THE CENTER FOR BIOETHICS AND CULTURE NETWORK

EGG Act

AS INTRODUCED

An Act relating to human oocytes; prohibiting certain acts; creating civil liability; providing penalties; and providing an effective date.

SECTION 1. SHORT TITLE: This Act may be cited as the "Egg Guidelines and Governance Act" ("EGG Act").

SECTION 2. PROHIBITING COMPENSATION: In the interest of protecting the ovarian health of women, especially university students and low-income women who are disproportionately vulnerable to being monetarily induced to compromise their reproductive and ovarian health, it shall be unlawful for any person, scientific entity, or business organization to intentionally or knowingly:

A. Provide valuable consideration, or to solicit to provide valuable consideration, to procure human oocytes from a woman.
B. Refer individuals to out-of-state oocyte harvesters or in-state referral services and to receive valuable consideration for such services.

SECTION 3. ESTABLISHING DOCUMENTATION: In the interest of protecting the physical, mental and emotional health of children, it shall be unlawful for any person, scientific entity, or business organization to intentionally or knowingly:

A. Procure human oocytes from a woman without obtaining appropriate personal information about the donor and maintaining adequate documentation to provide future progeny of the donor with such information upon request.
B. Refer individuals to out-of-state oocyte harvesters or in-state referral services for such services without adequate documentation.

SECTION 4. ESTABLISHMENT OF EGG GOVERNANCE AND GUIDANCE PROGRAM

A. No later than ninety (90) days after enactment, the Secretary ("Secretary") of the Department of Health and Human Services ("Department") shall establish an Egg Guidelines and Governance ("Program") for the collection and reporting of data submitted by oocyte collection agencies and research facilities. The Secretary shall also maintain records of participation in the Program, including the name, address, and reporting data (described in Section 7 of the Act) of each oocyte collection agency or research facility.

B. Each oocyte collection agency or research facility shall submit to the Department by electronic means the information described in Section 7 of the Act, below.

SECTION 5. RULEMAKING: The Secretary shall promulgate rules and regulations specifying the format to be used for the transmission of information that each oocyte collection agency or research facility shall submit to the Department.

SECTION 6. INFORMED CONSENT:

A. Oocytes obtained from women shall be donated with voluntary and informed consent, including a signed statement giving a child/children born from their oocytes access to certain information, including detailed written information of the donor's health and genetic history.
B. Such informed consent shall be documented in writing and shall include medically accurate information regarding any and all risks of oocyte removal and donation, such as infertility, hospitalization or death resulting from complications of oocyte stimulation and extraction.

SECTION 7. ADEQUATE DOCUMENTATION: "Adequate documentation" means the recording and maintaining of information by oocyte collection agencies or research facilities including but not limited to the following:

A. Whether the oocyte collection agency or research facility offers the following services:
   (1) Oocyte donation;
   (2) Sperm donation;
   (3) Surrogacy (include gestational vs. biological and altruistic vs. commercial);
   (4) Embryo donation;
   (5) Pre-implantation genetic diagnosis;
   (6) Sex selection;
   (7) Oocyte sorting and/or grading;
   (8) Fertility treatment for non-infertile persons;
B. The disposition of each oocyte sample, including whether the oocytes were:
   (1) Frozen;
   (2) Used for fertilization;
   (3) Discarded because of poor quality; or
   (4) Donated to research;
C. The method of disposal if the oocytes were discarded.
D. Whether informed consent was obtained before the oocytes were donated; and
E. Documentation of donors' informed consent for the disposition of oocytes or a copy of the informed consent agreement.
F. The total number of oocyte donors annually and the sum total per oocyte collection agency or research facility.

G. The procedures by which donors are screened prior to acceptance into the oocyte collection agency or research facility's donor program, including any method of psychological screening.
H. The contact information for each donor, including name, electronic mail address, physical address, and phone number.
I. The medical information provided by each donor to the oocyte collection agency or research facility.
J. The rights of any future children created from a donor's oocytes, including:
   (1) The mechanism in place to provide future children access to their medical, biological and genetic information; and
   (2) The process whereby donors and future children may contact one another.
K. A calculation of payment for services per donor per year in total and documentation of funding sources, including but not limited to private insurance, as well as private, federal, and/or state funds.
   (1) Whether the oocyte collection agency or research facility is a member of the American Society for Reproductive Medicine/Society for Assisted Reproductive Technology (ASRM/SART) and, if so, whether the entity adheres to ASRM/SART guidelines.
   (2) Whether the oocyte collection agency or research facility is in compliance with CDC reporting requirements.
   (3) Whether the oocyte collection agency or research facility is accredited and, if so, by what organization; and
   (4) The process by which the oocyte collection agency or research facility advertises its services and recruits donors and surrogates.

SECTION 8. CIVIL PENALTIES:

A. A civil action may be filed by any person entitled to receive information under the Act or by the [state] Attorney General in state court for any violation of this Act.
B. Any violation of this section shall constitute unprofessional conduct for a professional licensed in this state, who shall be remanded to the appropriate licensure board for review.
C. No female shall be subject to any penalty for being induced to accept or accepting valuable consideration for egg donation without adequate documentation.

SECTION 9. CONFLICTS OF INTEREST: Medical clinics and research facilities must also disclose in writing any potential conflict of interest, including fiduciary duties, financial benefits, and referral agreements.

SECTION 10. DEFINITIONS: For purposes of this Act:

A. DONATION: The term "donation" means the giving or selling of eggs to an oocyte collection agency or research facility.

B. DONOR: The term "donor" means a female who donates or sells eggs to an oocyte collection agency or research facility.
C. EGG SORTING/GRADING: a process of rating oocytes based on chance of implantation, using criteria such as cell number, cell regularity, degree of fragmentation, presence of multinucleation, and appearance.
D. OOCYTE: The term "oocyte" means a female gamete or sex cell.
E. OOCYTE COLLECTION AGENCY: The term "oocyte collection agency" means a clinic or other facility, including an egg bank, that retrieves and stores human eggs mainly from egg donors, primarily for the purpose of achieving pregnancies through third-party reproduction, which pregnancies are typically achieved through artificial insemination.
F. REPORTING DATA: The term "reporting data" means any of the information or data, as explained in Section 3 of the Act.
G. RESEARCH FACILITY: The term "research facility" means a clinic or laboratory that collects and stores human eggs mainly from egg donors, primarily for the purpose of research.
H. SURROGACY:
   (1) gestational: a surrogacy arrangement requiring the implantation of a previously created embryo.
   (2) biological: a surrogacy arrangement using the surrogate's own oocyte.
   (3) altruistic: a surrogacy agreement in which the surrogate receives compensation equal to or less than the reimbursement of medical and other reasonable expenses.
   (4) commercial: a surrogacy agreement in which the surrogate receives compensation beyond the reimbursement of medical and other reasonable expenses.
I. VALUABLE CONSIDERATION: The term "Valuable consideration" means financial gain or advantage, including cash, in-kind payments, reimbursement of any cost incurred in connection with the processing, disposal, preservation, quality control, storage, transfer, or donation of human eggs, including lost wages of the donor, endorsements, patient referrals, research donations, grant monies, as well as any other consideration, with the exception of reasonable medical expenses of the donor that are directly related to oocyte retrieval.

SECTION 11. EFFECTIVE DATE: This Act shall become effective (DATE).