

OFFICE OF POLICY AND LEGAL ANALYSIS

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To: Joint Standing Committee on Health & Human Services

From: Samuel Senft, Esq., MPH, Legislative Analyst

LD 1582 An Act To Enact the Maine Psilocybin Services Act

SUMMARY: This bill enacts the Maine Psilocybin Services Act, which establishes a regulatory framework in order to provide psilocybin products to clients in Maine. The bill provides for the following:

1. It amends Title 28-B (Adult Use Marijuana) and renames it the Adult Use Marijuana and Psilocybin Act and establishes the Maine Psilocybin Services Act in Part 2.
2. It establishes the Maine Psilocybin Advisory Board, to include 19 members. The Board's duties include adoption of rules; making recommendations to DHHS related to its duties under the Psilocybin Service Act; developing and maintaining a long-term strategic plan for ensuring that psilocybin services will become and remain a safe, accessible and affordable therapeutic option for all persons who are 21 years of age or older and for whom psilocybin services may be appropriate; monitoring and studying federal laws, regulations and policies regarding psilocybin; and attempting to meet with the United States Attorney for the District of Maine to discuss the Maine Psilocybin Services Act and potential federal enforcement policies regarding psilocybin in this State after the program development period.
3. It exempts individuals licensed to possess psilocybin from civil and criminal liability for use of drug paraphernalia.
4. It makes clear that MaineCare and private health insurers are not required to reimburse a person for costs associated with the use of psilocybin products; that it makes no changes to employment law; that it does not impact landlord-tenant matters; that it does not prohibit a recipient or applicant of a federal grant from prohibiting the use, possession or manufacture of psilocybin products to the extent necessary to satisfy federal requirements for the grant; that it does not prohibit a party to a federal contract or a person applying to be a party to a federal contract from prohibiting the use, possession or manufacture of psilocybin products to the extent necessary to comply with the terms and conditions of the contract or to satisfy federal requirements for the contract; that it does not require a person to violate federal law; and that it does not exempt a person from a federal law or allow the person to obstruct the enforcement of a federal law.
5. It directs DHHS to adopt routine technical rules on issues including but not limited to possession limits, age verification for clients, licensing requirements, license fees and tracking.
6. It provides that a medical diagnosis is not required for a person to receive psilocybin services.
7. It requires DHHS to develop, implement and administer a system for tracking psilocybin products and to enter into an agreement with the Department of Administrative and Financial Services under which the department may use the tracking system used for marijuana to track the transfer of psilocybin products.

8. It provides that a client may purchase, possess or consume a psilocybin product only at a psilocybin service center and under the supervision of a psilocybin service facilitator.
9. It prohibits a licensee or licensee representative from selling or delivering a psilocybin product to a person under 21 years of age, unless authorized to do so by the department by rule.
10. It establishes as a class E crime false identification of age for the purposes of acquiring psilocybin or entering a psilocybin service center.
11. It prohibits purchasing, possessing or consuming a psilocybin product outside licensed premises.
12. It establishes as a class E crime selling, giving or otherwise make available a psilocybin product to a person who is visibly intoxicated.
13. It establishes as a class E crime giving a psilocybin product as a prize, premium or consideration for a lottery, contest, game of chance, game of skill or competition of any kind.
14. It establishes as a class E crime employment by a licensee of a person under 21 years of age
15. It requires DHHS to publish on a publicly accessible website available medical, psychological and scientific studies, research and other information, including but not limited to information submitted to the department by the board, relating to the safety and efficacy of psilocybin in treating mental health conditions, including but not limited to substance use disorder, depression, anxiety disorders and end-of-life psychological distress.
16. It states that a contract involving psilocybin products is not unenforceable on the basis that manufacturing, distributing, dispensing, possessing or using psilocybin products is prohibited by federal law.
17. It requires DHHS to maintain a telephone hotline for certain government designees to inquire if an address is the location of a licensee's premises.
18. It makes confidential certain information held by DHHS in relation to psilocybin licensees.
19. It requires DHHS to, beginning of January 15, 2023, issue the following license types: a psilocybin service center license; a psilocybin service facilitator license; a psilocybin manufacturing facility license; and a testing facility license. Licenses are effective for one year and may be renewed.
20. It prohibits DHHS from restricting the number of licenses issued but allows for denial of a license based on good cause.
21. It directs DHHS to develop a system for issuing permits to individuals providing psilocybin services; possessing, manufacturing, securing, selling or tracking of psilocybin products; or verifying a client's age.
22. It provides that a psilocybin manufacturing facility licensee may deliver psilocybin products to premises for which a license has been issued and receive psilocybin products from another psilocybin manufacturing facility licensee.
23. It states that a psilocybin manufacturing facility licensee is not required to manufacture a psilocybin product by means of chemical synthesis.
24. It establishes prohibited conduct for a psilocybin manufacturing facility licensee.
25. It allows a psilocybin service center licensee to engage in the following activities in accordance with rules adopted by the department: deliver psilocybin products to premises for which a license has been issued; receive psilocybin products from a psilocybin

- manufacturing facility licensee or another psilocybin service center licensee; and sell psilocybin products to a client on the premises for which the license has been issued.
26. It establishes prohibited conduct for a psilocybin service center licensee.
 27. It requires that an applicant for a testing facility license must meet qualifications, including accreditation standards, established by the department by rule.
 28. It requires the department to adopt rules requiring a testing facility licensee to test psilocybin products sold or transferred to others by a psilocybin manufacturing facility licensee.
 29. It requires that department to adopt rules establishing standards for testing psilocybin products and identify appropriate tests for different types of psilocybin products and manufacturing processes that are necessary to protect the public health and safety, including but not limited to protection from microbiological contaminants, pesticides, other contaminants, solvents and excessive psilocybin concentration.
 30. It establishes prohibited conduct for a testing facility licensee.
 31. It requires DHHS to adopt rules regarding the services provided by psilocybin service centers and the provision of psilocybin services to a client by a psilocybin service facilitator. The rules must: require a psilocybin service facilitator to hold a preparation session with a client before the client participates in an administration session; require a psilocybin service facilitator to certify, in a form and manner prescribed by the department, that the client completed a preparation session; and permit a preparation session to be held at a psilocybin service center or another location.
 32. It requires DHHS to adopt rules requiring a client to complete and sign a client information form prescribed by the department
 33. It requires DHHS to adopt rules governing administration sessions. The rules must: require that a client complete a preparation session and a client information form prior to an administration session; require an administration session to occur at a psilocybin service center; require a psilocybin service facilitator to certify, in a form and manner prescribed by the department, that the client completed an administration session; and prohibit a psilocybin service facilitator from consuming a psilocybin product during an administration session that the psilocybin service facilitator is supervising.
 34. It requires DHHS to adopt rules governing integration sessions. The rules must: require, upon completion of an administration session, that a psilocybin service facilitator offer to the client the opportunity to participate in an integration session; allow a client to decline to participate in an integration session; allow any integration session to occur at a psilocybin service center or another location; and require a psilocybin service facilitator to certify, in a form and manner prescribed by the department, if a client completed an integration session.
 35. It requires that a psilocybin service center and psilocybin service facilitator maintain confidential information that may be used to identify a client or any communication made by a client during the course of providing psilocybin services or selling psilocybin products to the client, except in specified circumstances.
 36. It provides that the a municipality may adopt ordinances that impose reasonable regulations governing activities on premises for which a license has been issued, except that a municipality may not require a license to conduct any activity licensed under this chapter, impose a tax or fee on the manufacture or sale of psilocybin products or the sale of psilocybin services or prohibit more than one psilocybin service center from being located in the municipality as long as the distance between the centers is greater than 1,000 feet.

37. It allows the governing body of a municipality to prohibit the establishment and operation of a psilocybin manufacturing facility, psilocybin service center or both or remove such a prohibition previously established.
38. It states that the Maine Land Use Planning Commission may prohibit the establishment and operation of a psilocybin manufacturing facility or remove such a prohibition previously established, within an area subject to the jurisdiction of the Maine Land Use Planning Commission.
39. It states that if a governing body adopts a measure prohibiting or removing a prohibition, that measure must be submitted to the electors of the municipality, or within the affected unorganized territory, for approval at the next statewide general election. The measure takes effect only if approved by a majority of the electors voting at that election.
40. It requires DHHS to adopt rules necessary to protect the public health and safety that establish standards for the labeling and packaging of psilocybin products.
41. It requires DHHS to adopt rules establishing the maximum concentration of psilocybin that is permitted in a single serving of a psilocybin product and the number of servings that are permitted in a psilocybin product package.
42. It establishes certain license violations as Class C crimes
43. It allows DHHS to establish administrative penalties of up to \$5,000 for certain violations.
44. It establishes the Psilocybin Control and Regulation Fund, to be funded with Money received from the license fees and administrative penalties and by money from any other source, whether public or private, designated for deposit into or credited to the fund. Money credited to the fund may be used by the department for the purposes of implementing, administering and enforcing the Psilocybin Services Act.
45. It imposes a tax of 15% upon the retail sale of psilocybin products in this State. The tax imposed by this section is a direct tax on the client, for which payment upon retail sale is required. The tax must be collected at the point of sale of a psilocybin product by a psilocybin service center operator at the time at which the retail sale occurs.
46. It provides that for the purpose of compensating psilocybin service center operators for expenses incurred in collecting the tax imposed under this chapter, each psilocybin service center operator may deduct and retain 2% of the amount of taxes that are collected by the psilocybin service center operator from all retail sales of psilocybin products conducted by the psilocybin service center operator.
47. It provides that a psilocybin service center operator shall file a return with the State Tax Assessor on or before the last day of January, April, July and October of each year for the previous calendar quarter.
48. It provides that all money received by the State Tax Assessor under this chapter must be deposited in a nonlapsing administrative account. The State Tax Assessor may pay expenses for the administration and enforcement of this chapter from the account. After the payment of administrative and enforcement expenses and refunds or credits arising from erroneous overpayments, the State Tax Assessor shall transfer on a quarterly basis the balance of the funds to the Psilocybin Control and Regulation Fund.
49. It provides that The Department of Health and Human Services shall adopt rules no later than November 15, 2023 in order to implement, administer the Psilocybin Services Act
50. It provides that later than June 15, 2022, the Department of Health and Human Services shall first publish information about psilocybin in accordance with the Maine Revised Statutes, Title 28-B, section 2012.

51. It provides that the Department of Health and Human Services, in consultation with the Department of Agriculture, Conservation and Forestry and the State Tax Assessor, shall examine laws of this State and develop recommendations for any amendments to those laws to conform to this Act and to otherwise make this Act as consistent as possible in substance to the laws governing psilocybin in Oregon. No later than December 1, 2021, the department shall submit its recommendations together with suggested legislation to the Joint Standing Committee on Health and Human Services. The Joint Standing Committee on Health and Human Services may report out a bill related to the recommendations of the department to the Second Regular Session of the 130th Legislature.

ISSUES FROM TESTIMONY:

- Many commenters testified as to the medicinal value of psilocybin in the treatment of a number of medical conditions.
- Maine Revenue Services requested that the taxation of psilocybin products be incorporated into Maine’s existing sales tax structure instead of enacting the provisions found in Section 21 of this bill.
- The Maine Municipal Association expressed concern that the bill assumes psilocybin services are authorized unless the community moves to prohibit the industry from operating within municipal boundaries. The Association noted that opt-out requires approval by the legislative body and that the community’s residents must validate that decision at a subsequent statewide general election, which is held in November. The Association expressed concern that the timing will enable providers to operate in communities before voters act. The Association also expressed concern that the bill states that municipalities can only adopt and enforce “reasonable regulations” limited to: (1) conditions on the manufacturing of related products and services; (2) operating hours; (3) public access to licensed premises; and (4) limits on where premises may be located.
- Some commenters raised concerns that psilocybin has not yet been fully vetted by the FDA.
- Some commenters raised concerns that the bill does not provide for medical supervision of psilocybin use. Others argued that the bill provided for adequate protections.
- Some commenters suggests that the bill be amended to allow for use outside of psilocybin service centers.
- The Maine CDC expressed concern that the bill established recreational use facilities rather than medical treatment facilities, puts limitations on the Department’s ability to regulate safe use, and does not incorporate sufficient behavioral and public health input to the structure.

EXISTING LAW

- [14-A MRSA §1102](#) lists psilocybin as a Schedule X drug.
- Criminal violations related to psilocybin in Maine include:
 - Trafficking: [17-A MRSA §1103, sub-§1-A](#) = Class C crime
 - Aggravated trafficking: [17-A MRSA §1105, sub-§1, ¶A, sub-¶\(3\)](#) = Class B crime

- Furnishing: [17-A MRSA §1106, sub-§1-A, ¶B](#) = Class D crime
- Aggravated furnishing: [17-A MRSA §1105-C, sub-§1, ¶A, sub-¶\(3\)](#) = Class C crime
- Possession: [17-A MRSA §1107-A, sub-§1, ¶D](#) = Class D crime
- Acquiring by deception: [17-A MRSA §1108, sub-§1, ¶B](#) = Class C crime
- Stealing: [17-A MRSA §1109, sub-§2, ¶A](#) = Class C crime
- Illegal importation: [17-A MRSA §1118, sub-§2, ¶B](#)
- Aggravated illegal importation: [17-A MRSA §1118-A, sub-§1, ¶A, sub-¶\(2\)](#)

DRAFTING/ POTENTIAL LEGAL ISSUES

1. Psilocybin remains a [Schedule 1](#) controlled substance at the federal level. Individuals engaged in research are required to obtain DEA approval in order to study the drug. This bill may create a conflict with federal law.
2. This bill does not explicitly decriminalize psilocybin use or possession in Maine.
3. This bill is complex and touches on a number of areas that may require detailed review by involved agencies, including DHHS, Maine Revenue Services, the Department of Agriculture, Conservation and Forestry and the Department of Administrative and Financial Services, as well as the Attorney General's Office.
4. The bill creates a number of new crimes and therefore will require review by the Committee on Criminal Justice and Public Safety.
5. The bill does not establish a medical model for use of psilocybin. It is unclear to what extent administration of psilocybin could be considered to impinge upon the practice of medicine. This may require analysis by the Office of the Attorney General and the Boards of Medicine and Osteopathic Medicine.
6. A number of the 25 MRSA §1542-A amendments (related to fingerprinting) may no longer be necessary, as language passed last session enacted many of the changes included in the bill
7. A number of deadlines in the bill will need to be adjusted, as these deadlines have either passed or will not be feasible given the timeline of the Second Session.

OTHER JURISDICTIONS

Oregon: In November of 2020, voters approved an initiative authorizing the Oregon Health Authority to establish a program to permit licensed service providers to administer psilocybin-producing mushroom and fungi products to adults. The text of the Oregon Psilocybin Services Act is [here](#). That Act is similar to the Maine Psilocybin Services Act. The Oregon Health Authority's website related to the Oregon Psilocybin Services Act is [here](#). Their Scientific Literature review webpage is [here](#).

Washington D.C.: In November of 2020, voters approved a [ballot initiative](#) that decriminalized the personal cultivation and possession of "entheogenic plants and fungi", which include psilocybin.

ADDITIONAL INFORMATION:

- Carhart-Harris R, Giribaldi B, Watts R, et al. Trial of psilocybin versus escitalopram for depression. N Engl J Med. 2021;384 (15):1402-11. DOI: 10.1056/NEJMoa2032994. Available online at <https://www.nejm.org/doi/pdf/10.1056/NEJMoa2032994?articleTools=true>.
- [Johns Hopkins University Center for Psychedelic and Consciousness Research](#).
- [DOJ/DEA Drug Fact Sheet: Psilocybin](#)

FISCAL IMPACT: Not yet determined