SENATE COMMITTEE ON HEALTH

Senator Dr. Richard Pan, Chair

BILL NO:	AB 1896
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VERSION:	June 15, 2022
HEARING DATE:	June 22, 2022
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SUBJECT: Gamete banks

SUMMARY: Requires gamete banks to provide specified information to individuals obtaining donor gametes in order to conceive children, including the limitations of donor screening, the increased possibility of consanguineous relationships between half-siblings or closely related individuals from large donor-sibling groups, and any other information the California Department of Public Health (CDPH) deems appropriate. Requires gamete banks to provide specified information to prospective gamete donors, including information regarding the potential of genetic technologies to reveal the relatedness of the donor to children conceived with the donor's gametes, even if the donor has chosen to remain anonymous at the time of donation. Requires CDPH to develop the guidance to be provided in consultation with specified stakeholders and to post that guidance on their website. Authorizes CDPH to suspend or revoke the license of a gamete bank for a violation of these provisions.

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:

3) 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]

4) 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]

5) 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]

6) 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]

7) 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 family secrecy about family formation has the potential to negatively affect children and family relationships, and 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 conceived with the same donor's gametes;
    c) The limitations of donor screening, including screening for genetic diseases and genetic disease risk factors;
    d) The possibility of one or more disease genes or genetic disease risk factors to be inherited by a DCP from a gamete donor;
    e) The increased possibility of consanguineous relationships between half-siblings or closely related individuals from large donor-sibling groups that may result in children as a result of unrestricted gamete use;
    f) The ability of a limit on the number of families that can be established with an individual donor's gametes, especially sperm, to reduce potential psychological, social, and genetic burdens on DCPs and their children; and,
    g) Whether or not the gamete bank places a limit on the number of children that can be conceived or the number of families that can be established with an individual donor's gametes. Requires, if the gamete bank has a limit, to additionally disclose it.

2) Requires a gamete bank to provide information on the following topics verbally and in writing to individuals donating gametes in the state and to make a good faith effort to provide information to individuals who donated gametes out of state and whose gametes are obtained by a gamete bank licensed in California on the following topics, starting January 1, 2024:

    a) The potential emotional and social impacts of donating gametes;
    b) The potential for the birth of one or more children in multiple families using the donor's gametes and the lack of tracking and data collection to ascertain the number of children born or families established from the donor's gametes; and,
    c) The potential of genetic technologies to reveal the relatedness of the donor to children conceived with the donor's gametes, even if the donor has chosen to remain anonymous.

3) Requires CDPH to consult with experts and stakeholders, including a DCP demonstrably involved in the representation of other DCPs, a licensed mental health professional with prior documented experience counseling recipient parents and DCPs, and a representative of a

sperm 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 children that can be established with an individual donor's gametes, and if so what that limit is. Permits CPDH to include other additional information it deems appropriate in this information and guidance.

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

5) Authorizes CDPH to suspend or revoke the license of a gamete bank that violates the above requirements.

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 mental well-being and interests of DCPs; 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, as well as in limiting the number of families that can be conceived from the same donor's gametes; the risks of large DCP sibling groups particularly when close in socioeconomic background, age, and location; and the negative impact of family secrecy about family formation on DPCs. Also makes findings that the advances in genetic sequencing technologies and direct-to-consumer genetic testing could potentially eliminate gamete donor anonymity and that sperm donors may face psychosocial harm upon discovery of or contacted by a large number of genetically related, but personally unfamiliar individuals.

FISCAL EFFECT: According to the Assembly Appropriations Committee, this bill has estimated General Fund (GF) costs to CDPH in the low hundreds of thousands of dollars over fiscal year (FY) 2022-23 and FY 2023-24 to convene a stakeholder group, develop the information for gamete banks to distribute and promulgate regulations. Ongoing GF costs of approximately $100,000 annually to CDPH to enforce the provisions of this bill.

PRIOR VOTES:

Assembly Floor:	75 - 1
Assembly Appropriations Committee:	16 - 0
Assembly Health Committee:	13 - 0

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) *Federal regulations.* The FDA regulates human cells or tissues intended for implantation, transplantation, infusion, or transfer into a human recipient. Under federal regulations, the FDA requires tissue banks that recover, process, store, and distribute human tissues to register with the FDA, comply with rules governing tissue establishments, and subject to periodic inspection. The FDA has issued three rules that set requirements for the following:

   a) Tissue establishments must list their tissue products with the FDA;
   b) Tissue establishments evaluate and screen donors to reduce the transmission of infectious diseases; and,
   c) Tissue establishments must track tissue products and adhere to standard operating procedures for facilities, including records management.

   The FDA's regulations on tracking tissue products includes specific provisions on record keeping after donor-eligibility determination is complete, which intends to protect donor privacy. The regulations stipulate that once donor-eligibility has been made, the tissue must be accompanied with following information at all times:

   a) A distinct identification code affixed to the container that links to the tissue's donor and the records of that donor. The linked record, however, cannot include the donor's name, social security number, or medical number;
   b) A statement of donor eligibility; and,
   c) A summary of records used to make donor eligibility, including the name and address of the tissue bank that made that determination and certification of tests and screening conducted.

   In addition, FDA regulations explicitly state that records accompanying the tissue at all times must not contain the donor's name or other personal information that might identify the donor. The prohibition on linking personal information does not apply if the donation is autologous, a directed reproductive donation, or a donation made by a first- or second-degree blood relative.

3) *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.

4) *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. However, it is becoming increasingly apparent that gamete banks have been using gametes from donors many times over.

   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.

5) *Prior legislation.* AB 785 (Bloom, Chapter 539, Statutes of 2019), updates existing law to streamline the transition of donor information from one bank to another by requiring gamete banks receiving donors’ gametes to maintain the contact information of the gamete bank from which the samples were received and to include oocyte and embryo donors.

AB 2684 (Bloom, Chapter 876, Statutes of 2018), updates and revises the Uniform Parentage Act relating to establishing a parent and child relationship to, among other things, refer instead to genetic testing and parentage. It also requires a licensed gamete bank to collect specified identifying information and medical information from a gamete donor, to provide the gamete donor with specified information, and, to obtain a declaration from the gamete donor regarding the disclosure or nondisclosure of his or her identity to a child that results from the donation, upon the child turning 18 years of age and requesting the information.

6) *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.

7) *Oppose unless amended.* ASRM write they are opposed unless amended because they are concerned that 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. They did not offer specific amendments.

8) *Policy comment.* The author may want to consider further defining what constitutes a "good faith effort" in the requirement to provide information to individuals donating gametes out of state.

SUPPORT AND OPPOSITION:

Support:	California Catholic Conference U.S. Donor Conceived Council, Inc.
Oppose:	American Society for Reproductive Medicine (unless amended)

-- END --