State Assisted Reproductive Technology Model Legislation

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Section One: Findings

The [State Body] finds the following:

1. One federal law, the Fertility Clinic Success Rate and Certification Act of 1992, requires the Centers for Disease Control and Prevention to track certain health outcomes and success rates of assisted reproductive technology. Nonetheless, this law lacks a strong enforcement mechanism and is too limited in scope. Additionally, the primary law governing assisted reproductive technology in [State], [Act], does not require fertility clinics to report key data points related to assisted reproductive technology, maternal and neonatal health, and the total number of embryos created through this procedure. As such, many prospective parents, lawmakers, researchers, and fertility clinics lack an adequate understanding of how assisted reproductive technology functions in the [State]; information that is essential for prospective parents as they make important decisions about their childbearing options.

Section Two: Definitions

- Human Embryo.—The term "human embryo" means a distinct and living organism of the species homo sapiens conceived either in the human body or produced in an artificial environment other than the human body, from the moment of fertilization (including the single-celled stage) until natural death, including such embryos that are in a state of cryopreservation or are otherwise unused.
- Transfer.—The term "transfer" means the process by which a medical professional places a fresh or frozen embryo within the uterus, fallopian tubes, or other part of a patient's body for the purpose of initiating a pregnancy.
- Human Embryo Implantation .—The term "human embryo implantation" means a human embryo has successfully attached itself to a patient's uterine wall lining which marks the beginning of pregnancy.
- Assisted Reproductive Technology.—The term ''assisted reproductive technology'' means any treatments or procedures that involve the handling of a human egg, sperm, and embryo outside of the body with the intent of facilitating a pregnancy, including artificial insemination, intrauterine insemination, in vitro fertilization, gamete intrafallopian fertilization, zygote intrafallopian fertilization, egg, embryo, and sperm cryopreservation, and egg, sperm, or embryo donation.
- Fertility Clinic.—The term "fertility clinic" means a medical facility that is licensed, registered, or certified in accordance with the standards put forward by Federal or State laws or regulations and is responsible for the collection and preservation of human reproductive material (including egg, sperm, or embryos) responsible for the creation of human embryos, and/or the placement of human reproductive material (including egg, sperm, or embryo) into the prospective patient.

- Health Care Professional.—The term “health care professional” means an individual licensed, registered, or certified under Federal or State laws or regulations to provide health care services.
- Human Reproductive Material.—The term “human reproductive material” means all or any part of a sperm, ovum, or embryo at any stage of development.
- Prospective Patient.—The term “prospective patient” means the patient who will undergo assisted reproductive technology treatments, including the transfer of human embryos for the purpose of initiating pregnancy.
- Infertility.—The term ‘‘infertility’’ means a symptom of an underlying disease or condition within a person’s body that makes it difficult or impossible to successfully conceive and carry a child to term, which is diagnosed after 12 months of intercourse without the use of a chemical, barrier, or other contraceptive method for women under 35 or after 6 months of targeted intercourse without the use of a chemical, barrier, or other contraceptive method for women 35 and older, where conception should otherwise be possible.
- Cycle.—The term “cycle” means a single procedure of in vitro fertilization, zygote intrafallopian transfer, gamete intrafallopian transfer, or egg retrieval. A complete cycle may only refer to egg retrieval if no eggs are fertilized and implanted into the patient or it may mean the complete process from egg retrieval to the transfer of human reproductive material.
- Egg Donor.—The term “egg donor” means a person unrelated by marriage to the prospective parent(s) who provides or agrees to provide ovum for the purpose of human reproduction, regardless of if the recipient has a diagnosis of infertility.
- Sperm Donor.—The term “sperm donor” means a person unrelated by marriage to the prospective parent(s) who provides or agrees to provide sperm for the purpose of human reproduction, regardless of if the prospective parent(s) has a diagnosis of infertility.
- Embryo Cryopreservation.—The term “embryo cryopreservation” means that human embryos are frozen in an undisturbed environment for the purpose of saving these embryos for future procreative use.
- Informed Consent.—The Term “informed consent” means written and verbal consent obtained from the prospective parent(s) by the fertility clinic, medical association, medical professional, gamete bank, gamete agency, or gamete donation clinic who handles human egg, sperm, or embryo.
- State Board.—The term “state board” means the [Department].

Section Three: Prohibition Section

Overview

This law should be adopted and enacted by the [Department], either within the existing [Act] or within another statute that ensures the best enforcement and data collection mechanisms for this law.

Section Four: Assisted Reproductive Technology Clinic Reporting Requirements

A. [State Body] directs the [Department] to expand fertility clinic reporting requirements for assisted reproductive technology. Annually, fertility clinics must track and report key data points to the appropriate state department for research and accountability purposes. These data points include:
    a. How many embryos each clinic creates in total through assisted reproductive technology cycles;
    b. What happens to each of the embryos they create:
    c. how many embryos (at any stage of development) are negligently destroyed each year due to the failure of a cryopreservation tank or technical and human error;
    d. how many embryos (at any stage of development) perish due to natural causes during fertilization, development, or implantation in assisted reproductive technology;
    e. how many embryos (at any stage of development) perish due to preimplantation genetic testing in assisted reproductive technology;
    f. how many embryos (at any stage of development) are intentionally destroyed at the discretion of the fertility clinic or the prospective parents;
        i. Require fertility clinics to specify, by selecting one of the four following options, why the fertility clinic and/or parents chose to discard the embryo: a) genetic or physical health concerns; b) wrong biological sex; c) unwanted or unused embryo; d) other (provide reason).
    g. how many embryos (at any stage of development) prospective parents relinquished to an embryo adoption clinic;
    h. how many embryos (at any stage of development) prospective parents donate for research purposes;
    i. how many embryos are created in each cycle of assisted reproductive technology (i.e. when a couple undergoes in vitro fertilization procedures, how many embryos are created in one cycle?)
    j. if, and how often, fertility clinics lose the reproductive material of prospective parents due to unknown or undisclosed reasons;
    k. report any instances of a medical professional knowingly transferring non-viable reproductive material into a prospective patient, with or without the patient's knowledge;
    l. the total number of embryos that are frozen in cryopreservation storage units (submit the number of embryos frozen prior to submitting the report each year, whenever that occurs);

m. how many embryos are transferred fresh versus frozen;
n. how many embryos are transferred in a single transfer cycle;
o. how many embryos successfully implant, when conceived with assisted reproductive technology, but are miscarried, perish naturally in the womb, or are stillborn;
p. how many pregnancies result from assisted reproductive technology procedures;
q. how many live births result from assisted reproductive technology procedures;
r. how many cases of multiple gestation (twins, triplets, quadruplets, or more) occur from assisted reproductive technology procedures.

Section Five: Assisted Reproductive Technology Annual Public Report

A. Within twelve months of receiving the annual assisted reproductive technology data from fertility clinics, the [Department] must compile and publish a comprehensive report, available for public use, cataloging key data points for research, accountability, and prospective patient use. These data points include:
    a. how many fertility clinics are registered to practice assisted reproductive technology;
    b. how many assisted reproductive technology and egg retrieval cycles each clinic performs;
    c. a percentage breakdown of the types of assisted reproductive technology procedures clinics (taken as a whole) perform;
    d. the success rate of each form of assisted reproductive technology, broken down by age, whether donor ovum or sperm was used, and the total number of cycles required for the successful birth of a live child per couple;
    e. compile and report the total outcomes of each of the individual fertility clinic data collection points from Section Four: Assisted Reproductive Technology Clinic Reporting Requirements.

Section Six: Maternal and Neonatal Health Outcomes Related to Assisted Reproductive Technology

A. In conjunction with the [Department], the [State Body] directs the [Department] to track and report maternal health outcomes throughout pregnancy, labor, and the postpartum period (a minimum of eighteen months) for women who conceive, or bear through gestational surrogacy, children with assisted reproductive technology.
B. In conjunction with the [Department], the [State Body] directs the [Department] to track and report neonatal health outcomes (including birth defects, diseases, genetic or physical conditions, chronic issues, physical abnormalities, mental health, or other health factors) of children conceived with assisted reproductive technology, including an implementation of an ongoing review of a child's genetic, physical, and emotional health

until the age of eighteen. [Given potential privacy concerns, a self-reporting option may be offered]

Section Seven: Severability Clause

If any provision of this Act, or the application of such provision to any person, entity, government, or circumstance, is held to be unconstitutional, the remainder of this Act, or the application of such provision to all other persons, entities, governments, or circumstances, shall not be affected thereby.

Donated Egg and Sperm Protection Act

Section One: Definitions

- Assisted Reproductive Technology.—The term ‘‘assisted reproductive technology’’ means any treatments or procedures that involve the handling of a human egg, sperm, and embryo outside of the body with the intent of facilitating a pregnancy, including artificial insemination, intrauterine insemination, in vitro fertilization, gamete intrafallopian fertilization, zygote intrafallopian fertilization, egg, embryo, and sperm cryopreservation, and egg, sperm, or embryo donation.
- Fertility Clinic.— The term “fertility clinic” means a medical facility that is licensed, registered, or certified in accordance with the standards put forward by Federal or State laws or regulations and is responsible for the collection and preservation of human reproductive material (including egg, sperm, or embryos) responsible for the creation of human embryos, and/or the placement of human reproductive material (including egg, sperm, or embryo) into the prospective patient.
- Health Care Professional.—The term “health care professional” means an individual licensed, registered, or certified under Federal or State laws or regulations to provide health care services.
- Egg.— The term “egg” means a human ovum.
- Egg Donor.—The term “egg donor” means a person unrelated by marriage to the recipient who provides or agrees to provide ovum for the purpose of human reproduction, regardless of if the recipient has a diagnosis of infertility.
- Sperm.—The term “sperm” means a male human gamete.
- Sperm Donor.—The term “sperm donor” means a person unrelated by marriage to the prospective parent(s) who provides or agrees to provide sperm for the purpose of human reproduction, regardless of if the prospective parent(s) has a diagnosis of infertility.

Section Two: Prohibitions

A. Eggs or sperm donated for the purpose of assisted reproductive technology may not be used for any destructive purposes, including but not limited to:
    a. Scientific or clinical research;
    b. Development of commercial products;
    c. Any other purpose not directly related to establishing a pregnancy.
B. A person shall not purchase or offer to purchase a human egg or sperm for human somatic cell nuclear transfer or for any purpose other than treating human infertility or for clinical investigation by a physician or clinic whose primary practice is treating human infertility.
C. This section does not prohibit compensation of egg donors or sperm donors who provide or agree to provide eggs or sperm for the treatment of human infertility or for clinical investigation by a physician or clinic whose primary practice is the treatment of human infertility.
D. This section does not prohibit any of the following:
    a. treatment of human infertility that involves donated eggs or donated sperm.

b. cryopreservation of human eggs or sperm.
c. donation of eggs or sperm without compensation for any purpose.

Section Three: Penalty and Enforcement Clause

A. Insert a strong enforcement mechanism with criminal and financial penalties for anyone who knowingly violates this law.

Section Four: Severability Clause

If any provision of this Act, or the application of such provision to any person, entity, government, or circumstance, is held to be unconstitutional, the remainder of this Act, or the application of such provision to all other persons, entities, governments, or circumstances, shall not be affected thereby.

Donor-Conceived Persons Protection Act

Section One: Definitions

- Human Embryo.—The term “human embryo” means a distinct and living organism of the species homo sapiens conceived either in the human body or produced in an artificial environment other than the human body, from the moment of fertilization (including the single-celled stage) until natural death, including such embryos that are in a state of cryopreservation or are otherwise unused.
- Transfer.—The term “transfer” means the process by which a medical professional places a fresh or frozen embryo within the uterus, fallopian tubes, or other part of a patient’s body for the purpose of initiating a pregnancy.
- Human Embryo Implantation .—The term “human embryo implantation” means a human embryo has successfully attached itself to a patient’s uterine wall lining which marks the beginning of pregnancy.
- Assisted Reproductive Technology.— The term ‘‘assisted reproductive technology’’ means any treatments or procedures that involve the handling of a human egg, sperm, and embryo outside of the body with the intent of facilitating a pregnancy, including artificial insemination, intrauterine insemination, in vitro fertilization, gamete intrafallopian fertilization, zygote intrafallopian fertilization, egg, embryo, and sperm cryopreservation, and egg, sperm, or embryo donation.
- Fertility Clinic.—The term “fertility clinic” means a medical facility that is licensed, registered, or certified in accordance with the standards put forward by Federal or State laws or regulations and is responsible for the collection and preservation of human reproductive material (including egg, sperm, or embryos) responsible for the creation of human embryos, and/or the placement of human reproductive material (including egg, sperm, or embryo) into the prospective patient.
- Health Care Professional.—The term “health care professional” means an individual licensed, registered, or certified under Federal or State laws or regulations to provide health care services.
- Human Reproductive Material.—The term “human reproductive material” means all or any part of a sperm, ovum, or embryo at any stage of development.
- Prospective Patient.—The term “prospective patient” means the patient who will undergo assisted reproductive technology treatments, including the transfer of human embryos for the purpose of initiating pregnancy.
- Infertility.—The term ‘‘infertility’’ means a symptom of an underlying disease or condition within a person’s body that makes it difficult or impossible to successfully conceive and carry a child to term, which is diagnosed after 12 months of intercourse without the use of a chemical, barrier, or other contraceptive method for women under 35 or after 6 months of targeted intercourse without the use of a chemical, barrier, or other

contraceptive method for women 35 and older, where conception should otherwise be possible.

- Cycle.—The term "cycle" means a single procedure of in vitro fertilization, zygote intrafallopian transfer, gamete intrafallopian transfer, or egg retrieval. A complete cycle may only refer to egg retrieval if no eggs are fertilized and implanted into the patient or it may mean the complete process from egg retrieval to the transfer of human reproductive material.
- Egg Donor.—The term "egg donor" means a person unrelated by marriage to the prospective parent(s) who provides or agrees to provide ovum for the purpose of human reproduction, regardless of if the prospective parent(s) has a diagnosis of infertility.
- Sperm Donor.—The term "sperm donor" means a person unrelated by marriage to the prospective parent(s) who provides or agrees to provide sperm for the purpose of human reproduction, regardless of if the prospective parent(s) has a diagnosis of infertility.
- Embryo Cryopreservation.—The term "embryo cryopreservation" means that human embryos are frozen in an undisturbed environment for the purpose of saving these embryos for future procreative use.
- Donor-Conceived Persons.—The term "donor-conceived persons" means a person who is conceived with the use of donor gametes from a person unrelated by marriage to the prospective parent(s) responsible for the creation of the person. This includes gametes that are received as a gift or by means of any financial or resource payment.
- Donor.—The term "donor" means a person who donates their gametes to prospective parent(s), a gamete bank, a gamete agency, or a medical association for the purpose of receiving financial, altruistic, or another form of payment in exchange for their gametes.
- Gamete.—The term "gamete" means human ovum or sperm.
- Gamete Bank or Gamete Agency.—The term "gamete bank" or "gamete agency" means an entity or organization that collects gametes from a donor or receives embryos and provides gametes or embryos to a prospective parent or parents or the prospective parent's medical provider when the prospective parent and donor are unknown to each other at time of donation, and that is located within or outside of [State] and provides gametes or embryos to a prospective parent or parents in, or who are residents of, [State].
- Identifying Information.—The term "identifying information" means the donors full name; the donors date of birth; and 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.
- Matches.—The term "matches" means the process of matching a donor with a prospective parent in, or who is a resident of, [State].

- Medical History.—The term “medical history” means information regarding any present physical illness of the donor; past illness of the donor; and social, genetic, and family medical history pertaining to the donor’s health.
- Mental Health Professional.—The term “mental health professional” means a person who is certified or licensed under [State] law or an out-of-state professional who is a licensed psychiatrist, clinical psychologist, or professional counselor.
- State Board.—The term “state board” means the [Department].
- Informed Consent.—The Term “informed consent” means written and verbal consent obtained from the prospective parent(s) by the fertility clinic, medical association, medical professional, gamete bank, gamete agency, or gamete donation clinic who handles human egg, sperm, or embryo.

Section Two: Gamete Donor Collection of Identifying Information and Medical History

A. A gamete agency, gamete bank, or fertility clinic that collects gametes from a donor or matches a donor with a prospective parent(s) 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.
B. 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 time gametes or embryos. a gamete bank or fertility clinic that collects gametes from a donor who was matched with a prospective parent(s) 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.
C. A fertility clinic that collects gametes from a donor who was matched with a prospective parent(s) by a gamete agency that is a separate entity is not subject to the requirements of the first paragraph 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.

Section Three: Declaration of Donor Disclosure of Identifying Information and Medical History

A. A gamete agency, gamete bank, or fertility clinic that matches or collects gametes from a donor who is unknown to the prospective parent(s) 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.

B. Except as provided in subsection (E) 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.
C. A gamete agency, gamete bank, or fertility clinic located in [State] shall not match or collect gametes from a donor who does not agree to the disclosure of the donor's identity set forth in this section.
D. A gamete agency, gamete bank, or fertility clinic located outside of [State] 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 the previous paragraphs of this section to a prospective parent(s) or parents located in, or who are residents of [State].
E. A gamete bank or fertility clinic that collects gametes from a donor who was matched with a prospective parent(s) by a gamete agency that is a separate entity is not subject to the requirements of subsection (a) or (b) of this section.

Section Four: Disclosure of Identifying Information and Medical History to the Donor-Conceived Person

A. Upon the request of a donor-conceived person who is fourteen 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.
B. Upon the request of a donor-conceived person who is fourteen years of age or older, or if the donor-conceived person is younger than fourteen years of age, a parent or guardian of the under-age fourteen 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

C. Upon the request of a donor-conceived person who is fourteen years of age or older, or, if the donor-conceived person is less than fourteen years of age, 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 prospective parent(s) 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 prospective parent(s).

Section Five: Record Keeping Requirements

A. 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 prospective parent 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;
    c. records of gamete screening and testing.

B. 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 prospective parent(s) 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 prospective parent.

C. In its application for a license, a gamete agency, gamete bank, or fertility clinic shall submit a proposed plan to permanently maintain the records described in 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.

D. 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 prospective parent(s) 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.

E. 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 [State].

Section Six: Written Materials for Donor-Conceived Persons

A. The department shall develop written materials for prospective parent(s). The department shall develop the materials in conjunction with licensed mental health professionals who have prior documented experience counseling gamete donors, prospective parent(s), and donor-conceived persons. 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.

B. The department shall develop the materials in conjunction with licensed mental health professionals who have prior documented experience counseling gamete donors, prospective parents, and donor-conceived persons. 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 prospective parent(s) 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.

C. A gamete agency, gamete bank, or fertility clinic located in [State] shall
    a. prior to an intended prospective parent(s) 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 prospective parent(s) of gametes from a donor who is unknown to the prospective parent(s); and
    b. Prior to the donation of gametes by a donor, provide the written materials described in 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 prospective parent(s) 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.

D. A gamete agency, gamete bank, or fertility clinic located outside of [State] that either matches donors to or provides gametes or embryos to prospective parent(s) in, or who are residents of, [State] shall:
    a. prior to a prospective parent(s) 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 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.

Section Seven: Gamete Donor Limitations

A. 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 prospective parent(s), as a condition of receiving donor gametes, to provide information on live births, and requesting information from prospective parent(s) 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 [State], 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 prospective parent(s) 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 section, a family is considered established when a prospective parent(s) 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 prospective parent(s) about whether and when a live birth has occurred, including requesting such information from a prospective parent(s) or the parent's medical provider using multiple commercially reasonable methods.
C. 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 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.
D. 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.
E. A gamete agency, gamete bank, or fertility clinic that collects gametes from a donor matched with a prospective parent(s) by a gamete agency that is a separate entity is not subject to this section's requirements.

Section Eight: Appropriation of Funds

[Potential Appropriation of Funds Requirement]

Section Nine: Penalty and Enforcement Clause

A. Insert a strong enforcement mechanism with criminal and financial penalties for anyone who knowingly violates this law.

Section Ten: Severability Clause

If any provision of this Act, or the application of such provision to any person, entity, government, or circumstance, is held to be unconstitutional, the remainder of this Act, or the application of such provision to all other persons, entities, governments, or circumstances, shall not be affected thereby.

Egg Donation Informed Consent Law

Section One: Definitions

- Human Embryo.—The term “human embryo” means a distinct and living organism of the species homo sapiens conceived either in the human body or produced in an artificial environment other than the human body, from the moment of fertilization (including the single-celled stage) until natural death, including such embryos that are in a state of cryopreservation or are otherwise unused.
- Transfer.—The term “transfer” means the process by which a medical professional places a fresh or frozen embryo within the uterus, fallopian tubes, or other part of a patient’s body for the purpose of initiating a pregnancy.
- Human Embryo Implantation .—The term “human embryo implantation” means a human embryo has successfully attached itself to a patient’s uterine wall lining which marks the beginning of pregnancy.
- Assisted Reproductive Technology.—The term ‘‘assisted reproductive technology’’ means any treatments or procedures that involve the handling of a human egg, sperm, and embryo outside of the body with the intent of facilitating a pregnancy, including artificial insemination, intrauterine insemination, in vitro fertilization, gamete intrafallopian fertilization, zygote intrafallopian fertilization, egg, embryo, and sperm cryopreservation, and egg, sperm, or embryo donation.
- Fertility Clinic.—The term “fertility clinic” means a medical facility that is licensed, registered, or certified in accordance with the standards put forward by Federal or State laws or regulations and is responsible for the collection and preservation of human reproductive material (including egg, sperm, or embryos) responsible for the creation of human embryos, and/or the placement of human reproductive material (including egg, sperm, or embryo) into the prospective patient.
- Health Care Professional.—The term “health care professional” means an individual licensed, registered, or certified under Federal or State laws or regulations to provide health care services.
- Human Reproductive Material.—The term “human reproductive material” means all or any part of a sperm, ovum, or embryo at any stage of development.
- Prospective Patient.—The term “prospective patient” means the patient who will undergo assisted reproductive technology treatments, including the transfer of human embryos for the purpose of initiating pregnancy.
- Infertility.—The term ‘‘infertility’’ means a symptom of an underlying disease or condition within a person’s body that makes it difficult or impossible to successfully conceive and carry a child to term, which is diagnosed after 12 months of intercourse without the use of a chemical, barrier, or other contraceptive method for women under 35 or after 6 months of targeted intercourse without the use of a chemical, barrier, or other

contraceptive method for women 35 and older, where conception should otherwise be possible.

- Cycle.—The term "cycle" means a single procedure of in vitro fertilization, zygote intrafallopian transfer, gamete intrafallopian transfer, or egg retrieval. A complete cycle may only refer to egg retrieval if no eggs are fertilized and implanted into the patient or it may mean the complete process from egg retrieval to the transfer of human reproductive material.
- Egg Donor.—The term "egg donor" means a person unrelated by marriage to the recipient who provides or agrees to provide ovum for the purpose of human reproduction, regardless of if the recipient has a diagnosis of infertility.
- Sperm Donor.—The term "sperm donor" means a person unrelated by marriage to the prospective parent(s) who provides or agrees to provide sperm for the purpose of human reproduction, regardless of if the prospective parent(s) has a diagnosis of infertility.
- Embryo Cryopreservation.—The term "embryo cryopreservation" means that human embryos are frozen in an undisturbed environment for the purpose of saving these embryos for future procreative use.
- Informed Consent.—The Term "informed consent" means written and verbal consent obtained from the prospective parent(s) by the fertility clinic, medical association, medical professional, gamete bank, gamete agency, or gamete donation clinic who handles human egg, sperm, or embryo.
- State Board.—The term "state board" means the Arkansas Department of Human Services.

Section Two: Prohibition Section

Overview

This law should be adopted and enacted by the [Department], either within the existing [Act] or within another statute that ensures the best enforcement and data collection mechanisms for this law.

Section Three: Egg Donation Informed Consent Requirements

A. For the purposes of the duty of care owed by a physician, an egg provider is a patient of the physician who harvests the eggs from the egg provider.
B. A physician shall not harvest eggs except in a hospital, clinic or other medical facility that meets the licensing standards for the facility prescribed by this title.
C. Before performing any medical procedure or prescribing any hormones or other drugs for an egg provider, a physician must provide the egg provider with the following information:

a. a description of all hormones and other drugs to be taken by the egg provider, including the dosage, frequency of administration, intended biochemical function and likely physiological response to each medication.
b. a description of all procedures to be performed on the egg provider, including the purpose, duration and estimated recovery time for each procedure.
c. medically accurate disclosures concerning all potential risks of egg donation that a reasonable patient would consider material to the decision of whether to undergo the procedure, including the medical risks associated with the surgical procedure and the drugs, medications and hormones prescribed for ovarian stimulation during the process.
d. a description of the effects that the surgical procedure and the drugs, medications and hormones may have on future attempts of the egg provider to become pregnant.
e. a list of additional sources of information on health and safety issues surrounding egg donation.
f. notice that the egg provider cannot be completely informed of all potential risks or effects because the process and risks related to egg harvesting are highly unstudied and unknown compared to other medical procedures and treatments.
g. the physician must obtain written and oral informed consent for the procedure from the egg provider before performing any medical procedure or prescribing any hormones or other drugs for the egg provider.

Section Four: Severability Clause

If any provision of this Act, or the application of such provision to any person, entity, government, or circumstance, is held to be unconstitutional, the remainder of this Act, or the application of such provision to all other persons, entities, governments, or circumstances, shall not be affected thereby.

Human Embryo Protection Act

Section One: Definitions

- Destructive Human Embryonic Stem Cell Research.—The term "destructive human embryonic stem cell research" means any research that involves the disaggregation of any human embryo for the purpose of creating human pluripotent stem cells or human pluripotent stem cell lines.
- Human-Animal Hybrid.—The term "human-animal hybrid" means any of the following:
    - A human embryo into which a nonhuman cell or cells, or any component part of a nonhuman cell or cells, have been introduced.
    - A hybrid human-animal embryo produced by fertilizing a human egg with a nonhuman sperm.
    - A hybrid human-animal embryo produced by fertilizing a nonhuman egg with human sperm.
    - An embryo produced by introducing a nonhuman nucleus into a human egg.
    - An embryo produced by introducing a human nucleus into a nonhuman egg.
    - An embryo containing at least haploid sets of chromosomes from both a human and a nonhuman life form.
    - A nonhuman life form engineered so that human gametes develop within the body of a nonhuman life form.
    - A nonhuman life form engineered so that it contains a human brain or a brain derived wholly or predominantly from human neural tissues.
- Human Embryo.—The term "human embryo" means a distinct and living organism of the species homo sapiens conceived either in the human body or produced in an artificial environment other than the human body, from the moment of fertilization (including the single-celled stage) until natural death, including such embryos that are in a state of cryopreservation or are otherwise unused.
- In Vitro.—The term "in vitro" means outside the human body.
- Purchase or Sell.—The term "purchase or sell" means an exchange of cash, an in-kind payment, or any other valuable financial or nonfinancial consideration. This does not include payment of costs related to the donation of a human embryo for the purpose of implantation in the body of a biological woman.

Section Two: Production of human embryo or human-animal hybrid; purchase or sale; prohibitions; violation; classification; exemptions

A. A person shall not intentionally or knowingly create or attempt to create an in vitro human embryo by any means other than fertilization through the combining of a human egg with a human sperm.
B. A person shall not intentionally or knowingly:
    a. Create or attempt to create a human-animal hybrid.
    b. Transfer or attempt to transfer a human embryo into a nonhuman womb.
    c. Transfer or attempt to transfer a nonhuman embryo into a human womb.
    d. Transport or receive for any purpose a human-animal hybrid.

C. A person shall not purchase or sell or offer to purchase or sell an in vitro human embryo or human-animal hybrid and shall not advertise for the purchase or sale of an in vitro human embryo or human-animal hybrid.
D. A person who violates this section is guilty of a Class 1 Misdemeanor.

Section Three: Destructive Human Embryonic Research

A. A person shall not intentionally or knowingly engage in destructive human embryonic stem cell research.

Section Four: Severability Clause

If any provision of this Act, or the application of such provision to any person, entity, government, or circumstance, is held to be unconstitutional, the remainder of this Act, or the application of such provision to all other persons, entities, governments, or circumstances, shall not be affected thereby.

Human Gamete Protection Act from Unlawful Experimentation

Section One: Definitions

- Human Embryo.—The term "human embryo" means a distinct and living organism of the species homo sapiens conceived either in the human body or produced in an artificial environment other than the human body, from the moment of fertilization (including the single-celled stage) until natural death, including such embryos that are in a state of cryopreservation or are otherwise unused.
- Transfer.—The term "transfer" means the process by which a medical professional places a fresh or frozen embryo within the uterus, fallopian tubes, or other part of a patient's body for the purpose of initiating a pregnancy.
- Human Embryo Implantation .—The term "human embryo implantation" means a human embryo has successfully attached itself to a patient's uterine wall lining which marks the beginning of pregnancy.
- Assisted Reproductive Technology.— The term ''assisted reproductive technology'' means any treatments or procedures that involve the handling of a human egg, sperm, and embryo outside of the body with the intent of facilitating a pregnancy, including artificial insemination, intrauterine insemination, in vitro fertilization, gamete intrafallopian fertilization, zygote intrafallopian fertilization, egg, embryo, and sperm cryopreservation, and egg, sperm, or embryo donation.
- Fertility Clinic.—The term "fertility clinic" means a medical facility that is licensed, registered, or certified in accordance with the standards put forward by Federal or State laws or regulations and is responsible for the collection and preservation of human reproductive material (including egg, sperm, or embryos) responsible for the creation of human embryos, and/or the placement of human reproductive material (including egg, sperm, or embryo) into the prospective patient.
- Health Care Professional.—The term "health care professional" means an individual licensed, registered, or certified under Federal or State laws or regulations to provide health care services.
- Human Reproductive Material.—The term "human reproductive material" means all or any part of a sperm, ovum, or embryo at any stage of development.
- Prospective Patient.—The term "prospective patient" means the patient who will undergo assisted reproductive technology treatments, including the transfer of human embryos for the purpose of initiating pregnancy.
- Infertility.—The term ''infertility'' means a symptom of an underlying disease or condition within a person's body that makes it difficult or impossible to successfully conceive and carry a child to term, which is diagnosed after 12 months of intercourse without the use of a chemical, barrier, or other contraceptive method for women under 35 or after 6 months of targeted intercourse without the use of a chemical, barrier, or other

contraceptive method for women 35 and older, where conception should otherwise be possible.

- Cycle.—The term "cycle" means a single procedure of in vitro fertilization, zygote intrafallopian transfer, gamete intrafallopian transfer, or egg retrieval. A complete cycle may only refer to egg retrieval if no eggs are fertilized and implanted into the patient or it may mean the complete process from egg retrieval to the transfer of human reproductive material.
- Egg Donor.—The term "egg donor" means a person unrelated by marriage to the recipient who provides or agrees to provide ovum for the purpose of human reproduction, regardless of if the recipient has a diagnosis of infertility.
- Sperm Donor.—The term "sperm donor" means a person unrelated by marriage to the prospective parent(s) who provides or agrees to provide sperm for the purpose of human reproduction, regardless of if the prospective parent(s) has a diagnosis of infertility.
- Embryo Cryopreservation.--The term "embryo cryopreservation" means that human embryos are frozen in an undisturbed environment for the purpose of saving these embryos for future procreative use.
- Informed Consent.—The Term "informed consent" means written and verbal consent obtained from the prospective parent(s) by the fertility clinic, medical association, medical professional, gamete bank, gamete agency, or gamete donation clinic who handles human egg, sperm, or embryo.
- State Board.—The term "state board" means the Arkansas Department of Human Services.

Section Two: Prohibit Medical Professionals and Fertility Clinics from Unlawful Experimentation

A. Medical professionals and fertility clinics are prohibited, under penalty of law, from experimenting on a prospective parent(s) human reproductive material, including sperm, ovum, or embryo at any stage of development without the express written permission and informed consent of the prospective parent(s).

Section Three: Informed Consent for Human Reproductive Material Experimentation

A. Medical professionals and fertility clinics must explain the risks, harms, and process of human reproductive material experimentation and research, including on sperm, ovum, or embryos at any stage of development, such as
    a. Medical research and experimentation on an embryo, at any stage of development, involves research and experimentation on a distinct, living, and unique member of the species homo sapiens. Such research and experimentation also results in the destruction and manipulation of human life. Such embryos, if

they are not destroyed through the research process, are required to be destroyed at around 14 days, per medical ethics.

b. Medical research and experimentation on human sperm and ovum, which does not involve fertilized human life, may result in the unknown creation of an embryo (without the donor's knowledge) that may or will be researched or experimented on, before being destroyed at 14 days. Unless prohibited, sperm and ovum could also be used for non-human fertilization in human-animal chimera research.
c. Upon donating one's human reproductive material for medical research or experimentation, prospective parent(s) lose all rights, including the ability to potentially conceive children, from these human reproductive material(s).

Section Four: Penalty and Enforcement Clause

A. Insert a strong enforcement mechanism including criminal and financial penalties for anyone who knowingly violates this law.

Section Five: Severability Clause

If any provision of this Act, or the application of such provision to any person, entity, government, or circumstance, is held to be unconstitutional, the remainder of this Act, or the application of such provision to all other persons, entities, governments, or circumstances, shall not be affected thereby.

Human-Animal Chimera Prohibition Act

Section One: Definitions

- Human Embryo.—The term "human embryo" means a distinct and living organism of the species homo sapiens conceived either in the human body or produced in an artificial environment other than the human body, from the moment of fertilization (including the single-celled stage) until natural death, including such embryos that are in a state of cryopreservation or are otherwise unused.
- Transfer.—The term "transfer" means the process by which a medical professional places a fresh or frozen embryo within the uterus, fallopian tubes, or other part of a patient's body for the purpose of initiating a pregnancy.
- Human Embryo Implantation .—The term "human embryo implantation" means a human embryo has successfully attached itself to a patient's uterine wall lining which marks the beginning of pregnancy.
- Assisted Reproductive Technology.—The term ''assisted reproductive technology'' means any treatments or procedures that involve the handling of a human egg, sperm, and embryo outside of the body with the intent of facilitating a pregnancy, including artificial insemination, intrauterine insemination, in vitro fertilization, gamete intrafallopian fertilization, zygote intrafallopian fertilization, egg, embryo, and sperm cryopreservation, and egg, sperm, or embryo donation.
- Fertility Clinic.—The term "fertility clinic" means a medical facility that is licensed, registered, or certified in accordance with the standards put forward by Federal or State laws or regulations and is responsible for the collection and preservation of human reproductive material (including egg, sperm, or embryos) responsible for the creation of human embryos, and/or the placement of human reproductive material (including egg, sperm, or embryo) into the prospective patient.
- Health Care Professional.—The term "health care professional" means an individual licensed, registered, or certified under Federal or State laws or regulations to provide health care services.
- Human Reproductive Material.—The term "human reproductive material" means all or any part of a sperm, ovum, or embryo at any stage of development.
- Prospective Patient.—The term "prospective patient" means the patient who will undergo assisted reproductive technology treatments, including the transfer of human embryos for the purpose of initiating pregnancy.
- Infertility.—The term ''infertility'' means a symptom of an underlying disease or condition within a person's body that makes it difficult or impossible to successfully conceive and carry a child to term, which is diagnosed after 12 months of intercourse without the use of a chemical, barrier, or other contraceptive method for women under 35 or after 6 months of targeted intercourse without the use of a chemical, barrier, or other

contraceptive method for women 35 and older, where conception should otherwise be possible.

- Cycle.—The term "cycle" means a single procedure of in vitro fertilization, zygote intrafallopian transfer, gamete intrafallopian transfer, or egg retrieval. A complete cycle may only refer to egg retrieval if no eggs are fertilized and implanted into the patient or it may mean the complete process from egg retrieval to the transfer of human reproductive material.
- Egg Donor.—The term "egg donor" means a person unrelated by marriage to the prospective parent(s) who provides or agrees to provide ovum for the purpose of human reproduction, regardless of if the recipient has a diagnosis of infertility.
- Sperm Donor.—The term "sperm donor" means a person unrelated by marriage to the prospective parent(s) who provides or agrees to provide sperm for the purpose of human reproduction, regardless of if the prospective parent(s) has a diagnosis of infertility.
- Embryo Cryopreservation.—The term "embryo cryopreservation" means that human embryos are frozen in an undisturbed environment for the purpose of saving these embryos for future procreative use.
- Informed Consent.—The Term "informed consent" means written and verbal consent obtained from the prospective parent(s) by the fertility clinic, medical association, medical professional, gamete bank, gamete agency, or gamete donation clinic who handles human egg, sperm, or embryo.
- State Board.—The term "state board" means the Arkansas Department of Human Services.
- Chimera.—The term "chimera" means
    - (A) a human embryo into which a nonhuman cell or cells (or the component parts thereof) have been introduced to render the embryo's membership in the species Homo sapiens uncertain
    - (B) a human-animal embryo produced by fertilizing a human egg with nonhuman sperm;
    - (C) a human-animal embryo produced by fertilizing a nonhuman egg with human sperm;
    - (D) an embryo produced by introducing a nonhuman nucleus into a human egg;
    - (E) an embryo produced by introducing a human nucleus into a nonhuman egg;
    - (F) an embryo containing at least haploid sets of chromosomes from both a human and a nonhuman life form;
    - (G) a nonhuman life form engineered such that human gametes develop within the body of a nonhuman life form;
    - (H) a nonhuman life form engineered such that it contains a human brain or a brain derived wholly or predominantly from human neural tissues;
    - (I) nonhuman life form engineered such that it exhibits human facial features or other bodily morphologies to resemble human features; or

- (J) an embryo produced by mixing human and nonhuman cells, such that—
  - (i) human gametes develop within the body of the resultant organism;
  - (ii) it contains a human brain or a brain derived wholly or predominantly from human neural tissues; or
  - (iii) it exhibits human facial features or other bodily morphologies to resemble human features.

Section Two: Prohibition Section

Overview

This law should be adopted and enacted by the [Department], either within the existing [Act] or within another statute that ensures the best enforcement and data collection mechanisms for this law.

Section Three: Human-Animal Chimera Prohibition

A. It shall be unlawful to
   a. Create or attempt to create a prohibited human-animal chimera;
   b. transfer or attempt to transfer a human embryo into a nonhuman womb;
   c. transfer or attempt to transfer a non- human embryo into a human womb; or
   d. transport or receive for any purpose a prohibited human-animal chimera.

Section Four: Penalty and Enforcement Clause

A. Insert a strong enforcement mechanism including criminal and financial penalties for anyone who knowingly violates this law.

Section Five: Severability Clause

If any provision of this Act, or the application of such provision to any person, entity, government, or circumstance, is held to be unconstitutional, the remainder of this Act, or the application of such provision to all other persons, entities, governments, or circumstances, shall not be affected thereby.

IVF Embryo Transfer Limit

Section One: Findings

The [State Body] finds the following:

1. The American Society for Reproductive Medicine, one of the largest fertility organizations in the United States, offers non-legally enforceable recommended guidelines encouraging fertility clinics to practice single embryo transfers in assisted reproductive technology, except in extenuating circumstances for older patients.
2. The American Society for Reproductive Medicine and the broader medical community are committed to promoting, where preemptively possible, singleton pregnancies in the best interests of the mother and neonatal child.
3. Multiple gestation (the conception of twins, triplets, quadruplets, or more) leads to an increased risk of poor maternal and neonatal health outcomes. These risks, compared to singleton pregnancies, result in a higher percentage of preterm labor and birth; severe maternal outcomes including death, transfer to an intensive care unit, blood transfusions, and hysterectomy; gestational hypertension; anemia; birth defects including congenital abnormalities such as neural tube defects, gastrointestinal, and heart abnormalities; miscarriage; cesarian delivery; and postpartum hemorrhage. These conditions threaten the health and safety of the mother and/or the child.
4. While the rates of multiple gestation have decreased in recent years, the percentage is substantially higher in assisted reproductive technology than among natural conception pregnancies. This led researchers to conclude that many fertility clinics, to increase success rates, continue to transfer more than one embryo in a single transfer cycle, to the detriment of mothers and children.
5. Unlike the United States, European nations tend to have well-established laws governing the practice of assisted reproductive technology, specifically addressing how many embryos may be transferred in a transfer cycle. For example, Australia and New Zealand limit the number of embryos that may be transferred at one time to 1-2, depending on circumstances; Germany limits the number to 3 or fewer embryos that may be transferred at one time, and Sweden limits the number of embryos that may be transferred at one time to 1, or 2 in special cases.

Section Two: Definitions

- Human Embryo.—The term “human embryo” means a distinct and living organism of the species homo sapiens conceived either in the human body or produced in an artificial environment other than the human body, from the moment of fertilization (including the single-celled stage) until natural death, including such embryos that are in a state of cryopreservation or are otherwise unused.

- Transfer.—The term “transfer” means the process by which a medical professional places a fresh or frozen embryo within the uterus, fallopian tubes, or other part of a patient’s body for the purpose of initiating a pregnancy.
- Human Embryo Implantation .—The term “human embryo implantation” means a human embryo has successfully attached itself to a patient’s uterine wall lining which marks the beginning of pregnancy.
- Assisted Reproductive Technology.— The term ‘‘assisted reproductive technology’’ means any treatments or procedures that involve the handling of a human egg, sperm, and embryo outside of the body with the intent of facilitating a pregnancy, including artificial insemination, intrauterine insemination, in vitro fertilization, gamete intrafallopian fertilization, zygote intrafallopian fertilization, egg, embryo, and sperm cryopreservation, and egg, sperm, or embryo donation.
- Fertility Clinic.—The term “fertility clinic” means a medical facility that is licensed, registered, or certified in accordance with the standards put forward by Federal or State laws or regulations and is responsible for the collection and preservation of human reproductive material (including egg, sperm, or embryos) responsible for the creation of human embryos, and/or the placement of human reproductive material (including egg, sperm, or embryo) into the prospective patient.
- Health Care Professional.— The term “health care professional” means an individual licensed, registered, or certified under Federal or State laws or regulations to provide health care services.
- Human Reproductive Material.—The term “human reproductive material” means all or any part of a sperm, ovum, or embryo at any stage of development.
- Prospective Patient.—The term “prospective patient” means the patient who will undergo assisted reproductive technology treatments, including the transfer of human embryos for the purpose of initiating pregnancy.
- Infertility.—The term ‘‘infertility’’ means a symptom of an underlying disease or condition within a person’s body that makes it difficult or impossible to successfully conceive and carry a child to term, which is diagnosed after 12 months of intercourse without the use of a chemical, barrier, or other contraceptive method for women under 35 or after 6 months of targeted intercourse without the use of a chemical, barrier, or other contraceptive method for women 35 and older, where conception should otherwise be possible.
- Cycle.—The term “cycle” means a single procedure of in vitro fertilization, zygote intrafallopian transfer, gamete intrafallopian transfer, or egg retrieval. A complete cycle may only refer to egg retrieval if no eggs are fertilized and implanted into the patient or it may mean the complete process from egg retrieval to the transfer of human reproductive material.

- Egg Donor.—The term “egg donor” means a person unrelated by marriage to the recipient who provides or agrees to provide ovum for the purpose of human reproduction, regardless of if the recipient has a diagnosis of infertility.
- Embryo Cryopreservation.—The term “embryo cryopreservation” means that human embryos are frozen in an undisturbed environment for the purpose of saving these embryos for future procreative use.

Section Three: Prohibitions Section

Overview

This law should be adopted and enacted by the [Department], either within the existing [Act] or within another statute that ensures the best enforcement and data collection mechanisms for this law.

Section Four: Informed Consent

A. Prior to the collection of human reproductive materials and the use of assisted reproductive technology, the prospective patient should receive informed consent about the number of embryos that may be transferred in each cycle given the woman’s age.
B. The prospective patient should also provide informed consent, regardless of their age, about the maternal health risks and neonatal concerns related to assisted reproductive technology. This should include data specific to in vitro fertilization maternal and neonatal outcomes and maternal and neonatal health risks associated with transferring multiple embryos in a single transfer cycle.
C. The prospective patient should also receive informed consent about the status and cryopreservation of unused embryos in between each transfer cycle.

Section Five: Transfer Cycle Age Requirements

A. For the prospective patient aged 37 years or younger, a medical professional in assisted reproductive technology may only transfer a single embryo per each transfer cycle, regardless of the embryo’s development stage. This applies to the age of the prospective patient who is receiving the transfer, not the age of the human eggs involved if the prospective patient relies on donor eggs.
B. For the prospective patient aged 38 years or older, a medical professional in assisted reproductive technology may only transfer a maximum of 3 embryos per each transfer cycle, regardless of the embryo’s developmental stage. This applies to the age of the prospective patient who is receiving the transfer, not the age of the human eggs involved if the prospective patient relies on donor eggs.

Section Six: Severability Clause

If any provision of this Act, or the application of such provision to any person, entity, government, or circumstance, is held to be unconstitutional, the remainder of this Act, or the application of such provision to all other persons, entities, governments, or circumstances, shall not be affected thereby.

Parental Informed Consent Laws for Assisted Reproductive Technology

Section One: Definitions

- Human Embryo.—The term "human embryo" means a distinct and living organism of the species homo sapiens conceived either in the human body or produced in an artificial environment other than the human body, from the moment of fertilization (including the single-celled stage) until natural death, including such embryos that are in a state of cryopreservation or are otherwise unused.
- Transfer.—The term "transfer" means the process by which a medical professional places a fresh or frozen embryo within the uterus, fallopian tubes, or other part of a patient's body for the purpose of initiating a pregnancy.
- Human Embryo Implantation .—The term "human embryo implantation" means a human embryo has successfully attached itself to a patient's uterine wall lining which marks the beginning of pregnancy.
- Assisted Reproductive Technology.— The term ''assisted reproductive technology'' means any treatments or procedures that involve the handling of a human egg, sperm, and embryo outside of the body with the intent of facilitating a pregnancy, including artificial insemination, intrauterine insemination, in vitro fertilization, gamete intrafallopian fertilization, zygote intrafallopian fertilization, egg, embryo, and sperm cryopreservation, and egg, sperm, or embryo donation.
- Fertility Clinic.—The term "fertility clinic" means a medical facility that is licensed, registered, or certified in accordance with the standards put forward by Federal or State laws or regulations and is responsible for the collection and preservation of human reproductive material (including egg, sperm, or embryos) responsible for the creation of human embryos, and/or the placement of human reproductive material (including egg, sperm, or embryo) into the prospective patient.
- Health Care Professional.— The term "health care professional" means an individual licensed, registered, or certified under Federal or State laws or regulations to provide health care services.
- Human Reproductive Material.—The term "human reproductive material" means all or any part of a sperm, ovum, or embryo at any stage of development.
- Prospective Patient.—The term "prospective patient" means the patient who will undergo assisted reproductive technology treatments, including the transfer of human embryos for the purpose of initiating pregnancy.
- Infertility.—The term ''infertility'' means a symptom of an underlying disease or condition within a person's body that makes it difficult or impossible to successfully conceive and carry a child to term, which is diagnosed after 12 months of intercourse without the use of a chemical, barrier, or other contraceptive method for women under 35 or after 6 months of targeted intercourse without the use of a chemical, barrier, or other

contraceptive method for women 35 and older, where conception should otherwise be possible.

- Cycle.—The term "cycle" means a single procedure of in vitro fertilization, zygote intrafallopian transfer, gamete intrafallopian transfer, or egg retrieval. A complete cycle may only refer to egg retrieval if no eggs are fertilized and implanted into the patient or it may mean the complete process from egg retrieval to the transfer of human reproductive material.
- Egg Donor.—The term "egg donor" means a person unrelated by marriage to the recipient who provides or agrees to provide ovum for the purpose of human reproduction, regardless of if the recipient has a diagnosis of infertility.
- Sperm Donor.—The term "sperm donor" means a person unrelated by marriage to the prospective parent(s) who provides or agrees to provide sperm for the purpose of human reproduction, regardless of if the prospective parent(s) has a diagnosis of infertility.
- Embryo Cryopreservation.—The term "embryo cryopreservation" means that human embryos are frozen in an undisturbed environment for the purpose of saving these embryos for future procreative use.
- State Board.—The term "state board" means the [Department].

Section Two: Prohibition Section

Overview

This law should be adopted and enacted by the [Department], either within the existing [Act] or within another statute that ensures the best enforcement and data collection mechanisms for this law.

Section Three: Parental Informed Consent Requirements for Assisted Reproductive Technology

A. A physician providing assisted reproductive technologies, at least twenty-four hours before the physician obtains a signed contract for services, must provide patients with the following information in writing and obtain a signed informed consent form before services commence:
    a. a description of the procedure.
    b. the likelihood that the patient will become pregnant, based on experience of that particular physician with patients of comparable age and medical conditions.
    c. if the physician operates out of a facility, statistics on the facility's success rate, including the total number of live births, the number of live births as a percentage of completed retrieval cycles, the rates for clinical pregnancy and delivery per completed retrieval cycle bracketed by age groups consisting of women under thirty years of age, women who are thirty through thirty-four years of age, women

who are thirty-five through thirty-nine years of age and women who are at least forty years of age.

d. a description of alternative therapies and treatments, including adoption and natural cycling.
e. the likelihood of the patient having a live-born child based on a forthright assessment of her particular age, circumstances and embryo transfer options.
f. a statement that the patient retains the right to withhold or withdraw consent at any time before transfer of gametes or embryos without affecting her right to future care or treatment or risking the loss or withdrawal of any program benefits to which the patient would otherwise be entitled.
g. a description of the known and potential risks, consequences and benefits of assisted reproductive technology, including psychological risks associated with all drugs and procedures considered, the inherent risk of embryo loss due to aneuploidy, failure of implantation or thawing, the risks associated with the use of hormones and other drugs that may be used, egg retrieval, multiple pregnancies and selective reduction.
h. the most recent statistics reported by the facility to federal and state agencies, along with information on where to obtain reported statistics from all other fertility facilities in the state and national statistics as reported to the united states centers for disease control and prevention, along with an explanation of the relevance of the statistics.
i. the anticipated price to the patient of all procedures, including any charges for procedures and medications not covered in the standard fee.
j. the average cost to patients of a successful assisted pregnancy.
k. the likelihood that selective reduction might be recommended as a response to multiple gestation, along with a clear explanation of the nature of selective reduction and the associated risks for the mother and any surviving child.
l. information about embryo conception and transfer, including the patient's right to determine the number of embryos or oocytes to conceive and transfer and the most recent scientific information on the number of embryos needed to be transferred for a successful pregnancy.
m. if the patient is using donor gametes, the psychological screening and the testing protocol used to ensure that gamete donors are free from known infection, including human immunodeficiency viruses, and free from carriers of known genetic and chromosomal diseases.
n. if the patient is using donor gametes, notice that use of an anonymous gamete donor will affect the genetic child and may have negative effects on the child, including tension, confusion and distress about the child's origins and ancestry.
o. the availability of embryo adoption for non-transferred embryos and information on agencies in the state that process or facilitate embryo adoption.

p. the risks of cryopreservation for embryos, including information concerning the current feasibility of freezing eggs rather than embryos, and any influence that may have on the likelihood of a live birth.
q. a description of the facility's practice regarding selecting embryos as viable to transfer, including whether embryos will be deemed not viable for transfer and the outcome for those embryos, including whether those embryos will be destroyed, used for training or used for research.
r. the current law governing disputes concerning non-transferred embryos.
s. information concerning disposition of non-transferred embryos that may be chosen by the patient, the rights of patients regarding that disposition and the need to state their wishes and intentions regarding disposition.
t. the effect on treatment, embryos and the validity of informed consent of clinic closings, divorce, separation, failure to pay storage fees for non-transferred embryos, failure to pay treatment fees, inability to agree on the fate of embryos, the death of a patient or others, withdrawal of consent for transfer after fertilization but before cryopreservation, incapacity, unavailability of agreed on disposition of embryos or loss of contact with the facility.
u. that there may be foreseen or unforeseen legal consequences and that it is advisable to seek legal counsel.
v. that all existing confidentiality protections apply and what these confidentiality protections are.
w. that a patient has access to all of the patient's medical information to the extent the law allows.

B. A patient must be informed of the option of additional counseling throughout future procedures, even if counseling was refused in the past.
C. Each time a new cycle is undertaken, informed consent must be obtained and information provided to the patient with the latest statistics and findings concerning the patient's status.
D. The provider must document informed consent in a record for each participant that must:
    a. be in plain language.
    b. be dated and signed by the provider and by the participant.
    c. state that disclosures have been made pursuant to this section.
    d. specify the length of time the consent remains valid.
    e. advise the party signing the informed consent document of the right to receive a copy of the record.
E. Except in an emergency, the record must be signed by the parties before informed consent is valid or the commencement of any assisted reproductive technology.
F. This section does not require a physician to provide additional information or obtain additional informed consent if the physician's current practices relating to informed consent already meet the standards prescribed by subsections a through d of this section.

G. A physician who knowingly violates this section commits an act of unprofessional conduct and is subject to license suspension or revocation.

Section Four: Required Disclosers in Assisted Reproductive Technology Procedures

A. Before each retrieval and each transfer, a physician must disclose to all participants the following possible dispositions of embryos, together with a statement as to which are allowed under applicable law:
    a. storage, including length of time, costs and location.
    b. transfer.
    c. donation as follows:
        i. to a known individual for transfer.
        ii. to an anonymous individual for transfer.
        iii. for scientific or clinical research, including the institution conducting the research and the intended nature of the research, if known.
    d. destruction.
B. A physician is not required to offer all possible dispositions, but the physician must inform the patient that other providers may offer other options and that the patient has the right to transport embryos to other providers.
C. Before each transfer cycle, the provider must provide each intended parent with the following information in a record, where applicable:
    a. the method used to achieve fertilization and the results of semen analysis, including, at a minimum, motility, count and morphology.
    b. the number of eggs retrieved.
    c. for the retrieval and transfer of fresh embryos:
        i. the number created.
        ii. the number viable for transfer.
        iii. the outcome for embryos deemed not viable for transfer.
        iv. the number to be transferred.
        v. the number preserved.
        vi. the quality of each embryo transferred.
        vii. the quality of each embryo preserved.
    d. for the transfer of preserved embryos:
        i. the number of embryos thawed.
        ii. the number of embryos viable for transfer after thawing.
        iii. the quality of embryos transferred.
D. A statement that failure to adhere to drug administration schedules may affect the outcome of the treatment.

Section Seven: Severability Clause

If any provision of this Act, or the application of such provision to any person, entity, government, or circumstance, is held to be unconstitutional, the remainder of this Act, or the application of such provision to all other persons, entities, governments, or circumstances, shall not be affected thereby.