

111TH CONGRESS
2^D SESSION

S. 3751

AN ACT

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Stem Cell Therapeutic
3 and Research Reauthorization Act of 2010”.

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

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

9 (1) in subsection (a), by inserting “the inven-
10 tory goal of at least” before “150,000”;

11 (2) in subsection (c)—

12 (A) in paragraph (2), by striking “or is
13 transferred” and all that follows through the
14 period and inserting “for a first-degree rel-
15 ative.”; and

16 (B) in paragraph (3), by striking
17 “150,000”;

18 (3) in subsection (d)—

19 (A) in paragraph (1), by inserting “begin-
20 ning on the last date on which the recipient of
21 a contract under this section receives Federal
22 funds under this section” after “10 years”;

23 (B) in paragraph (2), by striking “; and”
24 and inserting “;”;

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

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

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

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

12 (4) in subsection (e)—

13 (A) in paragraph (1)—

14 (i) by striking “10 years” and insert-
15 ing “a period of at least 10 years begin-
16 ning on the last date on which the recipi-
17 ent of a contract under this section re-
18 ceives Federal funds under this section”;
19 and

20 (ii) by striking the second sentence
21 and inserting “The Secretary shall ensure
22 that no Federal funds shall be obligated
23 under any such contract after the date
24 that is 5 years after the date on which the

1 contract is entered into, except as provided
2 in paragraphs (2) and (3).”;

3 (B) in paragraph (2)—

4 (i) in the matter preceding subpara-
5 graph (A)—

6 (I) by striking “Subject to para-
7 graph (1)(B), the” and inserting
8 “The”; and

9 (II) by striking “3” and inserting
10 “5”;

11 (ii) in subparagraph (A) by striking
12 “150,000” and all that follows through
13 “and” at the end and inserting “the inven-
14 tory goal described in subsection (a) has
15 not yet been met;”;

16 (iii) in subparagraph (B)—

17 (I) by inserting “meeting the re-
18 quirements under subsection (d)”
19 after “receive an application for a
20 contract under this section”; and

21 (II) by striking “or the Sec-
22 retary” and all that follows through
23 the period at the end and inserting “;
24 or”; and

1 (iv) by adding at the end the fol-
2 lowing:

3 “(C) the Secretary determines that the
4 outstanding inventory need cannot be met by
5 the qualified cord blood banks under contract
6 under this section.”; and

7 (C) by striking paragraph (3) and insert-
8 ing the following:

9 “(3) EXTENSION ELIGIBILITY.—A qualified
10 cord blood bank shall be eligible for a 5-year exten-
11 sion of a contract awarded under this section, as de-
12 scribed in paragraph (2), provided that the qualified
13 cord blood bank—

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

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

1 “(C) annually provides to the Secretary a
2 plan for, and demonstrates, ongoing measurable
3 progress toward achieving self-sufficiency of
4 cord blood unit collection and banking oper-
5 ations.”;

6 (5) in subsection (g)(4), by striking “or par-
7 ent”;

8 (6) in subsection (h)—

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

11 “(1) AUTHORIZATION OF APPROPRIATIONS.—
12 There are authorized to be appropriated to the Sec-
13 retary to carry out the program under this section
14 \$23,000,000 for each of fiscal years 2011 through
15 2014 and \$20,000,000 for fiscal year 2015.”;

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

18 (C) in paragraph (2), as so redesignated,
19 by striking “in each of fiscal years 2007
20 through 2009” and inserting “for each of fiscal
21 years 2011 through 2015”.

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

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

1 “(6) The Secretary, acting through the Admin-
2 istrator of the Health Resources and Services Ad-
3 ministration, shall submit to Congress an annual re-
4 port on the activities carried out under this sec-
5 tion.”;

6 (2) in subsection (d)—

7 (A) in paragraph (2)—

8 (i) in the matter preceding subpara-
9 graph (A), by striking “With respect to
10 cord blood, the Program shall—” and in-
11 serting the following:

12 “(A) IN GENERAL.—With respect to cord
13 blood, the Program shall—”;

14 (ii) by redesignating subparagraphs
15 (A) through (H) as clauses (i) through
16 (viii) respectively;

17 (iii) by striking clause (iv), as so re-
18 designated, and inserting the following:

19 “(iv) support and expand new and ex-
20 isting studies and demonstration and out-
21 reach projects for the purpose of increas-
22 ing cord blood unit donation and collection
23 from a genetically diverse population and
24 expanding the number of cord blood unit
25 collection sites partnering with cord blood

1 banks receiving a contract under the Na-
2 tional Cord Blood Inventory program
3 under section 2 of the Stem Cell Thera-
4 peutic and Research Act of 2005, including
5 such studies and projects that focus on—

6 “(I) remote collection of cord
7 blood units, consistent with the re-
8 quirements under the Program and
9 the National Cord Blood Inventory
10 program goal described in section 2(a)
11 of the Stem Cell Therapeutic and Re-
12 search Act of 2005; and

13 “(II) exploring novel approaches
14 or incentives to encourage innovative
15 technological advances that could be
16 used to collect cord blood units, con-
17 sistent with the requirements under
18 the Program and such National Cord
19 Blood Inventory program goal;” and

20 (iv) by adding at the end the fol-
21 lowing:

22 “(B) EFFORTS TO INCREASE COLLECTION
23 OF HIGH QUALITY CORD BLOOD UNITS.—In
24 carrying out subparagraph (A)(iv), not later
25 than 1 year after the date of enactment of the

1 Stem Cell Therapeutic and Research Reauthor-
2 ization Act of 2010 and annually thereafter, the
3 Secretary shall set an annual goal of increasing
4 collections of high quality cord blood units, con-
5 sistent with the inventory goal described in sec-
6 tion 2(a) of the Stem Cell Therapeutic and Re-
7 search Act of 2005 (referred to in this subpara-
8 graph as the ‘inventory goal’), and shall identify
9 at least one project under subparagraph (A)(iv)
10 to replicate and expand nationwide, as appro-
11 priate. If the Secretary cannot identify a
12 project as described in the preceding sentence,
13 the Secretary shall submit a plan, not later
14 than 180 days after the date on which the Sec-
15 retary was required to identify such a project,
16 to the Committee on Health, Education, Labor,
17 and Pensions of the Senate and the Committee
18 on Energy and Commerce of the House of Rep-
19 resentatives for expanding remote collection of
20 high quality cord blood units, consistent with
21 the requirements under the National Cord
22 Blood Inventory program under section 2 of the
23 Stem Cell Therapeutic and Research Act of
24 2005 and the inventory goal. Each such plan
25 shall be made available to the public.

1 “(C) DEFINITION.—In this paragraph, the
2 term ‘remote collection’ means the collection of
3 cord blood units at locations that do not have
4 written contracts with cord blood banks for col-
5 lection support.”; and

6 (B) in paragraph (3)(A), by striking
7 “(2)(A)” and inserting “(2)(A)(i)”; and

8 (3) by striking subsection (f)(5)(A) and insert-
9 ing the following:

10 “(A) require the establishment of a system
11 of strict confidentiality to protect the identity
12 and privacy of patients and donors in accord-
13 ance with Federal and State law; and”.

14 (c) ADDITIONAL REPORTS.—

15 (1) INTERIM REPORT.—In addition to the an-
16 nual report required under section 379(a)(6) of the
17 Public Health Service Act (42 U.S.C. 274k(a)(6)),
18 the Secretary of Health and Human Services (re-
19 ferred to in this subsection as the “Secretary”), in
20 consultation with the Advisory Council established
21 under such section 379, shall submit to Congress an
22 interim report not later than 180 days after the date
23 of enactment of this Act describing—

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

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

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

12 (2) RECOMMENDATIONS.—Not later than 1
13 year after the date of enactment of this Act, the Ad-
14 visory Council shall submit recommendations to the
15 Secretary with respect to—

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

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

1 (d) AUTHORIZATION OF APPROPRIATIONS.—Section
2 379B of the Public Health Service Act (42 U.S.C. 274m)
3 is amended by striking “\$34,000,000” and all that follows
4 through the period at the end, and inserting “\$30,000,000
5 for each of fiscal years 2011 through 2014 and
6 \$33,000,000 for fiscal year 2015.”.

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

9 (1) IN GENERAL.—Not later than 1 year after
10 the date of enactment of this Act, the Comptroller
11 General of the United States shall submit to the
12 Committee on Health, Education, Labor, and Pen-
13 sions and the Committee on Appropriations of the
14 Senate, the Committee on Energy and Commerce
15 and the Committee on Appropriations of the House
16 of Representatives, and the Secretary of Health and
17 Human Services a report reviewing studies, dem-
18 onstration programs, and outreach efforts for the
19 purpose of increasing cord blood unit donation and
20 collection for the National Cord Blood Inventory to
21 ensure a high-quality and genetically diverse inven-
22 tory of cord blood units.

23 (2) CONTENTS.—The report described in para-
24 graph (1) shall include a review of such studies,
25 demonstration programs, and outreach efforts under

1 section 2 of the Stem Cell Therapeutic and Research
2 Act of 2005 (42 U.S.C. 274k note) (as amended by
3 this Act) and section 379 of the Public Health Serv-
4 ice Act (42 U.S.C. 274k) (as amended by this Act),
5 including—

6 (A) a description of the challenges and
7 barriers to expanding the number of cord blood
8 unit collection sites, including cost, the cash
9 flow requirements and operations of awarding
10 contracts, the methods by which funds are dis-
11 tributed through contracts, the impact of regu-
12 latory and administrative requirements, and the
13 capacity of cord blood banks to maintain high-
14 quality units;

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

18 (C) appropriate methods for improving
19 provider education about collecting cord blood
20 units for the national inventory and participa-
21 tion in such collection activities;

22 (D) estimates of the number of cord blood
23 unit collection sites necessary to meet the out-
24 standing national inventory need and the char-
25 acteristics of such collection sites that would

1 help increase the genetic diversity and enhance
2 the quality of cord blood units collected;

3 (E) best practices for establishing and sus-
4 taining partnerships for cord blood unit collec-
5 tion at medical facilities with a high number of
6 minority births;

7 (F) potential and proven incentives to en-
8 courage hospitals to become cord blood unit col-
9 lection sites and partner with cord blood banks
10 participating in the National Cord Blood Inven-
11 tory under section 2 of the Stem Cell Thera-
12 peutic and Research Act of 2005 and to assist
13 cord blood banks in expanding the number of
14 cord blood unit collection sites with which such
15 cord blood banks partner;

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

21 (H) a description of the methods used
22 prior to the date of enactment of this Act to
23 distribute funds to cord blood banks and rec-
24 ommendations for how to improve such methods
25 to encourage the efficient collection of high-

1 quality and diverse cord blood units, consistent
2 with the requirements of the C.W. Bill Young
3 Cell Transplantation Program and the National
4 Cord Blood Inventory program under section 2
5 of the Stem Cell Therapeutic and Research Act
6 of 2005.

7 (f) DEFINITION.—In this Act, the term “remote col-
8 lection” has the meaning given such term in section
9 379(d)(2)(C) of the Public Health Service Act.

Passed the Senate September 28, 2010.

Attest:

Secretary.

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