SENATE COMMITTEE ON PUBLIC SAFETY

Senator Nancy Skinner, Chair
2017 - 2018 Regular

Bill No:	AB 710	**Hearing Date:**	May 15, 2018
Author:	Wood		
Version:	April 2, 2018		
Urgency:	Yes	**Fiscal:**	Yes
Consultant:	SJ		

Subject: ***Cannabidiol***

HISTORY

Source: Epilepsy Foundation of Greater Los Angeles

Prior Legislation: SB 94 (Comm. on Budget and Fiscal Review), Ch. 27, Stats. of 2017
AB 845 (Wood), held in Senate Appropriations 2017
SB 643 (McGuire), Ch. 719, Stats. of 2015
AB 266 (Bonta) Ch. 689, Stats. of 2015
AB 243 (Wood) Ch. 688, Stats. of 2015

Support: Epilepsy Foundation of Northern California; Southern California Coalition; Vote Hemp

Opposition: None known

PURPOSE

The purpose of this bill is to authorize healing arts licensees to prescribe cannabidiol (CBD) products if one of specified changes in federal law occurs, and to amend the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA) to exclude federally approved products from regulation.

Existing federal law establishes the Controlled Substances Act (CSA) which regulates the manufacture, importation, possession, use, and distribution of controlled substances such as hallucinogens, narcotics, depressants, and stimulants. Categorizes drugs into five schedules based on their potential for abuse and medical utility. Specifies that Schedule I drugs, including marijuana, are considered the most harmful and have no medical benefits. (21 U.S.C. § 812.)

Existing law establishes the Uniform Controlled Substances Act (UCSA), which classifies controlled substances into five designated schedules, with the most restrictive limitations placed on Schedule I controlled substances, including cannabis, and the least restrictive limitations placed on Schedule 5 controlled substances. (Health & Saf. Code, § 11000 *et seq.*)

Existing law authorizes a physician, dentist, podiatrist, veterinarian, naturopathic doctor, a registered nurse, a certified nurse-midwife, a nurse practitioner, a physician assistant, or an optometrist to write or issue a prescription, as specified. (Health & Saf. Code, § 11150.)

Existing law requires a prescription for a controlled substance to be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. Indicates that the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Indicates that any person who knowingly violates this provision shall be punished by imprisonment not exceeding one year, or by a fine not exceeding $20,000, or by both fine and imprisonment. (Health & Saf. Code, § 11153.)

Existing law specifies the punishment for the unauthorized selling, dispensing, distributing, furnishing, administering, giving, or offering to sell, dispense, distribute, furnish, administer, or give, or possession for sale, any synthetic CBD compound, or any synthetic CBD derivative, to any person. (Health & Saf. Code, § 11357.5, subd. (a).)

Existing law establishes the regulation of the cultivation, processing, and sale of medicinal and adult-use cannabis within the state, and permits adults 21 years of age or older to legally grow, possess, and use cannabis for non-medical purposes, as specified. (Bus. & Prof. Code, § 26000 et seq.)

Existing law establishes the Bureau of Cannabis Control (Bureau) within the Department of Consumer Affairs for the licensure and regulation of cannabis. (Bus. & Prof. Code, § 26010.)

Existing law authorizes the cultivation, testing, manufacturing, and distribution of cannabis by state and local permit only. (Bus. & Prof. Code, §§ 26032, 26050, 26053.)

Existing law prohibits a physician and surgeon from recommending medical cannabis to a patient unless that person is the patient's attending physician. (Bus. & Prof. Code, § 2525.2.)

Existing law provides that recommending medical cannabis to a patient for a medical purpose without an appropriate prior examination and a medical indication is unprofessional conduct. (Bus. & Prof. Code, § 2525.3.)

This bill makes the following Legislative findings and declarations:

- Both children and adults with epilepsy are in need of new treatment options and that CBD has shown potential as an effective treatment option.
- If federal laws prohibiting the prescription of medications composed of CBD are repealed or if an exception from the general prohibition is enacted permitting the prescription of drugs composed of CBD, patients should have rapid access to this treatment option.
- The availability of this new prescription medication is intended to augment, not to restrict or otherwise amend, other cannabinoid treatment modalities including, but not limited to, industrial hemp products and derivatives containing CBD, currently available under state law.

This bill excludes from regulation under the MAUCRSA any medicinal product containing CBD that has been approved by the federal Food and Drug Administration (FDA) that has either been placed on a schedule of the federal CSA other than Schedule I, or has been exempted from one or more provisions of that act, and is intended for prescribed use for the treatment of a medical condition.

This bill provides that, upon change in federal law permitting the prescription, furnishing, or dispensing of a CBD product, a physician, pharmacist, or other authorized healing arts licensee acting within his or her scope of practice who prescribes, furnishes, or dispenses a CBD product in accordance with federal law, shall be deemed to be in compliance with state law.

This bill provides that, notwithstanding any other law, the prescribing, furnishing, dispensing, transfer, transportation, possession, or use of CBD products in accordance with federal law is authorized pursuant to the UCSA upon the effective date of the change in federal law.

This bill clarifies that this bill does not apply to any product containing CBD that is made or derived from industrial hemp, as specified.

This bill declares this act as an urgency statute necessary to ensure that patients are able to obtain access to a new treatment modality as soon as federal law makes it available.

COMMENTS

1. Need for This Bill

According to the author:

> Epilepsy is a medical condition that produces seizures affecting a variety of mental and physical functions. Approximately 1 in 26 Americans will develop epilepsy at some point in their lifetime. There is no "one size fits all" treatment option and about one million people live with uncontrolled or intractable seizures. Uncontrolled seizures can lead to disability, injury, and even death, and many individuals living with uncontrolled seizures suffer from rare epilepsies characterized by seizures that are difficult to treat with existing treatment options. Access to new treatments is particularly important for these individuals, who live with the continual risk of serious injuries and loss of life.
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> The FDA is currently reviewing at least one CBD derived therapy that shows promise for the treatment of rare epilepsy conditions. This potential treatment option has both "Orphan Drug Designation" and Fast Track Designation from the FDA. Given the Fast Track Designation, this potential treatment option could be available as soon as Summer 2018.
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> Currently, any product that contains any material, compound, mixture, or preparation, which contains any quantity of marijuana is considered a Schedule I Controlled Substance unless specifically exempted. Under current law, should a product derived from CBD, like Epidiolex, be approved and rescheduled, it would still be considered a Schedule I substance under California statute and therefore could not be prescribed by a physician unless specifically exempted. Individuals suffering from these rare forms of epilepsy and those living with uncontrolled seizures would not be able to access the medication. AB 710 will ensure Californians with uncontrolled seizures have continued access to FDA approved epilepsy treatments derived from CBD.

2. CBD

Cannabinoids are chemical components of cannabis that produce pharmacologic effects throughout the body, including the central nervous system and the immune system. The primary active cannabinoid in cannabis is delta-9-tetrahydrocannabinol (THC). Another active cannabinoid is CBD. According to the National Institute of Health, CBD is a compound isolated from cannabis which does not cause psychoactive activity and has pain relieving, anti-inflammatory, anti-psychotic, and tumor-inhibiting properties. Cannabinoids can be ingested, inhaled, or sprayed under the tongue. Two cannabinoids, dronabinol and nabilone, are FDA-approved drugs used for the prevention or treatment of chemotherapy-related nausea and vomiting.

There are currently over 100 clinical trials of CBD listed on the National Library of Medicine's website. These trials are testing CBD's utility in treating epilepsy, substance use disorders, pain, psychosis, and anxiety, among other disorders and conditions. (<https://clinicaltrials.gov/ct2/results?term=cannabidiol&Search=Clear&age_v=&gndr=&type=&rslt=> [as of May 1, 2018].)

3. FDA Drug Approval Process

The FDA reviews drug applications to determine whether new drugs are safe and effective through scientific investigations, including adequate and well-controlled clinical trials. The FDA has several programs to facilitate the approval of drugs for certain conditions. The Orphan Drug Act grants special status to a drug or biological product to treat a rare disease or condition which qualifies the sponsor for various development incentives, including tax credits for qualified clinical testing. "Fast track" is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions.

The FDA has "not yet approved any product containing or derived from botanical marijuana for any indication," meaning that the FDA "has not found any such product to be safe or effective for the treatment of any disease or condition." (<https://www.fda.gov/newsevents/publichealthfocus/ucm421168.htm#notapproved> [as of May 1, 2018].) However, the FDA has approved Marinol and Syndros—both of which contain dronabinol, a synthetic THC—for therapeutic uses, including for the treatment of anorexia associated with weight loss in AIDS patients. Another FDA-approved drug, Cesamet, contains the active ingredient nabilone, a synthetically derived cannabinoid which has a chemical structure similar to THC. (*Id.*)

Epidiolex is a CBD drug candidate manufactured by GW Pharmaceuticals that is currently in clinical trials with the FDA. GW Pharmaceuticals plans to market Epidiolex to treat Dravet syndrome and Lennox-Gastaut syndrome (LGS), two rare and severe forms of childhood epilepsy. On April 19, 2018, an FDA advisory committee recommended approval of Epidiolex. (<https://www.cnn.com/2018/04/19/health/fda-committee-marijuana-drug-epilepsy-bn/index.html> [as of May 1, 2018.]) The FDA's vote on whether to approve the drug is expected by late June. (<https://www.gwpharm.com/about-us/news/gw-pharmaceuticals-announces-acceptance-nda-filing-epidiolex%C2%AE-cannabidiol-treatment> [as of May 1, 2018].)

This bill is intended to facilitate the prescription of any FDA-approved CBD product by stating that federal reclassification or exemption from Schedule I triggers the safe prescription, furnishing, dispensing, transfer, possession, or use of a product composed of CBD in accordance with federal and state law. This bill also exempts such a product from regulation under the MAUCRSA.

4. Prior Legislation

A substantially similar bill, AB 845 (Woods), was introduced last year. AB 845 passed out of this Committee but was held in the Senate Appropriations Committee.

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