



131st MAINE LEGISLATURE

FIRST SPECIAL SESSION-2023

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S.P. 774	In Senate, May 9, 2023

An Act to Enact the Maine Psilocybin Health Access Act

Reference to the Committee on Health and Human Services suggested and ordered printed.

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DAREK M. GRANT Secretary of the Senate

Presented by Senator BAILEY of York. Cosponsored by Representative THERIAULT of Fort Kent and Senators: BRAKEY of Androscoggin, BRENNER of Cumberland, Representatives: ANKELES of Brunswick, BOYER of Poland, MALON of Biddeford.

1	Be it enacte	d by the People	of the State of N	Aaine as f o	ollows:	
2	Sec. 1.	5 MRSA §120	04-I, sub-§73-(C is enacte	d to read:	
3	<u>73-C.</u>	J. J				
4 5 6	Psilocybin	Maine Psilocy	vbin Advisory Bo	<u>pard</u>	Expenses and Legislative Per Diem	<u>28-B MRSA</u> <u>§2132</u>
7 8	Sec. 2. further amen		§1111-A, sub-	§1, as ame	ended by PL 20	21, c. 669, §1, is
9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	and material cultivating, processing, scheduled dr does not app to Title 22, or medical use of 28-B, to the to a cannabis relates to the is authorized paraphernali is authorized sale or offeri	Is of any kind t growing, harves preparing, pack ug in violation of ly to a person wh chapter 558-C, to of cannabis; to a p extent the drug p s store licensed pu s ale or offering d to possess psile a is used for that to possess psile ing for sale of psile used or intended	hat are used or ting, manufactur aging, repackag f this chapter or T to is authorized to the extent the person who is authorized araphernalia is us ursuant to Title 2 for sale of cannal ocybin pursuant person's personal cybin or to the ex- cilocybin. It included for use in pla	intended tring, comp ging, storin Fitle 22, sec to possess of drug parap thorized to sed for that 8-B, to the bis by the of to Title 2 <u>al use of psi- tent that th</u> des, but is p	for use in plant bounding, conve- ng, containing etion 2383, excep- cannabis for mea- bhernalia is used possess cannabi- person's adult u- extent that the d cannabis store; <u>c</u> 28-B, to the ext <u>clocybin, to the e- e drug paraphern</u> not limited to: pagating, cultiva	uipment, products ting, propagating, erting, producing, or concealing a pt that this section dical use pursuant l for that person's s pursuant to Title use of cannabis; or lrug paraphernalia or to a person who ent that the drug extent the licensee nalia relates to the ating, growing or which a scheduled
26 27 28	B. Kit	be derived; s used or inten ng, processing or				ding, converting,
29 30	C. Ison	0.1	s used or intend	•		ne potency of any
31 32	E. Scale drugs;	es and balances u	used or intended	for use in	weighing or mea	asuring scheduled
33 34		and lactose, use				annitol, mannite, rugs;
35 36	-	ration gins and s in otherwise clea				g twigs and seeds
37 38		ders, bowls, cont	· .	nd mixing o	levices used or i	ntended for use in
39 40		ules, balloons, e ng small quantitie			ners used or in	tended for use in

1 2	J. Containers and other objects used or intended for use in storing or concealing scheduled drugs.
3	Sec. 3. 28-B MRSA, headnote is amended to read:
4	TITLE 28-B
5	ADULT USE CANNABIS AND PSILOCYBIN
6 7	Sec. 4. 28-B MRSA Pt. 1 is enacted by adding before chapter 1 the following to read:
8	<u>PART 1</u>
9	ADULT USE CANNABIS
10	Sec. 5. 28-B MRSA Pt. 2 is enacted to read:
11	<u>PART 2</u>
12	<u>PSILOCYBIN</u>
13	<u>CHAPTER 5</u>
14	MAINE PSILOCYBIN HEALTH ACCESS ACT
15	SUBCHAPTER 1
16	GENERAL PROVISIONS
17	<u>§2001. Short title</u>
18	This chapter may be known and cited as "the Maine Psilocybin Health Access Act."
19	<u>§2002. Definitions</u>
20 21	As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.
22 23	<u>1. Administration session.</u> "Administration session" means a session in which a client consumes a psilocybin product under the supervision of a psilocybin service facilitator.
24 25 26 27	2. Approved medical provider. "Approved medical provider" means a physician or physician assistant licensed under Title 32, chapter 36 or 48, a certified nurse practitioner licensed under Title 32, chapter 31 or a naturopathic doctor licensed under Title 32, chapter 113-B.
28	3. Board. "Board" means the Maine Psilocybin Advisory Board under section 2132.

1 2 3	4. Business entity. "Business entity" means a corporation, limited liability company, limited partnership or other legal entity that is registered with the office of the Secretary of State.
4	5. Client. "Client" means an individual who receives psilocybin services in this State.
5 6	<u>6. Client information form.</u> "Client information form" means the form required to be completed by a client under subchapter 8.
7	7. Department. "Department" means the Department of Health and Human Services.
8 9 10	8. Integration session. "Integration session" means a meeting between a client and a psilocybin service facilitator that may occur after the client completes an administration session.
11 12	9. Licensee. "Licensee" means a person holding a current, valid license issued under this chapter.
13 14 15	<u>10. Licensee representative.</u> "Licensee representative" means an owner, director, officer, manager, employee, agent or other representative of a licensee to the extent that person acts in a representative capacity.
16 17 18 19 20	11. Manufacture. "Manufacture" means the cultivation, harvesting, production, preparation, propagation, compounding, conversion or processing of a psilocybin product by extraction from substances of natural origin or by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging of the psilocybin product or labeling of its container.
21 22	12. Personal use amount. "Personal use amount" means the amount of psilocybin authorized for a client's use under section 2091, subsection 1, paragraph A.
23 24 25 26 27	13. Premises. "Premises" means all public and private enclosed areas as well as areas outside of a building used for activities licensed under this chapter, including manufacturing psilocybin products, operating a psilocybin service center or providing psilocybin services to clients, and includes but is not limited to offices, kitchens, restrooms and storerooms.
28 29 30	14. Preparation session. "Preparation session" means a meeting between a prospective client and a psilocybin service facilitator that occurs before an administration session.
31 32 33	15. Psilocybin. "Psilocybin" means the naturally occurring compound produced by various species of fungi as well as psilocin, the substance into which psilocybin is converted in the human body.
34 35	<u>16. Psilocybin Control and Regulation Fund.</u> "Psilocybin Control and Regulation Fund" means the fund established under subchapter 14.
36 37	<u>17. Psilocybin manufacturing facility.</u> "Psilocybin manufacturing facility" means a <u>facility licensed under subchapter 4.</u>
38 39 40	18. Psilocybin product. "Psilocybin product" means psilocybin-producing fungi or mixtures or substances containing a detectable amount of psilocybin. "Psilocybin product" does not include psilocybin services.
41 42	19. Psilocybin service center. "Psilocybin service center" means a place where the activities licensed under subchapter 5 may be conducted.

1 2	<u>20. Psilocybin service center operator.</u> "Psilocybin service center operator" means a person or entity that operates a psilocybin service center.
3 4	21. Psilocybin service facilitator. "Psilocybin service facilitator" means a person or entity licensed in accordance with subchapter 6 to provide psilocybin services.
5 6 7	22. Psilocybin services. "Psilocybin services" means services provided to a client before, during and after the client's consumption of a psilocybin product, including a preparation session, administration session and integration session.
8 9 10	23. Risk assessment screening. "Risk assessment screening" means a questionnaire included in a client information form to guide a psilocybin service facilitator in determining whether a client is eligible for psilocybin services as required under section 2081.
11	24. Testing facility. "Testing facility" means a facility licensed under subchapter 7.
12	<u>§2003. Scope</u>
13 14	<u>1. Limitations.</u> A person may not possess, manufacture or test more than a personal use amount of psilocybin unless that person is a licensee authorized under this chapter.
15	2. Construction. This chapter may not be construed to:
16 17	A. Require the MaineCare program or private health insurance coverage to reimburse a person for costs of psilocybin products;
18	B. Amend or affect state or federal law pertaining to employment matters;
19	C. Amend or affect state or federal law pertaining to landlord-tenant matters;
20 21 22	D. Prohibit a recipient of or applicant for a federal grant from prohibiting the use, possession or manufacture of psilocybin products to the extent necessary to satisfy federal requirements for the grant;
23 24 25 26	<u>E. 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;</u>
27	F. Require a person to violate federal law;
28 29	<u>G. Exempt a person from a federal law or allow the person to obstruct the enforcement of a federal law;</u>
30 31 32 33	H. Permit a person to give away any amount of psilocybin as part of a business promotion or other commercial activity. This provision does not preclude the charitable donation of psilocybin or limit the ability of a psilocybin service center to donate psilocybin or provide psilocybin at reduced cost consistent with department rules; or
34	I. Authorize any activity that is not expressly authorized under this chapter.
35	3. Effect of authorized conduct. Conduct authorized under this chapter may not:
36 37	A. Constitute child abuse or neglect without a finding of actual threat to the health or welfare of a child based on all relevant factors;
38 39 40	B. Be the basis to restrict a person's parenting time with a child without a finding that the parenting time would endanger the child's physical health or significantly impair the child's emotional development;

1 2 3	C. Be the basis for detention, search or arrest or constitute reasonably articulable suspicion of a crime. Psilocybin as permitted by this chapter is not contraband nor subject to seizure and may not be harmed or destroyed;
4 5	D. Be the basis to deny eligibility for any public assistance program, unless required by federal law; or
6 7	E. Constitute the use of an illicit substance or otherwise disqualify a person from medical care or medical insurance, including organ transplants.
8	<u>§2004. Rulemaking</u>
9 10	<u>The department shall adopt all rules necessary to implement, administer and enforce</u> this chapter, including but not limited to rules governing the following:
11 12 13 14 15	1. Possession limits on premises. The quantity of psilocybin permitted on premises at one time. In adopting rules pursuant to this subsection, the department shall take into consideration the demand for psilocybin services in the State, the number and location of licensees that operate manufacturing facilities and whether the availability of psilocybin products in this State is commensurate with the demand for psilocybin services;
16 17	2. Age verification. The manner in which a licensee verifies a person's age for the purpose of ensuring that a client is 21 years of age or older;
18 19	3. Licensing requirements. The application process for licensure under this chapter and annual renewal of licensure;
20 21 22 23 24	4. License fees. License fees required for applicants applying for licensure in accordance with this chapter. License fees set by the department may not exceed the cost of administering this chapter. Notwithstanding Title 5, section 8071, subsection 3, paragraph B, rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A;
25 26	5. Prevention of diversion to unauthorized persons. The prevention of diversion of psilocybin products to persons that are not permitted to possess or use psilocybin; and
27 28 29	<u>6. Administration sessions.</u> A process to allow a psilocybin service facilitator to provide psilocybin services at locations other than a psilocybin service center, including a client's residence or a medical facility.
30 31	The department may not require a client to be diagnosed with or have any particular medical condition in order to receive psilocybin services.
32	In adopting rules, the department shall consider the recommendations of the board.
33 34	Except as otherwise provided in this chapter, rules adopted pursuant to this chapter are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.
35	§2005. Record keeping and inspection of records and premises; notice
36 37 38 39 40	1. Record keeping; inspection of records. A licensee shall maintain a complete set of all records of the licensee's business transactions, which must be open to inspection and examination by the department upon demand and with 72 hours' notice during all business hours. The department may not require the records of a licensee to be maintained on the premises of the licensee.

1 2 3	2. Inspection of premises. The department may at any time make an examination of premises for which a license has been issued for the purpose of determining compliance with the provisions of this chapter and the rules adopted pursuant to this chapter.
4	§2006. Administration sessions outside licensed premises prohibited; exception
5 6 7	A client may participate in an administration session only at a psilocybin service center, unless the department authorizes a psilocybin service facilitator to provide psilocybin services to the client at another location.
8	<u>§2007. Delivery and sale of psilocybin to persons under 21 years of age prohibited</u>
9 10 11 12	1. Licensee prohibition. A licensee or licensee representative may not sell or deliver a psilocybin product to a person under 21 years of age. Before selling or providing a psilocybin product to a client, the licensee must require the person to produce one of the following pieces of identification:
13	<u>A. A passport;</u>
14	B. A driver's license;
15	C. A nondriver identification card issued under Title 29-A, section 1410;
16	D. A United States military identification card;
17 18	E. An identification card issued by one of the federally recognized Indian tribes in this State; or
19 20 21	<u>F. Any other identification card issued by a state or territory of the United States that</u> bears a photograph of the person, the name of the person, the person's date of birth and a physical description of the person.
22 23 24	<u>A licensee or licensee representative is not in violation of this subsection if the licensee or licensee representative reasonably relied on an identification provided by a person that did not accurately provide that person's age.</u>
25 26	A person who violates this subsection commits a civil violation for which a penalty of not more than \$500 may be adjudged.
27 28	<u>2. False identification.</u> A person may not produce a piece of identification under subsection 1 that falsely indicates the person's age.
29	A person who violates this subsection commits a Class E crime.
30	§2008. Psilocybin product to visibly intoxicated person prohibited
31 32	A person may not sell, give or otherwise make available a psilocybin product to a person who is visibly intoxicated.
33 34	<u>A person who violates this section commits a civil violation for which a fine of not</u> <u>more than \$500 may be adjudged.</u>
35	§2009. Psilocybin product as a prize prohibited
36 37	A person may not give a psilocybin product as a prize, premium or consideration for a lottery, contest, game of chance, game of skill or competition of any kind.
38 39	<u>A person who violates this section commits a civil violation for which a fine of not more than \$500 may be adjudged.</u>

1 §2010. Employment of persons under 21 years of age prohibited

2 A licensee may not employ a person under 21 years of age. The department may verify a person's age in accordance with this section. During an inspection in accordance with 3 4 this chapter, the department may require proof that a person performing work at the 5 premises is 21 years of age or older. If the person does not provide the department with 6 acceptable proof of age upon request, the department may require the person to 7 immediately cease any activity and leave the premises until the department receives 8 acceptable proof of age. The department may request that the licensee provide proof that 9 the person is 21 years of age or older. Failure of the licensee to respond to the request is 10 prima facie evidence that the licensee has allowed the person to perform work at the 11 premises for which a license has been issued, except that it is an affirmative defense that 12 the person is only temporarily at the premises to make a service, maintenance or repair call 13 or for other purposes and is not an employee of the licensee.

A person who violates this section commits a civil violation for which a fine of not
 more than \$500 may be adjudged.

16 §2011. Publication of information related to use of psilocybin

17 The department shall publish on a publicly accessible website available medical, 18 psychological and scientific studies, research and other information, including but not 19 limited to information submitted to the department by the board, relating to the safety and 20 efficacy of psilocybin in treating mental health conditions, including but not limited to 21 substance use disorder, depression, post-traumatic stress disorder, anxiety disorders and 22 end-of-life psychological distress.

23 §2012. Investigation by criminal justice agency of unlawful activity

A criminal justice agency may investigate unlawful activity under this chapter and may conduct a criminal history record check of a licensee or its employees during an investigation of unlawful activity in relation to a licensee. A law enforcement officer may enforce any provision of this chapter and may assist the department in enforcing this chapter.

A law enforcement officer who has notice, knowledge or reasonable suspicion of a
 violation of this chapter shall immediately notify the district attorney who has jurisdiction
 over the violation and furnish that district attorney with names and addresses of any
 witnesses to the violation or other information related to the violation.

33 §2013. Cooperation of other state entities; immunity

All state agencies, including but not limited to the Department of Administrative and Financial Services, shall upon request of the department assist and cooperate with the department to the extent necessary for the department to carry out its duties under this chapter. The Department of Agriculture, Conservation and Forestry may possess, test and dispose of psilocybin products on behalf of the department.

- Notwithstanding any provision of law to the contrary, the State, its agencies and
 employees are immune from any liability arising out of the performance or nonperformance
 of any duty or function, or the exercise of any power, under this chapter or any other law
 of this State relating to psilocybin products.
- 43 §2014. Immunity; refusal to serve; insurance

1 **1. Reliance immunity.** A licensee or licensee representative may reasonably rely 2 upon all statements, declarations and representations made by a client on a client 3 information form unless a reasonable person would have reason to believe a statement. 4 declaration or representation on the form was incorrect or altered. A licensee or licensee representative who in good faith reasonably relies on statements, declarations and 5 6 representations made by a client on a client information form in accordance with this 7 subsection may not be found in violation of this chapter for selling or serving a psilocybin 8 product to that person based on those statements, declarations and representations. Nothing 9 in this subsection creates any immunity for a licensee or licensee representative who has 10 otherwise violated this chapter or a rule adopted pursuant to this chapter. 2. Refusal to serve. Nothing in this chapter requires a licensee or licensee 11 12 representative to provide psilocybin services to any person. Except as provided in this 13 section, a licensee or licensee representative may refuse to provide psilocybin services to 14 any person or may cease providing such services to a client for any reason or for no reason 15 as long as those reasons are not on the basis of the person's protected class status as defined 16 in the Maine Human Rights Act. A licensee or licensee representative may not cease 17 providing psilocybin services during an administration session after the client has 18 consumed a psilocybin product except as authorized by the department by rule or as 19 necessary in an emergency. 20 3. Insurance. The department may by rule require licensees to maintain general 21 liability insurance in an amount the department determines is reasonably affordable and 22 available for the purpose of protecting licensees against damages resulting from causes of 23 action related to activities undertaken pursuant to this chapter. 24 4. Discrimination. A licensee may not discharge, demote, suspend or in any manner 25 discriminate or retaliate against an employee of the licensee with regard to promotion, 26 compensation or other terms, conditions or privileges of employment on the basis that the 27 employee has in good faith reported information to the department about an action or 28 inaction of the licensee that the employee reasonably believes is a violation of this chapter 29 or any rules adopted pursuant to this chapter. 30 §2015. Enforceability of contracts 31 A contract involving psilocybin products is not unenforceable on the basis that 32 manufacturing, distributing, dispensing, possessing or using psilocybin products is 33 prohibited by federal law. 34 §2016. Department hotline for verification of license 35 The department shall maintain a telephone hotline for the following persons to inquire 36 if an address is the location of a licensee's premises or is the location of premises for which 37 an application for licensure has been submitted under this chapter: 38 **1. Designation by municipality.** A person designated by a municipality or a county as 39 a contact for purposes of this chapter; 40 2. Designation by state agency. A person designated by a state agency as a contact for 41 purposes of this chapter; and 42 **3. Designation by water district.** A person designated by a water district as a contact 43 for purposes of this chapter.

1	<u>§2017. Confidentiality</u>
2	1. Confidential. The following information obtained by the department under this
3	chapter is confidential and may not be disclosed except as provided in subsection 2:
4	A. Personally identifiable information, as defined by the department by rule, other than
5 6	the name of a direct owner. For purposes of this paragraph, "direct owner" means an individual listed on an application for a license who is an owner of the business
7	operating or to be operated under the license. "Direct owner" does not include a legal
8	entity other than an individual and does not include an individual who is a general
9 10	partner, limited partner, member, shareholder or other direct or indirect owner of such a legal entity;
10	B. The address of premises for which a license has been issued or for which an
12	applicant has proposed licensure under this chapter;
13	C. Information related to the security plan or the operational plan for premises for
14 15	which a license has been issued or for which an applicant has proposed licensure under this chapter; and
16	D. Information related to any record that the department determines by rule to contain
17	proprietary information of a licensee.
18 19	2. Exceptions. Information designated as confidential under subsection 1 may be disclosed to a law enforcement agency for law enforcement purposes.
17	disclosed to a faw emoreement agency for faw emoreement purposes.
20	SUBCHAPTER 2
21	GENERAL LICENSING REQUIREMENTS
22	<u>§2021. License process; license types</u>
23	Beginning January 15, 2025, the department, upon receipt of an application from an
24 25	applicant for a license under this chapter, shall, upon determination that all applicable requirements for that license are met, issue to the applicant the license. The department
26	may not unreasonably delay processing, approving or denying an application or, if an
27	application is approved, unreasonably delay issuing the license.
28 29	<u>1. License types.</u> The following licenses may be issued under this chapter in accordance with all applicable requirements of this chapter:
30	A. A psilocybin service center license;
31	B. A psilocybin service facilitator license;
32	C. A psilocybin manufacturing facility license; or
33	D. A testing facility license.
34	Except as otherwise provided in this chapter, the department may not impose any limitation
35	on the number of each type of license that it issues to a qualified applicant or on the total
36	
37	number of each type of license that it issues to qualified applicants pursuant to this chapter. §2022. General licensing criteria

37 §2022. General licensing criteria

1 2 3 4 5 6	An applicant for a license under this chapter shall meet each of the requirements of this section. An applicant shall disclose in or include with its application the name and address of the applicant and each natural person and business entity that would have a direct or indirect financial interest in the license and the nature and extent of that financial interest and, if applicable, the nature and extent of any financial interest the person or entity has in any other license applied for or issued under this chapter.
7 8 9	1. Age. The applicant must be at least 21 years of age. If the applicant is a business entity, every officer, director, manager and general partner of the business entity must meet this requirement.
10 11	<u>2. Incorporated in State.</u> If the applicant is a business entity, the business entity must be incorporated in the State or otherwise formed or organized under the laws of the State.
12 13 14 15 16 17 18 19	3. No disqualifying drug offense. The applicant may not have been previously convicted of violating a federal law, state law or local ordinance if the conviction is substantially related to the fitness and ability of the applicant to lawfully carry out activities under the license, as determined by the department by rule. If the applicant is a business entity, every officer, director, manager and general partner of the business entity must satisfy this requirement. The department may not determine that an individual's prior criminal history related to drug offenses relates to the fitness and ability of the applicant to lawfully carry out activities under the license.
20 21 22 23	<u>4. Criminal history record check.</u> The applicant must have submitted to a criminal history record check in accordance with section 2024. If the applicant is a business entity, every officer, director, manager and general partner of the business entity must satisfy this requirement.
24 25 26 27	5. Compliance. An applicant who has previously held a license under this chapter must have a good record of compliance with this chapter and any rules adopted in accordance with this chapter and may not have had a license issued under this chapter revoked for any reason.
28 29 30	<u>6. Truthfulness.</u> The applicant may not make any false statements to the department. If the applicant is a business entity, every officer, director, manager and general partner of the business entity is subject to this requirement.
31 32 33	7. Health and safety. The applicant must demonstrate an ability to meet any public health and safety standards and industry best practices established by the department by rule.
34 35 36 37 38	8. Form. The applicant must disclose the applicant's name, address, location where the licensed activities will be conducted and any other information requested by the department in the manner required by the department, except that an applicant for a psilocybin service facilitator license need not identify a location where the licensed activities will be conducted.
39 40 41	<u>9. Payment of fees.</u> The applicant must pay the fees established by the department by rule. Fees collected pursuant to this subsection must be deposited into the Psilocybin Control and Regulation Fund.
42	§2023. Additional licensing considerations

1 2 3 4	1. Financial disclosures. An applicant for a license under this chapter must submit, at the request of the department, the name and address of each person that has a financial interest in the business that will be operated under the license and the nature and extent of that financial interest.
5 6	2. Limitations on psilocybin service centers. A psilocybin service center may not be located:
7	A. In any area that is not within the limits of an incorporated municipality;
8	B. In any area that is zoned exclusively for residential use; or
9	C. Within 1,000 feet of a public or private elementary or secondary school, unless:
10 11 12	(1) The department determines that there is a physical or geographic barrier capable of preventing children from reaching the premises of the psilocybin service center; or
13 14	(2) The school had not previously been attended by children and was not attended by children at the time the license was issued.
15 16	A psilocybin service center must meet any other requirements for the facility established by the department by rule.
17	§2024. Criminal history record check
18 19 20 21 22 23 24	The department shall request a criminal history record check for each applicant for a license or permit under this chapter and may at any time require a person applying for a license or permit to submit to a criminal history record check in accordance with this section. If the applicant is a business entity, every officer, director, manager and general partner of the business entity and any individual who holds a financial interest in the business entity of at least 10% must submit to a criminal history record check in accordance with this section.
25 26 27 28	1. Record of public criminal history information required. Criminal history record information obtained from the Maine Criminal Justice Information System, established in Title 16, section 631, pursuant to this section must include a record of public criminal history record information as defined in Title 16, section 703, subsection 8.
29	2. Availability of criminal history record information. The subject of a Federal
30 31 32 33 34	Bureau of Investigation criminal history record check may obtain a copy of the criminal history record check by following the procedures outlined in 28 Code of Federal Regulations, Sections 16.32 and 16.33. The subject of a state criminal history record check may inspect and review the criminal history record information pursuant to Title 16, section 709.
35 36 37	3. Use of criminal history record information. State and national criminal history record information obtained by the department under this section may be used only for the purpose of screening an applicant for a license or permit under this chapter.
38 39 40 41	4. Confidentiality. All criminal history record information obtained by the department pursuant to this section is confidential, is for the official use of the department only and may not be disseminated outside of the department or disclosed to any other person or entity except as provided in subsection 2.

1 2 3	5. Rules. The department, after consultation with the Department of Public Safety, <u>Bureau of State Police, State Bureau of Identification, shall adopt rules to implement this</u> <u>section.</u>
4	§2025. Application process; issuance of license
5 6 7	1. Forms; payment of fees. An applicant for a license under this chapter shall file an application on a form prepared and furnished by the department for the license sought along with the appropriate application fee.
8 9 10	2. Application for multiple licenses. An applicant may apply for and be granted multiple licenses of any license type under this chapter, except that a person may not have a financial interest in:
11	A. More than one psilocybin manufacturing facility;
12	B. More than 5 psilocybin service centers; or
13 14	C. A testing facility and a psilocybin manufacturing facility or psilocybin service center.
15 16 17	3. Each license separate; locations. Each license issued by the department to an applicant under this chapter is separate and distinct from any other license issued by the department to that same applicant under this chapter.
18 19 20	A. Except in the case of a psilocybin service facilitator's license, a person must obtain a separate license under this chapter for each geographic location where the licensed activities will occur.
21 22	B. A person may hold a psilocybin manufacturing license and a psilocybin service center license at the same or different locations.
23 24 25 26 27 28 29	4. Licensee must maintain possession of premises. As a condition of licensure, a licensee must at all times maintain possession of the licensed premises under the license, whether pursuant to a lease, rental agreement or other arrangement for possession of the premises or by virtue of ownership of the premises. If a licensee fails to maintain possession of the licensed premises, the licensee shall immediately cease all licensed activities and may either apply to the department for relocation of the licensed premises or may terminate its license in accordance with this chapter.
30	§2026. Denial of license
31 32 33 34	1. Denial for good cause. The department, for good cause, may deny an application for an initial license, a license renewal, a transfer of ownership interests or a relocation of licensed premises. Denial of an application by the department pursuant to this section constitutes a final agency action as defined in Title 5, section 8002, subsection 4.
35 36	2. Good cause defined. As used in this section, "good cause" means a finding by the department that an applicant or licensee:
37 38	A. Has violated any provisions of this chapter or any rules adopted in accordance with this chapter; or
39 40 41	B. Has been convicted of a crime or an offense under this chapter, except that the department may not consider a conviction for an offense under this chapter if the date of the conviction is 2 or more years before the date of the application.

1 2	"Good cause" does not include a violation by an applicant or licensee of a federal law prohibiting manufacture, use or possession of psilocybin products.
3 4 5 6	3. Grounds for suspension or revocation. The department may suspend or revoke a license issued under this chapter for a violation by the licensee, or by an agent or employee of the licensee, of the provisions of this chapter, rules adopted pursuant to this chapter or the terms, conditions or provisions of the licensee's license or if the department finds:
7 8 9	A. That the licensee or an agent or employee of the licensee has made a false representation or statement to the department in order to induce or prevent action by the department;
10 11	B. That the licensee is insolvent or incompetent or physically unable to carry on the licensed activities;
12 13	<u>C. That the licensee or an agent or employee of the licensee has misrepresented to a person or the public any psilocybin products sold by the licensee;</u>
14 15 16 17	D. That the licensee or an agent or employee of the licensee has been convicted of any crime or found by a court of competent jurisdiction to have violated any provision of this chapter or of a municipal ordinance, if the violation of that ordinance occurred on the premises for which the license was issued;
18 19	E. That the licensee or an agent or employee of the licensee has diverted psilocybin products to an entity that is not operating legally under the laws of this State;
20 21 22	F. That the licensee or an agent or employee of the licensee has purchased or received a psilocybin product from an unlicensed source or has sold, stored or transferred a psilocybin product in a manner that is not permitted by the licensee's license; or
23 24 25 26	<u>G.</u> That a person with a financial interest in the business operating or to be operated under the license committed or failed to take an act if that act or failure to act would constitute grounds for the department to refuse to issue, or to suspend, revoke or refuse to renew, the license if the person were the licensee or applicant for the license.
27	<u>§2027. License term; renewal</u>
28 29	A license issued by the department pursuant to this chapter is effective for a period of one year from the date of issuance and may be renewed pursuant to this section.
30 31 32	<u>1. Application.</u> A licensee seeking to renew an existing license must file an application for renewal with the department, on forms prepared and furnished by the department, not less than 30 days prior to the date of expiration of the license.
33 34 35 36	2. Expired license. A person whose license has expired shall immediately cease all activities authorized under that license and ensure that all psilocybin in the possession of the person pursuant to that license is forfeited to the department for destruction in accordance with this chapter.
37	<u>§2028. License properties; transfer; leftover product</u>
38 39 40 41 42	A license issued under this chapter is a personal privilege, expires upon the death of the licensee except as otherwise expressly provided in this chapter, does not constitute property, is not alienable, is not subject to attachment or execution and may not be transferred by will, devise or intestate succession. The department may by rule provide for the manner and conditions under which:

- 1 **<u>1. Psilocybin products. Psilocybin products left by a deceased, insolvent or bankrupt</u> 2 person or licensee may be sold or otherwise disposed of and any security interest in the 3 products foreclosed or settled;**
- 4 **2. Business.** The business of a deceased, insolvent or bankrupt licensee may be 5 operated for a reasonable period following the death, insolvency or bankruptcy; and
- 6 **3. Security interest.** A person with a security interest in relevant property may 7 continue to operate at the premises for which a license has been issued under this chapter 8 for a reasonable period after default on the indebtedness by the licensee.
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SUBCHAPTER 3

PERMIT REQUIREMENTS; PERMIT VIOLATIONS

11 §2031. Permit required

- 12 <u>1. Permit.</u> A person who performs any of the following activities for or on behalf of a
 13 licensee must have a valid permit issued by the department under this subchapter:
- 14 <u>A. Providing psilocybin services;</u>
- 15 B. Possessing, manufacturing, securing or selling of psilocybin products; or
- 16 <u>C. Verifying a client's age.</u>

A licensee shall verify that a person has a valid permit before allowing that person to
 perform any of the activities listed in this subsection. A permit issued under this subsection
 is personal to the individual permittee and does not grant any authority to any person other
 than the named permittee.

21 2. Qualifications. The department shall adopt rules establishing the qualifications for
 22 obtaining a permit under this section, the term of a permit issued, procedures for applying
 23 for and renewing a permit and reasonable application, issuance and renewal fees for a
 24 permit.

25 The qualifications for the permit must include training requirements relating to checking 26 client identification, detecting intoxication, handling psilocybin products, manufacturing 27 psilocybin products, the requirements of this chapter or rules adopted in accordance with this chapter or any other matter the department determines necessary to protect the public 28 29 health and safety. The department may not require an individual to successfully complete 30 any training more than once, except as a precondition for lifting a suspension of a permit 31 or, after a revocation of a permit, for applying for a new permit. The department or other 32 provider of required training may charge a reasonable fee for that training.

- 33 3. Denial, revocation or suspension of permit. The department, for good cause, may
 34 deny an application for an initial permit or a permit renewal or in an adjudicatory
 35 proceeding in accordance with Title 5, chapter 375 may suspend or revoke a permit. Denial
 36 of an application by the department pursuant to this section constitutes a final agency action
 37 as defined in Title 5, section 8002, subsection 4. As used in this subsection, "good cause"
 38 means a finding by the department that:
- 39A. A person has violated any provisions of this chapter or any rules adopted in40accordance with this chapter; or

1	B. A person has been convicted of a crime or is convicted of an offense under this
2	chapter, except that the department may not consider a conviction for an offense under
3	this chapter if the date of the conviction is 2 or more years before the date of the
4	application or renewal.
5	"Good cause" does not include the fact that psilocybin products are prohibited by federal
6	law.
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7	<u>SUBCHAPTER 4</u>
8	LICENSING AND OPERATING REQUIREMENTS FOR PSILOCYBIN
8 9	MANUFACTURING FACILITIES
2	
10	§2041. Manufacturing facility license types; authorized and prohibited conduct
11	Subject to the requirements and restrictions of this subchapter and the other applicable
12	requirements of this chapter, the department may issue to an applicant a psilocybin manufacturing facility license. The department may by rule establish different types of
13 14	psilocybin manufacturing facility licenses that allow the licensee to engage in different
15	types of manufacturing activities. The department may by rule require information from
16	an applicant in addition to what is required under this chapter as a prerequisite to issuing
17	psilocybin manufacturing facility licenses.
18	1. Authorized conduct. A psilocybin manufacturing facility licensee may engage in
19	the following activities in accordance with rules adopted by the department:
20 21	A. Deliver psilocybin products to premises for which a license has been issued under this chapter;
22 23	B. Receive psilocybin products from another psilocybin manufacturing facility licensee; and
24	C. Manufacture psilocybin products.
25 26	A psilocybin manufacturing facility licensee is not required to manufacture a psilocybin product by means of chemical synthesis.
27	2. Prohibited conduct. A psilocybin manufacturing facility licensee may not:
28	A. Manufacture psilocybin products outdoors;
29	B. Sell or deliver a psilocybin product to a person under 21 years of age;
30	C. Employ a person under 21 years of age in manufacturing psilocybin products;
31	D. Make false representations or statements to the department in order to induce or
32	prevent action by the department;
33	E. Supply or sell impure or otherwise deleterious psilocybin products;
34	F. Misrepresent to a person or to the public any psilocybin products; or
35	G. Use information obtained to verify a person's age for any purpose other than
36	verifying a person's age.

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SUBCHAPTER 5

1 LICENSING AND OPERATING REQUIREMENTS FOR PSILOCYBIN 2 SERVICE CENTERS

3	<u>§2051. Conduct of psilocybin service center licensees</u>
4 5 6	Subject to the requirements and restrictions of this subchapter and the other applicable requirements of this chapter, the department may issue to an applicant a psilocybin service center license.
7 8	1. Authorized conduct. A psilocybin service center licensee may engage in the following activities in accordance with rules adopted by the department:
9	A. Deliver psilocybin products to premises for which a license has been issued;
10 11	<u>B. Receive psilocybin products from a psilocybin manufacturing facility licensee or another psilocybin service center licensee; and</u>
12 13	C. Sell psilocybin products to a client on the premises for which the license has been issued.
14	2. Prohibited conduct. A psilocybin service center licensee may not:
15	A. Sell or deliver a psilocybin product to a person under 21 years of age;
16	B. Employ a person under 21 years of age in the psilocybin service center;
17 18	<u>C. Make false representations or statements to the department in order to induce or prevent action by the department:</u>
19	D. Supply or sell impure or otherwise deleterious psilocybin products;
20	E. Misrepresent to a person or to the public any psilocybin products; or
21 22	F. Use information obtained to verify a person's age for any purpose other than verifying a person's age.
23	SUBCHAPTER 6
24 25	LICENSING AND OPERATING REQUIREMENTS FOR PSILOCYBIN SERVICE FACILITATORS
26	§2061. Minimum qualifications
27 28	1. Qualifications. In addition to the other applicable licensing requirements required by this chapter, an applicant for a psilocybin service facilitator license must:
29 30 31	A. Meet any education or training requirements established by the department by rule, except that the department may not require a degree from an institution of higher education;
32 33 34 35 36 37	B. Meet any examination requirements established by the department by rule, except that the department may provide for waivers of examination requirements in cases it determines appropriate. The department shall offer any required examination at least twice annually. The department may appoint a person to conduct or supervise examinations of applicants. An applicant may retake any failed section of the examination in accordance with rules adopted by the department; and

- C. Meet any other training, education, skill or fitness requirements adopted by the 1 2 department by rule, such as: 3 (1) Facilitation skills that are affirming, nonjudgmental and nondirective; and 4 (2) Support skills for clients during an administration session, including specialized 5 skills relating to client safety and clients who may have mental health conditions, 6 ability to establish a proper environment in which psilocybin services occur and 7 social and cultural skills. 8 2. Training course approval. The department shall establish a process to approve 9 training courses for psilocybin service facilitators. To obtain approval of a course, the person providing the course must submit an outline of instruction to the department and to 10 11 the Department of Education that includes the course topics, total hours of instruction, hours of lectures in theory and hours of instruction in application of practical skills. 12 13 **3.** Professional conduct. The department shall establish by rule a code of professional conduct, including a code of ethics, for psilocybin service facilitators. The department 14 15 shall establish standards of practice and professional responsibility for psilocybin service facilitators. 16 17 4. Authorized conduct; generally. A psilocybin service facilitator licensee may engage in the following activities in accordance with rules adopted by the department: 18 19 A. Deliver psilocybin products to premises for which a license has been issued under this chapter; 20 21 B. Receive psilocybin products from a psilocybin manufacturing facility licensee or 22 another psilocybin service facilitator licensee; and 23 C. Facilitate the use of psilocybin products by a client as part of an administration 24 session. 25 **SUBCHAPTER 7** 26 LICENSING AND OPERATING REQUIREMENTS FOR TESTING FACILITIES 27 §2071. Qualifications 28 In addition to meeting the licensing requirements under this chapter, an applicant for a 29 testing facility license must meet qualifications, including accreditation standards, 30 established by the department by rule. 31 §2072. Testing standards 32 The department may adopt rules requiring a testing facility licensee to test psilocybin products sold or transferred to others by a psilocybin manufacturing facility licensee. The 33 34 department may not require a psilocybin product to undergo the same test more than once 35 unless the product is processed into a different type of psilocybin product or the condition of the psilocybin product has fundamentally changed. In adopting rules under this section, 36
- 38 will affect the cost to clients. The department may not adopt rules that are more restrictive
 39 than is reasonably necessary to protect the public health and safety.

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the department shall consider the cost of a potential testing procedure and how that cost

1 2 3 4 5 6	The department shall 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. §2073. Conduct of testing facility licensees
7 8	1. Authorized conduct. A testing facility licensee may engage in the following activities in accordance with rules adopted by the department:
9 10	A. Deliver psilocybin products to premises for which a license has been issued under this chapter; and
11 12	B. Receive psilocybin products from a psilocybin manufacturing facility licensee or another psilocybin service center licensee.
13	2. Prohibited conduct. A testing facility licensee may not:
14	A. Sell or deliver a psilocybin product to a person under 21 years of age;
15	B. Employ a person under 21 years of age in the testing facility;
16 17	C. Make false representations or statements to the department in order to induce or prevent action by the department;
18 19	D. Allow licensed premises to be noisy or unsanitary or permit any person on the premises to be lewd or disorderly;
20	E. Supply or sell impure or otherwise deleterious psilocybin products;
21	F. Misrepresent to a person or to the public any psilocybin products; or
22 23	<u>G.</u> Use information obtained to verify a person's age for any purpose other than verifying a person's age.
24	SUBCHAPTER 8
25	OPERATING REQUIREMENTS FOR PROVIDING PSILOCYBIN SERVICES
26	<u>§2081. Psilocybin services</u>
27	1. Requirements. A psilocybin service center and psilocybin service facilitator shall
28	comply with the requirements of this section. The department shall adopt rules regarding

- 1. Requirements. A pshocybin service center and pshocybin service facilitator shall
 comply with the requirements of this section. The department shall 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:
- 31A. Require a psilocybin service facilitator to obtain a complete client information form32signed by the prospective client and, if department rules require, an approved medical33provider if the prospective client meets the criteria identified by the department in a34risk assessment screening;
- B. Require a psilocybin service facilitator to hold a preparation session with a client
 before the client participates in an administration session;

1 2 3	C. Require that, during the preparation session, the psilocybin service facilitator review the client information form with the client, including any required review by an approved medical provider;
4 5 6	D. Require a psilocybin service facilitator to certify, in a form and manner prescribed by the department, that the facilitator obtained a completed client information form and conducted a preparation session;
7 8 9 10	E. Require a psilocybin service facilitator to deliver a copy of the completed client information form signed by the client and, if department rules require, by an approved medical provider to the psilocybin service center licensee at which the administration session will be held; and
11 12	F. Permit a preparation session to be held at a psilocybin service center, another approved location or via telehealth.
13 14 15	2. Client information form. The department shall adopt rules governing client information and qualifications to receive psilocybin products and psilocybin services. The rules must:
16 17	A. Require a client to complete and sign a client information form prescribed by the department before a client participates in an administration session. The form must:
18 19 20 21 22 23	(1) Solicit from the client such information as may be necessary to enable a psilocybin service center licensee and a psilocybin service facilitator to determine whether the client is eligible to receive psilocybin products and participate in an administration session, including information that may identify risk factors and contraindications or that will assist the licensees in meeting any public health and safety standards and industry best practices during the administration session;
24 25 26	(2) Contain the risk assessment screening approved by the board that establishes a clear basis for eligibility and provides guidance for when additional consultation with an approved medical provider is required based on safety concerns;
27	(3) Contain health and safety warnings and disclosures to the client; and
28 29	(4) Contain the signature and approval of an approved medical provider, when required; and
30 31 32 33	B. Require a psilocybin service facilitator to deliver a copy of the completed and signed client information form to the psilocybin service center licensee at which the administration session will be held and to the psilocybin service facilitator supervising the administration session.
34 35 36 37	3. Additional medical review. The department shall adopt rules regarding when and how medical review by an approved medical provider must be provided prior to the provision of psilocybin products to a client by a psilocybin service facilitator based on criteria identified in a risk assessment screening. The rules must:
38 39 40	A. Provide clear guidance for psilocybin service facilitators to determine when additional medical review is indicated by results of the risk assessment screening on the client information form and who is approved to provide the review;
41 42	B. Provide a standardized format for requiring and obtaining written client consent when further medical review is indicated by the risk assessment screening in order to

1 2	determine whether the use of psilocybin products would put the prospective client at increased risk so as to be ineligible to receive psilocybin services at that time;
3 4 5 6 7 8	C. For prospective clients who meet any criteria that indicate additional medical review as determined by completion of the risk assessment screening, require an approved medical provider to sign the prospective client's client information form confirming that there is nothing in the client's disclosed health history indicating that use of psilocybin is likely to put the prospective client at an increased risk of an adverse health outcome compared to an average, healthy adult;
9 10 11 12	D. Require that a medical provider who has not previously signed off on a client information form for psilocybin services shall, prior to doing so, submit evidence, satisfactory to the department, of completion of training or education related to psilocybin, which may include self-directed study; and
13 14 15	E. Permit an approved medical provider who reviews and provides written confirmation for psilocybin services under this section to use telehealth services as long as it is a synchronous encounter.
16 17 18	Nothing in this chapter prevents a professional licensing board from sanctioning a medical provider for failing to properly evaluate or treat a person's medical condition or otherwise violating the applicable standard of care for evaluating or treating medical conditions.
19 20 21	<u>4. Informed consent required.</u> The department shall adopt rules requiring a prospective client to review and sign a document informing the client prior to an administration session of the likely effects and potential risks of psilocybin use.
22 23	5. Administration session. The department shall adopt rules governing administration sessions. The rules must:
24 25 26	<u>A. Require that a client complete a preparation session and a client information form</u> <u>confirming eligibility prior to an administration session, including additional medical</u> <u>review if required;</u>
27 28	B. Require an administration session to occur at a psilocybin service center or other location approved by the department;
29 30	C. Require a psilocybin service facilitator to certify, in a form and manner prescribed by the department, that the client completed an administration session; and
31 32	D. Prohibit a psilocybin service facilitator from consuming a psilocybin product during an administration session that the psilocybin service facilitator is supervising.
33 34	<u>6. Integration session.</u> The department shall adopt rules defining and governing integration sessions. The rules must:
35 36	<u>A. Require, upon completion of an administration session, that a psilocybin service facilitator offer to the client the opportunity to participate in an integration session;</u>
37	B. Allow a client to decline to participate in an integration session;
38 39	C. Allow any integration session to occur at a psilocybin service center, at another location or via telehealth; and
40 41	D. Require a psilocybin service facilitator to certify, in a form and manner prescribed by the department, if a client completed an integration session.

1 2 3 4	7. Confidentiality. A psilocybin service center and psilocybin service facilitator may not disclose any 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 when:
5 6	<u>A.</u> The client or a person authorized to act on behalf of the client gives consent to the disclosure;
7 8	<u>B. The client initiates legal action or makes a complaint against the psilocybin service center operator, psilocybin service facilitator or employee of either;</u>
9 10	<u>C.</u> The communication reveals the intent to commit a crime harmful to the client or <u>others</u> ;
11 12	D. The communication reveals that a minor may have been the victim of a crime or physical, sexual or emotional abuse or neglect;
13 14 15	E. Responding to an inquiry by the department made during the course of an investigation into the conduct of a psilocybin service center operator, psilocybin service facilitator or employee under this chapter; or
16 17	<u>F.</u> The information or communication is required or authorized to be released in accordance with Title 36, chapter 727.
18	SUBCHAPTER 9
19	PERSONAL USE OF PSILOCYBIN
20	§2091. Personal use of psilocybin
20 21 22 23 24 25 26	§2091. Personal use of psilocybin 1. Personal use. Subject to the limitations in this chapter, but notwithstanding any provision of law to the contrary, the following acts are not an offense under state law or the laws of any locality within the State or subject to a civil fine, penalty or sanction or the basis for detention, search or arrest, to deny any right or privilege or to seize or forfeit assets under state law or the laws of any locality if the person engaging in the act is 21 years of age or older:
21 22 23 24 25	1. Personal use. Subject to the limitations in this chapter, but notwithstanding any provision of law to the contrary, the following acts are not an offense under state law or the laws of any locality within the State or subject to a civil fine, penalty or sanction or the basis for detention, search or arrest, to deny any right or privilege or to seize or forfeit assets under state law or the laws of any locality if the person engaging in the act is 21 years of
21 22 23 24 25 26 27 28	 1. Personal use. Subject to the limitations in this chapter, but notwithstanding any provision of law to the contrary, the following acts are not an offense under state law or the laws of any locality within the State or subject to a civil fine, penalty or sanction or the basis for detention, search or arrest, to deny any right or privilege or to seize or forfeit assets under state law or the laws of any locality if the person engaging in the act is 21 years of age or older: A. Possessing, using, processing, transporting, obtaining, ingesting or giving away without remuneration to a person 21 years of age or older not more than 2 grams of a
21 22 23 24 25 26 27 28 29 30 31 32 33	 1. Personal use. Subject to the limitations in this chapter, but notwithstanding any provision of law to the contrary, the following acts are not an offense under state law or the laws of any locality within the State or subject to a civil fine, penalty or sanction or the basis for detention, search or arrest, to deny any right or privilege or to seize or forfeit assets under state law or the laws of any locality if the person engaging in the act is 21 years of age or older: A. Possessing, using, processing, transporting, obtaining, ingesting or giving away without remuneration to a person 21 years of age or older not more than 2 grams of a psilocybin product or 4 ounces of fungi containing psilocybin; B. Possessing, growing, cultivating or processing plants or fungi capable of producing psilocybin for personal use, as long as the plants and fungi and any psilocybin produced in excess of a personal use amount are kept at the person's home or other private residence or upon the grounds of that home or private residence and are secure from
21 22 23 24 25 26 27 28 29 30 31 32 33 34 35	 1. Personal use. Subject to the limitations in this chapter, but notwithstanding any provision of law to the contrary, the following acts are not an offense under state law or the laws of any locality within the State or subject to a civil fine, penalty or sanction or the basis for detention, search or arrest, to deny any right or privilege or to seize or forfeit assets under state law or the laws of any locality if the person engaging in the act is 21 years of age or older: A. Possessing, using, processing, transporting, obtaining, ingesting or giving away without remuneration to a person 21 years of age or older not more than 2 grams of a psilocybin product or 4 ounces of fungi containing psilocybin; B. Possessing, growing, cultivating or processing plants or fungi capable of producing psilocybin for personal use, as long as the plants and fungi and any psilocybin produced in excess of a personal use amount are kept at the person's home or other private residence or upon the grounds of that home or private residence and are secure from access by a person under 21 years of age; and C. Assisting another person who is 21 years of age or older, or allowing property to be

guilty of an offense under this chapter had it been in effect at the time of the offense may 1 2 file a petition before the trial court that entered the judgment of conviction in the person's 3 case to seal the record of the conviction at no cost. If there is no objection from the district attorney, the court shall automatically seal the record. If there is an objection by the district 4 attorney, a hearing must be held and the court shall determine if the record of the conviction 5 does not qualify to be sealed under this chapter. If the record does not qualify to be sealed, 6 the court shall deny the sealing of the record. Nothing in this section may be construed to 7 8 diminish or abrogate any rights or remedies otherwise available to the petitioner or applicant. 9

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SUBCHAPTER 10

LOCAL REGULATION

12 **§2101.** Preemption; limited regulation

13 The provisions of this chapter are intended to operate uniformly in this State and to preempt any inconsistent municipal regulation. In accordance with this section, a 14 15 municipality may adopt ordinances that impose reasonable regulations governing activities 16 on premises for which a license has been issued under this chapter, except that a municipality may not require a license to conduct any activity licensed under this chapter. 17 18 impose a tax or fee on the manufacture or sale of psilocybin products or the sale of 19 psilocybin services or prohibit more than one psilocybin service center from being located 20 in the municipality as long as the distance between the centers is greater than 1,000 feet. 21 For purposes of this subsection, "reasonable regulations" means the following, to the extent 22 consistent with the provisions of this chapter:

- 23 <u>1. Conditions for manufacturing facilities.</u> Conditions on the manner in which a
 24 psilocybin manufacturing facility licensee may manufacture psilocybin products;
- 25 2. Conditions for psilocybin service centers. Conditions on the manner in which a
 26 psilocybin service center licensee may provide psilocybin services;
 - 3. Hours. Limitations on the hours during which licensed premises may operate;
 - **<u>4. Public access.</u>** Requirements related to the public's access to licensed premises; and
 - 5. Location. Limitations on where licensed premises may be located.
- Nothing in this section prohibits a municipality from allowing the manufacture of
 psilocybin as a farm use on land zoned for farm or forest use.
 - SUBCHAPTER 11

34 <u>LABELING AND PACKAGING; ADVERTISING AND MARKETING; HEALTH</u> 35 <u>AND SAFETY</u>

36 §2111. Labeling requirements

1 2	The department shall adopt rules necessary to protect the public health and safety that establish standards for the labeling of psilocybin products.
3 4	<u>1. Labeling standards.</u> The department may establish different labeling standards for different varieties and types of psilocybin products.
5 6 7 8	2. Preapproval; fee. The department may require a licensee to submit a label intended for use on a psilocybin product for preapproval before the licensee may sell or transfer a psilocybin product bearing the label and the department may impose a fee for the preapproval process.
9 10	3. Cost. The department shall consider the cost of meeting a potential requirement and how that cost will affect the cost to the client.
11 12 13	4. Rules not more restrictive than necessary. The department may not adopt rules governing labeling that are more restrictive than reasonably necessary to protect the public health and safety.
14 15 16 17 18	5. Imprecise labeling. The department shall by rule prohibit a licensee from placing or allowing the placement of a mark or label on the container of a psilocybin product that is kept for sale if the mark or label does not precisely and clearly indicate the nature of the container's contents or if the mark or label in any way might deceive a person about the nature, composition, quantity, age or quality of the container's contents.
19 20 21	<u>6. Deceptive labeling; injurious or adulterated ingredients.</u> The department shall by rule prohibit a licensee from selling any psilocybin product that, in the department's judgment, is deceptively labeled or contains injurious or adulterated ingredients.
22	82112. Packaging requirements: advertising
22 23 24	<u>§2112. Packaging requirements; advertising</u> <u>As necessary to protect the public health and safety, the department shall adopt rules</u> establishing standards for the packaging and advertising of psilocybin products.
23	As necessary to protect the public health and safety, the department shall adopt rules
23 24 25	As necessary to protect the public health and safety, the department shall adopt rules establishing standards for the packaging and advertising of psilocybin products. 1. Prohibiting advertising. The department may adopt rules prohibiting advertising
23 24 25 26 27 28 29 30	As necessary to protect the public health and safety, the department shall adopt rules establishing standards for the packaging and advertising of psilocybin products. 1. Prohibiting advertising. The department may adopt rules prohibiting advertising psilocybin products to the public. 2. Regulating advertising. The department may adopt rules regulating and prohibiting advertising psilocybin services in a manner that is appealing to minors, promotes excessive use, promotes illegal activity, violates the code of professional conduct for psilocybin service facilitator licensees established by the department or otherwise presents a
23 24 25 26 27 28 29 30 31 32	 As necessary to protect the public health and safety, the department shall adopt rules establishing standards for the packaging and advertising of psilocybin products. 1. Prohibiting advertising. The department may adopt rules prohibiting advertising psilocybin products to the public. 2. Regulating advertising. The department may adopt rules regulating and prohibiting advertising psilocybin services in a manner that is appealing to minors, promotes excessive use, promotes illegal activity, violates the code of professional conduct for psilocybin service facilitator licensees established by the department or otherwise presents a significant risk to public health and safety. 3. Packaging standards. The department may establish different packaging standards
23 24 25 26 27 28 29 30 31 32 33 34 35	 <u>As necessary to protect the public health and safety, the department shall adopt rules establishing standards for the packaging and advertising of psilocybin products.</u> <u>1. Prohibiting advertising.</u> The department may adopt rules prohibiting advertising psilocybin products to the public. <u>2. Regulating advertising.</u> The department may adopt rules regulating and prohibiting advertising psilocybin services in a manner that is appealing to minors, promotes excessive use, promotes illegal activity, violates the code of professional conduct for psilocybin service facilitator licensees established by the department or otherwise presents a significant risk to public health and safety. <u>3. Packaging standards.</u> The department may establish different packaging standards for different varieties and types of psilocybin products. <u>4. Labeling standards.</u> The department may establish different labeling standards for different varieties and types of psilocybin packages and may consider the effect on the

1 2 3	7. Rules not more restrictive than necessary. The department may not adopt rules governing labeling that are more restrictive than is reasonably necessary to protect the public health and safety.
4	<u>§2113. Dosage requirements</u>
5 6 7	The department shall 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.
8	§2114. Prohibition on sale to protect health and safety
9 10 11 12 13 14	A person may not sell or offer for sale a psilocybin product unless the psilocybin product complies with the minimum standards prescribed by the provisions of this chapter and the rules adopted pursuant to this chapter. The department may prohibit the sale of a psilocybin product for a reasonable period of time for the purpose of determining whether the psilocybin product complies with the minimum standards prescribed by the provisions of this chapter and the rules adopted pursuant to this chapter.
15	SUBCHAPTER 12
16	LICENSE VIOLATIONS; PENALTIES
17	<u>§2121. General penalty</u>
18 19 20	Except as otherwise specified in this chapter, a violation of this chapter or any rules adopted pursuant to this chapter is a civil violation for which a fine of not more than \$500 may be adjudged.
21	§2122. Administrative penalties
22 23 24 25 26 27 28 29	1. Administrative penalties; generally. In addition to any other applicable penalty under this chapter, the department, on its own initiative or on complaint and after investigation, notice and the opportunity for a public hearing, may issue an order imposing an administrative penalty in accordance with this section on a licensee or suspend or revoke the licensee's license if the department finds that the licensee or an agent or employee of the licensee has violated any provision of this chapter, the rules adopted pursuant to this chapter or the terms, conditions or provisions of the licensee's license, including but not limited to a finding by the department:
30 31 32	A. That the licensee or an agent or employee of the licensee has made a false representation or statement to the department in order to induce or prevent action by the department;
33 34	B. That the licensee is insolvent or incompetent or physically unable to carry on the licensed activities;
35 36	<u>C. That the licensee or an agent or employee of the licensee has misrepresented to a person or the public any psilocybin products sold by the licensee;</u>
37 38 39 40	D. That the licensee or an agent or employee of the licensee has been convicted of any crime or found by a court of competent jurisdiction to have violated any provision of this chapter or of a municipal ordinance, if the violation of that ordinance occurred on the premises for which the license was issued;

1 2	<u>E. That the licensee or an agent or employee of the licensee has diverted psilocybin</u> products to an entity that is not operating legally under the laws of this State;
3 4	<u>F. That the licensee or an agent or employee of the licensee has purchased or received</u> a psilocybin product from an unlicensed source or has sold, stored or transferred a
5	psilocybin product in a manner that is not permitted by the licensee's license; or
6	G. That a person with a financial interest in the business operating or to be operated
7	under the license committed or failed to commit an act if that act or failure to act would
8 9	constitute grounds for the department to refuse to issue, or to suspend, revoke or refuse
	to renew, the license if the person were the licensee or applicant for the license.
10 11	<u>The department may not impose any penalty under this section on the basis of a finding</u> that the licensee or an agent or employee of the licensee has violated a provision of federal
12	law governing psilocybin products.
12	
13	2. Amounts; deposit. An administrative penalty imposed by the department on a licensee pursuant to this subchapter may not exceed \$5,000 per license violation. The
15	department shall adopt rules setting forth amounts of administrative penalties to be imposed
16	on a licensee based upon specific categories of violations by the licensee. All
17	administrative penalties paid to the department pursuant to this subchapter must be
18	deposited into the Psilocybin Control and Regulation Fund.
19	3. License suspension. A licensee whose license has been suspended pursuant to this
20	subchapter may not, for the duration of the period of suspension, engage in any activities
21	authorized by that license.
22	4. License revocation. A license whose license has been revoked pursuant to this
23	subchapter shall cease immediately all activities authorized by the license and shall ensure
24 25	that all psilocybin and psilocybin products in the possession of the licensee are forfeited to the department for destruction in accordance with this subchapter.
26 27	5. Enforcement actions may be cumulative. In addition to suspending or revoking a licensee's license, the department may impose an administrative penalty on the licensee
27	consistent with this section.
29	6. Additional penalties may be imposed. Any penalties imposed by the department
30	on a licensee pursuant to this subchapter are in addition to any criminal or civil penalties
31	that may be imposed pursuant to other applicable laws or rules.
32	7. Maine Administrative Procedure Act; appeals. The imposition of an
33	administrative penalty on a licensee or the suspension or revocation of the license of a
34	licensee by the department is governed by the Maine Administrative Procedure Act. A
35	final order of the department imposing an administrative penalty on a licensee or
36	suspending or revoking the licensee's license is a final agency action, as defined in Title 5,
37	section 8002, subsection 4, and the licensee may appeal that final order to the Superior
38	Court in accordance with Rule 80C of the Maine Rules of Civil Procedure.
39	<u>§2123. Disposition of unauthorized psilocybin or psilocybin products of licensee</u>
40	<u>1. Order; destruction of psilocybin or psilocybin products.</u> If the department issues
41	a final order imposing an administrative penalty on or a license suspension or revocation
42 43	against a licensee pursuant to this subchapter, the department may specify in the order, in addition to any other penalties imposed in the order, that all or a portion of the psilocybin
43	addition to any other penanties imposed in the order, that all of a portion of the pshocybin

1 2 3 4	or psilocybin products in the possession of the licensee are subject to destruction. A licensee subject to a final order directing the destruction of psilocybin or psilocybin products in the possession of the licensee shall forfeit the psilocybin or psilocybin products described in the order to the department for destruction.
5 6 7 8	2. Investigation. If the department is notified by a criminal justice agency that there is a pending investigation of a licensee subject to an order imposed under subsection 1, the department may not destroy any psilocybin or psilocybin products of that licensee until the destruction is approved by the criminal justice agency.
9 10 11	3. Conviction of licensee. A court, district attorney or municipal authority involved in trying or finding a violation of this chapter shall notify the department upon final adjudication or conviction of the offense.
12 13 14 15 16	4. Rules. The department shall adopt rules governing the imposition of administrative penalties, suspensions and revocations under this subchapter, which must include, but are not limited to, provisions relating to notice and conduct of hearings consistent with the Maine Administrative Procedure Act and provisions relating to the disposition of unauthorized psilocybin and psilocybin products of a licensee.
17	SUBCHAPTER 13
18	MAINE PSILOCYBIN ADVISORY BOARD
19	§2131. Definition
20 21 22	For purposes of this subchapter, "program development period" means the period beginning October 1, 2024 and continuing until all rules required under this chapter have been initially adopted.
23	<u>§2132. Establishment; purposes</u>
24 25 26 27 28	The Maine Psilocybin Advisory Board, established in Title 5, section 12004-I, subsection 73-C, is established within the department for the purposes of advising and making recommendations to the department, the Legislature and municipalities regarding the administration of this chapter in a manner that promotes the public health and safety. Recommendations by the board require the approval of a majority of the board's members.
29	<u>§2133. Membership</u>
30	The board consists of 16 members in accordance with this section.
31	<u>1. Ex officio members.</u> The following members serve as ex officio members:
32 33	<u>A. The Director of the Maine Center for Disease Control and Prevention within the department or the director's designee; and</u>
34	B. The Attorney General or the Attorney General's designee.
35 36 37	2. Members appointed by Governor. The Governor shall appoint members in accordance with this subsection. The Governor shall appoint any 4 of the following individuals:
38	A. A state employee who has technical expertise in the field of public health;

1 2	B. A representative from a district coordinating council for public health established pursuant to Title 22, section 412, subsection 4;
3	C. A representative of one of the federally recognized Indian tribes in the State;
4 5	D. A member of the Substance Use Disorder Services Commission, established in Title 5, section 12004-G, subsection 13-C;
6 7	<u>E. A member of the Permanent Commission on the Status of Racial, Indigenous and Tribal Populations, established in Title 5, section 12004-J, subsection 19;</u>
8 9	F. A member of the Palliative Care and Quality of Life Interdisciplinary Advisory Council, established in Title 5, section 12004-I, subsection 47-I; or
10 11	<u>G. An individual who represents individuals who provide public health services</u> <u>directly to the public.</u>
12 13 14	3. Members appointed by President of Senate. The President of the Senate shall appoint 5 members in accordance with this subsection. The President of the Senate shall appoint:
15 16	A. A psychologist licensed under Title 32, chapter 56 who has professional experience providing behavioral health services;
17	B. A physician licensed under Title 32, chapter 48; and
18	C. Any 3 of the following individuals:
19 20	(1) A person with professional expertise conducting scientific research regarding the use of psychedelic compounds in clinical therapy;
21	(2) A person who has experience in the field of mycology;
22	(3) A person who has experience in the field of ethnobotany;
23	(4) A person who has experience in the field of psychopharmacology; or
24	(5) A person who has experience in the field of psilocybin harm reduction.
25 26 27	<u>4. Members appointed by Speaker of House of Representatives.</u> The Speaker of the House of Representatives shall appoint 5 members in accordance with this subsection. The Speaker of the House of Representatives shall appoint:
28	A. A naturopathic doctor licensed under Title 32, chapter 113-B;
29 30	B. An individual with expertise in the field of public health who has a background in academia;
31	C. A representative of one of the federally recognized Indian tribes in the State; and
32	D. Any 2 of the following individuals:
33 34	(1) A person with professional expertise conducting scientific research regarding the use of psychedelic compounds in clinical therapy;
35	(2) A person who has experience in the field of mycology;
36	(3) A person who has experience in the field of ethnobotany;
37	(4) A person who has experience in the field of psychopharmacology; or
38	(5) A person who has experience in the field of psilocybin harm reduction.

1	5. Terms; vacancies. Board members, other than ex officio members, serve 2-year
2 3	terms and are eligible for reappointment. Before the expiration of the term of a member, the appointing authority shall appoint a successor whose term begins on the next January
3 4	1st. Board members serve at the pleasure of the appointing authority and are not subject to
5	legislative confirmation. If there is a vacancy for cause, the appointing authority shall make
6	an appointment to become immediately effective for the unexpired term.
7 8	<u>6. Chair. The board shall elect one of its members to serve as chair. The chair serves</u> <u>a one-year term in that office and is eligible for reelection.</u>
9	7. Meeting frequency. Until all rules necessary to implement this chapter have been
10	adopted, the board shall meet at least once every 2 calendar months at a time and place
11	determined by the chair or a majority of the members of the board. Thereafter the board
12	shall meet at least 4 times each year at regular intervals at a time and place determined by
13	the chair or a majority of the members of the board. The board may meet at other times
14	and places by the call of the chair or a majority of the members of the board.
15	8. Quorum. A majority of the board's members constitutes a quorum.
16	9. Establishment of subcommittees. The board may establish subcommittees
17	necessary for the operation of the board.
18	10. Expenses; reimbursement. Board members are entitled to compensation for
19	service on the board and for travel and board-related expenses in accordance with Title 5,
20	section 12004-I, subsection 73-C.
21	<u>§2134. Powers and duties</u>
22	1. Powers. The board may:
22 23	· · · · · · · · · · · · · · · · · · ·
	1. Powers. The board may: <u>A. Adopt rules necessary for the operation of the board.</u> Rules adopted pursuant to this section are routine technical rules pursuant to Title 5, chapter 375, subchapter 2-A; and
23	A. Adopt rules necessary for the operation of the board. Rules adopted pursuant to this
23 24	A. Adopt rules necessary for the operation of the board. Rules adopted pursuant to this section are routine technical rules pursuant to Title 5, chapter 375, subchapter 2-A; and
23 24 25	A. Adopt rules necessary for the operation of the board. Rules adopted pursuant to this section are routine technical rules pursuant to Title 5, chapter 375, subchapter 2-A; and B. Make recommendations to the department related to:
23 24 25 26	A. Adopt rules necessary for the operation of the board. Rules adopted pursuant to this section are routine technical rules pursuant to Title 5, chapter 375, subchapter 2-A; and B. Make recommendations to the department related to: (1) Administration of this chapter;
23 24 25 26 27	 A. Adopt rules necessary for the operation of the board. Rules adopted pursuant to this section are routine technical rules pursuant to Title 5, chapter 375, subchapter 2-A; and B. Make recommendations to the department related to: (1) Administration of this chapter; (2) Available medical, psychological and scientific studies, research and other
23 24 25 26 27 28	 <u>A. Adopt rules necessary for the operation of the board. Rules adopted pursuant to this section are routine technical rules pursuant to Title 5, chapter 375, subchapter 2-A; and B. Make recommendations to the department related to: (1) Administration of this chapter; (2) Available medical, psychological and scientific studies, research and other information on the safety and efficacy of psilocybin in treating behavioral health </u>
23 24 25 26 27 28 29	 <u>A. Adopt rules necessary for the operation of the board. Rules adopted pursuant to this section are routine technical rules pursuant to Title 5, chapter 375, subchapter 2-A; and B. Make recommendations to the department related to: (1) Administration of this chapter; (2) Available medical, psychological and scientific studies, research and other information on the safety and efficacy of psilocybin in treating behavioral health conditions, including but not limited to substance use disorder, depression, anxiety </u>
23 24 25 26 27 28 29 30	 <u>A. Adopt rules necessary for the operation of the board. Rules adopted pursuant to this section are routine technical rules pursuant to Title 5, chapter 375, subchapter 2-A; and B. Make recommendations to the department related to: (1) Administration of this chapter; (2) Available medical, psychological and scientific studies, research and other information on the safety and efficacy of psilocybin in treating behavioral health conditions, including but not limited to substance use disorder, depression, anxiety disorders and end-of-life psychological distress;</u>
23 24 25 26 27 28 29 30 31	 <u>A. Adopt rules necessary for the operation of the board. Rules adopted pursuant to this section are routine technical rules pursuant to Title 5, chapter 375, subchapter 2-A; and B. Make recommendations to the department related to: (1) Administration of this chapter; (2) Available medical, psychological and scientific studies, research and other information on the safety and efficacy of psilocybin in treating behavioral health conditions, including but not limited to substance use disorder, depression, anxiety disorders and end-of-life psychological distress; (3) Working with clients receiving psilocybin services, including: </u>
23 24 25 26 27 28 29 30 31 32 33 34	 A. Adopt rules necessary for the operation of the board. Rules adopted pursuant to this section are routine technical rules pursuant to Title 5, chapter 375, subchapter 2-A; and B. Make recommendations to the department related to: (1) Administration of this chapter; (2) Available medical, psychological and scientific studies, research and other information on the safety and efficacy of psilocybin in treating behavioral health conditions, including but not limited to substance use disorder, depression, anxiety disorders and end-of-life psychological distress; (3) Working with clients receiving psilocybin services, including: (a) The requirements, specifications and guidelines for providing psilocybin
23 24 25 26 27 28 29 30 31 32 33	 <u>A. Adopt rules necessary for the operation of the board. Rules adopted pursuant to this section are routine technical rules pursuant to Title 5, chapter 375, subchapter 2-A; and B. Make recommendations to the department related to: (1) Administration of this chapter; (2) Available medical, psychological and scientific studies, research and other information on the safety and efficacy of psilocybin in treating behavioral health conditions, including but not limited to substance use disorder, depression, anxiety disorders and end-of-life psychological distress;</u> (3) Working with clients receiving psilocybin services, including: (a) The requirements, specifications and guidelines for providing psilocybin services to a client, including but not limited to holding and verifying the
23 24 25 26 27 28 29 30 31 32 33 34	 A. Adopt rules necessary for the operation of the board. Rules adopted pursuant to this section are routine technical rules pursuant to Title 5, chapter 375, subchapter 2-A; and B. Make recommendations to the department related to: (1) Administration of this chapter; (2) Available medical, psychological and scientific studies, research and other information on the safety and efficacy of psilocybin in treating behavioral health conditions, including but not limited to substance use disorder, depression, anxiety disorders and end-of-life psychological distress; (3) Working with clients receiving psilocybin services, including: (a) The requirements, specifications and guidelines for providing psilocybin services to a client, including but not limited to holding and verifying the completion of a preparation session, an administration session and an integration session;
23 24 25 26 27 28 29 30 31 32 33 34 35	 A. Adopt rules necessary for the operation of the board. Rules adopted pursuant to this section are routine technical rules pursuant to Title 5, chapter 375, subchapter 2-A; and B. Make recommendations to the department related to: Administration of this chapter; Available medical, psychological and scientific studies, research and other information on the safety and efficacy of psilocybin in treating behavioral health conditions, including but not limited to substance use disorder, depression, anxiety disorders and end-of-life psychological distress; Working with clients receiving psilocybin services, including: The requirements, specifications and guidelines for providing psilocybin services to a client, including but not limited to holding and verifying the completion of a preparation session, an administration session and an integration session; The information that must be provided to a client before the client
23 24 25 26 27 28 29 30 31 32 33 34 35 36	 A. Adopt rules necessary for the operation of the board. Rules adopted pursuant to this section are routine technical rules pursuant to Title 5, chapter 375, subchapter 2-A; and B. Make recommendations to the department related to: (1) Administration of this chapter; (2) Available medical, psychological and scientific studies, research and other information on the safety and efficacy of psilocybin in treating behavioral health conditions, including but not limited to substance use disorder, depression, anxiety disorders and end-of-life psychological distress; (3) Working with clients receiving psilocybin services, including: (a) The requirements, specifications and guidelines for providing psilocybin services to a client, including but not limited to holding and verifying the completion of a preparation session, an administration session and an integration session;
23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38	 A. Adopt rules necessary for the operation of the board. Rules adopted pursuant to this section are routine technical rules pursuant to Title 5, chapter 375, subchapter 2-A; and B. Make recommendations to the department related to: (1) Administration of this chapter; (2) Available medical, psychological and scientific studies, research and other information on the safety and efficacy of psilocybin in treating behavioral health conditions, including but not limited to substance use disorder, depression, anxiety disorders and end-of-life psychological distress; (3) Working with clients receiving psilocybin services, including: (a) The requirements, specifications and guidelines for providing psilocybin services to a client, including but not limited to holding and verifying the completion of a preparation session, an administration session and an integration session; (b) The information that must be provided to a client before the client participates in an administration session, including health and safety warnings or other disclosures;
23 24 25 26 27 28 29 30 31 32 33 34 35 36 37	 A. Adopt rules necessary for the operation of the board. Rules adopted pursuant to this section are routine technical rules pursuant to Title 5, chapter 375, subchapter 2-A; and B. Make recommendations to the department related to: (1) Administration of this chapter; (2) Available medical, psychological and scientific studies, research and other information on the safety and efficacy of psilocybin in treating behavioral health conditions, including but not limited to substance use disorder, depression, anxiety disorders and end-of-life psychological distress; (3) Working with clients receiving psilocybin services, including: (a) The requirements, specifications and guidelines for providing psilocybin services to a client, including but not limited to holding and verifying the completion of a preparation session, an administration session and an integration session; (b) The information that must be provided to a client before the client participates in an administration session, including health and safety warnings or other disclosures; (c) The information that must be received from a client to determine whether
23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39	 A. Adopt rules necessary for the operation of the board. Rules adopted pursuant to this section are routine technical rules pursuant to Title 5, chapter 375, subchapter 2-A; and B. Make recommendations to the department related to: (1) Administration of this chapter; (2) Available medical, psychological and scientific studies, research and other information on the safety and efficacy of psilocybin in treating behavioral health conditions, including but not limited to substance use disorder, depression, anxiety disorders and end-of-life psychological distress; (3) Working with clients receiving psilocybin services, including: (a) The requirements, specifications and guidelines for providing psilocybin services to a client, including but not limited to holding and verifying the completion of a preparation session, an administration session and an integration session; (b) The information that must be provided to a client before the client participates in an administration session, including health and safety warnings or other disclosures;

1 2	any public health or safety standards or industry best practices during the administration session;
3 4	(d) Transportation needs of a client after the completion of an administration session; and
5 6	(e) Client access to common or outside areas on the premises of a psilocybin service center;
7 8	(4) Public health and safety standards and industry best practices for each type of licensee; and
9 10	(5) Required qualifications and practices of psilocybin service facilitators, including:
11	(a) Adherence to a code of professional and ethical conduct;
12	(b) Required education and training, including but not limited to:
13 14	(i) Client facilitation skills that are affirming, nonjudgmental and nondirective;
15 16 17	(ii) Providing support to clients during an administration session with specialized skills for client safety and clients who may have a mental health condition;
18 19	(iii) On the appropriate environment in which to provide psilocybin services;
20	(iv) Social and cultural considerations;
21	(v) The form of required training and education; or
22	(vi) Examinations or other requirements; and
23	(c) Holding an administration session, including but not limited to:
24	(i) Individual or group administration sessions; or
25 26	(ii) Circumstances under which an administration session is considered complete.
27	2. Duties. The board shall:
28 29 30 31	A. Develop and maintain 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;
32	B. Monitor and study federal laws, regulations and policies regarding psilocybin; and
33 34 35	<u>C. Attempt to meet with the United States Attorney for the District of Maine to discuss</u> this chapter and potential federal enforcement policies regarding psilocybin in this State after the program development period.
36 37 38 39 40	3. Report. The board shall submit annually a report to the department that contains the recommendations to the department described in subsection 1, paragraph B, the board's long-term strategic plan described in subsection 2, paragraph A and information and updates on federal laws, regulations and policies regarding psilocybin described in subsection 2, paragraphs B and C.

1	SUBCHAPTER 14
2	PSILOCYBIN CONTROL AND REGULATION FUND
3	§2141. Psilocybin Control and Regulation Fund
4 5 6	The Psilocybin Control and Regulation Fund, referred to in this section as "the fund," is established as a dedicated, nonlapsing fund within the department for the purposes specified in this section.
7	1. Sources of fund. The State Controller shall credit to the fund:
8 9	A. Money received from the license fees and administrative penalties imposed under this chapter;
10 11	B. All money from any other source, whether public or private, designated for deposit into or credited to the fund; and
12	C. Interest earned or other investment income on balances in the fund.
13 14	2. Uses of fund. Money credited to the fund may be used by the department for the purposes of implementing, administering and enforcing this chapter.
15	SUBCHAPTER 15
16	FOOD AND COMMODITY REGULATION
17	<u>§2151. Regulation as food additive</u>
18 19 20 21 22	Notwithstanding any provision of law to the contrary, the Department of Agriculture, Conservation and Forestry may not establish standards for psilocybin products as a food additive or consider psilocybin products to be an adulterant under Title 7, section 717, unless the concentration of a psilocybin product exceeds acceptable levels established by the department by rule under this chapter.
23	Sec. 6. 36 MRSA c. 727 is enacted to read:
24	CHAPTER 727
25	TAXATION OF PSILOCYBIN PRODUCTS
26	§4961. Definitions
27 28	As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.
29	1. Client. "Client" has the same meaning as in Title 28-B, section 2002, subsection 5.
30	2. Department. "Department" means the Department of Health and Human Services.
31 32	3. Psilocybin. "Psilocybin" has the same meaning as in Title 28-B, section 2002, subsection 15.

1 2	<u>4. Psilocybin Control and Regulation Fund. "Psilocybin Control and Regulation Fund" has the same meaning as in Title 28-B, section 2002, subsection 16.</u>
3 4	5. Psilocybin product. "Psilocybin product" has the same meaning as in Title 28-B, section 2002, subsection 18.
5 6	<u>6. Psilocybin service center.</u> "Psilocybin service center" has the same meaning as in <u>Title 28-B, section 2002, subsection 19.</u>
7 8	7. Psilocybin service center operator. "Psilocybin service center operator" has the same meaning as in Title 28-B, section 2002, subsection 20.
9 10	8. Retail sale. "Retail sale" means any transfer, exchange, gift or barter of a psilocybin product by any person to a client.
11 12	9. Retail sales price. "Retail sales price" means the price paid for a psilocybin product, excluding tax, to a psilocybin service center operator by or on behalf of a client.
13	§4962. Imposition of tax on retail sale of psilocybin products
14 15 16 17	1. Tax imposed. A tax is imposed 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.
18 19	A. The tax imposed under this section is at the rate of 15% of the retail sales price of psilocybin products.
20 21	B. If the tax imposed under this section does not equal an amount calculable to a whole cent, the tax is equal to the next higher whole cent.
22 23 24 25	2. Stated separately. Except as otherwise provided by the State Tax Assessor by rule, the amount of the tax must be separately stated on an invoice, receipt or other similar document that the psilocybin service center operator provides to the client at the time at which the retail sale occurs.
26	3. Prohibitions. The following prohibitions apply.
27 28 29	A. A person may not knowingly sell, purchase, install, transfer or possess electronic devices or software programs for the purposes of hiding or removing records of retail sales of psilocybin products or falsifying records of retail sales of psilocybin products.
30 31 32	B. A psilocybin service center operator may not discount a psilocybin product or offer a psilocybin product for free if the retail sale of the psilocybin product is made in conjunction with the retail sale of any other item or service.
33 34 35 36 37	4. Review of rate. The department shall regularly review the rate of tax under this section and make recommendations to the Legislature regarding appropriate adjustments to the rate to ensure the department has sufficient funds to administer and enforce Title 28-B, chapter 5 but that the amount of funds, together with fees collected under that chapter, do not exceed the costs of administering and enforcing that chapter.
38	§4963. Collection of tax; refund; credit; penalties
39 40 41	The tax imposed upon the client under this chapter must be collected at the point of sale and remitted by each psilocybin service center operator that engages in the retail sale of psilocybin products. The tax is imposed upon the psilocybin service center operator that

1	is required to collect the tax, and the psilocybin service center operator is liable for the tax
2	as the taxpayer. For the purpose of compensating psilocybin service center operators for
3	expenses incurred in collecting the tax imposed under this chapter, each psilocybin service
4	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
5 6	the psilocybin service center operator.
7	1. Filing. A psilocybin service center operator shall file a return with the State Tax
8	Assessor on or before the last day of January, April, July and October of each year for the
9	previous calendar quarter. A psilocybin service center operator shall file each return
10	required under this section regardless of whether any tax is owed.
11	A. The psilocybin service center operator shall pay the tax to the State Tax Assessor
12	in the form and manner prescribed by the State Tax Assessor, but not later than with
13	each quarterly return, without regard to an extension granted under this subsection.
14	B. For good cause, the State Tax Assessor may extend the time for filing a return under
15	this section. The extension may be granted at any time if a written request is filed with
16	the State Tax Assessor during or prior to the period for which the extension may be
17	granted. The State Tax Assessor may not grant an extension of more than 30 days.
18	Interest accumulates on late-filed returns at the rate established in section 186.
19	C. If a psilocybin service center operator fails to file a return or pay the tax as required
20	by this section, the State Tax Assessor may impose penalties or take actions as provided
21	in this chapter.
22	D. Refunds of any overpayment of tax are governed by section 2011, except as follows:
23	(1) The State Tax Assessor shall first apply any overpayment of tax by a psilocybin
24	service center operator to any tax imposed under this chapter that is owed by the
25	psilocybin service center operator;
26	(2) If after any offset under subparagraph (1) the overpayment of tax remains
27	greater than \$1,000, the remaining refund must be applied as a credit against the
28	next subsequent calendar quarter as an estimated payment; and
29	(3) The State Tax Assessor may not make a refund of, or credit, any overpayment
30	of tax that was credited to the account of a psilocybin service center operator under
31 32	subparagraph (2) if the return for that tax period is not filed within 3 years after the
	due date of that return.
33	<u>§4964. Psilocybin revenue estimate</u>
34	Not later than 30 days before the beginning of each calendar quarter, the department
35 36	shall forecast and prepare an estimate of the revenue that will be received during the
36 37	remainder of the current biennium and subsequent 3 biennia pursuant to the tax imposed under this chapter. The estimate may be made on the basis of all pertinent information
38	available to the department. Upon making the estimate, the department shall report the
39	estimate to the Office of Fiscal and Program Review and the State Tax Assessor. The State
40	Tax Assessor shall provide the department any information necessary for the department
41	to perform its duties under this section.
42	§4965. Enforcement; liability; notice of liability; notices of determination and
43	assessment

1 2	<u>1. Trust.</u> A person who collects any tax under this chapter shall hold the tax in trust for the State and for payment to the State Tax Assessor in accordance with this chapter.
2	
3 4	2. Enforcement. Except as otherwise provided in this section, the State Tax Assessor may impose penalties or take actions as provided in chapter 7 against a person who fails to
5	pay taxes required under this chapter in accordance with this chapter.
6	3. Joint liability. More than one officer or employee of a corporation may be held
7	jointly and severally liable for payment of taxes under this chapter.
8	A. Notwithstanding any provision of law to the contrary, if more than one officer or
9	employee of a corporation is jointly and severally liable for payment of taxes, the State
10 11	Tax Assessor may require any or all of the officers or employees who may be held liable to appear before the State Tax Assessor for a joint determination of liability. The
12	State Tax Assessor shall notify each officer or employee of the time and place set for
13	the determination of liability. Each person notified of a joint determination under this
14	subsection shall appear and present such information as is necessary to establish that
15	person's liability or nonliability for payment of taxes to the State Tax Assessor. If a
16 17	person who was notified fails to appear, the State Tax Assessor shall make its determination on the basis of all the information and evidence presented. The
17	department's determination is binding on all persons notified and required to appear
10	under this subsection and is a final agency action that may be appealed for review
20	pursuant to Title 5, section 11001.
21	B. If an appeal is taken from the decision of the State Tax Assessor by any person
22	determined to be liable for unpaid taxes under this subsection, each person required to
23	appear before the department under this subsection must be impleaded by the plaintiff.
24 25	The State Tax Assessor may implead any officer or employee who may be held jointly
25 26	and severally liable for the payment of taxes. Each person impleaded under this subsection must be made a party to the action and shall make available to all parties in
20 27	the appeal the information that was presented to the State Tax Assessor. The court may
28	determine that one or more persons impleaded under this subsection are liable for
29	unpaid taxes without regard to any earlier determination by the State Tax Assessor that
30	an impleaded person was not liable for unpaid taxes.
31	C. If a person required to appear before the court on appeal fails or refuses to appear
32	or bring required information in part or in whole, or is outside the jurisdiction of the
33 34	court, the court shall make its determination on the basis of all the evidence introduced.
34 35	All evidence presented in the court constitutes a public record and must be available to the parties and the court. The determination of the court is binding on all persons made
36	parties to the action under this subsection.
37	D. This subsection does not preclude a determination by the State Tax Assessor or the
38	court on appeal that more than one officer or employee are jointly and severally liable
39	for unpaid taxes.
40	§4966. Duty to keep receipts, invoices and other records
41	A psilocybin service center operator shall keep receipts, invoices and other pertinent
42	records related to retail sales of psilocybin products in accordance with chapter 7 and in the
43 44	form required by the State Tax Assessor. Each record must be preserved as provided in
44	section 135 or for as long as the psilocybin service center operator retains the psilocybin

1 products to which the record relates, whichever is later. During the retention period and at 2 any time prior to the destruction of records, the State Tax Assessor may give written notice 3 to the psilocybin service center operator not to destroy records described in the notice 4 without written permission of the State Tax Assessor. Notwithstanding any provision of 5 law to the contrary, the State Tax Assessor shall preserve reports and returns filed with the

6 department for at least 5 years.

7 §4967. Disclosure of information

8 Notwithstanding any provision of law to the contrary, the State Tax Assessor may 9 disclose information received under this chapter to the department as necessary for the 10 department to carry out the provisions of Title 28-B, chapter 5.

11 §4968. Right to appeal determination of tax liability

12 Except as otherwise provided in this chapter or chapter 7, a final determination of tax
 13 liability by the State Tax Assessor under this chapter is a final agency action that may be
 14 appealed for review pursuant to Title 5, section 11001.

15 §4969. Duty to return excess tax collected

16 When an amount represented by a psilocybin service center operator at retail to a client 17 as constituting the tax imposed under this chapter is computed upon an amount that is not 18 taxable or is in excess of the taxable amount and is actually paid by the client to the 19 psilocybin service center operator, the excess tax paid must be returned by the psilocybin 20 service center operator to the client upon written notification by the State Tax Assessor or 21 the client. The written notification must contain information necessary to determine the 22 validity of the client's claim. If the psilocybin service center operator does not return the 23 excess tax within 60 days after the mailing of the written notification, the client may appeal 24 to the State Tax Assessor for a refund of the amount of the excess tax, in the manner and 25 within the time allowed under rules adopted by the State Tax Assessor. If excess tax is 26 returned to the client by the State Tax Assessor, the assessor may issue a notice of 27 deficiency for the excess tax to the psilocybin service center operator.

28 §4970. Duties and powers of assessor; rules; interagency cooperation

The State Tax Assessor shall administer and enforce this chapter and may adopt rules and procedures necessary for the implementation and enforcement of this chapter. Except as otherwise expressly provided in this chapter, the State Tax Assessor may take any actions under chapter 7 necessary to the proper discharge of the State Tax Assessor's duties under this chapter. The department shall enter into an agreement with the State Tax Assessor for the purpose of administering and enforcing the provisions of this chapter and rules or procedures established by the assessor under this section.

36 §4971. Administrative account; payment of expenses; crediting balance to Psilocybin 37 Control and Regulation Fund

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. Sec. 7. Maine Psilocybin Advisory Board; initial board. Notwithstanding the
 Maine Revised Statutes, Title 28-B, chapter 5, subchapter 13, the following provisions
 apply to the Maine Psilocybin Advisory Board.

1. Staggered terms for members of Maine Psilocybin Advisory Board. At the first meeting of the Maine Psilocybin Advisory Board, board members shall draw lots to determine members' initial term lengths so that the initial terms of 7 members expire after one year and the initial terms of 7 members expire after 2 years.

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8 2. Initial appointments to Maine Psilocybin Advisory Board. The appointing
 9 authorities shall appoint initial board members to the Maine Psilocybin Advisory Board no
 10 later than October 15, 2023.

Initial meeting of Maine Psilocybin Advisory Board. The Maine Psilocybin
 Advisory Board shall hold its first meeting no later than November 15, 2023 at a time and
 place specified by the Governor.

14 4. Initial reports of Maine Psilocybin Advisory Board. The Maine Psilocybin Advisory Board shall submit no later than April 15, 2024 its findings and recommendations 15 to the Department of Health and Human Services regarding available medical, 16 psychological and scientific studies, research and other information related to the safety 17 and efficacy of psilocybin in treating mental health conditions, including but not limited to 18 substance use disorder, depression, anxiety disorders and end-of-life psychological 19 distress. The Maine Psilocybin Advisory Board shall submit no later than October 15, 2024 20 21 its findings and recommendations to the Department of Health and Human Services regarding the board's long-term strategic plan described in Title 28-B, section 2134, 22 23 subsection 2, paragraph A, information and updates on federal laws, regulations and 24 policies regarding psilocybin as described in Title 28-B, section 2134, subsection 2, 25 paragraphs B and C and proposed rules for the implementation of this Act.

Sec. 8. Rulemaking by Department of Health and Human Services. The
 Department of Health and Human Services shall adopt rules no later than July 15, 2024 in
 order to implement, administer and enforce the Maine Revised Statutes, Title 28-B, chapter
 5.

Sec. 9. Publicly available information regarding psilocybin. No later than
 December 1, 2024, the Department of Health and Human Services shall first publish
 information about psilocybin in accordance with the Maine Revised Statutes, Title 28-B,
 section 2011.

34 Sec. 10. Conforming amendments. The Department of Health and Human 35 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 36 37 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 38 than December 1, 2024, the department shall submit its recommendations together with 39 40 suggested legislation to the joint standing committee of the Legislature having jurisdiction over health and human services matters. The committee may report out a bill related to the 41 42 recommendations of the department to the 132nd Legislature in 2025.

1	SUMMARY
2 3 4	This bill enacts the Maine Psilocybin Health Access Act, which establishes a regulatory framework in order to provide psilocybin products to individuals in Maine who are 21 years of age or older.