California State Assembly

HEALTH

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AGENDA

Tuesday, January 9, 2024
1:30 p.m. -- 1021 O Street, Room 1100

BILLS HEARD IN FILE ORDER

TESTIMONY MAY BE LIMITED:

2 WITNESSES PER SIDE, 3 MINUTES EACH

1.	AB 1316	Irwin	Emergency services: psychiatric emergency medical conditions.
2.	AB 82	Weber	Dietary supplements for weight loss and over-the-counter diet pills.
3.	AB 941	Waldron	Controlled substances: psychedelic-assisted therapy.

Date of Hearing: January 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 1316 (Irwin and Ward) – As Amended January 3, 2024

SUBJECT: Emergency services: psychiatric emergency medical conditions.

SUMMARY: Revises the definition of "psychiatric emergency medical condition" to apply that definition regardless of whether the patient is voluntary, or is involuntarily detained for evaluation and treatment, under certain circumstances. Requires the Medi-Cal program to cover emergency services and care necessary to treat an emergency medical condition, as defined, including all professional physical, mental, and substance use treatment services, including screening examinations necessary to determine the presence or absence of an emergency medical condition and, if an emergency medical condition exists, for all services medically necessary to stabilize the beneficiary. Specifically, **this bill**:

1) Revises the definition of "psychiatric emergency medical condition" to clarify that the definition applies regardless of whether the patient is voluntary or involuntarily detained for evaluation and treatment pursuant to the Lanterman-Petris-Short Act (LPS Act).

2) Requires the Medi-Cal program to cover emergency services and care necessary to treat an emergency medical condition, as defined, including all professional physical, mental, and substance use treatment services, including screening examinations necessary to determine the presence or absence of an emergency medical condition.

3) Prohibits Medi-Cal requirements, duties or contractual agreements from unreasonably delaying or denying the provision of medically necessary care to a patient with a psychiatric emergency medical condition, regardless of whether the patient is voluntary or involuntarily detained for evaluation and treatment pursuant to the LPS Act.

EXISTING LAW:

1) Licenses and regulates hospitals, including GACHs and APH, by the Department of Public Health (DPH). Permits GACHs, in addition to the basic services all hospitals are required to offer, to be approved by DPH to offer special services, including, among other services, an ED, and psychiatric services. [Health and Safety Code (HSC) §1250 and §1255, *et seq*.]

2) Licenses PHFs by the Department of Health Care Services (DHCS), which are defined as health facilities that provide 24-hour inpatient care for people with mental health disorders, whose physical health needs can be met in an affiliated hospital or in outpatient settings. [HSC §1250.2]

3) Requires EDs, under the federal Emergency Medical Treatment and Active Labor Act (EMTALA) and also under similar provisions of state law (state EMTALA), to provide emergency screening and stabilization services without regard to the patient's insurance status or ability to pay. Federal EMTALA imposes this requirement on any hospital that participates in Medicare. State EMTALA imposes this requirement on any hospital that operates an ED. [42 United States Code §1395dd; HSC §1317]

4) Defines "emergency services and care," under state EMTALA, as medical screening, examination, and evaluation by a physician to determine if an emergency medical condition or active labor exists and, if it does, the care, treatment, and surgery, if within the scope of that person's license, necessary to relieve or eliminate the emergency medical condition, within the capability of the facility. [HSC §1317.1 (a)(1)]

5) Defines "emergency services and care," under state EMTALA, to also mean an additional screening, examination, and evaluation by a physician, or other personnel to the extent permitted by the scope of their licensure and clinical privileges, to determine if a psychiatric emergency medical condition exists, and the care and treatment necessary to relieve or eliminate the psychiatric emergency medical condition, within the capability of the facility. Specifies that the care and treatment necessary to relieve or eliminate a psychiatric emergency medical condition may include admission or transfer to a psychiatric unit within a GACH, or to an APH. [HSC §1317.1 (a)(2)]

6) Defines "emergency medical condition" to mean a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in any of the following:
   a) Placing the patient's health in serious jeopardy;
   b) Serious impairment to bodily functions; or,
   c) Serious dysfunction of any bodily organ or part. [HSC §1317.1 (b)]

7) Prohibits a person needing emergency services and care from being transferred from a hospital to another hospital for any nonmedical reason (such as the person's inability to pay for any emergency service or care) unless certain conditions are met, including that the person has been provided with emergency services so that it can be determined, within reasonable medical probability, that the transfer will not create a medical hazard to the person. [HSC §1317.2]

8) Requires a psychiatric unit within a GACH, a PHF of more than 16 beds, or an APH, to accept a transfer of a person with a psychiatric emergency medical condition, as defined, from a health facility that maintains and operates an ED and the receiving facility to provide emergency services and care to that person, regardless of whether the facility operates an ED, if all of the following requirements are met:
   a) The treating physician at the sending facility has determined that the patient is medically stable and appropriate for treatment in a psychiatric setting and has included that determination in the patient's medical record;
   b) The receiving facility has an available bed; and,
   c) The receiving facility has appropriate facilities and qualified personnel available to provide the services or care. [HSC §1317.4b]

9) Specifies that the provisions described in 8) above do not apply to a PHF that is county owned and operated. [*Id.*]

10) Specifies that the provisions in 8) above do not preempt any county or any other governmental agency acting within its authority from regulating emergency care or patient transfers, including the imposition of more specific duties. Clarifies that any inconsistent requirements imposed by the Medi-Cal program preempt the requirements in 8) above with respect to Medi-Cal beneficiaries, and to the extent hospitals and physicians enter into

contractual relationships with county or other governmental agencies that impose more stringent transfer requirements, those contractual agreements control. [HSC §1317.7]

11) Establishes the LPS Act and declares the intent of the Legislature to end the inappropriate, indefinite, and involuntary commitment of persons with mental health disorders, developmental disabilities, and chronic alcoholism, as well as to safeguard a person's rights, provide prompt evaluation and treatment, and provide services in the least restrictive setting appropriate to the needs of each person. [Welfare and Institutions Code (WIC) §5000, *et seq*.]

12) Authorizes a peace officer, member of the attending staff of a "designated facility," as defined, member of the attending staff of a designated facility, or other professional person designated by the county, upon probable cause, to take a person with a mental disorder who is a danger to self or others, or is gravely disabled, into custody (referred to as a "5150" hold) and place them in a designated facility. [WIC §5150]

13) Defines "designated facility" or "facility designated by the county for evaluation and treatment" as a facility that is licensed or certified as a mental health treatment facility or a hospital, as defined, and includes, but is not limited to, a licensed psychiatric hospital, a licensed psychiatric health facility, and a certified crisis stabilization unit. [WIC §5008]

14) Authorizes a county behavioral health director to develop procedures for the county's designation and training of professionals who will be designated to perform functions under Section 5150. Authorizes these procedures to include, but not be limited to, the following:
    a) The license types, practice disciplines, and clinical experience of professionals eligible to be designated by the county;
    b) The initial and ongoing training and testing requirements for professionals eligible to be designated by the county;
    c) The application and approval processes for professionals seeking to be designated by the county, including the timeframe for initial designation and procedures for renewal of the designation; and,
    d) The county's process for monitoring and reviewing professionals designated by the county to ensure appropriate compliance with state law, regulations, and county procedures. [WIC §5121]

15) Requires a health care service plan that covers hospital, medical, or surgical expenses, or its contracting medical providers, to provide 24-hour access for enrollees and providers, including, but not limited to, noncontracting hospitals, to obtain timely authorization for medically necessary care, for circumstances where the enrollee has received emergency services and care is stabilized, but the treating provider believes that the enrollee may not be discharged safely. [HSC §1371.4 (a)]

16) Requires a health care service plan, or its contracting medical providers, to reimburse providers for emergency services and care provided to its enrollees, until the care results in stabilization of the enrollee, except as provided in 17) below. Prohibits, as long as federal or state law requires that emergency services and care be provided without first questioning the patient's ability to pay, a health care service plan from requiring a provider to obtain authorization prior to the provision of emergency services and care necessary to stabilize the

enrollee's emergency medical condition. [HSC §1371.4 (b)]

17) Allows payment for emergency services and care to be denied only if the health care service plan, or its contracting medical providers, reasonably determines that the emergency services and care were never performed, in cases when the plan enrollee did not require emergency services and care; and, the enrollee reasonably should have known that an emergency did not exist. Authorizes a health care service plan to require prior authorization as a prerequisite for payment for necessary medical care following stabilization of an emergency medical condition. [HSC §1371.4 (c)]

18) Requires a health care service plan, if there is a disagreement between the health care service plan and the provider regarding the need for necessary medical care, following stabilization of the enrollee, to assume responsibility for the care of the patient either by having medical personnel contracting with the plan personally take over the care of the patient within a reasonable amount of time after the disagreement, or by having another GACH under contract with the plan agree to accept the transfer of the patient as provided in existing law. Prohibits this requirement from applying to necessary medical care provided in hospitals outside the service area of the health care service plan. [HSC §1371.4 (d)]

FISCAL EFFECT: Unknown. This bill has not yet been analyzed by a fiscal committee.

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, hospital EDs are a critical part of the safety net for Californians in a mental health crisis who desperately need psychiatric treatment. This bill supports hospitals and patients by ensuring psychiatric emergencies are treated with the same urgency and reimbursement practices used for patients with any other medical emergency. The author states that, if a person is on an involuntary hold, this bill ensures this legal status is not an impediment to getting them the psychiatric health care they need, while also ensuring ED beds are available for incoming trauma patients. The author concludes that this bill also makes it clear that Medi-Cal managed care plans must cover all hospital ED visits, including psychiatric emergencies.

2) **BACKGROUND.**

   a) **The LPS Act and designated vs nondesignated facilities**. The LPS Act was enacted in the 1960s to develop a statutory process under which individuals could be involuntarily held and treated in a county-designated facility in a manner that safeguarded their constitutional rights. The LPS Act was intended to balance the goals of maintaining the constitutional right to personal liberty and choice in mental health treatment. Since its passage in 1967, the field of mental health has continued to evolve toward even greater legal rights for mentally disordered persons. WIC Section 5150, part of the LPS Act, allows peace officers, staff members of county-designated facilities, or other county-designated professional persons to take an individual into custody and place them in a facility for 72-hour treatment and evaluation to determine if, due to a mental disorder, the individual is a danger to self or others, or is gravely disabled. The LPS Act imposes strict conditions relating to the detention, assessment, and treatment of the detainee. Provided that specified conditions are met, the peace officer and the medical director of the facility, as well as the professional staff responsible for the evaluation and treatment of the

person, are granted immunity from civil and criminal liability for releasing the detainee at any time prior to the end of the 72-hour hold or for any actions of the person released before or after the 72-hour hold.

Individual counties are responsible for determining whether GACHs, PHFs, APHs, and other licensed facilities qualify to be designated facilities. While the intent of the LPS Act is for authorized individuals to take a person who has been placed on a 5150 hold to a designated facility, if one does not exist, or a person is suffering from another condition that requires immediate emergency medical services, the person is transported to the nearest facility, which is often a non-designated facility with an ED, which under both federal and state EMTALA is required to provide emergency medical services to any individual who presents and requires emergency medical attention.

b) Lack of inpatient psychiatric beds and timeliness of transfers. According to the California Hospital Association (CHA), since 1995 the state has lost at least 37 facilities, either through the elimination of psychiatric inpatient care, or complete hospital closure, representing a 20% drop. CHA states that while there has been an increase in psychiatric beds over the past several years, California has lost nearly 30% of the psychiatric beds it had in 1995. On a per capita basis, accounting for the growth in California's population, this translates into a loss of more than 42% of the psychiatric inpatient beds per capita since 1995. California now has only 17 psychiatric beds for every 100,000 residents, compared to nearly 30 beds per 100,000 in 1995, and well short of the recommended minimum number of 50 psychiatric beds per 100,000.

According to information provided by CHA, the sponsor of this bill, in many instances, long stays in hospital EDs are due to hospitals' difficulty finding an available inpatient psychiatric bed. In the case of individuals with Medi-Cal and those who may be on an involuntary psychiatric hold, hospitals are often instructed by the county to hold the patient in the ED until the county finds the patient a bed. CHA states that hospitals report that it often takes disproportionately longer when awaiting the county to find an inpatient psychiatric bed than it does when the hospital makes the arrangements for all its other patients. This could be due to county workforce challenges that make it difficult to manage the bed finding process on a 24/7 basis. Since inpatient psychiatric services are a Medi-Cal benefit administered by the counties, they may also prefer waiting for an available bed to open up in only those hospitals with which they hold a contract.

c) APHs, PHFs, and crisis stabilization units. Generally, inpatient beds for acute psychiatric patients are either provided in a distinct behavioral health unit of a GACH, in a freestanding APH, or in a PHF. All of these can be, and most are, designated LPS facilities. There are 33 licensed APHs and 29 PHFs in California. APHs are licensed by DPH, and are required to provide medical, nursing, rehabilitative, pharmacy and dietary services, in addition to psychiatric services. PHFs are licensed by DHCS, and while not a hospital, are licensed to provide inpatient acute psychiatric care similar to a psychiatric hospital. However, the requirements for PHFs are not the same as those for APHs. For example, PHFs are not required to provide general medical services. While a PHF is required to have a physician on-call at all times, a patient can only be admitted to a PHF if the individual's physical health care could otherwise be managed on an outpatient basis. An APH, on the other hand, is required to provide a medical service as part of their basic services, which must include a general medicine component. The general medicine

component is required to provide all incidental medical services necessary for the care and support of patients, including general medicine and surgery. PHFs historically are county-run, or under contract by counties, to provide inpatient care to Medi-Cal beneficiaries through a county mental health plan.

In addition to inpatient facilities, counties can designate certain outpatient facilities under the LPS Act, such as crisis stabilization units. A crisis stabilization unit is generally open 24 hours a day, seven days a week, and provides up to 23 hours of psychiatric urgent care intended to stabilize a patient suffering from psychiatric distress, with the goal of stabilizing the patient and avoiding the need for inpatient care.

d) EMTALA. EMTALA was passed to address the problem of hospitals refusing to treat indigent, uninsured, or Medicaid patients, or "dumping" these patients by transferring them to county hospitals or other charity hospitals. Federal EMTALA obligates Medicare-participating hospitals that offer emergency services to provide a medical screening and treatment for an emergency medical condition, including active labor, regardless of an individual's ability to pay. State EMTALA imposes its obligation on any hospital that operates an ED, and has similar requirements to federal EMTALA. Hospitals are required to provide stabilizing treatment for patients with an emergency medical condition. A patient is "stabilized" when the patient's medical condition is such that, within reasonable medical probability, no material deterioration of the patient's condition is likely to result from the release or transfer of the patient. If a hospital is unable to stabilize a patient within its capability, then a patient is required to be transferred to an appropriate facility with the necessary specialized treatment services. Once a patient is stabilized, if the patient needs post-stabilization care, the hospital will typically seek more information about the medical history of the patient, including whether the patient has insurance.

e) Medi-Cal Managed Care Plan (MCP) Coverage of Emergency Services. The Medi-Cal provisions of this bill reflect current DHCS policy, and appear consistent with DHCS's intention to revise MCP contract language to clarify payment for emergency services.

Current contracts between MCPs and DHCS specify MCPs are responsible for coverage and payment of emergency services and post-stabilization care services. However, the current contract language carves out some exceptions to an MCP's responsibility for paying for emergency services, including: a) services provided by specified mental health providers; and, b) facility charges for ED visits that result in a psychiatric admission. DHCS is revising the contract to remove these exceptions and clarify MCPs bear financial responsibility for ED services, including behavioral health services. Specifically, updated MCP contracts effective January 1, 2024, require MCPs to pay for emergency room professional services provided by mental health providers, addressing a) above. However, the 2024 contract language does not require MCPs to pay for facility charges for emergency room visits that result in a psychiatric admission, as described in b) above. To address b) above, DHCS has stated it intends to amend MCP contracts again to codify plan responsibility to cover all facility charges claimed by EDs—essentially removing the exception related to ED visits that result in a psychiatric admission. DHCS has stated, furthermore, that this change would be retroactive. When this change is made, the contract language will align with guidance issued in a 2022 All-Plan Letter (APL)

titled "No Wrong Door for Mental Health Services." This bill codifies MCPs coverage of ED services without the two exceptions related to behavioral health care.

f) Modernizing California's Mental Health System. In March 2023, Governor Newsom announced in his plan to modernize California's mental health system. With the passage of AB 531 (Irwin), Chapter 789, Statutes of 2023, and SB 326 (Eggman), Chapter 790, Statutes of 2023 (and the placement of Proposition 1 on the March 2024 ballot) several new initiatives will be undertaken to:

- **i)** Build thousands of new behavioral health beds in state-of-the-art residential settings to house Californians with mental illness and substance use disorders, which could serve over 10,000 people every year in residential-style settings that have on-site services, including some locked facility beds;
- **ii)** Provide more funding specifically for housing for homeless veterans;
- **iii)** Amend the Mental Health Services Act (MHSA), leading to approximately $1 billion every year in local assistance for housing and residential services for people experiencing mental illness and substance use disorders, and allowing MHSA funds to serve people with substance use disorders; and,
- **iv)** Include new accountability and oversight measures for counties to improve performance.

3) SUPPORT. CHA is the sponsor of this bill and states that hospitals are seeing more Californians in crisis, but youth and adults spend disproportionately more time waiting in the ED than other patients. While the national quality standard for emergency hospital care is four hours or less, it is common for people in mental health crisis to languish in a hospital ED for days or even weeks while waiting for an inpatient mental health treatment bed to become available. CHA contends that while California's lack of inpatient psychiatric beds is a major reason for these delays, hospitals at times also are requested to retain a patient on an involuntary psychiatric hold rather than transfer the patient to a facility where they can get the care they need. This bill would clarify that hospital EDs should transfer patients in crisis to accepting inpatient psychiatric hospitals, regardless of whether the patient is on an involuntary hold.

CHA notes that this bill would also make it clear that Medi-Cal MCPs must pay hospital EDs for the care they provide to Medi-Cal beneficiaries experiencing a mental health crisis. Currently, the Medi-Cal managed care plans' contracts and state guidance provide conflicting information about financial obligations for ED visits. CHA concludes that this bill would codify the intent of the DHCS' APL 22-005, "No Wrong Door for Mental Health Services," which clarifies that Medi-Cal MCPs must cover and pay for all facility and professional services claimed by EDs for beneficiaries experiencing a behavioral health crisis.

4) RELATED LEGISLATION. AB 1001 (Haney) creates a new definition of "behavioral health emergency condition" which applies specifically to patients in the ED of GACHs. Requires GACHs to adopt policies to respond to a patient requiring behavioral health emergency services, as defined. Requires that these protocols meet standards established by DPH and consist of various parameters such as minimum staffing requirements for behavioral health emergency services, procedures for response by behavioral health emergency services personnel in a timely manner, and annual training. Creates the Behavioral Health Emergency Response and Training Fund to provide grants to fund new programs or support existing programs that increases the staffing of direct care personnel

who are trained in behavioral health care and behavioral health emergency services response or intervention, in specified hospitals. AB 1001 is currently pending in the Senate Health Committee.

5) PREVIOUS LEGISLATION.

a) AB 1164 (Lowenthal) of 2023 would have required a licensed GACH with an ED to determine the range of crowding scores that constitute each category of the crowding scale, as provided, for its ED. Would have required the hospital to calculate and record a crowding score at a minimum every four hours, except as specified, to assess the crowding condition of the hospital's ED. Would have required, by January 1, 2025, the hospital to develop and implement a full-capacity protocol for each of the categories of the crowding scale, and requires the hospital to file its protocol with the Department of Health Care Access and Information and to annually report any revisions to its protocol. AB 1164 was held on the Assembly Appropriations Committee suspense file.

b) AB 451 (Arambula), Chapter 438, Statutes of 2021, requires a psychiatric unit of a GACH, a PHF with more than 16 beds that is not county operated, and an APH, to accept a transfer of a person with a psychiatric emergency medical condition, regardless of whether the facility operates an ED, if the facility has appropriate facilities and qualified personnel available to provide the services.

REGISTERED SUPPORT / OPPOSITION:

Support

California Hospital Association (sponsor)
Adventist Health
Cedars Sinai
Disability Rights California
Loma Linda University Adventist Health Sciences Center and Its Affiliated Entities
Providence
Rady Children's Hospital
Tenet Healthcare Corporation

Opposition

None on file.

Analysis Prepared by: Lara Flynn / HEALTH / (916) 319-2097

Date of Hearing: January 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 82 (Weber) – As Introduced December 15, 2022

SUBJECT: Dietary supplements for weight loss and over-the-counter diet pills.

SUMMARY: Prohibits a retail establishment from selling, transferring, or otherwise furnishing dietary supplements for weight loss or over-the-counter (OTC) diet pills, as defined, to any person under 18 years of age without a prescription. Requires the California Department of Public Health (DPH) to develop a notice stating that certain dietary supplements for weight loss or OTC diet pills may contribute to specified health conditions or death and requires retail establishments to post it. Specifies a civil penalty of no more than $1,000 for each violation and exempts a retail clerk from any civil penalties, or disciplinary action or discharge by the retail establishment, for a violation of these provisions, except as specified. Makes the provisions of this bill operative on July 1, 2024, and includes a severability clause. Specifically, **this bill**:

1) Prohibits a retail establishment from selling, transferring, or otherwise furnishing dietary supplements for weight loss or OTC diet pills to any person under 18 years of age without a prescription.

2) Requires a retail establishment to request valid identification (ID) from any person who attempts to purchase a dietary supplement for weight loss or OTC diet pill if that person reasonably appears to the retail establishment to be under 18 years of age.

3) Requires a retail establishment to post the notice described in 4) below for purposes of dietary supplements for weight loss and OTC diet pills.

4) Requires DPH to develop a notice, for distribution to retail establishments to post pursuant to 3) above, stating that certain dietary supplements for weight loss or OTC diet pills may contribute to gastrointestinal impairment, tachycardia, hypertension, myocardial infarction, stroke, organ failure, other serious injury, death, or severe liver injury sometimes requiring transplant or leading to death.

5) Requires DPH, in consultation with the United States Food and Drug Administration (FDA) and stakeholders, including, but not limited to, representatives from the eating disorders community, to determine which dietary supplements for weight loss and OTC diet pills are subject to this bill, in a manner consistent with the definitions in 9) below and with a finding the supplement or pill may contribute to any of the health conditions described in 4) above.

6) Makes a person who violates this section liable for a civil penalty of no more than $1,000 for each violation, assessed and recovered in a civil action brought by the California Attorney General or by any district attorney, county counsel, or city attorney in any court of competent jurisdiction. Exempts a retail clerk from being subject to any civil penalty, or to any disciplinary action or discharge by the retail establishment, for a violation of this bill. Applies provisions of this bill to a retail clerk who is a willful participant in an ongoing conspiracy to violate this bill.

7) Requires the notice requirements described in this bill to be implemented only to the extent not in conflict with federal law.

8) Makes this bill effective on July 1, 2024 and includes severability clause.

9) Defines the following:

   a) Dietary supplements for weight loss as a class of dietary supplements that are labeled, marketed, or otherwise represented for the purpose of achieving weight loss and that are under the regulation of the Federal Food, Drug, and Cosmetic Act (FDCA), and regulations adopted thereunder. Includes products marketed with a Supplement Facts panel, pursuant to federal regulations, that contain either lawful dietary ingredients or ingredients deemed adulterated under Section 342 of Title 21 of the United States Code (U.S.C.), or both. Exempts dietary fiber products;

   b) OTC diet pills as a class of drugs that are labeled, marketed, or otherwise represented for the purpose of achieving weight loss and that are lawfully sold, transferred, or otherwise furnished without a prescription, under the regulation of the FDCA (21 U.S.C. Sec. 301, *et seq*.), and regulations adopted thereunder. Includes products marketed with a Drug Facts panel, pursuant to federal regulations, that contain either approved drug ingredients or ingredients deemed adulterated under Section 342 of Title 21 of the U.S.C., or both; and,

   c) Retail establishment as any vendor that, in the regular course of business, sells dietary supplements for weight loss or OTC diet pills at retail directly to the public, including, but not limited to, pharmacies, grocery stores, other retail stores, and vendors that accept orders placed by mail, telephone, electronic mail, internet website, online catalog, or software application.

EXISTING FEDERAL LAW:

1) Establishes the FDCA which among various provisions, gives the FDA authority to oversee the safety of food, drugs, medical devices, and cosmetics. Defines under the FDCA a dietary ingredient as a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances. [21 U.S.C. § 301, *et seq*.]

2) Establishes the Dietary Supplement Health and Education Act of 1994 (DSHEA), administered by the FDA, which among provisions, prohibits manufacturers and distributors of dietary supplements and dietary ingredients from marketing products that are adulterated or misbranded. Establishes under DSHEA labeling requirements for dietary supplements and permits dietary supplements to make certain structure function claims, but cannot be sold for the treatment, prevention, mitigation, or cure of diseases or conditions associated with known diseases. [21 U.S.C.§ 342]

3) Establishes the Current Good Manufacturing Practice for manufacturing, packaging, labeling, and holding operations for dietary supplements. [21 U.S.C. §§ 1-99, 200-299, 300-499, 600-799, and 800-1299]

4) Establishes under the FDA, the MedWatch program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

EXISTING STATE LAW:

1) Establishes the Sherman Food, Drug, and Cosmetic Law, administered by DPH, which regulates the packaging, labeling, and advertising of drugs and devices, including dietary supplements. [Health and Safety Code (HSC) § 109875, *et. seq*.]

2) Prohibits the sale or distribution of any dietary supplement product that contains ephedrine group alkaloids unless the product contains a specified label. Permits the sale of any dietary supplement containing ephedrine if the product label clearly and conspicuously contains specified warnings, including the following:

   a) "WARNING: NOT FOR USE BY INDIVIDUALS UNDER THE AGE OF 18 YEARS. DO NOT USE IF PREGNANT OR NURSING. Consult a physician or licensed qualified health care professional before using this product if you have, or have a family history of, heart disease, thyroid disease, diabetes, high blood pressure, depression or other psychiatric condition, glaucoma, difficulty in urinating, prostate enlargement, or seizure disorder, or if you are using a monoamine oxidase inhibitor or any other dietary supplement, prescription drug, or OTC drug containing ephedrine, pseudoephedrine, or phenylpropanolamine (ingredients found in certain allergy, asthma, cough or cold, and weight control products)."
   b) "Do not exceed recommended serving. Exceeding recommended serving may cause serious adverse health effects, including heart attack and stroke."
   c) "Discontinue use and call a physician or licensed qualified health care professional immediately if you experience rapid heartbeat, dizziness, severe headache, shortness of breath, or other similar symptoms."
   d) "Individuals who are sensitive to the effects of caffeine should consult a licensed health care professional before consuming this product."
   e) "KEEP OUT OF REACH OF CHILDREN." [HSC § 110423(a)]

3) Prohibits the sale or distribution of dietary supplements containing steroid hormone precursors unless the product label for these dietary supplements clearly and conspicuously contains the following warning:

   "WARNING: NOT FOR USE BY INDIVIDUALS UNDER THE AGE OF 18 YEARS. DO NOT USE IF PREGNANT OR NURSING. Consult a physician or licensed qualified health care professional before using this product if you have, or have a family history of, prostate cancer, prostate enlargement, heart disease, low "good" cholesterol, or if you are using any other dietary supplement, prescription drug, or OTC drug. Do not exceed recommended serving. Exceeding recommended serving may cause serious adverse health effects. Possible side effects include acne, hair loss, hair growth on the face (in women), aggressiveness, irritability, and increased levels of estrogen. Discontinue use and call a physician or licensed qualified health care professional immediately if you experience rapid heartbeat, dizziness, blurred vision, or other similar symptoms. KEEP OUT OF REACH OF CHILDREN." [HSC § 110423(b)]

4) Requires the product label for any dietary supplement product containing ephedrine group alkaloids or steroid hormone precursors to clearly and conspicuously display the following statement: "To report any adverse events call 1-800-332-1088" [MedWatch program]. [HSC § 110423(c)]

5) Establishes the California Unfair Practices which prohibits unfair competition and any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising. [Business and Professions Code (BPC) § 17500]

6) Makes it a misdemeanor to sell, furnish, give, or cause to be sold, furnished, or given away, any alcoholic beverage to any person under the age of 21 years. Makes it a misdemeanor for any person under the age of 21 years to purchase any alcoholic beverage, or to consume any alcoholic beverage, as specified. [BPC § 25658]

7) Requires all persons engaging in the retail sale of tobacco products to check the ID of tobacco purchasers, to establish the age of the purchaser, if the purchaser reasonably appears to be under 21. [BPC § 22956]

FISCAL EFFECT: Unknown. This bill has not been analyzed by a fiscal committee.

COMMENTS:

1) PURPOSE OF THIS BILL. According to the author, children are abusing OTC weight loss products without the knowledge of their parents and without the supervision of their doctors. With limited regulatory oversight, some dietary supplements are laced with banned pharmaceuticals, steroids, and other toxic ingredients. Dangerous stimulants are also often found in widely available supplements for weight loss. The author concludes that due to the ease of accessibility of these products, minors take them to lose weight quickly, while ignoring the label on the bottle stating the products are not to be consumed by those under 18 years of age.

2) BACKGROUND. According to the FDA, dietary supplements are regulated as food, not as drugs. The FDA notes, however, many dietary supplements contain ingredients that have strong biological effects which may conflict with a medicine you are taking or a medical condition you may have. Products containing hidden drugs are also sometimes falsely marketed as dietary supplements, putting consumers at even greater risk. For these reasons, the FDA notes that it is important to consult with a health care professional before using any dietary supplement.

The FDCA was amended in 1994 by the DSHEA, which defined "dietary supplement" and set out FDA's authority regarding such products. The FDA does not have the authority to approve dietary supplements for safety and effectiveness, or to approve their labeling, before the supplements are sold to the public. Under the FDCA, it is the responsibility of dietary supplement companies to ensure their products meet the safety standards for dietary supplements and are not otherwise in violation of the law. Dietary supplement labels are required to have nutrition information in the form of a Supplement Facts label that includes the serving size, the number of servings per container, a listing of all dietary ingredients in the product, and the amount per serving of those ingredients. They also must have a statement on the front of the product identifying it as a "dietary supplement" or similar

descriptive term (e.g., "herbal supplement" or "calcium supplement"). In general, even if a product is labeled as a dietary supplement, a product intended to treat, prevent, cure, or alleviate the symptoms of a disease is a drug, and subject to all requirements that apply to drugs.

Estimates on the revenue from vitamin and nutritional supplement production reached nearly $31 billion in the United States in 2018 and the industry is set to add over a billion more in revenue in 2019. By 2024 the value of the U.S. dietary supplement market is expected to reach $56.7 billion. According to research cited by the Office of Dietary Supplements, part of the National Institutes of Health, approximately 15% of U.S. adults have used a weight-loss dietary supplement at some point in their lives; more women report use (21%) than men (10%). Americans spend about $2.1 billion a year on weight-loss dietary supplements in pill form (e.g., tablets, capsules, and softgels), and one of the top 20 reasons why people take dietary supplements is to lose weight.

a) Health impact of weight loss or dietary supplements on children. A 2019 study published in the *American Journal of Public Health* conducted by researchers from Harvard T.H. Chan School of Public Health and Boston Children's Hospital found that young women who use diet pills and laxatives for weight control had higher odds of receiving a subsequent first eating disorder diagnosis within one to three years than those who did not report using these products. The researchers analyzed data from 10,058 women and girls ages 14 to 36 years who participated in the U.S.-based Growing Up Today Study from 2001 to 2016. The researchers found that among participants without an eating disorder, 1.8% of those who used diet pills during the past year reported receiving a first eating disorder diagnosis during the next one to three years compared to 1% of those who did not use the products. They also found that among these participants, 4.2% of those who used laxatives for weight control received a subsequent first eating disorder diagnosis compared to 0.8% of those who did not use these products for weight control.

A 2015 article cited by the author in the *Journal of Public Health Management & Practice* states that adolescents use dietary supplements marketed for weight loss or muscle building, but these are not recommended by physicians. These products are often ineffective, adulterated, mislabeled, or have unclear dosing recommendations, and consumers have suffered injury and death as a consequence. When Congress passed the DSHEA, it stripped the FDA of its premarket authority, rendering regulatory controls too weak to adequately protect consumers. The article makes the case that state government intervention is warranted.

b) Current restriction on the sale of dietary supplements to persons under 18 years of age. Existing law makes it a misdemeanor for any manufacturer, wholesaler, retailer or other person to sell, transfer or furnish any of the following to anyone under 18 years of age:

i) A dietary supplement containing an ephedrine group alkaloid;
ii) A dietary supplement containing any of the following (forms or classes of steroids):

(1) Androstanediol;
(2) Androstanedione;
(3) Androstenedione;

(4) Norandrostenediol;
(5) Norandrostenedione; and,
(6) Dehydroepiandrosterone.

A seller must request valid ID from any individual who attempts to purchase a dietary supplement specified in i) and ii) above if that individual reasonably appears to the seller to be under 18 years of age. A violation of the above provisions carries a penalty of $1,000 for the first violation, $2,000 for the second violation and $5,000 for the third and each subsequent violation. It should be noted that a retail clerk who fails to request ID is not guilty of a misdemeanor nor is subject to any civil penalties, or any disciplinary action or discharge by his or her employer unless the retail clerk is a willful participant in a criminal conspiracy, as specified. Moreover, a retail establishment that sells, transfers, or otherwise furnishes a dietary supplement product in violation of i) and ii) above is not guilty of a misdemeanor if certain conditions are met including that the checkout clerks have fulfilled specified standardized training and checkout scanners or computers used to check out customers with purchases are programmed to identify dietary supplement products; or if every checkout clerk has received a written list of dietary supplement products subject to this article that are sold by the retail establishment that may be posted at the checkout station for easy access. This bill expands existing law that already prohibits dietary supplements with the ingredients specified in i) and ii) above to also prohibit the sale of dietary supplements (to be determined by DPH) for weight loss or OTC diet pills to any person under 18 years of age without a prescription.

3) **Other states.** New York recently passed legislation that will ban the sale of OTC diet pills and supplements for weight loss and muscle building to minors based on studies that found these products are laced with unapproved pharmaceutical ingredients, illicit anabolic steroids, experimental and banned stimulants, and other dangerous chemicals. Supporters also note that research often demonstrates that the use of these products may be a warning sign for the presence or risk of an eating disorder. Young people who take OTC diet pills are more likely to develop an eating disorder than those who do not. More than 1.7 million, or 9% of New Yorkers, will suffer from an eating disorder throughout their lifetime. Eating disorders cause immense harm to individuals and communities, costing New York more than $3.9 billion a year in direct medical care costs and lost productivity. More than 10,000 lose their lives each year nationally as a direct result of an eating disorder. The New York law focuses on the marketing and advertising of OTC diet pills and muscle-building supplements to minors by establishing age verification guidelines for retailers and delivery sellers.

   In 2017-2018, HB 1195 was introduced in the Massachusetts legislature that would have banned the sale of weight-loss and muscle-building dietary supplements to minors, similar to this bill. HB 1195 eventually became a study bill.

4) **SUPPORT.** Various organizations, individuals, professors and physicians write in support citing scientific study after study showing that dietary supplements pose serious health risks to consumers. In the absence of FDA prescreening, many dietary supplements on the consumer market, especially those sold for weight loss, have been found to be laced with prescription pharmaceuticals, banned substances, heavy metals, pesticides, and other dangerous chemicals. Supporters cite a study led by the FDA which tested a small selection of the tens of thousands of dietary supplements on the market and found hundreds of those sold for weight loss to be adulterated with pharmaceutical drugs and banned chemicals,

which often are associated with serious health consequences. Another study found that youth using weight-loss supplements were three times more likely than those using ordinary vitamins to experience severe medical harm, including hospitalization, disability, and even death. Studies have linked weight loss supplements to organ failure, heart attacks, stroke, and death. The Centers for Disease Control and Prevention estimates that supplement use leads to 23,000 emergency room visits every year, with a quarter due to the weight-loss category alone. The American Academy of Pediatrics recently issued a report strongly cautioning against teens using these products for any reason. Supporters note that youth who use OTC diet pills are six times more likely to be diagnosed with an eating disorder compared to nonusers.

5) **OPPOSITION.** The Natural Products Association (NPA) writes that supplements are natural products found in food and nature. NPA contends that its members invest significant human resources and capital to ensure their products are safe. These include good manufacturing processes, random product testing, adhering to appropriate marketing guidelines, and following every other rule and regulation that the FDA and the Federal Trade Commission have made for 25 years. NPA contends that some have incorrectly stated that the FDA does not review dietary supplements for safety before entering the market or have incorrectly lumped OTC diet pills such as Alli, as dietary supplements when in fact they are regulated as OTC drugs by the FDA, which differs to how dietary supplements are regulated. The FDCA requires manufacturers and distributors to notify the FDA about their ingredients. The notification must include information that is the basis on which the manufacturer or distributor has concluded the dietary supplement is expected to be safe under the conditions of use suggested in the labeling. NPA states that this bill will place onerous restrictions, most notably on small businesses such as local pharmacy, convenience, or health food stores, by prohibiting the sale of popular products. Restricting access to them is unfair to Californians who value health and wellness, hurts responsible retailers, and drains California's budget through lost sales taxes. According to NPA, no one wants consumers to use unlawful products. Still, they are already illegal by law, and the FDA uses its enforcement authority against companies that attempt to sell these products. The federal government has vast enforcement powers and has a long track record of punishing criminals who break the law and NPA supports vigorous enforcement of the law to protect consumers. The NPA concludes that the FDA, the chief regulator of dietary supplements, found no data suggesting weight-management and muscle-building dietary supplement use is correlated to eating disorders.

6) **PREVIOUS LEGISLATION.**

   a) AB 1341 (C. Garcia) of 2021, is substantially similar to this bill and was vetoed by Governor Newsom with the following message:

   This bill would prohibit retail establishments from selling, transferring, or providing, dietary supplements for weight loss or OTC diet pills to anyone under 18 years of age without a prescription, or valid ID prior to purchasing. The bill would also require DPH to establish a list of dietary supplements that would be subject to this bill.

   I commend the work of the author as this bill raises an important public health issue related to the safety of diet or weight loss pills that can result in injury. However, dietary supplements for weight loss are not considered drugs and, therefore, this measure would

require DPH to evaluate every individual weight loss and dietary supplement product for safety, which is beyond the scope of the department's capabilities.

Recognizing the need to educate and protect the public-particularly California's youth-of the dangers of using dietary supplements for weight loss, I am directing DPH to form a workgroup, inclusive of academic and medical experts, that would develop public policy recommendations on the best way to address this important public health challenge.

DPH is prepared to work with the legislature next session to address sales age limits and other potential legislative actions to address the responsible sale of dietary supplements for weight loss and OTC diet pills that do not require the state to undertake lengthy and costly pharmacological studies on the many supplements on the market today.

For these reasons, I cannot sign this bill.

b) AB 3042 (Limon) of 2019 was substantially similar to this bill but due to the shortened Legislative calendar brought on by the COVID-19 pandemic, this bill was not set for a hearing in the Assembly Health Committee.

7) AMENDMENTS. As this bill moves forward, the author may wish to amend this bill to reflect a later implementation date to 2025 as intended in the introduced version of this bill.

8) DOUBLE REFERRAL. This bill has been double-referred; upon passage of this Committee, it will be referred to the Assembly Judiciary Committee.

9) COMMENTS. In response to the Governor’s veto of AB 1341 from 2021, DPH convened a stakeholder group and according to the author, DPH has yet to publicly share the results of this work.

REGISTERED SUPPORT / OPPOSITION:

Support

Academy for Eating Disorders
Alaska Eating Disorders Alliance
Alliance for Eating Disorders Awareness
Be Real USA
Center for Science in The Public Interest
Children's Advocacy Institute
Eating Disorders Coalition
Erevna, Policy for The People
Finxerunt Policy Institute
For You
International Socioeconomic Society & Finxerunt Policy Institute
Multi-service Eating Disorders Association
National Association of Anorexia Nervosa and Associated Disorders
National Eating Disorders Association
Ncarth
Project Heal
Realize Your Beauty, INC.

Renfrew Center for Eating Disorders
Strategic Training Initiative for The Prevention of Eating Disorders
The Eating Disorder Foundation

Opposition

Natural Products Association

Analysis Prepared by: Kristene Mapile / HEALTH / (916) 319-2097

Date of Hearing: January 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 941 (Waldron) – As Amended January 4, 2024

SUBJECT: Controlled substances: psychedelic-assisted therapy.

SUMMARY: Requires the California Health and Human Services Agency (CHHSA) to convene a workgroup to study and make recommendations on the establishment of a framework governing psychedelic-assisted therapy, as defined. Requires the workgroup to send a report to the Legislature containing those recommendations on or before January 1, 2026. Makes, contingent upon the Legislature enacting a framework governing psychedelic-assisted therapy, the use of hallucinogenic/psychedelic substances for psychedelic-assisted therapy lawful. Specifically, **this bill**:

1) Requires CHHSA to convene a workgroup to study and make recommendations on the establishment of a framework governing psychedelic-assisted therapy using all of the following:
   a) Psilocybin;
   b) Ibogaine; and,
   c) Any controlled substance the federal Food and Drug Administration (FDA) may approve for use in the future, including, but not limited to Dimethyltryptamine (DMT) or Mescaline sourced from nonpeyote cacti.

2) Requires the Secretary of CHHSA, or their designee, to serve as the chairperson of the workgroup and requires that workgroup to also include, but not be limited to, all of the following:
   a) Persons with expertise in psychedelic therapy, medicine and public health, drug policy, harm reduction, and youth drug education;
   b) Law enforcement and emergency medical services or fire service first responders;
   c) People with experience with the traditional indigenous use of psychedelic substances, including representatives from the National Council of the Native American Church and Indian tribes in California;
   d) Veterans groups;
   e) University researchers with expertise in psychedelics;
   f) Research scientists with expertise in clinical studies and drug approval process under the FDA; and,
   g) Individuals from other states that have decriminalized psychedelics and established regulatory frameworks for the lawful use of psychedelics.

3) Requires the workgroup to study subjects, including, but not limited to, all of the following:
   a) Research on the safety and efficacy of using each of the controlled substances identified in 1) above in a therapeutic setting for treating post-traumatic stress disorder (PTSD), depression, anxiety, addiction, and other mental health conditions;
   b) Long-term impacts of supervised psychedelic or dissociative drug use with seeking and misusing other substances, including alcohol, cannabis, illicit substances, and unregulated psychedelic or dissociative drugs;

c) Perceptions of harm of psychedelic or dissociative drugs following enactment of decriminalization both on a personal use and therapeutic use level;
d) Impacts of different regulatory frameworks on different health outcomes among vulnerable populations, including youth, people with substance use disorders (SUDs), and minority or disenfranchised groups;
e) Regulated use models for the controlled substances specified in 1) above from other jurisdictions;
f) Content and scope of educational campaigns that have proven effective in accurate public health approaches regarding use, effect, and risk reduction for the substances specified in 1) above, including, but not limited to, public service announcements, educational curricula, appropriate crisis response, and appropriate training for first responders and multi-responders, including law enforcement, emergency medical services, fire service, and unarmed co-responder units;
g) Policies for minimizing use-related risks, including information related to appropriate use and impacts of detrimental substance use; and,
h) Appropriate frameworks to govern the therapeutic use of controlled substances, including qualifications and training for therapists or facilitators.

4) Requires the workgroup to develop policy recommendations regarding, but not limited to, all of the following:
   a) Development of a statewide program or programs for the training of individuals providing therapeutic psychedelic services in therapeutic settings, including facilitated and supported use settings;
   b) Development of a statewide credentialing process for individuals providing therapeutic psychedelic services in therapeutic settings, including facilitated or supported use settings;
   c) The content and scope of educational campaigns and accurate public health approaches regarding use, effect, risk reduction, and safety for the substances specified in 1) above;
   d) Policies for minimizing use-related risks, including information related to appropriate use and impacts of detrimental substance use;
   e) Policies for the regulation of controlled substances specified in 1) above, including responsible marketing, product safety, and cultural responsibility; and,
   f) Policies for the safe and equitable production, access, use, and delivery of the controlled substances specified in 1) above.

5) Provides that subsequent to the Legislature's adoption of a framework governing therapeutic use of the substances described in 1) above, it is the intent of the Legislature that the transfer of a substance described in 1) above, without financial gain, in the context of psychedelic-assisted therapy, be decriminalized.

6) Defines "psychedelic-assisted therapy" to be the supervised, lawful medical use of a controlled substance for treatment, including but not limited to group counseling and community-based healing, under the care of, administration by, and treatment of a licensed professional in a clinical setting.

7) Requires the workgroup to submit a report to the Legislature detailing its findings and recommendations on or before January 1, 2026.

8) Repeals the study provisions of this bill effective January 1, 2027.

9) Provides that notwithstanding any other law, and upon the Legislative enactment of a framework governing psychedelic-assisted therapy, the use of hallucinogenic/psychedelic substances for psychedelic-assisted therapy is lawful.

10) Provides that the scope of the psychedelic-assisted therapy may vary based on the treatment required and injury or disorder being treated.

11) Provides that 9) and 10) above are contingent upon the Legislature enacting a framework for the governing of psychedelic-assisted therapy.

12) Finds and declares that clinical research demonstrates the potential use of some psychedelic compounds, in conjunction with therapy, for the treatment of mental health, such as end-of-life anxiety, depression, PTSD, and SUDs.

EXISTING FEDERAL LAW:

1) 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 United States Code (U.S.C.) § 844]

2) 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)]

3) 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, for the purpose of unlawfully manufacturing, storing, distributing, or using a controlled substance. [21 U.S.C. § 856, (b)]

EXISTING STATE LAW:

1) Lists controlled substances into five "schedules" intended to list drugs in decreasing order of harm and increasing medical utility or safety and provides penalties for the possession of and the engagement in commerce of a controlled substances. Includes in Schedule I the most serious and heavily controlled substances, with Schedule V being the least serious and most lightly controlled substances. [Health and Safety Code (HSC) § 11054-11058]

2) Classifies several hallucinogenic substances including DMT, Ibogaine, mescaline, psilocybin, and psilocyn as Schedule I substances. [HSC § 11054(d)]

3) Provides that, upon change in federal law permitting the prescription, furnishing, or dispensing of a cannabidiol product, a physician, pharmacist, or other authorized healing arts licensee acting within their scope of practice who prescribes, furnishes, or dispenses a cannabidiol product in accordance with federal law, is deemed to be in compliance with state law. [HSC §11150.2(a)]

4) Prohibits the possession of numerous specified controlled substances. [HSC §11350(a)]

5) Makes it is unlawful to possess any device, instrument, or paraphernalia used for unlawfully injecting or smoking specified controlled substances, except as specified. [HSC §11364(a)]

6) Makes 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. [HSC §11364.7]

7) Makes it unlawful to visit or to be in any room or place where specified controlled substances are being unlawfully smoked or used with knowledge that such activity is occurring. [HSC §11365(a)]

8) Provides that the possession of methamphetamine and other specified controlled substances is unlawful. [HSC §11377(a)]

9) 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. [HSC § 11379]

10) Makes it unlawful for a person to agree, consent, or in any manner offer to unlawfully sell, furnish, transport, administer, or give specified controlled substances.[HSC §11382]

11) Provides that it is unlawful to be under the influence of specified controlled substances. [HSC §11550(a)]

12) 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. [HSC §11390]

13) Makes it unlawful to transport, import into this state, sell, furnish, give 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. [HSC § 11391]

FISCAL EFFECT: This bill has not yet been analyzed by a fiscal committee.

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, allowing for the controlled, therapeutic use of psychedelics for those with mental health disorders has the potential to save countless lives. By studying the best possible way to begin administering these treatments, we can protect the most vulnerable Californians who are suffering every day.

2) BACKGROUND.

a) California and Federal Drug Schedules. California and Federal drug schedules closely mirror each other. Both have five schedules intended to list drugs in decreasing order of harm and increasing medical utility or safety and provides penalties for possession of and engaging in the commerce of controlled substances. Schedule I includes the most serious and heavily controlled substances, with Schedule V being the least serious and most lightly controlled substances. The drugs on each schedule are largely consistent.

Schedule I – The drug has a high potential for abuse; the drug has no currently accepted medical use in treatment in the United States (U.S.); there is a lack of accepted safety for use of the drug under medical supervision.

Schedule II – The drug has a high potential for abuse; the drug has a currently accepted medical use in treatment in the U.S. or a currently accepted medical use with severe restrictions; abuse of the drug may lead to severe psychological or physical dependence.

Schedule III – The drug has potential for abuse less than the drugs or other substances in Schedule I and II; the drug has a currently accepted medical use in treatment in the U.S.; abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

Schedule IV – The drug has a low potential for abuse relative to the drugs in Schedule III; the drug has a currently accepted medical use in the U.S.; abuse of the drug may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III.

Schedule V – The drug has a low potential for abuse relative to the drugs or other substances in IV; the drug has a currently accepted medical use in treatment in the U.S.; abuse of the drug may lead to limited physical dependence of psychological dependence relative to the drugs or other substances in Schedule IV.

b) Hallucinogens. 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 lysergic acid diethylamide (LSD), DMT, psilocybin, peyote, mescaline, and ketamine.

Many hallucinogenic substances, including LSD, DMT, mescaline, and psilocybin 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. (Davis et. al, "Effects of Psilocybin-Assisted Therapy on Major Depressive Disorder," *JAMA Psychiatry* (2020);

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); Köck et al., "A Systematic Literature Review of Clinical Trials and Therapeutic Applications of Ibogaine, Journal of Substance Abuse Treatment" (2022)).

In recent years, the FDA has designated psilocybin as a "breakthrough therapy" to treat severe depression. (Saplakoglu, "FDA Calls Psychedelic Psilocybin a 'Breakthrough Therapy' for Severe Depression," *Live Science* (Nov. 25, 2019). 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."

While research on hallucinogenic substances is promising, their use is not without risk. Hallucinogens included in this bill are associated with significant harms. The absence of adequate reporting systems to track these harms hampers the ability to quantify them, however, a review of the medical literature, demonstrates these drugs contribute to non-trivial risks for individuals and the public health. Case reports document adverse effects of psilocybin and other hallucinogens including acute panic *(*Nordic Council of Ministries, 2009; Riley and Blackman, 2008; van Amsterdam et al., 2011), risk of physical self-harm (Allen et al., 1991; Schwartz and Smith, 1988; van Amsterdam et al., 2011), self-harm resulting in death, including in cases with no known medical or psychiatric history (Honyiglo et al., 2019), medical help-seeking (Allen et al., 1991; Nordic Council of Ministries, 2009; Mowry et al., 2014), and enduring negative psychological or psychiatric problems (Allen et al., 1991; Nordic Council of Ministries, 2009; Nielen et al., 2004; Espiard et al., 2020; Hendin et al., 2021).

c) Reform Efforts Related to Hallucinogens. Across the nation, local and statewide 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. That same year, the Oakland, California, 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." Similarly, a resolution passed by the Santa Cruz, California, City Council in 2020 made the personal possession and use of entheogenic plants and fungi a low priority for law enforcement. The Ann Arbor, Michigan, City Council passed a similar measure that same year. 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. Additional jurisdictions have passed similar measures since 2020.

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 two-year 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. Psilocybin services are expected to be available to the public by early 2024.

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. 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.

In 2021, Texas adopted House Bill 1802, which directed their Department of State Health Services to, in collaboration with the Texas Medical Board, conduct a study to evaluate the therapeutic efficacy of alternative therapies, including the use of 3, 4-methylenedioxmethamphetamine (MDMA), psilocybin, and ketamine in the treatment of mental health and other medical conditions including, depression, anxiety, PTSD; bipolar disorder; chronic pain and migraines. The evaluation is to include a determination of whether alternative therapies are effective in treating the mental health and other medical conditions described in the bill and to compare the efficacy of the alternative therapies with the efficacy of treatments currently used for those conditions.

d) FDA Draft Guidance on Clinical Trials with Psychedelic Drugs. On June 23, 2023, FDA published a new draft guidance to highlight fundamental considerations to researchers investigating the use of psychedelic drugs for potential treatment of medical conditions, including for psychiatric conditions or SUDs. This is the first FDA draft guidance that presents considerations to industry for designing clinical trials for psychedelic drugs.

There has been growing interest in the therapeutic potential of psychedelic drugs in recent years. They are being evaluated for use in the potential treatment of conditions such as depression, PTSD, SUDs and other conditions. However, designing clinical studies to evaluate the safety and effectiveness of these compounds presents a number of unique challenges that require careful consideration.

According to Tiffany Farchione, M.D., director of the Division of Psychiatry in the FDA's Center for Drug Evaluation and Research, "Psychedelic drugs show initial promise as potential treatments for mood, anxiety and SUDs. However, these are still investigational products." Dr. Farchione further states that "sponsors evaluating the

therapeutic potential of these drugs should consider their unique characteristics when designing clinical studies." By publishing this draft guidance, the FDA hopes to outline the challenges inherent in designing psychedelic drug development programs and provide information on how to address these challenges. The goal is to help researchers design studies that will yield interpretable results that will be capable of supporting future drug applications."

The purpose of the draft guidance is to advise researchers on study design and other considerations as they develop medications that contain psychedelics. Within the draft guidance, the term psychedelics refers to "classic psychedelics," typically understood to be drugs such as psilocybin and LSD that act on the brain's serotonin system, as well as "entactogens" or "empathogens" such as MDMA.

The FDA draft guidance describes basic considerations throughout the drug development process including trial conduct, data collection, subject safety and new drug application requirements. For example, psychedelic drugs may produce psychoactive effects such as mood and cognitive changes, as well as hallucinations. As a result, there is the potential for abuse of these drugs, which is a drug safety issue that requires careful consideration and putting sufficient safety measures in place for preventing misuse throughout clinical development. For psychedelics that are currently Schedule I controlled substances, the draft guidance notes that activities associated with investigations under an Investigational New Drug Application must comply with applicable Drug Enforcement Administration regulatory requirements.

The evidentiary standard for establishing effectiveness of psychedelic drugs is the same as for all other drugs. However, there are unique factors investigators may need to consider when designing their clinical trials if those trials are to be considered adequate and well-controlled. The draft guidance also addresses the role of psychotherapy in psychedelic drug development, considerations for safety monitoring and the importance of characterizing dose-response and the durability of any treatment effect.

e) Criminal Under Federal Law. State authorization does not nullify federal drug laws, and the substances included in this bill remain illegal under federal law. As a result, state authorization for personal possession or for facilities providing "facilitated and supported use" of mescaline, DMT, Ibogaine, psilocybin, and psilocin would not prevent the federal government from shutting down those facilities. Likewise, state authorization does not provide immunity from federal criminal proceedings, if federal law enforcement was inclined to pursue them.

i) For example, federal law provides, "It shall be unlawful for any person knowingly or intentionally to 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 his professional practice," or as otherwise specified. As noted in existing law above, federal law also makes it unlawful to do either of the following: Knowingly open, lease, rent, use, or maintain any place, whether permanently or temporarily, for the purpose of manufacturing, distributing, or using any controlled substance; or,

ii) Manage or control any place, whether permanently or temporarily, either as an owner, lessee, agent, employee, occupant, or mortgagee, and knowingly and intentionally

rent, lease, profit from, or make available for use, with or without compensation, the place for the purpose of unlawfully manufacturing, storing, distributing, or using a controlled substance.

It should be noted that provisions of this bill decriminalizing personal possession of specified hallucinogens and creating a pathway for their facilitated and supported use would still be considered unlawful under federal law.

3) PREVIOUS LEGISLATION.

a) SB 58 (Weiner) of 2023 would have decriminalized for personal use, the use of specified hallucinogenics by individuals 21 years of age or older, created the workgroup as delineated in this bill and upon enactment of a framework for psychedelic-assisted treatment authorized the use of psychedelics for therapeutic treatment. SB 58 was vetoed by Governor Newsom with the following veto statement:

> "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."

b) SB 250 (Umberg), Chapter 106, Statutes of 2023, provides that a person is immune from prosecution for possession of a controlled substance or controlled substance analog for personal use if they deliver the substance to the local public health agency or to local law enforcement.

c) SB 519 (Wiener) of 2022 was substantially similar to SB 58. SB 519 died on the Assembly inactive file.

d) SB 57 (Wiener) of 2022 would have authorized the City and County of San Francisco, the County of Los Angeles, and the City of Oakland to approve entities to operate overdose prevention program for adults supervised by healthcare professionals or other trained staff where people who use drugs can safely consume drugs and get access or referrals SUD treatment services, primary medical care, mental health services, and social services. SB 57 was vetoed by Governor Newsom whose veto message stated in part:

> "I have long supported the cutting edge of harm reduction strategies. However, I am acutely concerned about the operations of safe injection sites without strong, engaged local leadership and well-documented, vetted, and thoughtful operational and

sustainability plans. The unlimited number of safe injection sites that this bill would authorize - facilities which could exist well into the later part of this decade - could induce a world of unintended consequences. It is possible that these sites would help improve the safety and health of our urban areas, but if done without a strong plan, they could work against this purpose. These unintended consequences in cities like Los Angeles, San Francisco, and Oakland cannot be taken lightly. Worsening drug consumption challenges in these areas is not a risk we can take."

e) AB 362 (Eggman) of 2020 would have authorized the City and County of San Francisco to approve entities to operate an overdose prevention program for adults supervised by healthcare professionals or other trained staff where people who use drugs can safely consume drugs and get access to referrals to addiction treatment. AB 362 was never heard in the Senate Health Committee.

f) AB 2495 (Eggman) of 2016 would have decriminalized conduct connected to use and operation of an adult public health or medical intervention facility that is permitted by state or local health departments and intended to reduce death, disability, or injury due to the use of controlled substances. SB 2495 was heard for testimony in the Assembly Public Safety Committee and returned to the desk.

4) PUBLIC HEALTH CONSIDERATIONS.

a) Risk and Benefit Assessment. This bill, following state adoption of a framework governing the use, would authorize the therapeutic use of hallucinogenic substances that have not been subjected to the rigorous drug approval process of the FDA. Typically, prior to consumers' access and consumption of most drugs, particularly when used for therapies for certain conditions, these drugs have gone through the FDA drug approval process. The reverse order of this bill, legalization before FDA approval, could place individuals at unknown risk of harm. Additionally, it establishes a precedent for future drug decriminalization and provides an avenue for factors other than rigorous, science based research, to influence decisions regarding the safety and availability of drugs in California. The assessment for public health determinations should always be whether the benefits of allowing the therapeutic use of the hallucinogenics outweigh the known and potential risks for the intended population.

b) Oversight of Research on Scheduled Substances in California. Current law [HSC §11480 & §11481] requires that proposed research studies using certain opioid, stimulant, and hallucinogenic drugs classified as Schedule I and Schedule II Controlled Substances as their main study drug(s), are to be reviewed and authorized by the Research Advisory Panel of California (Panel) within the Attorney General's Office. The Panel primarily seeks to ensure the safety and protection of participating human research subjects and adequate security of the controlled substances are used in the study. The Panel evaluates the scientific validity of each proposed project, and may reject proposals where the research is poorly conceived, would produce conclusions of little scientific value, or would not justify the exposure of California subjects to the risk of research. It is unclear whether decriminalizing the hallucinogenics specified in this bill would remove them from the only existing oversight of research involving these substances in California.

REGISTERED SUPPORT / OPPOSITION:

Support

None on file.

Opposition

None on file.

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