REFERENCE TITLE: gamete donors; informed consent

State of Arizona Senate Fiftieth Legislature Second Regular Session 2012

SB 1360

Introduced by Senators Barto, Antenori, Yarbrough: Allen, Driggs, Gould, Melvin, Murphy, Shooter; Representative Yee

AN ACT

CHANGING THE DESIGNATION OF TITLE 36, CHAPTER 14, ARIZONA REVISED STATUTES, TO "HUMAN GAMETES"; AMENDING SECTIONS 36-1701 AND 36-1702, ARIZONA REVISED STATUTES; AMENDING TITLE 36, CHAPTER 14, ARTICLE 1, ARIZONA REVISED STATUTES, BY ADDING SECTIONS 36-1704 AND 36-1705; RELATING TO GAMETES.

(TEXT OF BILL BEGINS ON NEXT PAGE)

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Be it enacted by the Legislature of the State of Arizona:
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Section 1. <u>Heading change</u>

The chapter heading of title 36, chapter 14, Arizona Revised Statutes, is changed from "HUMAN EGGS" to "HUMAN GAMETES".

Sec. 2. Section 36-1701, Arizona Revised Statutes, is amended to read: 36-1701. <u>Definitions</u>

In this article, unless the context otherwise requires:

- 1. "Clinical investigation" means activity conducted for the purpose of developing, refining or training in the process of in vitro fertilization for the treatment of human infertility, including experiments, investigations, clinical trials,— and the development of new technology. Clinical investigation does not include human somatic cell nuclear transfer.
 - "Egg" means an oocyte or egg cell of a human female.
- 3. "Egg donor" means a woman who provides or agrees to provide her eggs for purposes other than her own impregnation with those eggs.
 - 4. "GAMETE" MEANS A HUMAN EGG OR HUMAN SPERMATOZOA.
- 5. "GAMETE DONOR" MEANS AN EGG DONOR OR A PERSON WHO IS UNRELATED BY MARRIAGE TO THE RECIPIENT AND WHO PROVIDES OR AGREES TO PROVIDE GAMETES FOR THE PURPOSES OF TREATING HUMAN INFERTILITY.
- 4. 6. "Human somatic cell nuclear transfer" has the same meaning prescribed in section 35-196.04.
- $\frac{5.}{7.}$ "Physician" means a person who is licensed pursuant to title 32, chapter 13 or 17.
- 6. 8. "Purchase" includes providing any cash, in-kind payment or other valuable financial or nonfinancial consideration.
 - Sec. 3. Section 36-1702, Arizona Revised Statutes, is amended to read: 36-1702. <u>Informed consent for egg donation: requirements: unprofessional conduct: violation</u>

A. For the purposes of the duty of care owed by a physician, an egg donor is a patient of the physician who retrieves the eggs from the egg donor.

- B. A physician shall not retrieve eggs except in a hospital, clinic or other medical facility that meets the licensing standards for the facility prescribed by this title.
- C. A PERSON OR ENTITY THAT POSTS AN ADVERTISEMENT SEEKING EGG DONATION FOR ANY PURPOSE THAT INCLUDES ASSISTED EGG PRODUCTION AND A FINANCIAL PAYMENT OR COMPENSATION OF ANY KIND MUST INCLUDE THE FOLLOWING INFORMATION IN A CLEAR AND CONSPICUOUS MANNER:
- 1. EGG DONATION INVOLVES A SCREENING PROCESS, WHICH MEANS THAT NOT ALL POTENTIAL EGG DONORS WILL BE SELECTED AND NOT ALL SELECTED EGG DONORS WILL RECEIVE THE MONETARY AMOUNTS OR COMPENSATION ADVERTISED.
- 2. EGG DONATION REQUIRES SELF-INJECTION OF HORMONES THAT, IN SOME CASES, ARE NOT APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION FOR OVARIAN STIMULATION AND MAY CAUSE SIDE EFFECTS, INCLUDING PELVIC PAIN, WEIGHT

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GAIN, DIARRHEA, NAUSEA AND VAGINAL BLEEDING, WITH RARE CASES RESULTING IN HOSPITALIZATION, INFERTILITY OR DEATH.

- 3. COMPREHENSIVE RESEARCH HAS NOT BEEN DONE TO DETERMINE THE HEALTH RISKS ASSOCIATED WITH ASSISTED EGG PRODUCTION AND SURGICAL RETRIEVAL FROM EGG DONORS.
- 4. POTENTIAL EGG DONORS ARE ADVISED TO CONSULT WITH THEIR OWN DOCTOR AND LEGAL COUNSEL BEFORE ENTERING INTO A DONOR CONTRACT.
- D. A PHYSICIAN OR ANY PERSON WHO ACTS AS A BROKER OR AGENCY SEEKING EGG DONATION FOR ANY PURPOSE SHALL NOT KNOWINGLY MAKE FALSE OR MISLEADING REPRESENTATIONS ABOUT THE RISKS OF EGG DONATION TO A PROSPECTIVE OR CURRENT EGG DONOR.
- 6. E. Before performing any medical procedure or prescribing any hormones or other drugs for an egg donor, a physician must comply with all requirements prescribed by the federal UNITED STATES food and drug administration and provide the egg donor with the following information:
- 1. A description of all hormones and other drugs to be taken by the egg donor, including the dosage, frequency of administration, intended biochemical function and likely physiological response to each medication.
- 2. A description of all procedures to be performed on the egg donor, including the purpose, duration and estimated recovery time for each procedure.
- 3. Medically accurate disclosures concerning all potential risks of egg donation that a reasonable patient would consider material to the decision of whether to undergo the procedure, including the medical risks associated with the surgical procedure and the drugs, medications and hormones prescribed for ovarian stimulation during the process.
- 4. A description of the effects that the surgical procedure and the drugs, medications and hormones may have on future attempts of the egg donor to become pregnant.
- 5. Notice that the egg donor cannot be completely informed of all potential risks or effects because all potential risks or effects and the magnitude of those risks or effects may not be known.
- 6. NOTICE THAT THE EGG DONOR IS ADVISED TO CONSULT WITH HER OWN PHYSICIAN AND HER OWN LEGAL COUNSEL BEFORE ENTERING INTO ANY CONTRACT TO PROVIDE EGGS.
- D. F. The physician or the physician's agent or designee must provide the information required by subsection C E of this section before the physician or the physician's agent or designee performs any screening or testing of a potential egg donor. The physician must obtain written and oral informed consent for the procedure from the egg donor, INCLUDING THE EGG DONOR'S INITIALS BY EACH OF THE ITEMS PRESCRIBED IN SUBSECTION E, PARAGRAPHS 1 THROUGH 6 OF THIS SECTION, before performing any medical procedure that is not part of the screening process or prescribing any hormones or other drugs for the egg donor.

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\stackrel{\hbox{\it E.}}{} G. This section does not require a physician to provide additional information or obtain additional informed consent if the physician's current practices relating to informed consent already meet the standards prescribed by subsections \stackrel{\hbox{\it C.}}{} E and \stackrel{\hbox{\it D.}}{} F of this section.
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- H. AN EGG DONOR MAY CONDITION DONATION ON REASONABLE USE OR DISPOSITION RESTRICTIONS AS PRESCRIBED IN A WRITTEN RECORD BEFORE A DONATION.
- F. I. A physician who knowingly violates this section commits an act of unprofessional conduct and is subject to license suspension or revocation pursuant to title 32, chapter 13 or 17.
- J. A PERSON WHO KNOWINGLY VIOLATES SUBSECTION C OR D OF THIS SECTION COMMITS A VIOLATION OF SECTION 44-1522 AND IS SUBJECT TO ALL PENALTIES AND ENFORCEMENT PRESCRIBED PURSUANT TO TITLE 44, CHAPTER 10, ARTICLE 7.
- Sec. 4. Title 36, chapter 14, article 1, Arizona Revised Statutes, is amended by adding sections 36-1704 and 36-1705, to read:

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36-1704. <u>Egg donations; reporting requirements; unprofessional conduct; civil penalties; violations; classification</u>
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- A. A PHYSICIAN WHO PERFORMS OR ATTEMPTS TO PERFORM ANY PART OF AN EGG DONATION PROCEDURE TO PROCURE HUMAN EGGS FOR ANY PURPOSE MUST COMPLETE AN ACCURATE REPORT FOR EACH WOMAN UNDERGOING ANY PART OF AN EGG DONATION PROCEDURE. THE PHYSICIAN MUST RETAIN THE REPORT IN THE WOMAN'S MEDICAL RECORD FOR AT LEAST SEVEN YEARS.
- B. AN INDIVIDUAL EGG DONOR REPORT FOR EACH WOMAN WHO UNDERGOES ANY PORTION OF AN EGG DONATION PROCEDURE MUST BE COMPLETED AND SIGNED BY THE ATTENDING PHYSICIAN AND SUBMITTED TO THE DEPARTMENT OF HEALTH SERVICES WITHIN THIRTY DAYS AFTER THE SURGICAL EGG RETRIEVAL OR ATTEMPTED EGG RETRIEVAL ON A FORM PRESCRIBED BY THE DEPARTMENT. IF THE WOMAN CHOOSES TO FORGO THE SURGICAL EGG RETRIEVAL, HER REPORT MUST INDICATE THIS CHOICE. THE REPORT MUST REMAIN CONFIDENTIAL AND NOT IDENTIFY THE WOMAN BY NAME BUT MUST INCLUDE THE FOLLOWING INFORMATION:
- 1. THE NAME AND ADDRESS OF THE FACILITY WHERE THE SURGICAL EGG RETRIEVAL WAS PERFORMED, OR IF THE SURGERY DOES NOT TAKE PLACE, THE FACILITY MONITORING THE HORMONE INJECTIONS.
 - 2. THE DATE THAT THE WOMEN WAS INSTRUCTED ON HORMONE INJECTIONS.
 - 3. THE DRUG NAMES, DOSES AND INSTRUCTIONS FOR INJECTION.
 - 4. THE DATES OF SURGICAL EGG RETRIEVAL.
 - 5. THE NUMBER OF EGGS RETRIEVED.
 - 6. THE COUNTY IN WHICH THE EGG RETRIEVAL WAS PERFORMED.
 - 7. THE WOMAN'S AGE.
- 39 8. THE WOMAN'S EDUCATIONAL BACKGROUND BY HIGHEST GRADE COMPLETED AND, 40 IF APPLICABLE, LEVEL OF COLLEGE COMPLETED.
 - 9. THE COUNTY AND STATE IN WHICH THE WOMAN RESIDES.
 - 10. THE WOMAN'S RACE AND ETHNICITY.
- 43 11. THE WOMAN'S MARITAL STATUS.
- 12. THE NUMBER OF PRIOR PREGNANCIES OF THE WOMAN.
- 45 13. THE WOMAN'S EMPLOYMENT STATUS.

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- 14. THE AMOUNT OF COMPENSATION AND REIMBURSEMENT FOR EXPENSES PAID TO THE WOMAN.
 - 15. THE METHOD OF DONOR SOLICITATION.
- C. A HEALTH PROFESSIONAL WHO PROVIDES MEDICAL CARE OR TREATMENT TO A WOMAN WHO, IN THE GOOD FAITH JUDGMENT OF THE HEALTH PROFESSIONAL, IS IN NEED OF MEDICAL CARE BECAUSE OF A COMPLICATION OR COMPLICATIONS RESULTING FROM ANY PORTION OF THE EGG DONATION PROCEDURE MUST FILE A REPORT WITH THE DEPARTMENT ON A FORM PRESCRIBED BY THE DEPARTMENT. THE REPORT SHALL NOT IDENTIFY THE INDIVIDUAL PATIENT BY NAME BUT MUST CONTAIN THE FOLLOWING INFORMATION AND OTHER INFORMATION AS THE DEPARTMENT MAY REQUIRE:
 - 1. THE DATE OF THE EGG DONATION PROCEDURE.
 - 2. THE WOMAN'S AGE.
- 3. THE NAME AND ADDRESS OF THE FACILITY WHERE THE EGG DONATION PROCEDURE WAS PERFORMED.
 - 4. THE NATURE AND SEVERITY OF THE COMPLICATION OR COMPLICATIONS.
 - 5. THE MEDICAL TREATMENT GIVEN.
- 6. THE NATURE AND EXTENT, IF KNOWN, OF ANY PERMANENT CONDITION CAUSED BY THE COMPLICATION.
- 7. THE NAME AND ADDRESS OF THE FACILITY WHERE THE POST EGG DONATION CARE WAS PERFORMED.
- D. A REPORT FILED PURSUANT TO THIS SECTION MUST BE FILED ELECTRONICALLY AT AN INTERNET WEBSITE THAT IS DESIGNATED BY THE DEPARTMENT UNLESS THE PERSON REQUIRED TO FILE THE REPORT APPLIES FOR A WAIVER FROM ELECTRONIC REPORTING BY SUBMITTING A WRITTEN REQUEST TO THE DEPARTMENT.
- E. A REPORT REQUIRED BY THIS ARTICLE SHALL NOT CONTAIN THE NAME OF THE EGG DONOR, COMMON IDENTIFIERS, SUCH AS THE WOMAN'S SOCIAL SECURITY NUMBER, DRIVER LICENSE NUMBER OR INSURANCE CARRIER IDENTIFICATION NUMBERS, OR ANY OTHER INFORMATION OR IDENTIFIERS THAT WOULD MAKE IT POSSIBLE TO IDENTIFY IN ANY MANNER OR UNDER ANY CIRCUMSTANCES THE WOMAN WHO HAS UNDERGONE AN EGG DONATION PROCEDURE.
- F. THE DEPARTMENT SHALL COLLECT ALL EGG DONOR REPORTS AND COMPLICATION REPORTS AND PREPARE A COMPREHENSIVE ANNUAL STATISTICAL REPORT BASED ON THE DATA GATHERED IN THE REPORTS. THE STATISTICAL REPORT SHALL NOT LEAD TO THE DISCLOSURE OF THE IDENTITY OF ANY PERSON ABOUT WHOM A REPORT IS FILED. THE DEPARTMENT SHALL MAKE THE STATISTICAL REPORT AVAILABLE ON ITS WEBSITE AND FOR PUBLIC INSPECTION AND COPYING.
- G. ORIGINAL COPIES OF ALL REPORTS FILED PURSUANT TO THIS SECTION ARE AVAILABLE TO THE ARIZONA MEDICAL BOARD AND THE ARIZONA BOARD OF OSTEOPATHIC EXAMINERS IN MEDICINE AND SURGERY FOR USE IN THE PERFORMANCE OF THEIR OFFICIAL DUTIES. THE ARIZONA MEDICAL BOARD AND THE ARIZONA BOARD OF OSTEOPATHIC EXAMINERS IN MEDICINE AND SURGERY MUST MAINTAIN THE CONFIDENTIALITY OF ANY EGG DONOR IDENTIFIED IN REPORTS OBTAINED PURSUANT TO THIS SUBSECTION.
- H. A PERSON WHO IS REQUIRED BY THIS ARTICLE TO FILE A REPORT, KEEP ANY RECORDS OR SUPPLY ANY INFORMATION AND WHO WILFULLY FAILS TO FILE THAT REPORT,

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KEEP RECORDS OR SUPPLY INFORMATION AS REQUIRED BY LAW IS GUILTY OF UNPROFESSIONAL CONDUCT AND IS SUBJECT TO DISCIPLINE, INCLUDING LICENSE SUSPENSION OR REVOCATION.

- I. A PERSON WHO WILFULLY DELIVERS OR DISCLOSES TO THE DEPARTMENT ANY REPORT, RECORD OR INFORMATION KNOWN BY THAT PERSON TO BE FALSE COMMITS A CLASS 1 MISDEMEANOR.
- J. IN ADDITION TO THE PENALTIES PRESCRIBED BY SUBSECTIONS H AND I OF THIS SECTION, AN ORGANIZATION OR FACILITY THAT WILFULLY VIOLATES THE REPORTING REQUIREMENTS OF THIS ARTICLE IS SUBJECT TO DISCIPLINE BY THE DEPARTMENT, INCLUDING CIVIL PENALTIES AS PRESCRIBED IN SECTION 36-431.01.

36-1705. <u>Gamete donors; informed consent; unprofessional</u>

12 <u>conduct</u> 13 A. BEFORE ACCEPTING

- A. BEFORE ACCEPTING GAMETES FROM A GAMETE DONOR OR BEFORE PERFORMING ANY MEDICAL PROCEDURE OR PRESCRIBING ANY HORMONES OR OTHER DRUGS FOR AN EGG DONOR, A PHYSICIAN OR THE PHYSICIAN'S AGENT OR DESIGNEE MUST PROVIDE THE GAMETE DONOR WITH A DESCRIPTION OF THE POTENTIAL USES AND OUTCOMES OF THE DONATED GAMETES, INCLUDING THE FOLLOWING INFORMATION:
- 1. EMBRYOS MAY NOT BE FORMED AND THE GAMETES MAY BE DISCARDED AS MEDICAL WASTE OR USED IN RESEARCH.
- 2. EMBRYOS FORMED FROM THE DONOR'S GAMETES MAY BE IMMEDIATELY DISCARDED OR USED IN RESEARCH.
 - 3. PREGNANCY MAY NOT OCCUR OR MAY END IN A MISCARRIAGE.
- 4. THE RECIPIENT AND HER DOCTOR WILL DECIDE HOW MANY EMBRYOS TO TRANSFER AND THE RECIPIENT MAY BECOME PREGNANT WITH MORE THAN ONE BABY.
- 5. IF THE RECIPIENT BECOMES PREGNANT WITH MULTIPLE BABIES, THE RECIPIENT MAY CHOOSE TO UNDERGO SELECTIVE REDUCTION IN WHICH ONE OR MORE BABIES ARE ABORTED TO LOWER THE NUMBER THAT CONTINUE TO DEVELOP.
- 6. MORE EMBRYOS MAY DEVELOP IN THE LABORATORY THAN CAN SAFELY BE TRANSFERRED TO THE RECIPIENT AND THE REMAINING EMBRYOS MAY BE FROZEN AND KEPT IN STORAGE FOR LATER USE.
 - 7. FROZEN EMBRYOS MAY NEVER BE TRANSFERRED TO THE ORIGINAL RECIPIENT.
- 8. THE RECIPIENT MAY DONATE UNTRANSFERRED EMBRYOS TO ANOTHER COUPLE, DONATE THE EMBRYOS TO RESEARCH, LEAVE THE EMBRYOS FROZEN INDEFINITELY OR ALLOW THE EMBRYOS TO BE DESTROYED.
- 9. THE GAMETE DONOR CANNOT BE CERTAIN WHEN A GENETIC CHILD FORMED FROM THE DONOR'S GAMETES MAY BE BORN.
 - 10. THE GAMETES MAY GO TO MORE THAN ONE RECIPIENT.
 - 11. THE DONOR'S GENETIC CHILD MAY SEEK TO CONTACT THE DONOR.
- 12. THE DECISION TO DONATE ANONYMOUSLY WILL AFFECT THE GENETIC CHILD AND MAY HAVE NEGATIVE EFFECTS ON THE CHILD, INCLUDING TENSION, CONFUSION AND DISTRESS ABOUT THE CHILD'S ORIGINS AND ANCESTRY.
- B. THE PHYSICIAN OR THE PHYSICIAN'S AGENT OR DESIGNEE MUST PROVIDE THE INFORMATION REQUIRED BY SUBSECTION A OF THIS SECTION AND OBTAIN WRITTEN AND ORAL INFORMED CONSENT FROM THE GAMETE DONOR. INCLUDING THE GAMETE DONOR'S

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INITIALS BY EACH OF THE ITEMS LISTED IN SUBSECTION A OF THIS SECTION, BEFORE PERFORMING ANY SCREENING OR TESTING OF A POTENTIAL GAMETE DONOR.

- C. THIS SECTION DOES NOT REQUIRE A PHYSICIAN TO PROVIDE ADDITIONAL INFORMATION OR OBTAIN ADDITIONAL INFORMED CONSENT IF THE PHYSICIAN'S CURRENT PRACTICES RELATING TO INFORMED CONSENT ALREADY MEET THE STANDARDS PRESCRIBED BY SUBSECTIONS A AND B OF THIS SECTION.
- D. A PHYSICIAN WHO KNOWINGLY VIOLATES THIS SECTION COMMITS AN ACT OF UNPROFESSIONAL CONDUCT AND IS SUBJECT TO LICENSE SUSPENSION OR REVOCATION PURSUANT TO TITLE 32, CHAPTER 13 OR 17.

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