

AMENDED IN ASSEMBLY AUGUST 31, 2007

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

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~~ ~~biomedical resources program~~. *blood: research.*

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

Existing law, administered by ~~State Department of Health Services~~, ~~also the department~~, 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 *other* 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 Cord 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.

Existing law, the Hereditary Disorders Act, requires the ~~State Department of Health Services~~ *department* 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.

Existing law also provides for the Birth Defects Monitoring Program, administered by the department, which includes the storage of pregnancy blood for research-related purposes.

~~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 authorize a primary prenatal care provider to provide information required to be developed pursuant to the Umbilical Cord 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~~ *provide any umbilical cord blood samples it receives pursuant to the Umbilical Cord Blood Community Awareness Campaign to the Birth Defects Monitoring Program, for storage and research,* and would require the department to ~~establish fees relating to these purposes to be collected from researchers and health care providers, who have been approved by the department, to use the umbilical cord blood samples for research,~~ to cover the costs of administering the program. The bill would set forth the various duties of the department ~~in implementing the program~~

relating to collecting and storing the samples, and would require that information collected pursuant to the program in connection with the samples be confidential, and be used solely for the purposes of the program, as specified. The bill would create the ~~Umbilical Cord Blood Biomedical Resources~~ Birth Defects Monitoring 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~~ paying the costs associated with the department's duties with respect to umbilical cord blood samples, 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 a donor's personal information are met before umbilical cord blood *samples that have been collected under the program may be used* are released for research activities.

The bill would provide that these provisions shall only become operative if AB 34, of the 2007–08 Regular Session, is enacted and becomes operative on or before January 1, 2008.

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.

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

3 123371. (a) (1) The State Department of Health Services shall
4 develop standardized, objective information about umbilical cord
5 blood donation that is sufficient to allow a pregnant woman to
6 make an informed decision on whether to participate in a private
7 or public umbilical cord blood banking program. The information
8 developed by the department shall enable a pregnant woman to be
9 informed of her option to do any of the following:

10 (A) Discard umbilical cord blood.

11 (B) Donate umbilical cord blood to a public umbilical cord
12 blood bank.

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

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

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

19 (B) The benefits and risks involved in umbilical cord blood
20 banking.

21 (C) The medical process involved in umbilical cord blood
22 banking.

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

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

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

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

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

34 (b) The information provided by the department pursuant to
35 subdivision (a) shall be made available in Cantonese, English,
36 Spanish, and Vietnamese, and shall be updated by the department
37 as needed.

38 (c) The information provided by the department pursuant to
39 subdivision (a) shall be made available on the Internet Web sites

1 of the licensing boards that have oversight over primary prenatal
2 care providers.

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

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

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

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

23 124991. (a) The State Department of Public Health shall
24 ~~establish the Umbilical Cord Blood Biomedical Resources Program~~
25 ~~for the purpose of collecting, processing, and storing umbilical~~
26 ~~cord blood stem cells to be used for transplantation and research.~~
27 *provide any umbilical cord blood samples it receives pursuant to*
28 *Section 123371 to the Birth Defects Monitoring Program for*
29 *storage and research.*

30 ~~(b) In implementing this program, the department shall do all~~
31 ~~of the following:~~

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

37 ~~(2) Establish a system to retrieve and transport umbilical cord~~
38 ~~blood donations.~~

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

1 ~~(e) (1) All information collected pursuant to the Umbilical Cord~~
2 ~~Blood Biomedical Resources Program shall be confidential, and~~

3 ~~(b) (1) All information relating to umbilical cord blood samples~~
4 ~~collected and utilized by the Birth Defects Monitoring Program~~
5 ~~shall be confidential, and shall be used solely for the purposes of~~
6 ~~the program. Access to confidential information shall be limited~~
7 ~~to authorized persons who agree, in writing, to maintain the~~
8 ~~confidentiality of that information.~~

9 (2) The department shall maintain an accurate record of all
10 persons who are given confidential information pursuant to this
11 section, and any disclosure of confidential information shall be
12 made only upon written agreement that the information will be
13 kept confidential, used for its approved purpose, and not be further
14 disclosed.

15 (3) Any person who, in violation of a written agreement to
16 maintain confidentiality, discloses any information provided
17 pursuant to this section, or who uses information provided pursuant
18 to this section in a manner other than as approved pursuant to this
19 section may be denied further access to any confidential
20 information maintained by the department, and shall be subject to
21 a civil penalty not exceeding one thousand dollars (\$1,000). The
22 penalty provided in this section shall not be construed as to limit
23 or otherwise restrict any remedy, provisional or otherwise, provided
24 by law for the benefit of the department or any other person
25 covered by this section.

26 ~~(4) Notwithstanding the restrictions of this section, an individual~~
27 ~~to whom the confidential information pertains shall have access~~
28 ~~to his or her own personal information.~~

29 ~~(d)~~

30 (c) In order to implement this program, the department shall
31 establish fees of an amount that shall not exceed the costs of
32 administering the program, which the department shall collect
33 from researchers and health care providers who have been approved
34 by the department and who seek to use the umbilical cord blood
35 ~~samples for research or transplantation.~~

36 ~~(e)~~

37 (d) Fees collected pursuant to subdivision ~~(d)~~ (c) shall be
38 deposited into the ~~Umbilical Cord Blood Biomedical Resources~~
39 ~~Birth Defects Monitoring Program Fund~~, which is hereby created
40 in the State Treasury. The fund shall be composed of all fees

1 collected pursuant to subdivision ~~(d)~~ (c) and, notwithstanding
2 Section 16305.7 of the Government Code, all interest and dividends
3 earned on money in the fund. The fund may be used by the
4 department, upon appropriation by the Legislature, for the purposes
5 specified in subdivision ~~(f)~~ (e).

6 ~~(f) The fund shall be used by the department in accordance with~~
7 ~~both of the following:~~

8 ~~(1) For fees collected related to umbilical cord blood that is~~
9 ~~used for research, the fees shall pay for costs related to data~~

10 ~~(e) Moneys in the fund shall be used for the costs related to data~~
11 ~~management, including data linkage and entry, and umbilical cord~~
12 ~~blood storage, retrieval, processing, inventory, and shipping.~~

13 ~~(2) For fees collected related to umbilical cord blood that is~~
14 ~~used for transplantation, the fees shall pay for the costs related to~~
15 ~~conducting and analyzing tests, transplants, or other medical~~
16 ~~activities, as approved by the department and in accordance with~~
17 ~~this section.~~

18 ~~(g)~~

19 (f) The department shall adopt rules and regulations ~~necessary~~
20 ~~for the purpose of implementing this section:~~ *pursuant to existing*
21 *requirements in the Birth Defects Monitoring Program, as set forth*
22 *in Chapter 1 (commencing with Section 103825) of Part 2 of*
23 *Division 102.*

24 ~~(h)~~

25 (g) The department, health care providers, and local health
26 departments shall maintain the confidentiality of patient
27 information in accordance with existing law and in the same
28 manner as other medical record information with patient
29 identification that they possess, and shall use the information only
30 for the following purposes:

31 (1) Research to identify risk factors for children's and women's
32 diseases.

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

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

35 (4) Research to develop and evaluate treatments.

36 ~~(i)~~

37 (h) (1) For purposes of ensuring the security of a donor's
38 personal information, before any umbilical cord blood ~~is~~ *samples*
39 *are* released pursuant to this section for research purposes, the

1 State Committee for the Protection of Human Subjects (CPHS)
2 shall determine if all of the following criteria have been met:

3 (A) ~~The Umbilical Cord Blood Biomedical Resources~~*Birth*
4 *Defects Monitoring* Program contractors or other entities approved
5 by the department have provided a plan sufficient to protect
6 personal information from improper use and disclosures, including
7 sufficient administrative, physical, and technical safeguards to
8 protect personal information from reasonable anticipated threats
9 to the security or confidentiality of the information.

10 (B) ~~The Umbilical Cord Blood Biomedical Resources~~ *Birth*
11 *Defects Monitoring* Program contractors or other entities approved
12 by the department have provided a sufficient plan to destroy or
13 return all personal information as soon as it is no longer needed
14 for the research activity, unless the program contractors or other
15 entities approved by the department have demonstrated an ongoing
16 need for the personal information for the research activity and have
17 provided a long-term plan sufficient to protect the confidentiality
18 of that information.

19 (C) ~~The Umbilical Cord Blood Biomedical Resources~~ *Birth*
20 *Defects Monitoring* Program contractors or other entities approved
21 by the department have provided sufficient written assurances that
22 the personal information will not be reused or disclosed to any
23 other person or entity, or used in any manner not approved in the
24 research protocol, except as required by law or for authorized
25 oversight of the research activity.

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

29 (A) Determine whether the requested personal information is
30 needed to conduct the research.

31 (B) Permit access to personal information only if it is needed
32 for the research activity.

33 (C) Permit access only to the minimum necessary personal
34 information needed for the research activity.

35 (D) Require the assignment of unique subject codes that are not
36 derived from personal information in lieu of social security
37 numbers if the research can still be conducted without social
38 security numbers.

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

4 ~~(j)~~

5 (i) In addition to the fees described in subdivision ~~(d)~~ (c), the
6 department may bill a researcher for the costs associated with the
7 department's process of protecting personal information, including,
8 but not limited to, the department's costs for conducting a portion
9 of the data processing for the researcher, removing personal
10 information, encrypting or otherwise securing personal information,
11 or assigning subject codes.

12 ~~(k)~~

13 (j) Nothing in this section shall prohibit the department from
14 using its existing authority to enter into written agreements to
15 enable other institutional review boards to approve research
16 activities, projects or classes of projects for the department,
17 provided the data security requirements set forth in this section
18 are satisfied.

19 *SEC. 3. This act shall only become operative if Assembly Bill*
20 *34, of the 2007–08 Regular Session, is enacted and becomes*
21 *operative on or before January 1, 2008.*

22 ~~SEC. 3.~~

23 *SEC. 4.* No reimbursement is required by this act pursuant to
24 Section 6 of Article XIII B of the California Constitution because
25 the only costs that may be incurred by a local agency or school
26 district will be incurred because this act creates a new crime or
27 infraction, eliminates a crime or infraction, or changes the penalty
28 for a crime or infraction, within the meaning of Section 17556 of
29 the Government Code, or changes the definition of a crime within
30 the meaning of Section 6 of Article XIII B of the California
31 Constitution.