DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Services Administration
C.W. Bill Young Cell Transplantation Program: National Cord Blood Inventory Related Cord Blood Donor Demonstration Project

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

ACTION: Request for information.

SUMMARY: Public Law 109–129 requires the Secretary of Health and Human Services to establish a 3-year demonstration project for qualified cord blood banks to collect and store at no charge to families, umbilical cord blood units for families where a first-degree relative has been diagnosed with a condition that may benefit from blood stem cell transplantation. Umbilical cord blood units collected through the demonstration project do not count toward the current National Cord Blood Inventory (NCBI) goal of 150,000 cord blood units to be made available through the C.W. Bill Young Cell Transplantation Program. Qualified umbilical cord blood banks participating in the demonstration project must provide assurances that the cord blood units will be available for directed transplantation until such time as the cord blood unit is needed. Within 90 days of the termination of the demonstration project, the Secretary will submit to Congress a report on the outcomes of the project including recommendations with respect to the continuation of such a project.

HRSA’s Healthcare Systems Bureau (HSB), Division of Transplantation (DoT) is in the process of information-gathering to assist in implementation of the related cord blood demonstration project. The purpose of this solicitation is to receive public input on the following: (1) The key questions that should be studied through this project; (2) the mechanism for funding this project; and, (3) umbilical cord blood bank liability.

HRSA has identified the following key study questions to be considered in the design of this demonstration project: (1) What is the value and feasibility of implementing a long-term program modeled after this demonstration project; (2) how often and for what clinical indications are cord blood units banked through this project used for transplantation; (3) what is the breakdown of cord blood units collected, stored, and transplanted by race, ethnicity, and disease; (4) do those cord blood units, especially those released for transplant, represent rare Human Leukocyte Antigen (HLA) types such that the recipient would otherwise have been unable to find a matched unrelated donor; (5) how do transplant outcomes using these cord blood units compare to unrelated allogeneic umbilical cord blood transplants and unrelated allogeneic transplants using blood stem cells from adult donors; and, (6) what are the general physical characteristics of these units (e.g., total nucleated count, CD34+ content) and how does their quality compare to that of the general public inventory.

HRSA proposes to invite the first cohort of umbilical cord blood banks receiving NCBI contracts to submit competitive proposals for participation in this demonstration project with an emphasis on: (1) Establishment of nationwide collections; and, (2) encouraging banks to subcontract with other experienced, high-quality cord blood banks to assist in their education, collection, processing, and storing efforts. HRSA has approximately $200,000 available for this demonstration project this fiscal year and anticipates selecting 2 or 3 banks to participate in this demonstration project to be funded through modification of their existing NCBI contracts with HRSA.

HRSA recognizes the need for this service is likely greater than what can be satisfied in a limited demonstration project. Because of the great diversity in HLA types among African-Americans, HRSA recognizes that patients from this population are significantly less likely to find a suitably matched unrelated blood stem cell donor than patients from other racial or ethnic groups. Therefore, HRSA invites comments on the desirability of limiting participation to African-American families in which a first-degree relative has been diagnosed with a condition that may benefit from blood stem cell transplantation.

HRSA understands that there may be special considerations associated with liability for those umbilical cord blood banks participating in this project.

HRSA invites comment on how umbilical cord blood banks participating in this project may best address these concerns.

Interested parties are invited to submit written comments on the key study questions, the funding approach, and umbilical cord blood bank liability for this demonstration project to the address below.

DATES: Written comments must be received at HRSA by June 18, 2007. Comments will be made publicly available.
available by submitting a written request to the address below.

**ADDRESSES:** Please send all written comments to: James F. Burdick, M.D.; Attn: Related Cord Blood Demo Project; HHS/HRSA/HSB/DoT; 5600 Fishers Lane, Room 12C–06; Rockville, Maryland 20857; telephone (301) 443–7577; fax (301) 594–6095; or e-mail: jburdick@hrsa.gov. Please include in the subject line of electronic correspondence “Related Cord Blood Demo Project.”

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

**SUPPLEMENTAL INFORMATION:**

**Background**

On December 20, 2005, the Stem Cell Therapeutic and Research 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 successor to the National Bone Marrow Donor Registry. The National Cord Blood Inventory is to be comprised of 150,000 high quality, genetically diverse cord blood units to be made available through the C.W. Bill Young Cell Transplantation Program for patients in need of a blood stem cell transplant. The Act also authorizes establishment of a 3-year related cord blood donor demonstration project to begin in FY 2007.

**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.


Elizabeth M. Duke, Administrator.

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**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

**Federal Emergency Management Agency**

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice and request for comments.