

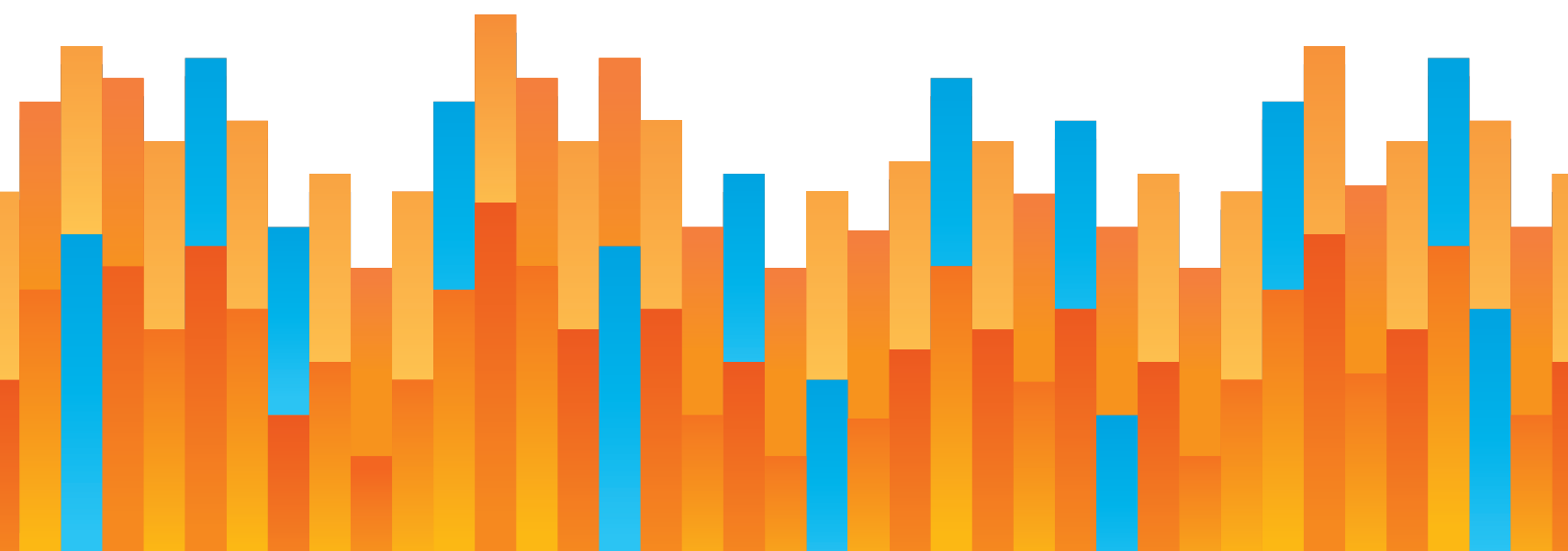


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PERSONAL PSYCHEDELICS LICENSE: A POLICY FRAMEWORK

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EXECUTIVE SUMMARY

This policy brief outlines a proposal to license consumers to purchase psychedelic substances. Similar to medical marijuana programs, psychedelics licenses would be overseen by a health professional and would be required for retail purchases. Psychedelic licenses for consumers have advantages over the current approach in two U.S. states that rely on professionals to dispense and facilitate services, because consumer-based licenses are far more accessible and cost-effective than professional-based licenses. Sample legislation is provided in the appendix.

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PART 1

INTRODUCTION

Two American states are already in the process of implementing a regulated market for psychedelic therapies, and several more are being proposed in state legislatures.¹ Under these emerging models, states license professional “facilitators.” Only these certified professionals are permitted to purchase psychedelics, and psychedelics can only be consumed on certified campuses. This model was first ratified in Oregon through a ballot initiative in 2020, and again in Colorado in 2022. Both states are in the process of implementing their regulatory frameworks governing legal psychedelic experiences with psilocybin, the active hallucinogen in “magic mushrooms.”

Though neither state has yet implemented the policy at scale, there are already serious market complications.² The first major issue is cost. There are estimates that a single psychedelic session will cost consumers upwards of \$3,000. This price range is inaccessible to many working-class Americans, especially considering that in Food and Drug Administration (FDA) trials designed to evaluate the effectiveness of psychedelic therapies, participants receive a minimum of three treatments.³

¹ “Psychedelic Legalization & Decriminalization Tracker,” Psychedelic Alpha, updated 29 Nov. 2023, www.psychedelicalpha.com/data/psychedelic-laws

² Ryan Haas, “Oregon’s emerging psilocybin mushroom market braces for dose of financial reality,” Oregon Public Broadcasting, updated 5 April 2023, www.opb.org/article/2023/03/24/oregon-psilocybin-mushroom-financial-undertaking-business-industry/?outputType=amp

³ Elliot Marseille, Jennifer Mitchell, & James Kahn, “Updated cost-effectiveness of MDMA-assisted therapy for the treatment of posttraumatic stress disorder in the United States: Findings from a phase 3 trial,” *PLoS ONE* 17 (2022).

Several factors contribute to this high retail price of treatment. Facilitators in Oregon are required to complete state-approved training programs, which can cost between \$8,000 and \$20,000 and can take more than four months.⁴ Additionally, the state charges thousands of dollars in licensing fees.



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Training programs are inherently expensive because Oregon has mandated over a dozen curricular modules (roughly 120 hours of total learning).⁵ Students must take classes on everything from the neurobiology of psilocybin to the importance of recognizing racial orientations in facilitation.

It's unclear how to offer these psychedelic facilitator trainings more cheaply, although this is an ongoing debate within the academic community.⁶ There is a bill in New York that attempts to accelerate credentialing by allowing existing licensed medical practitioners to facilitate psychedelic therapies, but it would still require additional coursework that could end up imposing barriers and costs similar to those witnessed in Oregon.⁷

In addition to training requirements, there are numerous expenses associated with managing a site certified to host psychedelic therapies ("healing center") or for manufacturing psilocybin products. For instance, there is a \$10,000 annual licensing fee for

⁴ Anthony Effinger, "The Expense of Opening a Psilocybin Service Center Will Make Shrooms a Costly Experience," *Willamette Week*, 8 March 2023, www.wweek.com/news/2023/03/08/the-expense-of-opening-a-psilocybin-service-center-will-make-shrooms-a-costly-experience/

⁵ *Oregon Administration Section 333-333-3060 - Psilocybin Training Curriculum Modules*, 2023.

⁶ Arda Ozcubukcu, "The Gold Standard for Psychedelic-Assisted Therapy," *Clerkenwell Health*, 9 March 2023, www.clerkenwellhealth.com/blog-articles/gold-standard-for-psychedelic-assisted-therapy-act

⁷ New York General Assembly, 2021-2022 Regular Sessions, Assembly Bill A08569A, www.nyassembly.gov/leg/?default_fld=&leg_video=&bn=A08569&term=2021&Summary=Y&Actions=Y&Memo=Y&Text=Y

both retail therapy providers and product manufacturers in Oregon.^{8,9} General business liability insurance is a variable cost and not well documented, but at least one report found that it could cost a service provider \$12,000.¹⁰

Any business involved in producing or selling psilocybin products also faces a substantial federal tax penalty. Internal Revenue Code 280E prohibits taxpayers who traffic in any Schedule I or Schedule II substance (including psilocybin), as listed under the federal Controlled Substances Act, from deducting expenses under the “ordinary and necessary” standard that applies to most taxpayers.¹¹ Instead, these taxpayers may deduct only the direct costs incurred in producing or purchasing inventory, while ordinary expenses like employee wages, rent or utilities may not be deductible. As a result, these taxpayers are assessed taxes on a modified gross-receipts basis rather than on net income and may owe substantial federal income tax even in years when they operate at a financial loss.



In one case, a prominent psychedelic services company in Oregon went bankrupt partly because a local jurisdiction voted to ban service centers, which each jurisdiction is allowed to do by law. The company had already invested millions of dollars in a retreat center and could not afford to relocate.



⁸ “Psilocybin Service Center License Application Guide for Applications Submitted Online,” Oregon Health Authority, oregon.gov, approved 30 Dec. 2022. www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Documents/Service-Center-License-Application-Guide-ONLINE.pdf (accessed 10 Jan. 2024).

⁹ “Oregon Psilocybin Services: How to become a licensed laboratory in Oregon,” Oregon Health Authority, oregon.gov, approved 30 Dec. 2022. www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Documents/Testing-Lab-License-Fact-Sheet.pdf (accessed 10 Jan. 2024).

¹⁰ Gregory Ferenstein, “California’s steps after bill vetoed, Kentucky ibogaine funds, and more,” Reason Foundation, 28 Nov. 2023, www.reason.org/psychedelics-policy/california-bill-vetoed-kentucky-ibogaine-more/

¹¹ De Lon Harris, “Providing Resources to Help Cannabis Business Owners Successfully Navigate Unique Tax Responsibilities,” Internal Revenue Service, irs.gov, 27 Sep. 2021. www.irs.gov/about-irs/providing-resources-to-help-cannabis-business-owners-successfully-navigate-unique-tax-responsibilities (accessed 10 Jan. 2024).

Finally, approval for retail campuses has been unpredictable and costly. In one case, a prominent psychedelic services company in Oregon went bankrupt partly because a local jurisdiction voted to ban service centers, which each jurisdiction is allowed to do by law.¹² The company had already invested millions of dollars in a retreat center and could not afford to relocate.

As a result of these and other regulatory issues, there are reports that most residents will continue to seek psychedelic therapy on the underground market.¹³

¹² Anthony Effinger, "Synthesis Institute Confirms Bankruptcy After Students Are Locked Out of Curriculum," *Willamette Week*, 7 March 2023, www.wweek.com/news/2023/03/07/synthesis-institute-confirms-bankruptcy-after-students-are-locked-out-of-curriculum/

¹³ Anthony Effinger, "Oregon's Appetite for Psilocybin Is Being Fed Outside the Law in the Mushroom Underground," *Willamette Week*, 26 April 2023, www.wweek.com/news/2023/04/26/oregons-appetite-for-psilocybin-is-being-fed-outside-the-law-in-the-mushroom-underground/

PART 2

DEVELOPING AN ALTERNATIVE SOLUTION: PERSONAL LICENSES FOR PSYCHEDELICS

Rather than licensing providers, the state could instead license consumers. Some of the leading figures in the psychedelics movement have long advocated for personal licenses. Iconic writer Timothy Leary once proposed the idea to Congress.¹⁴ Rick Doblin, the founder of the Multidisciplinary Association of Psychedelic Sciences, which oversees ongoing FDA-supervised clinical trials of MDMA, has also advocated personal licenses.

Fortunately, medical marijuana licenses provide a framework that could apply to psychedelic licenses as well. In many instances, a licensed physician recommends the use of medical marijuana to a patient after reviewing the patient's medical history and potential contraindications to determine whether cannabis use should be recommended for medical purposes. Most states then allow individuals to purchase marijuana at approved

¹⁴ "Timothy Leary," Wikipedia, updated 4 Jan. 2024, en.wikipedia.org/wiki/Timothy_Leary

retailers after showing a state-issued ID card. Because the federal government prohibits prescriptions for Schedule I drugs, states have designed these systems to allow doctors to recommend medical marijuana to patients who they believe might benefit from its use.

Regardless of the qualifications, the overall aim with medical marijuana is to keep licensed medical providers apprised of their patients' health status and provide at least minimal oversight of patients' marijuana consumption. Given that psychedelics have the potential for misuse and are potentially contraindicated for some mental health illnesses, it is prudent to also require a certified mental health professional to oversee a psychedelics license. The state could even require one in-person session to verify eligibility.

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When Oregon allowed psychedelic experiences under the supervision of a professional, it was an attempt to reduce abuse and protect consumer rights. Specifically, poor service from a subpar professional facilitator could lead to consumers becoming violent, reckless, or have long-term mental distress due to the facilitator's negligence or incompetence.

Unfortunately, the ultra-cautious approach of only licensing professionals imposes serious trade-offs. Affordability and accessibility of service can be sacrificed in a highly restrictive system, for instance, due to high compliance costs.

2.1

RULES TO GOVERN THE PERSONAL PSYCHEDELICS MARKET

There are many potential rules for personal psychedelic licenses that could mitigate threats to public safety, health, and privacy.

First, the state could require regular meetings with a mental health professional to ensure that consumers are healthy and capable of resolving psychedelic therapy. Therapists and

peer counselors could also make recommendations for eligibility, just as medical professionals make recommendations for medical marijuana.

Second, it may be prudent to require consumers to take a short course, perhaps 10 hours long, that would teach basic information about how to safely consume psychedelics and seek out professional guides. Such information already exists for patients undergoing FDA trials so that consumers approach these therapies with an appropriate set of expectations and admonitions.

PART 3

EXAMINING KEY POLICY ISSUES RELATED TO PERSONAL PSYCHEDELICS LICENSES

There are several ways in which a personal psychedelics license can improve affordability.

First, personal licenses will likely make psychedelics more cost effective. As detailed above, in Oregon, professionals charge extraordinary fees in order to recover the capital costs for building out and maintaining a campus and training employees. After professionals pay thousands of dollars in government registration fees for facilitators, site managers, and manufacturers, those costs are passed along to consumers, who can end up paying over \$3,000 for a single psychedelic session.

Instead, just as with a personal cannabis license, consumers could self-administer medically recommended doses at home, saving on the significant expense of maintaining commercial real estate.

Second, there are many applications of psychedelics that are inappropriate for an on-campus experience. For instance, many consumers take psychedelics for pain management.

Early research suggests that small, sub-hallucinogenic doses of psilocybin are beneficial for those who suffer from migraines.¹⁵ These opportunistic low doses can be anywhere from one-third to one-tenth the size of a more traditional high-dose experience.

In-person facilitators must charge roughly the same price to oversee any size dose, as the cost of manufacturing a psilocybin product is immaterial in relation to the cost of offering a licensed therapy session. As a result, consumers who need only low doses end up paying far more than is justified.

3.1

PUBLIC SAFETY IMPACTS

A Reason Foundation preliminary investigation into the public health impacts of psychedelic legalization in Colorado revealed there have been few recorded incidents of violence or abuse related to psychedelics despite the personal possession of multiple psychedelic substances becoming entirely legal under state law.¹⁶

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...personal licenses would mitigate harms from the relatively few consumers who might pose a threat to the public safety because they are screened for contraindicated mental health disorders and given basic training with altered states.

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Most consumers appear to use psychedelics safely and responsibly. However, personal licenses would mitigate harms from the relatively few consumers who might pose a threat to the public safety because they are screened for contraindicated mental health disorders and given basic training with altered states. Thus, medical psychedelics could reduce harms while maintaining equity and access to these important compounds for individuals who may need them as mental health treatments.

¹⁵ Bold Wold, “Small Doses of Psychedelics for Cluster Headaches,” Petrie-Flom Center Staff, 18 April 2022, blog.petrieflom.law.harvard.edu/2022/04/18/small-doses-of-psychedelics-for-cluster-headaches/

¹⁶ Gregory Ferenstein, “Early data suggest no health or safety harms from Colorado psychedelics legalization,” Reason Foundation, 22 May 2023, www.reason.org/commentary/early-data-suggest-no-health-safety-harms-from-colorado-psychedelics-legalization/

PART 4

ADVANCING PERSONAL PSYCHEDELICS LICENSE POLICY

A forward-looking state could implement this innovative mental health policy under existing pathways. To create a consumer license, a bill would need to charge the state health authority with creating regulations with the following criteria:

1. A retail market framework is established allowing any U.S. citizen that holds a valid license to purchase up to a set amount of psychedelic products beginning no more than one year after bill passage.
2. A valid license will be given to any individual who has any condition or use case that has been published in a peer-reviewed journal for the psychedelic substance and is seeing a licensed mental health professional on at least an every-two-months basis.
3. The framework can include any number of psychedelics, so long as it excludes cannabis and includes psilocybin.
4. The expected capitated regulatory costs of professional services for a group-based psychedelic therapy session cannot exceed \$500. The expected costs will be determined by an independent financial model and be based on business profitability, taking into account all regulations, taxes, and fees. If the regulations are predicted to make costs exceed \$500, they must be modified.

5. A telehealth provision should be included that allows mental health professionals to meet with patients remotely and recommend psychedelic treatment if the professional believes it will be beneficial. Regulated inventory could be delivered on an intrastate basis by private couriers.
6. The framework protects privacy, meaning that it must allow a purchaser to remain anonymous and have their personally identifiable information outside of any database.
7. The framework offers protection for consumers. This protection includes legal action related to occupational licenses, parental rights, business contracts, and government benefits.
8. Localities can regulate the “time, place, and manner” of dispensary operations, but cannot outright ban them.

There are already several states that have considered convening legislative or advisory working groups to evaluate a prospective regulatory approach for psychedelic therapies. The policy for consumer licenses can simply be amended onto these bills.

PART 5

CONCLUSION

This brief outlines a public policy proposal for a personal license to purchase and consume psychedelic substances for medical purposes.

Similar to how states have handled medical marijuana, this approach aims to address the challenges posed by the current model adopted by Colorado and Oregon, which relies on licensed professionals overseeing psychedelic experiences in person at approved locations.

The primary issues with in-person oversight include prohibitive costs, limited accessibility, and regulatory complexities. Site licensing and federal tax penalties contribute to the financial strain of professional-facilitated sessions, while regulatory issues have led to continued underground market use, necessitating an alternative strategy.

A Reason Foundation investigation of Colorado's recent legalization of personal possession plant-based psychedelics revealed this policy change has exerted no noticeable impact on public health or safety.

This proposal, replete with accompanying model language, outlines criteria for a regulatory framework, allowing U.S. citizens with valid licenses to purchase psychedelic products. It emphasizes mental health professional oversight, regular consultations for license eligibility, and a capitated cost structure to ensure affordability. The proposal supports a telehealth provision for remote consultations, privacy protection, and comprehensive

consumer safeguards. It suggests integrating this approach into existing state legislative efforts through expert working groups.

A system of personal licenses for psychedelics presents a pragmatic, consumer-centric approach to address the limitations of the current professional-centric model. By leveraging successful frameworks, this proposal aims to make psychedelic therapy more accessible, affordable, and adaptable to individual needs, fostering a balanced regulatory environment that prioritizes public safety and consumer rights.

ABOUT THE AUTHOR

Greg Ferenstein is a Senior Fellow at the Reason Foundation publishing on psychedelics public policy. He is also the CEO of Frederick Research, a legal affairs firm. His policy work has appeared in numerous publications and outlets, including the *Washington Post*, Bloomberg, and The Brookings Institution.

APPENDIX: MENTAL HEALTH ACCESS ACT MODEL LANGUAGE

**An ACT concerning health; providing for the medical use of psychedelics; and amending existing law.

Short Title

This Act may be cited as the “Mental Health Access Act”.

Findings and Declarations

The Legislature finds and declares that the medical use of psychedelics in the state is necessary for the health and welfare of its people and should be regulated accordingly.

Definitions

For the purposes of this Act, unless the context otherwise requires:

- (a) “Certified Health Professional” means a person licensed to practice medicine, psychiatry, psychology, professional counseling, psychiatric pharmacy, osteopathy, or advanced practice registered nursing in the state.

- (b) “Department” means the Department of Health or a comparable agency.
- (c) “Qualifying Patient” means a person who has been diagnosed by a certified health professional as having a qualified condition.
- (d) “Qualified Condition” means depression, anxiety, substance use disorder, post-traumatic stress disorder, major depressive disorder, or any other medical condition, so long as the efficacy of medical use of psychedelics for such condition has been demonstrated in a study published in a peer-reviewed medical or scientific journal.
- (e) “Medical Use of Psychedelics” means the acquisition, possession, use, delivery, transfer, or administration of Psychedelics or related supplies and educational materials.
- (f) “Psychedelics” means psilocybin, psilocin, mescaline, ibogaine, lysergic acid, diethylamide, dimethyltryptamine, or 5-methoxy-N,N dimethyltryptamine.

Section: Certification of Non-Licensed Health Professionals

The Department shall establish a certification program for Certified Health Professionals wishing to recommend the medical use of Psychedelics. The program shall include education about the Medical Use of Psychedelics and its potential risks and benefits. Certified Health Professionals may recommend the Medical Use of Psychedelics to Qualifying Patients.

The Department shall create a pathway for professionals without an existing medical or mental health license to become certified to recommend the Medical Use of Psychedelics to Qualifying Patients. The pathway may not require any academic, trade, or university-based degree. The pathway may not require training that would exceed 50 cumulative hours of coursework.

The Department may require a remotely administered evaluation of competence for certification in lieu or in addition to a certification program.

Section: Patient Licensing

- (a) Upon receiving a recommendation from a Certified Health Professional for the Medical Use of Psychedelics, a qualifying patient shall be eligible to obtain a state-issued license permitting the acquisition, possession, and use of medical psychedelics in accordance with this Act.
- (b) The Department shall issue temporary licenses for qualifying patients under conditions determined by the Department.
- (c) The license shall serve as proof of the qualifying patient's entitlement to the protections provided by this Act regarding the Medical Use of Psychedelics.
- (d) The total time necessary for a patient to be recommended for a license, inclusive of all education and medical screenings or advisement required by the Department, may not exceed 10 hours.

Section: Establishment of Commercial Licensees

The Department shall establish a regulatory framework for the licensing and operation of retail establishments for the sale of medical Psychedelics. Such establishments shall comply with all state and local laws and regulations, including zoning and business licensing requirements.

The Department shall establish a regulatory framework for the licensing and operation of cultivation or manufacturing establishments that produce medical Psychedelics products. The Department shall implement an electronic inventory monitoring system for Psychedelics products and require its use by all entities licensed to cultivate, manufacture, test, transfer, distribute, or dispense Psychedelics products. The Department shall not attempt to impose price controls nor production quotas on Psychedelics products nor limit the number of licenses available to operate a commercial Psychedelics establishment of any type.

Section: Regular Appointments with Certified Health Professionals

- (a) To maintain the validity of a patient license for the Medical Use of Psychedelics, a Qualifying Patient may be required by state rules to attend regular appointments with a Certified Health Professional.
- (b) The required cadence of these appointments shall not exceed once per month. The purpose of these appointments is to monitor the patient's health status, and the efficacy of the Psychedelics treatment.
- (c) The Department shall establish guidelines for these appointments, including the qualifications of the attending mental health professionals and the documentation required to verify the appointments.

Section: Limitations

- (a) No Certified Health Professional may recommend the Medical Use of Psychedelics to a patient under the age of 18 unless the patient's legal guardian consents in writing on a form prescribed by the Department.
- (b) No Certified Health Professional may recommend the Medical Use of Psychedelics to a patient if the professional knows or should know that the patient is pregnant, unless the potential benefits outweigh the potential risks to the fetus.
- (c) No Certified Health Professional may recommend the Medical Use of Psychedelics to a patient if the professional has a financial interest in any entity licensed to cultivate, manufacture, test, transfer, distribute, or dispense Psychedelics products.

Section: Medical Psychedelics Program

The Department shall establish a medical Psychedelics program. The program shall provide for the registration of Qualifying Patients and their designated caregivers, the licensure of entities that will cultivate, manufacture, test, transfer, distribute, or dispense Psychedelics products, and the tracking of medical Psychedelics from cultivation or manufacture to retail sale.

Section: Possession and Use

- (a) A Qualifying Patient may possess and use Psychedelics as recommended by a Certified Health Professional.
- (b) A designated caregiver may assist a Qualifying Patient with the Medical Use of Psychedelics.

Section: Protection from Criminal Prosecution

No person shall be subject to arrest, prosecution, or penalty in any manner for the Medical Use of Psychedelics as allowed by this Act.

Section: Protection of Parental Rights

- (a) No person shall be denied custody of, or visitation or parenting time with, a minor for acting in accordance with this Act and the regulations promulgated thereunder.
- (b) No person shall be subject to prosecution or penalty in any manner, or denied any right or privilege, including but not limited to civil penalty or disciplinary action by a court or the Department of Child Safety, solely for conduct permitted under this Act.
- (c) The Medical Use of Psychedelics in compliance with this Act shall not be considered a factor in child welfare investigations, proceedings, or determinations, and shall not form the sole or primary basis for detaining, removing a child from, or continuing to remove a child from the home or custody of a person authorized for the Medical Use of Psychedelics under this Act.

Section: Protection of Vocational License Holders

- (a) No person shall be subject to arrest, prosecution, or penalty in any manner, or denied any right or privilege, including but not limited to civil penalty or disciplinary action by a business, occupational or professional licensing board or bureau, solely for conduct permitted under this Act.
- (b) The Medical Use of Psychedelics in compliance with this Act shall not be considered a factor in vocational licensing investigations, proceedings, or determinations, and shall not form the sole or primary basis for disciplinary action, suspension, revocation, or denial of a vocational license or certification held or sought by a person authorized for the Medical Use of Psychedelics under this Act.

Section: Independent Economic Audit

The [Agency name] shall conduct an independent economic audit to assess the impact of regulations on the price of a gram of Psychedelics. If the audit determines that regulations would increase the average commercial price of one gram of any Psychedelic by \$50 or more, then the Health Authority must submit renewed regulations until an independent audit finds that the estimated costs of regulatory compliance are below this threshold.

Section: Protection of Contractual Rights

- (a) No person shall be subject to any adverse action, penalty, or denied any right or privilege in a contractual dispute, solely for conduct permitted under this Act.
- (b) The Medical Use of Psychedelics in compliance with this Act shall not be considered a factor or grounds for dispute in the establishment, execution, or enforcement of any contract, including but not limited to contracts involving employment, housing, insurance, or child custody.
- (c) No contract shall be unenforceable on the basis that the Medical Use of Psychedelics is prohibited by federal law. Any clause in a contract that purports to deny any right or privilege under this Act, or to waive any right to sue or any remedy available under this Act, is void and unenforceable.
- (d) A person's Medical Use of Psychedelics in compliance with this Act shall not constitute a breach of contract or a default condition that triggers penalties, termination, or other adverse action under a contract.

Section: Penalties

Violation of this Act or any rules adopted under this Act may result in civil or criminal penalties as determined by the Department.

Section.: Effective Date

This Act shall take effect on [DATE].

Section: Severability

If any provision of this Act or its application to any person or circumstance is held invalid, the remainder shall continue in force.

