SENATE COMMITTEE ON PUBLIC SAFETY

Senator Aisha Wahab, Chair 2023 - 2024 Regular

Bill No: SB 1012 Hearing Date: April 23, 2024

Author: Wiener

Version: March 20, 2024

Urgency: No Fiscal: Yes

Consultant: SJ

Subject: The Regulated Psychedelic Facilitators Act and the Regulated

Psychedelic-Assisted Therapy Act

HISTORY

Source: Heroic Hearts

Law Enforcement Action Partnership Veterans Exploring Treatment Options

Prior Legislation: SB 58 (Wiener), vetoed in 2023

SB 519 (Wiener), died on the Assembly Inactive File in 2022

Support: A New Path; Alameda County Democratic Central Committee; An Empathic

Society; Board of Psychedelic Medicine and Therapies; California Association of Social Rehabilitation Agencies; California Coalition for Psychedelic Safety and

Education; California Public Defenders Association; City of Berkeley

Councilmember Ben Bartlett; City of West Hollywood; Dr. Bronner's; End Well Foundation; Institute for Rural Psychedelic Care; NEST Harm Reduction & Consulting; New Approach Advocacy Fund; Sacramento Institute for

Psychotherapy; Shamynds Healing Center; Smart Justice California; Smart Justice California; Sonoma County Democratic Party; Steinberg Institute; William G.

Nash Foundation; 3 individuals

Opposition: Alliance for Better and Safer California; Americans Against the Legalization of

Marijuana; Arcadia Police Officers' Association; Burbank Police Officers' Association; California Baptist for Biblical Values; California Coalition Against Drugs; California Coalition of School Safety Professionals; California Family Council; California Narcotic Officers' Association; California Reserve Peace Officers Association; California State Sheriffs' Association; Chinese American Institute for Empowerment; Citizens Commission on Human Rights; Claremont Police Officers Association; Corona Police Officers Association; Culver City Police Officers' Association; Deputy Sheriffs' Association of Monterey County; Fullerton Police Officers' Association; Interfaithstatewide Coalition; Los Angeles School Police Management Association; Los Angeles School Police Officers Association; Murrieta Police Officers' Association; Newport Beach Police Association; Novato Police Officers Association; Organization for Justice and Equality; Palos Verdes Police Officers Association; Placer County Deputy Sheriffs' Association; Pomona Police Officers' Association; Riverside Police Officers Association; Riverside Sheriffs' Association; SafeLaunch; Santa Ana

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Police Officers Association; Traditional Values for Next Generations; Upland Police Officers Association; 12 individuals

PURPOSE

The purpose of this bill is to establish the Regulated Psychedelic Facilitators Act (Facilitators Act) and Regulated Psychedelic-Assisted Therapy Act (Assisted Therapy Act) administered by new state entities, each of which is required to undertake regulatory efforts to determine, define, and establish standards for psychedelic facilitation in the state, and exempts from prosecution certain conduct related to controlled substances when the conduct occurs lawfully under the Facilitators Act or the Assisted Therapy Act.

Existing law classifies controlled substances into five schedules according to their danger and potential for abuse. Schedule I controlled substances have the greatest restrictions and penalties, including prohibiting the prescribing of a Schedule I controlled substance. (Health & Saf. Code, §§ 11054-11058.)

Existing law classifies several hallucinogenic substances including DMT, mescaline, psilocybin, and psilocyn as Schedule I substances. (Health & Saf. Code, § 11054, subd. (d).)

Existing law prohibits the possession of several specified controlled substances. (Health & Saf. Code, § 11350, subd. (a).)

Existing law makes it unlawful for a person to possess for sale or purchase for purpose of sale specified controlled substances. (Health & Saf. Code, § 11351.)

Existing law makes it unlawful for a person to transport, import, sell, furnish, administer, or give away, or offer or attempt to transport, import, sell, furnish, administer, or give away specified controlled substances. (Health & Saf. Code, § 11352.)

Existing law make it unlawful for any person to deliver, furnish, or transfer, possess with intent to deliver, furnish, or transfer, or manufacture with the intent to deliver, furnish, or transfer, drug paraphernalia, knowing that it will be used to plant, propagate, cultivate, grow, harvest, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, conceal, inject, ingest, inhale, or otherwise introduce into the human body a controlled substance. (Health & Saf. § 11364.7.)

Existing law provides that the possession of methamphetamine and other specified controlled substances is unlawful. (Health & Saf. Code, § 11377, subd. (a).)

Existing law makes it unlawful for a person to possess for sale specified controlled substances. (Health & Saf. Code, § 11378.)

Existing law makes it unlawful for a person to transport, import into this state, sell, furnish, administer, or give away, or offer to transport, import into this state, sell, furnish, administer, or give away, or attempt to import into this state or transport specified controlled substances. (Health & Saf. Code, § 11379.)

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Existing law makes it unlawful for a person who, with the intent to produce psilocybin or psilocyn, cultivates any spores or mycelium capable of producing mushrooms or other material which contains such a controlled substance. (Health & Saf. Code, § 11390.)

Existing law makes it unlawful to transport, import into this state, sell, furnish, gives away, or offer to transport, import into this state, sell, furnish, or give away any spores or mycelium capable of producing mushrooms or other material which contain psilocybin or psilocyn. (Health & Saf. Code, § 11391.)

Existing law provides that a controlled substance analog shall be treated the same as the controlled substance classified in Section 11054 or 11055. Defines "controlled substance analog" to mean either of the following: (1) a substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance classified in Section 11054 or 11055; or (2) a substance that has, is represented as having, or is intended to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to, or greater than, the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance classified in Section 11054 or 11055. (Health & Saf. Code, § 11401, subds. (a) & (b).)

Existing law 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 and include statutory requirements for education, training, clinical experience, competency assessments in order to become licensed, as well as specific statutory practice authority. (Bus. & Prof. Code, § 500 et seq.)

Existing law prohibits any person from writing or issuing a prescription for a controlled substance other than a physician, dentist, podiatrist, veterinarian, naturopathic doctor (according to certain supervision and protocol requirements), pharmacist (according to certain authorization and according to certain policies and procedures), certified nurse-midwife (if furnished or ordered incidentally to the provision of family planning services, routine health care or perinatal care, or care rendered consistent with their practice; occurs under physician and surgeon supervision; and is in accordance with standardized procedures or protocols as specified), nurse practitioner (if it is consistent with their 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 physician assistant acting within the scope of an experimental health workforce project; an optometrist licensed under the Optometry Practice Act, or an out-of-state prescriber acting in an emergency situation. (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, the state Confidentiality of Medical Information Act, prohibits a provider of health care and others from intentionally sharing, selling, using for marketing, or otherwise using any medical information, as defined, for any purpose not necessary to provide health care services to a patient, except as expressly authorized by the patient, enrollee, or subscriber, as specified, or as otherwise required or authorized by law. (Civ. Code, § 56 et seq.)

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Existing federal law, the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), establishes certain requirements relating to the provision of health insurance, including provisions relating to the confidentiality of health records. (Public Law 104–191, 104th Congress)

Existing federal law makes it unlawful for any person to knowingly or intentionally possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of their professional practice, or as otherwise specified. (21 U.S.C. § 844.)

Existing federal law makes it unlawful to knowingly open, lease, rent, use, or maintain any place, whether permanently or temporarily, for the purpose of manufacturing, distributing, or using any controlled substance. (21 U.S.C. § 856 (a).)

Existing federal law makes it unlawful to manage or control any place, whether permanently or temporarily, either as an owner, lessee, agent, employee, occupant, or mortgagee, and knowingly and intentionally renting, leasing, profiting from, or making available for use, with or without compensation, the place for the purpose of unlawfully manufacturing, storing, distributing, or using a controlled substance. (21 U.S.C. § 856, (b).)

This bill defines various terms for purposes of regulation by the Board of Regulated Psychedelic Facilitators (Board) and the Division of Regulated Psychedelic-Assisted Therapy (Division), including, among others:

- "Administration session" means a session conducted at an approved location during which a participant consumes and experiences the effects of a regulated psychedelic substance under the supervision of a facilitator.
- "Approved location" means a location approved by the Division or a clinic, center, or other facility licensed by the State Department of Public Health (DPH).
- "Approved school" means a school or educational program approved by the Board that meets minimum standards for training and curriculum in regulated psychedelic facilitation and related subjects.
- "Integration session" means counseling provided by a facilitator or other personnel trained in postpsychedelic support that is intended to help the participant better understand their psychedelic experience and apply insights from their experience to their daily life.
- "Regulated psychedelic substances" means the following substances as defined in Section 11054 of the Health and Safety Code: DMT, mescaline, MDMA, psilocybin, psilocyn and spores or mycelium capable of producing mushrooms that contain psilocybin or psilocyn. Specifies that regulated psychedelic substances does not include peyote.
- "Safety screen" means a screening for medical conditions, mental health conditions, family history, contraindications, and pharmacological interactions that must be provided to every participant before an administration session.

This bill specifies various aspects of the Board, including:

• Requires membership of nine be appointed by the Governor, one public member appointed by the Senate Committee on Rules, and one public member appointed by the

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Speaker of the Assembly. Requires the board to include five members who have expertise in psychedelic facilitation and four public members. Requires at least one member to have experience as a facilitator as part of a U.S. Food and Drug Administration-approved clinical trial; at least one member to have experience in training and supervising facilitators; at least one member to be a licensed physician or licensed advanced practice clinician; at least one member to have experience providing mental health care to veterans; and at least one member to be a licensed marriage and family therapist, a licensed clinical social worker or board-certified chaplain.

- Prohibitions on family members of individuals with economic interests in psychedelic facilitation education programs and institutions from being Board members.
- Administrative operations such as the authority to hire staff, being subject to open meetings laws, authority to require licensees to collect and report relevant information and data, and the requirement that the Board establish, through regulations, a complaint, review, and disciplinary process for facilitators who engage in misconduct.
- Requirements for the Board to establish all of the professional standards for facilitators
 and for the Board to develop a system to allow for the purchase and administration of
 regulated psychedelic substances in the presence of a facilitator but without the facilitator
 directly handling the regulated psychedelic substances so that the facilitator may avoid
 trafficking in Schedule I or Schedule II substances.
- Authority for the Board to establish all fees related to the regulation of facilitators.

This bill requires the Board to adopt regulations by January 1, 2026 and begin accepting applications for licensure as a facilitator by April 1, 2026 that outline how regulated facilitation happens, including but not limited to regulations establishing:

- The scope of practice for facilitators and the qualifications, education, and training requirements that facilitators must meet.
- Requirements for holding and verifying completion of medical and mental health screenings, including a safety screen, at least one preparation session, an administration session, at least one follow-up evaluation, and at least one integration session.
- A medical, mental health, family history and contraindications safety screen that a participant must complete prior to an administration session.
- The informed consent form that each regulated psychedelic facilitator and participant must sign before providing or receiving regulated psychedelic facilitation verifying the participant was provided accurate and complete health information, the participant was informed the regulated psychedelic substances have not received FDA approval, and the participant was informed of potential and identified risks, benefits, contraindications, and negative outcomes of the psychedelic substance, and the method of administration and facilitation process.
- Conditions of the set and setting in which the administration session must take place and proper locations for where regulated psychedelic facilitation may take place.
- Age verification procedures to ensure that a participant is 21 years of age or older.

This bill specifies that education standards the Board adopts through regulation include education and training on participant safety, contraindications, mental health, mental state, physical health, physical state, social and cultural considerations, physical environment, screening, preparation, administration, integration, ethics, facilitation skills, and compliance with California regulations and laws. Allows for limited waivers of education and training requirements based on an applicant's prior experience, training, or skill with regulated psychedelic substances. Requires

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education and training standards adopted by the Board to include practicum requirements with a practicum supervisor but specifies that a facilitator is not required to have a professional license or professional degree other than a facilitator license. Authorizes the Board to consider expedited approval or partial approval for education programs that are already in existence in the state to train licensed mental health professionals in the provision of psychedelic facilitation.

This bill requires Board regulations to also include de-identified data collection and reporting requirements for facilitators in order to comprehensively measure the Facilitators Act's success, safety, quality, impact on individuals' well-being and public health, including adverse events experienced during, immediately after, or after the passage of time with information about substance, dosage, and other contextual information.

This bill authorizes the Board to license facilitators 21 years of age or older who: complete the education and curriculum requirements the Board will establish by regulation at a Board approved school; who passes a facilitator competency assessment the Board creates and administers or that is offered by an entity designated by the Board; who successfully passes a background investigation; who pays all fees the Board will establish through regulation or; who holds a current and valid registration, licensure, or license from any other state whose licensure requirements meet or exceed these.

This bill establishes various prohibited activities for applicants and licensees.

This bill provides title protection for facilitators.

This bill specifies various aspects of the Division, including:

- The purpose and intent of the Division is to establish a comprehensive system to control and regulate the provision of psychedelic facilitation; the production, distribution, transportation, storage, processing, manufacturing, testing, quality control, and sale of regulated psychedelic substances for use only in conjunction with regulated psychedelic facilitation at approved locations; the approval of locations where regulated psychedelic facilitation may take place and; the collection and publication of deidentified and aggregate data and information on the implementation and outcomes of the Act.
- The Director is appointed by the Governor and subject to confirmation by the Senate Committee on Rules.
- The Division has as the power, duty, purpose, responsibility, and jurisdiction to regulate regulated psychedelic substances and the provision of psychedelic facilitation, and to approve locations where psychedelic facilitation may take place.
- The Division must adopt regulations by January 1, 2026 concerning psilocybin, psilocyn, the spores or mycelium capable of producing mushrooms that contain psilocybin and psilocyn, and MDMA and must, at least every two years thereafter, adopt regulations concerning additional substances identified as regulated psychedelic substances, if recommended by the Oversight Committee.
- Authority to employ individuals who are not peace officers to provide investigative services.

This bill requires the Division to convene the Oversight Committee to advise the Division and the Board, composed of 14 individuals who reside in California appointed by the Governor with at least one person in expertise in the following areas: mental or behavioral health; psychedelic

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facilitation; issues confronting veterans; developing and implementing evaluation methodologies to assess the outcomes of a program, including its achievements, safety, quality, and impact on individuals; health care insurance or barriers in access to health care; emergency medical services or first responders; mycology and regulated psychedelic substance cultivation; training psychedelic facilitators; the provision of harm reduction; harm reduction systems; regulated psychedelic substance research; indigenous uses of psychedelic substances; public health data collection and; expertise in naturopathic medicine.

This bill requires the Division to adopt regulations to establish categories of licensure and registration including, but not limited to:

- A cultivation, processing, or manufacture license that would allow solely for the provision and sale of regulated psychedelic substances at the premises of an approved location for use during the administration session of a regulated psychedelic facilitation at that approved location.
- A testing license for the testing of regulated psychedelic substances for quality, concentration, and contaminants.

This bill requires the Division to adopt regulations for:

- Limitations on the number of licenses for cultivation, processing, or manufacture of regulated psychedelic substances and the volume of regulated psychedelic substances produced by licensees to ensure the amount of regulated psychedelic substances does not exceed the amount necessary to meet the demand for regulated psychedelic facilitation.
- Requirements and standards for testing regulated psychedelic substances for quality, concentration, and contaminants.
- Requirements for labeling regulated psychedelic substances.
- Prohibitions on advertising, branding, and marketing regulated psychedelic substances, including prohibitions on claiming the regulated psychedelic substance is safe and effective or making health or medical claims about regulated psychedelic substances unless in compliance with federal law.
- Requirements governing the licensing and operation of licensees, including psychedelic facilitation centers and approved locations
- Procedures, policies, and programs to ensure that the licensing of regulated psychedelic substances and the provision of regulated psychedelic facilitation is equitable and inclusive and to promote the licensing of and the provision of regulated psychedelic facilitation to persons from low-income communities; to persons who face barriers to access to health care; to persons who have a history of traditional or indigenous use of regulated psychedelic substances; to persons who are or were first responders; and to persons who are veterans.

This bill requires the Division to enforce laws related to the cultivation, producing, manufacturing, processing, preparing, delivery, storage, sale, and testing of regulated psychedelic substances.

This bill requires the Division to collect and annually publish information on the its website pertaining to the implementation and outcomes of the Assisted Therapy Act to comprehensively measure its success, safety, quality, and impact on individuals' well-being and public health. Requires the Division to consult with DPH on the best data collection, processing, and reporting

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methodologies and authorizes it to contract or collaborate with one or more California public universities to research and evaluate the Assisted Therapy Act. Specifies that information is deidentified or aggregated so no individual participant is identified and that information and data shall not be sold.

This bill establishes a Psychedelic Substances Public Education and Harm Reduction Fund available to the Office of Community Partnerships and Strategic Communications within the Governor's Office of Planning and Research upon appropriation by the Legislature to award grants for public education relating to psychedelic substances, including their limitations and potential risks, and mitigation measures, in addition to potential benefits as well as harm reduction.

This bill authorizes a city, county, or a city and county to reasonably regulate the time, place, and manner of regulated psychedelic facilitation within its boundaries but prohibits a city, county, or a city and county from banning or completely prohibiting facilitator operations and regulated psychedelic facilitation. Prohibits a city, county, or a city and county from enacting a greater fine or penalty for conduct related to regulated psychedelic facilitation or substances than is allowed under state law and from requiring an additional license or the payment of a fee in addition to the state license and fee for conduct related to regulated psychedelic facilitation or regulated psychedelic substance licensees, other than generally applicable licenses and fees that apply to all businesses operating with the jurisdiction. Prohibits a city, county, or a city and county from prohibiting the transportation of regulated psychedelic substances through its jurisdiction on public roads by a licensee or as otherwise allowed by the Acts.

This bill prohibits an individual form being arrested, prosecuted, penalized, sanctioned, or otherwise denied any benefit and prohibits a person from being subject to seizure or forfeiture of assets for allowing property the person owns, occupies, or manages to be used for any of the activities conducted lawfully under the Acts at an approved location or for enrolling or employing a person who engages in regulated psychedelic substance-related activities lawfully. Specifies that the use of regulated psychedelic substances in connection with regulated psychedelic facilitation shall not disqualify a person from any needed medical procedure or medical treatment or any other lawful health-related service, shall not, by itself, be the basis for punishing a person currently under parole, probation, or other state-supervised release, including pretrial release. Specifies that the Acts shall not restrict the sale, possession, display, or cultivation of living fungi, plants, or seeds that were lawful before the enactment of the Acts and that engaging in regulated psychedelic substance-related activities shall not, by itself, be the basis to deny eligibility for any public assistance program, unless required by federal law.

This bill makes it a misdemeanor for any person who violates any of the provisions of the Facilitator's Act punishable by imprisonment in county jail not exceeding six months, by a fine not to exceed \$2500, or by both, and which may result in the suspension or revocation of the licenseholder's license.

This bill includes uncodified findings and declarations.

This bill contains a severability provision.

This bill contains technical and conforming changes.

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COMMENTS

1. Need For This Bill

According to the author:

Senate Bill 1012 authorizes the use of certain psychedelic substances in a regulated, therapeutic context under the supervision of a licensed and trained facilitator for adults 21 and older. SB 1012 establishes the Regulated Psychedelic Substances Advisory Committee to oversee and make recommendations to the Board of Regulated Psychedelic Facilitators to license and train facilitators in providing psychedelic assisted therapy, including preliminary safety screenings and follow-up integration sessions. This bill does not allow the sale, personal possession, or use of psychedelics outside of a regulated context.

When administered with proper screening and support, psychedelics have been shown to offer powerful relief to people struggling with mental health and addiction disorders. SB 1012 takes an evidence-based approach to providing access to these promising treatments.

Last fall, the Legislature passed SB 58, my legislation that would have decriminalized the personal use and possession of certain psychedelic substances. In a message explaining his decision to veto the bill, Governor Newsom urged the Legislature to send him a bill establishing therapeutic guidelines for the use of psychedelics in California. As the Governor stated in his veto message: "Both peer-reviewed science and powerful personal anecdotes lead me to support new opportunities to address mental health through psychedelic medicines like those addressed in this bill. Psychedelics have proven to relieve people suffering from certain conditions such as depression, PTSD, traumatic brain injury, and other addictive personality traits. This is an exciting frontier and California will be on the front-end of leading it. . . . I urge the legislature to send me legislation next year that includes therapeutic guidelines."

Senate Bill 1012 is a direct response to the Governor's well-articulated request.

2. Hallucinogens

Hallucinogens¹ are a diverse group of drugs that alter a person's perception or awareness of their surroundings. Some hallucinogens are found in plants and fungi, and some are synthetically produced. According to the National Institute on Drug Abuse, hallucinogens are commonly split into two categories: classic hallucinogens and dissociative drugs. Both types can cause hallucinations, and dissociative drugs can cause the user to feel disconnected from their body or environment. Hallucinogens can be consumed in a variety of ways, including swallowed as tablets, pills, or liquid, consumed raw or dried, snorted, injected, inhaled, vaporized, smoked, or

¹ Some advocates and researchers use the term psychedelic rather than hallucinogen while others use the terms interchangeably. Notably, some sources define psychedelics as a subset of hallucinogens. The term entheogenic has come into use more recently to describe this class of substances. This analysis uses the term hallucinogen due to its use in the controlled substance schedules in the state's Uniform Controlled Substances Act.

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absorbed through the lining of the mouth using drug-soaked pieces of paper. Common hallucinogens include DMT, psilocybin, peyote, and mescaline.

Many hallucinogenic substances, including DMT, mescaline, psilocybin, and psilocyn are classified as Schedule I substances under the state's Uniform Controlled Substances Act. Schedule I substances are defined as those controlled substances having no medical utility and that have a high potential for abuse. There is research, however, that indicates that many of these substances have therapeutic benefits. (See Davis et. al, *Effects of Psilocybin-Assisted Therapy on Major Depressive Disorder*, JAMA Psychiatry (2020) available at https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2772630; D'Souza et al., *Exploratory Study of the Dose-Related Safety, Tolerability, and Efficacy of Dimethyltryptamine (DMT) in Healthy Volunteers and Major Depressive Disorder*, Neuropsychopharmacol (2022) available at https://www.nature.com/articles/s41386-022-01344-y.)

In recent years, the U.S. Federal Drug Administration (FDA) has designated psilocybin as a "breakthrough therapy" to treat severe depression. (https://www.livescience.com/psilocybin-depression-breakthrough-therapy.html [as of Mar. 15, 2023].) The "breakthrough therapy" designation is "a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint." (https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy> [as of Mar. 15, 2023].)

3. Reform Efforts Related to Hallucinogens

Local Efforts

Efforts to deprioritize the policing or prosecution of conduct related to certain hallucinogens and to acknowledge the therapeutic value of hallucinogens have gained support in recent years. In 2019, voters in Denver approved a measure to make the personal use and possession of psilocybin by adults 21 years of age and older the lowest law enforcement priority and to prohibit the city from spending resources to impose criminal penalties related to such conduct. (Tom Angell, Denver Voters Approve Measure to Decriminalize Psychedelic Mushrooms (May 8, 2019) available at https://www.forbes.com/sites/tomangell/2019/05/08/denver-voters- approve-measure-to-decriminalize-psychedelic-mushrooms/?sh=7c3f101b3ddc>.) The same year, the Oakland City Council passed a resolution prohibiting the use of city funding "to assist in the enforcement of laws imposing criminal penalties for the use and possession of entheogenic plants by adults" and specifies that investigating people for growing, buying, distributing or possessing those substances "shall be amongst the lowest law enforcement priority for the City of Oakland." (Merritt Kennedy, Oakland City Council Effectively Decriminalizes Psychedelic Mushrooms (Jun. 5, 2019) available at https://www.npr.org/2019/06/05/730061916/oakland- city-council-effectively-decriminalizes-psychedelic-mushrooms>.) A resolution passed by the Santa Cruz City Council in 2020 made the personal possession and use of entheogenic plants and fungi a low priority for law enforcement. (David E. Carpenter, Santa Cruz is Third U.S. City to Decriminalize Psilocybin, Plant Medicine, as Advocacy Expands (Feb. 1 2020) available at .) A similar measure was passed by the Ann Arbor City Council the same year. (Associated Press, Ann Arbor Decriminalizes Magic Mushrooms, Psychedelic Plants (Sept. 26, 2020) available at

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https://apnews.com/article/plants-archive-fungi-ann-arbor-

b0ce69ca0961c150e0f900e8ea4cf432>.) Initiative 81, the Entheogenic Plant and Fungus Policy Act of 2020, makes "the investigation and arrest of persons 18 years of age or older, for non-commercial planting, cultivating, purchasing, transporting, distributing, engaging in practices with, and/or possessing entheogenic plants and fungi" among the lowest enforcement priorities for Washington D.C.'s local police department. (https://decrimnaturedc.org/wp-content/uploads/2020/02/Entheogenic_Plant_and_Fungus_Policy_Act_of_2020_published_2_18_2020.pdf) Additional jurisdictions have passed similar measures since 2020.

Statewide Efforts

In 2020, Oregon voters approved Measure 109, the Psilocybin Services Act, which directed the Oregon Health Authority to create a state-licensed, psilocybin-assisted therapy program over a two-year period. (Kristian Foden-Vencil, *Oregon Voters Legalize Therapeutic Psilocybin* (Nov. 4, 2020) available at https://www.opb.org/article/2020/11/04/oregon-measure-109-psilocybin/>.) In implementing Measure 109, Oregon had to determine how to license and regulate the manufacturing, transportation, delivery, sale and purchase of psilocybin products as well as the provision of psilocybin services.

(https://www.oregon.gov/oha/ph/preventionwellness/pages/oregon-psilocybin-services.aspx) Following the two-year development period for psilocybin services, the state began taking license applications on January 2, 2023.

(https://sharedsystems.dhsoha.state.or.us/DHSForms/Served/le4226.pdf.) Psilocybin services refers to preparation, administration, and integration sessions provided by a licensed facilitator. (*Id.*) Psilocybin services are available to individuals aged 21 and older and do not require a prescription or medical referral. (*Id.*) The psilocybin products consumed must be cultivated or produced by a licensed psilocybin manufacturer and can only be provided to a client at a licensed psilocybin service center during an administration session. (*Id.*) Psilocybin services are expected to be available to the public later this year. (Andrew Selsky and Mike Corder, *Oregon Closer to Magic Mushroom Therapy, But Has Setback* (Mar. 10, 2023) available at ">https://apnews.com/article/magic-mushroom-therapy-psilocybin-legalization-oregon-bd1b3c43cab74437e8868751c9c9591d>">https://apnews.com/article/magic-mushroom-therapy-psilocybin-legalization-oregon-bd1b3c43cab74437e8868751c9c9591d>">https://apnews.com/article/magic-mushroom-therapy-psilocybin-legalization-oregon-bd1b3c43cab74437e8868751c9c9591d>">https://apnews.com/article/magic-mushroom-therapy-psilocybin-legalization-oregon-bd1b3c43cab74437e8868751c9c9591d>">https://apnews.com/article/magic-mushroom-therapy-psilocybin-legalization-oregon-bd1b3c43cab74437e8868751c9c9591d>">https://apnews.com/article/magic-mushroom-therapy-psilocybin-legalization-oregon-bd1b3c43cab74437e8868751c9c9591d>">https://apnews.com/article/magic-mushroom-therapy-psilocybin-legalization-oregon-bd1b3c43cab74437e8868751c9c9591d>">https://apnews.com/article/magic-mushroom-therapy-psilocybin-legalization-oregon-bd1b3c43cab74437e8868751c9c9591d>">https://apnews.com/article/magic-mushroom-therapy-psilocybin-legalization-oregon-bd1b3c43cab74437e8868751c9c9591d>">https://apnews.com/article/magic-mushroom-therapy-psilocybin-legalization-oregon-bd1b3c43cab74437e8868751c9c9591d>">https://apn

During the same election, Oregon voters approved Measure 110 which reduced the personal noncommercial possession of small amounts of a Schedule I-IV controlled substance, including several hallucinogens, from a criminal offense to a civil violation resulting in a maximum fine of \$100. (Legislative Policy and Research Office, *Measure 110 (2020): Background Brief* (December 2020) available at

https://www.oregonlegislature.gov/lpro/Publications/Background-Brief-Measure-110-(2020).pdf.)

More recently, Colorado voters approved Proposition 122 which, among things, decriminalized the personal possession and use of psilocybin, psilocyn, DMT, ibogaine and mescaline for adults aged 21 and older. (Andrew Kenney, *Coloradans Voted to Legalize Psilocybin. What's Next?* (Nov. 25, 2022) available at https://www.cpr.org/2022/11/25/colorado-psilocybin-legalization-whats-next/.) The measure additionally establishes a program for licensed "healing centers" to administer psilocybin and psilocyn to adults by licensed professionals, and creates a regulatory framework for the manufacture, cultivation, testing, storage, transport, transfer, delivery, sale, and purchase of the covered substances between healing centers and other permitted entities. (*Id.*; https://www.sos.state.co.us/pubs/elections/Initiatives/titleBoard/filings/2021-2022/58Final.pdf)

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4. SB 58

SB 58 (Wiener) was vetoed last year. SB 58 would have made it lawful to possess, prepare, obtain, or transport specified quantities of psilocybin, psilocyn, dimethyltryptamine (DMT), and mescaline, for personal use, as defined, by persons 21 years of age or older. In his veto message, Governor Newsom wrote:

This bill would, beginning on January 1, 2025, decriminalize the possession, preparation, obtaining, or transportation of specified quantities of mescaline, dimethyltryptamine (DMT), psilocybin, and psilocyn, for personal use by persons 21 years of age or older. This bill would also decriminalize the therapeutic use of the substances following the Legislature's adoption of a framework governing therapeutic use.

Both peer-reviewed science and powerful personal anecdotes lead me to support new opportunities to address mental health through psychedelic medicines like those addressed in this bill. Psychedelics have proven to relieve people suffering from certain conditions such as depression, PTSD, traumatic brain injury, and other addictive personality traits. This is an exciting frontier and California will be on the front-end of leading it.

California should immediately begin work to set up regulated treatment guidelines - replete with dosing information, therapeutic guidelines, rules to prevent against exploitation during guided treatments, and medical clearance of no underlying psychoses. Unfortunately, this bill would decriminalize possession prior to these guidelines going into place, and I cannot sign it.

I urge the legislature to send me legislation next year that includes therapeutic guidelines. I am, additionally, committed to working with the legislature and sponsors of this bill to craft legislation that would authorize permissible uses and consider a framework for potential broader decriminalization in the future, once the impacts, dosing, best practice, and safety guardrails are thoroughly contemplated and put in place.

5. Effect of This Bill

This bill establishes the Regulated Psychedelic Facilitators Act and Regulated Psychedelic-Assisted Therapy Act administered by new state entities, each of which is required to undertake regulatory efforts to determine, define, and establish standards for psychedelic facilitation in the state. For a detailed analysis of the provisions of the bill related to the creation of that regulatory framework, please see the Senate Committee on Business and Professions analysis.

This bill makes it a misdemeanor for any person to violate the provisions of the Facilitators Act punishable by imprisonment in county jail not exceeding six months, by a fine not to exceed \$2,500, or by both, and provides that a violation may result in the suspension or revocation of the licenseholder's license.

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This bill makes a violation of the Assisted Therapy Act a misdemeanor punishable by imprisonment in county jail for six months, a fine of not less than one thousand dollars \$1,000, or both, and forfeiture of any license granted under its provisions.

Finally, this bill exempts from prosecution certain conduct related to controlled substances when the substance involved is a "regulated psychedelic substance" and the conduct occurs lawfully within the context of the Facilitators Act or the Assisted Therapy Act. For example, possession of one of the "regulated psychedelic substances" when possessed lawfully under the Facilitators Act or the Assisted Therapy Act would not be subject to prosecution under Health and Safety Code section 11350. The bill includes exemptions for the following drug offenses when the conduct lawfully occurs under the Facilitators Act or the Therapy Act: possession for sale; transporting, importing, selling, furnishing, administering or giving away, or offering or attempting to do any of those things; delivering, furnishing, or transferring, possessing with intent to deliver, furnish, or transfer, or manufacturing with the intent to deliver, furnish, or transfer, drug paraphernalia, knowing that it will be used to plant, propagate, cultivate, grow, harvest, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, conceal, inject, ingest, inhale, or otherwise introduce into the human body a controlled substance; cultivating any spores or mycelium capable of producing mushrooms or other material which contains such a controlled substance with the intent to produce psilocybin or psilocyn; and transporting, importing, selling, furnishing, giving away, or offering to transport, import, sell, furnish, or give away any spores or mycelium capable of producing mushrooms or other material which contain psilocybin or psilocyn.

6. CSAP Concerns

The California State Association of Psychiatrists submitted a letter to the Committee raising concerns with the bill but did not take a position. CSAP writes:

CSAP's concerns with SB 1012 are related to the care of a vulnerable patient population with behavioral health illnesses and who best is able to provide the specialized care to help these patients. While new and innovative treatments to depression, anxiety, and other psychiatric disorders are needed, the evidence to support the therapeutic use of psychedelics is not yet robust enough to justify widespread access, especially for unsupervised use or use in the presence of non-medical individuals.

CSAP believes the Legislature should exercise extreme caution in this area until there is more specifically validated information on psychedelics with respect to the risks, benefits, and alternatives, not just at the individual level, but also at the level of public health and behavioral health.

. . .

CSAP also has concerns about the claim that psychedelics are rarely addictive when administered by a doctor to a patient with a mental illness. As with any mind-altering drug, psychedelics have the potential to be addictive. ... [T]here is no system requirement in place for these substances to be required to be reported on the CURES database so other health care providers are aware that patients are on these substances that can affect their health and have medication interactions.

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CSAP's bottom line on SB 1012 or any other psychedelics-related legislation is patient safety and that no harm occurs to individuals who may seek them out. ...

. . .

Ideally, controlled substances administered in California would only be those approved by the FDA and only prescribed by those who have a license to practice medicine and a DEA specific license for controlled substances.

7. Argument in Support

Heroic Hearts Project, one of the bill's co-sponsors writes:

Senate Bill 1012 establishes a professional licensing board under the California Business, Consumer Services, and Housing Agency for regulated psychedelic facilitators to develop safety screening protocols, training programs, ethical standards, scope of practice guidelines, and regulatory oversight. This legislation will provide therapeutic access for persons 21 and older to certain psychedelic substances under the supervision of a licensed and trained facilitators at approved locations. The proposed legislation regulates the production and testing of certain psychedelic substances and establishes an expert oversight committee to direct all aspects of the program. The bill would create a public-private fund to support public health education related to psychedelics. This bill does not remove criminal penalties for activates involving psychedelic substances outside of the regulated program nor allow for retail sales for use outside the regulated, therapeutic context.

. . .

There is a growing body of credible evidence to show that psychedelics can help reduce symptoms of depression, anxiety, and PTSD when used in proper settings with safeguards like those proposed in this bill, which includes screening, preparation, integration and therapeutic support. ...

Safety is paramount when it comes to psychedelics. Right now, many Californians are seeking psychedelics abroad or from underground sources. By establishing a regulated program for the therapeutic use of psychedelics, SB 1012 aims to enable more equitable and safer access to therapeutic psychedelic services within the state. ...

SB 1012 takes an evidence-based approach to providing access and mitigates risks by requiring that patients and practitioners collaborate to help ensure a safe experience. ...

• •

Last fall, the Legislature passed SB 58, legislation that would have decriminalized the personal use and possession of certain psychedelic substances. In a message explaining his decision to veto the bill, Governor Newsom urged the Legislature

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to send him a bill establishing therapeutic guidelines for the use of psychedelics in California.

• • •

Senate Bill 1012 is a direct response to the Governor's well-articulated request.

8. Argument in Opposition

According to the California Narcotics Officers' Association:

SB 1012 omits any requirement that a licensed therapist, psychologist or psychiatrist to oversee the legalized psychedelic therapeutic treatment. The bill doesn't limit the use of psychedelic substances for therapeutic treatment purposes – despite the proponents' semantic gymnastics. Therapists were replaced [following amendments to the bill] with undefined, ambiguous "facilitators."

... The purpose of SB 1012 is to make psychedelic facilitation available to the public with no requirement that medically-overseen "psychedelic-assisted therapy" take place.

SB 1012 remains inconsistent with Governor Newsom's directive when he vetoed SB 58 (Wiener) that would have decriminalized various hallucinogens, but not ecstacy/MDMA. ...

SB 1012 seeks to replicate and expand upon the Oregon psychedelic law which is limited to only mushrooms. ...

SB 1012 permits non-doctors and others with no mental health training (facilitators) to dispense the most restricted of all drugs- Schedule I (including ecstasy) without a prescription, or a psychiatric referral or even a showing of a medical/therapeutic need. ...

. . .

The psychological consequences of psilocybin use include hallucinogens and an inability to discern fantasy from reality. ...

. . .

Under SB 1012, psychedelic "facilitators" will oversee the health and safety of persons using hallucinogenic drugs, despite no mandated education, licensing or training standards in the bill. ...

• • •

Our dedicated law enforcement professionals know all too well the detrimental and deadly effects caused by the decriminalization of intoxicating controlled substances – and we are not alone. Recently, the state of Oregon repealed their

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drug decriminalization laws after years of increasing addiction, homelessness, crime, overdoses and death.

SB 1012 is not a real medical, psychedelic-assisted psychotherapy bill. Regrettably, the public safety risks, local management issues and detrimental impact to our communities significantly outweigh the harm that decriminalizing these drugs under the guise of facilitated use will cause.