



HRSA Update

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Health Resources and Services Administration
U.S. Department of Health and Human Services

Presentation Overview

- Review statutory goals of the C.W. Bill Young Cell Transplantation Program (Program) and National Cord Blood Inventory (NCBI)
- Provide information on the appropriation level for C.W. Bill Young Cell Transplantation Program (Program) and National Cord Blood Inventory (NCBI)
- Provide NCBI update
 - FY 2013 Data
- Provide Program update
 - FY 2013 Data
 - Notice of Public Rule Making

C.W. Bill Young Cell Transplantation Program (Program)

- Authorized by Stem Cell Therapeutic and Research Act of 2005 (P.L. 109-129)
 - Reauthorized October, 2010 (P.L. 111-264)
- Goals are to increase:
 - Number of unrelated-donor transplants
 - Recruitment of potential marrow donors
 - Patient and donor advocacy services
 - Public and professional education re transplantation
 - Analysis and reporting of transplant outcomes data
- Opportunity to help more patients obtain transplants, other therapies, with blood stem cells

National Cord Blood Inventory (NCBI)

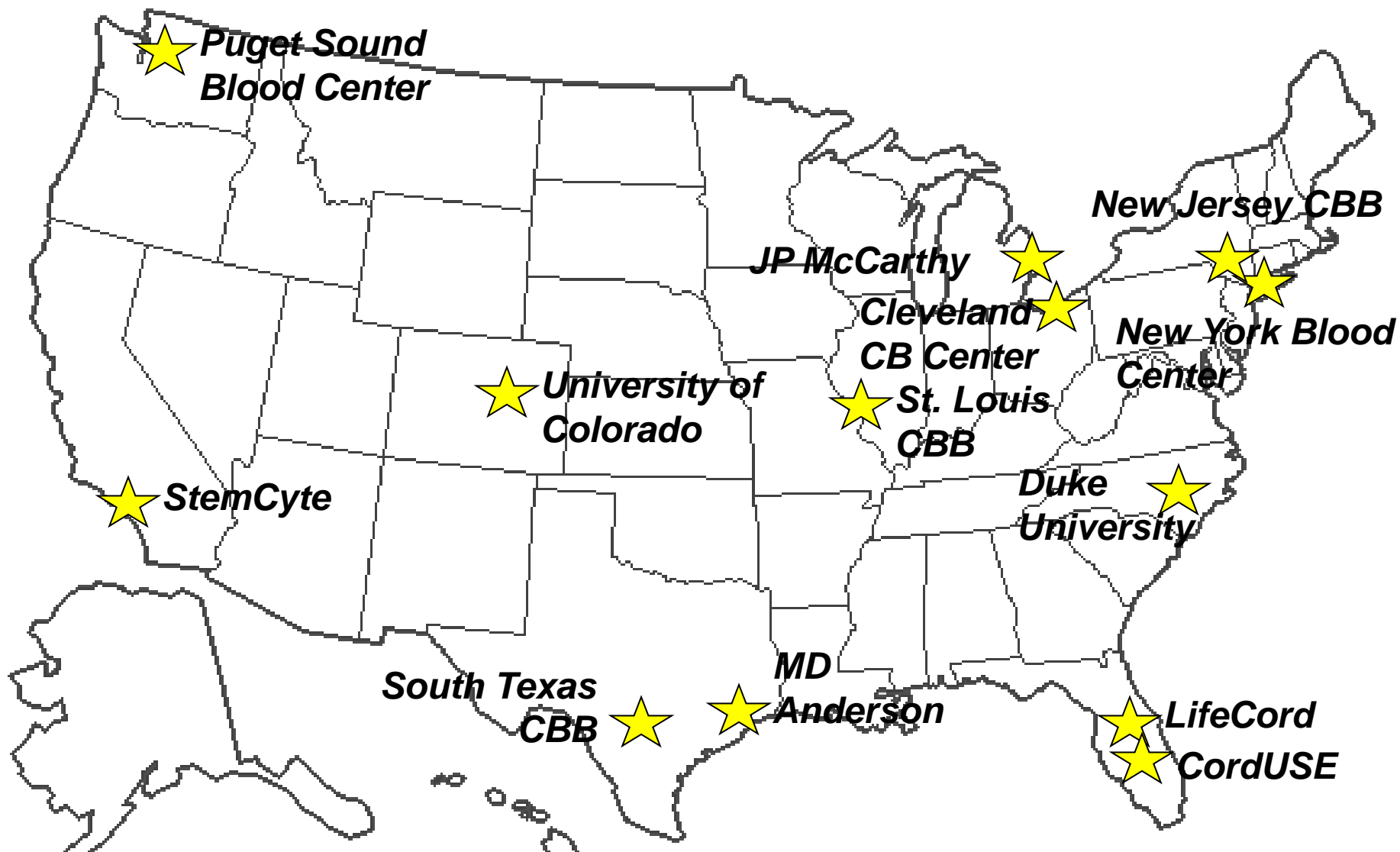
- Authorized by Stem Cell Therapeutic and Research Act of 2005 (reauthorized in 2010)
- Goals are to:
 - Provide funding to cord blood banks to collect, process, store and make available high-quality, diverse umbilical cord blood units (CBU)
 - Target the collection of at least 150,000 new units
 - Make cord blood units that are not appropriate for transplantation available for research

Appropriation Level by Fiscal Year	C.W. Bill Young Cell Transplantation Program	National Cord Blood Inventory (NCBI)
2013 Final	\$21,877,000	\$11,147,000
2014 Final	\$22,154,000	\$11,238,000
2015 President's Budget	\$22,109,000	\$11,266,000

The National Cord Blood Inventory (NCBI)

NCBI Update

- The NBCI consists of high quality CBU collected by contractors representing thirteen accredited, public, cord blood banks.
- The NCBI cord blood banks are geographically dispersed across the United States.
- The NCBI contractors collect cord blood units from approximately 110 birthing centers. Some NCBI banks also make kits available to expectant mothers for remote collection capabilities.



NCBI Statistics

- 63,960 NCBI cord blood units available through the Program, as of September 30, 2013
 - Subsequent slide provides updated # of CBU demographics and contract targets
- 714 NCBI CBU distributed for transplant in FY 2013
 - 714 in FY 2012

NCBI Demographics and Funded Targets

	Black/ African- American	Asian	Native Hawaiian & American Indian /Alaska Native	White (non- Hispanic or Latino)	White (Hispanic or Latino)	Multiple Race	Total
# of NCBI CBU Available through Program as of 9/30/2013 (%)	8,706 (13.6)	2,919 (4.6)	159 (0.2)	24,588 (38.4)	20,042 (31.3)	7,546 (11.8)	63,960
# NCBI Funded Target (through FY 2013)	11,914 (14.9)	4,027 (5.0)	232 (0.3)	30,167 (37.9)	23,660 (29.7)	9,592 (12.1)	79,592

C.W. Bill Young Cell Transplantation Program

Update on the C.W. Bill Young Cell Transplantation Program (Program), cont'd

- The Program serves a growing number of patients in need of unrelated donor transplantation
 - As of September 30, 2013 (end FY 2013), the Program's registry included approximately 11.2 million adult donors
 - More than 3.05 million (27 percent) self-identify as belonging to a racial/ethnic minority
 - In FY 2013, 397,584 adult donors were added to the Program's registry
 - 205,607 (52%) self-identified as belonging to racial/ethnic minority group

Update on the C.W. Bill Young Cell Transplantation Program (Program), cont'd

- The total number of cord blood units available through the Program in FY 2013 exceeded 193,000
- The total number of transplants facilitated in FY 2013 was 6,283 (compared to 5,832 in FY 2012 – a 7.7% increase)
- The total number of domestic transplants was 4,866 in FY 2013 (compared to 4,427 in FY 2012 - a 9.7% increase)
- The total number of cord blood transplants (NCBI and non-NCBI) was 1,102 (compared to 1,191 in FY 2012 –a decrease of 7.4%)
- The total number of cord blood units (NCBI and non-NCBI) shipped in FY 2013 was 1,575 (compared to 1,637 in FY 2012 –a decrease of 3.8%)

Publically available information on HRSA's Notice of Proposed Rule Making (NPRM)

- Released on October 2, 2013
- Purpose – To seek public comment on the proposed change in the definition of “human organ” in section 301 of the National Organ and Transplant Act of 1984, as amended, (NOTA) to explicitly incorporate hematopoietic stem cells (HSCs) within peripheral blood in the definition of “bone marrow.” This would clarify that the prohibition on transfers of human organs for valuable consideration applies to HSCs regardless of whether they were recovered directly from bone marrow (by aspiration) or from peripheral blood (by apheresis). This amendment will also conform section 301 to the provisions of the Stem Cell Research and Therapeutic Act of 2005, as amended.

Publically available information on HRSA's NPRM (cont'd)

- Deadline: December 2, 2013
- Comments received: 533
- Next steps: pending

Questions?



Contact Information



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