

Blood Supply: Summary of Crucial Regulatory Options Already Available from FDA

PURPOSE:

Based on growing concerns and questions from hospitals and blood centers about inventory management strategies, AABB has confirmed our understanding with FDA to help you identify the current flexible shipping options that are widely misunderstood and underutilized! FDA's clarification is included in the **Summary of Crucial Shipping Options Already Available from FDA**

AABB is clarifying crucial regulatory options available to your facility today:

- to correct widespread misconceptions on shipping limitations
- to clarify that hospitals and unlicensed blood centers can ship licensed products across state lines
- to increase your ability to move licensed blood components in response to critical patient need
- to prevent the unnecessary outdate of blood products during this difficult time or anytime!

Please direct your questions to Regulatory@aabb.org

1. Shipment Of Licensed Blood Products Across State Lines

AABB has confirmed with FDA that both hospital transfusion services and blood collection establishments, regardless of FDA registration or licensure, may ship blood components across state lines if the blood component is:

- A licensed blood product, labeled with the license number of the manufacturer
- Transported in a validated shipping container as required by FDA and described below in Section 3.
- **At AABB's request, FDA confirmed the following on 1/19/22:**

"The 2021 'Ask the FDA' answer below is correct, however, to further clarify, the registered-only facility may distribute blood products from their licensed supplier to any facility intrastate or interstate, as long as the products are FDA-licensed."

From the AABB 2021 Annual Meeting [Ask the FDA Session](#):

Example: *We are an FDA registered (but not licensed) hospital-based blood collection facility. For the most part we are able to supply our own needs. However, there are times when we must purchase blood from outside sources. The purchased RBCs are labeled with the Blood Supplier license number.*

Question 9: *As an FDA registered only collection facility can we ship RBC inventory labeled with the license number of the supplier across state lines to a "sister" hospital Transfusion Service using shipping containers that we have validated for this purpose?*

FDA/OBRR Response to Question 9:

“Yes. The registered-only facility may distribute blood products from their supplier to a ‘sister’ facility in another state, as long as the products are FDA-licensed.”

Based on FDA’s confirmed response, AABB has developed the following table to supplement your understanding:

Shipment Of Licensed Blood Products Across State Lines	By an FDA Licensed Blood Collection Establishment	By an FDA Registered Blood Collection Establishment	By an FDA Registered Hospital Transfusion Service	By an Unregistered Transfusion Service
Shipment of an FDA-LICENSED blood product across states lines. <u>(the product is labeled with the license number of the manufacturer)</u>	ALLOWED (the blood component label displays the license number of the manufacturer)	ALLOWED (the blood component label displays the license number of the manufacturer)	ALLOWED (the blood component label displays the license number of the manufacturer)	ALLOWED only if the blood component label displays the license number of the manufacturer as confirmed via communication with FDA. Unregistered Transfusion Services which regularly engage in the shipment of blood should consider FDA registration.
Shipment of an UNLICENSED blood product across state lines. <u>(the product is not labeled with a manufacturer license number)</u>	NOT ALLOWED	NOT ALLOWED	NOT ALLOWED	NOT ALLOWED

EXAMPLES:

- 1) An FDA registered-only Transfusion Service in Texas may ship red blood cells, labeled with the manufacturer’s license number, across state lines to a Blood Center or Transfusion Service in Tennessee.
- 2) An FDA registered-only Blood Collection Establishment in Virginia may ship Fresh Frozen Plasma (purchased from a licensed manufacturer), labeled with the manufacturer’s license number across state lines to a Blood Center or Transfusion Service in Pennsylvania.

- 3) An unregistered Hospital Transfusion Service in Michigan may ship apheresis platelets, labeled with the manufacturer's license number, across state lines to a blood center or Transfusion Service in Ohio.
Note: Unregistered Transfusion Services which regularly engage in the shipment of blood should consider FDA registration.

2. Emergency Shipment of Unlicensed Products Across State Lines

- At AABB's request, FDA confirmed the following on 1/19/22:

“Regarding unlicensed blood products, Per Public Health Service Act Sec.351(a) (42 USC 262) ‘No person shall introduce or deliver for introduction into interstate commerce any biological product unless a biological license...is in effect for the biological product.’

However, per FDA Compliance Policy Guide (CPG) 220.100 entitled “Interstate Shipment Biologicals for Medical Emergency at weblink: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-220100-shipment-biologicals-medical-emergency>, **unscheduled and infrequent interstate shipments** of unlicensed blood products can take place in **medical emergencies**. In these cases, the Agency reserves the right to review the documentation relating to such incidents on an individual basis, to prevent the interstate shipment of unlicensed blood products under the guise of responding to a medical emergency. Such documentation must be maintained at the establishment that ships the product in response to the emergency. A blood product deviation report would not be required, provided the product was distributed using an emergency protocol, it was labeled appropriately, and all documentation is maintained and available for future FDA inspection.”

From the AABB 2021 Annual Meeting [Ask the FDA Session](#):

“Unscheduled and infrequent interstate shipments of blood products for use in medical emergencies, for which documentation is maintained and made available for Agency examination, do not ordinarily constitute the types of transactions that would require licensure.

The Agency reserves the right to review the documentation relating to such incidents on an individual basis, to prevent the interstate shipment of unlicensed blood products under the guise of responding to a medical emergency. Such documentation must be maintained at the establishment that ships the product in response to the emergency. A blood product deviation report would not be required, provided the product was distributed using an emergency protocol, it was labeled appropriately, and all documentation is maintained.”

3. OTHER CONSIDERATIONS:

- **Shipping Container Validation**

AABB has developed this [slide presentation](#) for your consideration to serve as a useful tool as your Transfusion Service considers shipment of blood and blood components.

- **Blood Drives Conducted Across State Lines by an FDA Registered-Only Blood Collection Establishment**

AABB has confirmed with FDA that an FDA Registered-Only Blood Collection Establishment may conduct a blood drive across state lines provided the blood is labeled by the registered establishment within the state listed on the registration and is not distributed outside of the state in which the facility is registered. A blood component from a registered establishment may not be distributed outside of the state in which it was labeled because it is an unlicensed product.

From the AABB 2021 Annual Meeting [Ask the FDA Session](#):

Question: *As an FDA registered only collection facility, can we conduct a mobile blood drive in a neighboring state if all the blood collected is returned to the location of the FDA registered facility for processing and labeling, but never distributed across state lines following labeling and lot release?*

FDA/OBRR Response:

“Yes, components collected on mobiles are associated with the registration number/FEI of the facility from which they originate. The components, however, are not considered licensed and cannot be distributed in interstate commerce.”

- **UPDATE FROM FDA - False-Positive MHA-TP Testing**

This adds new information related to increased discard of blood products:

Based on member feedback, AABB is aware of increasing deferrals due to false positive syphilis test results. AABB’s TTD Committee (TTD) has raised concerns to FDA about the increase in false-positive tests for syphilis.

In response to AABB’s invitation to the test manufacturer to present information to the TTD, Beckman Coulter shared, “We are exploring questions about this reagent with the manufacturer and others, as well as carrying on internal discussions. We will reach out to you when we have completed our assessment and have relevant information to share.”

FDA has confirmed the following-

1. With respect to the increase in false-positive testing for syphilis:
FDA: “We are aware of this issue and are investigating it.”
2. What can AABB do to support the agency’s efforts to resolve this?
FDA: “It is important for the blood establishments to report complaints in the appropriate FDA database and to the assay manufacturer.”

3. What options can be utilized by blood centers to resolve these false positive test results and avoid these deferrals?

FDA: There is a Newmarket treponemal test that was cleared on BC PK7400 assay platform. An alternative is to use an FDA-cleared non-treponemal donor screening test as the test of reference.

4. Is there any alternative procedure that would permit centers to label and distribute the product?

FDA: "No, FDA would not consider an alternative procedure that would permit a syphilis reactive unit to be labeled and distributed for use."

5. We noted that FDA [alerted](#) clinical laboratory staff and health care providers that "false reactivity, or "false-positive", Rapid Plasma Reagin (RPR; non-treponemal) test results, when using the Bio-Rad Laboratories BioPlex 2200 Syphilis Total & RPR kit, can occur in some people who received a COVID-19 vaccine. Based on information provided by the manufacturer, Bio-Rad Laboratories, RPR false reactivity was observed in some individuals for at least five months following a COVID-19 vaccination." Could the increase in false-positive MHA-TP testing be associated with the COVID-19 vaccine?

FDA: "We are aware of this issue. As of now, there is no evidence to infer an association of MHA-TP testing with COVID-19 vaccine."