

AMENDED IN SENATE APRIL 19, 2007

AMENDED IN SENATE APRIL 12, 2007

SENATE BILL

No. 962

Introduced by Senator Migden

February 23, 2007

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 ~~collection~~ *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, 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. The bill would also require the department to include the information developed by the department about umbilical cord blood banking options in the information provided to pregnant women about prenatal screening pursuant to the above-described regulations. It would also to require a primary prenatal care provider to provide this information 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 ~~banking~~ *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, ~~including updating the information currently provided by clinicians to pregnant women pursuant to the above-described existing regulations, by providing prescribed information.~~ The bill would create the Umbilical Cord Blood ~~Collection~~ *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 ~~expanding the definition of an existing~~ *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. ~~This~~ *The*
13 *information developed by the department shall enable a pregnant*
14 *woman to be 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 (1)
- 6 (A) The current and potential future medical uses of stored
7 umbilical cord blood.
- 8 (2)
- 9 (B) The benefits and risks involved in umbilical cord blood
10 banking.
- 11 (3)
- 12 (C) The medical process involved in umbilical cord blood
13 banking.
- 14 (4)
- 15 (D) Medical or family history criteria that can impact a family's
16 consideration of umbilical cord banking.
- 17 (5)
- 18 (E) An explanation of the differences between public and private
19 umbilical cord blood banking.
- 20 (6)
- 21 (F) The availability and costs of public or private umbilical cord
22 blood banks.
- 23 (7)
- 24 (G) Medical or family history criteria that can impact a family's
25 consideration of umbilical cord blood banking.
- 26 (8)
- 27 (H) An explanation that the practices and policies of blood banks
28 may vary with respect to accreditation, cord blood processing and
29 storage methods, costs, and donor privacy.
- 30 (b) The information provided by the department pursuant to
31 subdivision (a) shall be made available in Cantonese, English,
32 Spanish, and Vietnamese, *and shall be updated by the department*
33 *as needed.*
- 34 (c) The information provided by the department pursuant to
35 subdivision (a) shall be made available on the Internet Web sites
36 of the licensing boards that have oversight over primary prenatal
37 care providers.
- 38 (d) (1) ~~The primary prenatal care provider of a woman who is~~
39 ~~known to be pregnant may, during the first prenatal visit, provide~~
40 ~~her with information developed by the department regarding her~~

1 options with respect to umbilical cord blood banking at the same
2 time the provider provides information regarding the use and
3 availability of prenatal screening for birth defects of the fetus, as

4 (A) *Upon the development of the information required by*
5 *subdivision (a), the department shall include this information in*
6 *the prenatal screening information required by Section 6527 of*
7 *Title 17 of the California Code of Regulations.*

8 (B) *A primary prenatal care provider of a woman who is known*
9 *to be pregnant shall, during the first prenatal visit, provide the*
10 *information required by subparagraph (A) to the pregnant woman.*

11 (2) For purposes of this article, a “prenatal care provider” means
12 a health care provider licensed pursuant to Division 2 (commencing
13 with Section 500) of the Business and Professions Code, or
14 pursuant to an initiative act referred to in that division, who
15 provides prenatal medical care within his or her scope of practice.

16 (e) ~~The department shall only implement this article upon a~~
17 ~~determination by the Director of Finance, that sufficient~~ *may accept*
18 *private donations that have been collected and deposited into the*
19 *Umbilical Cord Blood Education Account, which is hereby created*
20 *in the State Treasury. The moneys in the account shall be available,*
21 *upon appropriation by the Legislature, for the purposes of this*
22 *article. No public funds shall be used to implement this article. If*
23 *sufficient funds are collected and deposited into the account, the*
24 *Director of Finance shall file a written notice thereof with the*
25 *Secretary of State.*

26 ~~SEC. 2:~~

27 *SEC. 3.* Section 124991 is added to the Health and Safety Code,
28 to read:

29 124991. (a) The State Department of Public Health shall
30 establish the Umbilical Cord Blood ~~Collection~~ *Biomedical*
31 *Resources* Program for the purpose of collecting, processing, and
32 storing umbilical cord blood stem cells to be used for
33 transplantation and research.

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

36 (1) Establish a *public* repository for umbilical cord blood cells
37 that ensures that all umbilical cord blood is collected, stored, and
38 distributed in accordance with the donor’s wishes. *The department*
39 *may contract with existing facilities that are licensed and certified*
40 *to perform this task.*

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

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

5 ~~(4) Update the information provided to pregnant women~~
6 ~~pursuant to Section 6527 of Title 17 of the California Code of~~
7 ~~Regulations with information about this program. The requirements~~
8 ~~associated with this section shall also include the option of~~
9 ~~umbilical cord blood banking. For purposes of this section, these~~
10 ~~options shall include all of the following:~~

11 ~~(A) Discarding the stem cells.~~

12 ~~(B) Donating the stem cells to a public umbilical cord blood~~
13 ~~bank.~~

14 ~~(C) Storing the stem cells in a family umbilical cord blood bank~~
15 ~~for the use by immediate and extended family members.~~

16 (c) In order to implement this program, the department shall
17 establish fees of an amount that shall not exceed the costs of
18 administering the program, which the department shall collect
19 from researchers and health care providers who have been approved
20 by the department and who seek to use the umbilical cord blood
21 for research or transplantation.

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

30 (e) The fund shall be used by the department in accordance with
31 both of the following:

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

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

1 (f) The department shall adopt rules and regulations necessary
2 for the purpose of implementing this section.

3 (g) *The department, health care providers, and local health*
4 *departments shall maintain the confidentiality of patient*
5 *information in accordance with existing law and in the same*
6 *manner as other medical record information with patient*
7 *identification that they possess, and shall use the information only*
8 *for the following purposes:*

9 (1) *Research to identify risk factors for children's and women's*
10 *diseases.*

11 (2) *Research to develop and evaluate screening tests.*

12 (3) *Research to develop and evaluate prevention strategies.*

13 (4) *Research to develop and evaluate treatments.*

14 (h) (1) *For purposes of ensuring the security of a donor's*
15 *personal information, before any umbilical cord blood is released*
16 *pursuant to this section for research purposes, the State Committee*
17 *for the Protection of Human Subjects (CPHS) shall determine if*
18 *all of the following criteria have been met:*

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

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

35 (C) *The Umbilical Cord Blood Biomedical Resources Program*
36 *contractors or other entities approved by the department have*
37 *provided sufficient written assurances that the personal information*
38 *will not be reused or disclosed to any other person or entity, or*
39 *used in any manner not approved in the research protocol, except*

1 *as required by law or for authorized oversight of the research*
2 *activity.*

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

6 *(A) Determine whether the requested personal information is*
7 *needed to conduct the research.*

8 *(B) Permit access to personal information only if it is needed*
9 *for the research activity.*

10 *(C) Permit access only to the minimum necessary personal*
11 *information needed for the research activity.*

12 *(D) Require the assignment of unique subject codes that are not*
13 *derived from personal information in lieu of social security*
14 *numbers if the research can still be conducted without social*
15 *security numbers.*

16 *(E) If feasible, and if cost, time, and technical expertise permit,*
17 *require the agency to conduct a portion of the data processing for*
18 *the researcher to minimize the release of personal information.*

19 *(i) In addition to the fees described in subdivision (c), the*
20 *department may bill a researcher for the costs associated with the*
21 *department's process of protecting personal information, including,*
22 *but not limited to, the department's costs for conducting a portion*
23 *of the data processing for the researcher, removing personal*
24 *information, encrypting or otherwise securing personal*
25 *information, or assigning subject codes.*

26 *(j) Nothing in this section shall prohibit the department from*
27 *using its existing authority to enter into written agreements to*
28 *enable other institutional review boards to approve research*
29 *activities, projects or classes of projects for the department,*
30 *provided the data security requirements set forth in this section*
31 *are satisfied.*

32 **SEC. 3.** No reimbursement is required by this act pursuant to
33 Section 6 of Article XIII B of the California Constitution because
34 the only costs that may be incurred by a local agency or school
35 district will be incurred because this act creates a new crime or
36 infraction, eliminates a crime or infraction, or changes the penalty
37 for a crime or infraction, within the meaning of Section 17556 of
38 the Government Code, or changes the definition of a crime within

1 the meaning of Section 6 of Article XIII B of the California
2 Constitution.

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