111TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPORT
111–643

STEM CELL THERAPEUTIC AND RESEARCH REAUTHORIZATION ACT OF 2010

SEPTEMBER 28, 2010.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. WAXMAN, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 6081]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 6081) to amend the Stem Cell Therapeutic and Research Act of 2005, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

89–006

AMENDMENT

The amendment is as follows:
Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Stem Cell Therapeutic and Research Reauthorization Act of 2010".

SEC. 2. AMENDMENTS TO THE STEM CELL THERAPEUTIC AND RESEARCH ACT OF 2005.

(a) CORD BLOOD INVENTORY.—Section 2 of the Stem Cell Therapeutic and Research Act of 2005 (42 U.S.C. 274k note) is amended—

(1) in subsection (a), by inserting "the inventory goal of at least" before "150,000";

(2) in subsection (c)—

(A) in paragraph (2), by striking "or is transferred" and all that follows through the period and inserting "for a first-degree relative."; and

(B) in paragraph (3), by striking "150,000";

(3) in subsection (d)—

(A) in paragraph (1), by inserting "beginning on the last date on which the recipient of a contract under this section receives Federal funds under this section" after "10 years";

(B) in paragraph (2), by striking "; and" and inserting ";";

(C) by redesignating paragraph (3) as paragraph (5); and

(D) by inserting after paragraph (2) the following:

"(3) will provide a plan to increase cord blood unit collections at collection sites that exist at the time of application, assist with the establishment of new collection sites, or contract with new collection sites;

"(4) will annually provide to the Secretary a plan for, and demonstrate, ongoing measurable progress toward achieving self-sufficiency of cord blood unit collection and banking operations; and";

(4) in subsection (e)—

(A) in paragraph (1)—

(i) by striking "10 years" and inserting "a period of at least 10 years beginning on the last date on which the recipient of a contract under this section receives Federal funds under this section"; and

(ii) by striking the second sentence and inserting "The Secretary shall ensure that no Federal funds shall be obligated under any such contract after the date that is 5 years after the date on which the contract is entered into, except as provided in paragraphs (2) and (3).";

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A)—

(I) by striking "Subject to paragraph (1)(B), the" and inserting "The"; and

(II) by striking "3" and inserting "5";

(ii) in subparagraph (A) by striking "150,000" and all that follows through "and" at the end and inserting "the inventory goal described in subsection (a) has not yet been met;";

(iii) in subparagraph (B)—

(I) by inserting "meeting the requirements under subsection (d)" after "receive an application for a contract under this section"; and

(II) by striking "or the Secretary" and all that follows through the period at the end and inserting "; or"; and

(iv) by adding at the end the following:

"(C) the Secretary determines that the outstanding inventory need cannot be met by the qualified cord blood banks under contract under this section."; and

(C) by striking paragraph (3) and inserting the following:

"(3) EXTENSION ELIGIBILITY.—A qualified cord blood bank shall be eligible for a 5-year extension of a contract awarded under this section, as described in paragraph (2), provided that the qualified cord blood bank—

"(A) demonstrates a superior ability to satisfy the requirements described in subsection (b) and achieves the overall goals for which the contract was awarded;

"(B) provides a plan for how the qualified cord blood bank will increase cord blood unit collections at collection sites that exist at the time of consideration for such extension of a contract, assist with the establishment of new collection sites, or contract with new collection sites; and

"(C) annually provides to the Secretary a plan for, and demonstrates, ongoing measurable progress toward achieving self-sufficiency of cord blood unit collection and banking operations.";

(5) in subsection (g)(4), by striking "or parent"; and

(6) in subsection (h)—

(A) by striking paragraphs (1) and (2) and inserting the following:

"(1) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary to carry out the program under this section $23,000,000 for each of fiscal years 2011 through 2014 and $20,000,000 for fiscal year 2015.";

(B) by redesignating paragraph (3) as paragraph (2); and

(C) in paragraph (2), as so redesignated, by striking "in each of fiscal years 2007 through 2009" and inserting "for each of fiscal years 2011 through 2015".

(b) NATIONAL PROGRAM.—Section 379 of the Public Health Service Act (42 U.S.C. 274k) is amended—

(1) by striking subsection (a)(6) and inserting the following:

"(6) The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall submit to Congress an annual report on the activities carried out under this section.";

(2) in subsection (d)—

(A) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by striking "With respect to cord blood, the Program shall—" and inserting the following:

"(A) IN GENERAL.—With respect to cord blood, the Program shall—";

(ii) by redesignating subparagraphs (A) through (H) as clauses (i) through (viii) respectively (with appropriate indentation);

(iii) by striking clause (iv), as so redesignated, and inserting the following:

"(iv) support and expand new and existing studies and demonstration and outreach projects for the purpose of increasing cord blood unit donation and collection from a genetically diverse population and expanding the number of cord blood unit collection sites partnering with cord blood banks receiving a contract under the National Cord Blood Inventory program under section 2 of the Stem Cell Therapeutic and Research Act of 2005, including such studies and projects that focus on—

"(I) remote collection of cord blood units, consistent with the requirements under the Program and the National Cord Blood Inventory program goal described in section 2(a) of the Stem Cell Therapeutic and Research Act of 2005; and

"(II) exploring novel approaches or incentives to encourage innovative technological advances that could be used to collect cord blood units, consistent with the requirements under the Program and such National Cord Blood Inventory program goal;"; and

(iv) by adding at the end the following:

"(B) EFFORTS TO INCREASE COLLECTION OF HIGH QUALITY CORD BLOOD UNITS.—In carrying out subparagraph (A)(iv), not later than 1 year after the date of enactment of the Stem Cell Therapeutic and Research Reauthorization Act of 2010 and annually thereafter, the Secretary shall set an annual goal of increasing collections of high quality cord blood units, consistent with the inventory goal described in section 2(a) of the Stem Cell Therapeutic and Research Act of 2005 (referred to in this subparagraph as the 'inventory goal'), and shall identify at least one project under subparagraph (A)(iv) to replicate and expand nationwide, as appropriate. If the Secretary cannot identify a project as described in the preceding sentence, the Secretary shall submit a plan, not later than 180 days after the date on which the Secretary was required to identify such a project, to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives for expanding remote collection of high quality cord blood units, consistent with the requirements under the National Cord Blood Inventory program under section 2 of the Stem Cell Therapeutic and Research Act of 2005 and the inventory goal. Each such plan shall be made available to the public.

"(C) DEFINITION.—In this paragraph, the term 'remote collection' means the collection of cord blood units at locations that do not have written contracts with cord blood banks for collection support."; and

(B) in paragraph (3)(A), by striking "(2)(A)" and inserting "(2)(A)(i)"; and

(3) by striking subsection (f)(5)(A) and inserting the following:

"(A) require the establishment of a system of strict confidentiality to protect the identity and privacy of patients and donors in accordance with Federal and State law; and".

(c) ADDITIONAL REPORTS.—

(1) INTERIM REPORT.—In addition to the annual report required under section 379(a)(6) of the Public Health Service Act (42 U.S.C. 274k(a)(6)), the Secretary of Health and Human Services (referred to in this subsection as the "Secretary"), in consultation with the Advisory Council established under such section 379, shall submit to Congress an interim report not later than 180 days after the date of enactment of this Act describing—

(A) the methods to distribute Federal funds to cord blood banks used at the time of submission of the report;

(B) how cord blood banks contract with collection sites for the collection of cord blood units; and

(C) recommendations for improving the methods to distribute Federal funds described in subparagraph (A) in order to encourage the efficient collection of high-quality and diverse cord blood units.

(2) RECOMMENDATIONS.—Not later than 1 year after the date of enactment of this Act, the Advisory Council shall submit recommendations to the Secretary with respect to—

(A) whether models for remote collection of cord blood units should be allowed only with limited, scientifically-justified safety protections; and

(B) whether the Secretary should allow for cord blood unit collection from routine deliveries without temperature or humidity monitoring of delivery rooms in hospitals approved by the Joint Commission.

(d) AUTHORIZATION OF APPROPRIATIONS.—Section 379B of the Public Health Service Act (42 U.S.C. 274m) is amended by striking "$34,000,000" and all that follows through the period at the end, and inserting "$30,000,000 for each of fiscal years 2011 through 2014 and $33,000,000 for fiscal year 2015.".

(e) REPORT ON CORD BLOOD UNIT DONATION AND COLLECTION.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate, the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, and the Secretary of Health and Human Services a report reviewing studies, demonstration programs, and outreach efforts for the purpose of increasing cord blood unit donation and collection for the National Cord Blood Inventory to ensure a high-quality and genetically diverse inventory of cord blood units.

(2) CONTENTS.—The report described in paragraph (1) shall include a review of such studies, demonstration programs, and outreach efforts under section 2 of the Stem Cell Therapeutic and Research Act of 2005 (42 U.S.C. 274k note) (as amended by this Act) and section 379 of the Public Health Service Act (42 U.S.C. 274k) (as amended by this Act), including—

(A) a description of the challenges and barriers to expanding the number of cord blood unit collection sites, including cost, the cash flow requirements and operations of awarding contracts, the methods by which funds are distributed through contracts, the impact of regulatory and administrative requirements, and the capacity of cord blood banks to maintain high-quality units;

(B) remote collection or other innovative technological advances that could be used to collect cord blood units;

(C) appropriate methods for improving provider education about collecting cord blood units for the national inventory and participation in such collection activities;

(D) estimates of the number of cord blood unit collection sites necessary to meet the outstanding national inventory need and the characteristics of such collection sites that would help increase the genetic diversity and enhance the quality of cord blood units collected;

(E) best practices for establishing and sustaining partnerships for cord blood unit collection at medical facilities with a high number of minority births;

(F) potential and proven incentives to encourage hospitals to become cord blood unit collection sites and partner with cord blood banks participating in the National Cord Blood Inventory under section 2 of the Stem Cell Therapeutic and Research Act of 2005 and to assist cord blood banks in expanding the number of cord blood unit collection sites with which such cord blood banks partner;

(G) recommendations about methods cord blood banks and collection sites could use to lower costs and improve efficiency of cord blood unit collection without decreasing the quality of the cord blood units collected; and

(H) a description of the methods used prior to the date of enactment of this Act to distribute funds to cord blood banks and recommendations for how to improve such methods to encourage the efficient collection of high-quality and diverse cord blood units, consistent with the requirements of the C.W. Bill Young Cell Transplantation Program and the National Cord Blood Inventory program under section 2 of the Stem Cell Therapeutic and Research Act of 2005.

(f) DEFINITION.—In this Act, the term "remote collection" has the meaning given such term in section 379(d)(2)(C) of the Public Health Service Act.

PURPOSE AND SUMMARY

H.R. 6081, the "Stem Cell Therapeutic and Research Reauthorization Act of 2010", was introduced by Rep. C. W. Bill Young (R–FL) and Doris O. Matsui (D–CA) on August 9, 2010, and referred to the Committee on Energy and Commerce.

The goal of H.R. 6081 is to reauthorize the C.W. Bill Young Cell Transplantation Program, which includes the National Registry for adult donors of bone marrow, peripheral blood (adult) stem cells, and umbilical cord blood units; the Office of Patient Advocacy; and the Stem Cell Therapeutic Outcomes Database. H.R. 6081 also reauthorizes the National Cord Blood Inventory (NCBI) Program, a program that provides grants to public cord blood banks to assist them in collecting donated cord blood units, which, in turn, are listed on the National Registry.

BACKGROUND AND NEED FOR LEGISLATION

A bone marrow or cord blood transplant replaces a patient's diseased blood-forming cells with healthy ones. The procedure is used in treating some people with a blood cancer (such as leukemia or lymphoma) or an inherited metabolic or immune system disorder. According to the Health Resources and Services Administration (HRSA), at any given time there are some 6,000 people across the United States searching for a matched bone marrow donor or cord blood unit.

HRSA funds two major programs that facilitate the provision of blood stem cell units to individuals in need of a transplant. The C.W. Bill Young Cell Transplantation Program supports activities to increase the number of transplants for recipients suitably matched to biologically unrelated donors of bone marrow and cord blood. The National Cord Blood Inventory (NCBI) Program supports the collection, processing, and storage of a genetically and ethnically diverse inventory of high-quality umbilical cord blood for transplantation. These cord blood units, as well as other units in the inventories of participating cord blood banks, are made available to physicians and patients for blood stem cell transplants through the C.W. Bill Young Cell Transplantation Program.

The reauthorization of both the C.W. Bill Young Cell Transplantation Program and the NCBI Program is necessary to allow HRSA to continue these important and life-saving activities.

COMMITTEE CONSIDERATION

H.R. 6081, the "Stem Cell Therapeutic and Research Reauthorization Act of 2010", was introduced by Mr. Young of Florida and

Ms. Matsui of California on August 9, 2010, and referred to the Committee on Energy and Commerce. The bill was subsequently referred to the Subcommittee on Health on August 10, 2010. On September 15, 2010, the Subcommittee held a legislative hearing on the bill. The Subcommittee met in open markup session to consider H.R. 6081 on September 16, 2010. During subcommittee consideration, an amendment in the nature of a substitute (manager's amendment) by Mr. Pallone of New Jersey was adopted by a voice vote. Subsequently, H.R. 6081 was favorably forwarded to the full Committee, amended, by a voice vote.

On September 23, 2010, the Committee on Energy and Commerce met in open markup session to consider H.R. 6081 as approved by the Subcommittee. During the Committee's consideration, an amendment in the nature of a substitute was offered by Ms. Matsui of California, which was adopted by a voice vote. Subsequently, the Committee ordered H.R. 6081 favorably reported to the House, amended, by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list each record vote on the motion to report legislation and amendments thereto. A motion by Mr. Waxman ordering H.R. 6081 reported to the House, amended, was approved by a voice vote. There were no record votes taken during consideration of this bill.

COMMITTEE OVERSIGHT FINDINGS AND RECOMMENDATIONS

In compliance with clause 3(c)(1) of rule XIII and clause (2)(b)(1) of rule X of the Rules of the House of Representatives, the oversight findings and recommendations of the Committee are reflected in the descriptive portions of this report, including the finding that reauthorization of the C.W. Bill Young Cell Transplantation Program is important to support activities to increase the number of transplants for recipients suitably matched to biologically unrelated donors of bone marrow and cord blood.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Regarding compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 6081 would result in no new budget authority, entitlement authority, or tax expenditures or revenues.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

In accordance with clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the performance goals and objectives of the Committee are reflected in the descriptive portions of this report, including the goal of reauthorizing the C.W. Bill Young Cell Transplantation Program.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the constitutional au-

thority for H.R. 6081 is provided under article I, section 8, clauses 3 and 18 of the Constitution of the United States.

EARMARKS AND TAX AND TARIFF BENEFITS

H.R. 6081 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9 of rule XXI of the Rules of the House of Representatives.

FEDERAL ADVISORY COMMITTEE STATEMENT

The Committee finds that the legislation does not establish or authorize the establishment of an advisory committee within the definition of 5 U.S.C. App., section 5(b) of the Federal Advisory Committee Act.

APPLICABILITY OF LAW TO THE LEGISLATIVE BRANCH

Section 102(b)(3) of Public Law 104–1 requires a description of the application of this bill to the legislative branch where the bill relates to terms and conditions of employment or access to public services and accommodations. H.R. 6081 contains no such provisions.

FEDERAL MANDATES STATEMENT

Section 423 of the Congressional Budget and Impoundment Control Act of 1974 (as amended by section 101(a)(2) of the Unfunded Mandates Reform Act, Public Law 104–4) requires a statement on whether the provisions of the report include unfunded mandates. In compliance with this requirement the Committee adopts as its own the analysis of federal mandates prepared by the Director of the Congressional Budget Office regarding H.R. 6081.

COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the cost estimate of H.R. 6081 prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

With respect to the requirements of clause (3)(c)(3) of rule XIII of the Rules of the House of Representatives and section 402 of the Congressional Budget Act of 1974, the Committee has received the following cost estimate for H.R. 6081 from the Director of Congressional Budget Office:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, September 23, 2010.

Hon. HENRY A. WAXMAN,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 6081, the Stem Cell Therapeutic and Research Reauthorization Act of 2010.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Lisa Ramirez-Branum.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

H.R. 6081—Stem Cell Therapeutic and Research Reauthorization Act of 2010

H.R. 6081 would reauthorize the National Cord Blood Inventory program and the C.W. Bill Young Cell Transplantation program. In 2010, over $35 million was appropriated for these purposes. The bill also would require the Government Accountability Office to conduct a report that reviews the studies, demonstration programs, and outreach efforts for the purpose of increasing cord blood unit donations and collections for the National Cord Blood Inventory program.

The bill would authorize the appropriation of $53 million in fiscal year 2011 and $265 million for fiscal years 2011 through 2015. Assuming appropriation of those amounts, and based on historical spending patterns for similar programs, CBO estimates that implementing H.R. 6081 would cost $220 million over the 2011–2015 period as shown in the following table. The costs of this legislation fall primarily within budget function 550 (health). Enacting H.R. 6081 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply.

	By fiscal year, in millions of dollars—					
	2011	2012	2013	2014	2015	2011–2015
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Authorization Level	53	53	53	53	53	265
Estimated Outlays	21	44	51	52	52	220

H.R. 6081 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would not affect the budgets of state, local or tribal governments.

The CBO staff contact for this estimate is Lisa Ramirez-Branum. This estimate was approved by Holly Harvey, Deputy Assistant Director for Budget Analysis.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 designates that the Act may be cited as the "Stem Cell Therapeutic and Research Reauthorization Act of 2010".

Section 2. Amendments to the Stem Cell Therapeutic and Research Act of 2005

Subsection (a) of section 2 clarifies the requirement regarding the number of new units of high-quality cord blood for the NCBI Program to be "the inventory goal of at least 150,000". It also makes numerous changes to the application requirements for qualified blood banks that wish to participate in the Cord Blood Inventory and allows for the extension of a cord blood bank contract from three to five years under specified circumstances. In addition, subsection (a) provides for the authorization of appropriations for the NCBI Program at a level of $23 million for each of FY2011 through FY2014 and $20 million for FY2015.

Subsection (b) of section 2 clarifies the functions with regard to cord blood under the C.W. Bill Young Cell Transplantation Program to include support for studies and demonstration and outreach projects designed to increase cord blood unit donation and collection from a genetically diverse population and to expand the number of cord blood unit collection sites partnering with cord blood banks that participate in the NCBI Program. Such studies and projects include those designed to explore novel approaches or incentives to encourage innovative technological advances that could be used to collect cord blood units. Subsection (b) also directs the Secretary of Health and Human Services to set an annual goal of increasing collections of high-quality cord blood units consistent with the inventory goal established through the NCBI Program and provides for the expansion of remote collection (as defined in the legislation) of high-quality cord units under certain conditions.

Subsection (c) of section 2 requires the Secretary to submit an interim report to Congress in addition to the annual report required under the C.W. Bill Young Cell Transplantation Program.

Subsection (d) of section 2 provides for the authorization of appropriations for the C.W. Bill Young Cell Transplantation Program at a level of $30 million for each of FY2011 through FY2014 and $33 million for FY2015.

Subsection (e) directs the Government Accountability Office (GAO) to submit a report to Congress on cord blood unit donation and collection, including recommendations on efforts to increase cord blood unit donation and collection for the NCBI Program. Such report shall address, among other issues, methods used to distribute funds to cord blood banks prior to the date of enactment of this legislation.

EXPLANATION OF AMENDMENTS

During the Subcommittee on Health markup of H.R. 6081, Mr. Pallone of New Jersey offered an amendment in the nature of a substitute (manager's amendment), which was adopted by a voice vote. During the full Committee consideration of the bill as approved by the Subcommittee, Ms. Matsui of California offered an amendment in the nature of a substitute, which was also adopted by a voice vote. The substance of each amendment is reflected in the section-by-section analysis contained in this report.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

STEM CELL THERAPEUTIC AND RESEARCH ACT OF 2005

* * * * * * *

SEC. 2. CORD BLOOD INVENTORY.

(a) IN GENERAL.—The Secretary of Health and Human Services shall enter into one-time contracts with qualified cord blood banks to assist in the collection and maintenance of *the inventory goal of at least* 150,000 new units of high-quality cord blood to be made available for transplantation through the C.W. Bill Young Cell Transplantation Program and to carry out the requirements of subsection (b).

* * * * * * *

(c) RELATED CORD BLOOD DONORS.—

(1) * * *

(2) AVAILABILITY.—Qualified cord blood banks that are operating a program under paragraph (1) shall provide assurances that the cord blood units in such banks will be available for directed transplantation until such time that the cord blood unit is released for transplantation **[**or is transferred by the family to the C.W. Bill Young Cell Transplantation Program in accordance with guidance or regulations promulgated by the Secretary.**]** *for a first-degree relative.*

(3) INVENTORY.—Cord blood units collected through the program under this section shall not be counted toward the **[**150,000**]** inventory goal under the C.W. Bill Young Cell Transplantation Program.

* * * * * * *

(d) APPLICATION.—To seek to enter into a contract under this section, a qualified cord blood bank shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require. At a minimum, an application for a contract under this section shall include a requirement that the applicant—

(1) will participate in the C.W. Bill Young Cell Transplantation Program for a period of at least 10 years *beginning on the last date on which the recipient of a contract under this section receives Federal funds under this section*;

(2) will make cord blood units collected pursuant to this section available through the C.W. Bill Young Cell Transplantation Program in perpetuity or for such time as determined viable by the Secretary**[**; and**]***;*

(3) will provide a plan to increase cord blood unit collections at collection sites that exist at the time of application, assist with the establishment of new collection sites, or contract with new collection sites;

(4) will annually provide to the Secretary a plan for, and demonstrate, ongoing measurable progress toward achieving

self-sufficiency of cord blood unit collection and banking operations; and

[(3)] *(5)* if the Secretary determines through an assessment, or through petition by the applicant, that a cord blood bank is no longer operational or does not meet the requirements of section 379(d)(4) of the Public Health Service Act (as added by this Act) and as a result may not distribute the units, transfer the units collected pursuant to this section to another qualified cord blood bank approved by the Secretary to ensure continued availability of cord blood units.

(e) DURATION OF CONTRACTS.—

(1) IN GENERAL.—Except as provided in paragraph (2), the term of each contract entered into by the Secretary under this section shall be for [10 years] *a period of at least 10 years beginning on the last date on which the recipient of a contract under this section receives Federal funds under this section*. [The Secretary shall ensure that no Federal funds shall be obligated under any such contract after the earlier of—

[(A) the date that is 3 years after the date on which the contract is entered into; or

[(B) September 30, 2010.] *The Secretary shall ensure that no Federal funds shall be obligated under any such contract after the date that is 5 years after the date on which the contract is entered into, except as provided in paragraphs (2) and (3).*

(2) EXTENSIONS.—[Subject to paragraph (1)(B), the] *The* Secretary may extend the period of funding under a contract under this section to exceed a period of [3] *5* years if—

(A) the Secretary finds that [150,000 new units of high-quality cord blood have not yet been collected pursuant to this section; and] *the inventory goal described in subsection (a) has not yet been met;*

(B) the Secretary does not receive an application for a contract under this section *meeting the requirements under subsection (d)* from any qualified cord blood bank that has not previously entered into a contract under this section [or the Secretary determines that the outstanding inventory need cannot be met by the one or more qualified cord blood banks that have submitted an application for a contract under this section.]*; or*

(C) the Secretary determines that the outstanding inventory need cannot be met by the qualified cord blood banks under contract under this section.

[(3) PREFERENCE.—In considering contract extensions under paragraph (2), the Secretary shall give preference to qualified cord blood banks that the Secretary determines have demonstrated a superior ability to satisfy the requirements described in subsection (b) and to achieve the overall goals for which the contract was awarded.]

(3) EXTENSION ELIGIBILITY.—A qualified cord blood bank shall be eligible for a 5-year extension of a contract awarded under this section, as described in paragraph (2), provided that the qualified cord blood bank—

(A) demonstrates a superior ability to satisfy the requirements described in subsection (b) and achieves the overall goals for which the contract was awarded;

(B) provides a plan for how the qualified cord blood bank will increase cord blood unit collections at collection sites that exist at the time of consideration for such extension of a contract, assist with the establishment of new collection sites, or contract with new collection sites; and

(C) annually provides to the Secretary a plan for, and demonstrates, ongoing measurable progress toward achieving self-sufficiency of cord blood unit collection and banking operations.

* * * * * * *

(g) DEFINITIONS.—In this section:

(1) * * *

* * * * * * *

(4) The term "first-degree relative" means a sibling [or parent] who is one meiosis away from a particular individual in a family.

* * * * * * *

(h) AUTHORIZATION OF APPROPRIATIONS.—

[(1) EXISTING FUNDS.—Any amounts appropriated to the Secretary for fiscal year 2004 or 2005 for the purpose of assisting in the collection or maintenance of cord blood shall remain available to the Secretary until the end of fiscal year 2007.

[(2) SUBSEQUENT FISCAL YEARS.—There are authorized to be appropriated to the Secretary $15,000,000 for each of fiscal years 2007, 2008, 2009, and 2010 to carry out this section.]

(1) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary to carry out the program under this section $23,000,000 for each of fiscal years 2011 through 2014 and $20,000,000 for fiscal year 2015.

[(3)] *(2)* LIMITATION.—Not to exceed 5 percent of the amount appropriated under this section [in each of fiscal years 2007 through 2009] *for each of fiscal years 2011 through 2015* may be used to carry out the demonstration project under subsection (c).

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PUBLIC HEALTH SERVICE ACT

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

* * * * * * *

PART I—C.W. BILL YOUNG CELL TRANSPLANTATION PROGRAM

SEC. 379. NATIONAL PROGRAM.

(a) ESTABLISHMENT.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall by one or more contracts establish and maintain a C.W. Bill Young Cell Transplantation Program (referred to in this section as the "Program"), successor to the National Bone Marrow Donor Registry, that has the purpose of increasing the number of transplants for recipients suitably matched to biologically unrelated donors of bone marrow and cord blood, and that meets the requirements of this section. The Secretary may award a separate contract to perform each of the major functions of the Program described in paragraphs (1) and (2) of subsection (d) if deemed necessary by the Secretary to operate an effective and efficient system that is in the best interest of patients. The Secretary shall conduct a separate competition for the initial establishment of the cord blood functions of the Program. The Program shall be under the general supervision of the Secretary. The Secretary shall establish an Advisory Council to advise, assist, consult with, and make recommendations to the Secretary on matters related to the activities carried out by the Program. The members of the Advisory Council shall be appointed in accordance with the following:

(1) * * *

* * * * * * *

[(6) The Secretary, acting through the Advisory Council, shall submit to the Congress—

[(A) an annual report on the activities carried out under this section; and

[(B) not later than 6 months after the date of the enactment of the Stem Cell Therapeutic and Research Act of 2005, a report of recommendations on the scientific factors necessary to define a cord blood unit as a high-quality unit.**]**

(6) The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall submit to Congress an annual report on the activities carried out under this section.

* * * * * * *

(d) FUNCTIONS.—

(1) * * *

(2) CORD BLOOD FUNCTIONS.—**[**With respect to cord blood, the Program shall—**]**

(A) IN GENERAL.—With respect to cord blood, the Program shall—

[(A)**]** *(i)* operate a system for identifying, matching, and facilitating the distribution of donated cord blood units that are suitably matched to candidate patients and meet all applicable Federal and State regulations (including informed consent and Food and Drug Administration regulations) from a qualified cord blood bank;

[(B)] *(ii)* consistent with paragraph (3), allow transplant physicians, other appropriate health care professionals, and patients to search by means of electronic access all available cord blood units made available through the Program;

[(C)] *(iii)* allow transplant physicians and other appropriate health care professionals to reserve, as defined by the Secretary, a cord blood unit for transplantation;

[(D) support studies and demonstration and outreach projects for the purpose of increasing cord blood donation to ensure a genetically diverse collection of cord blood units;]

(iv) support and expand new and existing studies and demonstration and outreach projects for the purpose of increasing cord blood unit donation and collection from a genetically diverse population and expanding the number of cord blood unit collection sites partnering with cord blood banks receiving a contract under the National Cord Blood Inventory program under section 2 of the Stem Cell Therapeutic and Research Act of 2005, including such studies and projects that focus on—

(I) remote collection of cord blood units, consistent with the requirements under the Program and the National Cord Blood Inventory program goal described in section 2(a) of the Stem Cell Therapeutic and Research Act of 2005; and

(II) exploring novel approaches or incentives to encourage innovative technological advances that could be used to collect cord blood units, consistent with the requirements under the Program and such National Cord Blood Inventory program goal;

[(E)] *(v)* provide for a system of patient advocacy through the office established under subsection (h);

[(F)] *(vi)* coordinate with the qualified cord blood banks to support informational and educational activities in accordance with subsection (g);

[(G)] *(vii)* maintain and expand medical contingency response capabilities, in coordination with Federal programs, to prepare for and respond effectively to biological, chemical, or radiological attacks, and other public health emergencies that can damage marrow, so that the capability of supporting patients with marrow damage from disease can be used to support casualties with marrow damage; and

[(H)] *(viii)* with respect to the system under subparagraph (A), collect, analyze, and publish data in a standardized electronic format, as required by the Secretary, on the number and percentage of patients at each of the various stages of the search process, including data regarding the furthest stage reached, the number and percentage of patients who are unable to complete the search process, and the reasons underlying such circumstances.

(B) EFFORTS TO INCREASE COLLECTION OF HIGH QUALITY CORD BLOOD UNITS.—In carrying out subparagraph (A)(iv), not later than 1 year after the date of enactment of the Stem Cell Therapeutic and Research Reauthorization Act of 2010 and annually thereafter, the Secretary shall set an annual goal of increasing collections of high quality cord blood units, consistent with the inventory goal described in section 2(a) of the Stem Cell Therapeutic and Research Act of 2005 (referred to in this subparagraph as the "inventory goal"), and shall identify at least one project under subparagraph (A)(iv) to replicate and expand nationwide, as appropriate. If the Secretary cannot identify a project as described in the preceding sentence, the Secretary shall submit a plan, not later than 180 days after the date on which the Secretary was required to identify such a project, to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives for expanding remote collection of high quality cord blood units, consistent with the requirements under the National Cord Blood Inventory program under section 2 of the Stem Cell Therapeutic and Research Act of 2005 and the inventory goal. Each such plan shall be made available to the public.

(C) DEFINITION.—In this paragraph, the term "remote collection" means the collection of cord blood units at locations that do not have written contracts with cord blood banks for collection support.

(3) SINGLE POINT OF ACCESS; STANDARD DATA.—

(A) SINGLE POINT OF ACCESS.—The Secretary shall ensure that health care professionals and patients are able to search electronically for and facilitate access to, in the manner and to the extent defined by the Secretary and consistent with the functions described in paragraphs (1)(A) and ⟦(2)(A)⟧ *(2)(A)(i)*, cells from bone marrow donors and cord blood units through a single point of access.

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(f) BONE MARROW CRITERIA, STANDARDS, AND PROCEDURES.—The Secretary shall enforce, for participating entities, including the Program, individual marrow donor centers, marrow donor registries, marrow collection centers, and marrow transplant centers—

(1) * * *

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(5) standards that—

⟦(A) require the establishment of a system of strict confidentiality of records relating to the identity, address, HLA type, and managing marrow donor center for marrow donors and potential marrow donors; and⟧

(A) require the establishment of a system of strict confidentiality to protect the identity and privacy of patients and donors in accordance with Federal and State law; and

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SEC. 379B. AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out this part, there are authorized to be appropriated **[**$34,000,000 for fiscal year 2006 and $38,000,000 for each of fiscal years 2007 through 2010.**]** *$30,000,000 for each of fiscal years 2011 through 2014 and $33,000,000 for fiscal year 2015.*

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