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Healthcare Alert

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Increasing regulation of reproductive tissue banks

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Recent regulatory efforts to increase oversight of reproductive tissue donation may have widespread consequences for the industry.



What's the Impact?

- / Federal and state regulation of reproductive tissue donation imposes additional requirements for disclosure of certain donor information.
- / Such laws implicate anonymity considerations related to donor identity and medical records, and could increase compliance burden on tissue banking facilities.

The reproductive tissue donation process involves a number of issues related to the collection, storage, testing, implantation, and disposition of these tissues, and includes participation by various providers such as tissue banks (also known as cryobanks), assisted reproductive technology laboratories, and fertility providers (both in-office and surgery). As the industry continues to evolve, so inevitably will state and federal regulations and oversight of tissue banks.

One key aspect of gamete and embryo donation involves the use of eggs, sperm, or embryos from donors that are preserved through cryopreservation—the cooling and storage of these tissues at very low temperatures for a prolonged period. The eggs, sperm, or embryos are

collected and stored in reproductive tissue bank facilities that coordinate with donors, intended recipients, and providers for use in assisted reproductive technologies.

Gamete (meaning, eggs and sperm) and embryo donation and banking has become an increasingly regulated activity. Recently, there has been a push at the federal and state level to foster information transparency for donors—whether these donors are anonymous or “known” directed—including new verification requirements for tissue banks that collect, store, and handle reproductive tissue. These regulations increase the compliance burden on tissue banking facilities and implicate donor anonymity. Proponents of expanded regulation regarding transparency of third-party donation argue that such disclosures protect donor-conceived persons from long-term health consequences and strengthen safety for facilities.

Federal regulation

At the federal level, gamete banks are currently regulated by the federal Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER) under 21 CFR Part 1271.¹ The FDA has broad oversight of gamete centers and requires these facilities to register with FDA. Specifically, Part 1271 requires tissue establishments to evaluate donors through screening and testing to reduce the transmission of infectious diseases, establish good tissue practices, prepare and follow written procedures for the prevention of the spread of communicable disease, and maintain records. Notably, there are also differing requirements based on the type of donor and the donor’s relationship to the intended recipient.

A recent bill introduced in Congress, H.R.8307² known as Steven’s Law, if enacted, would mandate that reproductive tissue donors provide certain medical information upon donation. In addition, Steven’s Law would require reproductive tissue banks to verify the donor’s non-identifying medical information and provide it to recipients, doctors, and resulting donor conceived persons. Under the current bill, a tissue bank would not be required to release personally identifying information about the donor, meaning that anonymous donation is still available.

State regulation

In addition to federal regulation, tissue banks are regulated at the state level. While states like New York, Colorado, and California have robust regulatory schemes, the majority of states do not regulate tissue banks. Existing state regulations typically mandate licensure of the tissue bank facility, and certain states impose heightened requirements for reproductive tissue, including standards for donor qualifications, testing, informed consent, record retention, and storage/disposition of tissue.

New York regulations governing reproductive tissue banks are particularly stringent, requiring routine inspection of all reproductive tissue bank facilities, mandating facilities to obtain

¹ Human Cells, Tissues, and Cellular and Tissue-Based Products, 21 CFR Part 1271.

² H.R.8307 117th Cong. (2022).

complete medical history of donors, and requiring that facilities keep records open to inspection by the New York Department of Health, with specific retention requirements dependent on whether the tissue donation resulted in a live birth (up to seven years if not resulting in a live birth, and 25 years if resulting in a live birth).³

In Colorado, a newly enacted statute that goes into effect on January 1, 2025⁴ eliminates anonymous egg and sperm donation and adds limitations on the number of families established per gamete donor. In particular, the law requires a donor to provide consent to release the donor's identifying information, upon request, to any person conceived through their donations once that person turns 18.⁵ Under the statute, any gamete agency, gamete bank, or fertility clinic must collect a donor's identifying information and medical history and make a good-faith effort to maintain current contact information and updates on the donor's medical history by requesting updates from the donor at least once every three years. The bill imposes additional responsibilities on these entities to permanently maintain records of donor identifying information and medical history, the number of families established with each donor's gametes, and genetic screening and testing.

California requires that a gamete bank obtain an affirmative declaration stating whether the donor does or does not authorize disclosure of donor information to any resulting children when they reach age 18 that request the donor's information. If there is no affirmative declaration of donor anonymity, the gamete bank must release donor information to the person upon request at age 18. Even further, the California law requires the tissue bank, upon the donor-child's request (once the child reaches 18), to use good faith efforts to contact and offer the donor one more chance to disclose their identity.⁶ A recent bill introduced in California was vetoed by the governor for "limited impact."⁷ The bill would have required gamete banks licensed in the state to provide and discuss written educational materials with prospective donors and intended recipients, aimed at creating transparency and ensuring that individuals understand and acknowledge the limitations of donor health screenings.

Impact & analysis

The recently proposed federal and state legislation indicates a broader trend to expand regulation and oversight of reproductive tissue banks and increase access to donor health information and identity. These steps may result in the imposition of additional compliance requirements for reproductive healthcare service providers, impact the ability of donors to be

³ New York Codes, Rules and Regulations (NYCRR), Title 10, SubPart 52-8 - Reproductive Tissue Banks § 52-8.

⁴ Colorado Revised Statutes §§ 25-57-101 — 25-57-112; SB22-224, [Protections For Donor-conceived Persons And Families](#).

⁵ Prior to the donor-conceived person turning 18, a parent or guardian can access the donor's nonidentifying medical records.

⁶ Cal. Health & Safety Code 1644.3.

⁷ [AB-1896](#), 2022 Leg. Sess. (CA 2022).

anonymous, reduce donor eligibility and supply, while providing access to donor medical history to address health issues of donor-conceived people.

Implications for compliance by reproductive tissue banks

The Colorado statute is more expansive than any existing state regulation on the donation of gametes and rights of donor-conceived persons. Requiring tissue banks to follow up with donors raises both compliance and operational considerations, since maintaining adequate records and contact information of each donor could significantly expand administrative burdens and costs on facilities.

On a practical level, it may be unreasonable for reproductive tissue banks to keep accurate, up-to-date records of donors and track the number of live births resulting from that donor's gametes. Although tissue banks are responsible for storing reproductive material, tissue banks do not implant the tissue or maintain a provider-patient relationship with recipients of donated material. Further, individuals who donate on an anonymous basis typically do not expect to have ongoing contact with the tissue bank regarding their medical history, and tissue banks may be unable to contact donors who are unwilling to respond to requests for updated information.

The enforcement of the Colorado law (and others that may follow) remains to be seen, and it is not yet clear whether state agencies will take action against individual donors who fail to comply with these requirements, and the tissue banks that cannot satisfy their ongoing obligations due to a donor's noncompliance or otherwise.

Anonymity and disclosure of donor identifying information

Although Colorado is eliminating anonymous donation, gamete donations in other states throughout the US can be anonymous or directed (meaning, known), and generally, a donor's identity cannot be disclosed without a specific informed consent for such disclosure.

In the US, although there is industry support and advocacy for the release of *non-identifying* donor information for genetic and medical reasons, as well as acknowledgement that there is a possibility of a donor's loss of anonymity due to technological advances, releasing *identifying* information about a donor (and/or mandating this) still appears controversial and is handled in various ways by fertility centers, banks, and donor programs. Certain states may have laws that require a tissue bank or provider to affirmatively contact the donor to obtain consent for releasing the donor's identifying information. Other than in California and Colorado, it does not appear to be typical in the US to require fertility centers or donor programs to approach prior donors about the release of identifying information. Accordingly, tissue banks should have clear policies in place, and should ensure that informed consents forms identify the potential disclosure/contact obligations of the facility.

Other countries, including Austria, U.K., Sweden, and New Zealand, have laws banning egg donor and sperm donor anonymity in some form, and a growing number of jurisdictions in Canada have abolished donor anonymity.

It is also noteworthy that recent industry guidance identifies that donors should be advised on the possibility of the loss of anonymity in the decision to become a donor, implying that anonymity remains an important aspect for certain donors and future contact by the donor-conceived child may be impactful to the donor's life. Thus, tissue banks, fertility centers, and donor programs should develop policies to prepare for the possibility that donor-conceived offspring will contact them in the future to seek information about their donor, and clearly document informed consents of the donor regarding released or identifying information. Further, these entities should inform donors that donor-conceived persons might attempt to make contact to request more information or contact with the donor and that the internet and technological advances in DNA tracing have made it easier for donor-conceived offspring to locate donors with only non-identifying information, and therefore, providers can no longer guarantee their anonymity.

Requiring donors to give access to their medical records and/or identifying information, whether the information those records contain involve hereditary conditions or not, could impact donors' right to anonymity, and raises important considerations for reproductive healthcare entities, which must address these issues through policies and informed consent.

Donor eligibility and supply

The Colorado law is the first state law legally limiting the number of donations by a donor to 25 families. Many clinics also self-regulate based on American Society for Reproductive Medicine (ASRM) guidelines that recommend a cap of six egg retrievals for egg donors, and limit the number of families that can use a particular sperm donor to 25. However, there is no registry of listed donors, so tissue banks and providers do not have a comprehensive way to verify how many donations have been made and how many children are conceived from one donor.

Increasing regulation and elimination of anonymity may also limit the number of interested or eligible donors or lead individuals to turn to alternatives to conceive. Other countries that have addressed this issue, including the U.K., which eliminated donor anonymity in 2005, have seen limited impact on the long-term supply of donor gametes. As donor supply became scarce during the COVID-19 pandemic, unregulated directed donations, where the donor is a known individual to the receiving party, but without an intervening gamete bank, became a sought after alternative for some individuals. However, as individuals skirt federal and state regulations, other issues such as paternity and maternity rights, and health and safety concerns of the donated gametes arise.

Looking ahead

As the industry surrounding gamete donations inevitably grows and evolves, so will federal and state regulations. The effects of increased regulation are still to be seen, but could impact how donors and recipients engage with gamete centers and choices made in the process of facilitated reproduction.

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