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COMMITTEE PRINT

[SHOWING TEXT OF H.R. 6081 AS FORWARDED BY THE SUBCOMMITTEE ON HEALTH ON SEPTEMBER 16, 2010]

111TH CONGRESS
2D SESSION

H. R. 6081

To amend the Stem Cell Therapeutic and Research Act of 2005.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 9, 2010

Mr. YOUNG of Florida (for himself and Ms. MATSUI) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Stem Cell Therapeutic and Research Act of 2005.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

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 ''at least'' before ''150,000'';

(2) in subsection (c)—

(A) in paragraph (2), by striking ''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'' and inserting ''until such time that the cord blood unit is released for transplantation for a first-degree relative''; and

(B) in paragraph (3), by striking ''the 150,000 inventory goal'' and inserting ''the inventory goal of at least 150,000'';

(3) in subsection (d)—

(A) in paragraph (1), by striking ''a period of at least 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'';

(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)—

(I) by inserting ''at least'' before ''150,000''; and

(II) by striking ''; and'' and inserting '';'';

(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 paragraph (2) and inserting the following:

''(2) 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. Such funds so appropriated shall remain available until expended.''; and

(B) in paragraph (3), 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 Advisory Council, shall submit to Congress an annual report on the activities carried out under this section.'';

(2) by striking subsection (d)(2)(D) and inserting the following:

''(D) support studies and demonstration and outreach projects for the purpose of increasing cord blood unit donation and collection from a genetically diverse population, including exploring novel approaches or incentives, such as remote or other innovative technological advances that could be used to collect cord blood units, to expand the number of cord blood unit collection sites partnering with cord blood banks that receive a contract under the National Cord Blood Bank Inventory program under section 2 of the Stem Cell Therapeutic and Research Act of 2005;''; 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) 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. Such funds so appropriated shall remain available until expended.''.

(d) 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 impact of regulatory and administrative requirements, and the capacity of cord blood banks to maintain high-quality units;

(B) remote 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; and

(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.