

[Federal Register: April 27, 2006 (Volume 71, Number 81)]  
[Notices]  
[Page 24858-24859]  
From the Federal Register Online via GPO Access [wais.access.gpo.gov]  
[DOCID:fr27ap06-51]

-----  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

C.W. Bill Young Cell Transplantation Program: National Cord Blood Inventory; Recognition of Cord Blood Bank Accreditation Program(s)

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of opportunity for public comment through conference calls.

-----  
SUMMARY: Public Law 109-129 requires the Secretary of Health and Human Services to recognize one or more cord blood accreditation entities for the accreditation of cord blood banks participating in the collection and maintenance of umbilical cord blood units for the National Cord Blood Inventory. These cord blood units will be made available for unrelated donor blood stem cell transplants through the C.W. Bill Young Cell Transplantation Program. The HRSA, Healthcare Systems Bureau (HSB), Division of Transplantation (DoT) is in the process of information-gathering to assist in the determination of which cord blood bank accreditation program(s) to recognize on an interim basis for the initial cycle of funding for the National Cord Blood Inventory. The purpose of this solicitation is to receive public input on the following: (1) Approaches to accreditation required to ensure quality cord blood bank operations (including collection sites); (2) Utilization of accreditation programs to ensure product quality and best practices; (3) Degree to which accreditation standards are evidence based and supported by published literature; (4) Extent to which accreditation standards allow for variations in cord blood bank practices; (5) Criteria for the Secretary to consider in recognizing cord blood bank accrediting programs for the National Cord Blood Inventory, C.W. Bill Young Cell Transplantation Program.

The HRSA intends for this interim process to be followed by a formal, more comprehensive recognition process that will include input from both the Advisory Council, once it is established, and the interested public as required in the legislation. The purpose of this Notice is to invite interested parties to register for and participate in either of two conference calls, described below, that HRSA is scheduling to obtain comment on factors relevant to determining which accrediting organization(s) to recognize for the initial cycle of funding under the National Cord Blood Inventory.

DATES: The conference calls will be held on May 9, 2006, at 2 to 4 p.m. e.s.t. and May 15, 2006, at 2 p.m. to 4 p.m. e.s.t. Participants are asked to register for the conference by contacting Anita Wabeke at (301) 443-4747 or e-mail [awabeke@hrsa.gov](mailto:awabeke@hrsa.gov). The registration deadline is May 3, 2006 for both conferences. Registration is not guaranteed; it is on a first come basis. Since the topics listed above will be discussed on both calls, and to facilitate hearing all points of view, HRSA requests that organizations and individuals wishing to participate do so in only one of the calls. Due to the limited number of lines

available for the calls, organizations with multiple participants are encouraged to register for one line to allow maximum participation from all interested parties. Parties wishing to submit written comments should ensure that the comments are postmarked or E-mailed no later than May 17, 2006 for consideration.

ADDRESSES: Please send all written comments to James F. Burdick, M.D., Director, DoT, HSB, HRSA, Room 12C-06, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443-7577; fax (301) 594-6095; or e-mail: [jburdick@hrsa.gov](mailto:jburdick@hrsa.gov).

FOR FURTHER INFORMATION CONTACT: James F. Burdick, M.D., Director, DoT, HSB, HRSA, Parklawn Building, Room 12C-06, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443-7577; fax (301) 594-6095; or e-mail: [jburdick@hrsa.gov](mailto:jburdick@hrsa.gov).

SUPPLEMENTARY INFORMATION:

Background

On December 20, 2005, the Stem Cell Therapeutic Act of 2005 was enacted as Public Law 109-129. The Act authorizes the establishment of the National Cord Blood Inventory and the C.W. Bill Young Cell Transplantation Program as the successor to the National Bone Marrow Donor Registry. The National Cord Blood Inventory is to be a high quality, genetically diverse inventory of cord blood units for patients who need a blood stem cell transplant and who lack an available related donor. The cord blood units in the National Cord Blood Inventory will be made available for transplantation through the C.W. Bill Young Cell Transplantation Program. Cord blood banks collecting and maintaining units for the National Cord Blood Inventory must meet the statutory definition of a qualified cord blood bank, which includes a requirement that cord blood banks be accredited by an accreditation entity recognized by the Secretary for this purpose.

Program Authority

The C.W. Bill Young Cell Transplantation Program is authorized by Public Law 109-129, which amends Part I of the Public Health Service Act.

Dated: April 20, 2006.

Elizabeth M. Duke,  
Administrator.

[FR Doc. E6-6313 Filed 4-26-06; 8:45 am]  
BILLING CODE 4165-15-P