COLORADO
Department of Public Health & Environment

To: Members of the Colorado State Board of Health

From: Heather Krug, Regulatory Programs Branch Chief, Colorado State Public Health Laboratory

Through: Emily Travanty, PhD, Colorado State Public Health Laboratory and Scientific Director, Division of Disease Control and Public Health Response (DCPHR)
Scott Bookman, Senior Director for Public Health Readiness and Response

Date: March 20, 2024

Subject: 2024 Board of Health Rulemaking for Gamete Bank and Fertility Clinic Program 5 CCR 1005-6, Donor-conceived Persons and Gamete Agencies, Gamete Banks, and Fertility Clinics

---

The Division of Disease Control and Public Health Response (DCPHR) within the Colorado Department of Public Health and Environment (CDPHE) is requesting a rulemaking hearing to establish new rules related to §25-57-101, et seq. Colorado Revised Statute (C.R.S.), Donor-conceived Persons and Families of Donor-conceived Persons Protection Act.

CDPHE developed the draft rules in response to Senate Bill (SB) 22-224, passed by the legislature in 2022 and signed into law by Governor Polis. In this law, the General Assembly declared that anonymity in gamete donation and a lack of transparency in the related industry causes significant harm to donor-conceived people and their families. To address this, SB 22-224 directed CDPHE to establish a licensure program for fertility clinics, gamete banks, and gamete agencies that operate as such in Colorado or match or provide gametes or embryos to recipients in, or who are residents of, Colorado.

Under the draft rules, to qualify for a license, applicants must provide documentation of processes related to their adherence to the laws of SB 22-224, including but not limited to:

1. Limiting the number of families established from a single donor's gametes to 25, except in cases where the donor is known to the recipients;
2. Disclosing the individual medical history, family medical history, and identifying information of donors to the donor-conceived person when they turn 18 years old;
3. Creating a plan to permanently maintain records of donor identifying information, medical histories, number of families established with a donor's materials, and genetic screening and testing, even in cases of dissolution or bankruptcy;
4. Limiting the number of egg retrieval cycles of a single donor to not more than six; and

COLORADO
Department of Public Health & Environment

5. Distributing educational materials for potential gamete recipients and donors on topics, such as, but not limited to: the mental health impacts of concealing donor parentage; how a donor-conceived person can learn about their donor's identity; the limitations of donor screening; and emotional and social impacts of donating gametes.

This legislation is the first in the United States to regulate gamete banks, gamete agencies, and fertility clinics around donor identity disclosure and limits on the number of families established from a single donor. In response, DCPHR created the Gamete Bank and Fertility Clinic Program, a new program within the State Public Health Laboratory.

The drafting and revising of the proposed rules involved an intensive stakeholder process, with more than 15 one-on-one or small group meetings, followed by five public meetings to review draft rules in which DCPHR requested suggestions, concerns, and questions. DCPHR also took written feedback via an online Google form and email. While consensus was not reached on every issue, the draft rules are the product of negotiation, legal research, and close interpretation of the law and are necessary to implement the requirements of the law and protect the interests of donor-conceived people.

COLORADO
Department of Public Health & Environment

STATEMENT OF BASIS AND PURPOSE AND SPECIFIC STATUTORY AUTHORITY
for
5 CCR 1005-6, Donor-conceived Persons and Gamete Agencies, Gamete Banks, and Fertility Clinics

Overview of SB 22-224 and donated reproductive materials

SB 22-224: Protections for Donor-conceived Persons and Families Act creates state requirements regarding the donation, matching, and use of gametes (unfertilized eggs and sperm) or, in some cases, embryos, in assisted reproduction. Assisted reproduction is defined in the legislation as, "a method of causing pregnancy other than sexual intercourse," including intrauterine or intracervical insemination; donation of gametes or embryos; in-vitro fertilization and transfer of embryos; and intracytoplasmic sperm injection.

In the United States, families can be established using a third-party sperm, egg, or embryo provider through some form of assisted reproduction. In a given year, an estimated 170,000 women in the United States undergo artificial insemination using donated sperm or donated eggs and embryos.[1] One estimate suggests there are about 68,000 children born from donated reproductive tissue in the United States every year.[2] This mechanism of assisted reproduction can occur between an anonymous donor and the recipient through the mediation of a fertility clinic, gamete bank, or gamete agency. The fertility clinic, gamete bank, or gamete agency may connect donors and recipients; collect sperm or eggs from donors; screen donors; distribute or give gametes or embryos to a recipient; or perform assisted reproductive procedures on a recipient.

SB 22-224 regulates interactions between fertility clinics, gamete banks, or gamete agencies; donors; and recipients of donated materials when the donor and the recipient are unknown to each other. The law does not apply in a situation such as when a family member is gifting another family member with eggs or sperm). To regulate these interactions, SB 22-224 establishes a licensure program within CDPHE to ensure fertility clinics, gamete agencies, and gamete banks follow the requirements for them set out in the legislation.

No system is currently in place nor could CDPHE find any evidence of one that accurately tracks information related to donated reproductive materials: how frequently they are used, who is using them, who is disseminating them, how frequently they result in live births, or

[1] Heled, Yaniv, Hillel Y. Levin, Timothy D. Lytton, and Liza Vertinsky. "Righting a Reproductive Wrong: A Statutory Tort Solution to Misrepresentation by Reproductive Tissue Providers." SSRN Scholarly Paper. Rochester, NY, November 8, 2022. https://papers.ssrn.com/abstract=4270874.
[2] Heled, Yaniv, Hillel Y. Levin, Timothy D. Lytton, and Liza Vertinsky. "Righting a Reproductive Wrong: A Statutory Tort Solution to Misrepresentation by Reproductive Tissue Providers." SSRN Scholarly Paper. Rochester, NY, November 8, 2022. https://papers.ssrn.com/abstract=4270874.

how often a donor's materials are used.[3] Existing quantitative data on this industry comes from a combination of surveys; registries with a potentially non-representative sample (such as the Donor Sibling Registry[4]); or expert estimates. As far as the Department is aware, there are no Colorado-specific analyses.

Advocates and legislators have identified that anonymity, a lack of transparency, and a lack of regulations in the donor gamete industry can result in harm to donor-conceived people and families. As described in the legislative declaration of the bill:

> "It is important to many, but not all, donor-conceived persons to know the identity of the gamete donor used in their conception. A donor-conceived person must have the ability to access identifying information about the gamete donor used in the donor-conceived person's conception on or after the donor-conceived person reaches eighteen years of age."

Section 25-57-102(1)(c), C.R.S. This legislation is the first in the United States to regulate gamete banks, gamete agencies, and fertility clinics around donor identity disclosure and limits on the number of families established from a single donor. In response, DCPHR created the Gamete Bank and Fertility Clinic Program, a new program within the State Public Health Laboratory.

Key points of Colorado's law are summarized below:

1. **Recordkeeping and distribution**: Gamete agencies, fertility clinics, and gamete banks must collect and store identifying information and medical information on gamete donors and distribute that information to donor-conceived people upon request.
2. **Educational materials**: CDPHE must write, and gamete agencies, fertility clinics, and gamete banks must distribute to donors and recipients, literature on the psychological and medical aspects of the stipulations of the legislation, the effects and consequences of utilizing donated reproductive materials, and how to talk to a child who was conceived using donated reproductive materials.
3. **Family limit from a single donor**: A gamete agency, gamete bank, or fertility clinic shall not match or provide gametes from a donor once they have record of or should "reasonably know" that 25 families have been established using a single donor's gametes in the world.
4. **Establishing a Colorado licensure program**: Pursuant to C.R.S. § 25-57-110, on or after January 1, 2025, "a gamete agency, gamete bank, or fertility clinic shall not operate as a gamete agency, gamete bank, or fertility clinic in Colorado, or match or

[3] Heled, Yaniv, Hillel Y. Levin, Timothy D. Lytton, and Liza Vertinsky. "Righting a Reproductive Wrong: A Statutory Tort Solution to Misrepresentation by Reproductive Tissue Providers." SSRN Scholarly Paper. Rochester, NY, November 8, 2022. https://papers.ssrn.com/abstract=4270874.
[4] https://donorsiblingregistry.com/

> provide gametes or embryos to recipients in Colorado, without having first obtained a license from the Department."

This legislation applies to gamete banks, gamete agencies, or fertility clinics both **in** the state of Colorado and entities that provide gametes or services to residents **of** Colorado. This means that a gamete bank that ships materials to a Colorado clinic must be licensed by the State. Or, if a Colorado resident travels to a different state for care related to donated gametes, then that facility must also be licensed by the State of Colorado. These licensure requirements also extend to facilities outside of the United States.

Overview of proposed rules

The draft rules establish the requirements for the licensure of fertility clinics, gamete banks, and gamete agencies. Authority to promulgate rules can be found in C.R.S. § 25-57-111:

> "On or before July 1, 2024, the State board shall promulgate any rules necessary to implement this Article 57. In promulgating rules, the State Board shall consider and protect the interests of donor-conceived persons and families of donor-conceived persons, including lesbian, gay, bisexual, and transgender parents and donor-conceived persons and single parents."

The rule sections can be summarized as follows:

Section 1: Purpose and Authority

This section defines the legislative authority and reiterates from the legislation that these rules are to regulate the use of donated gametes provided from gamete agencies, gamete banks, or fertility clinics located inside or outside of Colorado to recipients in, or who are residents of, Colorado.

Section 2: Definitions

While most definitions are quoted verbatim from the legislation, the rules provide additional detail on a few terms and define a few other terms that need greater clarity, as determined by Department analysis and CDPHE's stakeholder process. These include

- A definition of "family" was added to provide clarity regarding how to count the number of families established from a single donor's gametes to maintain compliance with the 25-family limit.
- A definition of "unknown" was also added to prevent entities from seeking to circumvent the law trying to categorize their donations as "known."

- The definition of "matches" was expanded to prevent regulatory ambiguity and ensure that a family is able to continue using a single donor's gametes for every child in the family, even if the gametes were collected prior to the effective dates of this law.

Section 3: Licensing

This section describes the details of licensing, including a requirement for annual licensure; contents of the application; and required fees. This section also describes the specific technical information the entity must establish, maintain, and provide to the Department. This includes policies and procedures for:

- Collecting and updating donor's identifying information and medical history.
- Collecting and maintaining contact information of any gamete banks, gamete agencies, or fertility clinics used to obtain gametes or embryos.
- Obtaining a declaration from the donor agreeing to disclosure of the donor's identity to donor-conceived offspring when they turn 18 years old.
- Providing donor identification and medical history to donor-conceived people.
- Confirming how the entity will permanently maintain the required records.
- Providing educational or informational materials to donors, potential donors, and gamete recipients.
- Conforming to egg retrieval and family limits.
    - This section limits egg retrieval to no more than six retrieval cycles per ovum donor in their lifetime and the number of families established from a single donor's gametes to 25 families.
- Permanently maintaining records in the event of bankruptcy, insolvency, or dissolution.

This section also requires licensees to provide documentation as to whether the owners or chief administrators have been subject to, or a party to, criminal conviction, license or certification denial, revocation or suspension, or civil or criminal judgment related to substandard care or health care fraud.

Lastly, this section describes the Department's right to investigate and inspect and includes requirements for licensees to submit corrective action plans if the Department finds violations.

Section 4: Licensing Requirements for a Provisional License

In order to provide additional cushion and space for entities to come into alignment with the law, the Department may issue a provisional license for an initial license that shall be valid for no longer than 90 days. The Department may issue an entity a second provisional license that shall be valid for no longer than 90 days.

COLORADO
Department of Public Health & Environment

Section 5: Licensing Period

This section specifies a licensing period shall not exceed 12 months.

Section 6: Mandatory Reporting Requirements for Licensees

This section specifies events which licensees are mandated to report to CDPHE, including change of name; loss of insurance; ownership change; or discovery of an action by staff, patient, or other party that may result in an adverse action on the license.

Section 7: Licensing Renewal

This section requires a licensee to submit a renewal application and fees no later than 60 days prior to expiration of the existing license and reserves the possibility of a renewal inspection by the Department.

Section 8: License Revocation and Fines

This section outlines that the Department may fine entities or revoke their license in case of any violation of documented procedures or the law. Penalties may not be more than $20,000 per day the person, corporation, or entity is in violation, as specified in the law. The Department may vary the amount of the fine depending on the size of the licensed entity, the potential for harm or injury, the responsibility of the entity, history of non-compliance, economic benefit of the violation, and whether there is a pattern of potential or actual harm or injury.

Stakeholder engagement and issues of concern

CDPHE worked diligently to hear from a wide range of people who have an interest or expertise in the issues related to SB 22-224. These included, but are not limited to, donor advocacy groups, people working in the fertility industry, donor-conceived people, researchers, and people who have used or donated donor gametes or are considering it.

The Department held five sessions with stakeholders to discuss the draft rules. Each session was open to the public and was two hours in length. CDPHE posted details of the sessions on the program's webpage. The Department also received written feedback using an online form and email.

The draft rules meet the requirements of the law and establish rules that are implementable by both industry and regulators. The substantive subjects of dissenting opinions are described below, followed by the Department's rationale for consideration by the Board of Health.

COLORADO
Department of Public Health & Environment

The rules require Colorado to license and regulate out-of-state and out-of-country entities if they serve Colorado residents. Stakeholders expressed concerns about both the practical viability and legal authority of Colorado being able to regulate entities outside of the state.

Department rationale: The law does not allow for flexibility and requires licensure of out-of-state entities. Some stakeholders supported the requirement, stating that such widespread enforcement was necessary to achieve the legislation's intent.

The definition of "family" does not define the word "parent."

Department rationale: Further narrowing the definition of "family" by defining "parent" may harm families with donor-conceived children, particularly by creating legal burdens for families with different structures and potentially preventing siblings from being created from the same donor's gametes. The rules specify that this definition should only be used for the purposes of counting families established in this law and not for any other legal purpose.

The definition of "matches" does not align with industry understanding of the term.

Department rationale: Several points in the legislation refer to when a gamete is "matched" with recipient parents. What exactly "match" means is important in delineating when the rules or law would apply to a particular donor or recipient. Stakeholders expressed that to the majority of industry, "match" is only a term used in egg donation. However, the legislative language definitively applies this term to both sperm and eggs.

CDPHE expanded the legislative definition of "matches" to provide clarity and address the following concern: ensuring that parents who conceive a child with one donor may continue to conceive future children with that donor, even if that donor's materials are not compliant with the new laws.

The rules describe that a "gamete agency" will make matches with both egg and sperm donors. However, a majority of industry stakeholders contended that gamete agencies are only involved in egg donation.

Department rationale: The law states that "'gamete agency' means an oocyte or sperm donor matching agency." Additionally, advocate stakeholders and CDPHE research indicates that there are agencies that match both egg and sperm donors with recipient families. Maintaining alignment with the legislative definition becomes particularly important in sections of the rules that carve out exceptions for gamete agencies.

Industry stakeholders contend that it will be extremely difficult to track the number of families established from a single donor to maintain compliance with the rule's family limits.

COLORADO
Department of Public Health & Environment

Department rationale: The legislation mandates that a gamete agency, gamete bank, or fertility clinic shall not match or provide gametes from a donor to additional families once the licensee has record of or should reasonably know that 25 families have been established using a single donor's gametes.

CDPHE must be able to copy and collect records from licensees in order to enforce the law, but there are concerns over privacy, especially for LGBTQ+ donors, parents, and potential parents.

Department rationale: According to the legislation, CDPHE shall not **keep** any of the records. Additionally, collecting records is part of the work of common in public health, so privacy and security are ingrained.

Best practices for tracking the number of births from a single donor should be included in the rules.

Department rationale: In order to give licensed entities the maximum amount of flexibility and discretion they need to follow the law, CDPHE will not list specific practices or methods that licensees should follow to track the number of families established from a single donor. However, CDPHE will provide recommended practices in guidance documents.

Fundamentally, the draft rules are necessary to enact this legislation. While stakeholder consensus was not achieved on all aspects of the rules, careful consideration has been given to protect the interests of donor-conceived people and LGBTQ+ families, and to provide clarifying guidance for entities that will be required to enact this law.

Specific Statutory Authority: C.R.S. § 25-57-111

Is this rulemaking due to a change in state statute?
__X__ Yes Rules are __ authorized _X_ required.
____ No

Does this rulemaking include proposed rule language that incorporates materials by reference?
_____ Yes ___ URL ___X__ No

Does this rulemaking include proposed rule language to create or modify fines or fees?
__X___ Yes _____ No

Does the proposed rule language create (or increase) a state mandate on local government?
_X__ No.

COLORADO
Department of Public Health & Environment

- The proposed rule does not require a local government to perform or increase a specific activity for which the local government will not be reimbursed;
- The proposed rule requires a local government to perform or increase a specific activity because the local government has opted to perform an activity, or;
- The proposed rule reduces or eliminates a state mandate on local government.

COLORADO
Department of Public Health & Environment

REGULATORY ANALYSIS
for
5 CCR 1005-6, Donor-conceived Persons and Gamete Agencies, Gamete Banks, and Fertility Clinics

1. A description of the classes of persons affected by the proposed rule, including the classes that will bear the costs and the classes that will benefit from the proposed rule.

Group of persons/entities affected by the proposed rule	Size of the group	Relationship to the proposed rule Select category: C/S/B
Gamete banks, gamete agencies, and fertility clinics that are in Colorado or provide gametes to people in or residents of Colorado	~135	C
Donor-conceived persons born to parents who were residents of or in Colorado	UNK	B
People who are in families with donor-conceived members in Colorado	UNK	S
Families and individuals who are looking to conceive using donor gametes in or who are residents of Colorado	UNK	B
People outside of Colorado or who are not residents of Colorado who are looking to conceive with donor gametes	UNK	S
Current and potential future gamete donors	UNK	B
Past gamete donors	UNK	S

While all are stakeholders, groups of persons/entities connect to the rule and the problem being solved by the rule in different ways. To better understand those different relationships, use this relationship categorization key:

C = Individuals/entities who implement or apply the rule.
S = Individuals/entities who do not implement or apply the rule but are interested in others applying the rule.
B = Individuals who are ultimately served, including the customers of our customers. These individuals may benefit, be harmed by, or be at risk because of

the standard communicated in the rule or the manner in which the rule is implemented.

More than one category may be appropriate for some stakeholders.

2. To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

Economic outcomes
All economic outcomes for all groups are rough estimates or predictions based on research and stakeholder engagement. Given the many unknowns in the industry, it is impossible to generate precise estimates.

C: Gamete banks, gamete agencies, and fertility clinics who are in Colorado or provide gametes to people in or residents of Colorado

Potential costs

- **License fees**: To be licensed, each entity must provide a fee of approximately $500 annually. If an entity applies and is only granted a provisional license because of a failure to comply with the law, then CDPHE may levy a second $500 fee.
- **Decreased profit margins per gamete donor**: Most of the costs incurred by a gamete bank or fertility clinic involve the onboarding and screening of a new donor. These costs are recovered by repeatedly selling the same donor's materials. By limiting the number of families that can use a particular donor's materials, the margins decrease. At this time, the Department is unable to estimate this cost.
- **Costs of hiring additional staff to support regulations/procedures involved in the process**: Given the variation of current recordkeeping practices among banks, entities, and clinics, it is possible that additional staff may be needed to comply with state laws. However, CDPHE cannot estimate those exact labor costs at this time.
- **Fewer donors**: Stakeholders indicated that the laws related to requiring identity and medical history disclosure may decrease the number of people willing to donate their gametes. This could decrease the pool of available donors or lead to entities needing to expend greater resources to recruit donors.
- **Entities may cease providing services in Colorado or to residents of Colorado**: Stakeholders also indicated that some entities may choose to leave Colorado or to explicitly exclude Coloradans from their services to ensure they do not have to obtain a Colorado license.

S: Individuals/entities who do not implement or apply the rule but are interested in others applying the rule.

Unknown economic effect

COLORADO
Department of Public Health & Environment

- **Past donors may find their materials to be valued differently**: Given that this law may affect the market for donated gametes, some people who donated gametes in the past may find their materials to be valued differently. At this time, the Department is unsure whether the value may increase or decrease.

B: Individuals who are ultimately served, including the customers of our customers.

Potential costs

- **Using donated gametes will likely be more expensive**: As noted above, gamete banks and clinics expend resources per donor. By limiting how many families can be established with a single donor and increasing the regulation around the process, this could lead to increased costs for consumers. Additionally, stakeholders noted that if gamete agencies, gamete banks, and fertility clinics choose to leave Colorado, it may be significantly more expensive for families to obtain gametes, potentially preventing lower income families from being able to access donated gametes. As an example, according to one gamete bank's website, anonymous donor sperm costs $1,195. Sperm with donor identity disclosure costs $2,195. Sperm that will only be provided to 2-10 families costs $35,000.[5] These price estimates were retrieved from the website before Colorado regulations went into effect and are intended only to provide a sense of potential price increases.

Potential benefits

- **Donors may be able to ask for a higher price:** Additionally, stakeholder feedback included statements that there could be fewer donors willing to comply with the medical history and identity disclosure elements of the legislation. This may allow other donors to demand higher prices for their gametes.

Non-economic outcomes

Summarize the anticipated favorable and unfavorable non-economic outcomes (short-term and long-term), and, if known, the likelihood of the outcomes for each affected class of persons by the relationship category.

Listed outcomes are based on inference, stakeholder predictions, and (in some cases) research from other countries that have implemented similar laws.

C: Individuals/entities that apply the rule

Potential positive outcomes

[5] Prices accessed on bank website on 1/31/2024.

- **Increased transparency and trust of the industry**: Regulation could increase customers' trust in the donated gamete industry through greater transparency, accountability, and externally-driven controls on industry.

Potential negative outcomes

- **Organizational change**: For some entities, these laws may require a significant overhaul of their current practices and procedures, potentially increasing work-related stress and tension among the owners and employees of agencies, clinics, and banks.

S: Individuals/entities who do not implement or apply the rule but are interested in others applying the rule.

Potential positive outcome

- **Families outside of Colorado who are interested in using gametes from donors who agree to identity disclosure may have more donors to choose from**: While the law only applies to Colorado, some stakeholders noted that many potential recipients prefer gametes where the donor has agreed to disclose their identities. It is possible that implementation of the law may shift the market and broadly increase the availability of open-donor gametes to people outside of Colorado.

B: Individuals who are ultimately served, including the customers of our customers.

Potential positive outcomes

- **Greater awareness of the process and potential risks of donation for potential gamete donors:** The legislation requires that agencies, banks, and clinics provide educational materials to potential donors. These materials will be created by the Department and help donors and recipients to better understand the donation process, potential consequences of open identity donation, and potential health effects of donating.
- **Greater awareness among recipient parents about communicating biological origins with donor-conceived children**: Potential recipients will receive information about the benefits of communicating with their donor-conceived child about their genetic origin and provide guidance on how to have those conversations. Studies have shown that when a person discovers their donor-conceived origin as an adolescent or adult, it can potentially damage relationships in the family or cause other forms of distress.[6] The American Society of Reproductive Medicine (ASRM) recommends disclosure of a child's biological origins to the child in an age-appropriate manner.[7]

[6] Shepard, Ashley, David Diamond, Laura Willard, Jennifer Staples, Kirshjah Martin, and Nicole Witherspoon. "Discovering Misattributed Paternity After DNA Testing and Its Impact on Psychological Well-Being and Identity Formation." *American Journal of Qualitative Research* 6, no. 3 (November 6, 2022): 189–211. https://doi.org/10.29333/ajqr/12611.
[7] Daar, Judith, Jean Benward, Lee Collins, Owen Davis, Joseph Davis, Leslie Francis, Elena Gates, et al. "Informing Offspring of Their Conception by Gamete or Embryo Donation: An Ethics Committee Opinion." Fertility and Sterility 109, no. 4 (April 2018): 601–5. https://doi.org/10.1016/j.fertnstert.2018.01.001.

COLORADO
Department of Public Health & Environment

- **Greater awareness of potential medical problems for donor-conceived people and families:** The legislation requires that licensed entities collect donors' medical history and family medical history and that entities are responsible for updating this information every three years. The rules specify that family history should include three generations, whenever possible, in accordance with ASRM guidelines.[8]
- **Fewer children from a single donor**: Family limits will help to prevent situations in which donor-conceived people learn they have 100 half-siblings.[9] This can also prevent more extreme stories of half-siblings accidentally dating or getting married.[10,11] One stakeholder said that the realization that one has dozens of half-siblings can make donor-conceived people "feel like a commodity." This may also address concerns expressed by stakeholders that large numbers of children from a single gamete donor can lead to a propagation of genetic conditions in a large group of people.
- **Donor-conceived people will have access to information about their origins and other genetic relatives:** The legislation requires that licensed entities make identifying donor information available to donor-conceived people after they turn 18 years old. Some advocates, ethicists, and donor-conceived people say it is important to know one's genetic origins and heritage. Other stakeholders contend that being able to find and connect to half-siblings or donors can be a mentally empowering and positive process.[12,13]
- **Greater accountability and transparency from industry:** Because entities will be licensed by the State of Colorado under this law, recipients of donated gametes can report concerns to the State. Additionally, the documentation around processes and license information will be a matter of public record.
- **Protection from unknown health effects from frequent egg donation**: Experts at ASRM have noted that "there are no clearly documented long-term risks associated with oocyte donation," and "no definitive data upon which to base absolute recommendations." However, these experts have also noted that there may be "possible cumulative risks to and future needs of an individual donor."[14] In deference to potential health risks, ASRM panel suggests setting the upper limit for oocyte donations to six. The law states that regulations may limit oocyte donations to six

[8] American Society for Reproductive Medicine. "Guidance Regarding Gamete and Embryo Donation." *Fertility and Sterility* 115, no. 6 (June 2021): 1395–1410. https://doi.org/10.1016/j.fertnstert.2021.01.045.
[9] One such story can be found here: https://www.nytimes.com/2011/09/06/health/06donor.html
[10] Yoffe, Emily. "My Wife Is My Sister." *Slate*, February 19, 2013. https://slate.com/human-interest/2013/02/dear-prudence-my-wife-and-i-came-from-the-same-sperm-donor.html.
[11] Kuznia, Rob, Allison Gordon, Nelli Black, and Kyung Lah. "'I Slept with My Half-Sibling': Woman's Horror Story Reflects Loosely Regulated Nature of US Fertility Industry." CNN, February 14, 2024. https://www.cnn.com/2024/02/14/us/fertility-fraud-accidental-incest-invs/index.html.
[12] Hertz, Rosanna. "Sociological Accounts of Donor Siblings' Experiences: Their Importance for Self-Identity and New Kinship Relations." *International Journal of Environmental Research and Public Health* 19, no. 4 (February 11, 2022): 2002. https://doi.org/10.3390/ijerph19042002.
[13] Scheib, J E, E McCormick, J Benward, and A Ruby. "Finding People like Me: Contact among Young Adults Who Share an Open-Identity Sperm Donor." *Human Reproduction Open* 2020, no. 4 (October 3, 2020): hoaa057. https://doi.org/10.1093/hropen/hoaa057.
[14] Practice Committee of the American Society for Reproductive Medicine and Practice Committee of the Society for Assisted Reproductive Technology. "Repetitive Oocyte Donation: A Committee Opinion." *Fertility and Sterility* 113, no. 6 (June 2020): 1150–53. https://doi.org/10.1016/j.fertnstert.2020.03.030.

times or below. The proposed rules follow ASRM guidelines and limit an individual to six oocyte retrieval cycles.

Potential negative outcomes

- **Reduced access to donated gametes from certain groups:** Stakeholders said that these new regulations may lead to some entities reducing or eliminating services in Colorado or to Colorado residents. Coloradans, in particular Black, Indigenous, and People of Color (BIPOC) populations seeking gametes from other BIPOC individuals, could see a reduction in the donated gametes made available by entities. A 2022 analysis by the Washington Post estimated that of the four major banks, fewer than 2% of available sperm donors were Black.[15] One stakeholder contended that international gamete banks and agencies were particularly important for these populations.
- **Reduced access to other forms of reproductive care**: Fertility care with donated gametes is a significant financial benefit for clinics providing this service. Without this revenue stream or with it compromised, it is possible that some clinics will close or move out of state, potentially making it more difficult for Coloradans to get other kinds of fertility or reproductive health care.

3. The probable costs to the agency and any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

Costs to the agency are divided between three categories: program staff, information-technology equipment, and travel expenses. Cost estimates are based on the potential of investigating approximately 10 in-state facilities, 40 out-of-state facilities, and 85 international facilities. The Department does not plan to perform onsite inspections of international facilities; however, in the event on-site inspections are required to effectively evaluate compliance or investigate problems, a cost estimate per facility is included below.

Expenditure type	Explanation	Annual estimated costs
FTE	Based on one facility inspector and two administrative program staff	$292,964
IT	Equipment, including laptops and cell phones, for all staff.	$5,650
Inspection travel: Facilities in Colorado	Travel expenses, including the use of a fleet vehicle for local facilities, gas, hotel stays, and per diem allowances	$14,070

[15] Ferguson, Amber. “America Has a Black Sperm Donor Shortage. Black Women Are Paying the Price.” Washington Post, October 20, 2022. https://www.washingtonpost.com/business/2022/10/20/black-sperm-donors/.

COLORADO
Department of Public Health & Environment

Inspection travel: Facilities out of state, in the US	Travel expenses, including flights, car rentals, gas, hotel stays, and per diem allowances	$54,280
Total		**$366,964**
Inspection travel: Per 1 facility out of the US	Travel expenses, including flights, car rentals, gas, hotel stays, and per diem allowances	$3,321

Anticipated personal services, operating costs, or other expenditures by another state agency: N/A

Anticipated revenues for another state agency: N/A

4. A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

Along with the costs and benefits discussed above, the proposed revisions:

_X_ Comply with a statutory mandate to promulgate rules.
___ Comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.
___ Maintain alignment with other states or national standards.
___ Implement a Regulatory Efficiency Review (rule review) result
_X_ Improve public and environmental health practice.
_X_ Implement stakeholder feedback.
___ Advance the following CDPHE Strategic Plan priorities:

Goal 1, Implement public health and environmental priorities
Goal 2, Increase Efficiency, Effectiveness and Elegance
Goal 3, Improve Employee Engagement
Goal 4, Promote health equity and environmental justice
Goal 5, Prepare and respond to emerging issues, and
_X_Comply with statutory mandates and funding obligations

Strategies to support these goals:

___ Substance Abuse (Goal 1)
___ Mental Health (Goal 1, 2, 3 and 4)
___ Obesity (Goal 1)
___ Immunization (Goal 1)
___ Air Quality (Goal 1)
___ Water Quality (Goal 1)
_X_ Data collection and dissemination (Goal 1, 2, 3, 4, 5)

COLORADO
Department of Public Health & Environment

___ Implement quality improvement/a quality improvement project (Goal 1, 2, 3, 5)
___ Employee Engagement (Goal 1, 2, 3)
_X_ Decisions incorporate health equity and environmental justice (Goal 1, 3, 4)
_X_ Detect, prepare, and respond to emerging issues (Goal 1, 2, 3, 4, 5)
___ Advance CDPHE Division-level strategic priorities.

5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

Rulemaking is proposed when it is the least costly method or the only statutorily allowable method for achieving the purpose of the statute. The specific rules proposed in this rulemaking were developed in conjunction with stakeholders. The benefits, risks, and costs of these proposed rules were compared to the costs and benefits of other options. The proposed revisions provide the most benefit for the least amount of cost, are the minimum necessary, or are the most feasible manner to achieve compliance with statute.

6. Alternative rules or alternatives to rulemaking considered and why rejected.

As legislation mandates that rules be established, no alternative to rulemaking was considered.

7. To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.

Given the vast amounts of uncertainty and lack of precedence for this law, a quantitative analysis was not practical.

Literature that helped inform the rules

- American Society for Reproductive Medicine. "Guidance Regarding Gamete and Embryo Donation." *Fertility and Sterility* 115, no. 6 (June 2021): 1395–1410. https://doi.org/10.1016/j.fertnstert.2021.01.045.
- Avni, Chen, Dana Sinai, Uri Blasbalg, and Paz Toren. "Discovering Your Presumed Father Is Not Your Biological Father: Psychiatric Ramifications of Independently Uncovered Non-Paternity Events Resulting from Direct-to-Consumer DNA Testing." *Psychiatry Research* 323 (May 2023): 115142. https://doi.org/10.1016/j.psychres.2023.115142.
- Bowles, Nellie. "The Sperm Kings Have a Problem: Too Much Demand." *The New York Times*, January 8, 2021, sec. Business. https://www.nytimes.com/2021/01/08/business/sperm-donors-facebook-groups.html.
- Centers for Disease Control and Prevention. "Assisted Reproductive Technology (ART) Data Assisted Reproductive Health Data: Clinic ," 2020.

https://nccd.cdc.gov/drh_art/rdPage.aspx?rdReport=DRH_ART.ClinicsList&SubTopic=&State=CO&Zip=&Distance=50.

- Djoulakian, Hasmik. "The 'Outing' of Sperm Donor 9623." Center for Genetics and Society. Biopolitical Times, June 30, 2016. https://www.geneticsandsociety.org/biopolitical-times/outing-sperm-donor-9623.
- Fenberg, Stephen, Kerry Tipper, Bob Gardner, and Matt Soper. Protections For Donor-conceived Persons And Families, Pub. L. No. SB22-224 (2022). https://leg.colorado.gov/bills/sb22-224.
- Ferguson, Amber. "America Has a Black Sperm Donor Shortage. Black Women Are Paying the Price." Washington Post, October 20, 2022. https://www.washingtonpost.com/business/2022/10/20/black-sperm-donors/.
- Fox, Dov. "Donor 9623." Accessed February 7, 2024. https://www.audible.com/pd/Donor-9623-Part-One-Podcast/B08GC5KWW8.
- Golombok, Susan, Elena Ilioi, Lucy Blake, Gabriela Roman, and Vasanti Jadva. "A Longitudinal Study of Families Formed through Reproductive Donation: Parent-Adolescent Relationships and Adolescent Adjustment at Age 14." *Developmental Psychology* 53, no. 10 (October 2017): 1966–77. https://doi.org/10.1037/dev0000372.
- "Guidance Regarding Gamete and Embryo Donation." Accessed February 6, 2024. https://www.asrm.org/practice-guidance/practice-committee-documents/guidance-regarding-gamete-and-embryo-donation-2021/.
- Heled, Yaniv, Hillel Y. Levin, Timothy D. Lytton, and Liza Vertinsky. "Righting a Reproductive Wrong: A Statutory Tort Solution to Misrepresentation by Reproductive Tissue Providers." SSRN Scholarly Paper. Rochester, NY, November 8, 2022. https://papers.ssrn.com/abstract=4270874.
- Hertz, Rosanna. "Sociological Accounts of Donor Siblings' Experiences: Their Importance for Self-Identity and New Kinship Relations." *International Journal of Environmental Research and Public Health* 19, no. 4 (February 11, 2022): 2002. https://doi.org/10.3390/ijerph19042002.
- Kuznia, Rob, Allison Gordon, Nelli Black, and Kyung Lah. "'I Slept with My Half-Sibling': Woman's Horror Story Reflects Loosely Regulated Nature of US Fertility Industry." CNN, February 14, 2024. https://www.cnn.com/2024/02/14/us/fertility-fraud-accidental-incest-invs/index.html.
- Lewin, Tamar. "10 Things to Know About Being a Sperm Donor." *The New York Times*, November 3, 2016, sec. Health. https://www.nytimes.com/2016/11/08/health/sperm-donor-facts.html.
- Martineau, Paris. "Inside the Quietly Lucrative Business of Donating Human Eggs." *Wired*, April 23, 2019. https://www.wired.com/story/inside-lucrative-business-donating-human-eggs/.
- Mroz, Jacqueline. "The Case of the Serial Sperm Donor." *The New York Times*, February 1, 2021, sec. Health. https://www.nytimes.com/2021/02/01/health/sperm-donor-fertility-meijer.html.

COLORADO
Department of Public Health & Environment

- Scheib, J E, E McCormick, J Benward, and A Ruby. “Finding People like Me: Contact among Young Adults Who Share an Open-Identity Sperm Donor.” *Human Reproduction Open* 2020, no. 4 (October 3, 2020): hoaa057. https://doi.org/10.1093/hropen/hoaa057.
- Scheib, Joanna E., Alice Ruby, and Jean Benward. “Who Requests Their Sperm Donor’s Identity? The First Ten Years of Information Releases to Adults with Open-Identity Donors.” *Fertility and Sterility* 107, no. 2 (February 2017): 483–93. https://doi.org/10.1016/j.fertnstert.2016.10.023.
- Shepard, Ashley, David Diamond, Laura Willard, Jennifer Staples, Kirshjah Martin, and Nicole Witherspoon. “Discovering Misattributed Paternity After DNA Testing and Its Impact on Psychological Well-Being and Identity Formation.” *American Journal of Qualitative Research* 6, no. 3 (November 6, 2022): 189–211. https://doi.org/10.29333/ajqr/12611.
- Spector, Nicole. “Swipe Right for ... a Sperm Donor? New App Matches Parents-to-Be.” NBC News, May 9, 2017. https://www.nbcnews.com/tech/tech-news/swipe-right-sperm-donor-new-tinder-style-app-matches-prospective-n756821.
- We Are Egg Donors. “Our Stories: Why Donor Advocacy Matters with Rachel Lemmons,” May 11, 2022. https://www.weareeggdonors.com/blog/dcp-protection-act.
- Yoffe, Emily. “My Wife Is My Sister.” *Slate*, February 19, 2013. https://slate.com/human-interest/2013/02/dear-prudence-my-wife-and-i-came-from-the-same-sperm-donor.html.

COLORADO
Department of Public Health & Environment

STAKEHOLDER ENGAGEMENT
for
5 CCR 1005-6, Donor-conceived Persons and Gamete Agencies, Gamete Banks, and Fertility Clinics

State law requires agencies to establish a representative group of participants when considering to adopt or modify new and existing rules. This is commonly referred to as a stakeholder group.

Stakeholder engagement for this rulemaking has been extensive, involving many different people with varied interests. A significant number of interactions highlighted stakeholder concerns with the legislation itself, especially from stakeholders representing gamete banks, fertility clinics, and people who have used donated gametes to conceive. As with any set of rules that regulates a previously unregulated space, there were concerns and issues to work through with stakeholders in devising the rules. Internal analyses and stakeholder engagement uncovered inconsistencies and ambiguities in terms, dates, and language in the legislation itself. Additionally, stakeholders expressed that some terms as written in the legislation do not match common industry use. Many concerns from stakeholders were less about the rules than the legislative language itself. The multi-part stakeholder process can be summarized in the following table:

Early stakeholder engagement		**Formal stakeholder engagement**	
Phase 1: Initial outreach and research	**Phase 2: Rulemaking listening sessions and feedback**	**Phase 3: Responses and feedback after request for rulemaking**	**Phase 4: Board of Health rulemaking**
Approximately 15 meetings between CDPHE staff and experts and stakeholders to increase Departmental knowledge of the industry and key issues and concerns related to the legislation.	Soliciting feedback on draft rules. Five open listening sessions, each approximately two hours long. Emails inviting stakeholders to sessions, including social media toolkits for organizational stakeholders to assist them in spreading the information. Written feedback solicited via email or form throughout the	After the Request for Rulemaking hearing, feedback and comments will continue to be collected by the program via email and referrals from Board of Health comments.	The rulemaking hearing will be held May 2024, during which stakeholders can comment during the public hearing.

COLORADO
Department of Public Health & Environment

	entire process.		

Phase 1: Initial outreach and research

Stakeholder outreach for this project began in early 2023. Policy Advisor Jennifer Barr and Lab Regulatory Programs Branch Chief Heather Krug conducted a series of one-on-one and small group interviews with experts and stakeholders. These interviews and discussions served to help CDPHE staff understand the issues around donated gametes and donor-conceived people. CDPHE first identified stakeholders with a list from bill sponsor Senator Steve Fenberg, and secondarily, through referrals. Research, which focused on white papers and literature by experts in the field, supplemented the interviews.

Phase 1 Engagement list: One-on-one or small group discussions

Organization	Description	Region(s)	Individual role	Names
University of San Diego	Research university	National	Professor of law, creator of podcast Donor 9263	Dov Fox
Georgia State University	Research university	National	Professor of law, expert in gamete industry	Yaniv Heled
University of Maryland, Baltimore	Research university	National	Professor of law, expert in gamete industry	Liza Vertinsky
Colorado Fertility Advocates	Advocacy group for gamete banks, fertility clinics, and associated professionals in the fertility and donated gamete industry	Statewide	Family lawyer	Ellen Trachman
			Family lawyer	John Husson
			Fertility doctor	Dr. Natalia Grob
			Family lawyer and parent to donor-conceived people	Judith Hoescht
			Acupuncturist	Geina Horton
			Fertility doctor	Dr. Evelyn Llerenacari

			Fertility doctor	Dr. Althea O'Shaughnessy
			Therapist specializing in adoption and donor conception	Alison Wilson
			Fertility doctor	Dr. Christina Yannetsos
Cryogam	Colorado-based gamete bank	National, based in Loveland, CO	Owners	Betsy Cairo
				Gerica LaVelle
U.S. Donor Conceived Council (USDCC)	Donor-conceived person advocacy group	National, based in Atlanta		Tyler Sniff
				Jillian Phillips
Fairfax Cryobank	One of the nation's large gamete banks	National	Legal counsel	Sara Kraner
We Are Egg Donors	Advocacy and education group for egg donors	National		Rachel Lemmons
Circle Egg Donation and Surrogacy	Egg and surrogacy agency	National	Founder	John Weltman
Society for Ethics in Egg Donation	Professional association for egg donation	National	President	
Sperm Bank of California	LGBTQ+-oriented sperm bank	National, based in California	Executive Director	Alice Ruby
University of Alabama	Expert on egg donation	National	Professor	Diane Tober

Phase 2: Rulemaking listening sessions and written feedback

COLORADO
Department of Public Health & Environment

After Phase 1, the Department developed a set of draft rules, published them on the Department website, and engaged in outreach in order to invite stakeholders to comment on the draft rules. Stakeholders chose to participate or provide feedback in the following ways:

1. Submit feedback via a Google form posted on the Gamete Bank and Fertility Clinic Program webpage and linked to on stakeholder emails (form closed January 6, 2024);
2. Attend listening sessions on Zoom and provide verbal feedback; or
3. Email the program directly.

Stakeholders were contacted via email. For organizational stakeholders, a media toolkit was provided that included social media graphics and newsletter copy to facilitate the organizations sharing information with their members.

The Department developed the stakeholder list by drawing from several sources:

- LGBTQ+ organizations who have worked with CDPHE, such as the Center on Colfax and One Colorado;
- Senator Fenberg's list of stakeholders his office consulted with in drafting the legislation;
- People who testified both for and against the original legislation;
- Fertility-related support groups found via internet research; and
- Networks of Phase 1 stakeholders.

While CDPHE's outreach was broad, there are some interested parties that do not organize or identify publicly in such a way as to make them accessible to contact by the State. Potential gamete donors, gamete recipients, or donor-conceived people who have not chosen to join advocacy groups on this issue were not easy to find. Some groups may have been underrepresented in discussions. Stakeholder outreach was also necessarily national, with many of the people present at the listening sessions not based in Colorado.

CDPHE emailed the list of stakeholders to notify them of the first four listening sessions and link to the online form for written feedback. The Department sent reminder emails with an attached agenda to all stakeholders approximately a week before each session. Meetings were held via Zoom, and all of the sessions were approximately two hours. Sessions were not recorded in order to protect the privacy of the participants.

The first four feedback sessions covered all of the sections in the draft rules. Attendees could participate during the sessions or submit written feedback, along with any additional suggestions, questions, or concerns.

Using all of the feedback, the Department created a revised draft of the rules. This draft was available on the program's webpage, along with a link to register for a fifth feedback session.

COLORADO
Department of Public Health & Environment

The fifth session covered revisions. The details of the public feedback sessions are summarized in the following table:

Session	Date	Number of attendees
Session 1: Introductions	Nov. 11, 2023	20
Session 2: Donor consent, tracking donor information, and donor information disbursal	Nov. 15, 2023	27
Session 3: Educational materials and licensing processes	Nov. 30, 2023	22
Session 4: Family limits and retrieval limits	Dec. 21, 2023	24
Session 5: Revisions	Jan. 29, 2024	25

Forty-four stakeholders representing the following groups attended at least one of the five public feedback sessions:

- Entities that would be regulated under the new legislation
- Donor-conceived people
- LGBTQ+ organizations
- Parents of donor-conceived people
- Mental health professionals specializing in this area
- Lawyers specializing in family issues

Of the 44 stakeholders who attended at least one listening session, 41% were in Colorado, 57% were in another U.S. state, and 2% were in other countries. However, even if the individual was in another state, many of those who attended provided services to Coloradans. A full list of attendees can be found in the below table.

Phase 2 engagement list: stakeholder feedback session attendance

Organization	Description	Region(s)	Role	Name
Donor Conceived Australia	Nonprofit that offers support, education, and advocacy for DCPs	Australia	National Director	Aimee Shackleton
Everie Donation	Egg donor agency	National/ international	Director	Aisha Lewis
			Director	Rachel Campbell

COLORADO
Department of Public Health & Environment

The Sperm Bank of California	Nonprofit LGBTQ+-oriented sperm bank	National/ international	Executive Director	Alice Ruby
			Research Director	Joanna Scheib
CNY Fertility	Fertility clinic	Colorado Springs, CO	Nurse	Allyson Santoro
			Privacy Officer	Debra Woodhouse
			Egg Donor Coordinator	Pati Breh
Conceptions RMA	Fertility clinic chain	Littleton, Denver, Lafayette, and Lone Tree in CO	Reproductive Endocrinology and Infertility Specialist	Dr. Althea O'Shaughnessy
			Donor Nurse Coordinator	Charly Liscomb
			Embryology Team	Zelda Fowler
US Fertility	Fertility clinic chain	National	Counsel	Amy Altman
Wall Street Journal	United States newspaper	National	Journalist	Amy Marcus
California Cryobank	One of the largest gamete banks in the United States	National	Consultant	Angie Howes
CryoGam	The only sperm bank based in Colorado	National, based in Loveland, CO	Director	Betsy Cairo
			Laboratory Supervisor and owner	Gerica LaVelle
University of San Diego	Research university	National	Professor of law	Dov Fox
Connection Centered Counseling, PLLC	Psychotherapy service	Colorado and Texas	Mental health professional	Elizabeth Reisen
Trachman Law Center, LLC	Legal firm that specializes in family formation and surrogacy law	National, based in Denver	Lawyer	Ellen Trachman
Colorado	Nonprofit that	Statewide	Director	Geina Horton

COLORADO
Department of Public Health & Environment

Fertility Advocates	provides fertility awareness, education, and support		Lawyer, parent to DCP	Judith Hoechst
			Chair	Rebeckah Navitsky
			Mental health professional	Judy Becerra
EM•POWER with Moxi	Embryo matching	National	Genetic Counselor	Gina Davis
Donor Egg Bank USA	Egg bank	National	Executive Vice President	Heidi Hayes
Donor Conceived Community	Resource center for DCPs	National	Program Coordinator	Jamie Spiers
			Executive Director	Melissa Lindsey
U.S. Donor Conceived Council	Nonprofit that advocates for the rights of donor conceived people	National	Mental health professional	Jana Rupnow
			Vice President of Development	Melissa Bornico
			Vice President of Legal Affairs	Tyler Levy Sniff
			Therapist	Carole Lieber Wilkins
EDC Nexus	Egg donor registry	National	Operations Manager	Jenna Lake
American Society for Reproductive Medicine	Nonprofit that advocates for the advancement of science and practice of reproductive medicine	National	Mental health professional	Jessie Losch
Circle Egg Donation and Surrogacy	Surrogacy and egg donation agency	National	Owner	John Weltman
COLAGE	Organization that provides support for LGBTQ+ parents	National	Executive Director	Jordan Budd
Koupal Law Firm	Firm that specializes in reproductive law	Denver	Lawyer	Laura Koupal

COLORADO
Department of Public Health & Environment

	and adoption legal services			
Luminary Life Sciences	Fertility clinic	National	Field worker	Margarita Lainez
NY State Department of Health, Tissue Resources Program	Division of NY State government regulating sperm banks and other tissue banks	New York	Director	Matthew Kohn
Shady Grove Fertility	Fertility clinic	National, based in Greenwood Village, CO	Donor Program Director	Michele Purcell
Genetics and IVF Institute	Fertility clinic	National	Assistant General Counsel	Michelle Misler
National Center for Lesbian Rights	Nonprofit that advocates for equitable public policies for the LGBTQ+ population	National	Lawyer	Nesta Johnson
Fairfax Cryobank	One of the largest gamete banks in the country	National	General Counsel	Sara Kraner
Donor Sibling Registry	Nonprofit organization that provides a registry of donor offspring, sperm donors, egg donors, and other donor-conceived people	National, based in Nederland, CO	Director	Wendy Kramer
Individual	Private citizen	Colorado	Parent of donor-conceived people	

Below is a summary of feedback received from stakeholders of the most contentious issues identified through this stakeholder engagement process.

Matching donors and recipients

COLORADO
Department of Public Health & Environment

Several points in the legislation refer to when a gamete is "matched" with recipient parents. What "match" means is important in determining when the rules or law would apply to a particular set of parents or a donor. Specifically, many of the stipulations of the law only apply to gametes "matched or collected" after January 1, 2025. The current legislative definition of "matches" says that it "means the process of matching a donor with a recipient in, or who is a resident of, Colorado" (C.R.S. § 25-57-103-11). This definition does not provide clear guidance as to what precisely constitutes a "match:" A shipping date for gametes? Implantation date? A contract? The Department's research and stakeholder engagement indicate that these dates can be wildly different, and thus, clarity in the definition is vital in ensuring the law is followed.

Conversations with stakeholders around "match" were further complicated by how the industry uses the term. During stakeholder engagement, it became clear that in the majority of the industry, "match" is only a term used in egg donation. In this context, a donor is first "matched" with a recipient parent or parents before the gametes are collected. When the donor ovulates, then the actual egg retrieval may take place. Eggs tend to be used fresh, as opposed to sperm, which are more likely to be stored for a period of time before use, which necessitates the need for matching prior to gamete collection.

According to some stakeholders, while many industry entities tend to use the word "match" primarily in the context of egg donation, the legislative language requires that the term be applied to both sperm and eggs.

In order to provide clarity, CDPHE drafted a definition in the rules that clarifies what "match" means for these rules and this law. In addition to creating a more precise definition, CDPHE sought to address another stakeholder concern: ensuring that parents who conceive a child with one donor may continue to conceive future children with that donor, even if that donor's materials are not compliant with the new laws, such as because they were collected prior to January 1, 2025, and the donor has not agreed to identity disclosure.

The Department anticipates testimony both for and opposed to this definition at the rulemaking hearing. However, the presented language has been carefully considered and crafted to address competing concerns within the allowances of the law.

Difficulty tracking the number of families established from a single donor.

A recurring concern from some stakeholders — especially those representing industry groups — is that it is and will be extremely difficult to track the number of families established from a single donor. The legislation mandates that a single donor may not establish more than 25 families in the world. This means that licensed entities will be responsible for tracking and verifying whether donors have donated at other entities globally and how many families were established through other entities, whether those entities are licensed by Colorado or not.

COLORADO
Department of Public Health & Environment

Given that entities may be fiscally and legally responsible for exceeding limits, licensed entities need to be able to track or estimate how many families have been established from a single donor's gametes.

It was difficult for the Department to evaluate industry concerns about how arduous it will be to track the number of families established from a single donor's gametes. Stakeholders raised several reasons why it may be difficult to track how many families have been established, including

1. In some cases, recipients may not know which of several vials was the one which resulted in a birth. According to representatives from one gamete bank, some people will order many vials of sperm from different donors, use them at once or in quick succession, and remain uncertain about which vial or donor resulted in the birth.
2. Industry stakeholders also reported that not all recipient parents report outcomes. This legislation does not require that recipients report outcomes, and so it becomes the responsibility of the entity to try to obtain the information. One bank reported performing rigorous monitoring and auditing of their records, including follow-up with their clients. While their system has been reportedly successful, CDPHE was not able to determine whether similar processes would yield similar results for larger facilities.
3. Not every form of donated gamete conception may be encompassed within this regulatory program. This licensure program encompasses fertility clinics, gamete banks, and gamete agencies. However, people can find a sperm donor through an app[16] or a Facebook group.[17] In other cases, an OB-GYN office, midwife, or individual person may order donor materials in such a way that a birth is not counted.
4. The United States healthcare system is largely fragmented and privatized, meaning that comprehensive tracking of medical procedures is not possible.

Because of these issues, it is possible that some entities could choose to no longer work in or provide gametes to residents of Colorado. While some stakeholders suggested several potential methods for tracking or estimating the number of families established,[18] none of these is comprehensive enough to provide absolute certainty.

[16] Spector, Nicole. "Swipe Right for ... a Sperm Donor? New App Matches Parents-to-Be." NBC News, May 9, 2017. https://www.nbcnews.com/tech/tech-news/swipe-right-sperm-donor-new-tinder-style-app-matches-prospective-n756821.

[17] Bowles, Nellie. "The Sperm Kings Have a Problem: Too Much Demand." The New York Times, January 8, 2021, sec. Business. https://www.nytimes.com/2021/01/08/business/sperm-donors-facebook-groups.html.

[18] For example: tracking and auditing outcomes; requiring recipients to sign contracts mandating they will disclose pregnancy outcomes; holds on vials that are nearing the limit; or incentivizing recipients to report outcomes

COLORADO
Department of Public Health & Environment

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT
Division of Disease Control and Public Health Response
Donor-conceived Persons and Gamete Agencies, Gamete Banks, and Fertility Clinics
5 CCR 1005-6

Section 1: Purpose and Authority

A. The Department shall implement the Licensing Program (Program) to ensure that a gamete agency, gamete bank, or fertility clinic shall not operate in Colorado, or match or provide gametes or embryos to recipients in, or who are residents of, Colorado, without demonstrating compliance with the applicable standards, requirements, and other provisions of Title 25, Article 57.
B. Section 25-57-111, C.R.S. directs the State Board of Health to promulgate rules necessary to implement the Program.
C. These rules regulate the use of donated gametes provided from gamete agencies, gamete banks, or fertility clinics located inside or outside of Colorado to recipients in, or who are residents of, Colorado.
    a. These rules are promulgated to consider and protect the interests of donor-conceived persons and families of donor-conceived persons.

Section 2: Definitions

A. Assisted reproduction: method of causing pregnancy other than sexual intercourse. The term includes:
    a. intrauterine or intracervical insemination;
    b. donation of gametes or embryos;
    c. in-vitro fertilization and transfer of embryos; and
    d. intracytoplasmic sperm injection.
B. Department: the Colorado Department of Public Health and Environment.
C. Donor: individual who produces eggs or sperm collected by a gamete agency, gamete bank, or fertility clinic or whose eggs or sperm is used to create an embryo received by a gamete agency, gamete bank, or fertility clinic for use in assisted reproduction by a recipient who is unknown to the donor of the gametes at the time of donation. The term “donor” only applies to the regulation of gamete agencies, gamete banks, or fertility clinics pursuant to article 57 and does not apply for the purposes of determining parentage.
D. Donor-conceived person: an individual of any age who was born as a result of assisted reproduction using gametes from a donor unknown to the recipient parent or parents at the time of donation.
E. Family: For the purposes of counting families established in this licensure program, a “family” is a unit of one or more parents and the children they

Commented [1]: "Family" was not defined in the legislation. However, a clear and specific definition of "family" will enable licensees to count for the family limit. We utilized a modified definition from a small nonprofit gamete bank serving primarily LGBTQ+ communities since we discussed it and decided it would be appropriately inclusive and flexible to accommodate a range of family arrangements.

COLORADO
Department of Public Health & Environment

parent. This includes new partners of anyone already parenting a child conceived with donor gametes. This definition only applies to these rules.

F. Fertility clinic: entity or organization that performs assisted reproduction medical procedures and receives donor gametes for a recipient in, or who is a resident of, Colorado, and the recipient and gamete donor are unknown to each other at the time of donation.

G. Gamete: unfertilized oocytes or sperm.

H. Gamete agency: oocyte or sperm donor matching agency that is located within or outside of Colorado and matches gamete donors with recipients in, or who are residents of Colorado, and the potential recipients and gamete donors are unknown to each other at time of donation.

I. Gamete bank: entity or organization that collects gametes from a donor or receives embryos and provides gametes or embryos to a recipient parent or parents or the recipient parent's medical provider when the recipient and donor are unknown to each other at time of donation, and that is located within or outside of Colorado and provides gametes or embryos to a recipient parent or parents in, or who are residents of, Colorado.

J. Identifying information: donor's full name; donor's date of birth; donor's permanent, and, if different, current address or other contact information at the time of donation, or, if different, the donor's current address or other contact information or both as retained by the gamete agency, gamete bank, or fertility clinic.

K. Matches: means the process of matching a donor with a recipient in, or who is a resident of, Colorado.

   a. For the purpose of these rules, a "match" is considered made when any of the following occur:

      i. a potential recipient parent signs a legally binding agreement with a licensed entity to receive a specific donor's materials;

      ii. a donor's materials are shipped to a recipient parent or facility; OR

      iii. a recipient parent purchases a single donor's materials.

   A family can be considered "matched" even if multiple samples from a single donor are utilized for multiple pregnancies or pregnancy attempts.

L. Medical history: information regarding present physical illness of donor; past illness of donor; and social, genetic, and family medical history pertaining to donor's health.

   a. For the purpose of these rules and according to American Society of Reproductive Medicine recommendations, "family medical history" should include a detailed 3-generation family history to the extent

Commented [2]: The topline definition of "match" is from legislation. Further clarification was needed to ensure the rules are clear. This definition of "match" is intended to respond to a couple different stakeholder concerns: (1) there was a consensus among stakeholders that "match" needs to be very clearly defined, especially since so many dates are contingent on it; (2) there was a concern about families being able to continue to use a single donor's gametes for every child in the family. By defining "match" in this way, we can address that concern.

COLORADO
Department of Public Health & Environment

possible. Donors who are adopted and those who are unable to provide any family history information about their genetic relatives should be considered on a case-by-case basis.

M. Mental health professional: a person who is certified or licensed pursuant to Article 245 of Title 12 or an out-of-state professional who is a licensed psychiatrist, clinical psychologist, or professional counselor.

N. Recipient or recipient parent: a person who receives donor gametes or embryos as an intended parent from a gamete agency, gamete bank, or fertility clinic for use in assisted reproduction for the purpose of conceiving a child.

O. State board: the Colorado State Board of Health.

P. Unknown: in the context of deciding whether a donor is “unknown” to the recipient family, a donor and recipient parents are “unknown” to each other if the licensed entity initiated or facilitated the match or connection. This definition only applies to these rules.

Commented [3]: While the legislation does not define "unknown" or "known", the legislation only applies to situations in which the donor and recipients are "unknown" to each other at the time of gamete exchange. Stakeholder feedback during listening sessions strongly indicated the importance of ensuring that this term was clearly defined.

Section 3: Licensing

3.1 License Required

A. Pursuant to Section 25-57-110, C.R.S., on or after January 1, 2025, a gamete agency, gamete bank, or fertility clinic shall not operate as a gamete agency, gamete bank, or fertility clinic in Colorado, or match or provide gametes or embryos to recipients in, or who are residents of, Colorado, without having first obtained a license.
   a. Such a license is conditioned on compliance with the applicable standards, requirements, and other provisions of Article 57 and these rules.
   b. A gamete agency, gamete bank, or fertility clinic shall submit an annual application and fee for a license to operate in the form and manner prescribed by the Department.
   c. Licensees are responsible for verifying legal residency of residents of Colorado outside of Colorado.

B. The license shall be displayed conspicuously on any public-facing website.

C. If necessary, the Department shall suspend or revoke a license in accordance with Section 24-4-104, C.R.S.

D. A gamete agency, gamete bank, or fertility clinic shall comply with reporting requirements about gamete screening and testing in accordance with federal law and applicable laws of this state in addition to those set forth in Article 57 or these rules.

E. The Department may request records from an applicant or licensee at any time.

COLORADO
Department of Public Health & Environment

a. If applicants fail to comply with records requests within thirty (30) business days, applicants shall be denied a license.
b. Failure of a licensee to respond within thirty (30) business days shall be considered a violation of these rules and a fine may be levied as described in Section 24-4-105, C.R.S.

3.2 Fees Required

A. The applicant shall annually submit to the Department the applicable fee(s) set forth in these rules.
B. Licensing Fees
1. Each gamete agency, gamete bank, or fertility clinic seeking initial or renewal licensure pursuant to Section 3 shall submit a licensing fee to the Department.
2. The licensing fee may be based on the direct and indirect costs incurred by the Department for the regulatory oversight of this program.
3. The following fees, which may be adjusted annually for inflation, shall be assessed as part of the facility's initial and renewal licensing application:
a. Gamete Banks: $500;
b. Fertility Clinics: $500;
c. Gamete Agencies: $500.
4. A gamete agency, gamete bank, or fertility clinic that is a nonprofit organization is exempt from the fees detailed herein.

Commented [4]: Many exceptions within the rules mirror exceptions written into the legislation.

3.3 Content of Application for a License

A. An application to match or provide gametes or embryos to recipients in, or who are residents of, Colorado, shall consist of general information, specific technical information, and institutional information as set forth in these rules.
B. The licensee shall submit written statements under oath upon request of the Department, to enable the Department to determine whether the entity is in compliance with the requirements under Article 57 and these rules.
C. The Department shall not retain any identifying information about donors, recipients, or donor-conceived persons, and shall keep confidential all health-care information or documents obtained or viewed during an inspection or investigation of a gamete agency, gamete bank, or fertility clinic. All records, information, or documents so obtained are exempt from disclosure pursuant to Sections 24-72-204 and 25-1-124, C.R.S.

D. Each application shall be signed under penalty of perjury by an authorized corporate officer, general partner, or sole proprietor of the applicant entity as appropriate.

3.4 General Information

A. Identity information of the applicant shall include:
   a. The full name, address, telephone number and description of the business of the applicant and the gamete and embryo-related services it provides;
   b. If the applicant is a partnership, the name and address of each partner and the principal location where the partnership does business;
   c. If the applicant is a corporation or an unincorporated association,
   (i) the state or country where it is incorporated or organized and the principal location where it does business, and
   (ii) the names and addresses of its directors and principal officers.

B. The applicant must have written policies and procedures that describe how its gamete agency, gamete bank, or fertility clinic complies with reporting requirements about gamete screening and testing in accordance with federal law and applicable laws of this state, other than those set forth in Article 57 and these rules.

C. The applicant must specify if the applicant is seeking licensure as a gamete bank, gamete agency, and/or fertility clinic. Applicants may apply for licensure in more than one categories.

3.5 Specific Technical Information

A. To assess the adequacy of protections in place for donors and donor-conceived persons, every applicant or licensee shall make available for reference and inspection a detailed manual of its policies and procedures. Staff at each gamete agency, gamete bank, or fertility clinic shall be familiar and comply with policies contained within the manual. Contents of the manual must apply to gametes and embryos matched or collected on or after January 1, 2025, for use by recipient parents who are unknown to the donor at the time of the donation. Licensees are responsible for ensuring their policies and procedures accurately reflect the actual practices of the licensee. Licensee deviations from approved policies and procedures may be subject to an investigation, inspection, fine, or license revocation. The manual shall include:
   a. A written procedure used to collect and update identifying information and medical history for donors. The donor's identifying information and medical history shall be disclosed to a donor conceived person who is

COLORADO
Department of Public Health & Environment

eighteen years of age or older pursuant to the requirements of section 25-57-106, C.R.S.

i. Applicants must demonstrate that they have made a good faith effort to maintain current information and updates on medical history by requesting updates of this information at least every three years.

ii. The gamete agency, gamete bank, or fertility clinic should maintain a record of attempts of contact with donors. If there is no response to the initial contact attempt, the gamete agency, gamete bank, or fertility clinic should provide proof of at least three attempts to contact the donor by at least two different methods, such as phone records, email copies, or certified mail receipts.

iii. A fertility clinic that collects gametes from a donor who was matched with a recipient by a gamete agency that is a separate entity shall provide copies of any and all medical and screening records of the donor, including the results of genetic testing, to the gamete agency that matched the donor.

iv. Applicability: This section (a) applies only to gametes collected and embryos formed with gametes collected by a gamete agency, gamete bank, or fertility clinic on or after January 1, 2025, for use by a recipient parent or parents who are unknown to the donor at the time of the donation.

b. A written procedure used to collect and maintain the contact information of any gamete banks, gamete agencies, or fertility clinics used to obtain gametes or embryos. Such information shall include the name, address, telephone number, e-mail address, and Colorado license number of the gamete agency, gamete bank, or fertility clinic from which it received the gametes or embryos at the time it receives time gametes or embryos. The contact information shall be disclosed pursuant to the requirements of section 25-57-106, C.R.S.

c. A written procedure that describes the methods by which the gamete bank, gamete agency, or fertility clinic collects donor identification and contact information.

i. Such procedure must describe how the gamete agency, gamete bank, or fertility clinic:

1. Provides the donor with information about disclosure of identifying information and medical histories;

2. Obtains a declaration from the donor agreeing to the identity disclosure; and
3. Maintains identifying information and medical history about each donor, including records of donor and gamete screening in a manner that complies with reporting requirements, is in accordance with federal law and applicable laws of this state, and is consistent with the guidelines of the American Medical Association and the American Society for Reproductive Medicine.

ii. Such procedure must describe how a gamete agency, gamete bank, or fertility clinic has each donor sign a declaration, attested by a notarial officer or witness, that the donor agrees to the disclosure of the donor's identity and the conditions when such a disclosure is required pursuant to Article 57.

1. A gamete agency, gamete bank, or fertility clinic located in Colorado shall not match or collect gametes from a donor who does not agree to the disclosure of the donor's identity.
2. A gamete agency, gamete bank, or fertility clinic located outside of Colorado shall not match or provide gametes to a recipient parent or parents are located in, or who are residents of, Colorado from a donor who does not agree to the disclosure of the donor's identity

iii. Applicability: Parts i. and ii.2 do not apply to a gamete bank or fertility clinic that collects gametes from a donor who was matched with a recipient by a gamete agency that is a separate entity.

d. A written procedure that describes the methods by which the gamete bank, gamete agency, or fertility clinic provides the identifying information or non-identifying medical history of a donor to donor-conceived persons or guardians.

i. Such procedure must describe how the gamete agency, gamete bank, or fertility clinic that matched or collected the gametes used in the assisted reproduction of such donor-conceived person complies with a request from a donor-conceived person who is eighteen years of age or older to provide the donor-conceived person with the identifying information of the donor who provided the gametes or embryo. Such procedure should not impede or prohibit communication between an adult donor-conceived person

COLORADO
Department of Public Health & Environment

and the donor whose gametes were used to conceive the donor-conceived person.

1. Requiring a donor-conceived person to provide information that is reasonably available to them to establish a link to a specific donor is not considered impeding or prohibiting contact.

ii. Such procedure must describe how the gamete agency, gamete bank, or fertility clinic that matched or collected the gametes used in the assisted reproduction of such donor-conceived person complies with a request from a donor-conceived person who is eighteen years of age or older, or the parent or guardian of a minor donor-conceived person, for access to any non-identifying medical history of the donor that is maintained by the gamete agency, gamete bank, or fertility clinic.

iii. Such procedure must describe compliance with a request from a donor-conceived person who is eighteen years of age or older, or the parent or guardian of a minor donor-conceived person, to provide the donor-conceived person with the following disclosures:

1. A gamete agency, gamete bank, or fertility clinic that received the gametes or embryo used in the assisted reproduction from another gamete agency, gamete bank, or fertility clinic shall disclose the name, address, telephone number, and e-mail address of the gamete agency, gamete bank, or fertility clinic from which it received the gametes or embryo.
2. A gamete bank or fertility clinic that collected gametes from a donor who was matched with a recipient by a gamete agency that is a separate entity shall disclose the name, address, telephone number, and email address of the gamete agency that matched the donor and the recipient.
3. Such compliance is only applicable to gametes or embryos received by a gamete agency, gamete bank, or fertility clinic on or after July 1, 2023.

iv. Applicability: Parts i. and ii. do not apply to a gamete bank or fertility clinic that collects gametes from a donor who was matched with a recipient by a gamete agency that is a separate entity.

e. A written procedure that describes the methods by which the gamete bank, gamete agency, or fertility clinic permanently maintain the following records:
   i. Records used by a gamete agency, gamete bank, or fertility clinic, including:
      1. Identifying information and medical history for each donor with which it matches or from which it collects gametes for use by a recipient parent or parents who are unknown to the donor at the time of the donation;
      2. Information about the number of families established with each donor's gametes and the efforts of the gamete agency, gamete bank, or fertility clinic to obtain that information pursuant to Section 25-57-109, C.R.S.; and
      3. Records of gamete screening and testing.
   ii. On or after July 1, 2024, records used by a gamete agency, gamete bank, or fertility clinic, that receives gametes or embryos from another gamete agency, gamete bank, or fertility clinic, including the name, address, telephone number, and e-mail address of the gamete agency, gamete bank, or fertility clinic from which it received the gametes or embryos.
   iii. On or after July 1, 2024, records used by a gamete bank or fertility clinic that collected gametes from a donor who was matched with a recipient by a gamete agency that is a separate entity, including the name, address, telephone number, and email address of the gamete agency that matched the donor and the recipient.
   iv. Applicability: Part i.1 and 2) do not apply to a gamete bank or fertility clinic that collects gametes from a donor who was matched with a recipient by a gamete agency that is a separate entity.
f. A written procedure that describes the methods by which the gamete bank, gamete agency, or fertility clinic will distribute educational or informational materials provided by the Department to donors, potential donors, and gamete recipients.
   i. On or before January 1, 2025, the Department will develop written materials for intended recipient parents pursuant to the requirements in Section 25-57-108, C.R.S.

COLORADO
Department of Public Health & Environment

ii. On or before January 1, 2025, the Department will develop written materials for gamete donors pursuant to the requirements in Section 25-57-108, C.R.S.

iii. A gamete agency, gamete bank, or fertility clinic located in Colorado shall:

1. Provide the written materials described in subsection (i) of this section to each intended recipient of gametes from a donor who is unknown to the recipient or recipients, prior to an intended recipient matching with or receiving donor gametes obtained through that gamete agency, gamete bank, or fertility clinic;
2. Provide the written materials described in subsection (ii) of this section to each potential donor of gametes collected by the gamete agency, gamete bank, or fertility clinic from a donor who is unknown to the recipient or recipients and discuss these materials with the donor prior to the donation of gametes by a donor; and

iv. A gamete agency, gamete bank, or fertility clinic located outside of Colorado that matches donors to or provides gametes or embryos to recipients in, or who are residents of, Colorado shall:

1. Provide written materials to recipients that, at a minimum, cover the topics described in subsection iii. of this section, prior to an intended recipient matching with or receiving donor gametes; and
2. Provide written materials to the donor that, at a minimum, cover the topics described in subsection iii.2 of this section and discuss these materials with the donor, prior to the donation of gametes by a donor.

B. Limits

a. Each gamete agency, gamete bank, or fertility clinic shall limit the total number of donor retrieval cycles to no more than six (6) cycles per ovum donor in their lifetime. Every applicant or licensee shall make available for reference and inspection a written procedure that describes the methods by which staff at each gamete agency, gamete bank, or fertility clinic assess and monitor adherence to this limit.

i. An exception to this limit may be made for prior donors who provide informed consent to undergo additional retrieval cycles

Commented [5]: The law states that the rules must place a limit of six donation cycles or fewer. We have chosen to follow ASRM guidelines in these rules and set the limit as six.

for families intending to conceive a child using the same donor used to conceive their other child(ren).

1. Every applicant or licensee shall make available for reference and inspection a written procedure that describes the methods by which staff at each gamete agency, gamete bank, or fertility clinic assess and monitor the use of this exception.

b. Each gamete agency, gamete bank, or fertility clinic shall limit donations to those individuals who are 21 years of age or older. Every applicant or licensee shall make available for reference and inspection a written procedure that describes the methods by which staff at each gamete agency, gamete bank, or fertility clinic assess and monitor adherence to this limit.

c. Each gamete agency, gamete bank, or fertility clinic shall limit the use of a single donor's gametes to the establishment of twenty-five (25) families or fewer in or outside of Colorado. Every applicant or licensee shall make available for reference and inspection a written procedure that describes the methods by which staff at each gamete agency, gamete bank, or fertility clinic will track or estimate how many families have been established using a single donor's gametes to assess and monitor adherence to this limit.

   i. Such procedure should include a description of the good-faith efforts undertaken to achieve these limits, including:

      1. Sufficient record keeping;
      2. Requiring recipients, as a condition of receiving donor gametes, to provide information on live births, and requesting information from recipients on live births; and
      3. Using industry best practices, or multiple commercially reasonable methods, to account for the number or percentage of live births, whether reported or not reported.

   ii. Such procedure should describe how a gamete agency, gamete bank, or fertility clinic ensures that they do not match or provide gametes from a donor to additional families once the gamete agency, gamete bank, or fertility clinic has record of or should reasonably know that twenty-five (25) or more families have been established using a single donor's gametes.

      1. This limit does not include any children conceived by the donor as a parent or children conceived with the donor's

Commented [6]: While we have received feedback indicating that some stakeholders would like us to specify the best practices around this in the rules, we want to give maximum flexibility for different gamete suppliers to be able to utilize the methods that are going to best work for them. We'll include some of the suggested best practices in the guidance documents.

COLORADO
Department of Public Health & Environment

gametes when the donor is known to the recipient parent or parents at the time of the donation.

2. This limit does not include donations of embryos from one family to another family.

d. A gamete agency, gamete bank, or fertility clinic that collects gametes from a donor who was matched with a recipient by a gamete agency that is a separate entity is not subject to the requirements of subsection (B) of this section.

e. This subsection (B) applies only to gametes matched or collected on or after January 1, 2025, for use by recipient parents who are unknown to the donor at the time of the donation.

3.6 Institutional information – Financial Information and Assurances

A. Each applicant must provide to the Department a statement signed and dated contemporaneously with the application stating whether, within the previous ten (10) years of the date of application, the owners or chief administrators of the applicant entities have been the subject of, or a party to, one or more of the following events, regardless of whether action has been stayed in a judicial appeal or otherwise settled between the parties:

a. Been convicted of a felony or misdemeanor involving moral turpitude under the laws of any state or of the United States. A guilty verdict, a plea of guilty or a plea of nolo contendere (no contest) accepted by the court is considered a conviction.

b. Had a state license or federal certification denied, revoked, or suspended by another jurisdiction.

c. Had a civil judgment or a criminal conviction in a case brought by federal, state or local authorities that resulted from the operation, management, or ownership of a health facility or other entity related to substandard care or health care fraud, including, but not limited to the misuse of gametes as described in Section 18-13-131, C.R.S.

B. If applicable, each applicant must provide to the Department a statement regarding the information requested in paragraph (A) to include the following:

a. If the event is an action by federal, state or local authorities, the full name of the authority, its jurisdiction, the case name, and the docket, proceeding or case number by which the event is designated, and a copy of the consent decree, order or decision.

b. If the event is a felony or misdemeanor conviction involving moral turpitude, the court, its jurisdiction, the case name, the case number, a

COLORADO
Department of Public Health & Environment

description of the matter or a copy of the indictment or charges, and any plea or verdict entered by the court.

c. If the event involves a civil action or arbitration proceeding, the court or arbiter, the jurisdiction, the case name, the case number, a description of the matter or a copy of the complaint, and a copy of the verdict, the court or arbitration decision.

C. In regards to the information disclosed described in paragraphs A and B of this section, the Department will assess whether the disclosed information indicates that there is a significant issue of concern and/or a pattern of harmful or fraudulent behavior that may indicate an increased potential for harm to the public or stakeholders connected to the applicant entity.

a. If any staff member of an applicant entity has been convicted or faced civil liabilities under C.R.S. Section 13-21-132 concerning the misuse of human reproductive materials, CDPHE reserves the right to deny the applicant's license.

D. Provide the Department with results of any investigations, disciplinary actions, or exclusions that impact or have the potential to impact the quality of care provided to clients as requested by the Department.

E. Each applicant who provides gametes matched or collected on or after January 1, 2025, for use by a recipient parent or parents who are unknown to the donor at the time of the donation must provide to the Department a written plan for bankruptcy, insolvency, or dissolution that describes its intent to permanently maintain the records held by the bank, agency or clinic.

a. The plan may include identification of a named entity to receive or maintain the records, obtaining a surety bond in favor of a third party in an amount sufficient to cover the costs of permanent record-keeping, an obligation to condition any sale on the acquiring entity's obligation to maintain records consistent with this section, or similar methods.

i. The Department shall not issue a license pursuant to Section 25-57-110, C.R.S. until it approves a plan that it finds sufficient to ensure that the records will be permanently maintained by a viable entity.

ii. Upon dissolution, insolvency, or bankruptcy, a gamete agency, gamete bank, or fertility clinic shall:

1. Implement the plan approved by the Department;
2. File with the Department a statement providing the name and contact information of the successor entity, if any, that will receive and maintain the records; and

Commented [7]: This is a reference to the Misuse of Human Reproductive Material Act.
The Misuse of Human Reproductive Material Act created a new civil cause of action and crime if a health care provider, in the course of performing or assisting with an assisted reproduction procedure, knowingly uses gametes from a donor without the express consent of the patient to use the donor's gametes.

3. Inform by mail and electronic mail sent to the last known address on file all gamete donors whose gametes were collected, matched, or received by the gamete agency, gamete bank, or fertility clinic, as well as recipient parent or parents who received gametes or embryos from the gamete agency, gamete bank, or fertility clinic and reported a pregnancy or live birth, the name and contact information of the successor entity that will receive and maintain the records.

b. A gamete bank or fertility clinic that collects gametes from a donor who was matched with a recipient by a gamete agency that is a separate entity is not subject to the requirements of this subsection (D).

3.7 Application for Colorado Licensing and Licensing Processes

A. All applicants seeking a Colorado license must submit to the Department the following:
   a. A completed application, including the required general information, specific technical information, institutional information, and the application fee as set forth in these rules;
   b. Copies of the gamete agency, gamete bank, or fertility clinic's written policy and procedure manual(s), operational protocols, and other documentation the Department may deem necessary;
   c. Results of any investigations, disciplinary actions, or exclusions that impact or have the potential to impact the quality of services provided; and
   d. An attestation that the facility carries all types of insurance coverage required by Colorado law and industry best practices for the specific facility.

B. The Department shall investigate and review each original application and each renewal application for a license to operate as a gamete agency, gamete bank, or fertility clinic.
   a. The Department has the authority to conduct an inspection or reinspection of the gamete agency, gamete bank, or fertility clinic, including a review of relevant documentation, at any time it deems necessary to ensure compliance with these rules and to protect donors and donor-conceived persons.
   b. The applicant shall provide accurate and truthful information to the Department during inspections, investigations and licensing activities.

c. Each licensee or applicant shall make available to the Department for inspection, upon reasonable notice, records kept by it pursuant to these regulations.
d. Authorized representatives of the Department may copy and take away copies of, for the Department's use, any record required to be kept pursuant to these regulations.
e. When investigating or reviewing the records of a gamete agency, gamete bank, or fertility clinic located outside of Colorado, the Department shall investigate and review only the records pertaining to donors whose gametes or embryos were matched or provided to recipients in, or who are residents of, Colorado.
f. The Department shall not retain any identifying information about donors, recipients, or donor-conceived persons, and shall keep confidential all health-care information or documents obtained or viewed during an inspection or investigation of a gamete agency, gamete bank, or fertility clinic. All records, information, or documents so obtained are exempt from disclosure pursuant to Sections 24-72-204 and 25-1-124, C.R.S.
g. The Department may evaluate the quality of any submitted procedures in relation to industry best practices. Inadequate procedures may subject the license applicant to a corrective action plan or denial of license application or renewal.

C. Corrective Action Plan
a. As necessary, the gamete agency, gamete bank, or fertility clinic shall submit in writing, in a form and manner prescribed by the Department, a corrective action plan detailing the measures it will take to correct any violations found by the Department as a result of inspections undertaken pursuant to these rules.
i. The Department shall conduct a follow-up inspection to ensure implementation of the corrective action plan.

D. The Department may determine by on-site inspection or other appropriate investigation the applicant's compliance with applicable statutes and regulations concerning each entity’s ability to operate as a gamete agency, gamete bank, or fertility clinic.

E. Licenses granted pursuant to these rules are not transferable except in the following situations:
a. A change of legal ownership of the entity;
b. The licensed entity’s operations are moved to another subsidiary of the parent company; or

c. The operations of the entity shifted to the parent company.

Ownership changes described above must be reported to the Department within fourteen (14) business days or a license may be revoked.

Section 4: Licensing Requirements for a Provisional License

A. The Department may issue a provisional license to an applicant for an initial license to operate a gamete agency, gamete bank, or fertility clinic if:
   a. The applicant has submitted a complete initial application for licensure, and is awaiting final review and/or full inspection by the Department;
   b. The operation of the applicant's gamete agency, gamete bank, or fertility clinics will not adversely affect protections for donors or donor conceived persons, or the health, safety and welfare of the public;
   c. The applicant demonstrates it is making good faith efforts to achieve compliance with the applicable standards required under Article 57 and these rules; and
   d. The applicant is temporarily unable to conform to all the minimum standards required under Article 57 and these rules.

B. A provisional license issued by the Department shall be valid for a period not to exceed ninety (90) days, except that the Department may issue a second provisional license for the same duration and shall charge the same fee as for the first provisional license.
   a. If the licensee has made a timely and sufficient application for renewal of the provisional license, the existing license shall not expire until the Department has acted upon the renewal application.
   b. The Department may not issue a third or subsequent provisional license to the applicant within the same year as the second issuance, and in no event shall a service be provisionally licensed for a period to exceed one hundred eighty (180) calendar days.

C. A second provisional license shall not require the payment of fees if the Department bears the responsibility for the second provisional due to issues such as a logistical backlog. If the second provisional license is required due to an entity's inability to conform with the requirements of the license, a second fee of $500 will be required.

D. The applicant shall submit to the Department the applicable fee(s) set forth in these rules.

Section 5: Licensing Period

COLORADO
Department of Public Health & Environment

A. Any non-provisional license issued to a gamete agency, gamete bank, or fertility clinic by the Department shall be valid for a period not to exceed twelve (12) months.
B. The Department shall issue or renew a non-provisional license to operate as a gamete agency, gamete bank, or fertility clinic when it is satisfied that the applicant or licensee is in compliance with the requirements set forth in this article 57 and these rules.

Section 6: Mandatory Reporting Requirements for Licensees

A. A gamete agency, gamete bank, or fertility clinic operating with a provisional or non-provisional license must notify the Department:
   a. At least thirty (30) calendar days prior to the effective date of the change of any name of the gamete agency, gamete bank, or fertility clinic and submit a new initial application for licensure as stated herein and all applicable licensing fees.
   b. At least thirty (30) calendar days prior to the effective date of any change of ownership as listed in Section 3.4 Licensing - General Information, the new owner or operator must file for and obtain a license from the Department prior to beginning operations.
   c. Within five (5) business days when there has been a reduction or loss of insurance coverage that places the entity out of compliance with other federal or state laws.
   d. Within five (5) business days of discovery of any action by staff of the gamete agency, gamete bank, or fertility clinic, or an action by a patient or other party, that may cause an adverse action such as suspension or revocation, or assessment of penalties, on the facility's license or the license of another licensee if discovered by the Department.

Section 7: Licensing Renewal

A. To renew an existing license to operate as a gamete agency, gamete bank, or fertility clinic, the licensee shall submit a renewal application and fees, as set by the Department, no later than sixty (60) calendar days prior to the date of existing license expiration.
B. A renewal inspection may be required by the Department to ensure services provided by the licensee comply with these rules.
C. Except as otherwise provided in these rules, the Department shall renew a license when it is satisfied that the requirements of these rules have been met.

D. If the licensee has made a timely and sufficient application for renewal of the license, the existing license shall not expire until the Department has acted upon the renewal application.
E. If the Department denies a renewal license application, it shall provide the licensee with a notice explaining the basis for the action. The notice shall also inform the licensee of its right to appeal and the procedure for appealing the action.

Section 8: License Revocation and Fines

A. It is a violation of these rules and Article 57 for any person, corporation, or other entity to operate as a gamete agency, gamete bank, or fertility clinic in Colorado, or match or provide gametes or embryos to recipients in, or who are residents of, Colorado, without a valid license or in violation of the terms and conditions of a license.
B. The Department may suspend, revoke or not renew the license, in accordance with the procedures set forth in Section 24-4-104, C.R.S., of a licensed gamete agency, gamete bank, or fertility clinic that fails to adhere to the terms and conditions of its license and the standards and requirements established by rule pursuant to Article 57.
C. The Department may assess a civil penalty of not more than twenty thousand ($20,000) dollars, adjusted annually for inflation, for each day the person, corporation or entity is in violation of Article 57 and these rules.
    a. The Department may vary the amount of the fine depending on the size of the licensed entity, the potential for harm or injury, the responsibility of the entity, history of non-compliance, economic benefit of the violation, and whether there is a pattern of potential or actual harm or injury.
    b. The assessed penalty accrues from the date the Department finds that the person, corporation, or entity is in violation of these rules and Article 57.
    c. If the violation(s) is a one-time event with a longer time frame of effect (such selling of non-compliant gametes) or an event that cannot be redressed, the Department will assess the appropriate fees depending on the severity of the violation and whether it is indicative of a pattern of non-compliance on the part of the entity.
    d. The Department shall assess, enforce, and collect the penalty in accordance with Article 4 of Title 24 and credit the money to the general fund.

COLORADO
Department of Public Health & Environment

e. Enforcement and collection of the penalty occurs following the decision reached in accordance with procedures set forth in Section 24-4-105, C.R.S.

D. If the Department revokes or suspends a license, denies an initial license application, or assesses a civil penalty, it shall provide the licensee with a notice explaining the basis for the action. The notice shall also inform the licensee of its right to appeal and the procedure for appealing the action.