# SENATE COMMITTEE ON
# BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT
**Senator Richard Roth, Chair**
**2023 - 2024 Regular**

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| **Bill No:** | AB 1021 | **Hearing Date:** | June 12, 2023 |
| **Author:** | Wicks | | |
| **Version:** | June 6, 2023 | | |
| **Urgency:** | No | **Fiscal:** | Yes |
| **Consultant:** | Sarah Mason | | |

**Subject:** Controlled substances: rescheduling

**SUMMARY:** Provides 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.

**NOTE:** This bill is double referred to the Senate Committee on Public Safety, second.

**Existing law:**

1) Establishes various practice acts in the Business and Professions Code (BPC) governed by various boards within the Department of Consumer Affairs (DCA) which provide for the licensing and regulation of health care professionals including: physicians and surgeons (under the Medical Practice Act), dentists (under the Dental Practice Act), veterinarians (under the Veterinary Medicine Practice Act); registered nurses, nurse practitioners (NP) and certified nurse-midwives (CNM) (under the Nursing Practice Act); physician assistants (PA) (under the Physician Assistant Practice Act); osteopathic physicians and surgeons (under the Osteopathic Medical Practice Act); naturopathic doctors (ND) (under the Naturopathic Doctors Act); optometrists (under the Optometry Practice Act); doctors of podiatric medicine (under the Podiatric Act) and; pharmacies, pharmacists and wholesalers of dangerous drugs or devices (under the Pharmacy Law). (Business and Professions Code (BPC) §§ 500 *et seq*.)

2) 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 a physician, dentist, podiatrist, optometrist, veterinarian or ND. (BPC § 4059)

3) Establishes the Uniform Controlled Substances Act which regulates controlled substances and defines an opiate as any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. (Health and Safety Code (HSC) § 11020)

4) Classifies controlled substances into five schedules according to their danger and potential for abuse. (HSC §§ 11054-11058)

5) Prohibits any person other than a physician, dentist, podiatrist, veterinarian, ND (according to certain supervision and protocol requirements), pharmacist (according to certain authorization and according to certain policies and procedures), CNM (if furnished or ordered incidentally to the provision of family planning services, routine health care or perinatal care, or care rendered consistent with the CNM's practice; occurs under physician and surgeon supervision; and is in accordance with standardized procedures or protocols as specified), NP (if it is consistent with a NP's educational preparation or for which clinical competency has been established and maintained; occurs under physician and surgeon supervision; and is in accordance with standardized procedures or protocols as specified); a pharmacist or registered nurse or PA acting within the scope of an experimental health workforce project authorized by the Office of Statewide Health Planning and Development (HSC §§ 128125 *et seq*.); an optometrist licensed under the Optometry Practice Act, or an out-of-state prescriber acting in an emergency situation from writing or issuing a prescription for a controlled substance.
(HSC § 11150)

6) States 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 his or her 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. (HSC § 11153)

7) Establishes CURES, a prescription drug management program maintained by the Department of Justice for the purpose of collecting records of dispensed controlled substances for review by licensed prescribers and dispensers, regulatory investigators, law enforcement, and statistical researchers. Requires health care practitioners to consult the CURES database to review a patient's controlled substance history before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every six months thereafter if the substance remains part of the treatment of the patient. Provides numerous exemptions from the duty to consult CURES for certain patient populations and under various circumstances. (HSC §§11165(a) and 11165.4)

8) 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. (HSC §§ 11362.5 *et seq.*)

9) 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. (Business and Professions Code (BPC) § 26000)

10) Establishes the Department of Cannabis Control (DCC) to administer and regulate provisions of MAUCRSA. (BPC § 26010)

11) 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. (HSC § 11150.2)

12) Specifies that cases that involve repeated acts of clearly excessive recommending of cannabis to patients for medical purposes, or repeated acts of recommending cannabis to patients for medical purposes without a good faith prior examination of the patient and a medical reason for the recommendation be given the highest priority by the Medical Board of California and California Board of Podiatric Medicines. Specifies that recommending medical cannabis to a patient for a medical purpose without an appropriate prior examination and a medical indication constitutes unprofessional conduct. (BPC §§ 2220.05 and 2525.2)

**This bill**:

1) Provides that if any substance listed in Schedule I of the Uniform Controlled Substances Act in California is excluded from Schedule I of the federal Controlled Substances Act, other than cannabis or a cannabis product regulated under MAUCRSA and either rescheduled or exempted from one or more provisions of the Act, a physician, pharmacist, or other healing arts licensee who prescribes, furnishes, or dispenses that product in accordance with federal law shall be deemed to be in compliance with applicable California law.

2) Additionally provides that a product composed of the excluded substance may be prescribed, furnished, dispensed, transferred, transported, possessed, or used in accordance with federal law upon the effective date of the change in federal law.

**FISCAL EFFECT:** This bill is keyed fiscal by Legislative Counsel. According to the Author,

**COMMENTS:**

1. **Purpose.** This bill is sponsored by MAPS Public Benefit Corporation. According to the Author, the measure "seeks to resolve a predictable future ambiguity for professional, licensed healing arts practitioners 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."

   The Author notes that "California has no mechanized law or process that clearly permits healing arts licensees to prescribe, furnish, or dispense a drug that contains a substance currently in California's Schedule I when a drug product containing such a substance has been approved by the FDA for a medical use and that drug product has been subsequently federally classified in a schedule other than the federal Schedule I (or exempted from scheduling). Federal preemption of the drug product scheduling is also not clear from a State policy perspective. Clear action from the legislature will alleviate confusion and prevent delays in patient access to potentially life-saving FDA approved treatments.

If a medicinal product composed of a Schedule I substance is approved by the FDA and either placed on a schedule of the federal Controlled Substances Act or exempted from one or more provisions of that act, AB 1021 would deem a physician, pharmacist, or other authorized healing arts licensee who prescribes, furnishes, or dispenses a product composed of a Schedule I controlled substance, in accordance with federal law, to be in compliance with state law governing those acts and provides that, upon the effective date of one of the changes in federal law, the prescription, dispensing, transfer, transportation, possession, or use of that product in accordance with federal law is for a legitimate medical purpose and is authorized pursuant to state law."

2. **Background.**

*Federal vs. State 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, typically when the federal government reschedules a substance or exempts a specific drug from the Controlled Substances Act. When this occurs, statute in California typically must be legislatively 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.

*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 continue 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 author of this bill believes that California should immediately allow health professionals to prescribe, furnish, and dispense those substances as part of federally lawful treatment. 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 California Uniform Controlled Substances Act. Nothing in this bill would legalize any controlled substance that is currently prohibited.

3. **Arguments in Support.** Supporters note that this bill would prevent a situation in which the federal government reschedules a drug out of Schedule 1, but it still cannot be legally prescribed and dispensed in California until the state legislature acts by passing legislation to reschedule the specific drug.

**SUPPORT AND OPPOSITION:**

Support:

California Medical Association
Kaiser Permanente
Maps Public Benefit Corporation

Opposition:

None received

**-- END --**