donor units [21 CFR 606.100(b)(8)]. For example

a) Your firm failed to establish a written SOP to ensure that pre-Page transfusion test results are entered into the **(b)(4)** database system correctly and that there is a review of the data entry.
Specifically, on October 7, 2008, a blood bank technician entered a patient's (ID# **(b)(4)**) blood group as A Positive in the **(b)(4)** database system. This result was obtained using the manual technique and was incorrect. The patient's correct type, O Positive, had previously been determined using automated typing. As a consequence of the error, the patient received two ABO incompatible units of red cells and the FOA was notified of a possible transfusion related fatality on October 11, 2008.

b) Your firm failed to establish a procedure to describe the steps necessary to validate discrepant pre-transfusion test results.
Specifically, on April 11, 2008, Patient ID**(b)(4)** was found to be positive for a red cell antibody using the automated **(b)(4)** method. When the antibody screen was repeated using a manual method, the result was negative. The result from the manual test was accepted without investigating the discrepant result obtained on the automated instrument.

c) Your firm's SOP, Test Result Entry **(b)(4)** Computer System. is incomplete because it fails to provide detailed instructions to ensure correct specimen identification. Specifically, on October 6, 2008, a blood bank technician, performing a manual ABO retype on a specimen, identified the specimen by scanning the barcode affixed to a Blood Bank Sample Collection Record instead of the barcode affixed to the specimen. Consequently, an incorrect blood group was entered in the computer database for the patient and as described above, the patient received two units of ABO incompatible red cells.

d) Your firm's SOP, Sample Collection and Retention **(b)(4)** System, dated May 8, 2008, fails to provide adequate
directions regarding the correct method for applying the **(b)(4)** ID Label (barcode label) to the sample collection tube.
"Proper application of the label is essential to ensure that the sample is correctly identified by the **(b)(4)** automated testing instrument.

e) Your firm has failed to establish a written SOP to describe the steps necessary to identify blood bank specimens when either the **(b)(4)** hand held scanner is unable to read the **(b)(4)** ID Label or during system downtime. Specifically, on October 6, 2008, a blood bank technician was unable to use the scanner to enter results for patient ID# **(b)(4)** in the **(b)(4)** instrument database. The technician manually entered a
random number which failed to provide a link to the patient's specimen. Consequently, an incorrect blood group was entered in the computer database for the patient and as described above, the patient received two units of ABO incompatible red cells.

2) Failure to review all records pertinent to the lot or unit before the release or distribution of a lot or unit of final product. A thorough investigation of any unexplained discrepancy or the failure of a lot or unit to meet any of it's specifications must be made and recorded [21 CFR 606.100(c)].

a) Your firm failed to follow your SOP, Patient and Specimen Management **(b)(4)** Computer System. Specifically, on August 11, 2007 and July 19, 2008, your firm failed to adequately search the historical data for two patients who had previously demonstrated clinically significant antibodies. As a result, both patients received units that were not phenotypically matched. Your investigation and follow-up activities did not include revision of the SOPs in order to prevent a reoccurrence of the transfusion of unsuitable blood.

b) From January 19 through October 25, 2008 errors were made during data entry operations. You failed to conduct an adequate investigation into these occurrences. Specifically, there was no determination of a cause for the errors and the corrective actions implemented were inadequate.

3) Failure to ensure that equipment used in the compatibility testing of blood and blood products performs in the manner for which it was designed so as to assure compliance with requirements for blood and blood products. [21 CFR 606.60(a)]. Specifically, during the inspection, the FDA investigator noted that the **(b)(4)** occasionally failed to function properly. The
scanner IS-used 'to 'electronically identify patient specimens submitted for

compatibility testing.

April 3, 2009 FDA 483:

1) Failure to establish adequate laboratory controls to provide for identification and handling of all test samples so that they are accurately related to the specific unit of product being tested [21 CFR 606.140(c)]. Specifically, on February 26, 2009, a blood bank technician placed a barcode label for Patient ID# **(b)(4)** on the blood sample for Patient ID# **(b)(4)**. In addition, the technician placed the barcode label for Patient ID# **(b)(4)** on the blood sample from Patient ID# **(b)(4)** The mislabeled blood samples were then tested by the **(b)(4)** automated test instrument. A second technician, who subsequently performed manual ABO retypes on the two blood samples, failed to identify the tubes as being mislabeled. Consequently, Patient ID# **(b)(4)** was transfused with two units of ABO incompatible red cells on February 26, 2009. On March 13, 2009 FDA was notified of a possible transfusion related fatality.

2) Failure to review all records pertinent to the lot or. unit before the release or distribution of a lot or unit of final product. A thorough investigation of any unexplained discrepancy or the failure of a lot or unit to meet any of its specifications must be made and recorded [21 CFR 606.100(c)]. Specifically, on January 19, 2009, a blood bank technician performed an antibody identification on a sample from a patient with a previously positive antibody screen. The technician failed to identify an anti-E antibody in the sample and the patient received two units of incompatible E positive units. The units were distributed without a review of pertinent antibody records, which was not conducted until two days later.

3) Failure to observe, standardize, and maintain equipment and failure of equipment to perform in the manner for which it was designed so as to assure compliance with the official requirements for blood and blood components [21 CFR 606.60(a)]. Specifically, the following observations were made during review of your firm's validation of the interface between the automated blood testing instrument **(b)(4)** and the database system, **(b)(4)**

a) Validation sample testing and data collection was conducted on December 9, 2008, prior to approval of the validation test plan on. December 19, 2008;
b) The validation pass/fail criteria was not met;
c) The validation test plan was not followed; and
d) The validation data was incomplete.

4) Failure to maintain and follow written SOPs including all steps to be followed

in the compatibility testing and storage of blood and blood components for homologous transfusion [21 CFR 606.100(b)].

a.) The following SOPs fail to include all steps to be followed:

i. Patient Re-Types Transfusion Services effective January 11, 2009, permits the same blood bank technician to perform both the manual and automated test if a second blood bank technician is not available. Your firm indicated that this instruction should have been removed 'during revisions following the December 2008 inspection.

ii. **(b)(4)** Operation Manual, effective February 14, 2009, permits the blood' bank technician to affix
the barcode accession label on the blood specimen collection tube without verification of adequate labeling prior to testing. This contradicts your SOP, Blood Bank Sample Collection, effective March 18, 2009, which indicates barcode labels are to be placed on specimen collection tubes by a nurse or phlebotomist and verified at the time of collection.

b.) Written SOPs were not followed:

iii. On January 19, 2009, a blood bank technician did not use the "homozygous rule-out" in accordance with the SOP Antibody Identification Gel testing. dated November 14, 2008.
iv. The Patient Retypes Transfusion Services SOP, dated January 11, 2009, requires performance of ABO retypes by a second technician, if there is one available. On February 26, 2009, the same blood bank technician performed both automated and manual testing when another blood bank technician was available for the retype.
v. The Communication Log. was not reviewed **(b)(4)** in accordance with your SOP, Communication Between Shift Transfusion Services Operation Manual, effective November 25, 2008.

This letter is not intended to be an all-inclusive list of deficiencies at Baptist Medical Center. It is your responsibility to ensure that all blood and blood components processed and issued by your blood bank are in compliance with the Act and the cGMP regulations. You should investigate and determine the cause of the violations and take prompt action to correct these violations. Failure to correct these violations may result in administrative and/or regulatory action without further notice.

We request that you notify this office in writing, within' fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of specific steps you are taking to identify and prevent recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days. please state the reason for the delay and the time frame within which the corrections will be completed.

Please send your reply to: Sherrie L. Krolczyk, Compliance Officer at the above address. If you have any questions regarding any issue in the letter, please contact Ms. Krolczyk at (214) 253-5312.
Sincerely,
/S/
Reynaldo R. Rodriguez, Jr.
Dallas District Director
RRR:slk