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111TH CONGRESS
1ST SESSION

H. R. 2107

To direct the Secretary of Health and Human Services to conduct a public education campaign on umbilical cord blood stem cells, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 27, 2009

Ms. SPEIER introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Education and Labor, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To direct the Secretary of Health and Human Services to conduct a public education campaign on umbilical cord blood stem cells, and for other purposes.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Cord Blood Education and Awareness Act of 2009''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. FINDINGS.

Congress finds the following:

(1) Every 10 minutes, another child or adult is expected to die from leukemia, lymphoma or myeloma. Leukemia, lymphoma, and myeloma caused the deaths of an estimated 52,910 people in the United States in 2007 and accounted for nearly 9.4 percent of the deaths from cancer in 2008. In addition, leukemia causes more deaths than any other cancer among children and young adults under the age of 20.

(2) As many as 16,000 leukemia patients diagnosed each year require a bone marrow transplant but have no matched relative or cannot find a match in the national bone marrow registry. There is a 1 in 4 chance that an newborn baby's cord blood cells would be a perfect match to a sibling that suffers from 1 of 70 blood diseases.

(3) Umbilical cord blood stem cells (in this Act referred to as ''cord blood cells'') have effectively been used in the treatment of these conditions. To date, cord blood cells have been used in more than

14,000 transplants worldwide during the last 20 years.

(4) Cord blood cells, like marrow and blood, is a rich source of stem cells for allogeneic transplantation, especially for children. Cord blood cells used in transplant result in a lower rate of graft versus host disease than bone marrow and are easier to match based on HLA typing. In addition, cord blood cells have also been used to treat effectively non-malignant blood, immune, and metabolic disorders such as aplastic anemia, sickle cell anemia, severe combined immunodeficiencies, and leukodystrophies.

(5) Researchers have found that in addition to blood cell precursors, cord blood cells contains many different types of stem cells—the building blocks of bones, the heart, liver, and nervous system. Further, cord blood cells have proven to be pluripotent, which means they have the ability to differentiate into every cell type in the human body. Cord blood cells have also been shown decrease inflammation and stimulate tissue repair.

(6) Clinical research and experimental clinical use is underway to study the use of autologous cord blood cells to treat type 1 diabetes, brain injury, and cerebral palsy. In addition, preclinical research using

cord blood cells is showing promise in treating hearing loss, renal failure, spinal cord injury, and congenital heart valve defects.

(7) Of the more than 4,000,000 births in the United States each year, more than 90 percent of the cord blood cells are discarded as medical waste. Currently, less than one quarter of the States requires that expectant parents receive information regarding their options to bank their baby's cord blood in public or private blood banks.

(8) In 2005, the Institute of Medicine submitted a report to Congress entitled ''Establishing National Hematopoietic Stem Cell Bank Program'', and recommended that ''donors must be provided with clear information about their options'', for cord blood cells and that ''the information provided to a donor must include a balanced perspective on the different options for banking'' cord blood cells. The Institute also recommended that ''informed consent for the collection storage and use of cord blood should be obtained before labor and delivery, and after the adequate disclosure of information.''.

SEC. 3. PUBLIC EDUCATION CAMPAIGN.

Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services

(in this Act referred to as the ''Secretary'') shall develop and make publicly available, including by posting on the public website of the Department of Health and Human Services, a publication relating to umbilical cord blood that includes the following information:

(1) An explanation of the potential value and uses of umbilical cord blood, including cord blood cells and stem cells, for individuals who are, as well as individuals who are not, biologically related to a mother or her newborn child.

(2) An explanation of the differences between using one's own cord blood cells (autologous) and using related or unrelated cord blood stem cells (allogeneic use) in the treatment of disease.

(3) An explanation of the differences between public and private umbilical cord blood banking.

(4) The options available to a mother relating to stem cells that are contained in the umbilical cord blood after the delivery of her newborn, including—

(A) donating the stem cells to a public umbilical cord blood bank (where facilities are available);

(B) storing the stem cells in a private family umbilical cord blood bank for use by immediate and extended family members;

(C) storing the stem cells for immediate or extended family members through a family or sibling donor banking program that provides free collection, processing, and storage where there is an existing medical need; and

(D) discarding the stem cells.

(5) The medical processes involved in the collection of cord blood.

(6) Medical or family history criteria that can impact a family's consideration of umbilical cord blood banking, including the likelihood of using a baby's cord blood to serve as a match for a family member who has a medical condition.

(7) Options for ownership and future use of donated umbilical cord blood.

(8) The average cost of public and private umbilical cord blood banking.

(9) The availability of public and private cord blood banks, including—

(A) a list of public cord blood banks within the United States and the hospitals served by such banks;

(B) a list of private cord blood banks that are accredited, as determined by the Secretary; and

(C) the availability of free family banking and sibling donor programs where there is an existing medical need by a family member.

(10) An explanation of which racial and ethnic groups are in particular need of publicly donated cord blood samples based upon medical data developed by the Health Resources and Services Administration.

SEC. 4. PATIENT INFORMED CONSENT DOCUMENT.

(a) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall develop a written patient informed consent document relating to cord blood disposition to be presented and signed, to the extent feasible, by an expectant woman not later than 2 weeks before her estimated delivery date.

(b) CONTENTS.—The document developed under subsection (a) shall include the following:

(1) Information providing a balanced perspective on the different options for cord blood banking, including public donation, private banking, and disposal.

(2) Information on the medical value of cord blood stem cells in the treatment of disease.

(3) A declaration, to be signed, of a woman's chosen option for the disposition of a child's cord

blood stem cells, whether public donation, private banking, or other disposal.

SEC. 5. DUTY OF CERTAIN PROFESSIONALS TO DISCLOSE INFORMATION TO, AND OBTAIN INFORMED CONSENT FROM, PREGNANT PATIENTS.

(a) DISCLOSURE OF OPTIONS.—Effective 1 year after the date of the enactment of this Act, each physician or other health care professional who is primarily responsible for the furnishing ambulatory prenatal care to a pregnant woman shall—

(1) prior to the beginning of the third trimester of the pregnancy (or, if later, at the first visit of such pregnant woman to the provider), provide her with information developed under section 3 relating to the woman's options with respect to umbilical cord blood banking; and

(2) after providing such information and, to the extent feasible, not later than 2 weeks before the woman's estimated date of delivery, obtain a written informed consent described in section 4 relating to the woman's decision regarding disposition of cord blood stem cells or document that the provider sought such consent and the woman refused or declined to provide it.

(b) APPLICATION.—

(1) MEDICAID.—

(A) Section 1902(a) of the Social Security Act (42 U.S.C. 1396b(a)) is amended—

(i) by striking ''and'' at the end of paragraph (72);

(ii) by striking the period at the end of paragraph (73) and inserting ''; and''; and

(iii) by inserting after paragraph (73) the following new paragraph:

''(74) provide (A) that each physician or other health care professional who is primarily responsible for the furnishing ambulatory prenatal care to a pregnant woman and who is receiving funds under the plan for the furnishing of such care shall comply with the requirements of such section with respect to any pregnant woman to whom the provider furnishes such care; and (B) for a method to enforce such requirements.''.

(B) Section 1903 of such Act (42 U.S.C. 1396c) is amended by adding at the end the following new subsection:

''(aa) If the Secretary finds that a State has not complied with the requirement of section 1902(a)(74)(B), the Secretary may provide for such reduction in payment oth-

erwise made to the State under section 1902(a)(7) as may be appropriate, taking into account the costs the State would have incurred in complying with such requirement.''.

(2) CHIP.—Section 2107(e)(1) of such Act (42 U.S.C. 1397hh(e)(1)) is amended by adding at the end the following new subparagraph:

''(M) Sections 1902(a)(74) and 1903(aa) (relating to informing pregnant women concerning blood cord banking).''.

(3) EMPLOYER GROUP HEALTH PLANS UNDER ERISA.—Section 609 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1169) is amended—

(A) by redesignating subsection (e) as subsection (f); and

(B) by inserting after subsection (d) the following new subsection:

''(e) INFORMING PREGNANT WOMEN CONCERNING BLOOD CORD BANKING.—

''(1) IN GENERAL.—A group health plan, and a health insurance issuer that offers group health insurance coverage, that provides benefits for ambulatory prenatal care for a pregnant woman through an agreement or arrangement with a physician or other

health care professional who is primarily responsible for the furnishing ambulatory prenatal care to a pregnant woman shall require, as part of such agreement or arrangement with the physician or other professional, that the physician or professional comply with the requirements of such section with respect to any pregnant woman to whom the physician or professional furnishes such care.

''(2) CONTINUED APPLICABILITY OF STATE LAW.—Section 731(a) shall apply with respect to paragraph (1) in the same manner as such section applies to part 7.''.

(4) EFFECTIVE DATE.—The amendments made by this subsection shall apply to physicians and other health care professionals with respect to agreements and arrangements entered into or renewed on or after the date of the enactment of this Act.

SEC. 6. PROFESSIONAL EDUCATION.

The Secretary shall develop professional educational materials on umbilical cord blood stem cells, including the publication developed under section 3, for health care providers who provide prenatal services to pregnant women.

SEC. 7. TARGETED EDUCATION GRANTS.

(a) IN GENERAL.—The Secretary may make grants to entities for targeted education on current and medically

accurate information about umbilical cord blood stem cells and the different options for banking such cells.

(b) TARGETED GROUPS.—In making grants under this section, the Secretary shall consider making grants for targeted education to—

(1) health care providers pursuant to section 6;

(2) ethnic and racial minorities for whom public cord blood samples may be difficult to find;

(3) families with a genetic history of diseases treated by cord blood; and

(4) populations specifically affected by conditions currently treated with cord blood stem cells or conditions that may one day be treated with cord blood stem cells.

SEC. 8. AUTHORIZATION OF APPROPRIATIONS.

To carry out this Act, there are authorized to be appropriated $10,000,000 for fiscal year 2010 and $5,000,000 for each of fiscal years 2011 through 2014.

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