AMENDED IN SENATE MAY 27, 2005

AMENDED IN SENATE MAY 12, 2005

AMENDED IN SENATE APRIL 26, 2005

AMENDED IN SENATE FEBRUARY 22, 2005

SENATE BILL No. 18

Introduced by Senators Ortiz and Runner
(Coauthors: Senators Bowen and Chesbro)
(Coauthors: Assembly Members Bermudez, Chan, Cohn, Jones, Karnette, Koretz, Laird, and Lieber)

December 6, 2004

An act to add Chapter 2 (commencing with Section 125330) to Part 5.5 of Division 106 of, and to add and repeal Article 4 (commencing with Section 125292.15) of Chapter 3 of Part 5 of Division 106 of, the Health and Safety Code, relating to reproductive health.

LEGISLATIVE COUNSEL'S DIGEST

SB 18, as amended, Ortiz. Reproductive health and research.

The California Stem Cell Research and Cures Act, an initiative measure, establishes the California Institute for Regenerative Medicine, the purpose of which is, among other things, to make grants and loans for stem cell research, for research facilities, and for other vital research opportunities to realize therapies, protocols, and medical procedures that will result in, the cure for, or substantial mitigation of, diseases and injuries. Existing law establishes the Independent Citizen's Oversight Committee (ICOC), composed of appointed members, that is required to perform various functions and duties with regard to the operation of the institute.

Existing law requires that a patient provide informed consent prior to the receiving various medical treatments.

This bill, *with certain exceptions,* would require a physician and surgeon, prior to providing assisted oocyte production, as defined, for purposes of donating eggs for medical research or for developing medical therapies, obtain written consent from his or her patient and provide to his or her patient a standardized written summary of health and consumer issues.

Existing law prohibits a person from knowingly, for valuable consideration, purchase or sell embryonic or cadaveric fetal tissue for research purposes.

This bill would prohibit human oocytes or embryos from being acquired, sold, received, or otherwise transferred for valuable consideration for medical research or development of medical therapies, and would prohibit payment in excess of the amount of reimbursement of expenses to be made to any research subject to encourage her to produce human oocytes for the purposes of medical research.

Existing law requires the State Auditor to conduct financial and performance audits as directed by statute. Existing law authorizes the State Auditor to conduct these audits of any state agency, local governmental agency, school, special district, or any publicly created entity.

This bill would require the State Auditor to conduct a performance audit of the institute and the ICOC and to provide the audit report to the Legislature on or before June 30, 2006. It would also require the State Auditor, on or before October 2007, to provide to certain legislative committees an analysis of the auditee's implementation of the recommendations contained in the audit report.

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

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

SECTION 1. Article 4 (commencing with Section 125292.15) is added to Chapter 3 of Part 5 of Division 106 of the Health and Safety Code, to read:

Article 4. State Auditor Review

125292.15. (a) The State Auditor shall conduct a performance audit of the California Institute for Regenerative Medicine established pursuant to Article XXXV of the California Constitution and the Independent Citizens Oversight Committee (ICOC) created pursuant to Section 125290.15. The audit shall be conducted pursuant to Chapter 6.5 (commencing with Section 8543) of Division 1 of Title 2 of the Government Code, and shall include a review of policies and procedures established by the ICOC to determine whether the ICOC has established a suitable structure for administering the California Institute for Regenerative Medicine, whether those policies and procedures comply with relevant laws and regulations and best practices, and, to the extent possible, whether the institute is complying with those policies and procedures. The audit shall include, but not be necessarily limited to, the following:

(1) The strategic policies and plans developed by the institute and the ICOC.

(2) Policies and procedures for issuance of contracts and grants and a review of a sample of contracts and grants executed by the institute and the ICOC.

(3) Policies and procedures relating to protection or treatment of intellectual property rights associated with research funded or commissioned by the institute.

(b) The State Auditor shall issue and provide the audit report to the Legislature on or before June 30, 2006.

(c) The State Auditor shall provide to the Chairs of the Senate Health and Human Services Committee, the Assembly Health Committee, and the Joint Legislative Audit Committee an analysis of the auditee's implementation of the recommendations contained in the audit report on or before October 2007. It is the intent of the Legislature, if the results of the analysis warrant further inquiry, that the Joint Legislative Audit Committee direct the State Auditor to conduct additional audit work, as described in this section, and to issue an additional audit report by June 2008. If circumstances continue to warrant additional work, it is the intent of the Legislature that the Joint Legislative Audit Committee direct the State Auditor to issue a third audit report by December 2009.

(d) This article shall remain in effect only until January 1, 2010, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2010, deletes or extends that date.

SEC. 2. Chapter 2 (commencing with Section 125330) is added to Part 5.5 of Division 106 of the Health and Safety Code, to read:

CHAPTER 2. ASSISTED REPRODUCTIVE TECHNOLOGY SERVICES

125330. The following definitions shall apply to this chapter:

(a) "Assisted oocyte production" or "AOP" means pharmaceutically induced manipulation of oocyte production through the use of ovarian stimulation.

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

125335. (a) Prior to providing AOP to a patient for the purpose of donating oocytes for medical research or development of medical therapies, a physician and surgeon shall provide to his or her patient a standardized written summary of health and consumer issues associated with assisted oocyte production. The failure to provide to a patient this standardized 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 be printed and made available by the department to physicians and surgeons. The summary shall include, but not be limited to, disclosures concerning the potential risks of AOP and oocyte donation, including the risk of decreased fertility and the risks associated with using the drugs, medications, and hormones prescribed for ovarian stimulation during the AOP or oocyte donation process.

(c) For purposes of this subdivision, a standardized written summary of health and consumer issues associated with assisted oocyte production shall mean the patient guide published and updated by the American Society for Reproductive Medicine entitled, "Assisted Reproductive Technology: A Guide for Patients."

(d) This section shall not affect the suitability or availability of oocytes procured for research before January 1, 2006, or procured for research outside of the state of California, if the

oocytes were donated pursuant to protocols or standards that are generally recognized and accepted by national or international scientific bodies.

125340. *(a)* Prior to providing AOP to a patient for the purposes of medical research or development of medical therapies, a physician and surgeon shall obtain written consent from his or her patient. The failure to obtain written consent from the patient 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 patient's informed consent after fully explaining the proposed treatment or procedure. The requirement that a physician and surgeon provide the standardized written summary pursuant to Section 125335 is in addition to, and does not supplant, other existing legal requirements regarding informed consent.

(b) This section shall not affect the suitability or availability of oocytes procured for research before January 1, 2006, or procured for research outside of the state of California, if the oocytes were donated pursuant to protocols or standards that are generally recognized and accepted by national or international scientific bodies.

125350. No human oocyte or embryo shall be acquired, sold, received, or otherwise transferred for valuable consideration for the purposes of medical research or development of medical therapies. For purposes of this section, "valuable consideration" does not include reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of oocytes or embryos.

125355. No payment in excess of the amount of reimbursement of expenses shall be made to any research subject to encourage her to produce human oocytes for the purposes of medical research.

125356. The Independent Citizen's Oversight Committee established pursuant to Section 125290.15 is encouraged to review existing studies concerning the health risks and benefits of ovarian stimulation drugs used for assisted oocyte production, identify gaps in existing knowledge concerning health risks and

benefits, and *to* undertake further research as *the ICOC deems* necessary to characterize the risks and benefits of those drugs.

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