



# e-Network Forum

## CALIFORNIA BLOOD BANK SOCIETY

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### *Regulatory requirements for transferring crossmatched RBC units between facilities of a healthcare system/healthcare network*

A colleague who works at a **health system in Texas** has a question about transferring crossmatched RBC units between facilities that are part of a healthcare network or system. The inquiring colleague's healthcare system is **comprised of two hospitals and two Long Term Acute Care (LTAC) facilities** (which are partly owned by the system). The two **hospital labs** currently **perform all routine laboratory testing for the LTAC facilities, including pretransfusion compatibility testing**. The patients are properly identified before any blood samples are collected, the specimen tubes are properly labeled, and once collected the blood tubes are transported by system personnel to the appropriate hospital laboratory. Presently, when RBC units are ready to be issued for transfusion at an LTAC facility, a blood product transfer form is filled out, the regional blood supplier is called, and the RBC units are picked up from the hospital laboratory by the regional supplier and transferred to the LTAC facility. The blood supplier invoices the LTAC facility for the cost of the RBC unit(s) that they deliver. Recently, the regional **blood supplier has informed the hospital system that they can no longer transfer** crossmatched RBC units between the hospitals and the LTAC facilities citing liability concerns. Furthermore, the hospital system was reportedly advised by the regional blood supplier that **in order for the healthcare system to transfer crossmatched RBC units between their network facilities, the hospital labs would have to register with the FDA as Distribution Centers**. The inquiring colleague wants to know if it is truly required that in order to transfer crossmatched RBC units between facilities that their hospital laboratories would be required to become FDA registered as distribution centers?

**ADDENDA** July 11, 2008

1. **Editors' Note:** The **advice** given to the inquiring facility by their blood provider **may have been incorrect**. The editors suggest that the inquiring facility can **submit their question to CBER** by e-mailing to [matt@cber.fda.gov](mailto:matt@cber.fda.gov).

Incidentally, "matt" is not a person as many people think. It is an abbreviation for "Manufacturers Assistance and Technical Training Branch"

Please submit comments to the [e-Network Forum](#).

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