

AMENDED IN ASSEMBLY MARCH 29, 2012

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 2356

Introduced by Assembly Member Skinner

February 24, 2012

An act to amend Section 1644.5 of the Health and Safety Code, relating to human tissue.

LEGISLATIVE COUNSEL'S DIGEST

AB 2356, as amended, Skinner. 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), syphilis, and human T lymphotropic virus (HTLV), except as provided. Existing law requires that all donors of sperm be screened and found nonreactive under the above provisions, except as provided.

This bill would except screened sperm donated by a sexually intimate partner of the recipient, as defined, from these requirements.

Vote: majority. Appropriation: no. Fiscal committee: no.
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:

1 (a) Single women and same-sex female couples using a known
2 donor are unable to access the same fertility services as women
3 seeking to conceive using a male partner.

4 (b) Women seeking fertility services to help them conceive with
5 a male partner are able to be inseminated using fresh sperm.
6 Because of the practical difficulty of performing the required
7 testing and fears of liability, most fertility services will not provide
8 fresh insemination services to ~~women~~ *a woman* using a donor who
9 is not her partner. All other women are required to have their
10 ~~donor's donors'~~ sperm frozen, which significantly reduces the
11 chance of conceiving and, for many donors, means that conception
12 is not possible without much more expensive procedures.

13 (c) Federal Food and Drug Administration (FDA) regulations
14 require extensive testing, except when the donor is a “sexually
15 intimate ~~partner.”~~ *partner*” (21 C.F.R. 1271.90). This term is not
16 defined in regulations, but its explicit purpose is to allow donation
17 without testing when the recipient has already been exposed. Thus,
18 this term can be interpreted to include women who have already
19 attempted at-home inseminations with their ~~donor's donors'~~ sperm
20 because they have already been exposed through these attempts.
21 *Until the term sexually intimate partner is explicitly defined by the*
22 *FDA, it is the intent of the Legislature to provide a clarification*
23 *that, for the purposes of tissues donated for reproductive use, a*
24 *“sexually intimate partner” includes any woman who has been*
25 *exposed to the donor's sperm outside of a medical setting.*

26 (d) The definition of “sexually intimate partner” is limited to
27 this act and ~~does not~~ *is not intended* to have any effect on any
28 provision of the Family Code, including the definition of a “donor”
29 for purposes of determining legal parentage of a child.

30 SEC. 2. Section 1644.5 of the Health and Safety Code is
31 amended to read:

32 1644.5. (a) Except as provided in subdivision (c) or (d), no
33 tissues shall be transferred into the body of another person by
34 means of transplantation, unless the donor of the tissues has been
35 screened and found nonreactive by laboratory tests for evidence
36 of infection with human immunodeficiency virus (HIV), agents
37 of viral hepatitis (HBV and HCV), and syphilis. For tissues that
38 are rich in viable leukocytes, the tissue shall be tested for evidence
39 of infection with human T lymphotropic virus (HTLV) and found
40 nonreactive. The department may adopt regulations requiring

1 additional screening tests of donors of tissues when, in the opinion
2 of the department, the action is necessary for the protection of the
3 public, donors, or recipients.

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

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

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

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

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

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

1 (ii) Not later than January 1, 2014, the department shall adopt
2 regulations regulating facilities that perform sperm processing,
3 pursuant to this subparagraph, that prescribe standards for the
4 handling and storage of sperm samples of carriers of HIV, HTLV,
5 or any other virus as deemed appropriate by the department. The
6 department may propose to adopt, as initial regulations, the
7 recommendations made within the “Guidelines for Reducing Risk
8 of Viral Transmission During Fertility Treatment” as published
9 by the American Society for Reproductive Medicine. Notice of
10 the department’s proposed adoption of the regulations shall be
11 posted on the department’s Internet Web site for at least 45 days.
12 Public comment shall be accepted by the department for at least
13 30 days after the conclusion of the 45-day posting period. If a
14 member of the public requests a public hearing during the 30-day
15 comment period, the hearing shall be held prior to the adoption of
16 the regulations. If no member of the public requests a public
17 hearing, the regulations shall be deemed adopted at the conclusion
18 of the 30-day comment period. Comments received shall be
19 considered prior to the adoption of the final initial regulations. The
20 department may modify any guidance published by the American
21 Society for Reproductive Medicine. Adoption of initial regulations
22 by the department pursuant to this subdivision shall not be subject
23 to the rulemaking requirements of Chapter 3.5 (commencing with
24 Section 11340) of Part 1 of Division 3 of Title 2 of the Government
25 Code and written responses to public comments shall not be
26 required. Updates to the regulations shall be adopted pursuant to
27 the same process. Until the department adopts these regulations,
28 facilities that perform sperm processing pursuant to this section
29 shall follow facility and sperm processing guidelines for the
30 reduction of viral transmission developed by the American Society
31 for Reproductive Medicine. Nothing in this section shall prevent
32 the department from monitoring and inspecting facilities that
33 process sperm to ensure adherence to the regulations, or, until
34 regulations are adopted, to the guidelines set forth by the American
35 Society for Reproductive Medicine.

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

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

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

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

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

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

22 (v) The physician providing insemination or advanced
23 reproductive technology services shall recommend to the physician
24 who will be providing ongoing care to the recipient recommended
25 followup testing for HIV and HTLV according to the “Guidelines
26 for Reducing the Risk of Viral Transmission During Fertility
27 Treatment” published by the American Society for Reproductive
28 Medicine, which shall be documented in the recipient’s medical
29 record.

30 (vi) In the event that the recipient becomes HIV or HTLV
31 positive, the physician assuming ongoing care of the recipient shall
32 treat or provide information regarding referral to a physician who
33 can provide ongoing treatment of the HIV or HTLV.

34 (4) Sperm donated by a sexually intimate partner of the recipient
35 for reproductive use. For purposes of this paragraph, “sexually
36 intimate partner of the recipient” means a donor to whose sperm
37 the recipient has previously been exposed in a nonmedical setting
38 in an attempt to conceive.

39 (d) Subdivision (a) shall not apply to the transplantation of tissue
40 from a donor who has not been tested or, with the exception of

1 HIV and HTLV, has been found reactive for the infectious diseases
2 listed in subdivision (a) or for which the department has, by
3 regulation, required additional screening tests, if both of the
4 following conditions are satisfied:

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

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

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

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

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

21 (e) The penalties of Section 1621.5 shall not apply to a sperm
22 donor covered under subdivision (c).

23 (f) Human breast milk from donors who test reactive for agents
24 of viral hepatitis (HBV and HCV), HTLV, HIV, or syphilis shall
25 not be used for deposit into a milk bank for human ingestion in
26 California.

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