

December 20, 2016

Topic: Lookback services for non-conforming products

Blood Bank of Delmarva (BBD) Agreement Customer,

This memo is being distributed to our clients who hold a Blood Products and Blood Related Services Agreement with BBD to address updates to language in our agreements under the section titled "Look-Back service for non-conforming products." In this section of our current agreements we reference regulation 42 CFR 482.27(c). We want to advise that we also will perform look-back service in compliance with 42 CFR 482.27(b). Some customers have found that this particular provision of the federal law is referenced in some JCAHO inspection audits. At the time of your next BBD agreement renewal, we will update the language in the agreement to the following statement.

If BBD had supplied [customer] with BLOOD PRODUCTS, which are determined to be non-conforming for any reason by BBD, BBD will perform look back services at no charge to [customer] in compliance with applicable provisions of law, including, specifically pertinent provision of federal law codified in regulations at 21 CFR 610.46-610.47 and 42 CFR 482.27. Non-conforming products are defined as having the potential to impact the safety, purity, potency, and/or identity of the blood product.

Although our current language is generic enough in stating that we comply with applicable provisions of law, we believe this modification will aid in specifically addressing any external audit concerns you may encounter from JCAHO, AABB or others. We will leave off the reference of subpart (c) for code 42 CFR 482.27 as our practice is compliant with the entire provision.

In the meantime, please keep this notification with your agreement records as evidence of compliance in the event an auditor requests this information.

If you have any questions about this communication or change, please feel free to contact me.

Respectfully,



Richard C. Thomas

Vice President, Blood Services

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