AMENDED IN SENATE AUGUST 19, 2016

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 2531

Introduced by Assembly Member Burke

February 19, 2016

An act to *amend Section 125341 of, and to* add Section 125356 to, and to repeal and add Section 125355 of, the Health and Safety Code, relating to reproductive health.

LEGISLATIVE COUNSEL'S DIGEST

AB 2531, as amended, Burke. Reproductive health and research.

Existing law prohibits human oocytes or embryos from being acquired, sold, offered for sale, received, or otherwise transferred for valuable consideration for medical research or development of medical therapies, and prohibits payment in excess of the amount of reimbursement of direct expenses to be made to any research subject to encourage ~~her~~ *women* to produce human oocytes for the purposes of medical research. *Before obtaining informed consent from a subject for assisted oocyte production (AOP) or any alternative method of ovarian retrieval on a subject for the purpose of procuring oocytes for research or the development of medical therapies, existing law requires a physician and surgeon to provide to the subject a standardized medically accurate written summary of health and consumer issues associated with AOP, as specified.*

This bill would instead require women providing human oocytes for research to be compensated for their time, discomfort, and inconvenience in the same manner as other research subjects, as prescribed and determined by a human subject research panel or institutional review board. *The bill would make a research program or project that offers*

to compensate women for their time, discomfort, and inconvenience for providing human oocytes for research subject to specified provisions of existing law relating to institutional review board requirements and written records. The bill would require the institutional review board to disregard the amount of compensation if a woman providing human oocytes for fertility is compensated, human oocytes or embryos in excess of those needed for fertility are offered for research, and certain conditions are met. *The bill would additionally require an institutional review board that reviews and approves medical and scientific research to require of any research program or project that comes under its review that involves AOP or any alternative method of oocyte retrieval to inform the subject that ongoing studies will continue to assess the long-term health impacts of ovarian stimulation and oocyte retrieval.*

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. The Legislature finds and declares all of the following:

(a) The purpose of this act is to create protections for research subjects and it should not be construed to affect any other form of medical care.

(b) Scientific research can be most effectively achieved by establishing protocols to protect, respect, and promote human health, safety, dignity, autonomy, and rights in conducting research.

(c) This act seeks to support the requirements in law upholding the principle of voluntary and informed consent and to tailor them to this new area of pioneering research that utilizes human oocytes.

(d) For all research subjects, there is a concern for exploitation when subjects are asked to subject themselves to drugs, devices, or procedures they might not otherwise need to do for their own health but for the benefit of all. This can range from persons with terminal illnesses who might be so desperate for help they would subject themselves to a high-risk procedure with limited benefit, to otherwise healthy people who might be motivated primarily by a financial award. To address this concern of exploitation, and to recognize the need for people to participate in research, mechanisms were created to balance the need to reward research participants without creating undue inducement.

(e) In California, the mechanisms dedicated to judging this balance include human subject research panels, institutional review boards, and stem cell research organizations.

(f) Concerns that women will be exploited if compensated for providing human oocytes for research have not borne out in the states where compensation is allowed.

(g) The ban on compensation for women providing human oocytes for research was created due to concerns regarding the high volume of oocytes needed for embryonic stem cell research, but extends to all research. Without compensation, few women participate in research, creating barriers to reproductive research that could benefit all women. As an example, more research could be done on embryo quality so that women undergoing in vitro fertilization (IVF) can confidently choose to have a single embryo implanted with a high probability of achieving a successful pregnancy, instead of multiple embryos. Lowering the rate of multiple pregnancies in IVF is a high priority goal that benefits women, parents, the resulting children, and society. The best source of available embryos for research comes from embryos created for fertility using a compensated donor, as she is more likely to produce a higher volume of oocytes and excess viable embryos than the infertile woman. Due to the ban on compensation, oocytes and embryos not needed for fertility will be unsuitable for research and will likely be discarded.

(h) All patients, including those participating in ~~research~~ *research,* are due a reasonable duty of care. In addition, all women undergoing ovarian stimulation and oocyte retrieval have another layer of regulation as all cycles are reported to the federal Centers for Disease Control and Prevention.

(i) Sufficient protections are in place to treat women providing human oocytes for research, similar to any other research subject, knowing women are competent and able to make decisions for themselves.

(j) This act repeals the ban on compensation for women providing human oocytes for research. Compensation amounts will be determined by human subject research panels and institutional review boards.

SEC. 2. Section 125341 of the Health and Safety Code is amended to read:

125341. An institutional review board (IRB) that reviews and approves medical and scientific research shall require all of the following of any research program or project that comes under its review that involves AOP or any alternative method of oocyte retrieval:

(a) That it include a written summary as required under Section 125335 that would include information on health risks and potential adverse consequences of the procedure and describe the manner in which the subject will receive and review this written summary.

(b) That it inform the subject that ongoing studies will continue to assess the long-term health impacts of ovarian stimulation and oocyte retrieval.

~~(b)~~

(c) That it obtain informed consent in compliance with the Protection of Human Subjects in Medical Experimentation Act (Chapter 1.3 (commencing with Section 24170) of Division 20), including informed consent for information obtained pursuant to Section 125342.

~~(c)~~

(d) That it provide the subject with an objective and accurate statement about the existing state of the research for which the subject is providing oocytes.

~~(d)~~

(e) That it perform psychological and physical screening, in accordance with the appropriate standard of care, for all subjects prior to the oocyte retrieval procedure.

~~(e)~~

(f) That it ensure that after conducting AOP or any alternative method of oocyte retrieval on a subject, the subject be given a postprocedure medical examination at a time within the standard of care to determine if the subject has experienced an adverse health effect that is a result of the procedure. The subject shall be informed that she has the right to a second opinion if she has any medical concerns.

~~(f)~~

(g) That it ensure that the subject has access to and coverage for medically appropriate medical care that is required as a direct result of the procedure for research purposes. The research program or project shall ensure that payment or coverage of resulting medical expenses be provided at no cost to the subject and that a

summary of the arrangements the procuring entity has made for coverage or payment for medical care related to AOP or any alternative method of oocyte retrieval is provided to the subject prior to the procedure.

~~(g)~~

(h) That it provide a summary informing the subject that oocytes may not be sold or transferred for valuable consideration except as set forth in Section 125350.

~~(h)~~

(i) That it provide disclosure if the physician and surgeon and his or her immediate family members have any professional interest in the outcome of the research or of the oocyte retrieval procedure and, if so, that it provide disclosure that he or she carries the interest of both the subject and the success of the research.

~~SEC. 2.~~

SEC. 3. Section 125355 of the Health and Safety Code is repealed.

~~SEC. 3.~~

SEC. 4. Section 125355 is added to the Health and Safety Code, to read:

125355. *(a)* Notwithstanding Section 125350, a woman providing human oocytes for research shall be compensated for her time, discomfort, and inconvenience in the same manner as other research subjects. Payment pursuant to this section shall not be for the human oocytes themselves or predicated on the number of oocytes obtained, including if no human oocytes are obtained. Whether a proposed compensation amount is appropriate shall be determined by a human subject research panel or institutional review board. In the event that a human subject research panel or institutional review board determines that a proposed compensation amount is inappropriate, the panel or board shall determine an appropriate compensation amount.

(b) A woman providing human oocytes for research shall be provided with a summary of health and consumer issues associated with AOP as required under Section 125335 and informed consent requirements, as described in Section 125340.

(c) Any research program that offers compensation to women providing human oocytes for research pursuant to subdivision (a) is subject to Sections 125341 and 125342, including, but not limited to, coverage for medically appropriate medical care that is

required as a direct result of the procedure for research purposes, regardless of the level of compensation offered.

~~SEC. 4.~~

SEC. 5. Section 125356 is added to the Health and Safety Code, to read:

125356. If a woman providing human oocytes for the purposes of fertility is compensated, and any human oocytes or embryos in excess of those needed for fertility are offered for research, the institutional review board shall disregard the amount of compensation if all of the following conditions are met:

(a) The clinic performing oocyte retrieval is a member of the Society for Assisted Reproductive Technology.

(b) The procurement and disposition for research purposes of human oocytes initially provided for reproductive uses, either for use by the donor or another woman, shall not knowingly compromise the optimal reproductive success of the woman in the infertility treatment.

(c) The infertility treatment protocol is established prior to requesting or obtaining consent for donation for research purposes and the prospect of donation for research does not alter the timing, method, or procedures selected for clinical care.

(d) The woman in infertility treatment makes the determination that she does not want or need the oocytes for her own reproductive success.

(e) The donation of oocytes for research is done without valuable consideration as defined in Section 125350.

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