

CONCURRENCE IN SENATE AMENDMENTS

AB 1896 (Quirk)

As Amended August 24, 2022

Majority vote

SUMMARY

Requires a licensed gamete bank, on or after January 1, 2024, to provide specified information in writing to individuals obtaining donor gametes or donor embryos to conceive a child, including information on the following topics: 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; the ability of and tools available to a donor-conceived person to learn the identity of the donor whose gametes were used in the conception, as specified; that the personal medical and family medical history of the gamete donor whose gametes were used may influence some health conditions, as specified; and 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 use of an individual donor's gametes. Requires the information on potential emotional and social impacts of donating gametes to be provided verbally and in writing. Requires the Department of Public Health (DPH) to develop specified information and guidance in consultation with experts and stakeholders.

Senate Amendments

Make changes to the legislative findings and declarations and the information to be provided by gamete banks. Specify the organizations that DPH must consult in developing the information and guidance. Require DPH to establish a tiered penalty system allowing the gamete bank to cure any violations prior to any revocation or suspension of a gamete bank's license.

COMMENTS

- 1) *Federal regulations.* Human cells or tissue intended for implantation, transplantation, infusion, or transfer into a human recipient is regulated as a human cell, tissue, and cellular and tissue-based product (HCT/P). The Center for Biologics Evaluation and Research (CBER) regulates HCT/P. Examples of such tissues are bone, skin, corneas, ligaments, tendons, dura mater, heart valves, hematopoietic stem/progenitor cells derived from peripheral and cord blood, oocytes and semen. Federal regulations also require tissue establishments to screen and test donors, to prepare and follow written procedures for the prevention of the spread of communicable disease, and to maintain records. The federal Food and Drug Administration (FDA) also broadened the scope of products subject to regulation and to include more comprehensive requirements to prevent the introduction, transmission and spread of communicable disease. The rule also requires tissue establishments to register and list their HCT/Ps with the FDA. Additionally, tissue establishments must evaluate donors, through screening and testing, to reduce the transmission of infectious diseases through tissue transplantation. There are also quarantine requirements and retesting before the use of anonymous donation.
- 2) *Guidelines Regarding Gamete and Embryo Donation.* Currently, there are two organizations to which physicians who practice reproductive medicine generally belong. One is the American Society for Reproductive Medicine (ASRM) and the other is the Society for Reproductive Technology, an affiliate of ASRM. According to ASRM, the use of sperm,

oocyte, and embryo donation services has increased over the past several decades. The availability of donor gametes provides individuals and couples who otherwise may not be able to conceive with an opportunity to build a family. To optimize safety and outcomes, the FDA, American Association of Tissue Banks, US Centers for Disease Control and Prevention, and ASRM have developed their own guidance for the screening of donor tissue and recipients. The ASRM guidance also incorporates prenatal optimization, psychoeducational counseling of donors and recipients, and genetic risk assessment. This guidance for the screening and testing of gamete and embryo donors applies to all potential donors in the United States.

In California, DPH licenses gamete banks, defined as a tissue bank that collects, processes, stores, or distributes gametes including a facility that provides professional reproductive services, other than those facilities exempt from tissue bank licensure. Current law requires a gamete bank to collect and retain from a gamete donor the donor's identifying information and medical information at the time of the donation. A gamete bank that receives gametes from a donor collected by another bank to collect and retain the name, address, telephone number, and email address of the gamete bank for which the gametes were received. The ASRM guidance includes guidance for indications, screening and selection of sperm, oocyte donation, embryo donation, management of sperm/oocyte donors, screening and testing of recipients and their partners, and genetic screening and counseling.

- 3) *State requirements.* A gamete bank licensed in this state that collects gametes from a donor is required to: a) provide the donor with information in a record about the donor's choice regarding identity disclosure; b) obtain a declaration from the donor regarding identity disclosure; and, c) maintain identifying information and medical information about each gamete donor. A gamete bank is also required to give a donor the choice to sign an attested declaration that does either of the following: a) states that 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; or, b) states that the donor does not presently to disclose the donor's identity to the child but permits a withdrawal of this declaration at any time and replace it with a declaration to disclose.

A gamete bank, upon request of a child conceived by assisted reproduction using donor gametes and who is 18 years of age, is required to provide the child with identifying information of the donor who provided the gametes unless the donor signed and did not withdraw a declaration for nondisclosure. A gamete bank is required to make a good faith effort to notify the donor of their ability to withdraw a prior nondisclosure declaration and agree to release the donor's information. Additionally, a gamete bank that received gametes from another game bank is required to disclose the name, address, telephone number, and email address of the gamete bank from which the gametes were received. Upon request of a child who is 18 years of age or by the guardian or parent of a child, a gamete bank must provide access to nonidentifying medical information provided by the donor.

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.

According to the Author

Discussions around assistive reproductive technologies have left out the impacts on those who have the least say in the matter, but are most impacted: donor-conceived people (DCP). A lack of regulation and data collection has resulted in sperm banks using donations to produce dozens, even upwards of 100 children. Such large donor-sibling groups greatly increase the social, psychological, and genetic harms and risks on DCP. An unusually large number of half-siblings close in socioeconomic background, age, and location – influential determinants of partner selection among [United States] adults – may lead to unwitting intimate relationships between half-siblings or closely related individuals. Children born of such relationships are at greatly elevated risk of genetic disease. Unrestricted use of donor sperm also raises the odds of a genetic disease or disease risk factor being passed on to an unusually large number of DCP conceived from one donor. When DCP find out that they may be one of an unknown number of half-siblings, often through genetic tests like 23andMe, they report facing significant psychosocial burdens and mental health impacts. In a survey of over 480 donor-conceived individuals, 92% of respondents favor a limit on the number of families established from a single sperm donor and 71% reported experiencing negative emotions associated with their method of conception. Advances in direct-to-consumer genetic testing are also breaking down the barriers of anonymity. Sperm donors, who at the time of donation may have wanted to remain anonymous, face personal pressures and difficulty when contacted by a large number of biological children who desire to feel connected. Parents of DCP may fear the stigma they or their children may face as a result of the use of sperm donations and may also not know how or when to communicate with their children, making parent education a critical step to reducing risks. AB 1896 requires sperm banks to provide educational materials to recipients of sperm donations and to donors to explain the genetic, social, and psychological burdens faced, and best practices to mitigate these harms and risks. This bill also requires DPH to develop such information with input from stakeholders and subject matter experts.

Arguments in Support

In support, the California Catholic Conference states that this bill seeks to prevent the unfortunate incidences of genetic yet unknown half-siblings feeling drawn to each other, experiencing romantic attraction, and creating families together. The emotional and relational impact for these families cannot be understated.

Arguments in Opposition unless Amended

The American Society for Reproductive it is 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.

FISCAL COMMENTS

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

VOTES:**ASM HEALTH: 13-0-2**

YES: Wood, Aguiar-Curry, Arambula, Bigelow, Carrillo, Flora, Maienschein, McCarty, Nazarian, Luz Rivas, Rodriguez, Santiago, Kalra

ABS, ABST OR NV: Waldron, Mayes

ASM APPROPRIATIONS: 16-0-0

YES: Holden, Bigelow, Bryan, Calderon, Carrillo, Megan Dahle, Davies, Mike Fong, Fong, Gabriel, Eduardo Garcia, Levine, Quirk, Robert Rivas, Akilah Weber, Wilson

ASSEMBLY FLOOR: 75-1-2

YES: 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

NO: Bauer-Kahan

ABS, ABST OR NV: Berman, O'Donnell

UPDATED

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CONSULTANT: Rosielyn Pulmano / HEALTH / (916) 319-2097

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