131st Legislature **Senate of Maine**Senate District 31

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Testimony of Senator Donna Bailey introducing

LD 1914, An Act to Enact the Maine Psilocybin Health Access Act

Before the Joint Standing Committee on Veterans and Legal Affairs

May 15, 2023

Senator Hickman, Representative Supica, and Esteemed Members of the Veterans and Legal Affairs Committee, my name is Donna Bailey, and I proudly represent Senate District 31, which includes Buxton, Old Orchard Beach, and Saco. Today, I am pleased to introduce LD 1914, "An Act to Enact the Maine Psilocybin Health Access Act."

In the 130th Legislature, I introduced LD 1582, "An Act to Enact the Maine Psilocybin Services Act." In my testimony, I provided an overview of the breakthroughs in psilocybin therapy. Studies have shown that psilocybin helps long-time smokers quit smoking tobacco, ease anxiety in patients who have life-threatening cancers, and reduce alcohol intake for those who struggle with substance abuse. Psilocybin therapy also has the potential to treat people who are suffering from post-traumatic stress disorder (PTSD), which includes survivors of domestic or sexual abuse and veterans. When compared to the typical selective serotonin reuptake inhibitors (SSRIs) that patients take for mental health disorders, psilocybin works rapidly and robustly. While SSRIs take weeks or months to improve a patient's health, psilocybin therapy targets a broader range of symptoms and works within hours or days.

Now, as we all know, bills in the Legislature are like SSRIs: They can take some time before they become effective. As a lawmaker who has served in the House and Senate, I know that some bills require multiple legislative sessions before they become laws. That's why I'm happy to bring this bill back – with a few changes. But more on that later.

While some more conventional therapies can help individual patients, it's clear that we need to explore additional treatment options, such as psilocybin therapy. It breaks my heart to note that the first annual gun violence report from the Department of Health and Human Services shows that more than 85 percent of Maine's firearm deaths were suicides. Nationwide, domestic violence increased during the pandemic, especially when people were on lockdown or in isolation. I have another heartbreaking statistic. Maine set another record for overdose deaths in 2021. These 636 overdose-related deaths represent a 23 percent increase over the number of deaths for 2020. We have people dying from overdoses and suicides, and we have people hurting

For reference, please see <a href="http://www.mainelegislature.org/legis/bills/getTestimonyDoc.asp?id=10002633">http://www.mainelegislature.org/legis/bills/getTestimonyDoc.asp?id=10002633</a>.

from the after-effects of domestic abuse and violence. Reflecting on these statistics, I can't help but ask, "Why not try something new? Why not try all the tools we have?"

LD 1914 would give us another tool. It would establish a safe, tightly regulated program to make psilocybin treatment services available for veterans, first responders, and others in need. Licensed and trained facilitators would administer the treatment. This legislation is modeled on initiatives recently passed by voters in Colorado (2022) and Oregon (2020).

To be specific, LD 1914 would direct the Department of Health and Human Services (DHHS) – along with recommendations from an advisory board – to develop strict safety criteria to minimize risk and maximize benefit. The bill would require facilitators and clients to conduct a preparation session and risk assessment prior to administering psilocybin. It would also authorize DHHS to prohibit all advertising related to psilocybin services. Finally, it would provide state regulators a 12-month timeline to develop rules and procedures to ensure responsible implementation of the program and treatment.

Before I move on, I want to be clear that LD 1914 would not allow for the retail sale of psilocybin, and it would not allow for people under the age of 21 to access psilocybin.

Now a lot of work has gone into the drafting of this bill. It's a serious program, and the potential benefits for Maine people are great. Knowing this, I have a sponsor's amendment that I would like to direct the committee's attention to. I won't go through the changes, line by line, but I will share a few notes on why the changes were made. I want to make sure that the bill would not allow for the retail sale of psilocybin from treatment centers or licensed facilitators. I want to make sure that Maine models the best parts of the psilocybin treatment program in Oregon. I want to be sure that facilitators can decline to serve people with mental health conditions that psilocybin has not been proven to treat or that the facilitator does not have the training or skill set to treat.

At the end of the testimony, you will see two handouts. Please take your time to read through the materials. These materials include articles and studies, which help make a convincing case for allowing psilocybin therapy in Maine.

Thank you for your time, I would be happy to answer any questions.

**Donna Bailey** 

State Senator, Senate District 31

Buxton, Old Orchard Beach, and Saco



# Psilocybin-assisted therapy offers hope and healing

Maine is confronting epidemic levels of mental illness. Daily medications, therapy, and other coping mechanisms help some people get by — but for many, these tools aren't working. Promising research from America's top universities have found that psychedelic therapies can help in treatment-resistant anxiety, depression, and PTSD.

Psychedelic therapy with psilocybin shows so much promise that the FDA recently granted it a "breakthrough therapy" designation for depression, meaning that it may demonstrate substantial improvement over what's currently available.

Senator Donna Bailey's
Psilocybin Health Access Act
(LD 1914) would establish a
tightly regulated program to
make psilocybin treatment
services available for veterans,
first responders, and others in
need through licensed and
trained facilitators. The
legislation is modeled on
policies approved by voters in
Oregon and Colorado.



Voters in Oregon approved a 2020 ballot initiative to establish healing centers for psilocybin therapy now opening in 2023.



In 2022, voters in Colorado approved a similar measure to allow psychedelic-assisted therapy.



Over 25 states have introduced or enacted legislation related to psychedelic medicines since 2019

## The Maine Psilocybin Health Access Act LD 1914

The Maine Psilocybin Health Access Act, sponsored by Senators Donna Bailey (D), Daniel Ankeles (D), David Boyer (R), Eric Brakey (R), Stacy Brenner (D), Marc Malon (D), Austin Theriault (R), envisions a system of safe access to psilocybin therapy services provided by licensed and trained facilitators. The policy is modeled on Oregon's strictly regulated program, which was approved by voters in 2020.

#### What the bill does:

- Establishes regulated access to psilocybin therapy for adults who qualify under the supervision of a licensed, trained facilitator;
- Directs the Department of Health and Human Services, with recommendations from an advisory board, to develop strict safety criteria to minimize risk and maximize benefit for those in need;
- Requires facilitators and clients to conduct a preparation session and risk assessment screening prior to administering psilocybin;
- Authorizes the Department to prohibit all advertising related to psilocybin services; and
- Provides state regulators a 12-month timeline to develop rules and procedures to ensure responsible implementation.

#### What the bill does not do:

- The bill does not allow the retail sale of psilocybin; and
- The bill does not allow access to people under 21 years of age.

## Psychedelic-assisted therapy in the news

### The New York Times

"<u>Legal Use of Hallucinogenic Mushrooms Begins in Oregon</u>" Jan. 3, 2023

On Jan. 1, Oregon became the first state in the nation to legalize the adult use of psilocybin, a naturally occurring psychedelic that has shown significant promise for treating severe depression, post-traumatic stress disorder and end-of-life anxiety among the terminally ill, among other mental health conditions.

Although scientists are still working to understand their therapeutic dynamics, psilocybin and other psychedelics are thought to promote neuroplasticity, a rewiring of the brain that gives patients fresh perspectives on longstanding psychiatric problems.

One recent study on alcohol-use disorder, for example, found that two doses of psilocybin paired with talk therapy led to an 83 percent decline in heavy drinking among participants, and that nearly half of them had stopped drinking entirely by the end of the eight-month trial.

### DAMPBEAST

## "Why Veterans Are Lining Up for Legalized Magic Mushrooms" Dec. 30, 2022

The Heroic Hearts Program currently offers ayahuasca retreats in Mexico and Peru to veterans with a history of military combat and/or sexual assault. Founder Jesse Gould said he hopes to set up an outpost in Oregon within the next year. An Army veteran who credits ayahuasca for helping him heal from PTSD, Gould envisions a pilot program where veterans are treated with magic mushrooms in a group therapy setting led by veterans who've done their own healing through psychedelics.

"We're trying to create this self-supporting ecosystem to keep costs down, make it scalable and take the burden off of therapists," Gould said. "The veterans can help support their brothers and sisters who they relate to. It's training communities to heal themselves."

## Psychedelic-assisted therapy in the news

## NEW YORKER

### "Can Psychedelics Heal Ukrainians' Trauma?" February 27, 2023

A psychedelic solution has already been under discussion in Ukraine. After the panel convened, Yuriy Blokhin, who moved from Kyiv to Canada and who runs the North American branch of the Ukrainian Psychedelic Research Association, was reached by phone.

"Ayahuasca saved my life after an episode of depression," he said. "Then I met an Army Ranger, and we started using it to help special-ops veterans. We want to make sure that when the war in Ukraine ends there are world-class options. And it can become an additional stream of revenue for Ukraine." He added that there was "a critical mass of open-mindedness in Ukraine" and mentioned "the government's dynamic startup culture." Blokhin wants to train therapists who will treat Ukrainian refugees in the use of psychedelics.



## "How psilocybin may rewire the brain to ease depression, anxiety and more" June 11, 2022

"The data are strong from depression to PTSD to cluster headaches, which is one of the most painful conditions I'm aware of," said neurologist Richard Isaacson, director of the Alzheimer's Prevention Clinic in the Center for Brain Health at Florida Atlantic University.

"I'm excited about the future of psychedelics because of the relatively good safety profile and because these agents can now be studied in rigorous double-blinded clinical trials," Isaacson said. "Then we can move from anecdotal reports of 'I tripped on this and felt better' to 'Try this and you will be statistically, significantly better."

## Psilocybin-assisted therapy research

Pioneering studies at leading medical research institutions such as Johns Hopkins, NYU, Imperial College of London, and the University of Alabama show that psilocybin-assisted therapy can be effective in treating depression, trauma, end-of-life anxiety, addiction, and other conditions. A number of studies are currently underway throughout across the country and around the world.

#### Johns Hopkins University School of Medicine

Major depressive disorder: Research published in 2022 involved administration of psilocybin to patients with major depression. After a 12-month assessment, 75% of participants showed a significant positive response to the treatment, and 58% were in remission. The authors concluded, "These findings demonstrate that the substantial antidepressant effects of psilocybin-assisted therapy may be durable at least through 12 months."

**Cigarette smoking cessation:** A follow up on a previous study involving 15 heavy smokers who wanted to quit <u>found</u> that two-thirds of the participants remained abstinent 12 months following psilocybin-assisted therapy.

**End of life anxiety:** Research involving psilocybin-assisted therapy for cancer patients was published in 2016. Over 80% of the study's participants reported moderate to greatly increased well-being and life satisfaction.

#### Imperial College of London

*Major depressive disorder:* A double-blind, randomized, controlled trial involving 59 patients with major depressive disorder compared psilocybin with escitalopram (Lexapro), an SSRI. <u>The results</u> indicated that psilocybin was more effective than escitalopram (though the difference was not statistically significant due to small sample size) while producing better secondary outcomes for patients.

#### New York University Center for Psychedelic Medicine

Depression and anxiety among cancer patients: A pool of 29 patients with cancer-related anxiety and depression were randomly assigned a psilocybin treatment. At the 6.5-month follow-up, approximately 60–80% continued to show clinically significant reductions in depression or anxiety. Researchers concluded, "In conjunction with psychotherapy, single moderate-dose psilocybin produced rapid, robust and enduring anxiolytic and antidepressant effects in patients with cancer-related psychological distress."

**Alcohol use disorder:** Building on encouraging research originally published in 2015, Dr. Michael Bogenschutz, MD published a 2022 study that found participants given psilocybin-assisted therapy reduced heavy drinking by 83%.

#### Yale University

**Major depressive disorder:** Recent <u>research</u> led by Dr. Jordan Sloshower and a team of psychiatrists at Yale explores the therapeutic benefits of psilocybin therapy for major depression.

Obsessive compulsive disorder (OCD): Dr. Benjamin Kelmendi is conducting clinical trials to understand the benefits of psilocybin-assisted therapy for patients with OCD.

**Headache disorders:** Dr. Emmanuelle Schindler is conducting <u>research</u> into the effects of psilocybin for the treatment of cluster headaches, a severely painful condition that affects over 200,000 people in the US.

#### **University of Alabama**

Alleviation of psychological stress: <u>Dr. Peter Hendricks' work</u> indicates that the use of psychedelics is strongly associated with reduced psychological distress and suicidal thinking.

Protective effect against antisocial behavior: In another study, Dr. Henricks measured the relationship between criminal behavior and the use of psychedelics. His study found use of psychedelics like psilocybin predicted a 27% decrease in the odds of committing theft, a 12% reduction in the odds of committing assault, a 22% decrease in the odds of arrest for a property crime, and an 18% decrease in the odds of arrest for a violent crime.

#### The promise of psychedelic medicines

A growing compendium of research from leading scientific institutions shows that psychedelic therapy holds tremendous promise in helping millions of people who struggle with serious mental health challenges. Veteran suicide, substance use disorder, and other urgent public health crises could be significantly mitigated through with greater use of these treatments. After decades of stigma, educating the public about psychedelic medicines and those who can benefit is a critical need.

The studies presented below represent some of the most important advances in psychedelic medicine in recent years, but this is far from an exhaustive list. Additional articles, along with helpful analyses, can be found at <a href="https://blossomanalysis.com/papers/">https://blossomanalysis.com/papers/</a>. Additionally, dozens of clinical trials are currently underway and will continue to provide new insights on the potential therapeutic usefulness of psychedelics.

#### National mental health statistics

#### Veteran suicide

- From the Department of Veterans Affairs' <u>National Veteran Suicide Prevention Annual Report</u> (September 2022): "In 2020, there were 6,146 Veteran suicides. This was on average 16.8 per day."
  - According to research presented in a <u>September 2022 Military Times article</u>, these federal statistics may be severely undercounting the number of veteran suicides: "Officials from America's Warrior Partnership, in a joint study with University of Alabama and Duke University, reviewed census death data from 2014 to 2018 for eight states and found thousands of cases of suspected or confirmed suicides not included in federal calculations. If those figures were to be repeated across the other states, it would push the veterans suicide rate from about 17 individuals a day (the official estimate released by the Department of Veterans Affairs last year) to **44 veterans a day**."

#### Prevalence of mental health issues and substance use disorder

- According to the <u>National Alliance on Mental Illness</u>:
  - 21% of adults in the US have a mental illness; 5.6% of U.S. adults experienced serious mental illness in 2020 (14.2 million people)
  - o In the past year, among US adults:
    - 8.4% (21 million people) experienced a major depressive episode
    - 19.1% (48 million people) experienced an anxiety disorder
    - 3.6% (9 million people) experienced posttraumatic stress disorder
- Experts <u>estimate</u> that more than 20 million Americans over the age of 12 struggle with a substance use disorder

#### Recent scientific studies on psychedelics (2020 - 2022)

- Gukasyan N, et al (2022). Efficacy and safety of psilocybin-assisted treatment for major depressive disorder: Prospective 12-month follow-up. *Journal of Psychopharmacology*. 2022;36(2):151-158.
  - https://journals.sagepub.com/doi/full/10.1177/02698811211073759
    - "The results of this long-term follow-up of participants ... suggest that psilocybin-assisted treatment for MDD [major depressive disorder] produces large and stable antidepressant effects throughout at least 12 months after treatment."
- Jones GM, et al (2022). MDMA/ecstasy use and psilocybin use are associated with lowered odds of psychological distress and suicidal thoughts in a sample of US adults. Journal of Psychopharmacology. 2022;36(1):46-56.
   <a href="https://journals.sagepub.com/doi/abs/10.1177/02698811211058923">https://journals.sagepub.com/doi/abs/10.1177/02698811211058923</a>
  - o "[L]ifetime psilocybin use was associated with reduced odds of past month psychological distress (OR = 0.78; 95% CI = (0.73–0.84); p < 0.001) and past year suicidal thinking (OR = 0.90; 95% CI = (0.83–0.96); p < 0.01)"
- Bogenschutz MP, Ross S, Bhatt S, et al. (2022) Percentage of Heavy Drinking Days Following Psilocybin-Assisted Psychotherapy vs Placebo in the Treatment of Adult Patients With Alcohol Use Disorder: A Randomized Clinical Trial. JAMA Psychiatry, 79(10):953–962.
  - https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2795625
    - o "In this double-blind randomized clinical trial with 93 participants, the percentage of heavy drinking days during 32 weeks of follow-up was significantly lower in the psilocybin group than in the diphenhydramine group."
- Goodwin, G. M., et al (2022). Single-Dose Psilocybin for a Treatment-Resistant Episode of Major Depression. The New England journal of medicine, 387(18), 1637–1648. https://doi.org/10.1056/NEJMoa2206443
  - "In this phase 2 trial involving participants with treatment-resistant depression, psilocybin at a single dose of 25 mg, but not 10 mg, reduced depression scores significantly more than a 1-mg dose over a period of 3 weeks."
- Von Rotz, Robin, et al (2022) Single-dose psilocybin-assisted therapy in major depressive disorder: A placebo-controlled, double-blind, randomised clinical trial. The Lancet, Volume 56, 101809. <a href="https://doi.org/10.1016/j.eclinm.2022.101809">https://doi.org/10.1016/j.eclinm.2022.101809</a>
  - "These results suggest that a single, moderate dose of psilocybin significantly reduces depressive symptoms compared to a placebo condition for at least two weeks."

- Jones, G., et al (2022) Associations between classic psychedelics and opioid use disorder in a nationally-representative U.S. adult sample. Scientific Reports 12, 4099. https://doi.org/10.1038/s41598-022-08085-4
  - "We used recent data from the National Survey on Drug Use and Health (2015–2019) (N = 214,505) and multivariable logistic regression to test whether lifetime use (yes/no) of classic psychedelics was associated with lowered odds of OUD [opioid use disorder]. Lifetime psilocybin use was associated with lowered odds of OUD (aOR: 0.70; 95% CI [0.60, 0.83])."
- Davis AK, et al (2021). Effects of Psilocybin-Assisted Therapy on Major Depressive Disorder: A Randomized Clinical Trial. JAMA Psychiatry. 78(5):481–489. <a href="https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2772630">https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2772630</a>
  - "This randomized clinical trial found that psilocybin-assisted therapy was efficacious in producing large, rapid, and sustained antidepressant effects in patients with major depressive disorder."
- Agin-Liebes, G. I., et al (2020). Long-term follow-up of psilocybin-assisted psychotherapy for psychiatric and existential distress in patients with life-threatening cancer. *Journal of psychopharmacology*, 34(2), 155–166. https://doi.org/10.1177/0269881119897615
  - o "These findings suggest that psilocybin-assisted psychotherapy holds promise in promoting long-term relief from cancer-related psychiatric distress."

Be it enacted by the People of the State of Maine as follows:

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Sec. 1.	5 MRSA §12004-1, sub-§73-C is enac	cted to read:	
<u>73-C</u> . <u>Psilocybin</u>	Maine Psilocybin Advisory Board	Expenses and	<u> 28-B MRSA</u>
<del></del>		Legislative Per	<u> </u>

Sec. 2. 17-A MRSA §1111-A, sub-§1, as amended by PL 2021, e. 669, §1, is further amended to read:

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- 1. As used in this section the term "drug paraphernalia" means all equipment, products and materials of any kind that are used or intended for use in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, packaging, repackaging, storing, containing or concealing a scheduled drug in violation of this chapter or Title 22, section 2383, except that this section does not apply to a person who is authorized to possess cannabis for medical use pursuant to Title 22, chapter 558-C, to the extent the drug paraphernalia is used for that person's medical use of cannabis; to a person who is authorized to possess cannabis pursuant to Title 28-B, to the extent the drug paraphernalia is used for that person's adult use of cannabis; or to a cannabis store licensed pursuant to Title 28-B, to the extent that the drug paraphernalia relates to the sale or offering for sale of cannabis by the cannabis store; or to a person who is authorized to possess psilocybin pursuant to Title 28-B, to the extent that the drug paraphernalia is used for that person's personal use of psilocybin, to the extent the licensee is authorized to possess psilocybin or to the extent that the drug paraphernalia relates to the sale or offering for sale of psilocybin. It includes, but is not limited to:
  - A. Kits used or intended for use in planting, propagating, cultivating, growing or harvesting of any species of plant which is a scheduled drug or from which a scheduled drug can be derived;
  - B. Kits used or intended for use in manufacturing, compounding, convelling, producing, processing or preparing scheduled drugs;
  - C. Isomerization devices used or intended for use in increasing the potency of any species of plant that is a scheduled drug;
  - E. Scales and balances used or intended for use in weighing or measuring scheduled drugs;
  - Dilutants and adulterants, such as quinine hydrochloride, mannitol, mam1ite, dextrose and lactose, used or intended for use in cutting scheduled drugs;
  - G. Separation gins and sifters, used or intended for use in removing twigs and seeds from, or in otherwise cleaning or refining, marijuana;
- H. Blenders, bowls, containers, spoons and mixing devices used or intended for use in compounding scheduled drugs;
- I. Capsules, balloons, envelopes and other containers used or intended for use in 39 packaging small quantities of scheduled drugs; and 40

1 2	J. Containers and other objects used or intended for use in storing or concealing scheduled drngs.
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. I is enacted by adding before chapter I the following to read:
8	PART 1
9	ADULT USE CANNABIS
10	Sec. 5. 28-B MRSA Pt. 2 is enacted to read:
11	PART2
12	<u>PSILOCYBIN</u>
13	<u>CHAPTERS</u>
14	MAINE PSILOCYBIN HEALTH ACCESS ACT
15	SUBCHAPTER I
16	GENERAL PROVISIONS
17	§2001. Short title
18	This chapter may be known and cited as "the Maine Psilocybin Health Access Act."
19	§2002. Definitions
20 21	As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.
22 23	1. Administration session. "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.

2	limited partnership or other legal entity that is registered with the office of the Secretary of
3	State.
4	5. Client. "Client" means an individual who receives psilocybin services in this State.
5	6. Client information form. "Client information form" means the form required to be
6	completed by a client under subchapter 8.
7	7. Department. "Department" means the Department of Health and Human Services,
8	8. Integration session. "Integration session" means a meeting between a client and a
9	psilocybin service facilitator that may occur after the client completes an administration
0	session.
1	9. Licensee. "Licensee" means a person holding a current, valid license issued under
2	this chapter.
3	10. Licensee representative. "Licensee representative" means an owner, director,
4	officer, manager, employee, agent or other representative of a licensee to the extent that
5	person acts in a representative capacity.
6	11. Manufacture. "Manufacture" means the cultivation, harvesting, production,
7	preparation, propagation, compounding, conversion or processing of a psilocybin product
8	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
<del>)</del> )	psilocybin product or labeling of its container.
	12. Personal use amount. "Personal use amount" means the amount of psilocybin
2	authorized for a client's use under section 2091, subsection I, paragraph A.
	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
r	and storerooms.
3	14. Preparation session. "Preparation session" means a meeting between
)	prospective client and a psilocybin service facilitator that occurs before an administration
)	session.
	15. Psilocybin. "Psilocybin" means the naturally occur-ing compound produced by
2	various species of fungi as well as psilocin, the substance into which psilocybin is
3	converted in the human body.
	16. Psilocybin Control and Regulation Fund. "Psilocybin Control and Regulation Fund" means the fund established under subchapter 14.
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6	17. Psilocybin manufacturing facility. "Psilocybin manufacturing facility" means a

4. Business entity. "Business entity" means a corporation, limited liability company,

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facility licensed under subchapter 4.

does not include psilocybin services.

activities licensed under subchapter 5 may be conducted.

18. Psilocybin product. "Psilocybin product" means psilocybin-producing fungi or

19. Psilocybin service center. "Psilocybin service center" means a place where the

mixtures or substances containing a detectable amount ofpsilocybin. "Psilocybin product"

1 2	20. Psilocybin service center operator. "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.
<b>8</b> 9 10	23. Risk assessment screening. "Risk assessment screening" means a questionnaire included in a client infonnation 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	§2003. Scope
13	1, Limitations, Unless [TTI] otherwise permitted by law:
14 15	A. 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.  B.  TT2 Other than the sale of psilocybin from one licensee to another at permitted by this psilocybin may only be sold under this chapter for use by a client during an administration session under the supervision of a licensed psilocybin facilitator at a psilocybin service center other location approved by the department. Psilocybin sold by a licensee may only be consume at a psilocybin service center or other location approved by the department during an
	administration and may not be removed from the licensed or approved premises.
16	2. Construction. This chapter may not be construed to:
17 18	A. Require the MaineCare program or private health insurance coverage to reimburse a person for costs of psilocybin products;
19	B. Amend or affect state or federal law peliaining to employment matters;
20	C. Amend or affect state or federal law pertaining to landlord-tenant matters;
21 22 23	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;
24 25 26 27	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;
28	F. Require a person to violate federal law;
29 30	G. Exempt a person from a federal law or allow the person to obsttnet the enforcement of a federal law;
31 32 33 34	H. Penni! 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
35	I. Authorize any activity that is not expressly authorized under this chapter.
36	3. Effect of authorized conduct. Conduct authorized under this chapter may not:
37 38	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;
39	B. Be the basis to restrict a person's parenting time with a child without a finding that  DRAFT DRAFT DRAFT Page 4 - 131LR0311(01) DRAFT DRAFT DRAFT

chapter,

- the parenting time would endanger the child's physical health or significantly impair the child's emotional development: 40
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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:
6 7	E. [TT3]Be the sole basis for denial of a professional or occupational license or to subject the holder of a professional or occupational license to discipline; or
8 9	FE. Constitute the use of an illicit substance or otherwise disqualify a person from medical care or medical insurance, including organ transplants.
10	§2004. Rulemaking
11 12	The department shall adopt all rules necessary to implement, administer and enforce this chapter, including but not limited to rules governing the following:
14 15 16 17	1. [TT4] Possession limits on premises Production limits. The quantity of psilocybin permitted to be produced in the State. 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 conunensurate with the demand for psilocybin services:
18 19	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:
20 21	3. Licensing requirements. The application process for licensure under this chapter and annual renewal of licensure:
22 23 24 25 26	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:
27 28	5. Prevention of diversion to unauthorized persons. The prevention of diversion of psilocybin products to persons that are not pennitted to possess or use psilocybin: and
29 30 31	6. Administration sessions. 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.
32 33	The department may not require a client to be diagnosed with or have any particular medical condition in order to receive psilocybin services.
34	In adopting rules, the department shall consider the recommendations of the board,
35 36 <b>37</b>	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.  7. [TT5] Licensees. Procedures that encourage and support racial, ethnic, gender, economic, and geographic diversity among license applicants, licensees, employees, and facilitators.
38	§2005, Record keeping and inspection of records and premises; notice
39	1. Record keeping; inspection of records. A licensee shall maintain a complete set
40	of all records of the licensee's business transactions, which must be open to inspection and
41	examination by the depailment upon demand and with 72 hours' notice during all business
42	hours. The department may not require the records of a licensee to be maintained on the
43	premises of the licensee.

I 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 mies adopted pursuant to this chapter.
4	§2006. Administration sessions outside licensed premises prohibited: exception
<b>5</b> 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. A TT6 client may not remove psilocybin from the premises of a service center or other approved location.
8	§2007. Delivery and sale of psilocybin to persons under 21 years of age prohibited
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	A. A passport;
14	B. A driver's license;
15	C. A nondriver identification card issued under Title 29-A, section 1410;
16	D. A United States militmy identification card;
17 18	E. An identification card issued by one of the federally recognized Indian tribes in this State; or
19 20 21	F. Any other identification card issued by a state or territory of the United States that 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	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,
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	2. False identification. 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 [TT7]
31 — 32 —	A person may not sell, give or otherwise make available a psilocybin product to a person who is visibly intoxicated.
<del>33</del>	<u>A person who violates this section commits a civil violation for which a fine of not 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	A person who violates this section commits a civil violation for which a fine of not

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

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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 this chapter, the depatiment may require proof that a person performing work at the premises is 21 years of age or older. If the person does not provide the department with acceptable proof of age upon request, the department may require the person to immediately cease any activity and leave the premises until the depailment receives acceptable proof of age. The department may request that the licensee provide proof that the person is 21 years of age or older. Failure of the licensee to respond to the request is prima facie evidence that the licensee has allowed the person to perfonn work at the premises for which a license has been issued, except that it is an affirmative defense that the person is only temporarily at the premises to make a service, maintenance or repair call 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.

#### 82011. Publication of information related to use ofpsilocybin

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

#### 82012, Investigation by criminal justice agency of unlawful activity

A criminal justice agency may investigate unlawful activity under this chapter and may conduct a criminal hist01y 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.

#### §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 cany 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.

#### §2014. Immunity; refusal to serve: insurance

ŀ	1. Reliance immunity. A licensee or licensee representative may reasonably left
2	upon all statements, declarations and representations made by a client on a client
3	information fonn 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
5	representative who in good faith reasonably relies on statements, declarations and
6	representations made by a client on a client infonnation 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
IO	otherwise violated this chapter or a rule adopted pursuant to this chapter.
11	2. Refusal to serve. Nothing in this chapter requires a licensee or licensee
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[TT8] and there is not a medical basis to deny the
services.	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 depatiment may by rule require licensees to maintain general
21	liability insurance in an amount the department detennines 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 infonnation 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
	The department shall maintain a telephone hotline for the following persons to inquire
35	if an address is the location of a licensee's premises or is the location of premises for which
36	an application for licensure has been submitted under this chapter:
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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

for purposes of this chapter.

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3. Designation by water district. A person designated by a water district as a contact

1	§2017. Confidentiality
2	1. Confidential. The following infonnation 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	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
6 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	partner. limited partner. member, shareholder or other direct or indirect owner of such
10	a legal entity:
11	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. Infonnation related to the security plan or the operational plan for premises for
14	which a license has been issued or for which an applicant has proposed licensure under this chapter; and
15	D. Information related to any record that the department determines by rule to contain
16 <b>17</b>	proprietary information of a licensee.
 18	2. Exceptions, Information designated as confidential under subsection may be
19	disclosed to a law enforcement agency for law enforcement purposes.
20	SUBCHAPTER 2
21	GENERAL LICENSING REQUIREMENTS
22	§2021. License process; license types
23	Beginning January 15, 2025, the department, upon receipt of an application from an
24	applicant for a license under this chapter, shall, upon detel111ination that all applicable
25	requirements for that license are met. issue to the applicant the license. The department
26 27	may not unreasonably delay processing, approving or denying an application or, if an application is approved, unreasonably delay issuing the license.
	1. License types. The following licenses may be issued under this chapter m
28 29	accordance with all applicable requirements of this chapter:
30	A. A psilocybin service center license:
31	B. A psilocybin service facilitator license:
	C. A psilocybin manufacturing facility license: or
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33	D. A testing facility license.
34 35	Except as otherwise provided in this chapter, the department may not impose any limitation on the number of each type of license that it issues to a qualified applicant or on the total
35 36	number of each type of ficense that it issues to qualified applicants pursuant to this chapter.
	The [TT9] department may create and issue additional classes of licensure, including a sales-only that would allow for the sale of psilocybin to a client at the premises of a separately licensed
	service center or approved location for use during an administrative session at that service center
	of approved location.
37	§2022, General licensing criteria

license

- 3. No disqualifying drug ollense. 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 depatiment by rule. If the applicant is a business entity, every officer, director, manager and general patiner 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 cany out activities under the license.
- 4. Criminal history record check. The applicant must have submitted to a criminal history record check in accordance with section 2024. If the applicant is a business entity, evely officer, director, manager and general partner of the business entity must satisfy this requirement.
- 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.
- 6. Truthfulness. The applicant may not make any false statements to the depatiment. If the applicant is a business entity, every officer, director, manager and general partner of the business entity is subject to this requirement.
- 7. Health and safety. The applicant must demonstrate an ability to meet any public health and safety standards and induslly best practices established by the depmiment by rule.
- 8. Form. The applicant must disclose the applicant's name, address, location where the licensed activities will be conducted and any other infonnation requested by the depintment 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.
- 9. Payment of fees. 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.
- 82023. Additional licensing considerations

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I	1. Financial disclosures. An applicant for a license under this chapter must submit, at
2	the request of the department, the name and address of each person that has a financial
3	interest in the business that will be operated under the license and the nature and extent of
4	that financial interest.
5	2. Limitations on psilocybin service centers. A psilocybin service center may not be
6	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:
IO	(I) The department determines that there is a physical or geographic barrier capable
11	of preventing children from reaching the premises of the psilocybin service center;
12	<u>or</u>
13	(2) The school had not previously been attended by children and was not attended
14	by children at the time the license was issued.
15	A psilocybin service center must meet any other requirements for the facility established
16	by the department by rule.
17	§2024. Criminal history record check
18	The depmtment shall request a criminal hist01y record check for each applicant for a
19	license or permit under this chapter and may at any time require a person applying for a
20	license or pelmit to submit to a criminal histoly record check in accordance with this
21	section. If the applicant is a business entity, evely officer, director, manager and general
22	partner of the business entity and any individual who holds a financial interest in the
23	business entity of at least 10% must submit to a criminal history record check in accordance
24	with this section.
25	1. Record of public criminal history information required. Criminal histoly record
26	information obtained from the Maine Criminal Justice Information System, established in
27	Title 16, section 631, pursuant to this section must include a record of public criminal
28 .	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	Bureau of Investigation criminal history record check may obtain a copy of the criminal
31	history record check by following the procedures outlined in 28 Code of Federal
32	Regulations, Sections 16.32 and 16.33. The subject of a state criminal history record check
33	may inspect and review the criminal history record information pursuant to Title 16, section
34	<del>709.</del>
35	3. Use of criminal history record information. State and national criminal history
36	record information obtained by the department under this section may be used only for the
37	purpose of screening an applicant for a license or permit under this chapter.

person or entity except as provided in subsection 2.

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4. Confidentiality. All criminal history record infomlation obtained by the

depaltment pursuant to this section is confidential. is for the official use of the depaitment

only and may not be disseminated outside of the department or disclosed to any other

3	section.
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 JIPplication on a form prepared and furnished by the department for the license sought along with the appropriate application fee.
8 9 0	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:
1	A. More than one psilocybin manufacturing facility:
2	B. More than 5 psilocybin service centers: or
3 4	C. A testing facility and a psilocybin manufacturing facility or psilocybin service center.
5 6 7	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.
8 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	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 depaltment, 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 depmtment 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.

5. Rules. The department, after consultation with the Department of Public Safety. Bureau of State Police, State Bureau of Identification, shall adopt rules to implement this

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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:
IO 11	B. That the licensee is insolvent or incompetent or physically unable to carry on the licensed activities:
12 13	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:
14 15 16 17	D. That the licensee or an agent or employee of the licensee has been convicted of any felony 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 <b>25</b> 26	G. 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	§2027. License term: renewal
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	1. Application. A licensee seeking to renew an existing license must file an application for renewal with the depailment, 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	§2028. License properties: transfer: leftover product
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 2 3	1. Psilocybin products. Psilocybin products left by a deceased, insolvent or bankrupt person or licensee may be sold or otherwise disposed of and any security interest in the products foreclosed or settled;
4 5	2. Business. The business of a deceased, insolvent or bankrupt licensee may be operated for a reasonable period following the death, insolvency or bankruptcy; and
6 7 8	3. Security interest. A person with a security interest in relevant property may continue to operate at the premises for which a license has been issued under this chapter for a reasonable period after default on the indebtedness by the licensee.
9	SUBCHAPTER3
Ю	PERMIT REQUIREMENTS: PERMIT VIOLATIONS
11	§2031. Permit_required
12 13	1. Permit. A person who perfonns any of the following activities for or on behalf of a licensee must have a valid permit issued by the department under this subchapter:
14	A. Providing psilocybin services:
15	B. Possessing, manufacturing, securing or selling of psilocybin products; or
16	C. Verifying a client's age.
17 18 19 20	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 pelmit 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 22 23 24	2. Qualifications. The department shall adopt rules establishing the qualifications for obtaining a permit under this section, the term of a permit issued, procedures for applying for and renewing a permit and reasonable application, issuance and renewal fees for a permit.
25 26 27 28 29	The qualifications for the permit must include training requirements relating to checking client identification, detecting intoxication, handling psilocybin products, manufacturing 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 health and safety. The department may not require an individual to successfully complete any training 1 nore than once, except as a precondition for lifting a suspension of a pen 11 it
<b>30</b> 31	or, after a revocation of a permit, for applying for a new permit. The depat1ment or other
32	provider of required training may charge a reasonable fee for that training.
33 34 35 36 37 38	3. Denial, revocation or suspension of permit. The department, for good cause, may deny an application for an initial pelmit or a permit renewal or in an adjudicatory proceeding in accordance with Title 5, chapter 375 may suspend or revoke a permit. 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. As used in this subsection, "good cause" means a finding by the department that:
39	A. A person has violated any provisions of this chapter or any rules adopted in
40	accordance with this chapter; or

1	B. A person has been convicted of a <b>felony</b> crime [TT11] 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	<u>law</u> .
7	SUBCHAPTER4
	LICENSING AND OPERATING REQUIREMENTS FOR PSILOCYBIN
<b>8</b> 9	MANUFACTURING FACILITIES
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
13	manufacturing facility license. The department may by rule establish different types of
14	psilocybin manufacturing facility licenses that allow the licensee to engage in different
15	types of manufacturing activities. The [TT12] department may by rule allow a manufacturer to sell psilocybin directly to a client for
	use at a licensed psilocybin service center of other
	approved location. 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	A. Deliver psilocybin products to premises for which a license has been issued under
21	this chapter;
22	B. Receive psilocybin products from another psilocybin manufacturing facility
23	licensee; and
24	C. Manufacture psiloeybin products;
25	D. Deliver psilocybin products to premises for which a license has been issued; and
26	F. [TT13]Sale of psilocybin directly to clients for use during an administrative session, if allowed by department rule.
27	A psilocybin manufacturing facility licensee is not required to manufacture a psilocybin
28	product by means of chemical synthesis.
29	2. Prohibited conduct. A psilocybin manufacturing facility licensee may not:
30	A. Manufacture psilocybin products outdoors:
31	B. Sell or deliver a psilocybin product to a person under 21 years of age;
32	C. Employ a person under 21 years of age in manufacturing psilocybin products;
33	D. Make false representations or statements to the department in order to induce or
34	prevent action by the department;  E. Supply or sell impure or othel wise deleterious psilocybin products;
35	F. Misrepresent to a person or to the public any psilocybin products; or
36	G. Use information obtained to verify a person's age for any purpose other than
37	DO LOT DO LOT DO LOT
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38	verifying a	person's age	2

**SUBCHAPTERS** 39

I 2	LICENSING AND OPERATING REQUIREMENTS FOR PSILOCYBIN SERVICE CENTERS
3	§2051. Conduct of psilocybin service center licensees
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	1. Authorized conduct. A psilocybin service center licensee may engage in the
8	following activities in accordance with rnles adopted by the department:
9	A. Deliver psilocybin products to premises for which a license has been issued:
10 11	B. Receive psilocybin products from a psilocybin manufacturing facility licensee or another psilocybin service center licensee; and
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	C. Make false representations or statements to the department in order to induce or prevent action by the department;
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	1. Qualifications. In addition to the other applicable licensing requirements required
28	by this chapter, an applicant for a psilocybin service facilitator license must:
29 30	A. Meet any education or training requirements established by the department by rule, except that the department may not require a [TT14]professional degree from
	titution of higher education;
32 33	B. Meet any examination requirements established by the department by rule, except that the department may provide for waivers of examination requirements in cases i
34	determines appropriate. The department shall offer any required examination at least
35	twice annually. The department may appoint a person to conduct or supervise
36 37	examinations of applicants. An applicant may retake any failed section of the examination in accordance with rules adopted by the department; and
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2	C. Meet any other training, education, skill or fitness requirements adopted by the department by rule, such as:
3	/1) Facilitation skills that are affinning, nonjudgmental and nondirective: and
4 5 6 7	(2) Suppmt skills for clients during an administration session, including specialized skills relating to client safety and clients who may have mental health conditions, ability to establish a proper environment in which psilocybin services occur and social and cultural skills.
8 9 10 11 12	2. Training course approval. The department shall establish a process to approve 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 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.
13 14 15 16	3. Professional conduct. The department shall establish by mle a code of professional conduct, including a code of ethics, for psilocybin service facilitators. The department shall establish standards of practice and professional responsibility for psilocybin service facilitators.
17 18	4. Authorized [TT15]conduct: generally. A psilocybin service facilitator licensee may Engage, but shall not be required to engage, in the following activities in accordance with mies adopted by the depattment:
19	A. Deliver psilocybin products to premises for which a license has been issued under
20	this chapter:
21 22	B. Receive psilocybin products from a psilocybin manufacturing facility licensee or another psilocybin service facilitator licensee; and
23 24	C. Facilitate the use of psilocybin products by a client as part of an administration 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 mies requiring a testing facility licensee to test psilocybin
33	products sold or transferred to others by a psilocybin manufacturing facility licensee. The
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
36	of the psilocybin product has fundamentally changed. In adopting rules under this section,
37	the department shall consider the cost of a potential testing procedure and how that cost
38	will affect the cost to clients. The depattment may not adopt rules that are more restrictive
39	than is reasonably necessaty to protect the public health and safety.

1	The department shall adopt rules establishing standards for testing psilocybin products
2	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
3 4	to protection from microbiological contaminants, pesticides, other contaminants, solvents
5	and excessive psilocybin concentration.
6	§2073, Conduct of testing facility licensees
7	1. Authorized conduct. A testing facility licensee may engage in the following
8	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	G. Use information obtained to verify a person's age for any purpose other than
23	verifying a person's age.
24	SUBCHAPTER 8
25	OPERATING REQUIREMENTS FOR PROVIDING PSILOCYBIN SERVICES
26	§2081, Psilocybin services
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
29	the services provided by psiloeybin service centers and the provision of psilocybin services
30	to a client by a psilocybin service facilitator. The rules must:
31	A. Require a psilocybin service facilitator to obtain a complete client information form signed by the prospective client and, if department rules require, an approved medica
32 33	provider if the prospective client meets the criteria identified by the depmiment in a
33 34	risk assessment screening:
35	B. Require a psilocybin service facilitator to hold a preparation session with a clien
36	before the client participates in an administration session:

1 2 3	C. Reguire that, during the preparation session, the psiloeybin service facilitator review the client information f01m with the client, including any reguired 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 psiloeybin 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	(I) Solicit from the client such infolmation 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 infonnation 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 infonnation fmm 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 psiloeybin service facilitators to detennine 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	increased risk so as to be ineligible to receive psilocybin services at that time:
3	C. For prospective clients who meet any criteria that indicate additional medical review
4	as determined by completion of the risk assessment screening, require an approved
5	medical provider to sign the prospective client's client information form confiniting
6	that there is nothing in the client's disclosed health history indicating that use of
7	psilocybin is likely to put the prospective client at an increased risk of an adverse health
8	outcome compared to an average, healthy adult:
9	D. Require that a medical provider who has not previously signed off on a client
.0	information form for psilocybin services shall, prior to doing so, submit evidence,
1	satisfactory to the department, of completion of training or education related to
2	psilocybin, which may include self-directed study: and
13	E. Permit an approved medical provider who reviews and provides written confirmation for psilocybin services under this section to use telehcalth services as long
4	
15	as it is a synchronous encounter.
6	Nothing in this chapter prevents a professional licensing board from sanctioning a medical
17	provider for failing to properly evaluate or treat a person's medical condition or othetwise
18	violating the applicable standard of care for evaluating or treating medical conditions.
19	4. Informed consent required. The department shall adopt rules requiring a
20	prospective client to review and sign a document informing the client prior to an
21	administration session of the likely effects and potential risks of psilocybin use.
22	5. Administration session. The department shall adopt rules governing administration
23	sessions. The rules must:
24	A. Require that a client complete a preparation session and a client infonnation form
25	confirming eligibility prior to an adminish ation session, including additional medical
26	review ifrequired:
	B. Require an administration session to occur at a psilocybin service center or other
27	location approved by the department:
28	
29	C. Require a psilocybin service facilitator to certify, in a form and manner prescribed
30	by the department, that the client completed an administration session: and
31	D. Prohibit a psilocybin service facilitator from consuming a psilocybin product during
32	an administration session that the psilocybin service facilitator is supervising.
33	6. Integration session. The department shall adopt rules defining and governing
34	integration sessions. The rules must:
35	A. Require, upon completion of an administration session, that a psilocybin service
36	facilitator offer to the client the opportunity to participate in an integration session:
	B. Allow a client to decline to participate in an integration session:
37	
38	C. Allow any integration session to occur at a psilocybin service center, at another
39	location or via telehealth; and
40	D. Require a psilocybin service facilitator to certify, in a form and manner prescribed
41	by the department, if a client completed an integration session.

1 2	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
3 4	made by a client during the course of providing psilocybin services or selling psilocybin products to the client, except when:
5 6	A. The client or a person authorized to act on behalf of the client gives consent to the disclosure:
7 8	B. The client initiates legal action or makes a complaint against the psilocybin service center operator, psilocybin service facilitator or employee of either;
9	C. The communication reveals the intent to commit a crime harmful to the client or
IO	others;
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;
16 17	F. [TT16] Collecting or reporting data to the department beneficial to understanding the implementation of this chapter and the outcomes of psilocybin services provided under this chapter so long as the information does not contain personally identifying information and is collected and reported in accordance with department rules; or
18	G. F. The information or communication is required or authorized to be released in
19	accordance with Title 36, chapter 727.
20	SUBCHAPTER 9
21	PERSONAL USE OF PSILOCYBIN
22	§2091. Personal use of psilocybin
23	1. Personal use. Subject to the limitations in this chapter, but notwithstanding any
24	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
25 26	hasis for detention, search or an-est, to deny any right or privilege or to seize or forfeit assets
27	under state law or the laws of any locality if the person engaging in the act is 21 years of
28	age or older:
29	A. Possessing, using, processing, transpolting, obtaining, ingesting or giving away
30	without remuneration to a person 21 years of age or older not more than 2 grams of a
31	psilocybin product or 4 ounces of fungi containing psilocybin;
32	B. Possessing, growing, cultivating or processing plants or fungi capable of producing
33	psilocybin for personal use, as long as the plants and fungi and any psilocybin produced
34	in excess of a personal use amount are kept at the person's home or other private
35	residence or upon the grounds of that home or private residence and are secure from
36	access by a person under 21 years of age; and
37 38	C. Assisting another person who is 21 years of age or older, or allowing property to be used, in any of the actions or conduct permitted under this subsection.
39	§2092. Prior conviction
40	A person who has completed a sentence for a conviction of conduct authorized under
41	this chapter, whether by trial or plea of guilty or nolo contendere, who would not have been
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1	guilty of an offense under this chapter had it been in effect at the time of the offense may
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
4	attorney, the comt shall automatically seal the record. If there is an objection by the district
5	attorney, a hearing must be held and the court shall determine if the record of the conviction
6	does not qualify to be sealed under this chapter. If the record does not qualify to be sealed,
7	the court shall deny the sealing of the record. Nothing in this section may be construed to
8	diminish or abrogate any rights or remedies otherwise available to the petitioner or
9	applicant.
10	SUBCHAPTER 10
11	LOCAL REGULATION
12	§2101. Preemption: limited regulation
13	The provisions of this chapter are intended to operate unifonnly in this State and to
14	preempt any inconsistent municipal regulation. In accordance with this section, a
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
17	municipality may not reguire a license to conduct any activity licensed under this chapter,
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 a psilocybin service center from being located
20	in the municipality as long as the distance between the centers is greater than 1,000 feet[TT17].
21	For purposes of this subsection, "reasonable regulations" means the following, to the extent
22	consistent with the provisions of this chapter:
23	1. Conditions for manufacturing facilities. Conditions on the manner in which a
24	psilocybin manufacturing facility licensee may manufacture psiloeybin products:
25	2. Conditions for psilocybin service centers. Conditions on the manner in which a
26	psilocybin service center licensee may provide psilocybin services:
27	3. Hours. Limitations on the hours during which licensed premises may operate:
	4. Public access. Requirements related to the public's access to licensed premises:
28	
29	and
30	5. Location. Limitations on where licensed premises may be located.
31	Nothing in this section prohibits a municipality from allowing the manufacture of
32	psilocybin as a farm use on land zoned for fann or forest use.
33	SUBCHAPTER 11
34 35	LABELING AND PACKAGING: ADVERTISING AND MARKETING: HEALTH AND SAFETY
36	82111. Labeling requirements

	The department shall adopt mies necessary to protect the public health and safety that
2	establish standards for the labeling of psilocybin products.
3 4	1. Labeling standards. 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 <b>10</b>	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 depm1ment 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 nahtre 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	6. Deceptive labeling: injurious or adulterated ingredients. The department shall by rnle prohibit a licensee from selling any psilocybin product that, in the department's judgment, is deceptively labeled or contains injurious or adulterated ingredients.
22	§2112. Packaging requirements: advertising
23 24	As necessary to protect the public health and safety, the department shall adopt rules establishing standards for the packaging and advertising of psilocybin products.
25 26	1. Prohibiting advertising. The department may adopt rules prohibiting advertising psilocybin products and [TT18] services to the public.
27 28 29	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, makes false or unproven medical claims [TT19], violates the code of professional conduct for psilocybin
30 31	service facilitator licensees established by the department or otherwise presents a significant risk to public health and safety.
32 33	3. Packaging standards. The department may establish different packaging standards for different varieties and types of psilocybin products.
34 35 36	4. Labeling standards. The department may establish different labeling standards for different varieties and types of psilocybin packages and may consider the effect on the environment of requiring certain packaging.
37 38	5. Preapproval: fee. The department may require a licensee to submit packaging intended for use on a psilocybin product for preapproval before the licensee may sell or

transfer a psilocybin product packaged in the packaging and the depat1ment may impose a

6. Cost. The department shall consider the cost of meeting a potential requirement and how that cost will affect the cost to the client.

fee for the preapproval process.

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] 2	7. Rules [TT20] not more restrictive than necessary. The department may not adopt rules governing labeling that are more restrictive than is reasonably necessary to protect the
3	public health and safety.
4	§2113. Dosage requirements
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 pennitted in a psilocybin product package.
8	82114. Prohibition on sale to protect health and safety
9	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
10 11 12 13 14	and the rules adopted pursuant to this chapter. The depmtment 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	§2121. General penalty
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 cany on the licensed activities:
35 36	C. That the licensee or an agent or employee of the licensee has misrepresented to a person or the public any psiloeybin products sold by the licensee;
37 38 39	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
40	the premises for which the license was issued:

1	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;
2	F. That the licensee or an agent or employee of the licensee has purchased or received
3	a psilocybin product from an unlicensed source or has sold, stored or transferred a
4 5	psilocybin product in a manner that is not permitted by the licensee's license; or
-	G. That a person with a financial interest in the business operating or to be operated
6	under the license committed or failed to commit an act if that act or failure to act would
7 8	constitute grounds for the department to refuse to issue, or to suspend, revoke or refuse
9	to renew, the license if the person were the licensee or applicant for the license.
0	The department may not impose any penalty under this section on the basis of a finding
1	that the licensee or an agent or employee of the licensee has violated a provision of federal
.2	law governing psilocybin products.
13 14	2. Amounts: deposit. An administrative penalty imposed by the depriment 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 licensee whose license has been revoked pursuant to this
23	subchapter shall cease immediately all activities authorized by the license and shall ensure
24	that all psilocybin and psilocybin products in the possession of the licensee are forfeited to
25	the department for destruction in accordance with this subchapter.
26	5. Enforcement actions may be cumulative. In addition to suspending or revoking a
27	licensee's license, the department may impose an administrative penalty on the licensee
28	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 denminent 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 SOC of the Maine Rules of Civil Procedure.
39	§2123. Disposition of unauthorized psilocybin or psilocybin products of licensee
40	1. Order: destruction of psilocybin or psilocybin products. If the department issues
41	a final order imposing an administrative penalty on or a license suspension or revocation
42	against a licensee pursuant to this subchapter, the department may specify in the order, in
43	addition to any other penalties imposed in the order, that all or a pmilion of the psilocybin

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

•	B. A representative from a district coordinating council for public health established
2	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	E. A member of the Pcnnanent Commission on the Status of Racial, Indigenous and Tribal Populations, established in Title 5, section 12004-J, subsection 19;
8 9	F. A member of the Palliative Care and Quality of Life Interdisciplinary Advisory Council, established in Title 5, section 12004-L subsection 47-1; or
Ю	G. An individual who represents individuals who provide public health services
I 1	directly to the public.
12 13	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
14	appoint:
1 <i>5</i> 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	(I) 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 psychophannacology; or
24	(5) A person who has experience in the field of psilocybin harm reduction,
25 26 27	4. Members appointed by Speaker of House of Representatives. 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 I13-B;
29	B. An individual with expertise in the field of public health who has a background in
30	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	(I) 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 cthnobotany:
37	(4) A person who has experience in the field of psychophannacology: or
20	(5) A person who has experience in the field of psilocybin harm reduction.

1 2 3 4 5	5. Terms; vacancies. Board members, other than ex officio members, serve 2-year terms and are eligible for reappointment. Before the expiration of the term of a member, the appointing authority shall appoint a successor whose tenn begins on the next January 1st. Board members serve at the pleasure of the appointing authority and are not subject to legislative confirmation. If there is a vacancy for cause, the appointing authority shall make an appointment to become immediately effective for the unexpired tel111.
6 7 8	6. Chair. The board shall elect one of its members to serve as chair. The chair serves a one-year term in that office and is eligible for reelection.
9 10 11 12 13	7. Meeting frequency. Until all mies necessaty to implement this chapter have been adopted, the board shall meet at least once every 2 calendar months at a time and place determined by the chair or a majority of the members of the board. Thereafter the board shall meet at least 4 times each year at regular intervals at a time and place determined by the chair or a majority of the members of the board. The board may meet at other times 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 17	9. Establishment of subcommittees. The board may establish subcommittees necessary for the operation of the board.
18 19 20	10. Expenses; reimbursement. Board members are entitled to compensation for service on the board and for travel and board-related expenses in accordance with Title 5, section 12004-1, subsection 73-C.
21	§2134. Powers and duties
22	1. Powers. The board may:
23 24	A. Adopt mies necessaiy 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
25	B. Make recommendations to the department related to:
26	/1) Administration of this chapter:
27 28 29	(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
30	disorders and end-of-life psychological distress; (3) Working with clients receiving psilocybin services, including:
31	(3) Working with chefts receiving pshocyom services, including:  /a) The requirements, specifications and guidelines for providing psilocybin
32 33 34	services to a client, including but not limited to holding and verifying the completion of a preparation session, an administration session and an
35	integration session:
36 37 38	/b) The infonnation that must be provided to a client before the client pairticipates in an administration session, including health and safety warnings or other disclosures:
39	(c) The information that must be received from a client to determine whether
40 41	the client should participate in an administration session, including information that may identify risk factors and contraindications and infonnation related to

1 2	any public health or safety standards or industry best practices during the administration session:
3	(d) Transportation needs of a client after the completion of an administration
4	session: and
5 6	(e) Client access to common or outside areas on the premises of a psilocybin service center:
7	(4) Public health and safety standards and industry best practices for each type of licensee; and
9	(5) Required qualifications and practices of psilocybin service facilitators, including:
10	(a) Adherence to a code of professional and ethical conduct;
11	(b) Required education and training, including but not limited to:
12 13 14	(i) Client facilitation skills that are affinning, 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 ofreguired 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	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
31	be appropriate;  B. Monitor and study federal laws, regulations and policies regarding psilocybin; and
32	C. Attempt [TT21] to meet with the United States Attorney for the District of Maine to discuss
33 34 35	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.

# **SUBCHAPTER 14**

2	PSILOCYBIN CONTROL AND REGULATION FUND
3	§2141. Psilocybin Control and Regulation Fund
4 5 6	The Psilocybin Control and Regulation Fund, refell'ed 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:
IO 11	B. All money from any other source, whether public or private, designated for depositing 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	§2151. Regulation as food additive
18	Notwithstanding any provision of law to the contrary, the Department of Agriculture
19 20	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
21	unless the concentration of a psilocybin product exceeds acceptable levels established by
22	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	As used in this chapter, unless the context otherwise indicates, the following tenn
28	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	3. Psilocybin, "Psilocybin" has the same meaning as in Title 28-B. section 2002
32	subsection 15.

1 2	4. Psilocybin Control and Regulation Fund. "Psilocybin Control and Regulation Fund" has the same meaning as in Title 28-B, section 2002, subsection 16.
3 4	5. Psilocybin product. "Psilocybin product" has the same meaning as in Title 28-B. section 2002, subsection 18.
5	6. Psilocybin service center. "Psilocybin service center" has the same meaning as in Title 28-B, section 2002, subsection 19.
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 0	8. Retail sale. "Retail sale" means any transfer, exchange, gift or barter of a psilocybin product by any person to a client.
1 2	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.
3	§4962. Imposition of tax on retail sale of psilocybin products
4 5 6 7	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 [TT22] operator to a client at the time at which the retail sale occurs.
8 9	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 rnle, 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 pumoses of hiding or removing records of retail sales of position products or falsifying records of retail sales of position 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	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	84963. Collection of tax: refund: credit: penalties
39 40	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

is required to collect the tax, and the psilocybin service center operator is liable for the tax.

84966. Duty to keep receipts, invoices and other records

A psilocybin service center operator shall keep receipts, invoices and other pertinent records related to retail sales of psilocybin products in accordance with chapter 7 and in the form required by the State Tax Assessor. Each record must be preserved as provided in section 135 or for as long as the psilocybin service center operator retains the psilocybin

for unpaid taxes.

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

#### **§4967. Disclosure of infornation**

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

# 84968, Right to appeal determination of tax liability

Except as otherwise provided in this chapter or chapter 7, a final determination of tax liability by the State Tax Assessor under this chapter is a final agency action that may be appealed for review pursuant to Title 5, section I1001.

#### 84969. Duty to return excess tax collected

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

### 84970, 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.

### §4971. Administrative account; payment of expenses; crediting balance to Psilocybin-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 Psiloeybin 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 detennine members' initial term lengths so that the initial tenns of 7 members expire after one year and the initial terms of 7 members expire after 2 years.
- 2. Initial appointments to Maine Psilocybin Advisory Board. The appointing authorities shall appoint initial board members to the Maine Psilocybin Advisory Board no later than October 15, 2023.
- 3. 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.
- 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 to the Department of Health and Human Services regarding available medical, psychological and scientific studies, research and other information related to the safety and efficacy of psilocybin in treating mental health conditions, including but not limited to substance use disorder, depression, anxiety disorders and end-of-life psychological distress. The Maine Psilocybin Advisory Board shall submit no later than October 15, 2024 its findings and recommendations to the Depatiment of Health and Human Services regarding the board's long-term strategic plan described in Title 28-B, section 2134, subsection 2, paragraph A, information and updates on federal laws, regulations and policies regarding psilocybin as described in Title 28-B, section 2134, subsection 2, paragraphs Band C and proposed rules for the implementation of this Act.
- Sec. 8. Rulemaking by Department of Health and Hnman 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.
- Sec. 10. Conforming amendments. The Department of Health and Human Services, in consultation with the Department of Agriculture, Conservation and Forestry and the State Tax Assessor, shall examine laws of this State and develop recommendations for any amendments to those laws to conform to this Act and to othetwise make this Act as consistent as possible in substance to the laws governing psilocybin in Oregon. No later than December I, 2024, the department shall submit its recommendations together with 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 recommendations of the department to the 132nd Legislature in 2025.

# **SUMMARY**

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