May 2015 Final Rule Resources

Overview:

This web page is intended to consolidate AABB resources related to the Food and Drug Administration's (FDA) May 2015 Final Rule, "Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use," (referred to here as the Final Rule). In the Final Rule, the FDA finalized extensive changes. Many of the revisions in the 2007 proposed rule were finalized without further change; however, some proposals were modified, and others were not finalized.

Since FDA issued the Final Rule, AABB has published numerous documents and articles to keep members informed regarding changes necessary for compliance by the Final Rule's effective date of May 23, 2016.

Resources and postings related to the Final Rule:

05/22/15 FDA published the Final Rule, "Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use".

07/14/15 AABB posted an analysis of the May 2015 Final Rule, "Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use."

09/21/15 FDA Liaison Committee Meeting: AABB's FDA Liaison Committee met with staff from the Center for Biologics Research and Evaluation (CBER) to discuss the new requirements of the Final Rule, with specific questions and concerns related to hemoglobin, pulse, autologous and directed donors, plasma for further manufacture.

01/26/16 Ask the FDA and CMS/CLIA Transcript from 2015 AABB Annual Meeting: Opening presentations from FDA addressed a range of new requirements and changes in the Final Rule, including the addition of a definition for relevant transfusion transmitted infections (RTTI), changes in testing, donor screening, pulse, hemoglobin, and other eligibility criteria, adequate control of risk of bacterial contamination in platelets, and medical supervision. Questions were also addressed by representatives from the Division of Human Tissues, Office of Cellular, Tissue and Gene Therapies, CBER, and the Division of Laboratory Services, Survey & Certification Group, Center for Medicaid & State Operations, Center for Medicare and Medicaid Services.

05/09/16 AABB-FDA Executive Level Liaison Meeting – In this meeting of AABB and FDA staff, AABB shared the work in progress for development of "templates" to assist members who pursue FDA approval of standard operating procedures for collections from females with a hemoglobin level between 12.0 and 12.4 g/dL, as provided in the Final Rule.

05/20/16 In the article, FDA Acceptance of Version 2.0 Blood Donor Questionnaire Materials Still Pending, AABB addressed issues to consider when implementing new donor eligibility requirements in the Final Rule by the deadline of May 23, 2016 while awaiting FDA acceptance of v2.0 DHQ.

05/27/16 AABB News Flash: AABB posted version 2.0 Blood Donor History Questionnaires and accompanying materials formally recognized by FDA in guidance on 05/27/16 and

consistent with the new requirements of the Final Rule. The companion Weekly Report article, FDA Recognizes Version 2.0 DHQs and Accompanying Materials, provided additional details and directed readers to Change Tables for the v2.0 DHQ, located under the Supporting Documents Tab.

07/29/16 Female donors with hemoglobin less than 12.5 g/dL: AABB announced the posting of two new web pages with proposed strategies for collections from female blood donors with hemoglobin levels of 12.0 - <12.5 g/dL (a new option provided in 21 CFR 630.10(f)(3)(i)(A) of the Final Rule), on the web page, Management of risk for iron deficiency in female blood donors with HB levels of 12.0 - <12.5. The proposed strategies are intended to assist blood collection establishments with developing SOPs for submission to FDA in a prior approval supplement.

08/05/16 Clarification of Autologous Issues: AABB provided an overview of FDA's guidance document, Determining Donor Eligibility for Autologous Donors of Blood and Blood Components Intended Solely for Autologous Use, intended to clarify the agency's policy. FDA developed the guidance in response to questions concerning the Final Rule.

09/02/16 AABB posted analysis of Aug 2016 FDA Guidance : AABB provided an overview of the new authority granted to CBER in the Final Rule. The new regulations permitted the Director of CBER to approve an alternative procedure, to support recommendations for testing of all donors for Zika Virus (as a new RTTI) in the absence of licensed, approved, or cleared test required in § 630.3(h)(2). As a part of the analysis of the FDA's August 2016 Zika Guidance, the article explained FDA's use of the new regulations (found at § 640.120(b)) for the first time. The article gives insight into how CBER may use FDA's authority under the new regulations to make similar decisions in the future.