AMENDED IN ASSEMBLY MAY 1, 2019

AMENDED IN ASSEMBLY APRIL 22, 2019

AMENDED IN ASSEMBLY MARCH 21, 2019

CALIFORNIA LEGISLATURE—2019–20 REGULAR SESSION

ASSEMBLY BILL No. 617

Introduced by Assembly Member Mullin

February 14, 2019

An act to add ~~Chapter 3 (commencing with Section 125360) to Part 5.5 of Division 106 of the Health and Safety Code,~~ *and repeal Article 24.5 (commencing with Section 2524) of Chapter 5 of Division 2 of the Business and Professions Code,* relating to ~~public health.~~ *healing arts.*

LEGISLATIVE COUNSEL'S DIGEST

AB 617, as amended, Mullin. Stem Cell ~~Clinic~~ *and Regenerative Therapy* Regulation Advisory Group.

Existing law, including, among other laws, the Medical Practice Act, the Osteopathic Act, and the Nursing Practice Act, provides for the licensure and regulation of various health care practitioners by various boards within the Department of Consumer Affairs, including the Medical Board of California, the Osteopathic Medical Board of California, and the Board of Registered Nursing. Existing law requires licensed health care practitioners who perform stem cell therapies that are subject to regulation by the United States Food and Drug Administration (FDA), but are not FDA approved, to communicate to their patients specified information regarding the therapies in a notice and in writing prior to providing the initial stem cell therapy.

Existing law requires the State Department of Public Health to establish and maintain an anonymous registry of embryos that are

available for research. Existing law makes it the policy of the state that research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells shall be reviewed by a stem cell research oversight committee.

The California Stem Cell Research and Cures Act, an initiative measure approved by the voters at the November 2, 2004, statewide general election as Proposition 71, establishes the California Institute for Regenerative Medicine (CIRM), 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 prohibits amendment of Proposition 71 by the Legislature unless the amendment is approved by the voters, or the amendment is accomplished by a bill introduced after the first 2 full calendar years and approved by a vote of 70% of both houses, and only if the amendment enhances the ability of the institute to further the purposes of the grant and loan programs.

Existing federal law creates an electronic registration and listing system for establishments that manufacture human cells, tissues, and cellular and tissue-based products (HCT/Ps) and ~~to establish~~ *establishes* current good tissue practice and other procedures to prevent the introduction, transmission, and spread of communicable diseases by HCT/Ps. Existing federal law requires the ~~federal Food and Drug Administration~~ *FDA* to register, list, and regulate HCT/Ps for these purposes.

This bill would require the ~~department,~~ *Medical Board of California*, no later than February 1, 2020, to ~~convene~~ *establish* the Stem Cell ~~Clinic~~ *and Regenerative Therapy* Regulation Advisory Group ~~for purposes of, among other duties, holding~~ *comprised of specified members, including 3 members appointed by the CIRM, as specified. By imposing a duty on the CIRM to appoint members to the Stem Cell and Regenerative Therapy Regulation Advisory Group, the bill would require for passage a 70% vote. The bill, on or after July 1, 2020, would authorize the board to make the appointments that CIRM fails to make. The bill would require the advisory group to convene* a series of stakeholder meetings to review *the Medical Practice Act, the Osteopathic Act, and the State Department of Public Health's* current licensing and certification laws and ~~the department's~~ procedures to determine whether those laws and procedures provide for adequate

consumer protection for the use of stem cell therapies in ~~clinics, and~~ *clinics and other practice settings,* to make recommendations to the Legislature, on or before July 1, 2020, regarding how to improve state oversight of ~~clinics~~ *licensees* offering or providing stem cell therapies to ~~patients.~~ *patients, and to make recommendations to the board for the adoption of emergency regulations, as specified. The bill would authorize the board to adopt those recommended emergency regulations, as specified. The bill would repeal these provisions on January 1, 2024.*

Vote: ~~majority~~ *70%.* Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

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

SECTION 1. Article 24.5 (commencing with Section 2524) is added to Chapter 5 of Division 2 of the Business and Professions Code, to read:

Article 24.5. Stem Cell and Regenerative Therapy Regulation Advisory Group

2524. For purposes of this article, the following definitions apply:

(a) "Board" means the Medical Board of California.

(b) "Clinic" has the meaning set forth in Section 1200 of the Health and Safety Code.

(c) "Department" means the State Department of Public Health.

(d) "FDA" means the United States Food and Drug Administration.

(e) "HCT/Ps" means human cells, tissues, or cellular or tissue-based products, as defined in Section 1271.3 of Title 21 of the Code of Federal Regulations, as amended August 31, 2016, as published in the Federal Register (81 Fed. Reg. 60223).

(f) "Licensee" means a licensee of the Board of Registered Nursing, the Medical Board of California, or the Osteopathic Medical Board of California.

(g) "Stem cell therapy" means a therapy involving the use of HCT/Ps.

2524.1. (a) No later than February 1, 2020, the board shall establish the Stem Cell and Regenerative Therapy Regulation

Advisory Group comprised of the following members who shall serve in an advisory capacity:

(1) Three members appointed by the board that are members of the board, including two physician and surgeon members and one public member.

(2) Three members appointed by the California Institute for Regenerative Medicine no later than January 15, 2020. On or after July 1, 2020, the board may make those appointments that the California Institute for Regenerative Medicine fails to make pursuant to this paragraph.

(3) Two members of the Osteopathic Medical Board of California appointed by the Osteopathic Medical Board of California.

(4) One member of the Board of Registered Nursing appointed by the Board of Registered Nursing.

(b) The Stem Cell and Regenerative Therapy Regulation Advisory Group shall convene a series of stakeholder meetings for the following purposes:

(1) Review the Medical Practice Act, the Osteopathic Act, and the department's current licensing and certification laws and procedures to determine whether those laws and procedures provide for adequate consumer protection for the use of stem cell therapies in clinics and other practice settings.

(2) Make recommendations to the Legislature, on or before July 1, 2020, regarding how to improve state oversight of licensees offering or providing stem cell therapies to patients. A report submitted to the Legislature authorized by this paragraph shall be in compliance with Section 9795 of the Government Code.

(3) Make recommendations to the board, if appropriate, for the adoption of emergency regulations to protect the public against stem cell therapies that are not in compliance with federal laws and regulations, including regulations adopted by the FDA.

(c) The board may adopt emergency regulations recommended pursuant to paragraph (3) of subdivision (b). The board shall consult relevant stakeholders prior to adopting those regulations and shall provide a 90-day notice to stakeholders prior to adopting regulations. The adoption of these regulations is deemed to address an emergency, for purposes of Sections 11346.1 and 11349.6 of the Government Code, and is hereby exempted for this purpose

from the requirements of subdivision (b) of Section 11346.1 of the Government Code.

2524.2. This article shall remain in effect only until January 1, 2024, and as of that date is repealed.

~~SECTION 1. Chapter 3 (commencing with Section 125360) is added to Part 5.5 of Division 106 of the Health and Safety Code, to read:~~

~~CHAPTER 3. STEM CELL CLINIC REGULATION ADVISORY GROUP~~

~~125360. For purposes of this chapter, the following definitions apply:~~

~~(a) "Clinic" has the meaning set forth in Section 1200.~~

~~(b) "Department" means the State Department of Public Health.~~

~~(c) "FDA" means the federal Food and Drug Administration.~~

~~(d) "HCT/Ps" means human cells, tissues, or cellular or tissue-based products, as defined in Section 1271.3 of Title 21 of the Code of Federal Regulations, as amended August 31, 2016, as published in the Federal Register (81 Fed. Reg. 60223).~~

~~(e) "Stem cell therapy" means a therapy involving the use of HCT/Ps.~~

~~125361. (a) No later than February 1, 2020, the department shall convene the Stem Cell Clinic Regulation Advisory Group for purposes of holding a series of stakeholder meetings. The duties of the advisory group include all of the following:~~

~~(1) Review current licensing and certification laws and the department's procedures to determine whether those laws and procedures provide for adequate consumer protection for the use of stem cell therapies in clinics.~~

~~(2) Make recommendations to the Legislature, on or before July 1, 2020, regarding how to improve state oversight of clinics offering or providing stem cell therapies to patients.~~

~~(3) Adopt, if appropriate, emergency regulations to protect the public against stem cell therapies that are not in compliance with federal laws and regulations, including regulations adopted by the federal Food and Drug Administration. The department shall consult relevant stakeholders prior to promulgating regulations and shall provide a 90-day notice to stakeholders prior to adopting regulations. The adoption of these regulations is an emergency~~

~~and necessary for the immediate preservation of the public peace, health and safety, or general welfare.~~

~~(b) In carrying out the duties described in subdivision (a), the department shall consult with the medical community, bioethicists, legal scholars, and patient advocacy groups. The department is authorized to consult with the California Institute for Regenerative Medicine.~~

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