

AMENDED IN ASSEMBLY APRIL 10, 2007

AMENDED IN ASSEMBLY MARCH 13, 2007

CALIFORNIA LEGISLATURE—2007—08 REGULAR SESSION

ASSEMBLY BILL

No. 34

Introduced by Assembly Member Portantino
(Coauthors: Assembly Members Berg, De Leon, Dymally, and
Garcia Garcia, Huffman, Mullin, Nakanishi, and Wolk)
(Coauthor: Senator Romero)

December 4, 2006

An act to add and repeal Article 8 (commencing with Section 1627) to Chapter 4 of Division 2 of the Health and Safety Code, relating to umbilical cord blood banking.

LEGISLATIVE COUNSEL'S DIGEST

AB 34, as amended, Portantino. Umbilical cord blood collection program.

Existing law imposes various responsibilities upon the State Department of Health Services and prenatal care providers with respect to prenatal care, screening, and counseling.

Existing law, administered by the State Department of Health Services, contains provisions governing the licensure of blood banks, including provisions relating to licensure for purposes of umbilical cord blood banking. Existing law also requires the department to conduct the Umbilical Cord Blood Community Awareness Campaign. Effective July 1, 2007, responsibility for the administration of the above-described provisions will be transferred to the State Department of Public Health.

This bill would require the State Department of Public Health to establish, by July 1, 2009, the Umbilical Cord Blood Collection Program

for the purpose of collecting and storing umbilical cord blood for public use. The bill would ~~authorize~~ *require* the department to contract with up to 5 blood banks that are licensed *or accredited* to provide umbilical cord blood banking storage services to collect, and make available to doctors and their patients, umbilical cord blood.

The bill would require the department, on or before January 1, 2012, to submit an interim report to the Assembly Committee on Health and the Senate Committee on Health on the effectiveness of the program in diversifying the umbilical cord blood supply, and would require the program to conclude no later than December 31, 2018.

The bill would establish an ~~advisory~~ *implementing* committee to develop policy recommendations for purposes of implementing the program.

The bill would require that any funds available for purposes of the program be deposited into the Umbilical Cord Blood Collection Program Fund, which this bill would create. The bill would require that the moneys in the fund be available for expenditure, upon appropriation by the Legislature, for that purpose.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. The Legislature finds and declares all of the
- 2 following:
- 3 (a) Transplanted stem cells, called hematopoietic ~~stem cells~~
- 4 ~~(HSCs)~~ *progenitor cells (HPCs)*, can be used to treat and cure 70
- 5 different blood diseases. These include blood cancers, such as
- 6 leukemia, myeloma, and lymphoma, immunodeficiencies, and
- 7 genetic diseases, including sickle cell anemia ~~and thalassemia,~~
- 8 *thalassemia, inherited marrow failure disorders, and inherited*
- 9 *disorders or errors of metabolisms.*
- 10 ~~(b) A National Bone Marrow Donor Program has been~~
- 11 ~~established to register potential bone marrow donors. This registry~~
- 12 ~~can be searched for a match when a stem cell transplant is needed.~~
- 13 ~~However, the process to obtain bone marrow is an invasive and~~
- 14 ~~painful procedure.~~
- 15 (c)
- 16 (b) Cord blood has been found to contain very high
- 17 concentrations of ~~HSCs~~ *HPCs* and has been used successfully in

1 ~~over 2,000~~ *about 8,000* transplants since 1988. Collection of the
2 blood left in the *placenta and the* umbilical cord after the delivery
3 of an infant involves no pain or inconvenience to the infant or the
4 mother.

5 ~~(d)~~

6 *(c)* As the use of each of the different types of stem cells has its
7 own benefits and limitations, it is necessary to develop each source
8 of stem-cell *cells*.

9 ~~(e) In order to find the best tissue match for the most optimal
10 transplant outcome, genetic diversity is needed. According to the
11 National Marrow Donor Program, 35,000 people who search cord
12 blood and bone marrow registries cannot find a suitable match.
13 Ethnic minorities have a more difficult time finding a match for
14 HSCs because they are underrepresented in the national inventory.
15 Many of these patients die while waiting for a transplant.~~

16 *(d)* *The National Marrow Donor Program has been established
17 to register potential bone marrow donors. This registry can be
18 searched for a match when a stem cell transplant is needed. In
19 order to find the best tissue match for the most optimal transplant
20 outcome, genetic diversity is needed. According to the National
21 Marrow Donor Program, 35,000 children and adults could benefit
22 from a marrow or cord blood transplant each year. The Institute
23 of Medicine of the National Academies estimates patient candidates
24 for HPC transplants to be 11,700 annually. People of color have
25 a more difficult time finding a match for HPCs because they are
26 underrepresented in the national inventory. Many of these patients
27 die while waiting for a transplant.*

28 ~~(f)~~

29 *(e)* *The Institute of Medicine of the National Academies' report,
30 "Cord Blood – Establishing a National Hematopoietic Stem Cell
31 Bank Program (2005)" calls for an increase in the volume and
32 genetic diversity of the umbilical cord blood public bank inventory.
33 This report was the basis for establishing the 2005 National
34 Umbilical Cord Blood Program, which provides for the collection
35 and maintenance of human cord blood stem cells for the treatment
36 of patients and research.*

37 ~~(g)~~

38 *(f)* *The United States Congress has appropriated moneys to
39 partially fund these efforts.*

40 ~~(h)~~

1 (g) California was selected to participate in the national cord
2 blood program to increase the volume and diversity of umbilical
3 cord blood. California has also been a leader in cord blood ~~research~~
4 ~~transplants~~ *transplant research* and has a history of participation
5 in major projects contributing to its known and potential healing
6 remedies.

7 (†)

8 (h) The national cord blood program has a goal of collecting
9 150,000 genetically diverse units in order to obtain the best chances
10 of a tissue match. Due to a low supply of ethnically diverse cord
11 blood, they have specified target collection goals for specific
12 ethnicities, including, but not limited to, African-American, Asian,
13 Latino, and Native American people.

14 (‡)

15 (i) California is uniquely situated to substantially contribute to
16 these efforts with its high birth rate of more than 550,000 births
17 per year and ethnically diverse population, to be able to add high
18 volumes of genetically diverse umbilical cord blood units for public
19 banking. This contribution will serve the health needs of both the
20 national constituency and its own constituents. An increase in stem
21 cell transplants will save the state, insurers, and patients a
22 significant amount of money that is now being spent on less
23 effective treatments, and will relieve the ongoing pain and anguish
24 of affected patients and their families.

25 SEC. 2. Article 8 (commencing with Section 1627) is added
26 to Chapter 4 of Division 2 of the Health and Safety Code, to read:

27

28 Article 8. Umbilical Cord Blood Collection Program

29

30 1627. (a) On or before July 1, 2009, the State Department of
31 Public Health shall establish the Umbilical Cord Blood Collection
32 Program for the purpose of collecting and storing umbilical cord
33 blood for public use. The program shall conclude no later than
34 December 31, 2018.

35 (b) In implementing this program, the department shall consider
36 the policy recommendations of the advisory committee established
37 pursuant to Section 1627.5.

38 (c) The program shall attempt to meet all of the following
39 objectives:

1 (1) Increasing hospital participation in umbilical cord blood
2 *collection and storage* efforts.

3 (2) Developing and providing training to health care providers
4 relating to handling, labeling, *transporting*, and storing umbilical
5 cord blood.

6 (3) Obtaining patient consent to donate and store umbilical cord
7 blood. This objective shall include efforts to identify, understand,
8 and respect religious and personal beliefs relating to the removal
9 of human tissue.

10 (4) Creating specific umbilical cord blood inventory targets for
11 ethnically diverse populations.

12 (5) Identifying to what extent health care coverage issues exist
13 relating to umbilical cord blood storage procedures and services.

14 (6) Establishing a ratio for determining how many units of stored
15 umbilical cord blood may be used for research versus
16 transplantation, and a policy addressing the circumstances under
17 which units of blood may be used for either purpose.

18 (7) Developing a public awareness campaign, that may include,
19 but need not be limited to, activities described in Section 123370.

20 (8) Exploring the feasibility of operating the Umbilical Cord
21 Blood Collection Program as a self-funding program.

22 (9) Ensuring that the program complements the National Cord
23 Blood Program.

24 (d) In order to implement this program, the department ~~may~~
25 *shall* contract with up to five blood banks licensed *or accredited*
26 to provide umbilical cord blood banking storage services pursuant
27 to Section 1604.6, in order to build an inventory of umbilical cord
28 blood units and to make this *umbilical cord* blood available to
29 doctors and their patients. In selecting qualified facilities under
30 this subdivision, both of the following shall apply:

31 ~~(1) The department may use the federal Health Resources and
32 Services Administration's model of request for proposals to identify
33 qualified umbilical cord blood banks to implement this program.~~

34 (1) *The department may use a competitive bidding process to
35 identify qualified umbilical cord blood banks to administer this
36 program.*

37 (2) In order to qualify for selection under this section, a blood
38 bank shall have experience in blood collection, labeling, storage,
39 transportation, and distribution. The department shall endeavor to

1 select blood banks able to retrieve umbilical cord blood from
2 ethnically diverse communities.

3 (e) In implementing the program, the department shall make
4 every effort to avoid duplication or conflicts with existing and
5 ongoing programs and to leverage existing resources. The
6 department shall use its existing authority to promote the collection,
7 storage, and use of umbilical cord blood and advise the Legislature,
8 in its report prepared pursuant to subdivision (f), of its needs to
9 accomplish these goals.

10 1627.5. (a) There shall be established, within the State
11 Department of Public Health, an ~~advisory~~ *implementing* committee
12 to provide guidance and policy suggestions to the department on
13 the implementation of the Umbilical Cord Blood Collection
14 Program created pursuant to Section 1627.

15 (b) (1) The ~~advisory~~ *implementing* committee shall be composed
16 of ~~12~~ *15* members. The committee shall include representatives
17 with expertise and experience in all aspects of umbilical cord
18 collection and storage. The Governor, the Senate Committee on
19 Rules, and the Speaker of the Assembly shall each appoint ~~four~~
20 ~~members of the advisory~~ *five members of the implementing*
21 committee.

22 (2) *The implementing committee shall include all of the*
23 *following:*

24 (A) *A representative of blood banks licensed or accredited to*
25 *provide umbilical cord blood services.*

26 (B) *A representative of a stem cell transplant center that uses*
27 *umbilical cord blood.*

28 (C) *A representative of a participating birthing hospital.*

29 (D) *Four physicians of different practice types or geographical*
30 *regions with expertise in umbilical cord blood transplantation,*
31 *obstetrics and gynecology, oncology, hematology, or a pediatric*
32 *specialty that treats children with anemia, immune disorders, or*
33 *cancers that may be treated with stem cell transplantation.*

34 (E) *A patient or relative of a patient who has received*
35 *transplants using umbilical cord blood.*

36 (F) *A previous donor of umbilical cord blood or a person who*
37 *has searched or has been involved in searching for an unrelated*
38 *donor of umbilical cord blood.*

39 (G) *A person with expertise in typing, matching, and transplant*
40 *outcome data analysis.*

- 1 (H) *A scientist with expertise in stem cell biology.*
- 2 (I) *Three representatives of organizations focusing on medical*
- 3 *conditions that involve umbilical cord blood treatments or ethnic*
- 4 *or racial health disparities.*
- 5 (J) *A health plan medical director.*
- 6 (c) ~~Advisory~~ *Implementing* committee members shall serve
- 7 without compensation, except that members shall be reimbursed
- 8 for authorized travel costs and expenses.
- 9 (d) For purposes of implementing the Umbilical Cord Blood
- 10 Collection Program established pursuant to Section 1627, the
- 11 ~~advisory~~ *implementing* committee, by January 1, 2009, shall make
- 12 initial policy recommendations to the department and the
- 13 Legislature on meeting the objectives contained in subdivision (c)
- 14 of Section 1627.
- 15 1628. No later than January 1, 2012, the department shall
- 16 submit an interim report to the Assembly Committee on Health
- 17 and the Senate Committee on Health on the effectiveness of the
- 18 Umbilical Cord Blood Bank Collection Program in diversifying
- 19 the umbilical cord blood supply.
- 20 1628.5. (a) The department may accept public and private
- 21 funds for the purpose of implementing this article.
- 22 (b) Any funds made available for purposes of this article shall
- 23 be deposited into the Umbilical Cord Blood Collection Program
- 24 Fund, which is hereby created in the State Treasury. Moneys in
- 25 the fund shall be available, upon appropriation by the Legislature,
- 26 for purposes of this article.
- 27 (c) The fund shall include any federal, state, and private funds
- 28 made available for purposes of the program, and, notwithstanding
- 29 Section 16305.7 of the Government Code, any interest earned on
- 30 money in the fund.
- 31 1629. This article shall remain in effect only until January 1,
- 32 2019, and as of that date is repealed, unless a later enacted statute,
- 33 that is enacted before January 1, 2019, deletes or extends that date.