AMENDED IN SENATE JULY 6, 2009

AMENDED IN ASSEMBLY MAY 6, 2009

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL No. 1317

Introduced by Assembly Member Block

February 27, 2009

An act to add Chapter 1.5 (commencing with Section ~~125325.10)~~ *125325)* to Part 5.5 of Division 106 of the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 1317, as amended, Block. Assisted oocyte production: advertisement: information.

Existing law requires that an oocyte retrieval summary be provided to the donor of oocytes for research purposes. Existing law requires that a health care professional in the course of fertility treatment provide prescribed information to an embryo donor relating to donation of remaining embryos for research purposes.

This bill would, *with certain exceptions,* establish similar requirements for donors of oocytes for fertility treatment, and would require an advertisement seeking oocyte donation associated with the delivery of fertility treatment that includes assisted oocyte production *and a financial payment, or compensation of any kind,* to contain a prescribed notice relating to the potential health risks associated with human egg donation.

The bill would declare that it shall not be construed to amend Proposition 71, approved by the voters at the November 2, 2004, general election.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Chapter 1.5 (commencing with Section ~~125325.10)~~ *125325)* is added to Part 5.5 of Division 106 of the Health and Safety Code, to read:

CHAPTER 1.5. OOCYTE RETRIEVAL FOR FERTILITY TREATMENT

~~125325.10. (a) Except as set forth in subdivision (b), an~~ *125325. (a) An* advertisement seeking oocyte donation associated with the delivery of fertility treatment that includes assisted oocyte production *and a financial payment or compensation of any kind,* shall include the following notice *in a clear and conspicuous manner*:

~~"There are potential risks associated with human egg donation. Long-term risks associated with human egg donation have not been determined. Consultation with your physician and surgeon or other health care provider prior to entering into a donor contract is advised."~~

~~(b) Persons or entities that have signed and filed agreements~~ *"Egg donation involves a screening process. Not all potential egg donors are selected. Not all selected egg donors receive the monetary amounts or compensation advertised. As with any medical procedure, there may be risks associated with human egg donation. Before an egg donor agrees to begin the egg donation process, and signs a legally binding contract, she is required to receive specific information on the known risks of egg donation. Consultation with your doctor prior to entering into a donor contract is advised."*

(b) A summary, as described in Section 125335, pertaining to oocyte donation procedures, shall be provided to all potential egg donors before signing a legally binding contract to become an egg

donor, or beginning any egg donation procedures, as part of compliance with the informed consent requirements.

(c) Persons or entities that certify compliance with the American Society for Reproductive Medicine (ASRM) ~~to comply with ASRM guidelines~~ *guidelines by registering with ASRM* are exempt from the notice requirements set forth in subdivision (a). *Use of the exemption when the guidelines are violated shall constitute false advertising.*

(d) Donors recruited through the advertisement shall undergo the same disclosure, counseling, and informed consent process as donors recruited by those exempt from subdivision (a).

125325.15. The following definitions shall apply to this chapter:

(a) "Assisted oocyte production" or "AOP" means surgical extraction of oocytes following pharmaceutically induced manipulation of oocyte production through the use of ovarian stimulation for the purposes of fertility treatment.

(b) "Oocyte" means a female egg or egg cell of a human female.

~~(c) "Subject" means any person undergoing AOP or any alternative method of ovarian retrieval for fertility treatment.~~

~~(d) "Alternate method of oocyte retrieval" means a method of oocyte retrieval that does not involve the pharmaceutically induced manipulation of oocyte production.~~

~~(e) "Institutional review board" means a body established in accordance with federal regulations, including Part 46 (commencing with Section 46.101) of Subchapter A of Subtitle A of Title 45 of the Code of Federal Regulations.~~

~~125325.20. (a) Prior to obtaining informed consent from a subject for AOP or any alternative method of ovarian retrieval on a subject for the purpose of procuring oocytes for fertility treatment, a physician and surgeon shall provide to the subject a standardized medically accurate written summary of health and consumer issues associated with AOP and any alternative methods of oocyte retrieval. The failure to provide to a subject this standardized medically accurate written summary constitutes unprofessional conduct within the meaning of Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code.~~

~~(b) The summary shall include, but not be limited to, medically accurate disclosures concerning the potential risks of AOP or any alternative method of oocyte retrieval, including the risks~~

~~associated with the surgical procedure and with using the drugs, medications, and hormones prescribed for ovarian stimulation during the AOP process or any alternative method of oocyte retrieval. The summary shall also include a warning, in bold 14-point type, that the long term effects of taking the drugs associated with the egg retrieval process are unknown as of January 1, 2010.~~

~~(c) For purposes of subdivision (a), "written summary of health and consumer issues" means the guide published and updated by the American Society for Reproductive Medicine entitled, "Assisted Reproductive Technology: A Guide for Patients" or an alternative written medically accurate document prepared by a recognized authority on oocyte retrieval for fertility treatment that also meets the criteria included in this section. This alternative document may be one that has been approved and recommended by the State Department of Public Health and shall include all of the following:~~

~~(1) The document shall adhere to simplified reading standards, including, but not limited to, those generally accepted and required for government publications. The document shall be written in layperson's language and shall be made available in languages spoken by subjects in the study if their proficiency is largely in a language other than English. All information in the document shall be conveyed to the subject orally in easy to understand and nontechnical terms.~~

~~(2) The document shall include additional resources for, or list additional sources of, medical information on health and safety issues surrounding oocyte retrieval.~~

~~125325.25. (a) Prior to dispensing or administering any drug for AOP or any alternative method of ovarian retrieval to a subject for the purposes of providing fertility treatment, a physician and surgeon shall obtain written and oral informed consent for the procedure from the subject. Informed consent for the purposes of this chapter shall comply with the informed consent requirements of the Protection of Human Subjects in Medical Experimentation Act (Chapter 1.3 (commencing with Section 24170) of Division 20).~~

~~(b) The failure to obtain written informed consent from the subject prior to dispensing or administering any drug for AOP or any alternative method of ovarian retrieval to a subject for the~~

~~purposes of fertility treatment constitutes unprofessional conduct within the meaning of Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code. Nothing in this section shall be construed to relieve the physician and surgeon from other existing duties under the law, including, but not limited to, the duty to obtain a subject's informed consent after fully explaining the proposed procedure. The requirement that a physician and surgeon provide the standardized written summary pursuant to this article is in addition to, and does not supplant, other existing legal requirements regarding informed consent, including, but not limited to, compliance with the Protection of Human Subjects in Medical Experimentation Act (Chapter 1.3 (commencing with Section 24170) of Division 20, if applicable.~~

~~(c) This chapter shall not affect the suitability or availability of oocytes procured for fertility treatment before January 1, 2010, if the oocytes were donated pursuant to protocols or standards that are generally recognized and accepted by national or international scientific bodies.~~

~~(d) Any written document required pursuant to this article shall adhere to simplified reading standards, including, but not limited to, those generally accepted and required for government publications, and in layperson's language. The document shall be made available in languages spoken by subjects in the study if their proficiency is largely in a language other than English. All information in the written informed consent document shall also be conveyed to the subject orally in easy to understand and nontechnical terms.~~

SEC. 2. This act shall not be construed to amend Proposition 71, approved by the voters at the November 2, 2004, general election.

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