CHAPTER 279

CHILDREN AND DOMESTIC MATTERS

SENATE BILL 22-224

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AN ACT

CONCERNING THE CREATION OF THE "DONOR-CONCEIVED PERSONS AND FAMILIES OF DONOR-CONCEIVED PERSONS PROTECTION ACT", AND, IN CONNECTION THEREWITH, MAKING AN APPROPRIATION.

Be it enacted by the General Assembly of the State of Colorado:

SECTION 1. In Colorado Revised Statutes, **add** article 57 to title 25 as follows:

ARTICLE 57 Donor-conceived Persons and Gamete Agencies, Gamete Banks, and Fertility Clinics

25-57-101. Short title. The short title of this article 57 is the "Donor-conceived Persons and Families of Donor-conceived Persons Protection Act".

25-57-102. Legislative declaration. (1) The General assembly finds and declares that:

(a) Many Coloradans are conceived, or establish their families, through some form of assisted reproduction involving a third-party sperm, egg, or embryo provider, also known as a gamete "donor", whose identity is unknown to the family at the time of donation. The people conceived through assisted reproduction with a donor are referred to in this article 57 as "donor-conceived persons".

Capital letters or bold & italic numbers indicate new material added to existing law; dashes through words or numbers indicate deletions from existing law and such material is not part of the act.

- (b) The interests of donor-conceived persons must be considered and protected. Information about the personal and family medical history of the gamete donors used in conception can impact medical care for donor-conceived persons and their children, and non-identifying medical information about the gamete donor used in conception must be available to all donor-conceived persons and their parents.
- (c) 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. Some donor-conceived persons are or may be interested in contact with the donor and among persons conceived and families established with the same donor who was unknown to the donor-conceived person's recipient parents at the time of donation. A limit on the number of families per donor per gamete agency, gamete bank, or fertility clinic furthers the ability of these donor-conceived persons to establish this contact.
- (d) STUDIES HAVE SHOWN THAT FAMILY SECRECY ABOUT FAMILY FORMATION CAN NEGATIVELY AFFECT CHILDREN AND FAMILY RELATIONSHIPS;
- (e) Before using donated gametes, people who are considering using donated gametes to conceive children should have access to more information and resources about donor-conceived persons, including tools and resources for discussing donor conception with their children in ways that are age-appropriate and reflect the interests and lived experience of donor-conceived persons;
- (f) Before donating gametes, gamete donors should have access to information and resources about the interests of donor-conceived persons and have clarity about the information that may be shared with recipient parents and donor-conceived persons; and
- (g) Most gametes or embryos from donors that are provided to recipients located in Colorado are provided from gamete agencies, gamete banks, or fertility clinics located in other states.
- (2) Therefore, the general assembly finds that to protect the health and welfare of donor-conceived persons and their families in Colorado, it is essential to enact the "Donor-conceived Persons and Families of Donor-conceived Persons Protection Act" 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.
- **25-57-103. Definitions.** As used in this article 57, unless the context otherwise requires:
 - (1) "Assisted reproduction" means a 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.
- (2) "Department" means the Colorado department of public health and environment.
- (3) "Donor" means an individual who produces eggs or sperm collected by a gamete agency, gamete bank, or fertility clinic or whose eggs or sperm created 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 this article 57 and does not apply for the purposes of determining parentage.
- (4) "DONOR-CONCEIVED PERSON" MEANS 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.
- (5) "Fertility clinic" means an 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 time of donation.
 - (6) "GAMETE" MEANS UNFERTILIZED OOCYTES OR SPERM.
- (7) "GAMETE AGENCY" MEANS AN 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.
- (8) "Gamete agency, gamete bank, or fertility clinic" means any one of such entities as defined in this section.
- (9) "Gamete bank" means an 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.
 - (10) "Identifying information" means:

- (a) THE DONOR'S FULL NAME;
- (b) THE DONOR'S DATE OF BIRTH; AND
- (c) The donor's permanent and, if different, current address or other contact information at the time of the 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.
- (11) "MATCHES" OR "MATCHES GAMETES" MEANS THE PROCESS OF MATCHING A DONOR WITH A RECIPIENT IN, OR WHO IS A RESIDENT OF, COLORADO.
 - (12) "MEDICAL HISTORY" MEANS INFORMATION REGARDING ANY:
 - (a) Present physical illness of the donor;
 - (b) Past illness of the donor; and
- (c) Social, genetic, and family medical history pertaining to the donor's health.
- (13) "Mental health professional" means 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.
- (14) "RECIPIENT" OR "RECIPIENT PARENT" MEANS 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.
 - (15) "State Board" means the Colorado state board of Health.
- **25-57-104.** Collection of identifying information and medical history applicability. (1) Except as provided in subsection (3) of this section, a gamete agency, gamete bank, or fertility clinic that collects gametes from a donor or matches a donor with a recipient shall collect the donor's identifying information and medical history and shall make a good-faith effort to maintain current contact information and updates on medical history of the donor by requesting updates from the donor at least once every three years.
- (2) A GAMETE AGENCY, GAMETE BANK, OR FERTILITY CLINIC THAT RECEIVES GAMETES OR EMBRYOS COLLECTED BY A DIFFERENT GAMETE AGENCY, GAMETE BANK, OR FERTILITY CLINIC SHALL COLLECT 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 AT THE TIME IT RECEIVES THE GAMETES OR EMBRYOS. 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 SHALL COLLECT AND MAINTAIN THE NAME, ADDRESS, TELEPHONE NUMBER, AND EMAIL ADDRESS OF THAT GAMETE

AGENCY.

- (3) A 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 (1) OF THIS SECTION, BUT 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.
- (4) A gamete agency, gamete bank, or fertility clinic shall disclose the information collected pursuant to subsections (1) through (3) of this section pursuant to the requirements of section 25-57-106.
- (5) This section 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.
- **25-57-105.** Declaration regarding disclosure of identifying information and medical history applicability. (1) Except as provided in subsection (5) of this section, a gamete agency, gamete bank, or fertility clinic that matches or collects gametes from a donor who is unknown to the recipient parent or parents at the time of the donation shall:
- (a) Provide the donor with information about disclosure of identifying information and medical history in its records;
- (b) Obtain a declaration from the donor agreeing to the identity disclosure described in subsection (2) of this section; and
- (c) Maintain identifying information and medical history about each donor. The gamete agency, gamete bank, or fertility clinic that matched or collected the gametes shall maintain records of donor and gamete screening and testing and comply with reporting requirements, in accordance with federal law and applicable laws of this state other than those set forth in this article 57 and consistent with the guidelines of the American Medical Association and the American Society for Reproductive Medicine.
- (2) EXCEPT AS PROVIDED IN SUBSECTION (5) OF THIS SECTION, A GAMETE AGENCY, GAMETE BANK, OR FERTILITY CLINIC SHALL HAVE EACH DONOR SIGN A DECLARATION, ATTESTED BY A NOTARIAL OFFICER OR WITNESSES, THAT THE DONOR AGREES TO THE DISCLOSURE OF THE DONOR'S IDENTITY TO A DONOR-CONCEIVED PERSON CONCEIVED WITH THE DONOR'S GAMETES OR EMBRYO FORMED WITH THE DONOR'S GAMETES ON REQUEST OF THE DONOR-CONCEIVED PERSON AFTER THE DONOR-CONCEIVED PERSON IS EIGHTEEN YEARS OF AGE OR OLDER.
- (3) 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 AS SET FORTH IN SUBSECTION (2) OF THIS SECTION.

- (4) A GAMETE AGENCY, GAMETE BANK, OR FERTILITY CLINIC LOCATED OUTSIDE OF COLORADO SHALL NOT MATCH OR PROVIDE GAMETES FROM A DONOR WHO DOES NOT AGREE TO THE DISCLOSURE OF THE DONOR'S IDENTITY AS SET FORTH IN SUBSECTION (2) OF THIS SECTION TO A RECIPIENT PARENT OR PARENTS LOCATED IN, OR WHO ARE RESIDENTS OF, COLORADO.
- (5) 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 SUBSECTION (1) OR (2) OF THIS SECTION.
- (6) This section 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.
- **25-57-106.** Disclosure of identifying information and medical history applicability. (1) Except as provided in subsection (4) of this section, upon the request of a donor-conceived person who is eighteen years of age or older, a gamete agency, gamete bank, or fertility clinic that matched or collected the gametes used in the assisted reproduction of such donor-conceived person shall provide the donor-conceived person with the identifying information of the donor who provided the gametes or embryo. A gamete agency, gamete bank, or fertility clinic shall not impede or prohibit compliance with this section or communication between:
- (a) An adult donor-conceived person and the donor whose gametes were used to conceive the donor-conceived person; or
- (b) An adult donor-conceived person and the person's friends, family, or other third parties about the donor whose gametes were used to conceive the donor-conceived person.
- (2) EXCEPT AS PROVIDED IN SUBSECTION (4) OF THIS SECTION, UPON THE REQUEST OF A DONOR-CONCEIVED PERSON WHO IS EIGHTEEN YEARS OF AGE OR OLDER, OR, IF THE DONOR-CONCEIVED PERSON IS A MINOR, BY A PARENT OR GUARDIAN OF THE MINOR DONOR-CONCEIVED PERSON, A GAMETE AGENCY, GAMETE BANK, OR FERTILITY CLINIC THAT MATCHED OR COLLECTED THE GAMETES USED IN THE ASSISTED REPRODUCTION, REGARDLESS OF WHETHER THE GAMETE AGENCY, GAMETE BANK, OR FERTILITY CLINIC PERFORMED THE ASSISTED REPRODUCTION, SHALL PROVIDE THE DONOR-CONCEIVED PERSON, OR, IF THE DONOR-CONCEIVED PERSON IS A MINOR, BY A PARENT OR GUARDIAN OF THE MINOR DONOR-CONCEIVED PERSON, ACCESS TO ANY NON-IDENTIFYING MEDICAL HISTORY OF THE DONOR THAT IS MAINTAINED BY THE GAMETE AGENCY, GAMETE BANK, OR FERTILITY CLINIC.
- (3) Upon the request of a donor-conceived person who is eighteen years of age or older, or, if the donor-conceived person is a minor, a parent or guardian of the minor donor-conceived person:
 - (a) 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.

- (b) 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.
- (4) 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 subsections (1) or (2) of this section.
- (5) (a) Subsections (1) and (2) of this section apply 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) Subsection (3) of this section applies only to gametes or embryos received by a gamete agency, gamete bank, or fertility clinic on or after July 1,2023.
- **25-57-107.** Record keeping successor record-keeper applicability. (1) Except as provided in subsection (6) of this section, a gamete agency, gamete bank, or fertility clinic shall permanently maintain:
- (a) 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:
- (b) 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; and
 - (c) RECORDS OF GAMETE SCREENING AND TESTING.
- (2) A GAMETE AGENCY, GAMETE BANK, OR FERTILITY CLINIC THAT RECEIVES GAMETES OR EMBRYOS FROM ANOTHER GAMETE AGENCY, GAMETE BANK, OR FERTILITY CLINIC SHALL PERMANENTLY MAINTAIN 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. 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 PERMANENTLY MAINTAIN THE NAME, ADDRESS, TELEPHONE NUMBER, AND

EMAIL ADDRESS OF THE GAMETE AGENCY THAT MATCHED THE DONOR AND THE RECIPIENT.

- (3) Except as provided in subsection (6) of this section, in its application for a license pursuant to section 25-57-110, a gamete agency, gamete bank, or fertility clinic shall submit a proposed plan to permanently maintain the records described in subsections (1) and (2) of this section in the event of dissolution, insolvency, or bankruptcy. 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. The department shall not issue a license pursuant to section 25-57-110 until it approves a plan that it finds sufficient to ensure that the records will be permanently maintained by a viable entity.
- (4) EXCEPT AS PROVIDED IN SUBSECTION (6) OF THIS SECTION, UPON DISSOLUTION, INSOLVENCY, OR BANKRUPTCY, A GAMETE AGENCY, GAMETE BANK, OR FERTILITY CLINIC SHALL:
- (a) Implement the plan approved by the department pursuant to subsection (3) of this section;
- (b) 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 described in subsections (1) and (2) of this section; and
- (c) 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 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 described in subsections (1) and (2) of this section.
- (5) 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 OTHER THAN THOSE SET FORTH IN THIS ARTICLE 57.
- (6) 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 subsection (1), (3), or (4) of this section.
- (7) (a) Subsection (2) of this section applies only to gametes or embryos matched or received on or after July 1, 2024.

- (b) Subsections (1), (3), and (4) of this section apply only to 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.
- 25-57-108. Written materials for recipient parents and gamete donors. (1) On or before January 1, 2025, the department shall develop written materials for intended recipient parents. The department shall develop the materials in conjunction with licensed mental health professionals who have prior documented experience counseling gamete donors, recipients, and donor-conceived persons, as well as experience and competency in counseling families with lesbian, gay, bisexual, and transgender parents and single parents, along with organizations representing these communities. The materials must include information on the following subjects:
- (a) That, in light of studies showing that family secrecy about family formation can negatively affect children and family relationships, telling a donor-conceived child at a young age, in an age-appropriate manner, that the child is donor-conceived is associated with improved family functioning and well-being of the donor-conceived child;
- (b) The ability, and available tools for discussing the ability, that a donor-conceived person will have to learn the identity of the donor of the gametes used in the donor-conceived person's conception and the importance of understanding that many, but not all, donor-conceived persons have a strong desire to know the identity of the donor and of other donor-conceived persons conceived with the same donor's gametes;
 - (c) The needs and interests of donor-conceived persons;
 - (d) THE LIMITATIONS OF DONOR SCREENING;
- (e) FUTURE IMPLICATIONS FOR THE DONOR-CONCEIVED PERSON GIVEN THAT THERE MAY BE OTHER PERSONS IN OTHER FAMILIES CONCEIVED WITH THE SAME DONOR'S GAMETES; AND
- (f) Future implications of receiving medical history updates about the donor or other persons conceived with the same donor's gametes.
- (2) On or before January 1, 2025, the department shall develop written materials for gamete donors. The department shall develop the materials in conjunction with licensed mental health professionals who have prior documented experience counseling gamete donors, recipients, and donor-conceived persons, as well as experience and competency in counseling families with lesbian, gay, bisexual, and transgender parents and single parents, along with organizations representing these communities. The materials must include information on the following subjects:
 - (a) Understanding the potential emotional and social impacts of

DONATING GAMETES;

- (b) Understanding what information will be disclosed to the recipient parent or parents and donor-conceived persons;
- (c) Understanding the potential for the birth of children in multiple families using the donor's gametes; and
- (d) Understanding the future potential disclosure of the donor's identifying information to a person conceived with the donor's gametes.
- (3) A GAMETE AGENCY, GAMETE BANK, OR FERTILITY CLINIC LOCATED IN COLORADO SHALL:
- (a) PRIOR TO AN INTENDED RECIPIENT MATCHING WITH OR RECEIVING DONOR GAMETES OBTAINED THROUGH THAT GAMETE AGENCY, GAMETE BANK, OR FERTILITY CLINIC, PROVIDE THE WRITTEN MATERIALS DESCRIBED IN SUBSECTION (1) OF THIS SECTION TO EACH INTENDED RECIPIENT OF GAMETES FROM A DONOR WHO IS UNKNOWN TO THE RECIPIENT OR RECIPIENTS; AND
- (b) Prior to the donation of gametes by a donor, provide the written materials described in subsection (2) 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. Donor receipt of the written materials is not in lieu of any mental health evaluations of an unknown donor that are required by the individual practices of a gamete agency, gamete bank, or fertility clinic.
- (4) A GAMETE AGENCY, GAMETE BANK, OR FERTILITY CLINIC LOCATED OUTSIDE OF COLORADO THAT EITHER MATCHES DONORS TO OR PROVIDES GAMETES OR EMBRYOS TO RECIPIENTS IN, OR WHO ARE RESIDENTS OF, COLORADO SHALL:
- (a) PRIOR TO AN INTENDED RECIPIENT MATCHING WITH OR RECEIVING DONOR GAMETES, PROVIDE WRITTEN MATERIALS TO RECIPIENTS THAT, AT A MINIMUM, COVER THE TOPICS DESCRIBED IN SUBSECTION (1) OF THIS SECTION; AND
- (b) Prior to the donation of gametes by a donor, provide written materials to the donor that, at a minimum, cover the topics described in subsection (2) of this section and discuss these materials with the donor. Donor receipt of the written materials is not in Lieu of any mental health evaluations of an unknown ovum donor that are required by the individual practices of a gamete agency, gamete bank, or fertility clinic.
- **25-57-109.** Donor age limits limits on number of families per donor limits on egg-retrieval cycles per ovum donor rules applicability. (1) (a) EXCEPT AS PROVIDED IN SUBSECTION (4) OF THIS SECTION, A GAMETE AGENCY, GAMETE BANK, OR FERTILITY CLINIC SHALL MAKE A GOOD-FAITH EFFORT TO DETERMINE HOW MANY FAMILIES ARE ESTABLISHED WITH GAMETES MATCHED OR PROVIDED BY THE GAMETE AGENCY, GAMETE BANK, OR FERTILITY CLINIC FROM EACH DONOR BY CONDUCTING SUFFICIENT RECORD KEEPING, REQUIRING RECIPIENTS, AS A CONDITION

OF RECEIVING DONOR GAMETES, TO PROVIDE INFORMATION ON LIVE BIRTHS, AND REQUESTING INFORMATION FROM RECIPIENTS ON LIVE BIRTHS, AND USING INDUSTRY BEST PRACTICES, INCLUDING METHODS OR PROCESSES TO ACCOUNT FOR THE NUMBER OR PERCENTAGE OF LIVE BIRTHS THAT ARE LIKELY NOT REPORTED, SUCH AS THE CORRELATION BETWEEN THE NUMBER OF UNITS OF DONOR GAMETES SOLD OR RELEASED AND THE RESULTING LIVE BIRTHS. A GAMETE AGENCY, GAMETE BANK, OR FERTILITY CLINIC SHALL 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 FAMILIES HAVE BEEN ESTABLISHED USING A SINGLE DONOR'S GAMETES IN OR OUTSIDE OF COLORADO, WITH NO LIMIT ON THE NUMBER OF CHILDREN CONCEIVED BY EACH OF THE FAMILIES, UNLESS THE DONOR REQUESTS, AND THE GAMETE AGENCY, GAMETE BANK, OR FERTILITY CLINIC AGREES TO, A LOWER LIMIT ON THE NUMBER OF FAMILIES. 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. THIS LIMIT DOES NOT INCLUDE DONATIONS OF EMBRYOS FROM ONE FAMILY TO ANOTHER FAMILY.

- (b) For the purposes of this subsection (1), a family is considered established when a recipient parent or parents conceive a child using gametes from a donor and a live birth results or likely resulted. A gamete agency, gamete bank, or fertility clinic shall make reasonable good-faith efforts, and document such efforts, to obtain information from a recipient parent about whether and when a live birth has occurred, including requesting such information from a recipient parent or the parent's medical provider using multiple commercially reasonable methods.
- (2) On or before January 1, 2025, the state board shall promulgate a rule establishing a limit on the total number of donor retrieval cycles per ovum donor, which must not exceed a lifetime limit of six cycles per ovum donor. In promulgating the rule, the state board shall consult with the American Society for Reproductive Medicine and organizations representing the interests of ovum donors. In promulgating the rule, the state board may consider adopting an exception to this limit 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.
- (3) A donor must be at least twenty-one years of age or older at the time of collection of gametes, and a gamete agency, gamete bank, or fertility clinic shall verify the age of the donor at the time of the collection of gametes.
- (4) 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 (1) OF THIS SECTION.
 - (5) This section 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.

- **25-57-110.** License required application inspection issuance, denial, suspension, or revocation fees civil penalties rules. (1) 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 Colorado, without having first obtained a license from the department. Such license is conditioned on compliance with the applicable standards, requirements, and other provisions of this article 57 and its implementing rules.
- (2) (a) A GAMETE AGENCY, GAMETE BANK, OR FERTILITY CLINIC SHALL SUBMIT AN ANNUAL APPLICATION AND FEE FOR A LICENSE TO OPERATE ON THE FORM AND IN THE MANNER PRESCRIBED BY THE DEPARTMENT.
- (b) (I) On or before January 1, 2025, the state board shall promulgate rules establishing a schedule of fees of not more than five hundred dollars per year, subject to annual adjustment for inflation, based on the annual percentage change in the United States department of labor's bureau of labor statistics consumer price index for Denver-Aurora-Lakewood for all items paid by all urban consumers, or its applicable predecessor or successor index, to help meet the direct and indirect costs of administration and enforcement of this article 57. A gamete agency, gamete bank, or fertility clinic that is a nonprofit organization is exempt from such fees.
- (II) The department shall assess and collect, from each gamete agency, gamete bank, or fertility clinic that is applying for licensure pursuant to this section, a fee in accordance with the fee schedule established by the state board pursuant to subsection (2)(b)(I) of this section.
- (III) THE DEPARTMENT SHALL TRANSMIT FEES COLLECTED PURSUANT TO THIS SECTION TO THE STATE TREASURER, WHO SHALL CREDIT THE MONEY TO THE GAMETE AGENCY, GAMETE BANK, OR FERTILITY CLINIC FUND CREATED IN SECTION 25-57-112.
- (IV) Fees collected pursuant to this subsection (2) may be used by the department to provide technical assistance and education to the public and to gamete agencies, gamete banks, or fertility clinics related to the provision of and compliance with Colorado law, in addition to regulatory and administrative functions. The department may contract with private entities to assist the department in providing technical assistance and education but not in providing regulatory or administrative functions.
- (3) (a) (I) 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. The department shall determine an applicant's compliance with this article 57, and the rules adopted pursuant to this article 57, for the collection and provision of

GAMETES FROM DONORS WHO ARE UNKNOWN TO A RECIPIENT AT THE TIME OF THE DONATION BEFORE ISSUING A LICENSE.

- (II) The gamete agency, gamete bank, or fertility clinic shall submit in writing, in a form 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 this subsection (3). The department shall conduct a follow-up inspection to ensure implementation of the corrective action plan.
- (III) 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 Colorado.
- (b) 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 pursuant to subsection (3)(a) of this section. All records, information, or documents so obtained are exempt from disclosure pursuant to sections 24-72-204 and 25-1-124.
- (4) Except as otherwise provided in Subsection (5) of this section, the department shall issue or renew a 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 the rules promulgated pursuant to this article 57. Except for provisional licenses issued in accordance with subsection (5) of this section, a license issued or renewed pursuant to this section expires one year after the date of issuance or renewal. The department shall suspend or revoke a license in accordance with section 24-4-104.
- (5) The department may issue a provisional license to operate as a gamete agency, gamete bank, or fertility clinic to an applicant for the purpose of operating as a gamete agency, gamete bank, or fertility clinic for a period of ninety days if the applicant is temporarily unable to conform to all of the standards required pursuant to this article 57. As a condition of obtaining a provisional license, the applicant shall show proof to the department that significant good-faith attempts are being made to conform and comply with the applicable standards required pursuant to this article 57. The department may issue a second provisional license, for a like term and fee, to effect compliance. A further provisional license shall not be issued for the current year after the second issuance.
- (6) (a) It is a violation of this article 57 for any person, corporation, or other entity to operate as a gamete agency, gamete bank, or fertility clinic in Colorado without a valid license or in violation of the terms and conditions of a license. The department may revoke or not renew the

LICENSE IN ACCORDANCE WITH THE PROCEDURES SET FORTH IN SECTION 24-4-104 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 THIS ARTICLE 57.

- (b) The department may assess a civil penalty of not more than twenty thousand dollars, adjusted annually for inflation, based on the annual percentage change in the United States department of Labor's bureau of Labor statistics consumer price index for Denver-Aurora-Lakewood for all items paid by all urban consumers, or its applicable predecessor or successor index, for each day the person is in violation of this article 57. The assessed penalty accrues from the date the department finds that the person, corporation, or entity is in violation of this article 57. 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. Enforcement and collection of the penalty occurs following the decision reached in accordance with procedures set forth in section 24-4-105.
- **25-57-111.** Rule-making authority. 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.
- 25-57-112. Gamete agency, gamete bank, and fertility clinic fund created. The gamete agency, gamete bank, or fertility clinic fund, referred to in this section as the "fund", is created in the state treasury. The fund consists of money credited to the fund pursuant to section 25-57-110. The money in the fund is subject to annual appropriation by the general assembly for the direct and indirect costs of the department in performing its duties pursuant to this article 57. At the end of any fiscal year, all unexpended and unencumbered money in the fund remains in the fund and is not credited or transferred to the general fund or any other fund.
- **SECTION 2. Appropriation.** For the 2022-23 state fiscal year, \$192,293 is appropriated to the department of public health and environment for use by disease control and public health response. This appropriation is from the general fund and is based on an assumption that the department will require an additional 1.6 FTE. To implement this act, the department may use this appropriation for the regulatory oversight program related to laboratory services.
- **SECTION 3.** Act subject to petition effective date. This act takes effect at 12:01 a.m. on the day following the expiration of the ninety-day period after final adjournment of the general assembly; except that, if a referendum petition is filed pursuant to section 1 (3) of article V of the state constitution against this act or an item, section, or part of this act within such period, then the act, item, section, or part will not take effect unless approved by the people at the general election to be

held in November 2022 and, in such case, will take effect on the date of the official declaration of the vote thereon by the governor.

Approved: May 31, 2022