SENATE COMMITTEE ON PUBLIC SAFETY

Senator Aisha Wahab, Chair
2023 - 2024 Regular

Bill No:	AB 1021	**Hearing Date:**	June 20, 2023
Author:	Wicks		
Version:	June 6, 2023		
Urgency:	No	**Fiscal:**	Yes
Consultant:	SJ		

Subject: ***Controlled substances: rescheduling***

HISTORY

Source: MAPS Public Benefit Corporation

Prior Legislation: AB 527 (Wood), Ch. 618, Stats. 2021
AB 710 (Wood), Ch. 72, Stats. 2018
AB 2783 (O'Donnell), Ch. 589, Stats. 2018

Support: California Medical Association; California State Association of Psychiatrists

Opposition: None known

Assembly Floor Vote: 69 - 1

PURPOSE

The purpose of this bill is to provide that if any Schedule I controlled substance, other than cannabis and cannabis products currently regulated in California, is federally rescheduled or exempted from the Controlled Substances Act, it will automatically become lawful for health professionals to prescribe, furnish, or dispense under California law.

Existing law establishes the California Uniform Controlled Substances Act which regulates controlled substances. (Health & Saf. Code, §§ 11000 et seq.)

Existing law classifies controlled substances into five schedules according to their danger and potential for abuse. (Health & Saf. Code, §§ 11054-11058.)

Existing law provides that if any non-hemp cannabinoid is federally rescheduled or otherwise made a lawfully prescribed controlled substance, it shall also be deemed legal to prescribe under state law upon the effective date of the change in federal law. (Health & Saf. Code, § 11150.2.)

Existing law places cannabis, mescaline, 3,4-methylenedioxy amphetamine (MDMA), peyote, psilocybin, and tetrahydrocannabinols (THC) on Schedule I, among other controlled substances, within the classification of hallucinogenic substances. (Health & Saf. Code, § 11054.)

Existing law establishes various practice acts in the Business and Professions Code governed by various boards within the Department of Consumer Affairs (DCA) which provide for the licensing and regulation of health care professionals. (Bus. & Prof. Code, §§ 500 et seq.)

Existing law specifies certain requirements regarding the dispensing and furnishing of dangerous drugs and devices, and prohibits a person from furnishing any dangerous drug or device except upon the prescription of specified health care professionals. (Bus. & Prof. Code, § 4059.)

Existing law prohibits any person other than specified health care professionals from writing or issuing a prescription for a controlled substance. (Health & Saf. Code, § 11150.)

Existing law provides that a prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of their professional practice, and 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. (Health & Saf. Code, § 11153.)

Existing law establishes the Controlled Substance Utilization Review and Evaluation System (CURES), for the purposes of collecting records of dispensed Schedule II, III, IV, and V controlled substances. (Health & Saf. Code, § 11165.)

Existing law enacts the Compassionate Use Act of 1996, which first allowed patients to engage in the medical use of cannabis, and for patients and their primary caregivers to cultivate and possess medicinal cannabis, without being subject to criminal prosecution or punishment. (Health & Saf. Code, §§ 11362.5 et seq.)

Existing law enacts the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA) to provide for a comprehensive regulatory framework for the cultivation, distribution, transport, storage, manufacturing, processing, and sale of medicinal and adult-use cannabis. (Bus. & Prof. Code, §§ 26000 et seq.)

Existing law establishes the Department of Cannabis Control (DCC) to administer and regulate provisions of MAUCRSA. (Bus. & Prof. Code, § 26010.)

This bill provides, notwithstanding any other law, if a substance listed in Schedule I of Section 11054 is excluded from Schedule I of the federal Controlled Substances Act and placed on a schedule of the act other than Schedule I, or if a product composed of one of these substances is approved by the federal Food and Drug Administration and either placed on a schedule of the act other than Schedule I, or exempted from one or more provisions of the act, so as to permit a physician, pharmacist, or other authorized healing arts licensee acting within their scope of practice, to prescribe, furnish, or dispense that product, the physician, pharmacist, or other authorized healing arts licensee who prescribes, furnishes, or dispenses that product in accordance with federal law shall be deemed to be in compliance with state law governing those acts.

This bill specifies that if the above changes to federal law occur, the proscribed changes to state law will occur automatically.

This bill specifies that its provisions do not apply to cannabis or a cannabis product, as defined in Section 26001 of the Business and Professions Code. Provides that cannabis or cannabis products may be authorized pursuant to Section 11150.2.

COMMENTS

1. Need For This Bill

According to the author:

> AB 1021 eliminates confusion for prescribers and pharmacists in California, and prevents a gap in access to potentially life-saving legal medications. Upon FDA approval and subsequent DEA [re]scheduling, California medical professionals acting under all applicable laws and regulations of the state, would be authorized to prescribe legal medications approved by the Federal Government. AB 1021 allows for federal parity after extensive policy and law enforcement review. This effort does not decriminalize or legalize any controlled substance for any non-medical use. It specifically—and only—applies to prescription medicines approved by the FDA for medical use.

2. Controlled Substances Scheduling

The federal Controlled Substances Act classifies a number of drugs and chemicals into one of five schedules. Drugs falling within Schedules II through V may be prescribed only by health practitioners in possession of a DEA registration and are ranked according to the drug's potential for abuse, with lower numbered schedules representing drugs with a higher risk of abuse or dependence. Schedule I drugs have been determined to have no currently accepted medical use and a high potential for abuse. Schedule I drugs may not be prescribed by any health practitioner in the United States. Examples of Schedule I drugs include cannabis, LSD, peyote, heroin, and ecstasy.

California also has its own schedule of controlled substances under the Uniform Controlled Substances Act. While the federal and state schedules are typically aligned in regards to how medications are classified, there have been conflicts between the federal and state acts. This has typically occurred when the federal government reschedules a substance or exempts a specific drug from the Controlled Substances Act. When this occurs, California law generally must be amended to reconcile the differences. For example, cannabis is currently listed as a Schedule I drug both federally and under California law. While MAUCRSA allows for cannabis to be cultivated, manufactured, and sold by licensees of the Department of Cannabis Control, it generally remains ineligible to be prescribed, furnished, or dispensed. However, in 2018, the federal Food and Drug Administration (FDA) approved a drug called Epidiolex, an epilepsy medication containing highly-purified CBD from the cannabis plant. Advocates for the epileptic community actively championed the FDA's approval of Epidiolex, leading to it becoming the first federally approved drug containing cannabinoids. Prior legislation in California was subsequently enacted to ensure that the drug would also be legal in California. When the FDA later approved additional drugs containing other cannabinoids, the law was further amended to automatically make it lawful to prescribe, furnish, and dispense any FDA-approved drug containing cannabinoids.

3. Potential Approval of Hallucinogenic Therapies

Beyond cannabis, other controlled substances currently listed as Schedule I both federally in California have been the subject of research into whether they could have effective medical use. In the May 2020 issue of the *American Journal of Psychiatry*, an evidenced-based summary of

literature entitled "Psychedelics and Psychedelic-Assisted Psychotherapy" provided a literature review on the clinical application of psychedelic drugs in psychiatric disorders. A total of 1,603 articles were identified and screened. Articles that did not contain the terms "clinical trial," "therapy," or "imaging" in the title or abstract were filtered out. The remaining 161 articles were reviewed by two or more authors and 14 article were identified as reporting on well-designed clinical trials investigating the efficacy of LSD, MDMA, psilocybin, and ayahuasca for the treatment of mood and anxiety disorder, trauma and stress-related disorders and substance related and addictive disorders as well as end-of-life care.

The most significant database exists for MDMA and psilocybin, which have been designated by the FDA as "breakthrough therapies" for PTSD and treatment-resistant depression, respectively. The research on LSD and ayahuasca is observational, but available evidence suggests that these agents may have therapeutic effects in specific psychiatric disorders. The literature review concluded that while randomized clinical trials support the efficacy of MDMA in the treatment of PTSD and psilocybin in the treatment of depression and cancer-related anxiety, the research to support the use of LSD and ayahuasca (DMT) in the treatment of psychiatric disorders is preliminary, although promising. Overall, the database has been insufficient for FDA approval of any psychedelic compound for routine clinical use in psychiatric disorders at this time; however, continued research on the efficacy of psychedelics for the treatment of psychiatric disorders is warranted.

On April 5, 2023, MAPS Public Benefit Corporation, the sponsor of this bill, announced its preliminary findings from an observational study, *Long-Term Safety and Persistence of Effectiveness of Manualized MDMA-Assisted Therapy for the Treatment of Posttraumatic Stress Disorder*. According to MAPS Public Benefit Corporation, these preliminary findings "show that participants in this study demonstrated a durable response at least six months, and in some cases a year or more, after their final MDMA-assisted therapy session during the Phase 3 study." The preliminary findings further suggest that therapies utilizing hallucinogenic controlled substances could receive federal approval in the future.

In the event that MDMA, psilocybin, or other Schedule I controlled substances are either federally rescheduled or exempted from the Controlled Substances Act following FDA approval, the proponents of this bill contend that California should immediately allow health professionals to prescribe, furnish, and dispense those substances given that it would be lawful to do so under federal law. This bill would apply if any Schedule I controlled substance is excluded from Schedule I of the federal Controlled Substances Act and placed on a schedule of the act other than Schedule I, or if a product composed of one of these substances is approved by the FDA and either placed on a rescheduled or exempted from the Act. In that instance, California-licensed physicians, pharmacists, and other healing arts licensees would be immediately considered allowed to prescribe, furnish, and dispense those drugs, regardless of their classification within the state's Uniform Controlled Substances Act. Nothing in this bill would legalize any controlled substance that is currently prohibited.

4. Argument in Support

The California State Association of Psychiatrists supports this bill writing:

> This bill seeks to resolve a future predictable ambiguity for professionals by creating a pathway for prescribing substances containing a Schedule I substance, only after the federal government schedules a new drug product containing the

same chemical entity. Specifically, AB 1021 will allow relevant licensed healing arts professionals in California to appropriately prescribe and dispense FDA-approved drug products that contain controlled substances controlled in Schedule I.

This effort does not decriminalize or legalize any controlled substance for any non-medical use. It specifically applies to prescription medicines approved by the FDA for medical use. This is a necessary step to prevent a gap in access to potentially life-saving legal medications in the State and to eliminate any "gray area" for licensed healthcare providers or patients in California.

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