
THIRD READING

Bill No: AB 1896
Author: Quirk (D)
Amended: 8/24/22 in Senate
Vote: 21

SENATE HEALTH COMMITTEE: 9-0, 6/22/22
AYES: Pan, Melendez, Eggman, Gonzalez, Leyva, Limón, Roth, Rubio, Wiener
NO VOTE RECORDED: Grove, Hurtado

SENATE APPROPRIATIONS COMMITTEE: 7-0, 8/11/22
AYES: Portantino, Bates, Bradford, Jones, Laird, McGuire, Wieckowski

ASSEMBLY FLOOR: 75-1, 5/25/22 - See last page for vote

SUBJECT: Gamete banks

SOURCE: Author

DIGEST: This bill requires gamete banks to provide specified information to individuals obtaining donor gametes in order to conceive children, including the limitations of donor screening, and that some donor-conceived persons are or may be interested in contact with the donor whose gametes were used for their conception. In addition, this bill requires gamete banks to provide specified information to prospective gamete donors, including information regarding the potential of direct-to-consumer genetic testing to reveal the relatedness of the donor to children conceived with the donor's gametes, even if the donor has chosen not to reveal their identity. This bill requires the California Department of Public Health (CDPH) to develop the guidance to be provided in consultation with specified stakeholders and to post that guidance on their website. This bill requires CDPH to develop a tiered penalty system to be used prior to suspending or revoking the license of a gamete bank for a violation of these provisions.

Senate Floor Amendments of 8/24/22 are largely technical language changes regarding the disclosure of information to gamete donors, donor-conceived persons, and intended parents. The key substantive changes are that gamete banks will not be required to disclose the required information verbally to intended parent, but still do so in writing, and CDPH will be required to develop a tiered penalty system for gamete banks that violate the provisions of this bill prior to suspending or revoking a gamete bank's license. Some of the information required to be disclosed to gamete donors and intended parents has been modified for a more neutral tone.

ANALYSIS:

Existing federal law:

1) Establishes procedures to prevent the introduction, transmission, and spread of communicable diseases by human cells, tissues, and cellular and tissue-based products (HCT/Ps), including semen or other reproductive tissue through regulation by the Food and Drug Administration (FDA). Requires, before the completion of a donor-eligibility determination screening of a donor's medical records for specified risk factors for, and clinical evidence of, relevant communicable disease agents and diseases; quarantining semen from anonymous donors for at least six months after the date of donation; and retesting of anonymous semen donors by collecting a new specimen from the donor and testing it for evidence of infection due to human immunodeficiency virus (HIV), agents of viral hepatitis (HBV and HCV), syphilis, and human T lymphotropic virus (HTLV). [21 C.C.R.§1271.1, et seq.]

2) Establishes the Health Insurance Portability and Accountability Act of 1996 (HIPAA) which sets standards for privacy of individually identifiable health information and security standards for the protection of electronic protected health information, including, through regulations, known as the Privacy Rule, that a HIPAA covered entity may not condition the provision of treatment, payment, enrollment in the health plan, or eligibility for benefits on the provision of an authorization, except under specified circumstances. Provides that if HIPAA's provisions conflict with state law, the provision that is most protective of patient privacy prevails. [42 U.S.C. §300gg, 29 U.S.C. §1181, et seq., and 42 U.S.C. §1320d, et seq.]

Existing state law:

1) Requires every tissue bank operating in California to have a current and valid tissue bank license issued or renewed by CDPH, except as specified. Authorizes CDPH to revoke or suspend the license of any tissue bank that violates licensing standards pertaining to tissue banks. [HSC §1635.1, §1639.2, §1639.3]

2) Defines “tissue bank” to mean a place, establishment, or institution that collects, processes, stores, or distributes tissue for transplantation into human beings. Defines “gamete bank” to mean a tissue bank that collects processes, or distributes gametes, including a facility that provides professional reproductive services, other than those facilities exempt from tissue bank licensure. [HSC §1635]

3) Requires gamete banks licensed in this state to comply with the following requirements for gametes collected after January 1, 2020, except when the donor’s identity is known to the recipients of the gametes at the time of donation:

   a) Requires gamete banks to collect and retain from a gamete donor the donor’s identifying information and medical information at the time of the donation. Requires a gamete bank that receives gametes from a donor collected by another gamete bank to collect and retain the name, address, telephone number, and email address of the gamete bank from which the gametes were received. [HSC §1644.1]

   b) Requires gamete banks to provide the donor with information in a record about the donor’s choice regarding identity disclosure. Requires gamete banks to obtain a declaration from the donor regarding whether or not the donor agrees to disclose the donor’s identity to a child conceived by assisted reproduction with the donor’s gametes, on request, once the child attains 18 years of age. Requires gamete banks to permit a donor who has signed a declaration that the donor does not agree to disclose the donor’s identity to withdraw the declaration at any time by signing a declaration that the donor agrees to disclose the donor’s identity. Permits gamete banks to not collect gametes from donors who do not agree to disclose their identity. Requires the gamete bank to maintain identifying information and medical information about each gamete donor, maintain records of gamete screening and testing, and comply with state and federal reporting requirements. [HSC §1644.2]

   c) Requires gamete banks to, upon request of a child conceived by assisted reproduction using donor gametes who attains 18 years of age, provide the child with identifying information of the donor who provided the gametes, unless the donor signed a declaration that the donor does not agree to disclose their identity. Requires the gamete bank to make a good faith effort to notify the donor if the donor signed and did not withdraw the declaration, so that the donor may elect to withdraw the declaration and agree to release the their information. Requires the gamete bank to provide a child conceived using donor gametes who attains 18 years of age, or, if the child is a minor, by a parent or guardian of the child, access to nonidentifying medical information provided by the donor. Requires a gamete bank that received gametes from another bank used in the assisted reproduction of a child to disclose the name, address, telephone number, and email address of the gamete bank from which the gametes were received upon the request of that child who has attained 18 years of age. [HSC §1644.3]

4) Defines "identifying information" as the full name of the donor, the donor's date of birth, and the permanent address or other contact information, or both, given at the time of donation, or, if different, the current address or other contact information, or both, of the donor retained by the gamete bank. [HSC §1644]

5) Prohibits, under the state Confidentiality of Medical Information Act, a provider of health care, a health plan, a contractor, a corporation and its subsidiaries and affiliates, or any business that offers software or hardware to consumers, from intentionally sharing, selling, using for marketing, or otherwise using any medical information, as defined, for any purpose not necessary to provide health care services to a patient, except as expressly authorized by the patient, enrollee, or subscriber, or as otherwise required or authorized by law. States that a violation of these provisions that results in economic loss or personal injury to a patient is a crime.

This bill:

1) Requires a gamete bank to provide information on the following topics to individuals obtaining donor gametes in order to conceive a child starting January 1, 2024:

   a) That telling a donor-conceived child at an early age, in an age-appropriate manner, that the child is donor-conceived is associated with improved family functioning and well-being of the donor-conceived child;

   b) The ability of and tools available to a donor-conceived person (DCP) to learn the identity of the donor whose gametes were used in their conception and the importance of understanding that many, but not all, DCPs have a strong desire to know the identity of the donor and of other DCPs born using the same donor's gametes;

c) That the personal medical and family history of the gamete donor may influence some health conditions and inform medical care for DCPs and their children;

d) The limitations of donor screening, including screening for genetic diseases and genetic disease risk factors;

e) The possibility of one or more disease genes or genetic disease risk factors to be inherited by a DCP from a gamete donor;

f) That some DCPs may be interested in contact with their gamete donor or other persons born from the same donor's gametes;

g) The ability of a limit on the number of families that can be established with an individual donor's gametes, to improve the well-being of DCPs and gamete donors and to further the ability of DCPs to establish contact with their gamete donor, as well as other persons born using the same donor's gametes;

h) Whether or not the gamete bank attempts to meet a limit on the number of persons that can be born or the number of families that can be established with an individual donor's gametes. Requires, if the gamete bank has a policy or limit, to additionally disclose them; and,

i) Whether or not the gamete bank requests medical history updates from the donor and provides these updates to DCPs. If the gamete bank has such a policy, requires that policy to be disclosed.

2) Requires a gamete bank to provide information on the following topics verbally and in writing to individuals donating gametes in the state prior to the donation of gametes by a donor on the following topics, starting January 1, 2024:

a) The potential emotional and social impacts of donating gametes;

b) That it is important to many DCPs to know the identity of the donor whose gametes were used in their conception and that some DCPs may be interested in contact with the donor or other persons born using the same donor's gametes;

c) What information will be disclosed to intended parents and the potential of direct-to-consumer testing to reveal the identity of the donor and other persons born using the same donor's gametes even if the donor has chosen not to disclose their identity;

d) The potential for the birth of one or more children in multiple families using the donor's gametes;

e) Whether or not the gamete bank attempts to meet a limit on the number of persons that can be born or the number of families that can be established with an individual donor's gametes. Requires, if the gamete bank has a policy or limit, to additionally disclose them; and,

f) Whether or not the gamete bank requests medical history updates from the donor and provides these updates to DCPs. If the gamete bank has such a policy, requires that policy to be disclosed.

3) Requires CDPH to consult with experts and stakeholders, including organizations of DCPs demonstrably involved in the representation of other DCPs, organizations representing gay,lesbian, bisexual and transgender persons and families, organizations representing gamete donors or individuals with prior experience as gamete donors, licensed mental health professionals with prior documented experience counseling intended parents and DCPs, genetic counselors, licensed medial geneticists, licensed physicians with experience in third-party assisted reproduction, and representatives of gamete bank operating in the state, and to develop information and guidance required in 1) and 2) above, except the statement on whether the gamete bank places a limit on the number of persons that can be born or families that can be established established with an individual donor's gametes, and the statement on whether the gamete bank requests medical history updates from donors.

4) Requires CDPH to provide the information and guidance developed in 3) on its website.

5) Requires CDPH to establish a tiered penalty system allowing the gamete banks to cure violations of the above requirements prior to suspending or revoking the license of a gamete bank.

6) Prohibits this bill as being construed to require a physician to perform reporting, tracking, or mitigation of the risks outlined in 1) and 2), including, but not limited to, tracking gamete donors, reporting gamete donor usage, or determining if a child was born with a donor's gametes.

7) Makes legislative findings regarding the need to consider the health and welfare of gamete donors, intended parents, and DCPs; the medical and family history of a gamete donor can impact the medical care of DCPs and their children; the interest many DCPs place in knowing the identity of their gamete donor and

meeting their gamete donor or other DCPs conceived with the same donor's gametes; the psychosocial harm that can occur upon discovery of a large number of persons born using the same donor's gametes. Makes additional findings that early disclosure of donor conceptions is beneficial to DCPs; people considering using donated gametes should have access to resources about DCPs; access to direct-to-consumer genetic testing makes donor identification and the identification of other DCPs using the same gametes possible; gamete donors may experience psychosocial harm upon the discovery of a number of DCPs born as a result of their gametes; and donors should have access to information about the interests of DCPs and information that may be shared with intended parents and DCPs.

Comments

1) *Author's statement.* According to the author, for too long, discussions around assistive reproductive technologies have left out those who have the least say in the matter, but are most impacted: DCPs. A lack of regulation and data collection has meant that sperm banks are using donations to produce many dozens, at times upward of 100, children. When DCPs discover they have an unknown number of half-siblings, often through genetic tests like 23andMe, they report facing significant psychosocial burdens. Donors who may have wanted to remain anonymous at time of donation also face difficulty when contacted by a large number of biological offspring who desire to feel connected. Critically, large donor-sibling groups greatly increase the risks of unwitting relationships between half-siblings. Their children are at serious risk of suffering from severe genetic disorders. This bill takes a first step to address these issues by requiring gamete banks to provide key information to recipient parents and donors on the risks and harms faced by DCPs and the capability of direct-to-consumer genetic tests to connect DCPs to their donors and half-siblings.

2) *CDPH oversight of tissue banks*. CDPH licenses and surveys several types of tissue facilities, including assisted reproductive technology facilities, such as sperm banks, autologous tissue storage facilities, as well as fertility clinics. However, while various types of facilities are considered tissue banks, each may interact and use the tissue for different purposes. For instance, an assisted reproductive technology facility, like a sperm bank, may collect donor tissue and send it to a fertility clinic, where the tissue will be used. FDA regulations require the sperm bank to collect relevant donor information, conduct tests on the tissue, and make a determination of donor-eligibility. When the sperm bank sends the tissue to a fertility clinic for use, certain information must follow the

tissue. However, the sperm bank is generally not permitted to send the donor's personal information to the fertility clinic along with the tissue. The sperm bank will retain the donor's personal information along with a declaration of whether or not the donor wishes to disclose their identity.

3) *New awareness of large donor conceived sibling groups.* Direct-to-consumer genetic testing (e.g., 23andMe, AncestryDNA) and genealogy-based registries have revealed cases of large donor-sibling groups (many dozens to hundreds) and helped DCPs connect with each other. Given that conceptions using donor insemination have increased and donor sperm can be sold to recipient parents or distributed to other gamete banks without tracking of or limits on resultant births, the number and size of donor-sibling groups remains indeterminate.

   Current guidance from the American Society for Reproductive Medicine (ASRM) on single-donor conception states that institutions, clinics, and sperm banks should maintain sufficient records to allow a limit to be set for the number of pregnancies for which a given donor is responsible. The guidance states it is difficult to provide a precise number of times that a given donor can be used because one must take into consideration the population base from which the donor is selected and the geographic area that may be served by a given donor. ASRM further states that it has been suggested that in a population of 800,000, limiting a single donor to no more than 25 births would avoid any significant increased risk of inadvertent consanguineous conception. The guidance adds that this suggestion may require modification if the population using donor insemination represents an isolated subgroup or if the specimens are distributed over a wide geographic area. By comparison, many countries either forbid anonymous donations or have limits on the number of conceptions permitted per donor, usually ranging from three to 25.

   However, consanguineous conception is not the only consideration; there are also psychological factors for the DCP to consider. Meeting a few donor-linked families can be a positive experience; the impact of meeting 25 to 50 families may be more challenging or a negative experience. In a 2020 survey conducted by We Are Donor Conceived of 481 DCPs, 92% of respondents supported a limit on the number of offspring from a single donor. 94% of respondents agreed that they should have the option to know the number of half-siblings; 71% experienced negative emotions associated with their method of conception; and 43% expressed concern they may unwittingly enter a romantic relationship with a half-sibling.

There are no requirements in state law that address the genetic risks of consanguinity between related donor conceived people and any other related information that consumers may find useful. ASRM does include psychoeducational counseling as part of its recommendations for both the donor and the recipient on topics such as the challenges of anonymity because of direct-to-consumer DNA testing, technological advances, social media, and implications for donor-conceived families and future implications for the children of having persons who are linked through the same donor. Colorado recently passed legislation that will eventually give DCPs the ability to obtain the identity of the donor used to conceive them and set an enforceable limit of 25 families for any one gamete donor. The legislation also contains similar informational requirements for donors and recipients to those in this bill.

FISCAL EFFECT: Appropriation: No Fiscal Com.: Yes Local: No

According to the Senate Appropriations Committee, CDPH estimates costs of $375,000 (Tissue Bank Fund) over 3 years to develop the information specified in the bill and to oversee the implementation of clarifying regulations.

SUPPORT: (Verified 8/10/22)

California Catholic Conference
U.S. Donor Conceived Council

OPPOSITION: (Verified 8/10/22)

American Society for Reproductive Medicine
Department of Finance

ARGUMENTS IN SUPPORT: U.S. Donor Conceived Council, a group that advocates on behalf of the interests of DCPs writes that this bill ensures that recipient parents and gamete donors receive basic information on the potential genetic risks and psychosocial burdens created by the lack of regulation of the uses of gamete donations. DCPs have been vocal about these issues, which have been substantiated with data by subject matter experts. Of particular concern is the continually growing number of large donor-sibling groups. DCPs face significant psychosocial harm as their donor-sibling group continues to grow and it becomes apparent that half-siblings could live globally and no data on the actual number of half-siblings may ever be known. The unrestricted use of sperm donations also leads to an unusually large number of half-siblings close in socioeconomic background, age, and location – influential determinants of partner selection among U.S. adults. DCPs who are half-siblings may therefore go on to unwittingly have children together who would then be at a greatly elevated risk of genetic disease. Finally, they add, parents of DCP may fear the stigma they or their children may encounter as a result of the use of sperm donations. Parents may also not know how or when to best communicate with their children about their method of conception or the presence of an unknown number of half-siblings in other parts of the state, country, and beyond. Parental education and transparency are key and will set the stage for more awareness of the unique circumstances lived daily by DCP.

The California Catholic Conference writes that a sea change has recognized the rights of adoptees to documents about identity and origins. Yet DCPs face genealogical bewilderment at an even higher rate than adoptees, expressing this sense of loss on support sites like Anonymous Us and the Donor Sibling Registry. Donor conceived children are far more likely than children raised by their biological parents to say they feel no one understands them, to describe a lack of trust with their parents, to wonder about their donor and his family, if they have siblings, to worry about their health history, and wish for a connection to their ancestry, heritage and familial traits. In one study, nearly all donor-conceived adults sought to know any half-siblings they might have and to find their sperm donor, most seeing him as their biological father.

ARGUMENTS IN OPPOSITION: The American Society for Reproductive Medicine writes they are opposed because this bill would put an undue burden on physicians, who would be required to provide information on possible risks of unintentional consanguinity, risks that are unquantifiable by medicine or science. There is always some risk to reproduction, regardless of the method. Singling out donor-conception reproduction is not an effective mitigation strategy to combat those risks.

The Department of Finance writes that it is opposed to this bill as it creates additional cost pressure on the Tissue Bank License Fund, which is currently operating at a structural deficit, and this bill will exacerbate the fund’s structural imbalance. Finance notes that additional expenditures from the Tissue Bank License Fund may expedite the need for a fee increase.

ASSEMBLY FLOOR: 75-1, 5/25/22
AYES: Aguiar-Curry, Arambula, Bennett, Bigelow, Bloom, Boerner Horvath, Mia Bonta, Bryan, Calderon, Carrillo, Cervantes, Chen, Choi, Cooley, Cooper, Cunningham, Megan Dahle, Daly, Davies, Flora, Mike Fong, Fong, Friedman, Gabriel, Gallagher, Cristina Garcia, Eduardo Garcia, Gipson, Gray, Grayson,

Haney, Holden, Irwin, Jones-Sawyer, Kalra, Kiley, Lackey, Lee, Levine, Low, Maienschein, Mathis, Mayes, McCarty, Medina, Mullin, Muratsuchi, Nazarian, Nguyen, Patterson, Petrie-Norris, Quirk, Quirk-Silva, Ramos, Reyes, Luz Rivas, Robert Rivas, Rodriguez, Blanca Rubio, Salas, Santiago, Seyarto, Smith, Stone, Ting, Valladares, Villapudua, Voepel, Waldron, Ward, Akilah Weber, Wicks, Wilson, Wood, Rendon
NOES: Bauer-Kahan
NO VOTE RECORDED: Berman, O'Donnell

Prepared by: Jen Flory / HEALTH / (916) 651-4111
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