MISSISSIPPI LEGISLATURE REGULAR SESSION 2006

By: Senator(s) White

To: Public Health and Welfare

SENATE BILL NO. 2715

AN ACT ENTITLED THE "ASSISTED REPRODUCTIVE TECHNOLOGY (ART) DISCLOSURE AND RISK REDUCTION ACT"; TO PROVIDE DEFINITIONS; TO REQUIRE THE DISCLOSURE OF CERTAIN INFORMATION PRIOR TO THE EXECUTION OF A SIGNED CONTRACT FOR ASSISTED REPRODUCTIVE TECHNOLOGY SERVICES; TO REQUIRE DATA COLLECTION AND REPORTING REQUIREMENTS BY ART PROGRAMS; TO PROVIDE LIMITS ON TRANSFER OF EMBRYOS IN ANY REPRODUCTIVE CYCLE; TO PROVIDE CIVIL PENALTIES; TO AMEND SECTION 73-25-29, MISSISSIPPI CODE OF 1972, TO PROVIDE THAT VIOLATIONS OF THIS ACT ARE CONSIDERED UNPROFESSIONAL CONDUCT FOR PHYSICIAN LICENSURE PURPOSES; AND FOR RELATED PURPOSES.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MISSISSIPPI:

SECTION 1. Title. This act may be known and cited as the "Assisted Reproductive Technology (ART) Disclosure and Risk Reduction Act."

SECTION 2. Legislative findings and purposes. (1) The Legislature of the state finds that:

(a) Infertility is of grave concern to many couples who want to be parents.

(b) Assisted reproductive technology (ART) is a growing, Four Billion Dollar ($4,000,000,000.00) annual industry that serves an increasing number of patients.

(c) ART procedures are expensive; each cycle can cost Ten Thousand Dollars ($10,000.00) to Fifteen Thousand Dollars ($15,000.00), or more.

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

(e) Only one (1) federal statute, the Fertility Clinic Success Rate and Certification Act of 1992 (42 USCA Section 263a-1 et seq.), directly regulates ART procedures by requiring the reporting of clinic success rates.

(f) ART is subject to little state regulation. For example, Connecticut and Virginia require the disclosure and reporting of ART success rates. New Hampshire and Pennsylvania require some regulation of ART clinics. Several states require insurance coverage for ART.

(g) A number of countries regulate certain aspects of ART. Brazil, Denmark, Germany, Hungary, Saudi Arabia, Singapore, Sweden and Switzerland limit the number of embryos (from two (2) to four (4)) that can be transferred per cycle. Germany, Sweden, Denmark and Switzerland limit transfers to three (3) embryos, at most, per cycle. The United Kingdom limits the number transferred to two (2).

(h) Voluntary, self-regulation of ART programs is not completely effective. Not all ART programs are members of professional organizations, like the Society for Assisted Reproductive Technology (SART) or the American Society for Reproductive Medicine (ASRM), and the professional organizations do not independently confirm that their members follows their voluntary guidelines.

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

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

(k) 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. ART is unique because it produces a third party, the prospective child.

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

(m) One problem associated with ART is high-order multiple pregnancies (three (3) or more embryos implanting) and their associated health risks to mother and children, for which the economic burdens for parents and society are significant.

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

(2) Based on the findings in subsection (1) of this section, it is the purpose of this act to:

(a) Protect the safety and well-being of women using ART and the children conceived through ART;

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

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

(d) 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;

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

(f) Institute annual reporting requirements to the State Department of Health.

SECTION 3. Definitions. For purposes of this act only:

(a) "Assisted reproductive technology (ART)" means all treatments and procedures which include the handling of human eggs and sperm, including in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer, and such other specific technologies as the Department of Health may include in this definition.

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

(c) "Department" means the State Department of Health.

(d) "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 month of development.

(e) "Gamete" means human egg (oocyte) and sperm.

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

SECTION 4. Informed consent. (1) 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:

(a) Description of the procedure(s);

OUTCOMES AND SUCCESS:

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

(c) 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 (30) years of age, women aged thirty (30) through thirty-four (34) years, women aged thirty-five (35) through thirty-nine (39) years, and women aged forty (40) years and older;

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

(e) The program's most recently outcome statistics, as reported to the Centers for Disease Control (CDC);

(f) 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;

(g) Statistics reported by the program to federal and state agencies are to be provided to the patient, 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;

COSTS:

(h) The anticipated price (to the patient) of all procedures, including any charges for procedures and medications not covered in the standard fee;

(i) Average cost to patients of a successful assisted pregnancy;

MAJOR KNOWN RISKS:

(j) All major known risks and side effects, to mothers and children conceived, including psychological risks, associated with all ART drugs and procedures considered;

(k) The risks associated with any drugs, or fertility enhancing medications, proposed;

(l) The risks associated with egg retrieval and embryo and/or oocyte transfer;

(m) The risks associated with multiple gestation to mother and child;

MULTIPLE GESTATION AND FETAL REDUCTION:

(n) The likelihood that fetal reduction might be recommended as a response to multiple gestation;

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

DECISIONS ABOUT EMBRYO CONCEPTION AND TRANSFER:

(p) The patient's right to determine the number of embryos and/or oocytes to conceive and transfer;

DONOR GAMETES:

(q) If relevant, the testing protocol used to ensure that gamete donors are free from known infection, including with human immunodeficiency viruses, and free from carriers of known genetic and chromosomal diseases;

NONTRANSFERRED EMBRYOS:

(r) The availability of embryo adoption of nontransferred embryos and information on agencies in the state that process embryo adoption;

(s) 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;

(t) The current law governing disputes concerning excess embryos;

(u) Information concerning disposition of nontransferred 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;

CHANGES THAT MAY AFFECT THE CONTRACT:

(v) 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 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;

(w) 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.

(2) 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.

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

(4) 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.

(5) The State Board of Health is authorized to promulgate additional regulations providing more specific guidance for ensuring fully informed consent to ARTs.

SECTION 5. Data collection and reporting requirements. (1) 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 the State Department of Health not later than February 1 following any year such procedures were performed:

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: <30, 30-34, 35-37, 38-40, 41-42, >43;

(b) Rate of live births per transfer;

(c) Number of live births per ovarian stimulation, broken down into age groups;

STORAGE:

(d) Information regarding the safekeeping of embryos including:

(i) Storage location (if stored);

(ii) Location to which relocated (if transferred to another facility);

(iii) Purpose for which relocated (if transferred to another facility);

(iv) Time and date of disposal of each patient's embryos, if destroyed;

TECHNOLOGIES:

(e) Percentage usage of types of ART, including IVF, GIFT, ZIFT, combination, or other;

MULTIPLES:

(f) Percentage of pregnancies resulting in multi-fetal pregnancies, broken down by number of fetuses;

(g) Percentage of live births having multiple infants;

FETAL REDUCTION:

(h) Number of fetal reductions performed, individually reported, identifying the number of embryos transferred before the reduction;

(i) Percentage of transferred embryos that implant;

(j) Percentage of premature births per singleton and multiple births;

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

PREMATURITY AND OTHER ABNORMALITIES:

(l) Percentage of birth defects per singleton and multiple births;

(m) Percentage of fetal reductions that resulted in a miscarriage.

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

(3) The State Board of Health is authorized to promulgate additional regulations requiring additional or more specific data collection and reporting, as needed. The State Board of Health shall make the data available in such form as the board prescribes.

SECTION 6. Limits on transfer of embryos in any reproductive cycle. (1) It shall be unlawful for any ART clinic or its employees to transfer more than two (2) embryos per reproductive cycle.

(2) 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.

SECTION 7. Embryo donation and adoption. No ART program may limit or inhibit the option or availability by patients of embryo donation or adoption through psychological evaluations, increased costs or payments, or other conditions.

SECTION 8. Penalties. (1) Civil penalty. The Attorney General on the relation of the State Board of Health or any private party may file an injunction or civil action to enforce the provisions o this act. Any person or entity that violates any provision of this act and derives a pecuniary gain from such violation shall be fined twice the amount of gross gain at the discretion of the court.

(2) Unprofessional conduct. Any violation of this act shall constitute unprofessional conduct pursuant to Section 73-25-29 for medical doctors/surgeons and osteopathic doctors and shall result in sanctions increasing in severity from censure to temporary suspension of license to permanent revocation of license.

(3) 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.

(4) Facility licensing. Any violation of this act by an individual in the employ and under the auspices of a licensed health care 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 health care facility.

SECTION 9. The provisions and applications of this act are declared to be severable, and if any provision, word, phrase or clause of this act or the application thereof to any person shall be held invalid, such invalidity shall not affect the validity of the remaining provisions or applications of this act.

SECTION 10. Section 73-25-29, Mississippi Code of 1972, is amended as follows:

73-25-29. The grounds for the nonissuance, suspension, revocation or restriction of a license or the denial of reinstatement or renewal of a license are:

(1) Habitual personal use of narcotic drugs, or any other drug having addiction-forming or addiction-sustaining liability.

(2) Habitual use of intoxicating liquors, or any beverage, to an extent which affects professional competency.

(3) Administering, dispensing or prescribing any narcotic drug, or any other drug having addiction-forming or addiction-sustaining liability otherwise than in the course of legitimate professional practice.

(4) Conviction of violation of any federal or state law regulating the possession, distribution or use of any narcotic drug or any drug considered a controlled substance under state or federal law, a certified copy of the conviction order or judgment

rendered by the trial court being prima facie evidence thereof, notwithstanding the pendency of any appeal.

(5) Procuring, or attempting to procure, or aiding in, an abortion that is not medically indicated.

(6) Conviction of a felony or misdemeanor involving moral turpitude, a certified copy of the conviction order or judgment rendered by the trial court being prima facie evidence thereof, notwithstanding the pendency of any appeal.

(7) Obtaining or attempting to obtain a license by fraud or deception.

(8) Unprofessional conduct, which includes, but is not limited to:

(a) Practicing medicine under a false or assumed name or impersonating another practitioner, living or dead.

(b) Knowingly performing any act which in any way assists an unlicensed person to practice medicine.

(c) Making or willfully causing to be made any flamboyant claims concerning the licensee's professional excellence.

(d) Being guilty of any dishonorable or unethical conduct likely to deceive, defraud or harm the public.

(e) Obtaining a fee as personal compensation or gain from a person on fraudulent representation a disease or injury condition generally considered incurable by competent medical authority in the light of current scientific knowledge and practice can be cured or offering, undertaking, attempting or agreeing to cure or treat the same by a secret method, which he refuses to divulge to the board upon request.

(f) Use of any false, fraudulent or forged statement or document, or the use of any fraudulent, deceitful, dishonest or immoral practice in connection with any of the licensing requirements, including the signing in his professional

capacity any certificate that is known to be false at the time he makes or signs such certificate.

(g) Failing to identify a physician's school of practice in all professional uses of his name by use of his earned degree or a description of his school of practice.

(h) Any violation of Senate Bill No. ____, 2006 Regular Session, relating to informed consent and standards for Assisted Reproductive Technologies (ART).

(9) The refusal of a licensing authority of another state or jurisdiction to issue or renew a license, permit or certificate to practice medicine in that jurisdiction or the revocation, suspension or other restriction imposed on a license, permit or certificate issued by such licensing authority which prevents or restricts practice in that jurisdiction, a certified copy of the disciplinary order or action taken by the other state or jurisdiction being prima facie evidence thereof, notwithstanding the pendency of any appeal.

(10) Surrender of a license or authorization to practice medicine in another state or jurisdiction or surrender of membership on any medical staff or in any medical or professional association or society while under disciplinary investigation by any of those authorities or bodies for acts or conduct similar to acts or conduct which would constitute grounds for action as defined in this section.

(11) Final sanctions imposed by the United States Department of Health and Human Services, Office of Inspector General or any successor federal agency or office, based upon a finding of incompetency, gross misconduct or failure to meet professionally recognized standards of health care; a certified copy of the notice of final sanction being prima facie evidence thereof. As used in this paragraph, the term "final sanction" means the written notice to a physician from the United States Department of Health and Human Services, Officer of Inspector

General or any successor federal agency or office, which implements the exclusion.

(12) Failure to furnish the board, its investigators or representatives information legally requested by the board.

(13) Violation of any provision(s) of the Medical Practice Act or the rules and regulations of the board or of any order, stipulation or agreement with the board.

In addition to the grounds specified above, the board shall be authorized to suspend the license of any licensee for being out of compliance with an order for support, as defined in Section 93-11-153. The procedure for suspension of a license for being out of compliance with an order for support, and the procedure for the reissuance or reinstatement of a license suspended for that purpose, and the payment of any fees for the reissuance or reinstatement of a license suspended for that purpose, shall be governed by Section 93-11-157 or 93-11-163, as the case may be. If there is any conflict between any provision of Section 93-11-157 or 93-11-163 and any provision of this chapter, the provisions of Section 93-11-157 or 93-11-163, as the case may be, shall control.

SECTION 11. This act shall take effect and be in force from and after July 1, 2006.