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REPORT
116–549

TIMELY REAUTHORIZATION OF NECESSARY STEM-CELL PROGRAMS LENDS ACCESS TO NEEDED THERAPIES ACT OF 2019

SEPTEMBER 29, 2020.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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

R E P O R T

[To accompany H.R. 4764]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 4764) to reauthorize the Stem Cell Therapeutic and Research Act of 2005, and for other purposes, having considered the same, reports favorably thereon without amendment and recommends that the bill do pass.

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I. PURPOSE AND SUMMARY

H.R. 4764, the "Timely ReAuthorization of Necessary Stem-cell Programs Lends Access to Needed Therapies Act of 2019", or the "TRANSPLANT Act of 2019", introduced by Representatives Doris

O. Matsui (D–CA), Gus Bilirakis (R–FL), and Chellie Pingree (D–ME), reauthorizes the C.W. Bill Young Transplantation Program (the Program) at level funding of $30 million each year from fiscal year (FY) 2021 through FY 2025. The bill also requires Health Resources and Services Administration's (HRSA) Advisory Council on Blood Stem Cell Transplantation to meet at least twice a year and requires the Department of Health and Human Services (HHS) to review the state of the science related to adult stem cells and birthing tissues for the purpose of potentially including these innovative therapies in the Program. In addition, the bill would reauthorize the cord blood inventory program under the Stem Cell Therapeutic and Research Act of 2005 at level funding of $23 million for each year from FY 2021 through FY 2025.

II. Background and Need for the Legislation

The C.W. Bill Young Transplant Program was first established through a partnership with the Navy in 1986, transferred to the National Institutes of Health (NIH) for oversight in 1987, then authorized by the House Committee on Energy and Commerce in 1990; it has since been reauthorized in 1998, 2005, 2010, and 2015.[1]

This Program provides life-saving bone marrow and umbilical cord blood transplants to help patients suffering from more than 70 diseases for which hematologic or immunologic reconstruction using bone marrow, peripheral blood, and cord blood have been demonstrated to be safe and effective including, leukemia, lymphoma, sickle cell anemia, and certain other immune system disorders.[2] For some patients, these transplants may come from a familial donor, whereas other patients might require an unrelated donor.[3] The program's purpose is to assist transplant patients by providing additional information about bone marrow and cord blood transplants, maintaining an efficient process for identifying donor matches, increasing the number of unrelated donors available for transplant, and collecting data and expanding research to improve patient outcomes.[4]

The National Cord Blood Inventory (NCBI) receives Federal funding for the collection and storage of at least 150,000 cord blood units, which are then made available through the C.W. Bill Young Transplant Program.[5]

III. Committee Hearings

For the purposes of section 103(i) of H. Res. 6 of the 116th Congress, the following hearing was used to develop or consider H.R. 4764:

The Subcommittee on Health held a legislative hearing on July 29, 2020, entitled "Improving Access to Care: Legislation to Reauthorize Key Public Health Programs," to consider H.R. 4764, the

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[1] https://bethematch.org/support-the-cause/participate/join-our-legislative-advocacy-efforts/authorizing-statute/

[2] Health Resources and Services Administration, Blood Stem Cell, About (bloodstemcell.hrsa.gov/about) (accessed September 11, 2020).

[3] *Id.*

[4] *Id.*

[5] Health Resources and Services Administration, Blood Stem Cell, About, Contracts, National Cord Blood Inventory Contract Summary (NCBI) (bloodstemcell.hrsa.gov/about/contracts/national-cord-blood-inventory-contract-summary-ncbi) (accessed September 11, 2020).

"Timely ReAuthorization of Necessary Stem-cell Programs Lends Access to Needed Therapies Act of 2019" or the "TRANSPLANT Act of 2019". The Subcommittee received testimony from the following witnesses:

- Robert Boyd, M.C.R.P., M.Div., President, School-Based Health Alliance;
- Linda Goler Blount, M.P.H., President and CEO, Black Women's Health Imperative;
- Nancy Goodman, M.P.P., J.D., Founder and Executive Director, Kids v. Cancer;
- Aaron Seth Kesselheim, M.D., J.D., M.P.H., Professor of Medicine, Harvard Medical School;
- Brian Lindberg, Chief Legal Officer and General Counsel, National Bone Marrow Donor Program; and
- Travis T. Tygart, Chief Executive Officer, U.S. Anti-Doping Agency.

IV. Committee Consideration

Representatives Matsui (D–CA), Bilirakis (R–FL), and Pingree (D–ME) introduced H.R. 4764, the "Timely ReAuthorization of Necessary Stem-cell Programs Lends Access to Needed Therapies Act of 2019" or the "TRANSPLANT Act of 2019", on October 18, 2019, and the bill was referred to the Committee on Energy and Commerce. H.R. 4764 was then referred to the Subcommittee on Health on October 21, 2019. A legislative hearing was held on the bill on July 29, 2020.

On September 9, 2020, H.R. 4764 was discharged from further consideration by the Subcommittee on Health as it was called up for markup by the full Committee on Energy and Commerce. The full Committee met in virtual open markup session on September 9, 2020, pursuant to notice, to consider H.R. 4764. There were no amendments offered to H.R. 4764. Upon conclusion of consideration of the bill, the full Committee agreed to a motion on final passage by Mr. Pallone, Chairman of the committee, to order H.R. 4764 reported favorably to the House, without amendment, by a voice vote, a quorum being present.

V. 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. The Committee advises that there were no record votes taken on H.R. 4764, including the motion for final passage of the bill.

VI. Oversight Findings

Pursuant to 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 portion of the report.

VII. New Budget Authority, Entitlement Authority, and Tax Expenditures

Pursuant to 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the estimate of new budget authority, entitlement authority, or tax expenditures or revenues contained in the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

The Committee has requested but not received from the Director of the Congressional Budget Office a statement as to whether this bill contains any new budget authority, spending authority, credit authority, or an increase or decrease in revenues or tax expenditures.

VIII. Federal Mandates Statement

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

IX. Statement of General Performance Goals and Objectives

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to reauthorize the Stem Cell Therapeutic and Research Act of 2005 and provide technical and clarifying changes to the C.W. Bill Young Transplantation Program.

X. Duplication of Federal Programs

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 4764 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111–139 or the most recent Catalog of Federal Domestic Assistance.

XI. Committee Cost Estimate

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

XII. Earmarks, Limited Tax Benefits, and Limited Tariff Benefits

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 4764 contains no earmarks, limited tax benefits, or limited tariff benefits.

XIII. Advisory Committee Statement

No advisory committee within the meaning of section 5(b) of the Federal Advisory Committee Act was created by this legislation.

XIV. Applicability to Legislative Branch

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or

accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

XV. SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 designates that the short title may be cited as the "Timely ReAuthorization of Necessary Stem-cell Programs Lends Access to Needed Therapies Act of 2019" or the "TRANSPLANT Act of 2019".

Sec. 2. Reauthorization of the C.W. Bill Young Transplantation Program

Section 2 amends section 379 of the Public Health Service Act to reauthorize the C.W. Bill Young Transplantation Program for $30,000,000 for each fiscal year (FY) 2021 through 2025.

The section also requires the Secretary of the U.S. Department of Health and Human Services (the Secretary) to convene advisory council meetings at least two times each calendar year, provides a technical clarification to increase collection of high-quality cord blood units, and eliminates an obsolete provision in the underlying statute. Finally, section 2 requires the Secretary, in consultation with other Health and Human Services agencies, the Advisory Council, and other external stakeholders, to periodically review the state of adult stem cell and birthing tissue science and assess the ability to expand the C.W. Bill Young Transplantation Program to include new types of therapies. No later than June 30, 2024, the Secretary shall complete the review and share recommendations with the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor, and Pensions.

Sec. 3. Cord blood inventory

Section 3 reauthorizes funding for the cord blood inventory. It authorizes $23,000,000 for each of the fiscal years 2021 through 2025.

XVI. 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 italics, and existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

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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) Each member of the Advisory Council shall serve for a term of 2 years, and each such member may serve as many as 3 consecutive 2-year terms, except that—

(A) such limitations shall not apply to the Chair of the Advisory Council (or the Chair-elect) or to the member of the Advisory Council who most recently served as the Chair; and

(B) one additional consecutive 2-year term may be served by any member of the Advisory Council who has no employment, governance, or financial affiliation with any donor center, recruitment organization, transplant center, or cord blood bank.

(2) A member of the Advisory Council may continue to serve after the expiration of the term of such member until a successor is appointed.

(3) In order to ensure the continuity of the Advisory Council, the Advisory Council shall be appointed so that each year the terms of approximately one-third of the members of the Advisory Council expire.

(4) The membership of the Advisory Council—

(A) shall include as voting members a balanced number of representatives including representatives of marrow donor centers and marrow transplant centers, representatives of cord blood banks and participating birthing hospitals, recipients of a bone marrow transplant, recipients of a cord blood transplant, persons who require such transplants, family members of such a recipient or family members of a patient who has requested the assistance of the Program in searching for an unrelated donor of bone marrow or cord blood, persons with expertise in bone marrow and cord blood transplantation, persons with expertise in

typing, matching, and transplant outcome data analysis, persons with expertise in the social sciences, basic scientists with expertise in the biology of adult stem cells, and members of the general public; and

(B) shall include as nonvoting members representatives from the Department of Defense Marrow Donor Recruitment and Research Program operated by the Department of the Navy, the Division of Transplantation of the Health Resources and Services Administration, the Food and Drug Administration, and the National Institutes of Health.

(5) Members of the Advisory Council shall be chosen so as to ensure objectivity and balance and reduce the potential for conflicts of interest. The Secretary shall establish bylaws and procedures—

(A) to prohibit any member of the Advisory Council who has an employment, governance, or financial affiliation with a donor center, recruitment organization, transplant center, or cord blood bank from participating in any decision that materially affects the center, recruitment organization, transplant center, or cord blood bank; and

(B) to limit the number of members of the Advisory Council with any such affiliation.

(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.

(7) The Secretary shall convene the Advisory Council at least two times each calendar year.

(b) ACCREDITATION.—The Secretary shall, through a public process, recognize one or more accreditation entities for the accreditation of cord blood banks.

(c) INFORMED CONSENT.—The Secretary shall, through a public process, examine issues of informed consent, including—

(1) the appropriate timing of such consent; and

(2) the information provided to the maternal donor regarding all of her medically appropriate cord blood options.

Based on such examination, the Secretary shall require that the standards used by the accreditation entities recognized under subsection (b) ensure that a cord blood unit is acquired with the informed consent of the maternal donor.

(d) FUNCTIONS.—

(1) BONE MARROW FUNCTIONS.—With respect to bone marrow, the Program shall—

(A) operate a system for identifying, matching, and facilitating the distribution of bone marrow that is suitably matched to candidate patients;

(B) consistent with paragraph (3), permit transplant physicians, other appropriate health care professionals, and patients to search by means of electronic access all available bone marrow donors listed in the Program;

(C) carry out a program for the recruitment of bone marrow donors in accordance with subsection (e), including with respect to increasing the representation of racial and ethnic minority groups (including persons of mixed ancestry) in the enrollment of the Program;

(D) 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;

(E) carry out informational and educational activities in accordance with subsection (e);

(F) at least annually update information to account for changes in the status of individuals as potential donors of bone marrow;

(G) provide for a system of patient advocacy through the office established under subsection (h);

(H) provide case management services for any potential donor of bone marrow to whom the Program has provided a notice that the potential donor may be suitably matched to a particular patient through the office established under subsection (h);

(I) with respect to searches for unrelated donors of bone marrow that are conducted through the system under subparagraph (A), collect, analyze, and publish data in a standardized electronic format 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;

(J) support studies and demonstration and outreach projects for the purpose of increasing the number of individuals who are willing to be marrow donors to ensure a genetically diverse donor pool; and

(K) facilitate research with the appropriate Federal agencies to improve the availability, efficiency, safety, and cost of transplants from unrelated donors and the effectiveness of Program operations.

(2) CORD BLOOD FUNCTIONS.—

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

(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;

(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;

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

(iv) support and expand new and existing studies and demonstration and outreach projects for the purpose of increasing cord blood unit donation and collec-

tion 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;

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

(vi) coordinate with the qualified cord blood banks to support informational and educational activities in accordance with subsection (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

(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 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)(i), cells from bone marrow donors and cord blood units through a single point of access.

(B) STANDARD DATA.—The Secretary shall require all recipients of contracts under this section to make available a standard dataset for purposes of subparagraph (A) in a standardized electronic format that enables transplant physicians to compare among and between bone marrow donors and cord blood units to ensure the best possible match for the patient.

(4) DEFINITION.—The term "qualified cord blood bank" means a cord blood bank that—

(A) has obtained all applicable Federal and State licenses, certifications, registrations (including pursuant to the regulations of the Food and Drug Administration), and other authorizations required to operate and maintain a cord blood bank;

(B) has implemented donor screening, cord blood collection practices, and processing methods intended to protect the health and safety of donors and transplant recipients to improve transplant outcomes, including with respect to the transmission of potentially harmful infections and other diseases;

(C) is accredited by an accreditation entity recognized by the Secretary under subsection (b);

(D) has established a system of strict confidentiality to protect the identity and privacy of patients and donors in accordance with existing Federal and State law;

(E) has established a system for encouraging donation by a genetically diverse group of donors; and

(F) has established a system to confidentially maintain linkage between a cord blood unit and a maternal donor.

(e) BONE MARROW RECRUITMENT; PRIORITIES; INFORMATION AND EDUCATION.—

(1) RECRUITMENT; PRIORITIES.—The Program shall carry out activities for the recruitment of bone marrow donors. Such recruitment program shall identify populations that are underrepresented among potential donors enrolled with the Program. In the case of populations that are identified under the preceding sentence:

(A) The Program shall give priority to carrying out activities under this part to increase representation for such populations in order to enable a member of such a population, to the extent practicable, to have a probability of finding a suitable unrelated donor that is comparable to the probability that an individual who is not a member of an underrepresented population would have.

(B) The Program shall consider racial and ethnic minority groups (including persons of mixed ancestry) to be populations that have been identified for purposes of this paragraph, and shall carry out subparagraph (A) with respect to such populations.

(2) INFORMATION AND EDUCATION REGARDING RECRUITMENT; TESTING AND ENROLLMENT.—

(A) IN GENERAL.—The Program shall carry out informational and educational activities, in coordination with organ donation public awareness campaigns operated through the Department of Health and Human Services, for purposes of recruiting individuals to serve as donors of bone marrow, and shall test and enroll with the Program potential bone marrow donors. Such information and educational activities shall include the following:

(i) Making information available to the general public, including information describing the needs of patients with respect to donors of bone marrow.

(ii) Educating and providing information to individuals who are willing to serve as potential bone marrow donors.

(iii) Training individuals in requesting individuals to serve as potential bone marrow donors.

(B) PRIORITIES.—In carrying out informational and educational activities under subparagraph (A), the Program shall give priority to recruiting individuals to serve as donors of bone marrow for populations that are identified under paragraph (1).

(3) TRANSPLANTATION AS TREATMENT OPTION.—In addition to activities regarding recruitment, the recruitment program under paragraph (1) shall provide information to physicians, other health care professionals, and the public regarding bone marrow transplants from unrelated donors as a treatment option.

(4) IMPLEMENTATION OF SUBSECTION.—The requirements of this subsection shall be carried out by the entity that has been awarded a contract by the Secretary under subsection (a) to carry out the functions described in subsection (d)(1).

(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) quality standards and standards for tissue typing, obtaining the informed consent of donors, and providing patient advocacy;

(2) donor selection criteria, based on established medical criteria, to protect both the donor and the recipient and to prevent the transmission of potentially harmful infectious diseases

such as the viruses that cause hepatitis and the etiologic agent for Acquired Immune Deficiency Syndrome;

(3) procedures to ensure the proper collection and transportation of the marrow;

(4) standards for the system for patient advocacy operated under subsection (h), including standards requiring the provision of appropriate information (at the start of the search process and throughout the process) to patients and their families and physicians;

(5) standards that—

(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

(B) prescribe the purposes for which the records described in subparagraph (A) may be disclosed, and the circumstances and extent of the disclosure; and

(6) in the case of a marrow donor center or marrow donor registry participating in the program, procedures to ensure the establishment of a method for integrating donor files, searches, and general procedures of the center or registry with the Program.

(g) CORD BLOOD RECRUITMENT; PRIORITIES; INFORMATION AND EDUCATION.—

(1) RECRUITMENT; PRIORITIES.—The Program shall support activities, in cooperation with qualified cord blood banks, for the recruitment of cord blood donors. Such recruitment program shall identify populations that are underrepresented among cord blood donors. In the case of populations that are identified under the preceding sentence:

(A) The Program shall give priority to supporting activities under this part to increase representation for such populations in order to enable a member of such a population, to the extent practicable, to have a probability of finding a suitable cord blood unit that is comparable to the probability that an individual who is not a member of an underrepresented population would have.

(B) The Program shall consider racial and ethnic minority groups (including persons of mixed ancestry) to be populations that have been identified for purposes of this paragraph, and shall support activities under subparagraph (A) with respect to such populations.

(2) INFORMATION AND EDUCATION REGARDING RECRUITMENT; TESTING AND DONATION.—

(A) IN GENERAL.—In carrying out the recruitment program under paragraph (1), the Program shall support informational and educational activities in coordination with qualified cord blood banks and organ donation public awareness campaigns operated through the Department of Health and Human Services, for purposes of recruiting pregnant women to serve as donors of cord blood. Such information and educational activities shall include the following:

(i) Making information available to the general public, including information describing the needs of patients with respect to cord blood units.

(ii) Educating and providing information to pregnant women who are willing to donate cord blood units.

(iii) Training individuals in requesting pregnant women to serve as cord blood donors.

(B) PRIORITIES.—In carrying out informational and educational activities under subparagraph (A), the Program shall give priority to supporting the recruitment of pregnant women to serve as donors of cord blood for populations that are identified under paragraph (1).

(3) TRANSPLANTATION AS TREATMENT OPTION.—In addition to activities regarding recruitment, the recruitment program under paragraph (1) shall provide information to physicians, other health care professionals, and the public regarding cord blood transplants from donors as a treatment option.

(4) IMPLEMENTATION OF SUBSECTION.—The requirements of this subsection shall be carried out by the entity that has been awarded a contract by the Secretary under subsection (a) to carry out the functions described in subsection (d)(2).

(h) PATIENT ADVOCACY AND CASE MANAGEMENT FOR BONE MARROW AND CORD BLOOD.—

(1) IN GENERAL.—The Secretary shall establish and maintain, through a contract or other means determined appropriate by the Secretary, an office of patient advocacy (in this subsection referred to as the "Office").

(2) GENERAL FUNCTIONS.—The Office shall meet the following requirements:

(A) The Office shall be headed by a director.

(B) The Office shall be staffed by individuals with expertise in bone marrow and cord blood therapy covered under the Program.

(C) The Office shall operate a system for patient advocacy, which shall be separate from mechanisms for donor advocacy, and which shall serve patients for whom the Program is conducting, or has been requested to conduct, a search for a bone marrow donor or cord blood unit.

(D) In the case of such a patient, the Office shall serve as an advocate for the patient by directly providing to the patient (or family members, physicians, or other individuals acting on behalf of the patient) individualized services with respect to efficiently utilizing the system under paragraphs (1) and (2) of subsection (d) to conduct an ongoing search for a bone marrow donor or cord blood unit and assist with information regarding third party payor matters.

(E) In carrying out subparagraph (D), the Office shall monitor the system under paragraphs (1) and (2) of subsection (d) to determine whether the search needs of the patient involved are being met, including with respect to the following:

(i) Periodically providing to the patient (or an individual acting on behalf of the patient) information regarding bone marrow donors or cord blood units that are suitably matched to the patient, and other information regarding the progress being made in the search.

(ii) Informing the patient (or such other individual) if the search has been interrupted or discontinued.

(iii) Identifying and resolving problems in the search, to the extent practicable.

(F) The Office shall ensure that the following data are made available to patients:

(i) The resources available through the Program.

(ii) A comparison of transplant centers regarding search and other costs that prior to transplantation are charged to patients by transplant centers.

(iii) The post-transplant outcomes for individual transplant centers.

(iv) Information concerning issues that patients may face after a transplant.

(v) Such other information as the Program determines to be appropriate.

(G) The Office shall conduct surveys of patients (or family members, physicians, or other individuals acting on behalf of patients) to determine the extent of satisfaction with the system for patient advocacy under this subsection, and to identify ways in which the system can be improved to best meet the needs of patients.

(3) CASE MANAGEMENT.—

(A) IN GENERAL.—In serving as an advocate for a patient under paragraph (2), the Office shall provide individualized case management services directly to the patient (or family members, physicians, or other individuals acting on behalf of the patient), including—

(i) individualized case assessment; and

(ii) the functions described in paragraph (2)(D) (relating to progress in the search process).

(B) POSTSEARCH FUNCTIONS.—In addition to the case management services described in paragraph (1) for patients, the Office shall, on behalf of patients who have completed the search for a bone marrow donor or cord blood unit, provide information and education on the process of receiving a transplant, including the post-transplant process.

(i) COMMENT PROCEDURES.—The Secretary shall establish and provide information to the public on procedures under which the Secretary shall receive and consider comments from interested persons relating to the manner in which the Program is carrying out the duties of the Program. The Secretary may promulgate regulations under this section.

(j) CONSULTATION.—In developing policies affecting the Program, the Secretary shall consult with the Advisory Council, the Department of Defense Marrow Donor Recruitment and Research Program operated by the Department of the Navy, and the board of directors of each entity awarded a contract under this section.

(k) CONTRACTS.—

(1) APPLICATION.—To be eligible to enter into a contract under this section, an entity shall submit to the Secretary and obtain approval of an application at such time, in such manner, and containing such information as the Secretary shall by regulation prescribe.

(2) CONSIDERATIONS.—In awarding contracts under this section, the Secretary shall give consideration to the continued safety of donors and patients and other factors deemed appropriate by the Secretary.

(l) ELIGIBILITY.—Entities eligible to receive a contract under this section shall include private nonprofit entities.

(m) RECORDS.—

(1) RECORDKEEPING.—Each recipient of a contract or subcontract under subsection (a) shall keep such records as the Secretary shall prescribe, including records that fully disclose the amount and disposition by the recipient of the proceeds of the contract, the total cost of the undertaking in connection with which the contract was made, and the amount of the portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) EXAMINATION OF RECORDS.—The Secretary and the Comptroller General of the United States shall have access to any books, documents, papers, and records of the recipient of a contract or subcontract entered into under this section that are pertinent to the contract, for the purpose of conducting audits and examinations.

(n) PENALTIES FOR DISCLOSURE.—Any person who discloses the content of any record referred to in subsection (d)(4)(D) or (f)(5)(A) without the prior written consent of the donor or potential donor with respect to whom the record is maintained, or in violation of the standards described in subsection (f)(5)(B), shall be imprisoned for not more than 2 years or fined in accordance with title 18, United States Code, or both.

(o) PERIODIC REVIEW OF STATE OF SCIENCE.—

(1) REVIEW.—Not less than every two years, the Secretary, in consultation with the Director of the National Institutes of Health, the Commissioner of Food and Drugs, the Administrator of the Health Resources and Services Administration, the Advisory Council, and other stakeholders, where appropriate given relevant expertise, shall conduct a review of the state of the science of using adult stem cells and birthing tissues to develop new types of therapies for patients, for the purpose of considering the potential inclusion of such new types of therapies in the Program.

(2) RECOMMENDATIONS.—Not later than June 30, 2024, the Secretary shall—

(A) complete the second review required by paragraph (1); and

(B) informed by such review, submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives recommendations on the appropriateness of the inclusion of new types of therapies in the Program.

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SEC. 379B. AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out this part, there are authorized to be appropriated [$33,000,000 for fiscal year 2015 and

$30,000,000 for each of fiscal years 2016 through 2020] *$30,000,000 for each of fiscal years 2021 through 2025.*

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SECTION 2 OF THE STEM CELL THERAPEUTIC AND RESEARCH REAUTHORIZATION ACT OF 2015

SEC. 2. REAUTHORIZATION OF THE C.W. BILL YOUNG CELL TRANSPLANTATION PROGRAM.

(a) IN GENERAL.—Section 379(d)(2)(B) of the Public Health Service Act (42 U.S.C. 274k(d)(2)(B)) is amended—

(1) by striking "remote collection" and inserting "collection"; and

(2) by inserting "including remote collection," after "*goal of increasing collections of high quality* cord blood units,".

(b) AUTHORIZATION OF APPROPRIATIONS.—Section 379B of the Public Health Service Act (42 U.S.C. 274m) is amended—

(1) by striking "$30,000,000 for each of fiscal years 2011 through 2014 and"; and

(2) by inserting "and $30,000,000 for each of fiscal years 2016 through 2020" before the period at the end.

(c) SECRETARY REVIEW ON STATE OF SCIENCE.—The Secretary of Health and Human Services, in consultation with the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Administrator of the Health Resources and Services Administration, including the Advisory Council on Blood Stem Cell Transplantation established under section 379(a) of the Public Health Service Act (42 U.S.C. 274k(a)), and other stakeholders, where appropriate given relevant expertise, shall conduct a review of the state of the science of using adult stem cells and birthing tissues to develop new types of therapies for patients, for the purpose of considering the potential inclusion of such new types of therapies in the C.W. Bill Young Cell Transplantation Program (established under such section 379) in addition to the continuation of ongoing activities. Not later than June 30, 2019, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives recommendations on the appropriateness of such new types of therapies for inclusion in the C.W. Bill Young Cell Transplantation Program.

STEM CELL THERAPEUTIC AND RESEARCH ACT OF 2005

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SEC. 2. CORD BLOOD INVENTORY.

(a) IN GENERAL.—The Secretary of Health and Human Services shall enter into 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).

(b) REQUIREMENTS.—The Secretary shall require each recipient of a contract under this section—

(1) to acquire, tissue-type, test, cryopreserve, and store donated units of cord blood acquired with the informed consent of the donor, as determined by the Secretary pursuant to section 379(c) of the Public Health Service Act, in a manner that complies with applicable Federal and State regulations;

(2) to encourage donation from a genetically diverse population;

(3) to make cord blood units that are collected pursuant to this section or otherwise and meet all applicable Federal standards available to transplant centers for transplantation;

(4) to make cord blood units that are collected, but not appropriate for clinical use, available for peer-reviewed research;

(5) to make data available, as required by the Secretary and consistent with section 379(d)(3) of the Public Health Service Act (42 U.S.C. 274k(d)(3)), as amended by this Act, in a standardized electronic format, as determined by the Secretary, for the C.W. Bill Young Cell Transplantation Program; and

(6) to submit data in a standardized electronic format for inclusion in the stem cell therapeutic outcomes database maintained under section 379A of the Public Health Service Act, as amended by this Act.

(c) 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;

(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

(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.

(d) 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 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 date that is 5 years after the date on which the contract is entered into, except as provided in paragraphs (2), (3), and (4).

(2) EXTENSIONS.—The Secretary may extend the period of funding under a contract under this section to exceed a period of 5 years if—

(A) the Secretary finds that 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 (c) from any qualified cord blood bank that has not previously entered into 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) 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.

(4) CONSIDERATION OF BEST SCIENCE.—The Secretary shall take into consideration the best scientific information available in order to maximize the number of cord blood units available for transplant when entering into contracts under this section, or when extending a period of funding under such a contract under paragraph (2).

(5) CONSIDERATION OF BANKED UNITS OF CORD BLOOD.—In extending contracts pursuant to paragraph (3), and determining new allocation amounts for the next contract period or contract extension for such cord blood bank, the Secretary shall take into account the number of cord blood units banked in the National Cord Blood Inventory by a cord blood bank during the previous contract period, in addition to consideration of the ability of such cord blood bank to increase the collection and maintenance of additional, genetically diverse cord blood units.

(e) REGULATIONS.—The Secretary may promulgate regulations to carry out this section.

(f) DEFINITIONS.—In this section:

(1) The term "C.W. Bill Young Cell Transplantation Program" means the C.W. Bill Young Cell Transplantation Program under section 379 of the Public Health Service Act, as amended by this Act.

(2) The term "cord blood donor" means a mother who has delivered a baby and consents to donate the neonatal blood remaining in the placenta and umbilical cord after separation from the newborn baby.

(3) The term "cord blood unit" means the neonatal blood collected from the placenta and umbilical cord of a single newborn baby.

(4) The term "qualified cord blood bank" has the meaning given to that term in section 379(d)(4) of the Public Health Service Act, as amended by this Act.

(5) The term "Secretary" means the Secretary of Health and Human Services.

[(g) AUTHORIZATION OF APPROPRIATIONS.—

[(1) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary to carry out the program under this section $20,000,000 for fiscal year 2015 and $23,000,000 for each of fiscal years 2016 through 2020.]

(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $23,000,000 for each of fiscal years 2021 through 2025.

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