Assisted Reproductive Technologies Disclosure (ART) and Risk Reduction Act

Model Legislation & Policy Guide

Updated August 2023

Americans United for Life

Advancing the Human Right to Life in Culture, Law, and Policy

1150 Connecticut Avenue NW, Suite 500, Washington, DC 20036
aul.org | (202) 289-1478 | info@aul.org

INTRODUCTION

Since the first *in vitro* fertilization (IVF) birth was reported in the United States, the provision of IVF has become a multi-billion dollar industry.[1] However, regulation of IVF is highly inconsistent across the states, with the U.S. described as "the Wild West of the fertility industry."[2]

Although 37 states and the District of Columbia currently define the parental rights of the parties involved in an IVF procedure through statute or case law,[3] only 11 states have statutes that regulate facilities that collect and transfer human gametes and embryos.[4] Further, only two states impose an affirmative duty on medical providers to inform patients about the potential health hazards and success rates of IVF procedures.[5] At least ten states have laws or regulations related to the purchase, donation, transfer, solicitation,

[1] Michael Ollove, *Lightly regulated in vitro fertilization yields thousands of babies annually*, WASH. POST (Apr. 13, 2015, 3:26 PM), http://www.washingtonpost.com/national/health-science/lightly-regulated-in-vitro-fertilization-yields-thousands-of-babies-annually/2015/04/13/f1f3fa36-d8a2-11e4-8103-fa84725dbf9d_story.html.

[2] Naomi Cahn, *UVA Law Professor Examines the "Wild West" of the Fertility Industry*, UVA (Sept. 13, 2021), https://news.virginia.edu/content/uva-law-professor-examines-wild-west-fertility-industry#:~:text=In%20the%20U.S.%2C%20government%20regulation,issue%20concerning%20conception%20or%20embryos.

[3] Ala. Code §§ 26-17-701–26-17-704 ; Ariz. Rev. Stat. § 25-318.03; Ark. Code § 9-10-201 ; Cal. Fam. Code § 7613 ; Colo. Rev. Stat. §§ 15-11-120–15-11-121 ; Conn. Gen. Stat. §§ 46b-510–46b-538 ; Del. Code tit. 13 § 8-703 ; D.C. Code §§ 16-401–16-412 ; Fla. Stat. § 742.11 ; Ga. Code § 19-8-41 ; Idaho Code §§ 7-1601–7-1612 ; 750 ILCS 47/1-1800 ; Iowa Code § 252A.3 ; La. Stat. tit. 40 § 46.10 ; Me. Stat. tit. 19-A §§ 1921–1929; Mich. Comp. Laws § 722.861; Minn. Stat. § 524.2-120, *see also A. L. S. v. E. A. G*, No. A10-443, 2010 Minn. App. Unpub. LEXIS 1091 (Minn. Ct. App. Oct. 26, 2010); Nev. Rev. Stat. §§ 126.500–126.810; N.H. Rev. Stat. §§ 168-B:1–168-B:22; N.J. Stat. §§ 9:17-60–9:17-71; N.M. Stat. §§ 40-11A-701–40-11A-707; N.Y. Fam. Ct. Act §§ 581-301–581-307; *Quets v. Needham*, 682 S.E.2d 214 (N.C. Ct. App. 2009); N.D. Cent. Code §§ 30.1-04-19–30.1-04-20; *S.N. v. M.B.*, 935 N.E.2d 463 (Ohio Ct. App. 2010); Okla. Stat. tit. 10 §§ 554–56; Or. Rev. Stat. §§ 109.239–109.247; *In re S.S.*, 128 A.3d 296 (Pa. Super. Ct. 2015); R.I. Gen. Laws §§ 15-8.1-701–15-8.1-709; Tenn. Code §§ 36-2-401–36-2-403 ; Tex. Fam. Code §§ 160.701–160.707 ; Utah Code §§ 78B-15-702–78B-15-708 ; Vt. Stat. tit. 15C §§ 701–09 ; Va. Code §§ 20-156–20-165 ; Wash. Rev. Code §§ 26.26A.600–26.26A.635; *S.U. v. C.J.*, No. 18-0566, 2019 W. Va. LEXIS 517 (W. Va. Nov. 4, 2019); Wis. Stat. § 891.40; Wyo. Stat. §§ 14-2-901–14-2-907.

[4] Cal. Health & Saf. Code § 1635.1; Conn. Gen. Stat. §§ 46b-544–46b-547 ; Del. Code tit. 16 § 2801 ; 20 ILCS 2310/2310-330 ; Ind. Code § 35-46-5-3; Md. Code, Health-Gen. § 18-334; Mich. Comp. Laws § 333.20179; Nev. Rev. Stat. §§ 629.360–629.370; N.J. Stat. §§ 26:2A-23–26:2A-31; R.I. Gen. Laws § 15-8.1-903; Wash. Rev. Code §§ 26.26A.800–26.26A.825.

[5] Mass. Gen. Laws ch. 111L § 4; Va. Code § 54.1-2971.1.

and/or harvesting of human eggs.[6] Lastly, only two states, ban surrogacy contracts that provide for non-medically related renumeration, whereas one state bans all surrogacy contracts.[7]

This lack of regulation has led to the large-scale creation of embryonic human beings without oversight or accountability. There are now hundreds of thousands cryopreserved human embryos in laboratories across the United States, with unknown numbers being discarded each year. Abuses of IVF – by doctors and patients alike – are also publicized from time to time, as the infamous case of the "Octo-Mom" aptly demonstrates.[8] In 2008, "Octo-Mom" Nadya Suleman had her fertility doctor implant 12 embryos into her.[9] Not only was this six times the normal amount for a woman of Suleman's age, it also subjected Suleman and her preborn children—eight of which survived the transfer and were carried to term—to numerous health risks.[10]

Assisted reproductive technology (ART) is a broader term, which encompasses IVF and all newer forms of reproductive technology. According to the U.S. Centers for Disease Control and Prevention (CDC), as of 2019 there are a total of 489 clinics in the United States that provide ART procedures.[11] Between 2015 and 2019, approximately 14.3% of American women aged 25-44 had used infertility services.[12]

ART has enabled many married couples who suffer various forms of infertility to experience the joy of parenthood with biologically-related children. However, ART has also raised fundamental challenges to the nature of parenthood, the parent-child relationship, the identity of children, and the health of future children by fostering:

---

[6] Ala. Code §§ 26-17-704, 26-17-706-07; Ariz. Rev. Stat. §§ 36-1702-03; Cal. Health & Saf. Code § 125325; Conn. Gen. Stat. § 32-41jj ; Fla. Stat. §§ 742.14, 17; Indiana: Ind. Code § 35-46-5-3(d); Mass. Gen. Laws ch. 111L § 4; Md. Code Health-Gen. § 20-111; N.J. Stat. §§ 26:2A-23–26:2A-31; Okla. Stat. tit. 10 § 557.19.
[7] Ky. Rev. Stat. § 199.590(4); La. Stat. tit. 9 § 2720.5(B); Ind. Code § 31-20-1-1.
[8] *See Octomom's Fertility Doctor Has License Revoked*, CBS NEWS (June 2, 2011), https://www.cbsnews.com/news/octomoms-fertility-doctor-has-license-revoked/.
[9] *Id*.
[10] *Id*.
[11] Centers for Disease Control and Prevention, *State-Specific Assisted Reproductive Technology Surveillance*, https://www.cdc.gov/art/state-specific-surveillance/index.html#:~:text=data%20become%20available.-,Assisted%20Reproductive%20Technology%20Clinics,by%20state%20(or%20territory) (last updated Dec. 27, 2021).
[12] Centers for Disease Control and Prevention, *QuickStats: Percentage* of Women Aged 25–44 Years Who Had Ever Used Infertility Services,† by Type of Service — National Survey of Family Growth, United States, 2006–2010 and 2015–2019* (Oct. 8, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7040a5.htm.

- Surrogacy (or "gestational carrier") agreements;
- Egg harvesting and anonymous egg and sperm donation;
- New technologies like pre-implantation genetic diagnosis (PGD), which encourage the termination or disposal of embryos not deemed "perfect" or "fit";
- Proliferation of cryopreserved human embryos; and
- Embryo experimentation, human cloning, and embryonic stem cell research.

ART needs to be regulated, in large part, to protect the health of mothers and the children conceived, and to preserve parental relationships and the dignity of human procreation. AUL has drafted the *Assisted Reproductive Technology Disclosure and Risk Reduction Act* to accomplish these aims. This innovative legislation has three major components:

- Detailed informed consent requirements for ART;
- Data collection and reporting requirements; and
- Limits on the creation and transfer of embryos in a single reproductive cycle.

A State may choose to introduce this Act as an integrated whole or may choose specific components or Sections. For more information and drafting assistance, please contact AUL at Legislation@AUL.org.

ASSISTED REPRODUCTIVE TECHNOLOGY DISCLOSURE AND RISK REDUCTION ACT

HOUSE/SENATE BILL No. _____
By Representatives/Senators _____

Section 1. Short Title.

This Act may be known and cited as the "Assisted Reproductive Technology Disclosure and Risk Reduction Act."

Section 2. Legislative Findings and Purposes.

(a) The [*Legislature*] of the State of [*Insert name of State*] finds that:

(1) Infertility is of serious concern to many couples and individuals who want to be parents.

(2) Assisted reproductive technology (ART) is a growing, multi-billion dollar industry that serves an increasing number of patients.

(3) ART is an elective medical procedure and does not cure any underlying medical or physical disfunction. ART attempts to circumvent existing physical disabilities to enable a live pregnancy and delivery.

(4) ART procedures are expensive. Each [*treatment*] cycle can cost [*$10,000 to $15,000 or more*].

(5) Full information about the costs and risks, including the risks associated with multiple gestations, is necessary to patients' evaluation of ART.

(6) Only one federal statute, the *Fertility Clinic Success Rate and Certification Act of 1992* (42 U.S.C. § 263a-1, *et seq.*), directly regulates ART procedures by requiring the reporting of clinic success rates.

(7) ART is subject to little state regulation.

(8) A number of other nations regulate specific aspects of ART including the number of embryos that can be created. Belgium, Brazil, Denmark, Germany, Hungary, Italy, Saudi Arabia, Singapore, Spain, Sweden, Switzerland, and the United Kingdom limit the number of embryos that can be transferred per treatment cycle, typically limiting the number transferred to two (2) or three (3) embryos.

(9) Voluntary self-regulation of ART programs is ineffective. Not all ART programs or facilities are members of professional organizations, such as the Society for Assisted Reproductive Technology (SART) or the American Society for Reproductive Medicine (ASRM). Moreover, these professional organizations do not independently confirm that their members follow their voluntary guidelines.

(10) In most cases, ART involves the creation of multiple embryos, some of which are not subsequently used in the implantation (transfer) procedure.

(11) As noted by the United States Supreme Court in *Dobbs v. Jackson Women's Health Organization*, states have an interest in protecting maternal health and preserving prenatal life. Accordingly, this State has an interest in ensuring protection for mothers who undergo ART and for the future health of children conceived through ART.

(12) *Dobbs* held that deference should be given to the states in regulating maternal health, which includes reproductive technology. This Act is therefore constitutional under this State's police power.

(13) Informed consent is one of the core principles of ethical medical practice, and every patient has a right to information pertinent to an invasive medical procedure. Further, ART is unique because it produces a third party—the prospective child—who must also be considered and protected.

(14) Due to the significant risks ART poses to women, the standard for informed consent should be raised.

(15) Thorough recordkeeping and reporting are necessary to ensure meaningful public education about the rates of success for ART and the costs, risks, and benefits of ART, and to ensure proper accountability.

(16) One problem associated with ART is high-order multiple pregnancies (three (3) or more embryos implanting) and the associated risks to the health of mothers and children.

(17) Fetal reduction in the event of a high-order multiple pregnancy involves significant risks to the mother and to children subsequently born.

(b) Based on the findings in subsection (a), the purposes of this Act are to:

(1) Protect the safety and well-being of women who use ART and the children conceived through ART;

(2) Establish standards for obtaining informed consent from couples and individuals seeking ART;

(3) Require adequate reporting for facilities providing ART services;

(4) Stem the proliferation of cryopreserved human embryos being stored in fertility clinics [*and bring the State of [Insert name of State] into line with international norms*] by limiting the number of embryos that can be created in any reproductive cycle;

(5) Reduce the risk of high-order multiple gestations, pre-maturity, and other complications to mothers and children by limiting the number of embryos transferred in any reproductive cycle;

(6) Reduce the risks of fetal reduction to mothers and children; and

(7) Institute annual reporting requirements on certain aspects of ART to the [*Insert name of state health department or other appropriate agency*].

Section 3. Definitions.

As used in this Act only:

(a) "**ART facility**" or "**facility**" means any public or private organization, corporation, partnership, sole proprietorship, association, agency, network, joint venture, or other entity that is involved in providing assisted reproductive technology including but not limited to: hospitals, clinics, medical centers, ambulatory surgical centers, private physician's offices, pharmacies, nursing homes, university medical and nursing schools, medical training facilities, or other institutions or locations wherein assisted reproductive technology is offered to any person.

(b) "**ART program**" or "**program**" means all treatments or procedures which include the handling of both human eggs and sperm.

(c) "**Assisted reproductive technology (ART)**" means all clinical treatments and laboratory procedures which include the handling of human eggs, sperm, or embryos with the intent of establishing a pregnancy. It includes *in vitro* fertilization (IVF), gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), and such other specific technologies as the [*Department of Health*] may include in this definition.

(d) "**Department**" means the [*Insert name of state health department or other appropriate agency*].

(e) "**Embryo**" means the developing human organism however generated, beginning with the diploid cell resulting from the fusion of the male and female pronuclei, from somatic cell nuclear transfer, or by other means, until approximately the end of the second (2nd) month of development.

(f) "**Gamete**" means human egg (oocyte) or sperm.

(g) "**Fetal reduction**" means the induced termination of one (1) or more embryos or fetuses.

Section 4. Informed Consent.

(a) All ART programs providing assisted reproductive technologies must, at least twenty-four (24) hours prior to obtaining a signed contract for services, provide patients with the following information in writing and obtain a signed disclosure form before services commence:

(1) Description of the procedure(s).

(2) Outcomes and success:

a. The likelihood that the patient will become pregnant, based on experience at that particular program with patients of comparable age and medical conditions;

b. 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, and the rates for clinical pregnancy and delivery per completed retrieval cycle bracketed by age groups consisting of women under thirty (30) years of age, women aged thirty through thirty-four (30-34) years, women aged thirty-five through thirty-nine (35-39) years, and women aged forty (40) years and older;

c. The likelihood of the patient having a live-born child based on a forthright assessment of her particular age, circumstances, and embryo transfer options;

d. The program's most recent outcome statistics, as reported to the U.S. Centers for Disease Control and Prevention (CDC);

e. The existence of (and availability of data) from the *Fertility Clinic Success Rate and Certification Act* regarding pregnancy and live-birth success rates of ART programs, as well as a copy of the annual report by the ART program to the CDC pursuant to said Act; and

f. Statistics reported by the program to federal and state agencies, reported statistics from all other clinics in the State, and national ART

statistics as reported to the CDC, as well as an explanation of the relevance of the statistics.

(3) Costs:

a. The anticipated out-of-pocket price of all procedures, including any charges for procedures and medications not covered in the standard fee; and

b. Average cost to patients of a successful assisted pregnancy.

(4) Major known risks:

a. All major known risks and side effects to mothers and children conceived, including but not limited to all psychological risks associated with all ART drugs and procedures considered, cesarean delivery, pre-term birth, placental abruption, vascular complications, preeclampsia, acute kidney injury, ischemic stroke, arrhythmia, hypertension, postpartum hemorrhage, low birth weight of the child, the child being small for gestational age, perinatal mortality, and congenital malformation;

b. The risks associated with any drugs or fertility enhancing medications proposed, including but not limited to Ovarian Hyper Stimulation syndrome, ovarian tumors, hot flashes, bloating and abdominal discomfort, weight gain, headaches, mood swings, nausea, fatigue, blurred vision, depression, anxiety, joint pain, cancer, autoimmune disease, blood disorders, breast pain, dizziness, abnormal menstrual bleeding, and upper respiratory tract infection;

c. The risks associated with egg retrieval and embryo or oocyte transfer, including but not limited to Ovarian Hyper Stimulation syndrome, loss of fertility, ovarian torsion, stroke, kidney disease, fibroids, premature menopause, ovarian cysts, cancer, peritoneal bleeding, infection, vaginal wall lacerations and bleeding, bladder trauma, pelvic pain, and anesthetic complications; and

d. The risks associated with multiple gestations to the mother and children, including but not limited to preterm labor and delivery, gestational high blood pressure, gestational diabetes, anemia, birth defects, miscarriage, cord entanglement, cesarean delivery, postpartum hemorrhage, and abnormal amounts of amniotic fluid.

(5) Multiple gestation and fetal reduction:

a. The likelihood that fetal reduction might be recommended as a response to multiple gestations;

b. A clear explanation of the nature of fetal reduction and the associated risks for mother and any surviving child(ren); and

c. Decisions about embryo conception and transfer, including the patient's right to determine the number of embryos or oocytes to conceive and transfer.

(6) Donor gametes: If relevant, the testing protocol used to ensure that gamete donors are free from known infections including human immunodeficiency viruses and free from carriers of known genetic and chromosomal diseases.

(7) Non-transferred embryos:

a. The availability of embryo adoption for non-transferred embryos, the associated costs, and information on agencies in the State that process or facilitate embryo adoption;

b. 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;

c. The current law governing disputes concerning excess embryos; and

d. 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 [*her*] wishes and intentions regarding disposition.

(8) Changes that may affect the contract:

a. The effect on treatment, embryos, and the validity of informed consent of clinic closings, divorce, separation, failure to pay storage fees for excess embryos, failure to pay treatment fees, inability to agree on the fate of embryos, death of patient or others, withdrawal of consent for transfer after fertilization but before cryopreservation, incapacity, unavailability of agreed upon disposition of embryos, or loss of contact with the clinic; and

b. The patient's right to revoke consent at any time, and that charges will be limited to the services provided, with exceptions possibly made for some shared-risk programs, if relevant.

(b) This information must be discussed with the patient, and the ART program must provide written documentation that all relevant information required by this Section has been given to the patient.

(c) Patients shall be informed of the option of additional counseling throughout future procedures, even if counseling was refused in the past.

(d) 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.

(e) The [*Commissioner of Health or other appropriate office/individual*] is authorized to promulgate additional regulations providing more specific guidance for ensuring fully informed consent to ART.

Section 5. Data Collection and Reporting Requirements.

(a) All ART programs shall confidentially collect and maintain the following information, pertaining to the particular ART program, and confidentially report, on such forms as the Department prescribes, the following information to [*Insert name of state health department or other appropriate agency*], no later than [*Insert date*] following any year such procedures were performed:

(1) Success rates:

a. Rates of success, defined as the total number of live births achieved, the percentage of live births per completed cycle of egg retrieval, and the numbers of both clinical pregnancy and actual delivery as ratios against the number of retrieval cycles completed. These statistics must be broken down into the age group of patients: under thirty (30), thirty to thirty-four (30-34), thirty-five to thirty-seven (35-37), thirty-eight to forty (38-40), forty-one to forty-two (41-42), and forty-three (43) and older;

b. Rate of live births per transfer; and

c. Number of live births per ovarian stimulation, broken down into age groups: under thirty (30), thirty to thirty-four (30-34), thirty-five to thirty-seven (35-37), thirty-eight to forty (38-40), forty-one to forty-two (41-42), and forty-three (43) and older.

(2) Storage: Information regarding the storage and safekeeping of embryos including:

a. Storage location (if stored); or

b. Location to which relocated and purpose of relocation (if transferred to another facility); or

c. Time and date of disposal of each patient's embryos (if destroyed).

(3) Technologies: Percentage usage of types of ART, including IVF, GIFT, ZIFT, combination, or other.

(4) Multiples:

a. Percentage of pregnancies resulting in multi-fetal pregnancies, broken down by number of fetuses; and

b. Percentage of live births involving multiple infants.

c. Ratio of ART-conceived multiple births to all multiple births in a state.

(5) Fetal Reduction:

a. Number of fetal reductions performed on prior patients, number of fetal reductions individually reported, and identifying the number of embryos transferred to such patients before the reduction;

b. Percentage of transferred embryos that implant;

c. Percentage of premature births per single and multiple births; and

d. The use of pre-implantation genetic diagnosis (PGD) in the ART program, including data on its safety and efficacy.

(6) Prematurity and Other Abnormalities:

a. Percentage of birth defects per single and multiple births; and

b. Percentage of fetal reductions that resulted in a miscarriage.

(b) The program's medical director shall verify in writing the accuracy of the foregoing data.

(c) The [*Commissioner of Health or other appropriate office or individual*] is authorized to promulgate further regulations requiring additional or more specific data collection and reporting.

[*(d) The Commissioner shall make the data available in such form as the Commissioner prescribes.*]

Section 6. Limits on Creation and Transfer of Embryos in Single Reproductive Cycle.

(a) It shall be unlawful for any ART program, ART facility, or its employees to create more than [*two (2)*] embryos per reproductive cycle.

(b) It shall be unlawful for any ART program, ART facility, or its employees to transfer more than [*two (2)*] embryos per reproductive cycle.

(c) In subsequent assisted reproductive cycles, transfer shall first be attempted with cryopreserved embryos from previous cycles, if they exist. Only after transfer is attempted with cryopreserved embryos may new embryos be conceived through ART. [*Alternatively, subsection 6(b) could require presenting patients with the option of prioritizing the use of existing cryopreserved embryos in future cycles.*]

Section 7. Embryo Donation and Adoption.
No ART program may limit or inhibit the choice by patients of embryo donation or adoption through the employment of psychological evaluations, increased costs or payments, or other conditions.

Section 8. Civil Penalty. Any person or entity that violates any provision of this Act and derives a pecuniary gain from such violation shall be fined [*Insert appropriate amount*], twice the amount of gross gain, or, at the discretion of the court, any amount intermediate between the foregoing.

Section 9. Professional Sanctions.

(a) ***Unprofessional Conduct***. Any violation of this Act shall constitute unprofessional conduct pursuant to [*Insert appropriate state statutes, regulations, or administrative rules for medical doctors and surgeons and osteopathic doctors*] and shall result in sanctions increasing in severity from censure to temporary suspension of license to practice medicine to permanent revocation of license to practice medicine.

(b) ***Trade, Occupation, or Profession***. Any violation of this Act may be the basis for denying an application for, denying an application for the renewal of, or revoking any

license, permit, certificate, or any other form of permission required to practice or engage in a trade, occupation, or profession.

(c) ***Facility Licensing***. Any violation of this Act by an individual in the employ and under the control of a licensed healthcare facility and to which the management of said facility consents to, knows about, or should have known about may be the basis for denying an application for, denying an application for the renewal of, temporarily suspending, or permanently revoking any operational license, permit, certificate, or any other form of permission required to operate a healthcare facility.

Section 10. Severability.

Any provision of this Act held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to give it the maximum effect permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event such provision shall be deemed severable herefrom and shall not affect the remainder hereof or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances.

Section 11. Right of Intervention.

The [*Legislature*], by joint resolution, may appoint one or more of its members who sponsored or co-sponsored this Act, as a matter of right and in his or her official capacity, to intervene to defend this law in any case in which its constitutionality is challenged.

Section 12. Effective Date.

This Act takes effect on [*Insert date*].

For further information regarding this or other AUL policy guides, please contact:

AMERICANS UNITED FOR LIFE
1150 Connecticut Avenue NW, Suite 500
Washington, D.C. 200361
202.741.4917 | Legislation@aul.org

www.AUL.org