Session of 2010

SENATE BILL No. 509

By Senator Pilcher-Cook

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AN ACT concerning public health; relating to reporting by in vitro fertilization and research facilities and oversight of the donation or selling of gametes.

Be it enacted by the Legislature of the State of Kansas:

Section 1. Sections 1 through 12, and amendments thereto, of this act shall be known and may be cited as the women's health and embryo monitoring program act.

Sec. 2. As used in this act, unless the context otherwise requires:

(a) "Act" means the women's health and embryo monitoring program act.

(b) "ASRM/SART" means the American society for reproductive medicine and society for assistive reproductive technology.

(c) "CDC" means the center for disease control.

(d) "Department" means the department of health and environment.

(e) "Egg donor" means a woman who provides one or more eggs for the purpose of assisting in IVF or for scientific research. For the purposes of this act, an egg donor is one who donates for altruistic purposes or for monetary compensation.

(f) "Egg grading" means the method used to evaluate the quality of the human eggs.

(g) "Embryo grading" means the method used to evaluate the quality of the human embryos.

(h) "Fertility facility" means any facility which functions to provide services for individuals seeking fertility treatment or potential gamete donation or surrogacy.

(i) "Fetal reduction" means the purposeful termination of one or more embryos or fetuses.

(j) "Gamete" means a female egg cell or a male sperm cell.

(k) "Genetic screening" means any test or technique used to allow for genetic or medical diagnosis or sexual determination, or both, to be made.

(l) "GIFT" means gamete intrafallopian transfer which is a method of assisted reproductive technology where the eggs are removed from the woman's ovaries, combined with washed sperm and then both eggs and

sperm are transferred via catheter into the woman's fallopian tubes to facilitate fertilization occurring inside the body.

(m) "Human embryo" means an organism of the species Homo sapiens during the earliest stages of development, from one cell up to eight weeks.

(n) "ICSI" means intracytoplasmic sperm injection which is a method of assisted reproductive technology in which a single spermatozoon is injected into the cytoplasm of a single egg in order to facilitate fertilization. The fertilized egg is then implanted into the uterus.

(o) "In vitro fertilization" or "IVF" means all techniques where eggs are fertilized with sperm outside of the human body creating a human embryo in the laboratory.

(p) "Pre-implantation genetic diagnosis" or "PGD" means any test or technique performed on an embryo prior to implantation into the womb for the purpose of pre-natal diagnosis or sexual determination, or both.

(q) "Reporting agencies" means any agency, clinic, laboratory or business where IVF services are provided, infertile patients are treated, or those agencies who advertise for and solicit egg or sperm donors or surrogates, and any facility where human eggs, human sperm or human embryos are handled, processed, tested, collected or stored for research purposes or fertility treatments.

(r) "Reporting data" means the information reported pursuant to subsection (b) of section 3, and amendments thereto.

(s) "Research facility" means any facility which uses human eggs, human sperm or human embryos in their research activities.

(t) "Secretary" means the secretary of the department of health and environment.

(u) "Sex-selection" means the use of PGD or other genetic screening techniques for the purpose of intentional selection of an embryo or fetus based on sex.

(v) "Sperm donor" means a man who provides sperm for the purposes of assisting in IVF or for scientific research. For the purposes of this act, a sperm donor is one who donates for altruistic purposes or for monetary compensation.

(w) "Sperm grading" means the method used to evaluate the quality of human sperm.

(x) "Surrogate" means a woman who agrees to become pregnant and carry a child to term for someone else. Types of surrogacy include:

(1) "Altruistic surrogacy" which means a woman who without monetary compensation agrees to become pregnant and carry a child to term for someone else. She may or may not also provide her genetic material for the creation of the embryos.

(2) "Biological surrogacy" which means a woman who provides her

genetic material for the creation of the embryos and agrees to become pregnant and carry a child to term for someone else.

(3) "Commercial surrogacy" which means a woman who is monetarily compensated for agreeing to become pregnant and carry a child to term for someone else. She may or may not also provide her genetic material for the creation of the embryos.

(4) "Gestational surrogacy" which means a woman who does not provide her genetic material for the creation of the embryos and who agrees to become pregnant and carry a child to term for someone else.

(y) "ZIFT" means zygote intrafallopian transfer which is a method of assisted reproductive technology where fully formed embryos are transferred via a catheter into a woman's fallopian tubes in the hope that they will find their way into the uterine cavity and implant.

Sec. 3. (a) No later than July 1, 2011, the department shall establish and maintain a women's health and embryo monitoring program for the collection of data reported by reporting agencies in this state. The secretary of health and environment shall maintain records of program participation including the number of reporting agencies, reporting agency locations, research facilities and the reporting data obtained pursuant to subsection (b).

(b) Each reporting agency shall submit to the department by electronic means information required by the department regarding data to be collected under the women's health and embryo monitoring program. The secretary shall promulgate rules and regulations specifying the nationally recognized telecommunications format to be used for submission of information that each reporting agency shall submit to the department. Such information to be reported may include, but not be limited to:

(1) The number of female patients seen or treated or both.

(2) The number of male patients seen or treated or both.

(3) The marital status of patients seen and treated.

(4) The breakdown of patients seen for female, male, combination or unknown cause of infertility.

(5) The number of IVF cycles per year.

(6) The number of GIFT, ZIFT, IVF with ICSI, unstimulated and combination IVF cycles the reporting agency performed.

(7) The number of eggs retrieved per patient and information regarding how many eggs were fertilized, unused, disposed of or frozen for each patient, including the method of disposal of any eggs.

(8) (A) The number of embryos created and the methodology used for embryo grading or selection including whether an embryo was implanted, frozen, discarded or donated to research.

(B) If the embryo was donated to research was an informed consent obtained.

(9) (A) The method used to follow up a patient after treatment and what mechanism is in place for a patient to report health issues.

(B) The number of pregnancies per patient including information on:

(i) The number of embryos implanted per patient per cycle;

(ii) the number of embryos/fetus reductions per patient per cycle;

(iii) the methods of reduction used;

(iv) the rate of live births; and

(v) the percentage of multiple births to live birth rate.

(C) The number of failed IVF cycles per patient (miscarriage or no implantation).

(10) The services offered by a reporting agency or research facility including:

(A) Sperm donation;

(B) egg donation;

(C) the types and number of each type of surrogacy;

(D) donor embryos;

(E) PGD;

(F) sex selection;

(G) sperm sorting;

(H) fertility options for same-sex couples;

(I) fertility options for single parents; or

(J) fertility options for post-menopausal women.

(11) The number of eggs harvested per woman and:

(A) The number of eggs obtained per egg donor and per fertility patient per cycle;

(B) the number of women who had ovarian hyperstimulation syndrome;

(C) the number of women who required hospitalization and for how many days;

(D) the methodology used for egg grading;

(E) the disposition of each egg, including whether the egg was:

(i) Frozen;

(ii) fertilized;

(iii) discarded because of poor quality; or

(iv) donated to research;

(F) the method of disposal if the egg was discarded; and

(G) whether an informed consent was obtained before an egg was donated.

(12) The number of egg donors and:

(A) How the donors are screened prior to acceptance into the reporting agency's or research facility's donor program;

(B) what the reporting agency's or research facility's informed consent mechanism is;

(C) what the reporting agency's or research facility's standard protocol for hyperstimulation is;

(D) whether the reporting agency or research facility practices open or anonymous donation, or both; and

(E) how the donor is followed up after the donation, including:

(i) Whether the donor's medical records are maintained, and for how long; and

(ii) how the reporting agency or research facility tracks how many donation cycles a donor has attempted and completed.

(13) The number of sperm donors and:

(A) How are the donors screened prior to acceptance into the reporting agency's or research facility's donor program;

(B) what the informed consent mechanism is;

(C) what methodology of sperm grading is used;

(D) whether the reporting agency or research facility offers open or anonymous donation, or both; and

(E) how the sperm donor is followed up after the donation, including:

(i) Whether the sperm donor's medical records maintained, and for how long; and

(ii) how the reporting agency or research facility tracks how many donations are done by each donor.

(14) The rights of the future children, including:

(A) The mechanism in place to provide future children access to their medical, biological and genetic information; and

(B) the process for donors and future children to have the ability to be contacted or to make contact.

(15) The screening process of the reporting agency or research facility, including:

(A) The method of psychological screening used to evaluate prospective patients and donors; and

(B) the method of financial screening used to evaluate and ensure that future children's needs are met.

(16) The approximate breakdown of payment for services and documentation of funding sources of a reporting agency or research facility regarding:

(A) Private insurance;

(B) private moneys;

(C) federal funds;

(D) state funds.

(17) Whether the reporting agency or research facility contracted with a third party for egg, sperm donor or surrogacy services. If yes, which agencies does the reporting agency or research facility contract with.

(18) Whether the reporting agency or research facility is a member

of ASRM/SART and adheres to their guidelines.

(19) Whether the reporting agency or research facility is in compliance with CDC reporting.

(20) Whether the reporting agency's or research facility's providers have special certifications in surgery or reproductive medicine.

(21) Whether the reporting agency or research facility has any special certifications.

(22) Whether the reporting agency or research facility is accredited and if so by what organization.

(23) How and where the reporting agency or research facility advises and recruits donors and surrogates.

Sec. 4. The department shall not impose any charge for the establishment or maintenance of the women's health and embryo monitoring program database on a reporting agency or research facility. The department shall not charge any fees for the transmission of data to the database or for the receipt of information from the database, except that the department may charge a fee to an individual who requests the individual's own women's health and embryo monitoring information in accordance with procedures adopted by the department.

Sec. 5. (a) The women's health and embryo monitoring program database, all information contained therein and any records maintained by the department, or by any entity contracting with the department, submitted to, maintained or stored as a part of the database, shall be privileged and confidential; shall not be subject to subpoena or discovery in civil proceedings and may only be used for investigatory or evidentiary purposes related to violations of state or federal law and regulatory activities of entities charged with administrative oversight; shall not be a public record and shall not be subject to the Kansas open records act, K.S.A. 45-215 et seq., and amendments thereto, except as provided in subsections (c) and (d).

(b) The department shall maintain procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, transmitted and maintained is not disclosed to persons except as provided in subsections (c) and (d).

(c) The department is hereby authorized to provide data in the women's health and embryo monitoring program to the following persons:

(1) An individual who requests the individual's own women's health and embryo monitoring information in accordance with procedures established by the department;

(2) local, state and federal law enforcement or prosecutorial officials engaged in the administration, investigation or enforcement of the laws;

(3) persons authorized by a grand jury subpoena, inquisition sub-

poena or court order in a criminal action; and

(4) personnel of the department for purposes of administration and enforcement of this act, and amendments thereto.

(d) The department is hereby authorized to provide data in the women's health and embryo monitoring program to public or private entities for statistical, research or educational purposes after removing information that could be used to identify individual patients or persons who donated or sold their gametes to the patient.

Sec. 6. The department is hereby authorized to contract with another agency of this state or with a private vendor, as necessary, to ensure the effective operation of the women's health and embryo monitoring program. Any contractor shall be bound to comply with the provisions regarding confidentiality of women's health and embryo information in section 5, and amendments thereto, and shall be subject to the penalties specified in section 11, and amendments thereto, for unlawful acts.

Sec. 7. All information collected for the women's health and embryo monitoring program database and any records maintained by the department, or by any entity contracting with the department, submitted to, maintained or stored as a part of the database, shall be retained in perpetuity.

Sec. 8. No person shall be liable to any person in a civil action for damages or other relief for injury, death or loss to person or property on the basis that such person did not seek or obtain information from the women's health and embryo monitoring program. Nothing in this act shall be construed to create a duty to obtain information about a patient from the women's health and embryo monitoring program.

Sec. 9. Annually, the department shall review the effectiveness of the women's health and embryo monitoring program and submit a report to the senate standing committee on public health and welfare and the house standing committee on health and human services.

Sec. 10. The secretary is hereby authorized to promulgate rules and regulations necessary to carry out the provisions of this act.

Sec. 11. (a) A reporting agency that knowingly fails to submit women's health and embryo monitoring information to the department as required by this act or knowingly submits incorrect women's health and embryo monitoring information shall be guilty of a severity level 10, nonperson felony.

(b) A person authorized to have women's health and embryo monitoring information pursuant to this act who knowingly discloses such information in violation of this act shall be guilty of a severity level 10, nonperson felony.

(c) A person authorized to have women's health and embryo monitoring information pursuant to this act who knowingly uses such infor-

mation in a manner or for a purpose in violation of this act shall be guilty of a severity level 10, nonperson felony.

(d) It shall not be a violation of this act for a practitioner to disclose or use information obtained pursuant to this act when such information is disclosed or used solely in the course of such practitioner's care of the patient who is the subject of the information.

Sec. 12. This act shall take effect and be in force from and after its publication in the statute book.