

HRSA Requirements for Cord Blood Bank Accreditation

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Presentation Overview

- **Accreditation issue for Council's advice**
- **Background:**
 - Statutory requirements for National Cord Blood Inventory (NCBI) accreditation
 - HRSA NCBI contract requirements for accreditation
 - HRSA action on accreditation



Issue for Council's Advice

Issue: When an NCBI cord blood bank is accredited by more than one entity and its accreditation is suspended or terminated by one, what action, if any, should be taken?



Statutory Requirements

Stem Cell Therapeutic and Research Act of 2015, initial authorization in 2005

Cord Blood Bank Accreditation Requirements:

- Through a public process, the Secretary shall recognize one or more accreditation entities for the accreditation of cord blood banks
- Through accreditation standards, the Secretary shall ensure that a cord blood unit is acquired with the informed consent of the maternal donor



HRSA Action on Accreditation

- **In 2008, Advisory Council on Blood Stem Cell Transplantation (ACBSCT) approved Draft Specifications for NCBI Cord Blood Bank Accrediting Organizations**
 - Developed in consultation with ACBSCT
 - Specified minimum requirements for a recognized entity
- **In 2009, ACBSCT recommended “recognition” of AABB and Foundation for the Accreditation of Cellular Therapy (FACT)**
- **In 2011, Specifications approved by HRSA**
- **In 2011, HRSA Memoranda of Understanding with AABB & FACT, renewed annually**
- **In 2013, HRSA experience with AABB & FACT reviewed by ACBSCT (no changes proposed)**



HRSA NCBI Contract Requirements

- **Have and maintain cord blood bank accreditation from a recognized accrediting organization**
- **Submit new or renewed certifications and changes in status**
- **Report any deficiencies or non-conformities, and the final resolution and corrective actions**
- **Provide copies of inspection reports**
- **Comply with accreditation as a daily practice**
- **Comply with additional HRSA requirements that may be part of the accreditation process or an addendum**



HRSA NCBI Contract Requirements (cont'd)

- **Contract requirements may differ from accreditation standards**
- **Accrediting organization may be asked to assess the bank against specific HRSA criteria**



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