

**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**

*[Editor's Notes follow the text of the rules at the end of this CCR Document.]*

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**Adopted by the Board of Health on September 18, 2024**

**Section 1: Purpose and Authority**

- A. The Department must implement the Licensing Program (Program) to ensure that a gamete agency, gamete bank, or fertility clinic must not operate in Colorado, or match or provide gametes or embryos to recipients in 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 Colorado.
  - a. These rules are promulgated to consider and protect the interests of donor-conceived persons and families of donor-conceived persons.
- D. These rules only apply to gametes collected and matched on or after January 1, 2025, with the exception of the requirements in section 3.5.A.d.iii. and e.ii and e.iii.

**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. A donor and a recipient parent or parents are “unknown” to each other if a gamete agency, gamete bank, or fertility clinic introduced or initiated the match or connection between the donor and recipient parents, and the donor and recipient parent or parents do not mutually exchange identifying information. 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 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 located in Colorado that performs assisted reproduction medical procedures and receives donor gametes for a recipient 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:
  - a. Matches gamete donors with recipients; and
  - b. Matches the potential recipients and gamete donors who are unknown to each other at the time of donation; and
  - c.
    - I. Is located within Colorado; or
    - II. Is located outside of Colorado and matches intended recipients located in Colorado during the matching process with gamete donors.
- I. Gamete bank: entity or organization that
  - a. collects gametes from a donor or receives embryos; and
  - b. 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
  - c.
    - (I) is located within Colorado or
    - (II) provides gametes or embryos to a recipient parent or parents located in 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 or matches gametes: means the process of matching a donor with a recipient in Colorado. A “match” is made by a gamete agency, and a match is considered made when an intended recipient parent selects a specific potential donor, or agrees to receive a specific potential donor’s gametes, prior to the collection of the gametes.
  - a. For recipients who already have a child from a donor, the recipient is considered to be already “matched” with that donor when requesting additional samples.
- 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, “family medical history” must include a detailed 3-generation family history to the extent 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. Recipients in Colorado: people within Colorado, regardless of their residency, receiving the goods or services described in this rule that require a license. This does not include Colorado residents who leave Colorado to receive services.
- P. State board: the Colorado State Board of Health.

**Section 3: Licensing**

**3.1 License Required**

- A. On or after July 1, 2025, a gamete agency, gamete bank, or fertility clinic must not operate as a gamete agency, gamete bank, or fertility clinic in Colorado, or match or provide gametes or embryos to recipients in 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 must submit an annual application and fee for a license to operate in the form and manner prescribed by the Department.
- B. The license must be displayed conspicuously on any public-facing website.
- C. If necessary, the Department must suspend or revoke a license in accordance with section 24-4-104, C.R.S.
- D. A gamete agency, gamete bank, or fertility clinic must 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.
  - a. If applicants fail to comply with records requests within thirty (30) business days, applicants will be denied a license.
  - b. Failure of a licensee to respond within thirty (30) business days will 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 must annually submit to the Department the applicable fee(s) set forth in these rules.
- B. Licensing Fees
  - a. Each gamete agency, gamete bank, or fertility clinic seeking initial or renewal licensure pursuant to section 3 must submit a licensing fee to the Department.
  - b. The licensing fee may be based on the direct and indirect costs incurred by the Department for the regulatory oversight of this program.
  - c. The following fees, which may be adjusted annually for inflation, will be assessed as part of the facility's initial and renewal licensing application:
    - 1. Gamete Banks: \$500;
    - 2. Fertility Clinics: \$500;
    - 3. Gamete Agencies: \$500.
  - d. A gamete agency, gamete bank, or fertility clinic that is a nonprofit organization is exempt from the fees detailed herein.

### 3.3 Content of Application for a License

- A. An application to match or provide gametes or embryos to recipients in Colorado, must consist of general information, specific technical information, and institutional information as set forth in these rules.
- B. The licensee must submit written statements under penalty of perjury 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 will not retain any identifying information about donors, recipients, or donor-conceived persons, and will 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 must 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 must 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 category.

3.5 Specific Technical Information

- A. To assess the adequacy of protections in place for donors and donor-conceived persons, every applicant or licensee must make available for reference and inspection a detailed manual of its policies and procedures. Staff at each gamete agency, gamete bank, or fertility clinic must 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 must 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 must be disclosed to a donor conceived person who is 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 must 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 must 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 must 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 must 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 gametes or embryos. The contact information must 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 must 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 must not match or provide gametes to a recipient parent or parents located in Colorado or to a medical provider located in 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 parent or guardian of a minor donor-conceived person.
  - 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 the 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 must not impede or prohibit communication between an adult donor-conceived person 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 the 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 must 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 must disclose the name, address, telephone number, and email address of the gamete agency that matched the donor and the recipient.

3. 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 will 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.
  - 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 must:
  - 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 Colorado must:
  - 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.
- v. A gamete agency, gamete bank, or fertility clinic located outside of Colorado that matches donors to or provides gametes or embryos to recipients in Colorado may provide the Department materials described in 3.5A-f to satisfy the requirement described in section 3.5A-f-iv.

B. Limits

- a. Each gamete agency, gamete bank, or fertility clinic must 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 must 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 for families intending to conceive a child using the same donor used to conceive their other child(ren).
    - 1. Every applicant or licensee must 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 must limit donations to those individuals who are 21 years of age or older. Every applicant or licensee must 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 age limit.
- c. Each gamete agency, gamete bank, or fertility clinic must 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 must 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 must 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 must 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 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.
    - 3. The procedure must describe the process by which the entity informs a potential donor that they may request that their gametes be used for a lower number of families. The procedure must also describe how the entity ensures compliance with this agreement.
- 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 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 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 section 13-21-132, C.R.S 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 will 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 must:
      - 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
      - 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 (E).

### 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.

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- B. The Department will 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 on-site inspection or reinspection of the gamete agency, gamete bank, or fertility clinic to review relevant documentation, at any time it deems necessary to ensure compliance with these rules and to protect donors and donor-conceived persons. This inspection will consist of a review of pertinent documentation, systems, and processes required under these rules.
  - b. The applicant must provide accurate and truthful information to the Department during inspections, investigations and licensing activities.
  - c. Each licensee or applicant must 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 will investigate and review only the records pertaining to donors whose gametes or embryos were matched or provided to recipients in Colorado.
  - f. The Department will not retain any identifying information about donors, recipients, or donor-conceived persons, and will 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 must 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 will 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 article 57, title 25 and these rules 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;
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- 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 must 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 must 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 must 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 will a service be provisionally licensed for a period to exceed one hundred eighty (180) calendar days.
- C. A second provisional license will 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 must submit to the Department the applicable fee(s) set forth in these rules.

**Section 5: Licensing Period**

- A. Any non-provisional license issued to a gamete agency, gamete bank, or fertility clinic by the Department will be valid for a period not to exceed twelve (12) months.
- B. The Department will 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.

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**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 must 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 will 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 will not expire until the Department has acted upon the renewal application.
- E. If the Department denies a renewal license application, it will provide the licensee with a notice explaining the basis for the action. The notice will 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, to match or provide gametes or embryos to recipients in Colorado, without a valid license or in violation of the terms and conditions of a license.

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- 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 as selling of non-compliant gametes) or an event that cannot be redressed, the Department will assess the appropriate penalties 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 will assess, enforce, and collect the penalty in accordance with article 4 of Title 24 and credit the money to the general fund.
    - 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. or at the expiration of the appeal period.
  - D. If the Department revokes or suspends a license, denies an initial license application, or assesses a civil penalty, it will provide the licensee with a notice explaining the basis for the action. The notice will also inform the licensee of its right to appeal and the procedure for appealing the action.

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**Editor's Notes**

**History**

New rule eff. 11/14/2024.