### SENATE COMMITTEE ON APPROPRIATIONS Senator Anna Caballero, Chair 2023 - 2024 Regular Session

# SB 1012 (Wiener) - The Regulated Psychedelic Facilitators Act and the Regulated Psychedelic-Assisted Therapy Act

Version: March 20, 2024

Urgency: No Hearing Date: May 13, 2024 Policy Vote: B., P. & E.D. 7 - 4, PUB. S. 3 - 2 Mandate: Yes Consultant: Janelle Miyashiro

**Bill Summary:** SB 1012 establishes the Regulated Psychedelic Facilitators Act and Regulated Psychedelic-Assisted Therapy Act, to be administered by three new state entities: a Division of Regulated Psychedelic-Assisted Therapy, a Board of Regulated Psychedelic Facilitators, and a Regulated Psychedelic Substances Oversight Committee. SB 1012 tasks each new entity with specified regulatory oversight responsibilities to determine, define, and establish standards for psychedelic facilitation in California.

#### **Fiscal Impact:**

 Unknown significant ongoing costs, likely ranging in the low millions of dollars to establish and maintain the Board (General Fund and Regulated Psychedelic Facilitators Fund). The Board would require General Fund or other special fund support until it establishes and collects license fee revenue sufficient to support its operations. It is unknown at what level fees would need to be set, and will depend on the number of applicants who would seek licensure as a facilitator when the Board is required to accept applications in April 2026 and the extent that licensing may grow or be maintained in later years.

Based on boards of similar size, the Department of Consumer Affairs (DCA) estimates total costs of approximately \$1.96 million in Fiscal Year (FY) 2025-26, \$1.87 million in FY 2026-27, and \$1.98 in FY 2027-28 and annually ongoing to establish and maintain the Board. Costs would generally include at least 10.0 staff to support the Board's executive, licensing, and enforcement activities. Other costs would include board member training, per diem, IT expenses, and Attorney General and Office of Administrative Hearings costs. While the estimated fee revenue required to recover the Board's costs is unknown at this time, DCA estimates fees would need to be at least \$4,960 biennially between initial applications, renewals, and other licensing categories.

DCA's Office of Information Services (OIS) estimates an unabsorbable one-time cost of \$557,000 and ongoing costs of \$153,000 associated with setting up a new licensing and enforcement system and will likely require a delayed implementation date to complete necessary IT work.

• Unknown significant ongoing costs, ranging in the millions of dollars to establish and maintain the Division and Committee (General Fund and Regulated Psychedelic-Assisted Therapy Fund). Like the Board, the Division and Committee will also likely

require General Fund support until the Division can establish and collect fee revenue sufficient to support its operations. (See Staff Comments for additional detail.)

- The California Department of Public Health reports ongoing costs of approximately \$200,000 annually to provide guidance and best practices related to data collection, processing, and reporting methods for the Division (General Fund).
- Unknown fiscal impact to the Department of Justice's (DOJ) applicant services
  program to intake and process fingerprint and related background information from
  and transmit state- and federal-level criminal offender record information on
  applicants to the Board. The DOJ may recover its costs to intake and process
  requests through fees charged to the Board. Actual costs to DOJ will depend on,
  among other things, the volume of applicants the program will have to process. To
  the extent there are a significant number of applicants applying for licensure under
  the Acts, the DOJ may have significant workload impacts.
- Unknown, potentially significant cost pressure to the state funded trial court system (Trial Court Trust Fund, General Fund) to adjudicate the crime created by this bill. Certain rights to the defendants are attached to criminal proceedings, including the right to a jury trial and the right to counsel (at public expense if the defendants are unable to afford the costs of representation) and creating new crimes, with increased penalties, could lead to lengthier and more complex court proceedings with attendant workload and resource costs to the court. An eight hour court day costs approximately \$8,000 in staff in workload. If the bill results in 12 or more days spent in court, trial court costs could be in the hundreds of thousands of dollars.

While the courts are not funded on a workload basis, an increase in workload could result in delayed court services and would put pressure on the General Fund to fund additional staff and resources. For example, the 2021-22 Budget included \$90 million one time General Fund to address case backlogs—with \$30 million specifically for certain criminal case backlogs and \$60 million for backlogs across all case types. The Governor's 2024-25 state budget proposes \$83.1 million ongoing General Fund to continue to backfill the Trial Court Trust Fund for expected revenue declines.

 Unknown, potentially significant reimbursable annual costs (General Fund, local funds) to counties in the hundreds of thousands of dollars to low millions of dollars to counties for increased incarceration costs. The average annual cost to incarcerate a defendant in county jail is approximately \$29,000. If 10 defendants statewide are sentenced annually to an average of six months in county jail for any specified violation of the Acts, the total cost to counties would be \$145,000.

**Background:** Hallucinogens 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 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 psilocin 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.

Oregon Measure 109, Psilocybin Mushroom Services Program Initiative. 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. 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. Following the twoyear development period for psilocybin services, the state began taking license applications on January 2, 2023. Psilocybin services refers to preparation, administration, and integration sessions provided by a licensed facilitator. Psilocybin services are available to individuals aged 21 and older and do not require a prescription or medical referral. 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.

# **Proposed Law:**

## <u>Provisions related to the Psychedelic Facilitators Act, the Board of Regulated</u> <u>Psychedelic Facilitators, and Licensed Facilitators</u>

- Establishes the Board of Regulated Psychedelic Facilitators within the Department of Consumer Affairs. Requires the Board to be appointed by April 1, 2025, adopt regulations before January 1, 2026, and begin accepting license applications by April 1, 2026.
  - Requires the Board to carry out all necessary activities in the regulation of licensed psychedelic facilitators, as specified. This includes, among other things, adopting regulations consistent with recommendations made by the Regulations Psychedelic Substances Expert Oversight Committee; establishing educational, training, examination, practicum, and supervision requirements; establishing professional standards for facilitators; and establishing requirements and processes for approving schools and programs offering regulated psychedelic facilitation training.
  - Requires the Board to establish reasonable initial license and renewal fees to cover its operational costs. Requires the Board to assess renewal license fees biennially. Establishes the Regulated Psychedelic Facilitators Fund in the State Treasury.
- Establishes requirements for licensure as a regulated psychedelic facilitator, as specified. Provides that a license is valid for two years.

<u>Provisions related to the Regulated Psychedelic-Assisted Therapy Act, Division of</u> <u>Regulated Psychedelic-Assisted Therapy, and Marketplace Regulation for Psychedelic</u> <u>Facilitation</u>

- Establishes the Regulated Psychedelic-Assisted Therapy Act to 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.
  - The collection and publication of deidentified and aggregate data and information on the implementation and outcomes of the Act.
- Establishes the Division of Regulated Psychedelic-Assisted Therapy in the Business, Consumer Services, and Housing Agency. Provides that the Division has 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.
  - Requires the Division to convene the Regulated Psychedelic Substances Expert Oversight Committee by April 1, 2025. Tasks the Committee with advising the Division and the Board on the development of standards and regulations that protect public health and safety while ensuring a regulate environment to provide safe access to regulated psychedelic facilitation.
  - Requires the Division to establish categories of licensure and registration, as specified.
  - Tasks the Division with enforcing the laws and regulations relating to the cultivation, producing, manufacturing, processing, preparing, delivery, storage, sale, and testing of regulated psychedelic substances.
  - Requires the Division to begin to accept and process applications for licensure by April 1, 2026.
  - Authorizes the Division to establish license fees. Establishes the Regulated Psychedelic-Assisted Therapy Fund in the State Treasury to support the Division's administrative and enforcement operations.

# Other Provisions

- Establishes a Psychedelic Substances Public Education and Harm Reduction Fund. Provides that moneys in the Fund be 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.
- Establishes specified prohibitions for licenseholders and subjects them to enforcement and discipline by the Board and Division.
  - Creates a new misdemeanor and establishes specified penalties.

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- Provides that any penalties collected by the Board and Division be deposited directly into the General Fund.
- 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. Additionally prohibits these jurisdictions 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.
- Specifies that an individual shall not be arrested, prosecuted, penalized, sanctioned, or otherwise denied any benefit. Specifies an individual shall not be 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.
- States legislative declarations and intent.
- Establishes definitions for purposes of the new Acts.

**Related Legislation:** SB 58 (Weiner, 2023) would have decriminalized the use of certain psychedelics for personal use by individuals 21 years of age or older. SB 58 would have also created a workgroup to study and recommend a framework for governing the therapeutic use of psychedelics. SB 58 also would have defined "facilitated or supported use" as supervised or assisted personal use of a psychedelic by an individual or group of persons 21 years of age or older, or the assisting or

supervising of such persons in such use, within the context of spiritual guidance, community-based healing, or related service. SB 58 was vetoed.

**Staff Comments:** While the total fiscal impact of this bill is unknown at this time, onetime and ongoing costs will likely range in the millions of dollars and will depend on the scope and size of the licensing programs and the ability for the Board, Division, and Committee to meet their responsibilities on the timeline required by the bill. The programs will likely need significant General Fund or other special fund support until fees established by the Acts can support their operations.

For comparison, the Oregon Psilocybin Services (OPS) section in the Oregon Health Authority is tasked with similar regulatory responsibilities as those required of the Board, Division, and Committee under this bill.

Oregon passed its Measure 109 and after a two-year development process from January 1, 2021 to December 31, 2022 to establish regulations for implementation of the measure, OPS adopted rules on December 21, 2022 and began accepting applications for licensure on January 2, 2023. OPS received \$2.5 million General Fund and \$760,000 other special fund for start-up costs and 22.0 staff positions for the 2021-23 biennium to begin implementation. OPS additionally received \$3.1 million General Fund for the 2023-25 biennium, as OPS anticipated fees would take several months to a year following when it began accepting license applications before these fees could cover the cost of OPS's work<sup>1</sup>. OPS regulates four license types: Facilitator, Manufacturer, Service Center, and Laboratory.

This bill requires the Board to be appointed by April 1, 2025, adopt regulations by January 1, 2026, and begin accepting license applications by April 1, 2026. The bill requires the Division to convene the Committee by April 1, 2025, adopt regulations concerning psilocybin, psilocin, and MDMA by January 1, 2026, and begin accepting license applications by April 1, 2026. The bill also requires the Committee to publish its first annual report on its activities and recommendations by January 1, 2026. It is unknown if the Board, Division, and Committee may complete all necessary work—including hiring staff, developing and adopting regulations, conducting meetings and stakeholder outreach, approving programs, building an IT licensing system, and establishing professional qualifications for education, training, experience, professional practice, standards of care, and ethics—before the Board and Division would be required to start accepting license applications. To meet these timelines, these programs will likely have higher start-up costs that may necessitate greater General Fund or other special fund support until fee revenue is sufficient to cover their costs.

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<sup>&</sup>lt;sup>1</sup> <u>2023-25 Oregon Health Authority Legislatively Adopted Budget</u>. Noted in the Center for Health Protection Program Unit Summary.