

Amendment A00003
Solicitation Number VA256-17-R-0098
Questions & Answers

1. Page 5 – Credits and Incentives for MEDVAMC

It appears that this section is only referring to credits for returned RBCs. Does this section apply to all products? If so, do you expect 100% credit for all products returned within 2 days after expiration? If so, can you provide your outdate or expiration rate for the past 2 years by product?

Answer: A 100% credit applies for RBCs and Platelet. MEDVAMC do not return expired products and request a credit.

2. Question Section F, page 7- Labeling brings a concern to inventory management with limitations on our ability to ship O/A Rh negative blood with no more than (5) days from collection. Does this mean that all O/A Rh negative blood request has to filled with fresh products? Are there different standards for standing orders vs. non-standing orders?

Answer: The 5 days for O/A Rh negative product must be shipped not more than 5 days before the expiration date.

There is a difference between standing order and non -standing order.

A standing order is a blood product that the MEDVAMC need to have on the shelf on daily basis and the supplier is obligated to deliver these products daily.

Non-Standing order is blood product ordered from suppliers as needed.

3. Section J, page 9 – Storage – What is the meaning of “immediately after collection” when referring to the storage of RBCs? Is there a specific time requirement? Does this mean immediately after disconnecting the donor or immediately after processing the unit in our component lab?

Answer: Immediately after collection does not mean immediately after disconnecting the donor bag. Blood collected from the donor must go through the process of serologic screening test. It will be available as allogenic donor when the infectious marker test is completed. If blood products are received before the completion of the serologic test, it must be explained and the result of the serologic test must be communicated with the receiving facility.

4. The Blood Center has determined that a Business Associate Agreement is not applicable to our Services Agreement because the services we provide are part of an indirect treatment relationship as defined by the Health Insurance Portability and Accountability Act’s Privacy Rule, 45 CFR parts 160 and 164, subparts A and E (“HIPAA” or “Privacy Rule”). Accordingly, the contractual relationship between Hospital and The Blood Center does not meet the definition of a business associate as that term is defined in the Privacy Rule. Is this a requirement to providing blood services to MEDVAMC? The Blood Center is, of course, committed to the privacy principles in the HIPAA Privacy Rule and will maintain the confidentiality of protected health information as required by applicable Texas and federal laws. However, we believe a business associate agreement for this

contractual arrangement is neither required nor needed, and it places unnecessary obligations on each party to the agreement.

Answer: BAA is not applicable. Contractor will not be required to enter into a BAA with the MEDVAMC.

5. **Page 15, item # 0017 – Is this referring to platelets from whole blood donations or apheresis platelets?**

It refers to Apheresis platelet.