MISSISSIPPI LEGISLATURE REGULAR SESSION 2006

By: Representative Smith (39th)

To: Public Health and Human Services

HOUSE BILL NO. 1200

AN ACT TO CREATE THE "ASSISTED REPRODUCTIVE TECHNOLOGY (ART) DISCLOSURE AND RISK REDUCTION ACT"; TO PROMOTE INFORMED CONSENT FOR ASSISTED REPRODUCTIVE TECHNOLOGIES (ART) FOR CONFIDENTIALLY COLLECTING AND REPORTING CRITICAL HEALTH DATA; TO LIMIT THE NUMBER OF EMBRYOS TRANSFERRED IN ANY REPRODUCTIVE CYCLE; TO REDUCE THE RISKS AND COSTS TO MOTHERS AND CHILDREN OF HIGH-ORDER MULTIPLE PREGNANCIES AND PREMATURE BIRTHS; AND FOR RELATED PURPOSES.

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

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

SECTION 2. (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, annual industry of Four Hundred Billion Dollars ($400,000,000,00) 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 USCS 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 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) 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 (1) 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.

(3) Based on the findings in subsection (2) 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 prematurity 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; and

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

SECTION 3. As used in this act, the following words and phrases shall have the following meanings ascribed herein unless the context clearly indicates otherwise:

(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. (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);

(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 recent outcome statistics, as reported to the 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 Centers for Disease Control (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;

(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;

(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;

(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;

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

(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;

(r) The availability of embryo adoption for 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;

(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; and

(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 Health Officer is authorized to promulgate additional regulations providing more specific guidance for ensuring fully informed consent to ARTs.

SECTION 5. (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 Department of Health, not later than February 1 following any year such procedures were performed:

(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 following age group of patients: less than thirty (30), thirty (30) through thirty-four (34), thirty-five (35) through thirty-seven (37), thirty-eight (38) through forty (40), forty-one (41) through forty-two (42) and greater than forty-three (43);

(b) Rate of live births per transfer;

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

(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); and

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

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

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

(g) Percentage of live births having multiple infants;

(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 preimplantation genetic diagnosis (PGD), if used in the ART program, including data on its safety and efficacy;

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

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

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

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

SECTION 6. (1) It shall be unlawful for any ART clinic or its employees to transfer more than 2 (two) 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. 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. (1) Any person or entity that violates any provision of this act and derives a pecuniary gain from such violation shall be fined One Thousand Dollars ($1,000.00) or twice the amount of gross gain, or any amount intermediate between the foregoing, at the discretion of the court.

(2) Any violation of this act shall constitute unprofessional conduct and shall result in sanctions increasing in severity from censure to temporary suspension of license to permanent revocation of license.

(3) Any violation of this act may be the basis for the following: (a) denying an application for, (b) denying an application for the renewal of, or (c) revoking any license, permit, certificate, or any other form of permission required to practice or engage in a trade, occupation or profession.

(4) 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 the facility consents, knows, or should know may be the basis for the following: (a) denying an application for, (b) denying an application for the renewal of, (c) temporarily suspending, or (d) 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 the 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. This act shall take effect and be in force from and after its passage.