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AMENDED IN ASSEMBLY APRIL 2, 2009

CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

ASSEMBLY BILL

No. 1487

Introduced by Assembly Member Hill

(Coauthor: Senator Leno)

February 27, 2009

An act to amend ~~Section~~ *Sections 1635, 1644, and 1644.5* of the Health and Safety Code, relating to tissue donation, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

AB 1487, as amended, Hill. Tissue donation.

Existing law prohibits the transfer of any tissues, as defined, into the body of another person by means of transplantation, unless the donor of the tissues has been screened and found nonreactive for evidence of infection with human immunodeficiency virus (HIV), agents of viral hepatitis (HBV and HCV), human T lymphotropic virus-1 (HTLV-1), and syphilis, except as provided.

Existing law requires that all donors of sperm be screened and found nonreactive under the above provisions, except as provided. Under existing law, a sperm donor who has tested reactive for HIV or HTLV-1 may be used for insemination or advanced reproductive technology for a recipient who has tested negative only after processing to minimize the infectiousness of the sperm. The State Department of Public Health

is required to adopt regulations by January 1, 2010, regulating facilities that perform this processing.

Existing law further requires the physician providing insemination or advanced reproductive technologies to, among other things, inform the recipient that the processing may not eliminate the risk of infection, that the sperm may be tested to ensure that it is free from HIV or HTLV-1, and about the potential adverse effects of testing on the sperm.

This bill would *extend until January 1, 2014, the date for adopting regulations and would allow the department to adopt initial regulations based on the “Guidelines for Reducing Risk of Viral Transmission During Fertility Treatment” using a specified process.* The bill would also require the physician to inform the recipient that she must provide documentation to the physician providing insemination or advanced reproductive technology services prior to treatment that she has established an ongoing physician relationship with another physician to provide for her medical care during and after completion of fertility services and about the medical guidelines for testing after use of sperm from an HIV or HTLV reactive donor.

Under existing law, the physician performing insemination or advanced reproductive technology is required to provide prophylactic treatments, followup testing, and monitoring, as specified, to the recipient to minimize the risk of infection.

This bill would remove those requirements but would require the physician to recommend followup testing of the recipient for HIV and HTLV, as specified.

Existing law allows the use of sperm from a donor who has tested reactive for HIV or HTLV-1 if the recipient has also previously been documented with HIV or HTLV-1 and where mutual consent has been obtained.

This bill would remove this provision. The bill would also make all of the provisions above applicable to donors who have tested reactive for any of the human T lymphotropic viruses.

This bill would declare that it is to take effect immediately as an urgency statute.

Vote: $\frac{2}{3}$. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

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

1 **SECTION 1.** *Section 1635 of the Health and Safety Code is*
2 *amended to read:*

3 1635. (a) “Donor” ~~is~~ *means* an individual, living or deceased,
4 from whom tissue is removed.

5 (b) “Person” ~~is~~ *means* an individual, corporation, business trust,
6 estate trust, partnership, association, state or local government, or
7 subdivision or agency thereof, or any other legal entity.

8 (c) “Tissue” ~~is any~~ *means* a human cell, group of cells, tissue
9 or organ including the cornea, sclera, or vitreous humor and other
10 segments of, or the whole eye, bones, skin, arteries, sperm, blood,
11 other fluids, and any other portion of a human body.

12 (d) “Tissue bank” ~~is any~~ *means* a place, establishment, or
13 institution that collects, processes, stores, or distributes tissue for
14 transplantation into human beings.

15 (e) “Transplantation” ~~is~~ *means* the act or process of transferring
16 tissue, including by ingestion, from a donor to the body of the
17 donor or another human being.

18 (f) “~~State department~~” ~~is~~ “*Department*” *means* the State
19 Department of *Public Health Services*.

20 **SEC. 2.** *Section 1644 of the Health and Safety Code is amended*
21 *to read:*

22 1644. (a) For purposes of this chapter, “donor,” “person,”
23 “tissue,” “transplantation,” and “~~state department~~” “*department*”
24 shall have the meaning as defined for those terms in Section 1635.

25 (b) *For purposes of this chapter, “HIV” shall mean human*
26 *immunodeficiency virus.*

27 **SECTION 1.**

28 **SEC. 3.** *Section 1644.5 of the Health and Safety Code is*
29 *amended to read:*

30 1644.5. (a) No tissues shall be transferred into the body of
31 another person by means of transplantation, unless the donor of
32 the tissues has been screened and found nonreactive by laboratory
33 tests for evidence of infection with ~~HHV~~ *human immunodeficiency*
34 *virus (HIV)*, agents of viral hepatitis (HBV and HCV), human T
35 lymphotropic virus ~~HTLV~~ (*HTLV*), and syphilis, except as
36 provided in subdivision (c). The department may adopt regulations
37 requiring additional screening tests of donors of tissues when, in

1 the opinion of the department, the action is necessary for the
2 protection of the public, donors, or recipients.

3 (b) Notwithstanding subdivision (a), infectious disease screening
4 of blood and blood products shall be carried out solely in
5 accordance with Article 2 (commencing with Section 1602.5) of
6 Chapter 4.

7 (c) All donors of sperm shall be screened and found nonreactive
8 as required under subdivision (a), except in the following instances:

9 (1) A recipient of sperm, from a sperm donor known to the
10 recipient, may waive a second or other repeat testing of that donor
11 if the recipient is informed of the requirements for testing donors
12 under this section and signs a written waiver.

13 (2) A recipient of sperm may consent to therapeutic insemination
14 of sperm or use of sperm in other advanced reproductive
15 technologies even if the sperm donor is found reactive for hepatitis
16 B, hepatitis C, syphilis, HIV or HTLV if the sperm donor is the
17 spouse of, partner of, or designated donor for that recipient. The
18 physician providing insemination or advanced reproductive
19 technology services shall advise the donor and recipient of the
20 potential medical risks associated with receiving sperm from a
21 reactive donor. The donor and the recipient shall sign a document
22 affirming that each comprehends the potential medical risks of
23 using sperm from a reactive donor for the proposed procedure and
24 that each consents to it. Copies of the document shall be placed in
25 the medical records of the donor and the recipient.

26 (3) (A) Sperm whose donor has tested reactive for syphilis may
27 be used for the purposes of insemination or advanced reproductive
28 technology only after the donor has been treated for syphilis. Sperm
29 whose donor has tested reactive for hepatitis B may be used for
30 the purposes of insemination or advanced reproductive technology
31 only after the recipient has been vaccinated against hepatitis B.

32 (B) (i) Sperm whose donor has tested reactive for HIV or HTLV
33 may be used for the purposes of insemination or advanced
34 reproductive technology for a recipient testing negative for HIV
35 or HTLV only after the donor's sperm has been effectively
36 processed to minimize the infectiousness of the sperm for that
37 specific donation and where informed and mutual consent has
38 occurred.

39 (ii) Not later than January 1, ~~2010~~ 2014, the department shall
40 adopt regulations regulating facilities that perform sperm

1 processing, pursuant to this subparagraph, that prescribe standards
2 for the handling and storage of sperm samples of carriers of HIV,
3 HTLV, or any other virus as deemed appropriate by the department.
4 The department may propose to adopt, as initial regulations,
5 ~~guidelines made~~ *the recommendations made within the “Guidelines*
6 *for Reducing Risk of Viral Transmission During Fertility*
7 *Treatment” as published* by the American Society for Reproductive
8 Medicine. Notice of the department’s proposed adoption of the
9 regulations shall be posted on the department’s Internet Web site
10 for at least 45 days. Public comment shall be accepted by the
11 department for at least 30 days after ~~posting of the notice~~ *the*
12 *conclusion of the 45-day posting period*. If a member of the public
13 requests a public hearing during the 30-day comment period, the
14 hearing shall be held prior to the adoption of the regulations. *If no*
15 *member of the public requests a public hearing, the regulations*
16 *shall be deemed adopted at the conclusion of the 30-day comment*
17 *period*. Comments received shall be considered prior to the
18 adoption of the final initial regulations. The department may
19 modify any guidance published by the American Society for
20 Reproductive Medicine ~~based on the comments received~~. Adoption
21 of initial regulations by the department pursuant to this subdivision
22 shall not be subject to the rulemaking requirements of Chapter 3.5
23 (commencing with Section 11340) of Part 1 of Division 3 of Title
24 2 of the Government Code and written responses to public
25 comments shall not be required. Updates to the regulations shall
26 be adopted pursuant to the same process. Until the department
27 adopts these regulations, facilities that perform sperm processing
28 pursuant to this section shall follow facility and sperm processing
29 guidelines for the reduction of viral transmission developed by the
30 American Society for Reproductive Medicine. Nothing in this
31 section shall prevent the department from monitoring and
32 inspecting facilities that process sperm to ensure adherence to the
33 regulations, or, until regulations are adopted, to the guidelines set
34 forth by the American Society for Reproductive Medicine.

35 (iii) Prior to insemination or other advanced reproductive
36 technology services, the physician providing the services shall
37 inform the recipient of sperm from a donor who has tested reactive
38 for HIV or HTLV of all of the following:

39 (I) That sperm processing may not eliminate all of the risks of
40 HIV or HTLV transmission.

1 (II) That the sperm may be tested to determine whether or not
2 it is reactive for HIV or HTLV.

3 (III) That the recipient must provide documentation to the
4 physician providing insemination or advanced reproductive
5 technology services prior to treatment that she has established an
6 ongoing relationship with another physician to provide for her
7 medical care during and after completion of fertility services.

8 ~~(IV) The medical guidelines of the American Society for~~
9 ~~Reproductive Medicine regarding followup testing for HIV and~~
10 ~~HTLV after use of sperm from an HIV or HTLV reactive donor~~
11 ~~and that recommendations regarding followup testing will be~~
12 ~~documented in the recipient's medical record.~~

13 *(IV) The recommendations made within the "Guidelines for*
14 *Reducing the Risk of Viral Transmission During Fertility*
15 *Treatment" published by the American Society for Reproductive*
16 *Medicine regarding followup testing for HIV and HTLV after use*
17 *of sperm from an HIV or HTLV reactive donor and have the*
18 *recommendations regarding followup testing be documented in*
19 *the recipient's medical record.*

20 (iv) The physician providing insemination or advanced
21 reproductive technology services shall also verify, and document
22 in the recipient's medical record, that the donor of sperm who tests
23 reactive for HIV or HTLV is under the care of a physician
24 managing the HIV or HTLV.

25 ~~(v) The physician providing insemination or advanced~~
26 ~~reproductive technology services shall recommend to the physician~~
27 ~~who will be providing ongoing care to the recipient recommended~~
28 ~~followup testing for HIV and HTLV according to the medical~~
29 ~~guidelines of the American Society for Reproductive Medicine,~~
30 ~~which shall be documented in the recipient's medical record.~~

31 *(v) The physician providing insemination or advanced*
32 *reproductive technology services shall recommend to the physician*
33 *who will be providing ongoing care to the recipient recommended*
34 *followup testing for HIV and HTLV according to the "Guidelines*
35 *for Reducing the Risk of Viral Transmission During Fertility*
36 *Treatment" published by the American Society for Reproductive*
37 *Medicine, which shall be documented in the recipient's medical*
38 *record.*

39 (vi) In the event that the recipient becomes HIV or HTLV
40 positive, the physician assuming ongoing care of the recipient shall

1 treat or provide information regarding referral to a physician who
2 can provide ongoing treatment of the HIV or HTLV.

3 (4) The penalties of Section 1621.5 shall not apply to a sperm
4 donor covered under this subdivision.

5 (d) Subdivision (a) shall not apply to the transplantation of tissue
6 from a donor who has not been tested or, with the exception of
7 HIV and HTLV, has been found reactive for the infectious diseases
8 listed in subdivision (a) or for which the department has, by
9 regulation, required additional screening tests, if both of the
10 following conditions are satisfied:

11 (1) The physician and surgeon performing the transplantation
12 has determined any one or more of the following:

13 (A) Without the transplantation the intended recipient will most
14 likely die during the period of time necessary to obtain other tissue
15 or to conduct the required tests.

16 (B) The intended recipient already is diagnosed with the
17 infectious disease for which the donor has tested positive.

18 (C) The symptoms from the infectious disease for which the
19 donor has tested positive will most likely not appear during the
20 intended recipient's likely lifespan after transplantation with the
21 tissue or may be treated prophylactically if they do appear.

22 (2) Consent for the use of the tissue has been obtained from the
23 recipient, if possible, or if not possible, from a member of the
24 recipient's family, or the recipient's legal guardian. For purposes
25 of this section, "family" shall mean spouse, adult son or daughter,
26 either parent, adult brother or sister, or grandparent.

27 (e) Human breast milk from donors who test reactive for agents
28 of viral hepatitis (HBV and HCV), HTLV, HIV, or syphilis shall
29 not be used for deposit into a milk bank for human ingestion in
30 California.

31 SEC. 2. This act is an urgency statute necessary for the
32 immediate preservation of the public peace, health, or safety within
33 the meaning of Article IV of the Constitution and shall go into
34 immediate effect. The facts constituting the necessity are:

35 To help prevent the spread of HIV, at the earliest possible time,
36 it is necessary that this legislation take immediate effect.

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