Chapter 11 Section 5.1

Provider Standards For Potentially Human Immunodeficiency Virus (HIV) Infectious Blood And Blood Products

Issue Date: July 8, 1998
Authority: 21 CFR 606.100; 21 CFR 610.45, 46, and 47; 42 CFR 482.27
Revision:

1.0 ISSUE

Provider standards for potentially Human Immunodeficiency Virus (HIV) infectious blood and blood products.

2.0 POLICY

Authorized providers are subject to the requirements published in the **Federal Register** on September 9, 1996, by the Centers for Medicare and Medicaid Services (CMS) and the U.S. Food and Drug Administration (FDA) that will ensure proper health and safety steps are taken to minimize further spread of HIV infection. The CMS Final Rule provides standards for Medicare and Medicaid participating hospitals and the FDA Final Rule provides standards for blood establishments.

The CMS Final Rule requires hospitals participating in the Medicare and Medicaid programs to take appropriate action when the hospitals learn they have received blood or blood products that are at increased risk of transmitting HIV infection. If the hospital learns it has received blood or blood products collected from a donor recently exposed to HIV, before the donor has a sufficient level of antibody to be detected by the screening test for antibody to HIV, the hospital must quarantine any blood or blood products remaining in inventory pending confirmatory testing. If the presence of HIV is confirmed by more specific testing, the hospital must notify patients who received the blood or blood product.

The FDA Final Rule applies the same requirements to entities furnishing transfusion services that do not participate in Medicare and Medicaid programs and clarifies the responsibilities of blood establishments to identify and notify the transfusion service that received affected blood and blood products.

3.0 EFFECTIVE DATE

The effective date of these regulations is November 8, 1996.

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