

**AMENDMENT IN THE NATURE OF A SUBSTITUTE  
TO H.R. 6081**

**OFFERED BY M<sub>r.</sub> Pallone**

Strike all after the enacting clause and insert the following:

**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 “at least” be-  
10 fore “150,000”;

11           (2) in subsection (c)—

12               (A) in paragraph (2), by striking “until  
13 such time that the cord blood unit is released  
14 for transplantation or is transferred by the  
15 family to the C.W. Bill Young Cell Transplan-  
16 tation Program in accordance with guidance or  
17 regulations promulgated by the Secretary” and  
18 inserting “until such time that the cord blood

1 unit is released for transplantation for a first-  
2 degree relative”; and

3 (B) in paragraph (3), by striking “the  
4 150,000 inventory goal” and inserting “the in-  
5 ventory goal of at least 150,000”;

6 (3) in subsection (d)—

7 (A) in paragraph (1), by striking “a period  
8 of at least 10 years” and inserting “a period of  
9 at least 10 years beginning on the last date on  
10 which the recipient of a contract under this sec-  
11 tion receives Federal funds under this section”;

12 (B) in paragraph (2), by striking “; and”  
13 and inserting “;”;

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

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

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

23 “(4) will annually provide to the Secretary a  
24 plan for, and demonstrate, ongoing measurable

1 progress toward achieving self-sufficiency of cord  
2 blood unit collection and banking operations; and”;

3 (4) in subsection (e)—

4 (A) in paragraph (1)—

5 (i) by striking “10 years” and insert-  
6 ing “a period of at least 10 years begin-  
7 ning on the last date on which the recipi-  
8 ent of a contract under this section re-  
9 ceives Federal funds under this section”;  
10 and

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

18 (B) in paragraph (2)—

19 (i) in the matter preceding subpara-  
20 graph (A)—

21 (I) by striking “Subject to para-  
22 graph (1)(B), the” and inserting  
23 “The”; and

24 (II) by striking “3” and inserting  
25 “5”;

1 (ii) in subparagraph (A)—

2 (I) by inserting “at least” before  
3 “150,000”; and

4 (II) by striking “; and” and in-  
5 serting “;”;

6 (iii) in subparagraph (B)—

7 (I) by inserting “meeting the re-  
8 quirements under subsection (d)”  
9 after “receive an application for a  
10 contract under this section”; and

11 (II) by striking “or the Sec-  
12 retary” and all that follows through  
13 the period at the end and inserting “;  
14 or”; and

15 (iv) by adding at the end the fol-  
16 lowing:

17 “(C) the Secretary determines that the  
18 outstanding inventory need cannot be met by  
19 the qualified cord blood banks under contract  
20 under this section.”; and

21 (C) by striking paragraph (3) and insert-  
22 ing the following:

23 “(3) EXTENSION ELIGIBILITY.—A qualified  
24 cord blood bank shall be eligible for a 5-year exten-  
25 sion of a contract awarded under this section, as de-

1 scribed in paragraph (2), provided that the qualified  
2 cord blood bank—

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

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

14 “(C) annually provides to the Secretary a  
15 plan for, and demonstrates, ongoing measurable  
16 progress toward achieving self-sufficiency of  
17 cord blood unit collection and banking oper-  
18 ations.”;

19 (5) in subsection (g)(4), by striking “or par-  
20 ent”; and

21 (6) in subsection (h)—

22 (A) by striking paragraph (2) and insert-  
23 ing the following:

24 “(2) AUTHORIZATION OF APPROPRIATIONS.—

25 There are authorized to be appropriated to the Sec-

1       retary to carry out the program under this section  
2       \$23,000,000 for each of fiscal years 2011 through  
3       2014 and \$20,000,000 for fiscal year 2015. Such  
4       funds so appropriated shall remain available until  
5       expended.”; and

6               (B) in paragraph (3), by striking “in each  
7               of fiscal years 2007 through 2009” and insert-  
8               ing “for each of fiscal years 2011 through  
9               2015”.

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

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

14               “(6) The Secretary, acting through the Advi-  
15       sory Council, shall submit to Congress an annual re-  
16       port on the activities carried out under this sec-  
17       tion.”;

18               (2) by striking subsection (d)(2)(D) and insert-  
19       ing the following:

20               “(D) support studies and demonstration  
21       and outreach projects for the purpose of in-  
22       creasing cord blood unit donation and collection  
23       from a genetically diverse population, including  
24       exploring novel approaches or incentives, such  
25       as remote or other innovative technological ad-

1 vances that could be used to collect cord blood  
2 units, to expand the number of cord blood unit  
3 collection sites partnering with cord blood  
4 banks that receive a contract under the Na-  
5 tional Cord Blood Bank Inventory program  
6 under section 2 of the Stem Cell Therapeutic  
7 and Research Act of 2005;” 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) AUTHORIZATION OF APPROPRIATIONS.—Section  
15 379B of the Public Health Service Act (42 U.S.C. 274m)  
16 is amended by striking “\$34,000,000” and all that follows  
17 through the period at the end, and inserting “\$30,000,000  
18 for each of fiscal years 2011 through 2014 and  
19 \$33,000,000 for fiscal year 2015. Such funds so appro-  
20 priated shall remain available until expended.”.

21 (d) REPORT ON CORD BLOOD UNIT DONATION AND  
22 COLLECTION.—

23 (1) IN GENERAL.—Not later than 1 year after  
24 the date of enactment of this Act, the Comptroller  
25 General of the United States shall submit to the

1 Committee on Health, Education, Labor, and Pen-  
2 sions and the Committee on Appropriations of the  
3 Senate, the Committee on Energy and Commerce  
4 and the Committee on Appropriations of the House  
5 of Representatives, and the Secretary of Health and  
6 Human Services a report reviewing studies, dem-  
7 onstration programs, and outreach efforts for the  
8 purpose of increasing cord blood unit donation and  
9 collection for the National Cord Blood Inventory to  
10 ensure a high-quality and genetically diverse inven-  
11 tory of cord blood units.

12 (2) CONTENTS.—The report described in para-  
13 graph (1) shall include a review of such studies,  
14 demonstration programs, and outreach efforts under  
15 section 2 of the Stem Cell Therapeutic and Research  
16 Act of 2005 (42 U.S.C. 274k note) (as amended by  
17 this Act) and section 379 of the Public Health Serv-  
18 ice Act (42 U.S.C. 274k) (as amended by this Act),  
19 including—

20 (A) a description of the challenges and  
21 barriers to expanding the number of cord blood  
22 unit collection sites, including cost, the impact  
23 of regulatory and administrative requirements,  
24 and the capacity of cord blood banks to main-  
25 tain high-quality units;

1 (B) remote or other innovative techno-  
2 logical advances that could be used to collect  
3 cord blood units;

4 (C) appropriate methods for improving  
5 provider education about collecting cord blood  
6 units for the national inventory and participa-  
7 tion in such collection activities;

8 (D) estimates of the number of cord blood  
9 unit collection sites necessary to meet the out-  
10 standing national inventory need and the char-  
11 acteristics of such collection sites that would  
12 help increase the genetic diversity and enhance  
13 the quality of cord blood units collected;

14 (E) best practices for establishing and sus-  
15 taining partnerships for cord blood unit collec-  
16 tion at medical facilities with a high number of  
17 minority births;

18 (F) potential and proven incentives to en-  
19 courage hospitals to become cord blood unit col-  
20 lection sites and partner with cord blood banks  
21 participating in the National Cord Blood Inven-  
22 tory under section 2 of the Stem Cell Thera-  
23 peutic and Research Act of 2005 and to assist  
24 cord blood banks in expanding the number of

1 cord blood unit collection sites with which such  
2 cord blood banks partner; and  
3 (G) recommendations about methods cord  
4 blood banks and collection sites could use to  
5 lower costs and improve efficiency of cord blood  
6 unit collection without decreasing the quality of  
7 the cord blood units collected.

