

AMENDED IN ASSEMBLY AUGUST 20, 2007

AMENDED IN SENATE MAY 1, 2007

AMENDED IN SENATE APRIL 19, 2007

AMENDED IN SENATE APRIL 12, 2007

**SENATE BILL**

**No. 962**

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**Introduced by Senator Migden**

February 23, 2007

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An act to amend Section 123371 of, and to add Section 124991 to, the Health and Safety Code, relating to umbilical cord blood banking.

LEGISLATIVE COUNSEL'S DIGEST

SB 962, as amended, Migden. Umbilical cord blood biomedical resources 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 State Department of Health Services, also contains provisions governing the licensure of blood banks, including provisions relating to licensure or accreditation for purposes of umbilical cord blood banking. Existing law also requires the department to conduct the Umbilical Cord Blood Community Awareness Campaign, which, among things, authorizes a primary prenatal care provider, as defined, to provide to a woman who is known to be pregnant, during the first prenatal visit, certain information developed by the department regarding her options with respect to umbilical cord blood banking.

Existing law establishes the Umbilical Cord Blood Education Account, in which private donations are collected and deposited for the purpose

of funding the information developed by the department pursuant to the Umbilical Blood Community Awareness Campaign, *and* requires these funds to be available upon a determination by the Director of Finance that sufficient private donations have been collected and deposited into the account, ~~and provides that no public funds may be used for the purpose of funding the above-described provisions.~~

Existing law, the Hereditary Disorders Act, requires the State Department of Health Services to establish regulations and standards for a hereditary disorders program, including with respect to prenatal testing programs for newborns. A violation of these provisions is a crime.

Pursuant to this act, existing regulations require clinicians to provide all pregnant women, at the first prenatal visit, with information about the use and availability of prenatal screening for birth defects of the fetus. If a pregnant woman voluntarily requests prenatal screening, these regulations, among other things, require a clinician to make available to her the opportunity to read and sign a consent document, as specified.

Effective July 1, 2007, responsibility for the administration of the above-mentioned provisions will be transferred to the State Department of Public Health.

~~This bill would delete the requirements that the Director of Finance must make a determination that sufficient funds are available in this account, and that no public funds may be used to develop the information required pursuant to the Umbilical Blood Community Awareness Campaign. It would also authorize a primary prenatal care provider to provide this information *required to be developed pursuant to the Umbilical Blood Community Awareness Campaign* to a woman who is known to be pregnant during the first prenatal visit.~~

The bill would also require, as part of the Hereditary Disorders Act, the department to establish a state umbilical cord blood biomedical resources program to collect, process, and store umbilical cord blood stem cells for the purposes of transplantation and research, and would require the department to establish fees relating to these purposes to cover the costs of administering the program. The bill would set forth the various duties of the department in implementing the program and would require that information collected pursuant to the program be confidential, and be used solely for the purposes of the program, as specified. The bill would create the Umbilical Cord Blood Biomedical Resources Program Fund, into which fees collected pursuant to the bill would be deposited, with the fund to be used by the department, upon

appropriation by the Legislature, for purposes of administering the program, as prescribed.

The Committee for the Protection of Human Subjects (CPHS) serves as the institutional review board for the California Health and Human Services Agency, for the purpose of assuring that research involving human subjects is conducted ethically and with minimum risk to participants.

This bill would require CPHS to determine if certain criteria relating to the security and confidentiality of donor's personal information are met before umbilical cord blood collected under the program may be used for research activities.

By creating a new crime, this bill would create a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

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

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

1 SECTION 1. The Legislature finds and declares that the  
2 removal and discarding of umbilical cord blood from a pregnant  
3 woman at the time of birth delivery, without the understanding  
4 and approval of the expectant families, is a growing concern to  
5 the people of this state.

6 SEC. 2. Section 123371 of the Health and Safety Code is  
7 amended to read:

8 123371. (a) (1) The State Department of Health Services shall  
9 develop standardized, objective information about umbilical cord  
10 blood donation that is sufficient to allow a pregnant woman to  
11 make an informed decision on whether to participate in a private  
12 or public umbilical cord blood banking program. The information  
13 developed by the department shall enable a pregnant woman to be  
14 informed of her option to do any of the following:

15 (A) Discard umbilical cord blood.

16 (B) Donate umbilical cord blood to a public umbilical cord  
17 blood bank.

1 (C) Store the umbilical cord blood in a family umbilical cord  
2 blood bank for the use by immediate and extended family members.

3 (2) The information developed pursuant to paragraph (1) shall  
4 include, but not be limited to, all of the following:

5 (A) The current and potential future medical uses of stored  
6 umbilical cord blood.

7 (B) The benefits and risks involved in umbilical cord blood  
8 banking.

9 (C) The medical process involved in umbilical cord blood  
10 banking.

11 (D) Medical or family history criteria that can impact a family's  
12 consideration of umbilical cord banking.

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

15 (F) The availability and costs of public or private umbilical cord  
16 blood banks.

17 (G) Medical or family history criteria that can impact a family's  
18 consideration of umbilical cord blood banking.

19 (H) An explanation that the practices and policies of blood banks  
20 may vary with respect to accreditation, cord blood processing and  
21 storage methods, costs, and donor privacy.

22 (b) The information provided by the department pursuant to  
23 subdivision (a) shall be made available in Cantonese, English,  
24 Spanish, and Vietnamese, and shall be updated by the department  
25 as needed.

26 (c) The information provided by the department pursuant to  
27 subdivision (a) shall be made available on the Internet Web sites  
28 of the licensing boards that have oversight over primary prenatal  
29 care providers.

30 (d) (1) A primary prenatal care provider of a woman who is  
31 known to be pregnant may, during the first prenatal visit, provide  
32 the information required by subdivision (a) to the pregnant woman.

33 (2) For purposes of this article, a "prenatal care provider" means  
34 a health care provider licensed pursuant to Division 2 (commencing  
35 with Section 500) of the Business and Professions Code, or  
36 pursuant to an initiative act referred to in that division, who  
37 provides prenatal medical care within his or her scope of practice.

38 (e) The department ~~may accept private donations that shall only~~  
39 *implement this article upon a determination by the Director of*  
40 *Finance, that sufficient private donations have been collected and*

1 deposited into the Umbilical Cord Blood Education Account, which  
2 is hereby created in the State Treasury. The moneys in the account  
3 shall be available, upon appropriation by the Legislature, for the  
4 purposes of this article. *No public funds shall be used to implement*  
5 *this article.* If sufficient funds are collected and deposited into the  
6 account, the Director of Finance shall file a written notice thereof  
7 with the Secretary of State.

8 SEC. 3. Section 124991 is added to the Health and Safety Code,  
9 to read:

10 124991. (a) The State Department of Public Health shall  
11 establish the Umbilical Cord Blood Biomedical Resources Program  
12 for the purpose of collecting, processing, and storing umbilical  
13 cord blood stem cells to be used for transplantation and research.

14 (b) In implementing this program, the department shall do all  
15 of the following:

16 (1) Establish a public repository for umbilical cord blood cells  
17 that ensures that all umbilical cord blood is collected, stored, and  
18 distributed in accordance with the donor's wishes. The department  
19 may contract with existing facilities that are licensed and certified  
20 to perform this task.

21 (2) Establish a system to retrieve and transport umbilical cord  
22 blood donations.

23 (3) Establish a system for matching umbilical cord blood donors  
24 with recipients of umbilical cord blood for medicinal use.

25 (c) (1) All information collected pursuant to the Umbilical Cord  
26 Blood Biomedical Resources Program shall be confidential, and  
27 shall be used solely for the purposes of the program. Access to  
28 confidential information shall be limited to authorized persons  
29 who agree, in writing, to maintain the confidentiality of that  
30 information.

31 (2) The department shall maintain an accurate record of all  
32 persons who are given confidential information pursuant to this  
33 section, and any disclosure of confidential information shall be  
34 made only upon written agreement that the information will be  
35 kept confidential, used for its approved purpose, and not be further  
36 disclosed.

37 (3) Any person who, in violation of a written agreement to  
38 maintain confidentiality, discloses any information provided  
39 pursuant to this section, or who uses information provided pursuant  
40 to this section in a manner other than as approved pursuant to this

1 section may be denied further access to any confidential  
2 information maintained by the department, and shall be subject to  
3 a civil penalty not exceeding one thousand dollars (\$1,000). The  
4 penalty provided in this section shall not be construed as to limit  
5 or otherwise restrict any remedy, provisional or otherwise, provided  
6 by law for the benefit of the department or any other person  
7 covered by this section.

8 (4) Notwithstanding the restrictions of this section, an individual  
9 to whom the confidential information pertains shall have access  
10 to his or her own personal information.

11 (d) In order to implement this program, the department shall  
12 establish fees of an amount that shall not exceed the costs of  
13 administering the program, which the department shall collect  
14 from researchers and health care providers who have been approved  
15 by the department and who seek to use the umbilical cord blood  
16 for research or transplantation.

17 (e) Fees collected pursuant to subdivision (d) shall be deposited  
18 into the Umbilical Cord Blood Biomedical Resources Program  
19 Fund, which is hereby created in the State Treasury. The fund shall  
20 be composed of all fees collected pursuant to subdivision (d) and,  
21 notwithstanding Section 16305.7 of the Government Code, all  
22 interest and dividends earned on money in the fund. The fund may  
23 be used by the department, upon appropriation by the Legislature,  
24 for the purposes specified in subdivision (f).

25 (f) The fund shall be used by the department in accordance with  
26 both of the following:

27 (1) For fees collected related to umbilical cord blood that is  
28 used for research, the fees shall pay for costs related to data  
29 management, including data linkage and entry, and umbilical cord  
30 blood storage, retrieval, processing, inventory, and shipping.

31 (2) For fees collected related to umbilical cord blood that is  
32 used for transplantation, the fees shall pay for the costs related to  
33 conducting and analyzing tests, transplants, or other medical  
34 activities, as approved by the department and in accordance with  
35 this section.

36 (g) The department shall adopt rules and regulations necessary  
37 for the purpose of implementing this section.

38 (h) The department, health care providers, and local health  
39 departments shall maintain the confidentiality of patient  
40 information in accordance with existing law and in the same

1 manner as other medical record information with patient  
2 identification that they possess, and shall use the information only  
3 for the following purposes:

4 (1) Research to identify risk factors for children’s and women’s  
5 diseases.

6 (2) Research to develop and evaluate screening tests.

7 (3) Research to develop and evaluate prevention strategies.

8 (4) Research to develop and evaluate treatments.

9 (i) (1) For purposes of ensuring the security of a donor’s  
10 personal information, before any umbilical cord blood is released  
11 pursuant to this section for research purposes, the State Committee  
12 for the Protection of Human Subjects (CPHS) shall determine if  
13 all of the following criteria have been met:

14 (A) The Umbilical Cord Blood Biomedical Resources Program  
15 contractors or other entities approved by the department have  
16 provided a plan sufficient to protect personal information from  
17 improper use and disclosures, including sufficient administrative,  
18 physical, and technical safeguards to protect personal information  
19 from reasonable anticipated threats to the security or confidentiality  
20 of the information.

21 (B) The Umbilical Cord Blood Biomedical Resources Program  
22 contractors or other entities approved by the department have  
23 provided a sufficient plan to destroy or return all personal  
24 information as soon as it is no longer needed for the research  
25 activity, unless the program contractors or other entities approved  
26 by the department have demonstrated an ongoing need for the  
27 personal information for the research activity and have provided  
28 a long-term plan sufficient to protect the confidentiality of that  
29 information.

30 (C) The Umbilical Cord Blood Biomedical Resources Program  
31 contractors or other entities approved by the department have  
32 provided sufficient written assurances that the personal information  
33 will not be reused or disclosed to any other person or entity, or  
34 used in any manner not approved in the research protocol, except  
35 as required by law or for authorized oversight of the research  
36 activity.

37 (2) As part of its review and approval of the research activity  
38 for the purpose of protecting personal information held in agency  
39 databases, CPHS shall accomplish at least all of the following:

- 1 (A) Determine whether the requested personal information is  
2 needed to conduct the research.
- 3 (B) Permit access to personal information only if it is needed  
4 for the research activity.
- 5 (C) Permit access only to the minimum necessary personal  
6 information needed for the research activity.
- 7 (D) Require the assignment of unique subject codes that are not  
8 derived from personal information in lieu of social security  
9 numbers if the research can still be conducted without social  
10 security numbers.
- 11 (E) If feasible, and if cost, time, and technical expertise permit,  
12 require the agency to conduct a portion of the data processing for  
13 the researcher to minimize the release of personal information.
- 14 (j) In addition to the fees described in subdivision (d), the  
15 department may bill a researcher for the costs associated with the  
16 department’s process of protecting personal information, including,  
17 but not limited to, the department’s costs for conducting a portion  
18 of the data processing for the researcher, removing personal  
19 information, encrypting or otherwise securing personal information,  
20 or assigning subject codes.
- 21 (k) Nothing in this section shall prohibit the department from  
22 using its existing authority to enter into written agreements to  
23 enable other institutional review boards to approve research  
24 activities, projects or classes of projects for the department,  
25 provided the data security requirements set forth in this section  
26 are satisfied.
- 27 SEC. 3. No reimbursement is required by this act pursuant to  
28 Section 6 of Article XIII B of the California Constitution because  
29 the only costs that may be incurred by a local agency or school  
30 district will be incurred because this act creates a new crime or  
31 infraction, eliminates a crime or infraction, or changes the penalty  
32 for a crime or infraction, within the meaning of Section 17556 of  
33 the Government Code, or changes the definition of a crime within  
34 the meaning of Section 6 of Article XIII B of the California  
35 Constitution.

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