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**SB-512 Health care practitioners: stem cell therapy.** (2017-2018)

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**Senate Bill No. 512**

**CHAPTER 428**

An act to add Section 684 to the Business and Professions Code, relating to healing arts.

[ Approved by Governor October 02, 2017. Filed with Secretary of State October 02, 2017. ]

**LEGISLATIVE COUNSEL'S DIGEST**

SB 512, Hernandez. Health care practitioners: stem cell therapy.

Existing law provides for the licensure and regulation of various health care practitioners by boards and agencies within the Department of Consumer Affairs. Existing law requires a health care practitioner, as defined, to communicate to a patient his or her name, state-granted practitioner license type, and highest level of academic degree, in a specified manner.

This bill would require a licensed health care practitioner who performs a stem cell therapy that is not approved by the United States Food and Drug Administration (FDA) to communicate to his or her patient seeking stem cell therapy specified information regarding the provision of stem cell therapies on a specified notice in a prominent display in an area visible to patients in his or her office, posted conspicuously in the entrance of his or her office, and provided in writing to the patient prior to providing the initial stem cell therapy. The bill would not apply to a health care practitioner who has obtained approval for an investigational new drug or device from the FDA for the use of human cells, tissues, or cellular or tissue-based products. The bill would authorize the licensing board having jurisdiction of the health care practitioner to cite and fine the health care practitioner, not to exceed \$1,000 per violation, as specified. The bill would require the Medical Board of California to indicate specific enforcement information in its annual report, commencing with the 2018–19 annual report, with regard to its licensees who provide stem cell therapies.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: no

**THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:**

**SECTION 1.** Section 684 is added to the Business and Professions Code, to read:

**684.** (a) For the purpose of this section:

- (1) "FDA" means the United States Food and Drug Administration.
- (2) "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).
- (3) "Stem cell therapy" means a therapy involving the use of HCT/Ps.

(b) (1) A health care practitioner licensed under this division who performs a stem cell therapy that is not FDA-approved shall communicate to a patient seeking stem cell therapy the following information in English:

"THIS NOTICE MUST BE PROVIDED TO YOU UNDER CALIFORNIA LAW. This health care practitioner performs one or more stem cell therapies that have not yet been approved by the United States Food and Drug Administration. You are encouraged to consult with your primary care physician prior to undergoing a stem cell therapy."

(2) The information in paragraph (1) shall be communicated to the patient in all of the following ways:

(A) In a prominent display in an area visible to patients in the health care practitioner's office and posted conspicuously in the entrance of the health care practitioner's office. These notices shall be at least eight and one-half inches by 11 inches and written in no less than 40-point type.

(B) Prior to providing the initial stem cell therapy, a health care practitioner shall provide the patient with the notice described in paragraph (1) in writing. The notice shall be at least eight and one-half inches by 11 inches and written in no less than 40-point type.

(c) This section does not apply to a health care practitioner licensed under this division who has obtained approval for an investigational new drug or device from the FDA for the use of HCT/PS.

(d) (1) The licensing board having jurisdiction of the health care practitioner may cite and fine the health care practitioner, not to exceed one thousand dollars (\$1,000) per violation of this section.

(2) No citation shall be issued and no fine shall be assessed upon the first complaint against a health care practitioner who violates this section.

(3) Upon a second or subsequent violation of this section, a citation and administrative fine not to exceed one thousand dollars (\$1,000) per violation may be assessed.

(e) The Medical Board of California shall indicate in its annual report, commencing with the 2018–19 annual report, all of the following with regard to licensees who provide stem cell therapies:

(1) The number of complaints received.

(2) Any disciplinary actions taken.

(3) Any administrative actions taken.