ASSISTED REPRODUCTIVE TECHNOLOGY DISCLOSURE AND RISK REDUCTION ACT

Model Legislation & Policy Guide
For the 2013 Legislative Year

Changing Law to Protect Human Life, State by State
INTRODUCTION

The first baby born as a result of in vitro fertilization (IVF) was Louise Brown, born in Great Britain in July 1978. IVF is the fertilization of a human egg by a human sperm outside a woman’s body, in a laboratory. Since that time, the fertility industry has grown tremendously in the United States. There are currently 300-400 fertility clinics nationwide. Because IVF is unregulated or under-regulated in most states, there are now hundreds of thousands cryopreserved human embryos in laboratories across the United States. Moreover, there continue to be abuses of IVF by doctors and patients alike, as the infamous case of the “Octo-Mom” aptly demonstrates.

Assisted reproductive technology (ART) is a broader term, which encompasses IVF and all newer forms of reproductive technology. ART has enabled many married couples—who suffer various forms of infertility from different causes—to experience the joy of parenthood with biologically-related children. However, by disconnecting biological parenthood from the parental or marital relationship in many cases, 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:

- Surrogate motherhood;
- Anonymous sperm and egg donation;
- Single motherhood with anonymously-donated sperm;
- New technologies like intracytoplasmic sperm injection (ICSI) and preimplantation genetic diagnosis (PGD);
- 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.

In that regard, AUL has drafted the “Assisted Reproductive Technology Disclosure and Risk Reduction Act.” 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 many choose specific components or sections. For more information and drafting assistance, please contact AUL’s Legislative Coordinator at (202) 741-4907 or Legislation@AUL.org.

DENISE M. BURKE, ESQ.
Vice President of Legal Affairs
Americans United for Life
ASSISTED REPRODUCTIVE TECHNOLOGY DISCLOSURE AND RISK REDUCTION ACT

HOUSE/SENATE BILL No. ______
By Representatives/Senators ____________

Section 1. 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 grave concern to many couples and individuals who want to be parents.

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

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

(4) Full information about the costs and risks of ART is necessary for patients to evaluate ART, including the risks associated with multiple gestations.

(5) 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.

(6) ART is subject to little state regulation.

(7) A number of other nations regulate specific aspects of ART, including the number of embryos that can be created. Brazil, Denmark, Germany, Hungary, Saudi
Arabia, Singapore, Sweden, and Switzerland limit the number of embryos (from two to four) that can be transferred per treatment cycle. Specifically, Germany, Sweden, Denmark, and Switzerland limit transfers to, at most, three (3) embryos per treatment cycle. The United Kingdom limits the number transferred to two (2) embryos per treatment cycle.

(8) Voluntary self-regulation of ART programs is not completely effective. Not all ART programs or facilities are members of professional organizations, like 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.

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

(10) This State has an interest in ensuring protection for mothers who undergo ART and for the future health of children conceived through ART.

(11) 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.

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

(13) One problem associated with ART is high-order multiple pregnancies (three or more embryos implanting) and the associated health risks to mother and children, for which the economic burdens for parents and society are significant.

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

(b) Based on the findings in Subsection (a) of this Section, the purposes of this Act are to:
(1) Protect the safety and well-being of women using 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 and the risk of 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 to the [Insert name of State health department or other appropriate agency].

Section 3. Definitions.

For purposes of this Act only:

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

(b) “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 schools and nursing schools, medical training facilities, or other institutions or locations wherein assisted reproductive technology is offered to any person.

(c) “ART program” or “program” means all treatments or procedures which include the handling of both human eggs and sperm.

(d) “Department” means the state [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, or from somatic cell nuclear transfer, or by other means, until approximately the end of the second (2\textsuperscript{nd}) month of development.

(f) “Gamete” means human egg (oocyte) or sperm.

(g) “Fetal reduction” means the induced termination of one 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, the rates for clinical pregnancy and delivery per completed retrieval cycle bracketed by age groups consisting of women under 30 years of age, women aged 30 through 34 years, women aged 35 through 39 years, and women aged 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, and 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, along with reported statistics from all other clinics in the State and national ART statistics as reported to the CDC, along with an explanation of the relevance of the statistics.

(3) Costs:

a. The anticipated price (to the patient) 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 psychological risks associated with all ART drugs and procedures considered;

b. The risks associated with any drugs or fertility-enhancing medications proposed;

c. The risks associated with egg retrieval and embryo or oocyte transfer; and

d. The risks associated with multiple gestation to mother and children.

(5) Multiple gestation and fetal reduction:
a. The likelihood that fetal reduction might be recommended as a response to multiple gestation;

b. A clear explanation of the nature of fetal reduction and the associated risks for mother and any surviving child; 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 infection, 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 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, and the rights of patients regarding that disposition, and the need to state their 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 only 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 February 1 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 30, 30-34, 35-37, 38-40, 41-42, and 43 and above;

   b. Rate of live births per transfer; and
c. Number of live births per ovarian stimulation, broken down into age groups: under 30, 30-34, 35-37, 38-40, 41-42, and 43 and above.

(2) Storage: Information regarding the 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 having multiple infants.

(5) Fetal reduction:

a. Number of fetal reductions performed, individually reported, identifying the number of embryos transferred before the reduction;

b. Percentage of transferred embryos that implant;

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

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

(6) Prematurity and other abnormalities:

a. Percentage of birth defects per single and per 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 additional regulations requiring additional or more specific data collection and reporting, as needed. [The Commissioner shall make the data available in such form as the Commissioner prescribes.]


(a) It shall be unlawful for any ART program, ART facility, or its employees to create more than [two] embryos per reproductive cycle.
(b) It shall be unlawful for any ART program, ART facility, or its employees to transfer more than \( \text{two} \) 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. \( \text{In the alternative, Section 6(b) could require presenting patients with the option of emphasizing 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 psychological evaluations, increased costs or payments, or other conditions.

Section 8. Penalties.

(a) Civil Penalty. Any person or entity that violates any provision of this Act and derives a pecuniary gain from such violation shall be fined \( \text{Insert amount} \) or twice the amount of gross gain, or any amount intermediate between the foregoing, at the discretion of the court \( \text{as is just} \).

(b) Unprofessional Conduct. Any violation of this Act shall constitute unprofessional conduct pursuant to \( \text{Insert appropriate state statutes/regulations for 1) medical doctors/surgeons and 2) osteopathic doctors} \) and shall result in sanctions increasing in severity from censure to temporary suspension of license to permanent revocation of license.

(c) 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.

(d) Facility Licensing. Any violation of this Act by an individual in the employ and under the auspices of a licensed healthcare facility to which the management of said facility consents, knows, or should know 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 9. 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 10. 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 11. Effective Date.

This Act takes effect on [Insert date].
At least 11 states regulate the provision of assisted reproductive technologies, to varying degrees: AZ, CA, CT, FL, LA, MD, NH, OK, PA, WI, and VA.
At least four states require some level of informed consent before a patient undergoes assisted reproductive technologies: CA, CT, MA, and VA.
At least eight states have laws or regulations related to the purchase, donation, transfer, solicitation, and/or harvesting of human eggs: AZ, CA, CT, FL, IN, MD, MA, and NY.
More detailed information about the need and justification for state regulation of assisted reproductive technologies can be found in AUL’s annual publication *Defending Life 2012: Building a Culture of Life, Deconstructing the Abortion Industry*.

*Defending Life 2012* is available online at AUL.org.

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

AMERICANS UNITED FOR LIFE  
655 15th Street NW, Suite 410  
Washington DC  20005  
202.289.1478 | Fax 202.289.1473 | Legislation@AUL.org  
www.AUL.org

©2012 Americans United for Life

This policy guide may be copied and distributed freely as long as the content remains unchanged and Americans United for Life is referenced as the creator and owner of this content.