SENATE COMMITTEE ON PUBLIC SAFETY

Senator Steven Bradford, Chair
2021 - 2022 Regular

Bill No:	AB 527	**Hearing Date:**	July 13, 2021
Author:	Wood		
Version:	June 10, 2021		
Urgency:	No	**Fiscal:**	Yes
Consultant:	SJ		

Subject: ***Controlled substances***

HISTORY

Source: Author

Prior Legislation: AB 710 (Wood), Ch. 62, Stats. 2018
SB 94 (Comm. on Budget and Fiscal Review), Ch. 27, Stats. 2017
AB 845 (Wood), held in Senate Appropriations 2017
SB 643 (McGuire), Ch. 719, Stats. 2015
AB 266 (Bonta) Ch. 689, Stats. 2015
AB 243 (Wood) Ch. 688, Stats. 2015

Support: California Council for the Advancement of Pharmacy; Greenwich Biosciences; University of California

Opposition: None known

Assembly Floor Vote: 77 - 0

PURPOSE

The purposes of this bill are: 1) to expand existing law that authorizes healing arts licensees to prescribe cannabidiol (CBD) products if one of specified changes in federal law occurs to include all products with cannabinoids; 2) to require the Department of Justice to permit the University of California and its bona fide researches access to the Controlled Substances Utilization Review and Evaluation System (CURES), as specified; and 3) to align federal and state controlled substance schedules, as specified.

Existing law establishes the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA) to regulate the cultivation, distribution, transport, storage, manufacturing, processing, and sale of both medicinal cannabis and adult-use cannabis. (Bus. & Prof. Code, § 26000 et seq.)

Existing law establishes the Bureau of Cannabis Control under the Department of Consumer Affairs to regulate cannabis with the sole authority to create, issue, deny, renew, discipline, suspend, or revoke licenses for microbusinesses, transportation, storage unrelated to manufacturing activities, distribution, testing, and sale of cannabis and cannabis products within the state. (Bus. & Prof. Code, §§ 26010, 26012, subd. (a)(1).)

Existing law requires the Department of Food and Agriculture (CDFA) to administer the provisions of the MAUCRSA related to and associated with the cultivation of cannabis. Provides that CDFA has the authority to create, issue, deny, and suspend or revoke cultivation licenses for violations of the MAUCRSA. (Bus. & Prof. Code, § 26012, subd. (a)(2).)

Existing law requires the State Department of Public Health (DPH) to administer the provisions of the MAUCRSA related to and associated with the manufacturing of cannabis products. Provides that DPH has the authority to create, issue, deny, and suspend or revoke manufacturing licenses for violations of the MAUCRSA. (Bus. & Prof. Code, § 26012, subd. (a)(3).)

Existing law exempts products containing CBD that have been approved by the federal Food and Drug Administration (FDA) from regulation under MAUCRSA. (Bus. & Prof. Code, § 26002.)

Existing law establishes the Uniform Controlled Substances Act which classifies controlled substances into five designated schedules, with the most restrictive limitations placed on controlled substances classified as Schedule I, including cannabis, and the least restrictive limitations placed on Schedule 5. (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. Provides that the punishment for knowingly violates this provision is 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 provides, if one of specified changes in federal law regarding the controlled substance CBD occurs, a physician, pharmacist, or other healing arts licensee acting within the scope of his or her practice, who prescribes, furnishes, or dispenses a product composed of CBD, in accordance with federal law, to be in compliance with state law. (Health & Saf. Code, § 11150.2, subd. (a).)

Existing law provides that a CBD product composed of CBD may be prescribed, furnished, dispensed, transferred, transported, possessed, or used in accordance with federal law and is authorized pursuant to state law, so long as CBD is federally rescheduled or otherwise made a controlled substance that can be legally prescribed, furnished, dispensed, transferred, transported, possessed, or used. (Health & Saf. Code, § 11150.2, subd. (b).)

Exisitng federal law establishes the federal Controlled Substances Act (federal Act) 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, status in international treaties, and any medical benefits they may provide. Specifies that Schedule I drugs, including marijuana, are considered the most harmful and have no medical benefitsm and Schedule 5 substances are the least restricted. (21 U.S.C. § 801 et seq.)

Existing law establishes the Controlled Substance Utilization Review and Evaluation System (CURES), for the electronic monitoring of the prescribing and dispensing Schedule II, III, IV, and V controlled substances. (Health & Saf. Code, § 11165.)

Existing law requires health care practitioners to register for access to the CURES database. (Health & Saf. Code, § 11165.1.)

This bill exempts from Schedule III specific compounds, mixtures, or preparations that contain a nonnarcotic controlled substance in combination with a derivative of barbituric acid or any salt thereof that are listed in the federal Table of Exempted Prescription Products and have been exempted pursuant to federal law or regulation.

This bill exempts from Schedule IV specific compounds, mixtures, or preparations that contain a nonnarcotic controlled substance in combination with a chlordiazepoxide or phenobarbital that are listed in the federal Table of Exempted Prescription Products and have been exempted from scheduling under federal law or regulation.

This bill expands existing provisions authorizing the prescription, furnishing, dispensing, transfer, transportation, possession, or use of CBD products in accordance with federal law, upon the specified changes being made to federal law, to include all products with cannabinoids.

This bill requires the Department of Justice to provide the University of California and its bona fide researchers with access to identifiable CURES data for research purposes.

COMMENTS

1. Need for This Bill

According to the author:

> This bill seeks to more closely align California law and federal law related to the classification and scheduling of certain drugs. It also seeks to ensure that research surrounding the opioid crisis and other related research can continue with access to appropriate CURES data and with appropriate privacy safeguards. There are three parts to this bill.
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> [First], [c]urrent law, places any product that contains any material compound, mixture, or preparation, containing any quantity of cannabis as a Schedule I substance unless specifically exempted. In 2018, AB 710 (Wood), Chapter 62 exempted any newly approved prescription medication containing Cannabidiol (CBD) and that is controlled or decontrolled under a federal rule or interim rule. This bill would change the word "cannabidiol" to "cannabinoids" thereby extending the same exemption to other cannabis – derived medicines that may, following FDA-approval, be reclassified under the Federal Drug Enforcement drug scheduling in the same way the those containing CBD's were. This bill would expand the provisions authorizing the prescription furnishing, dispensing, transfer, transportation, possession, or use of cannabidiol products in accordance with federal law, to include all products with cannabinoids.

> [Second], this bill would exempt from Schedule III specific compounds, mixtures, or preparations that contain a nonnarcotic controlled substance in combination a derivative of barbituric acid or any salt thereof that are listed in the federal Table of Exempted Prescription Products. It would further exempt from Schedule IV specific compounds, mixtures, or preparations that contain a nonnarcotic controlled substance in combination with a chlordiazepoxide or phenobarbital that are listed in the federal Table of Exempted Prescription Products.
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> [Finally], spurred by AB 1751 (Low) Chapter 478, Statutes of 2018, the Department of Justice promulgated regulations regarding the access and use of information within CURES which went into effect on July 1, 2020. These new regulations essentially resulted in bona fide research being restricted and made difficult to do as a result of this limited access to meaningful data. …AB 527 would restore UC researchers' access to CURES data under the requirements that existed prior to the new regulations.

2. Background

Cannabinoids

Cannabinoids are chemical components of cannabis that produce pharmacologic effects throughout the body. Two of the most well-known cannabinoids are THC and 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. There are currently over 100 clinical trials of CBD listed on the National Library of Medicine's website that are either active or recruiting or enrolling participants. These trials are testing CBD's utility in treating epilepsy, substance use disorders, pain, psychosis, anxiety, and COVID-19 pulmonary infections, among other disorders and conditions. (<https://www.clinicaltrials.gov/ct2/results?term=cannabidiol&Search=Apply&recrs=a&recrs=f&recrs=d&age_v=&gndr=&type=&rslt=> [as of Jul. 7, 2021].)

FDA Drug Approval Process

The FDA reviews drug applications to determine whether they 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 and fill an unmet medical need. According to its website:

> To date, the FDA has not approved a marketing application for cannabis for the treatment of any disease or condition. The agency has, however, approved one cannabis-derived drug product: Epidiolex (cannabidiol), and three synthetic cannabis-related drug products: Marinol (dronabinol), Syndros (dronabinol), and Cesamet (nabilone). These approved drug products are only available with a prescription from a licensed healthcare provider. Importantly, the FDA has not approved any other cannabis, cannabis-derived, or cannabidiol (CBD) products

currently available on the market. (https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process)

3. California Cannabis Regulatory Background

Medical cannabis was first legalized for consumption in California by Proposition 215, the Compassionate Use Act in 1996. Proposition 215 protected qualified patients and primary caregivers from prosecution related to the possession and cultivation of cannabis for medicinal purposes. In 2015, the Legislature passed the Medical Cannabis Regulation and Safety Act (MCRSA). MCRSA established, for the first time, a comprehensive statewide licensing and regulatory framework for the cultivation, manufacture, transportation, testing, distribution, and sale of medicinal cannabis to be administered by the Bureau within Department of Consumer Affairs, the Department of Public Health, and the Department of Food and Agriculture, with implementation relying on each agency's area of expertise. Shortly following the passage of MCRSA, California voters passed Proposition 64 in November 2016, which legalized adult-use cannabis. In June 2017, the California State Legislature passed a budget trailer bill, SB 94 (Committee on Budget and Fiscal Review, Chapter 27, Statutes of 2017), that integrated MCRSA with Prop 64 to create the Medicinal and Adult-Use Cannabis Regulation and Safety Act.

4. Effect of This Bill

This bill does several things. First, this bill aligns federal and state controlled substance schedules. There are currently some discrepancies between the federal and state controlled substance schedules which has led to confusion among licensees. Specifically, federal law exempts from scheduling certain combination drugs that could be dangerous, including Fioricet (butalbital product with barbituric acid), Donnatal (combination product containing phenobarbital), and Librax (combination product containing chloradiazepoxide). These substances are not exempted under state law. Second, this bill allows UC and its bona fide researchers to have access to identifiable CURES data for research purposes. Under existing law, the DOJ must maintain CURES for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by a health care practitioner authorized to prescribe, order, administer, furnish, or dispense these drugs. Existing law limits the entities that can receive data from CURES, as well as the types of data that can be released and the uses of that data. Prior to last year, the University of California had access to information in the CURES database for research purposes. That access was lost when the department promulgated regulations required by AB 1751 (Low, Chapter 478, Statutes of 2018), which provided a framework for CURES to connect with other states' prescription drug monitoring programs. Finally, this bill expands existing law that authorizes healing arts licensees to prescribe CBD products if one of specified changes in federal law occurs to include all products with cannabinoids.

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