



Chapters 792 and 793 of 2024 establish the Maryland Task Force on Responsible Use of Natural Psychedelic Substances, staffed by the Maryland Cannabis Administration. The Task Force is charged with studying existing laws, policies, practices, and data relating to the use of psilocybin/psilocin (from mushrooms), dimethyltryptamine (from plants), and mescaline (from cacti); and making legislative recommendations which may involve access to regulated treatment, public education, safe production, and transition from criminalization

Executive Summary

This report **supersedes the July Interim report**, providing the recommendation to the Maryland legislature required by the Task Force's statutory responsibility. In addition, this document contains updated reference materials, a comprehensive analysis of the methodology used to arrive at the recommendations, clarifications, and updates from the July report.

The Maryland Task Force on Responsible Use of Natural Psychedelic Substances was **established by Chapters 792 & 793 of the Acts of 2024** to evaluate and recommend policy frameworks for legal access to natural psychedelic substances. Since convening in late 2024, the Task Force has held over 100 meetings, reflecting more than 700 hours volunteer service by Task Force members.

The Task Force aligned its work across 5 committees: Substances, Models of Access, Regulations and Governance, Public Education and Legislative Support, and Economic Impact. Committees conducted **extensive stakeholder** consultation, scientific literature review, public listening sessions, and a rigorous consensus-based process to form recommendations. Analysis drew on lessons from other states- DC, Oregon, Colorado, New Mexico, and others-whose pioneering psychedelic access policies offered valuable insights into both successful innovations and early challenges. To analyze the merits and risks of various access frameworks, the Task Force employed a modified Delphi methodology to evaluate 90 carefully crafted policy propositions.

Section I provides a broad overview of the relevant, ethnobotanical, biochemical,

pharmacological, and medical research pertaining to the natural psychedelic substances under this Task Force's purview. The primary focus of the research review was to evaluate the available safety data pertaining to these substances. Overall, psilocybin/psilocin, mescaline, and dimethyltryptamine (DMT) are generally well-tolerated, with **favorable safety profiles**, though they can present **unique psychological risks for certain populations**.

Section II examines the substances in context, finding that among natural psychedelic substances, use practices differ greatly from common comparators (e.g. cannabis, current antidepressant medications), quality of research evidence varies across a range of indications from treatment-resistant depression to chronic pain, associations with crime and poisonings appear minimal, and public perceptions reflect growing interest among common concerns.

Section III investigates opportunities to maximize public benefit and mitigate public risks, noting that natural psychedelic substances may be useful in the treatment of mental health, substance use, and/or chronic pain indications. Public health strategies consistent with Maryland's legacy and leadership in psychedelic science may be employed toward addressing existing unregulated markets.

<u>Section IV</u> provides <u>side-by-side</u> comparison of <u>existing psychedelic policy</u>, identifying that regulation may be grouped among seven distinct access models, each with unique considerations including tax revenue potential, administration costs, supply chain management, integration with healthcare, etc.

Recommendations to the General Assembly:

Finally, <u>Section V</u> presents the "Ensemble Model:" a multi-pathway framework for safe, broad, and equitable access to natural psychedelic substances, with an initial focus on psilocybin. This involves phased implementation of complementary elements from medical/therapeutic use and supervised adult use, to deprioritization, and to commercial sales. This model broadly and inclusively serves the needs of Maryland's diverse population while enabling unified safety standards, accountability, and viable economic pathways for small businesses.

• Phase 1, Regulatory Infrastructure

Establishes advisory board, robust safety protocols, comprehensive data monitoring, clear scope of practice guidelines, professional licensing protections, public education campaigns, facilitator training, testing laboratory licensing, quality control systems, law enforcement training, and immediate restorative justice measures.

• Phase 2, Launch with Medical Oversight

Deprioritization measures, medical screening requirements, medical/therapeutic treatment, supervised adult use facilities, personal cultivation for permitted individuals, comparative research programs, regular policy review processes.

• Phase 3, Full Operation and Expansion

Pending demonstrated safety outcomes and provider confidence, activates commercial sales for permitted individuals, evaluates readiness for expanding to additional natural psychedelic substances.

Safety and oversight measures ensure **responsible and gradual expansion of access** while maintaining capacity to identify and respond to emerging issues swiftly. This approach plans for long-term learning and improvement: **starting small**, **utilizing built-in evaluation and accountability mechanisms from the outset**, **gathering real-world data**, and **committing to an iterative approach to policymaking**.

The Task Force does not support delaying state action pending future federal FDA approval.

<u>The Appendices</u> include a companion report independently prepared by economists at *Johns Hopkins University* that **assesses the potential economic and social impacts of different regulatory frameworks**, among other informative resources. Though prepared independently, the report supports the positive economic impact of the ensemble model.

Acknowledgements

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Preface: A Primer on Psychedelics

Providing essential context for policymakers and the public

What are "Natural Psychedelic Substances"?

Psychedelic substances are a class of psychoactive substances that induce non-ordinary states of consciousness, characterized by profound alterations in perception, mood, and cognitive processes. While some psychedelic substances are synthesized exclusively in laboratories (LSD, MDMA, Ketamine, etc.), others naturally occur in plants, fungi, and animals.

	Psychedelic Substances							
Natural			Synthetic					
Psilocybin / Psilocin	, , , , , , , , , , , , , , , , , , , ,				LSD	MDMA	Ketamine	And others
Currently studied by this Task Force		Study deferred, may be added later		Out of scope, would require change in Legislative mandate to study				

Figure 1. Psychedelic Substances Within and Beyond the Scope of this Task Force Report

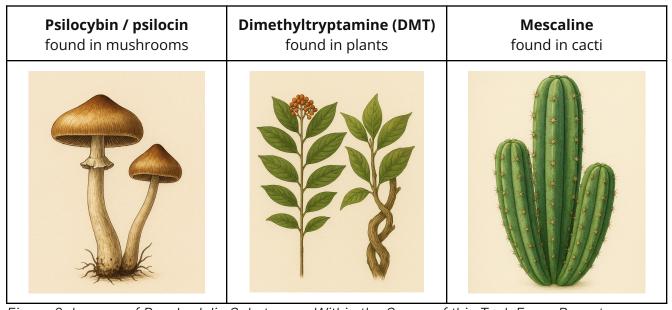


Figure 2. Images of Psychedelic Substances Within the Scope of this Task Force Report

The substances studied by this Task Force for this report are **physiologically safe** with low toxicity; low abuse potential; and **no known fatal dose** in humans. Use by individuals with certain health conditions or medications may be contraindicated. These substances present **unique psychological risks**, and **adverse psychiatric events can occur**, and may be largely preventable.

In the brain, "classic psychedelics" activate (agonize) the serotonin 5-HT2A receptor. Though the exact mechanism is unclear, it is hypothesized that this causes increased connectivity between brain regions, increased "entropy" or disorder in brain signaling, and thereby promotes neuroplasticity by stimulating new communication pathways between neurons (synaptogenesis). **Effects vary significantly** depending on the substance, route of administration and dosage:

- At lower "microdoses", users report **improved mood, cognition, and creativity**.
- At higher doses, users report a wide variety of effects including **altered perception of time and space**, mystical,transcendent, and ecstatic experiences, such as feeling as if they are "one with the universe," or reliving long-forgotten memories.
- Experiences also vary based on modifiable contextual factors "set and setting."

In many traditional and clinical settings, psychedelic use is framed not merely as a biochemical event, but as a socially and spiritually significant process. Whether in Indigenous ceremonies or structured therapeutic trials, practices often involve intentional preparation, facilitated/guided sessions, and post-experience integration—highlighting the essential role of context in shaping outcomes.

Historical and Scientific Overview

Psychedelic plants **have been used for millennia** by global cultures in traditional healing and spiritual ceremony. Psychedelic research was popular in the mid 20th century until largely halted in the 1960s due to prohibition. There has been a significant resurgence of scientific research in recent decades, exploring therapeutic potential:

- The Food and Drug Administration designated psilocybin a "breakthrough therapy."
- The **Department of Defense is funding psychedelic research** for military and veterans.
- Maryland passed SB709 (2022) funding research into psilocybin for PTSD.

Legal Overview

The natural psychedelic substances studied by this Task Force are classified Schedule I substances under the Controlled Substances Act (CSA): they are federally illegal and considered to have no accepted medical use and a high potential for abuse. **Despite federal prohibition, multiple states and cities have enacted reforms** to reduce penalties or establish regulatory frameworks for use. Regulatory models range **beyond traditional pharmaceutical models,** from licensed clinics to personal cultivation to community-based/spiritual-use models.

At this time, Marylanders interested in natural psychedelic access have few options:

- IRB-approved clinical trials
- Religious exemptions through the Religious Freedom Restoration Act (RFRA)
- Travel domestically to regulated state-programs (e.g. Oregon, Colorado)
- Unregulated or "gray markets" (e.g. D.C.)
- Travel abroad (e.g. Jamaica, the Netherlands, Peru)

The current presidential administration has taken an assertive stance on advancing psychedelic research. In July 2025, President Trump signed the Halt All Lethal Trafficking (HALT) of Fentanyl Act, which includes provisions that expedite research on psychedelics and other Schedule I substances. That same month, Health Secretary Robert F. Kennedy Jr. stated, "This line of therapeutics has tremendous advantage if given in a clinical setting, and we are working very hard to make sure that happens within 12 months."

As federal policy evolves, states face a strategic choice: wait for further federal action and adopt future national frameworks, or move proactively to establish state-specific policies. There are risks both to forging ahead as well as to delaying action. While findings from clinical research are preliminary and state-led programs remain in early stages, **Maryland has an opportunity to tailor its approach to the needs of its residents**—potentially leading national models rather than inheriting and reacting to them.

Psychedelics Compared to Other Substances

While lessons can be learned from rollout and access to other substances, fundamental differences between psychedelics, cannabis, and alcohol, require distinct regulatory approaches. For example, psilocybin provides a low addiction risk and a long-duration (approximately 6 hours) experience, often consumed within facilitated settings 1-6 times per year. This contrasts sharply with cannabis and alcohol, which are typically consumed near-daily for pleasure or relaxation. The biological nature of psilocybin-containing fungi also present distinct cultivation considerations from plants.

Table 1. Comparison of High-Level Characteristics of Alcohol, Cannabis and Psilocybin

	Cannabis	Psilocybin
Commonly Found In Plant, Extracts, Oils, Edibles		"Magic Mushrooms" Psilocybe spp.
Route of Administration	Smoking/Vaping, Drinking, Eating	Oral (Eating)
Typical Use Frequency	Up to daily	Often 1-6 times per yr
Onset Time	15 min (smoked) 30min-2hr (edibles)	20-30 minutes
Effect Duration (1 dose)	1-3 hour (smoked) 2-12 hours (edibles)	4-6 hours
Single Dose	Dosing of edibles ranges from 5mg- to 25m	<5mg (pure)/<500mg (dried mushroom) = microdose 5-10 mg/500mg -1gm = low dose >25mg/2.5 gm = treatment dose
Lethal Dose	In humans, no recorded instances of fatal overdoses from acute THC use.	In humans, no recorded instances of fatal overdose from psilocybin use
Positive Effects	Reduced anxiety, increased sociality, euphoria, increased creativity, pain reduction, anti-nausea	Increased sense of connectedness to self, others, and world, increased creativity, sensory alterations
Negative Effects	Social isolation, impaired cognition/decision making	Social isolation, disorientation, nausea, impaired cognition/decision making
Tolerance	After sustained Long term use	Rapid
Withdrawal symptoms	Yes	No

Scope and Activities of the Task Force

The Purpose of the Task Force and of this Report

The Maryland General Assembly created the Task Force on Responsible Use of Natural Psychedelic Substances through HB548/SB1009 (Chapters 792 and 793 of the Acts of 2024) in response to growing scientific evidence, public interest, and evolving policy across the country regarding psychedelic-assisted care. Recognizing both the potential public benefits and risks, the legislature charged this Task Force with a comprehensive mandate: to study, deliberate, and make recommendations for a safe, equitable, and evidence-informed statewide approach to natural psychedelic substances such as psilocybin, dimethyltryptamine (DMT), and mescaline excluding peyote.

This work is timely. Around the country, jurisdictions are moving forward with psychedelic policies while in parallel developing frameworks for safety, training, public education, and regulatory oversight. Despite this uncertainty, early results are encouraging, and **Maryland is well positioned to be among the first states to expand access to psychedelic substances.** Our ultimate goal is to recommend whether to create a Maryland Natural Psychedelic Substance Access Program, and if yes, how to do so while ensuring it builds upon lessons in other jurisdictions, reflects our values, and meets the diverse needs of our residents.

This report is a strategic tool to engage public agencies, professional boards, researchers, clinicians, advocates, and community members in constructive dialogue. By surfacing key questions and outlining initial policy directions under consideration, we aim to enable the input necessary to develop thoughtful, feasible, and impactful recommendations for consideration in the 2026 legislative session.

The work of the task force has been Maryland's chance to learn from the experiences of other states, to design systems that maximize benefits and avoid preventable harms, and to ensure that any future access to psychedelic substances is grounded in principles of **safety, equity, and accountability.**

How We Approached Our Work

From its inception, the Maryland Natural Psychedelic Substances Task Force has been guided by a clear intent: to provide a well-reasoned, evidence-informed foundation for future policy.

Since our first meeting in November 2024, we have structured our efforts through five committees:

- Substances
- Models of Access
- Public Education and Legislative Support
- Regulations and Governance
- Economic Impact

With administrative support from the Maryland Cannabis Administration, but without dedicated funding, our approach has emphasized collaboration, stakeholder engagement, and strategic use of limited resources. We conducted **public listening sessions** throughout the state with planned sessions in every county.. These sessions are designed to gather community input, elevate diverse voices, and better understand concerns and priorities from across the state.

We engaged subject matter experts from Johns Hopkins University, national advocacy groups, and from psychedelic access programs in other states. We identified **seven access models that** we deemed most promising for Maryland lawmakers to consider. We reviewed implementation lessons from Oregon, Colorado, and New Mexico, and participated in a collaborative literature review process. This review informed a comparative matrix examining each major psychedelic substance across the range of access models we identified.

Building on this foundation, we drafted **85 policy propositions** that identify the key decisions lawmakers may face—ranging from eligibility and safety protocols to taxation, equity provisions, deference to indigenous communities, and religious accommodations. An additional 5 policy propositions were added later in the process to integrate additional stakeholder input. To evaluate these propositions and move toward formal recommendations, we launched a **modified Delphi process**, a structured method for developing consensus among experts.

Recognizing that economic feasibility will be essential to any legislative proposal, we partnered with economists at the Johns Hopkins University Carey Business School. Their independent economic analysis models the costs and benefits of various access models under consideration, with particular attention to scalability, public health outcomes, and fiscal impact.

Below is a table that illustrates the activities of the Task Force to date, as related to the assigned duties in its authorizing legislation (Chapters 792&793 of 2024):

Table 2. Alignment Between Task Force Activities and Authorizing Legislation

Assigned Duties:	Task Force Actions:
"The Task Force shallstudyexisting laws, policiesrelating to the use of natural psychedelic substances"	Access Models Comparison Chart, Comparative Data Matrix,
"The Task Force shallstudypractices relating to the use of natural psychedelic substances"	Substances Template, Psilocybin/Psilocin Monograph, DMT Monograph, Mescaline Monograph, Public Listening Sessions, Public Comment Submissions, Stakeholder Presentations, Expert Consultations
"The Task Force shallstudythe best available science and data on public benefits of responsible access to and use of natural psychedelic substances;opportunities to maximize public benefits of responsible access to and use of natural psychedelic substances;the best available data on potential risks of access to and use of natural psychedelic substances; opportunities to mitigate potential risks of access to and use of natural psychedelic substancesbarriers health care practitioners and facilitators may encounter relating to natural psychedelic substances, including barriers relating to insurance, restrictions by licensing and credentialing entities, zoning, advertising, and financial services"	Substances Template, Psilocybin/Psilocin Monograph, DMT Monograph, Mescaline Monograph, Equity Definition, Impact Issues Catalog, Comparative Data Matrix, Initial Economic Estimations
"The Task Force shallmake recommendations regarding any changes to State law, policy, and practices needed to create a Maryland Natural Psychedelic Substance Access Program that enables broad, equitable, and affordable access to psychedelic substances, including:permitting requirements, including requirements regarding education and safety;access to treatment and regulated support; andproduction of natural psychedelic substances"	Comparative Data Matrix, Delphi Deliberation
"The Task Force shallmake recommendations to transition from criminalizing conduct involving natural psychedelic substances, including:punishing with civil penalties nonviolent infractions involving the planting, cultivating, purchasing, transporting, distributing, or possessing of or other engagement with natural psychedelic substances	Comparative Data Matrix, Delphi Deliberation

expunging the records of Marylanders with convictions for nonviolent criminal offenses relating to natural psychedelic substances; andreleasing Marylanders incarcerated for nonviolent criminal offenses relating to natural psychedelic substances."	
"The Task Force may consult with experts and stakeholders in conducting its duties."	Task Force Website, Public Listening Sessions, Public Comment Submissions, Stakeholder Presentations, Expert Consultations, State Agency Outreach, National and Regional Outreach, Communications and Media Outreach
"On or before July 31, 2025, the Task Force shall submit a report of its findings and recommendations to the Governor and, in accordance with § 2–1257 of the State Government Article, the General Assembly."	Interim Report submitted to Department of Legislative Services July 31, 2025

Why the Task Force is Uniquely Positioned to Deliver this Report

As a **nonpartisan**, **all-volunteer body supported by the Maryland Cannabis Administration**, we are not beholden to commercial interests or ideological agendas. We are grounded in public service and guided by a shared commitment to deliver clear, actionable recommendations that can inform responsible legislation in 2026 and beyond. Our authorizing legislation passed **unanimously in both chambers** of the Maryland General Assembly and was signed into law by Governor Wes Moore in 2024. This bipartisan consensus affirms a shared recognition: that natural psychedelic substances deserve thoughtful, proactive consideration rooted in science, public health, and equity.

Our composition reflects those same intentions. Each member of the Task Force was appointed by the Governor or other state official, as outlined in statute. All members underwent ethics review to identify potential conflicts of interest. Collectively, we bring interdisciplinary expertise, representing multiple interests in this new and emerging field: medicine, pharmacology, behavioral health, spirituality, law enforcement, drug policy, chronic pain, addiction treatment, and public health. We leverage Maryland's leadership in groundbreaking psychedelic research, including a representative from the University System of Maryland, a representative formerly from Sheppard Pratt and Johns Hopkins University's Center for Psychedelic and Consciousness

Research, and a leader of the private clinical research facility Sunstone Therapies. Per our mandate from the General Assembly, the Task Force reflects the socioeconomic, ethnic, and geographic diversity of the state. Our team also includes individuals with lived experience as patients and representation from tribal, religious, and rural communities.

Throughout our process, we have actively consulted with stakeholders and experts from across the country, including policymakers and authors of psychedelic legislation in other states. These conversations have helped us understand both the promises and pitfalls of early policy implementation and reinforced the value of Maryland's measured, inclusive process.

What This Report Adds

This report builds on the foundation laid by earlier state efforts in Oregon, Colorado, Minnesota, Nevada, Connecticut, Vermont, Washington state, and the District of Columbia. We drew upon published reports and the insights of regulators, researchers, and advocates who have generously shared their lessons learned. In addition to reviewing and comparing policy frameworks across jurisdictions, we are evaluating multiple access models simultaneously. To rigorously and efficiently formulate our recommendations, employed the modified Delphi method—a structured and transparent alternative to standard surveys or deliberations that requires a supermajority to reach consensus and results in graded and easily interpreted recommendations. We collaborated with an independent team of economists at Johns Hopkins University, who analyzed the economic impact of our recommendations and described how including both traditional and novel metrics may better reflect the social implications of reform. Taking an important lesson from early experiences in Oregon and Colorado, we will assist lawmakers and regulators to plan for long-term learning and improvement: starting small with phased access, building in evaluation and accountability mechanisms from the outset, gathering real-world data, and committing to an iterative approach to policymaking.

How the Task Force was Structured

Since its first meeting in November 2024, the Maryland Task Force on Responsible Use of Natural Psychedelic Substances has made substantial progress toward fulfilling its legislative mandate. As of the publication of this interim report, **the full Task Force has convened 24 times and its five committees have met more than 100 times in total**. These meetings represent **more than 500 hours of volunteer time** contributed by Task Force members, not including the hundreds of additional hours donated by external advisors, public participants, and national experts who informed the work of the Task Force.

The Maryland Cannabis Administration (MCA) has played an essential role in the success of the Task Force, providing administrative staffing, scheduling, communications, and documentation support for all full Task Force meetings and most committee meetings. The dedication of MCA staff has made it possible to coordinate a large and complex volunteer-driven policy development process.

To facilitate the efficient division of labor and to focus expertise where it was most needed, four committees were established early in the process by the Chair of the Task Force, based on input gathered from members during initial one-on-one consultations and early open meetings. These initial committees—Substances, Models of Access, Public Education and Legislature

Support, and Regulations and Governance—allowed the Task Force to structure its inquiry around both topic areas defined in statute and critical issues identified through consultation. In April 2025, a fifth committee on Economic Impact was created to address specific questions around fiscal risk, economic opportunity, and long-term social costs and benefits.

Together, these committees have overseen the development of dozens of key outputs, including: technical monographs, issue matrices, stakeholder engagement processes, economic modeling frameworks, and an 85-item set of policy propositions which were evaluated through a modified Delphi consensus process. Each committee has also drawn on public testimony, stakeholder presentations, academic literature, regulatory documents from other states, and the lived experience of Task Force members themselves.

The following section provides a detailed summary of each committee's scope, leadership, membership, and accomplishments to date, including complete and ongoing deliverables, key activities, and next steps. A full list of Task Force members and our professional affiliations appears in Appendix 1.

Table 3. Summary of Task Force Committees

Committee	Chair	Scope	Members	Key Deliverables Completed	Ongoing Work
Executive	Dr. Andy Coop	Coordination of Committee Deliverables	Bregman, Oglesby- Adepoju, Hamilton, Lewis, Nichols, Selleh	Agenda planning, oversight of Delphi process	Legislative Briefings
Substances	Ben Bregman, MD	Pharmacological study, literature review	Macri, Agrawal, Johnson, Nichols	Substances Template, Psilocybin/Psilocin Monograph, DMT Monograph, Mescaline Monograph, Data Matrix, Delphi Deliberation	
Models of Access	Candace Oglesby- Adepoju, MA, LCPC	Policy frameworks in other jurisdictions	Bosak, White, Selleh, Norte	Equity Definition, Access Models Comparison Chart, Data Matrix, Indigenous/Religious Use Consultation, Delphi Deliberation	
Public Education & Legislature Support	Timothy Hamilton	Stakeholder engagement, public education	Feldman, Martinez, Barrett, Coop	Task Force Website, Public Listening Sessions, Public Comment Submissions, Data Matrix, Delphi Deliberation	Legislative Briefings, Public Engagement
Regulations & Governance	Shanetha Lewis, MS	Regulatory structures and impact issues	Augustine, Shah, Sterling	Impact Issues Catalog, Data Matrix, Delphi Deliberation, Consultation with Regulatory Agencies	Legislative Briefings, Consultation with Regulatory Agencies
Economic Impact	Joey Nichols, MD, MPH	Economic risks and benefits	White	Initial Economic Estimations, Delphi Survey Mechanisms, Data Matrix, Delphi Deliberation	Consultation with Independent Hopkins Economists

Committee Highlights and Activities

Executive Committee: Led by Dr. Andy Coop, the Executive Committee ensures alignment and coordination across all committees. It has convened regularly to oversee progress, set agendas, and facilitate integration of committee outputs into Task Force-wide activities.

Substances Committee: Chaired by Dr. Benjamin Bregman, this committee has led the Task Force review of the pharmacology and therapeutic potential of psilocybin, mescaline, and DMT. Completed deliverables include detailed psilocybin/psilocin, mescaline, and DMT monographs and a general substance evaluation template. *Models of Access Committee:* Chaired by Candace Oglesby-Adepoju, this committee developed a structured framework for comparing different legal models of psychedelic access, including their equity impacts. It produced a widely referenced access model comparison chart and equity definition, and circulated considerations regarding indigenous/religious use.

Public Education and Legislature Support Committee: Chaired by Timothy Hamilton, this committee developed and maintained the Task Force's public-facing website, organized public listening sessions, and designed feedback mechanisms to collect public comment. These efforts ensured transparency and inclusivity across the process.

Regulations and Governance Committee: Chaired by Shanetha Lewis, this committee has focused on the regulatory mechanisms and governance frameworks needed to ensure public safety, transparency, and program integrity. It developed the initial impact issues framework and continues to collaborate on ongoing listening sessions and agency consultation.

Economic Impact Committee: Chaired by Dr. Joey Nichols, this committee works with economists from Johns Hopkins University Carey Business School assisting them with independently assessing the broader societal impacts of various access models. Deliverables included a high-level analysis of the access models and design and implementation of the Delphi survey.

Table 4. Meeting Schedule and Frequency of Task Force Committees

	Meeting Recurrence	# of Meetings to Date	
Full Task Force	Bi-Weekly	24	
Executive Committee	Weekly	37	
Substances Committee	Bi-Weekly	15	
Models of Access Committee	Bi-Weekly	18	
Public Education & Legislature Support Committee	Bi-Weekly	18	
Regulations & Governance Committee	Bi-Weekly	18	
Economic Impact Committee	As Needed	10	

Open Meetings

Task Force meetings that achieve a quorum are subject to the Maryland Open Meetings Act and are live-streamed via GoToWebinar as hosted by the MCA. Written Agenda and Audio/Video Minutes (recordings) are available on the MCA's Other Public Meetings webpage here: https://cannabis.maryland.gov/pages/other-public-meetings.aspx. In a logistical oversight, Task Force neglected to call roll at the beginning of these Open Meetings, and therefore the participation viewed on live-stream broadcast and recording of meetings does not reflect those members who were present with their cameras turned off.

Weekly Executive Committee Meetings and Bi-Weekly Committee Meetings are not subject to the Maryland Open Meetings Act and were not live streamed, although extensive records are kept internally to ensure transparency and efficient use of Task Force resources.

How We Engaged with Stakeholders

As authorized by the legislation establishing this Task Force, members were empowered to consult with experts and stakeholders to inform their deliberations. The Task Force has taken this responsibility seriously, investing significant time and effort into inclusive public engagement, outreach to industry experts, and consultations with Maryland constituents, organizations, and national leaders in psychedelic policy.

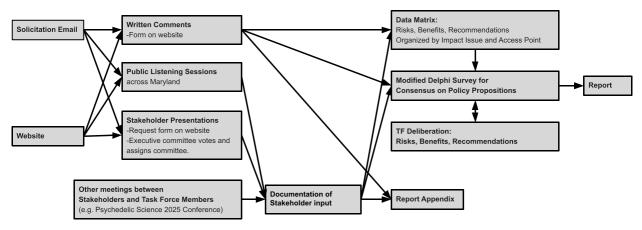


Figure 3. Workflow of Stakeholder Input Received by the Maryland Task Force on Responsible Use of Natural Psychedelic Substances

Public Listening Sessions

The Public Education and Legislature Support Committee organized ten public listening sessions across various regions of the state. These sessions were designed to gather input from Maryland residents who may be directly impacted by psychedelic policy reform. Each session included a brief educational overview followed by 1–2 hours of open testimony. Sessions were advertised through Task Force websites and media channels and allowed for anonymous participation to promote openness. Attendance ranged from 3 to 12 participants per session, and all input received was recorded and made available to Task Force members for review and analysis.

Following the six public listening sessions held in spring and summer, the Committee expanded outreach with three sessions in Hagerstown, North East, and Centreville, ensuring representation from Western Maryland, the northern counties, and the Eastern Shore. In addition, one online session was offered to allow participation from all Maryland residents as well as stakeholders with an interest in prospective legislation regarding access to natural psychedelics.

Consistent with earlier efforts, notices were distributed through press releases to local and regional media corresponding to each host community. Digital outreach also included targeted posts on relevant Reddit communities and Facebook pages and groups, broadening both awareness and participation. Alongside in-person testimony, comments submitted on these online platforms were collected and documented, ensuring that the full range of feedback was available to Task Force members for consideration.

Together, these ten sessions reflect a geographically balanced and inclusive approach to public engagement. They have provided the Task Force with an expanded record of community perspectives, concerns, and suggestions to help inform both public education strategies and legislative support efforts moving forward.

Table 5. Public Listening Sessions, March through October 2025

Date	Location	Time	City	County
March 27, 2025	Michael E. Busch Annapolis Library	5–6 PM	Annapolis	Anne Arundel
May 1, 2025	Rockville Memorial Library	6:30-7:30 PM	Rockville	Montgomery
May 12, 2025	Howard County Library Central Branch	6-7 PM	Columbia	Howard
May 19, 2025	Waldorf West Branch	6-7:30 PM	Waldorf	Charles
June 15, 2025	Arbutus Branch Library	6:30-7:30 PM	Baltimore	Baltimore
July 15, 2025	Severna Park Library	6:30-7:30 PM	Severna Park	Anne Arundel
September 18, 2025	Alice Virginia & David W. Fletcher Branch Library	6:30-7:30 PM	Hagerstown	Washington
September 22, 2025	Centreville Branch Library	6:30-7:30 PM	Centreville	Queen Anne's
September 25, 2025	North East VFW (VFW Post 6027)	6-8 PM	North East	Cecil
October 14	Virtual Meeting	7:30-8:30 PM	Statewide	Statewide



Figure 4. In-person Public Listening Sessions as of September 2025

Written Public Comments

To increase accessibility, a Google Form was embedded on the Task Force website, allowing members of the public to submit structured feedback on issues such as perceived benefits, risks, policy suggestions, and personal or professional affiliations. This input has been analyzed as part of the ongoing policy development process.

Stakeholder Presentations

The Task Force has welcomed presentations from a wide range of stakeholders and subject matter experts, spanning public health, law enforcement, harm reduction, religious freedom, policy innovation, and social equity. These in-depth presentations have provided diverse, nuanced, and often thought-provoking insights, offering valuable context and expertise to inform the Task Force's ongoing discussions and recommendations. Collectively, they have deepened the Task Force's understanding of both the potential benefits and risks associated with natural psychedelic substances, while highlighting key considerations for responsible policy development.

Presenters included:

- Maj. Neill Franklin (Ret.), Law Enforcement Action Partnership on police wellness and psychedelic therapy
- Erica Siegal, LCSW, NEST Harm Reduction & SHINE Collective on public health risks and harms
- Allison Hoots, Esq. & Kevin Lenaburg on New York's psilocybin permit bill
- Bob Wold & Kevin Lenaburg, Clusterbusters on psychedelic policy gaps and psychedelics for chronic pain
- Dr. Megan Meyer, University of Maryland on the role of social workers
- Kai River Blevins, GWU on Washington, DC's gray market
- Jesse Gould, Heroic Hearts Project on Veterans, governance, and equity
- Matt Zemon, MSc on religious access and public safety
- Mario Macis, PhD, Johns Hopkins University on economic modeling approaches
- Kal Shah, Mission Maryland, LLC on business & minority stakeholders
- Taylor Martin, Maryland's Marvelous Mushrooms, Maryland's Cannabis Reserve on home grow, cultivation, and testing
- Mark Huslage, Sahffi Lynne, Josh Halbedel, Baltimore Psychedelic Society on psychedelic use in Maryland
- Joanna Zeiger, Canna Research Foundation on psychedelic use for pain
- Nancy Alexander, Masters in Theological Studies on gifting, sharing, CPTSD, practitioner and patient perspectives
- Brad Stoddard, PhD, Luz Sagrada on religious use
- Deborah Servetnick, ServeMedicine on End of Life, Oregon model, practitioner and patient perspectives
- Trish Hall, Compliance Officer, Grow West on science, toxicology, safety
- Daniel Peterson, Association of Entheogenic Practitioners Inc. on religious use
- Heather Kuiper, Chris Alley, Missi Wooldridge, The Center for Psychedelic Public Health on public health perspectives
- Kristel Carrington, MD; Adam Foster, JD; David L. Nathan, MD, Doctors for Drug Policy Reform (D4DPR) on important factors of drug policy

Expert Consultations and Written Feedback

The Task Force has received one-on-one consultations and written comments from additional thought leaders including Dr. Charissa Fotinos (Washington State), Eileen Brewer (Psychedelics and Pain Association), Larry Norris, Ph.D. (Decriminalize Nature), Taylor West (Healing Advocacy Fund), Sherman Hom (Medicinal Genomics Corporation), Neil Markey (Beckley Retreats), among

others. Outreach was also extended to professional societies such as MedChi, the Maryland Academy of Family Physicians, the Maryland Society of Addiction Medicine, and Chesapeake Regional Safety Council.

State Agency Outreach

The Task Force is continuing direct outreach to state agencies likely to be affected by psychedelic policy legislation. These include:

- Maryland Department of Health
- Maryland Cannabis Administration
- Maryland Department of Agriculture
- Maryland Department of Disabilities
- Maryland Department of Veterans Affairs
- Maryland Department of Human Services
- Maryland Department of Public Safety and Correctional Services
- Maryland Judiciary / Administrative Office of the Courts
- Maryland Office of the Attorney General
- Maryland Department of Commerce
- Maryland State Police and local law enforcement agencies
- Maryland Commission on Indian Affairs

National and Regional Outreach

Members of the Task Force proactively sought to learn from other jurisdictions. Five Task Force members attended the MAPS Psychedelic Science 2025 Conference in Denver at their own expense. While there, they engaged in numerous informal consultations with policy experts, clinicians, and psychedelic advocates from around the country, enhancing Maryland's comparative policy knowledge and expanding its national network.

Communications and Media

The Task Force maintains an official webpage hosted by the Maryland Cannabis Administration and a secondary informational site (https://tfnps.com) to facilitate timely updates. Media engagement has included appearances in *Marijuana Moment* and *Montgomery County Media*, and outreach via Reddit, Facebook, and other platforms to ensure the public stays informed and invited to participate.

How We Overcame Challenges

The Maryland Task Force on Responsible Use of Natural Psychedelic Substances was created with an ambitious and forward-looking mandate: to evaluate whether and how the state might safely, equitably, and effectively create access to psychedelic substances for therapeutic, spiritual, and personal growth purposes. The work of the Task Force has been marked by a spirit of deliberation, openness, and principled caution. At the same time, this work has met serious challenges. This chapter outlines the most significant obstacles the Task Force has encountered to date and identifies emerging strategies to address them.

How We Addressed Barriers to Publicity and Outreach

The absence of a communications budget or staff has significantly hindered efforts to publicize meetings through official state channels. As an interim solution, the Task Force created its own publicly accessible website to host meeting announcements, recordings, and opportunities for public comment. The Task Force received news coverage from Fox 45, *Marijuana Moment*, *Montgomery Community Media*, and *Benziga*. Looking ahead, additional strategies under consideration include cross-posting announcements on other state and local government websites, utilizing existing local community discussion boards on social media, collaborating with public libraries, local health departments, and county councils to distribute physical and digital flyers, and enlisting student interns or volunteers to help maintain an outreach calendar and social media presence. These measures would support broader awareness and greater public participation.

How We Approached Reluctance, Stigma and Apathy

Identifying and engaging stakeholders—particularly those who have historically been opposed to drug policy reform—has proven difficult. In some cases, we expected to encounter reluctance stemming from skepticism about the legitimacy of psychedelics as a public health intervention. We also anticipated opposition rooted in concerns over safety, diversion, or the erosion of medical and licensing standards. To address this, the Task Force pursued targeted outreach to professional associations and licensing boards, offering confidential listening sessions to accommodate those hesitant to speak publicly, and maintaining a stakeholder registry to keep individuals and organizations informed of updates, comment periods, and working groups. These efforts are intended to turn passive observation into active participation and create space for concerns to be addressed through transparent, data-informed dialogue.

How We Sought Input from Religious and Spiritual Communities

The Task Force initially experienced challenges soliciting input from religious communities that use psychedelics sacramentally, possibly due to concerns about legal exposure, mistrust, and confidentiality. In response, the Task Force established a secure and confidential communications channel and reached out to national religious freedom organizations for help initiating dialogue with Maryland-based affiliates. The Task Force also extended an invitation to the Maryland Commission on Indian Affairs (MCIA) and leaders of the Piscataway-Conoy Tribe in an attempt to solicit input from representatives of the local Maryland indigenous community.

The Task Force closely reviewed aligned efforts in Colorado, Minnesota and Alaska, and invited commentary from experts and national organizations experienced in the use of natural psychedelic substances as sacred medicine. The Task Force received valuable input from The Association of Entheogenic Practitioners, Luz Sagrada, and Beneficente Spiritist Center União do Vegetal in the United States (UDV-US) on the topic of religious use. The Task Force also dedicated further deliberation and exploration of the topic among the group's internal expertise, which led to amended policy propositions. Further exploration also illustrated the need for greater differentiation between indigenous and religious use–two distinct use cases which were not appropriately separated in the Task Force's authorizing legislation, as illustrated by the chair for one person with expertise in both.

Protecting traditional and ceremonial use of psychedelics requires not just exemption from regulation but active partnership. Cooperative efforts in Maryland might include recognition of community-defined ceremonial practices, revenue-sharing from commercial programs to support traditional stewards, and consultation rights for Indigenous and diasporic communities. The Task Force remains committed to creating policy recommendations that respect religious freedom while protecting public safety.

Aspiring to embody the mandate "Nothing about us without us," the Task Force will continue its good faith efforts to engage members of religious and tribal communities that would be affected by our recommendations.

How We Considered Multiple Substances

While grouping psilocybin, psilocin, dimethyltryptamine (DMT), and mescaline together under the Task Force's mandate is a logical starting point—given their natural origins, serotonergic mechanisms, and relatively low risk profiles—it also introduces complexity to our analysis and recommendations. These substances differ significantly in pharmacokinetics and use contexts: for example, vaporized DMT produces effects lasting just 5–15 minutes, whereas oral mescaline

may last 8–12 hours. As a result, the safeguards and regulatory frameworks appropriate for each may vary considerably, requiring the Task Force to examine them both individually and comparatively.

To manage this complexity, the Task Force decided early in our process to focus first on the substances explicitly named in its authorizing legislation, before considering others such as ibogaine. Although ibogaine is gaining interest for opioid use disorder, PTSD and TBI, it presents substantially higher medical risks, especially related to cardiac toxicity. Preliminary results from the Task Force's first Delphi round indicate broad consensus around prioritizing psilocybin for initial program development, with the potential to expand to other natural psychedelics once foundational programs are safely and successfully established.

How We Collaborated with Johns Hopkins University

To help evaluate different psilocybin access models, a team of health economists affiliated with the Johns Hopkins Carey Business School and the Johns Hopkins Bloomberg School of Public Health conducted a scoping review of the literature to identify the key costs and revenues of different policy options, and to assess how these options might impact the state of Maryland, providers, and patients/consumers. A scoping review of the cost drivers of various psilocybin policy options has also been completed, with some frequently mentioned drivers including the psychotherapy component of psychedelic-assisted therapy and the cost of facilitator training. The team also identified key costs from cannabis legalization studies that may help inform the evaluation of psilocybin policy options. Finally, the team estimated the potential market size of some psilocybin access models considered by the Task Force, which is a necessary first step for making cost and revenue projections. These findings have been compiled into a comprehensive, independent report for the Task Force on Responsible Use of Natural Psychedelic Substances, which was separately released by the Johns Hopkins team and is included in the appendix of this report.

How We Formed Our Recommendations

As part of its mandate to explore the responsible use of natural psychedelic substances, the Task Force developed a structured framework to evaluate potential policy features. This work culminated in a curated set of 85 policy propositions, each representing a discrete policy decision point that could inform future legislation in Maryland.

These propositions were developed following extensive literature reviews, policy analysis from other jurisdictions, expert testimony, and public stakeholder input. The initial list included 120

propositions, which were then thematically categorized, reviewed for redundancy, and ranked for relevance and priority. This process led to the refinement and consolidation of the list to 85 high-value propositions, spanning the seven access models identified earlier in the process.

Each proposition addresses a specific regulatory question, such as whether psychedelic use should require a medical diagnosis, what types of training facilitators should complete, how equity can be advanced in industry participation, or whether a use permit system should be implemented. The aim was to distill the complex set of decisions facing lawmakers into clear, actionable elements that could be independently evaluated and refined.

To assess each proposition, the Task Force employed a modified Delphi method—an evidence-based consensus process that uses iterative rounds of anonymous input from experts to refine and converge on recommendations. This approach promotes transparency, reduces groupthink, and allows for the identification of both strong areas of agreement and issues requiring further deliberation. Notably, the Delphi method was used internally to identify consensus among task force members; we did not seek to make generalizable claims beyond our specific mandate. A full explanation of the Delphi methodology used, including grading criteria and participation metrics, is provided in Appendix 2. The Task Force considered 5 additional propositions using a Live Delphi process at its September 25, 2025 meeting.

Section I. Natural Psychedelic Substances

Introduction to the Psilocybin, Mescaline, and DMT Monographs

Lawmakers are being asked to make complex, high-stakes decisions about psychedelic substances, often in the absence of clear, consolidated, and unbiased information. Public interest has accelerated far more quickly than most regulatory systems can adapt. Meanwhile, clinical research has surged, early therapeutic programs are emerging, and communities are calling for frameworks that both provide safe access to these substances and respect longstanding cultural practices.

In this rapidly evolving landscape, policy choices carry real consequences: they can open access to potentially life-saving treatments, or inadvertently create public health risks; they can protect Indigenous and religious traditions, or unintentionally erode them. Effective policy requires not only scientific rigor, but cultural humility, ethical foresight, and a commitment to public safety.

The enclosed monographs on psilocybin/psilocin, mescaline, and DMT were created to support that effort. They are designed as evidence-based reference documents, integrating scientific research, clinical data, public health considerations, and cultural context, so that lawmakers can work from a foundation of reliable knowledge rather than fragmented or sensationalized narratives. Each monograph draws from contemporary biomedical literature as well as historical and ethnographic scholarship, presenting a clear and balanced view of these substances, their potential therapeutic applications, and their associated risks.

Using the Monographs

These monographs are intended to serve as foundational reference tools rather than prescriptive policy templates. They can be consulted to understand the scientific evidence, therapeutic potential, and risk profiles of each substance when drafting legislation, evaluating proposed regulatory models, or designing public health safeguards. Legislators may use them to inform scheduling decisions, guide the development of clinical access pathways, and anticipate

public health impacts of policy change. Because they compile and contextualize data from multiple disciplines (i.e. biomedical research, public health, law, and ethnography) they offer a common factual baseline that can support informed debate, cross-agency collaboration, and the creation of thoughtful, ethically grounded policy frameworks.

As conversations about psychedelics shift from speculation to implementation, these monographs offer a shared factual grounding from which debate and policy design can responsibly proceed.

Acknowledging Ibogaine

The Task Force recognizes that there is substantial interest in expanding access to ibogaine, a natural psychoactive alkaloid found in the root bark of the West African shrub *Tabernanthe iboga*, which is currently in Schedule I of the schedule of controlled substances. The Task Force acknowledges ibogaine's traditional use in spiritual ceremonies. Interest in ibogaine for its potential use in the treatment of life-endangering substance use disorders, including opiate use disorder is accelerating, especially following publication in the Washington Post on June 27, 2025 of an op-ed by former Texas Governor Rick Perry. In June 2025, Texas created a program to provide up to \$50 million in grants for clinical research in the use of ibogaine to treat substance use disorders. Meanwhile, in the 118th Congress, H.R.3684, the Douglas Mike Day Psychedelic Therapy to Save Lives Act of 2023, had 15 co-sponsors including Rep. David Trone of Maryland's 6th District.

The Task Force was formally mandated in its authorizing legislation (Chapters 792&793 of 2024) to study and make recommendations regarding psilocybin, psilocin, dimethyltryptamine, and mescaline (not including peyote). The authorizing legislation indeed included a provision for the Task Force to expand its scope to "any other substance determined by the Task Force to be a natural psychedelic substance," such as ibogaine. However, the Task Force faced notable complexity in effectively analyzing pharmacokinetics and clinical research of each of the four mandated substances, across eight regulatory frameworks, and exploring the best emerging policy propositions to maximize public benefit and mitigate public risks across multiple psychedelic use practices, among other variables. To expand the scope to include a fifth substance would have limited the depth of work this Task Force could have accomplished.

This challenge is magnified further when considering the complications ibogaine presents in comparison to the substances listed in this Task Force's mandate. Psilocybin, psilocin, dimethyltryptamine, and mescaline all share serotonergic mechanisms of action and relatively low risk profiles. Ibogaine, however, differs in that it involves multifaceted receptor interactions

(opiate, serotonin, dopamine, norepinephrine, NMDA, to name a few)¹. Ibogaine also presents significantly higher medical risks, especially related to cardiac toxicity. While psilocybin, psilocin, dimethyltryptamine, and mescaline all share low toxicity without the apparent ability to fatally overdose, there are recorded fatalities with ibogaine use, with deaths hypothesized to have been "a result of cardiac arrhythmias, caused by a dysregulation of the autonomic nervous system."² The regulatory framework needed to ensure safe access to ibogaine would likely differ from that of the substances listed in this Task Force's mandate. To manage these layers of complexity, the Task Force decided early in our process to focus first on the substances explicitly named in the authorizing legislation, before considering others such as ibogaine. This decision was further affirmed by the Delphi Policy Propositions which indicated a broad consensus around prioritizing psilocybin for initial program development, with the potential to expand to other natural psychedelics once foundational programs are safely and successfully established. Further study and recommendations into responsible use of ibogaine could be conducted at a later date.

¹ Sweetnam PM, Lancaster J, Snowman A, Collins JL, Perschke S, Bauer C, Ferkany J. Receptor binding profile suggests multiple mechanisms of action are responsible for ibogaine's putative anti-addictive activity. Psychopharmacology (Berl). 1995 Apr;118(4):369-76. doi: 10.1007/BF02245936. PMID: 7568622.

² U. Maas, S. Strubelt, Fatalities after taking ibogaine in addiction treatment could be related to sudden cardiac death caused by autonomic dysfunction, Medical Hypotheses, Volume 67, Issue 4, 2006, Pages 960-964, ISSN 0306-9877, https://doi.org/10.1016/j.mehy.2006.02.050. (https://www.sciencedirect.com/science/article/pii/S030698770600209X)

Psilocybin/Psilocin Monograph

Executive summary

Psilocybin and its active metabolite psilocin are naturally occurring psychoactive compounds found primarily in some species of mushrooms. Psilocybin has a long history of traditional use in indigenous cultures and is currently the subject of renewed scientific interest for potential therapeutic applications across a range of domains including psychiatric, neurological, and immunological. Psilocybin acts primarily on serotonin receptors in the brain, producing altered states of consciousness characterized by changes in perception, cognition, and mood. While generally considered to have low physiological toxicity and addiction potential, psilocybin use carries psychological risks, particularly for individuals with certain mental health conditions, predispositions, or for those using in unsafe settings. Psilocybin is currently designated a Schedule 1 controlled substance by the U.S. federal government, but recent years have seen significant policy reforms at the state level with several jurisdictions decriminalizing or creating regulated access pathways for these substances with varying outcomes. This monograph provides an evidence-based overview intended to inform policy considerations around these compounds.

Mycology

Psilocybin and psilocin are found primarily in mushrooms of the genus *Psilocybe*, though they also occur in other genera including *Panaeolus*, *Gymnopilus*, *Pluteus*, and *Inocybe*.^[3] Over 200 species across eight genera containing these compounds have been identified worldwide to

³ Pepe, M., Hesami, M., de la Cerda, K. A., Perreault, M. L., Hsiang, T., & Jones, A. M. P. (2023). A journey with psychedelic mushrooms: From historical relevance to biology, cultivation, medicinal uses, biotechnology, and beyond. Biotechnology advances, 69, 108247. https://doi.org/10.1016/j.biotechadv.2023.108247

date, with varying concentrations and distributions.^[4] *Psilocybe cubensis* is the most commonly cultivated species.^[5]

Psilocybin (4-phosphoryloxy-N,N-dimethyltryptamine) is a prodrug that is metabolized in the body to psilocin (4-hydroxy-N,N-dimethyltryptamine), which is the pharmacologically active compound. ^[6] Psilocybin content in dried mushrooms is highly variable, but typically ranges from 0.1% to 2.0% by weight, though some species may contain higher concentrations. ^{[7][8][9]} These mushrooms also have various levels of psilocin as well. Any potency analysis needs to account for both psilocybin and psilocin content.

Ethnomycology

Psilocybin mushrooms have been used in ritualistic and ceremonial contexts by indigenous cultures for centuries, particularly in Mesoamerica. Archaeological evidence suggests their use dating back at least 3,000 years, with mushroom stone effigies from Guatemala and southern Mexico representing some of the earliest artifacts associated with mushroom ceremonies. [10][11][12]

The Mazatec, Nahuatl, and other indigenous groups in Mexico incorporated psilocybin mushrooms into religious and healing ceremonies, often under the guidance of spiritual leaders.^[13] Western scientific awareness of these practices emerged significantly in the 1950s through the work of R. Gordon Wasson, who participated in traditional Mazatec ceremonies led

⁴ Van Court, R. C., Wiseman, M. S., Meyer, K. W., Ballhorn, D. J., Amses, K. R., Slot, J. C., Dentinger, B. T. M., Garibay-Orijel, R., & Uehling, J. K. (2022). Diversity, biology, and history of psilocybin-containing fungi: Suggestions for research and technological development. Fungal biology, 126(4), 308–319.

⁵ Guzmán, G.; Allen, J.W.; Gartz, J. (2000). "A worldwide geographical distribution of the neurotropic fungi, an analysis and discussion" (PDF). Annali del Museo Civico di Rovereto: Sezione Archeologia, Storia, Scienze Naturali. 14: 189–280. Archived (PDF) from the original on February 5, 2018. Retrieved April 5, 2022.

⁶ Nichols D. E. (2020). Psilocybin: from ancient magic to modern medicine. The Journal of antibiotics, 73(10), 679–686. https://doi.org/10.1038/s41429-020-0311-8

⁷ Nichols D. E. (2020). Psilocybin: from ancient magic to modern medicine. The Journal of antibiotics, 73(10), 679–686. https://doi.org/10.1038/s41429-020-0311-8

⁸ Gotvaldová, K., Borovička, J., Hájková, K., Cihlářová, P., Rockefeller, A., & Kuchař, M. (2022). Extensive Collection of Psychotropic Mushrooms with Determination of Their Tryptamine Alkaloids. International journal of molecular sciences, 23(22), 14068. https://doi.org/10.3390/ijms232214068

⁹ Stríbrný, J., Borovicka, J., & Sokol, M. (2003). Obsah psilocybinu a psilocinu v některých druzích hub [Levels of psilocybin and psilocin in various types of mushrooms]. Soudni lekarstvi, 48(3), 45–49.

¹⁰ Lowy, B. (1971). New Records of Mushroom Stones from Guatemala. Mycologia, 63(5), 983–993. https://doi.org/10.1080/00275514.1971.12019194

¹¹ F. Hernández Santiago, M. Martínez Reyes, J. Pérez Moreno, G. Mata. Pictographic Representation of the First Dawn and its Association with Entheogenic Mushrooms in a 16th Century Mixtec Mesoamerican Code 46, Scientia Fungorum (2017), pp. 19-28 ¹² Van Court, R. C., Wiseman, M. S., Meyer, K. W., Ballhorn, D. J., Amses, K. R., Slot, J. C., Dentinger, B. T. M., Garibay-Orijel, R., & Uehling, J. K. (2022). Diversity, biology, and history of psilocybin-containing fungi: Suggestions for research and technological development.

Fungal biology, 126(4), 308–319. https://doi.org/10.1016/j.funbio.2022.01.003

¹³ Guzmán, G. Hallucinogenic Mushrooms in Mexico: An Overview. Econ Bot 62, 404–412 (2008). https://doi.org/10.1007/s12231-008-9033-8

by curandera María Sabina.^[14] His accounts, published in Life magazine in 1957, introduced these practices to the broader public and scientific community, coinciding with the isolation and identification of psilocybin by Albert Hofmann in 1958. The compounds gained widespread attention during the 1960s counterculture movement, leading to increased recreational use and subsequent prohibition in many countries under the 1971 UN Convention on Psychotropic Substances, which classified psilocybin as a Schedule I substance.^{[15][16]} There remains some ritualistic use of psilocybin-containing mushrooms in parts of Mexico, but indigenous use is overall diminishing and has been largely supplanted by an industry of psychedelic tourism.^{[17][18]}

Mechanism of Action

Psilocybin itself is not directly psychoactive but is rapidly dephosphorylated in the body to psilocin, which is the active compound considered primarily responsible for psychoactive effects.^[19] Psilocin acts primarily as an agonist (activator) at serotonin (5-HT) receptors in the brain, with particularly high affinity for the 5-HT2A receptor subtype.^[20] This receptor activation is believed to be the primary mechanism underlying the psychedelic effects.

Short term effects typically begin within 20-40 minutes of ingestion, peak at 2-3 hours, and gradually diminish over 4-6 hours. ^[21] The subjective experience commonly includes altered visual and sensory perception, changes in thought patterns, emotional intensification, and in higher doses, profound alterations in the sense of self and reality. Longer term effects may result from promoting neuroplasticity and neural connectivity. ^[22] Some longer term effects, such as increases in prosocial behavior and relief from depressed mood and self-criticism, may be perceived as beneficial if they occur. Whereas other potential long term effects – such as suggestibility, paranoia, and derealization – may be unwelcome or harmful.

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¹⁴ Wasson, R. G. 1957. Seeking the Magic Mushroom. *Life*, May 13, New York.

¹⁵ United Nations. Convention on Psychotropic Substances. UNODC [online], (1971).

¹⁶ Nutt, D., King, L. & Nichols, D. Effects of Schedule I drug laws on neuroscience research and treatment innovation. Nat Rev Neurosci 14, 577–585 (2013). https://doi.org/10.1038/nrn3530

¹⁷ Guzmán, G. Hallucinogenic Mushrooms in Mexico: An Overview. Econ Bot 62, 404–412 (2008). https://doi.org/10.1007/s12231-008-9033-8

¹⁸ Vidriales, Arturo & Ovies, Diego. (2018). Psychedelic tourism in Mexico, a thriving trend. PASOS. Revista de Turismo y Patrimonio Cultural. 16. 1037-1050. 10.25145/j.pasos.2018.16.072.

¹⁹ Nichols D. E. (2020). Psilocybin: from ancient magic to modern medicine. The Journal of antibiotics, 73(10), 679–686. https://doi.org/10.1038/s41429-020-0311-8

²⁰ Dodd, S., Norman, T. R., Eyre, H. A., Stahl, S. M., Phillips, A., Carvalho, A. F., & Berk, M. (2023). Psilocybin in neuropsychiatry: a review of its pharmacology, safety, and efficacy. CNS spectrums, 28(4), 416–426. https://doi.org/10.1017/S1092852922000888

²¹ Dodd, S., Norman, T. R., Eyre, H. A., Stahl, S. M., Phillips, A., Carvalho, A. F., & Berk, M. (2023). Psilocybin in neuropsychiatry: a review of its pharmacology, safety, and efficacy. CNS spectrums, 28(4), 416–426. https://doi.org/10.1017/S1092852922000888

²² Agnorelli, C., Spriggs, M., Godfrey, K., Sawicka, G., Bohl, B., Douglass, H., Fagiolini, A., Parastoo, H., Carhart-Harris, R., Nutt, D., & Erritzoe, D. (2025). Neuroplasticity and psychedelics: A comprehensive examination of classic and non-classic compounds in pre and clinical models. Neuroscience and biobehavioral reviews, 172, 106132. https://doi.org/10.1016/j.neubiorev.2025.106132

Safety Profile

A. Physical Health

Psilocybin has demonstrated a relatively favorable physiological safety profile compared to many other psychoactive substances. Common effects associated with psilocybin include hallucinations, nausea, vomiting, sweating, and physical or emotional discomfort.^[23] These are typically short term and resolve as the active compounds are metabolized.^[24]

Toxicity: The lethal dose (LD_{50}) is estimated to be extremely high (approximately 280 mg/kg in rats), with very few confirmed cases of death directly attributed to psilocybin toxicity in humans. [25][26] The therapeutic index (ratio of toxic to effective dose) is wide.

Cardiovascular effects: Modest, transient increases in blood pressure and heart rate may occur, and this effect appears to be dose-dependent based on available data.^[27] While generally not clinically significant in healthy individuals, these hemodynamic changes could pose risks for individuals with severe cardiovascular disease, poorly controlled hypertension, or a history of cardiac events.^[28] FDA approved clinical trials have excluded those with significant cardiovascular disease including uncontrolled hypertension. A theoretical cardiovascular risk more relevant to chronic use (as with so-called microdosing) is that psilocybin activates a receptor (serotonin 2B) known to lead to heart valve disease. This is the same mechanism and risk that caused fenfluramine/phentermine (fen-phen) to be withdrawn by the FDA in 1997.

Hepatic effects: Unlike some psychoactive compounds, psilocybin demonstrates minimal hepatotoxicity. Standard liver function tests show no clinically significant alterations following

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²³ Yerubandi, A., Thomas, J. E., Bhuiya, N. M. M. A., Harrington, C., Villa Zapata, L., & Caballero, J. (2024). Acute Adverse Effects of Therapeutic Doses of Psilocybin: A Systematic Review and Meta-Analysis. JAMA network open, 7(4), e245960. https://doi.org/10.1001/jamanetworkopen.2024.5960

²⁴ Dodd, S., Norman, T. R., Eyre, H. A., Stahl, S. M., Phillips, A., Carvalho, A. F., & Berk, M. (2023). Psilocybin in neuropsychiatry: a review of its pharmacology, safety, and efficacy. CNS spectrums, 28(4), 416–426. https://doi.org/10.1017/S1092852922000888

²⁵ Tylš, F., Páleníček, T., & Horáček, J. (2014). Psilocybin--summary of knowledge and new perspectives. European neuropsychopharmacology: the journal of the European College of Neuropsychopharmacology, 24(3), 342–356. https://doi.org/10.1016/j.euroneuro.2013.12.006

²⁶ Kopra, E. I., Ferris, J. A., Winstock, A. R., Young, A. H., & Rucker, J. J. (2022). Adverse experiences resulting in emergency medical treatment seeking following the use of magic mushrooms. Journal of psychopharmacology (Oxford, England), 36(8), 965–973. https://doi.org/10.1177/02698811221084063

²⁷ Wsół A. (2023). Cardiovascular safety of psychedelic medicine: current status and future directions. Pharmacological reports: PR, 75(6), 1362–1380. https://doi.org/10.1007/s43440-023-00539-4

²⁸ MacCallum, C. A., Lo, L. A., Pistawka, C. A., & Deol, J. K. (2022). Therapeutic use of psilocybin: Practical considerations for dosing and administration. Frontiers in psychiatry, 13, 1040217. https://doi.org/10.3389/fpsyt.2022.1040217

controlled administration, and there is no evidence of long-term liver damage associated with periodic use. [29][30]

Neurological considerations: There is no evidence that psilocybin causes neurotoxicity or structural brain damage. Conversely, emerging research suggests potential neuroprotective properties through several mechanisms.^{[31][32]} There is a theoretical risk that **Hallucinogen Persisting Perception Disorder -** HPPD (discussed below) may have a neurological basis in susceptible individuals, although this is unconfirmed.

Teratogenicity and reproductive health: Limited data exists on effects during pregnancy or breastfeeding. Animal studies show no consistent evidence of teratogenicity at doses equivalent to human consumption, but the precautionary principle warrants avoiding use during pregnancy due to the lack of controlled human studies. No evidence suggests impacts on long-term fertility or reproductive function. [33][34]

B. Mental Health

The psychological effects of psilocybin present both risks and potential benefits:

Acute psychological distress: "Challenging experiences," which while difficult hold redeeming value, or "bad trips," which have no redeeming value, can occur. These are characterized by anxiety, paranoia, confusion, and fear. These reactions are influenced by dose, setting, expectation, and individual susceptibility. Approximately 25-30% of individuals may experience significant anxiety or challenging psychological symptoms during high-dose psilocybin

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²⁹ Straumann, I. et al. (2024) 'Safety pharmacology of acute psilocybin administration in healthy participants', Neuroscience Applied, 3. Available at: https://doi.org/10.1016/j.nsa.2024.104060.

³⁰ Dinis-Oliveira, R. J. (2017). Metabolism of psilocybin and psilocin: clinical and forensic toxicological relevance. Drug Metabolism Reviews, 49(1), 84–91. https://doi.org/10.1080/03602532.2016.1278228

³¹ Agnorelli, C., Spriggs, M., Godfrey, K., Sawicka, G., Bohl, B., Douglass, H., Fagiolini, A., Parastoo, H., Carhart-Harris, R., Nutt, D., & Erritzoe, D. (2025). Neuroplasticity and psychedelics: A comprehensive examination of classic and non-classic compounds in pre and clinical models. Neuroscience and biobehavioral reviews, 172, 106132. https://doi.org/10.1016/j.neubiorev.2025.106132

³² Kozlowska, U., Nichols, C., Wiatr, K., & Figiel, M. (2022). From psychiatry to neurology: Psychedelics as prospective therapeutics for neurodegenerative disorders. Journal of neurochemistry, 162(1), 89–108. https://doi.org/10.1111/jnc.15509

³³ Tombari, R. J., Mundy, P. C., Morales, K. M., Dunlap, L. E., Olson, D. E., & Lein, P. J. (2023). Developmental Neurotoxicity Screen of Psychedelics and Other Drugs of Abuse in Larval Zebrafish (Danio rerio). ACS chemical neuroscience, 14(5), 875–884. https://doi.org/10.1021/acschemneuro.2c00642

³⁴ Syed, O. A., Tsang, B., Petranker, R., & Gerlai, R. (2023). A perspective on psychedelic teratogenicity: the utility of zebrafish models. Trends in pharmacological sciences, 44(10), 664–673. https://doi.org/10.1016/j.tips.2023.08.001

experiences, although these typically resolve within 24-48 hours.^[35] Preparation, setting, and qualified supervision significantly reduce these risks.^[36]

Unprepared use and psychological impact: Individuals using psilocybin without adequate preparation, in inappropriate settings, or with underlying psychological vulnerabilities face increased risks of adverse psychological outcomes.^[37] The profound alterations in perception and cognition can be disorienting and frightening without proper context or support.^[38] These risks increase substantially with higher doses.

Behavioral responses to hallucinations: Despite popular misconceptions, true hallucinations (perceiving stimuli that do not exist) are relatively uncommon with psilocybin compared to illusions and perceptual distortions (misinterpreting existing stimuli). [39] Research does not support the notion that individuals commonly "act out" hallucinations in dangerous ways. However, impaired judgment, altered perception, and general intoxication can lead to risky behavior if proper precautions are not taken. [40][41]

Psychosis risk: Psilocybin may precipitate or exacerbate psychotic symptoms in predisposed individuals, particularly those with personal or family history of psychotic disorders. However, large population studies have not found associations between psychedelic use and increased

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³⁵ Simonsson, O., Hendricks, P. S., Chambers, R., Osika, W., & Goldberg, S. B. (2023). Prevalence and associations of challenging, difficult or distressing experiences using classic psychedelics. Journal of affective disorders, 326, 105–110. https://doi.org/10.1016/j.jad.2023.01.073

³⁶ Carbonaro, T. M., Bradstreet, M. P., Barrett, F. S., MacLean, K. A., Jesse, R., Johnson, M. W., & Griffiths, R. R. (2016). Survey study of challenging experiences after ingesting psilocybin mushrooms: Acute and enduring positive and negative consequences. Journal of psychopharmacology (Oxford, England), 30(12), 1268–1278. https://doi.org/10.1177/0269881116662634

³⁷ Borkel, L. F., Rojas-Hernández, J., Henríquez-Hernández, L. A., Santana Del Pino, Á., & Quintana-Hernández, D. J. (2024). Set and setting predict psychopathology, wellbeing and meaningfulness of psychedelic experiences: a correlational study. Expert review of clinical pharmacology, 17(2), 165–176. https://doi.org/10.1080/17512433.2023.2295997

³⁸ Breeksema, J.J., Niemeijer, A., Krediet, E. et al. Patient perspectives and experiences with psilocybin treatment for treatment-resistant depression: a qualitative study. Sci Rep 14, 2929 (2024). https://doi.org/10.1038/s41598-024-53188-9

³⁹ Leptourgos, P., Fortier-Davy, M., Carhart-Harris, R., Corlett, P. R., Dupuis, D., Halberstadt, A. L., Kometer, M., Kozakova, E., LarØi, F., Noorani, T. N., Preller, K. H., Waters, F., Zaytseva, Y., & Jardri, R. (2020). Hallucinations Under Psychedelics and in the Schizophrenia Spectrum: An Interdisciplinary and Multiscale Comparison. Schizophrenia bulletin, 46(6), 1396–1408. https://doi.org/10.1093/schbul/sbaa117

⁴⁰ Tomlinson, M. F., Brown, M., & Hoaken, P. N. S. (2016). Recreational drug use and human aggressive behavior: A comprehensive review since 2003. Aggression and Violent Behavior, 27, 9–29. https://doi.org/10.1016/j.avb.2016.02.004

⁴¹ Honyiglo, E., Franchi, A., Cartiser, N., Bottinelli, C., Advenier, A. S., Bévalot, F., & Fanton, L. (2019). Unpredictable Behavior Under the Influence of "Magic Mushrooms": A Case Report and Review of the Literature. Journal of forensic sciences, 64(4), 1266–1270. https://doi.org/10.1111/1556-4029.13982

prevalence of psychotic disorders in the general population.^{[42][43]} In FDA approved studies that screen for predisposition for psychotic disorder, there has not been any reported instigation of psychotic disorders among thousands of participants.

Mania and mood disorders: Case reports exist of psilocybin triggering manic episodes in individuals with bipolar disorder or predisposition to mania. The serotonergic activity of psilocybin may potentially destabilize mood regulation in vulnerable individuals. However, a recent small clinical trial administered psilocybin to Bipolar II patients without any instigation of manic episodes, and with a significant reduction in depressive symptoms. However, the risk of manic episode instigation has not been eliminated.

Hallucinogen Persisting Perception Disorder (HPPD): This is a rare condition involving persistent perceptual changes and symptoms of depersonalization or derealization following hallucinogen use, such as visual snow, halos, or trails. [46] HPPD is estimated to affect approximately 4% of psychedelic users, though severe cases are much rarer. [47] Risk factors may include pre-existing anxiety disorders and frequent use of multiple substances. [48]

C. Potential At-Risk Populations

- A. Certain populations may face elevated risks from psilocybin use:
 - a. *Individuals with psychotic disorders:* People with schizophrenia, schizoaffective disorder, bipolar disorder with psychotic features, or family history of these conditions may experience exacerbation of symptoms or precipitation of psychotic

⁴² Sabé, M., Sulstarova, A., Glangetas, A., De Pieri, M., Mallet, L., Curtis, L., Richard-Lepouriel, H., Penzenstadler, L., Seragnoli, F., Thorens, G., Zullino, D., Preller, K., Böge, K., Leucht, S., Correll, C. U., Solmi, M., Kaiser, S., & Kirschner, M. (2025). Reconsidering evidence for psychedelic-induced psychosis: an overview of reviews, a systematic review, and meta-analysis of human studies. Molecular psychiatry, 30(3), 1223–1255. https://doi.org/10.1038/s41380-024-02800-5

⁴³ Honk, L., Stenfors, C. U. D., Goldberg, S. B., Hendricks, P. S., Osika, W., Dourron, H. M., Lebedev, A., Petrovic, P., & Simonsson, O. (2024). Longitudinal associations between psychedelic use and psychotic symptoms in the United States and the United Kingdom. Journal of affective disorders, 351, 194–201. https://doi.org/10.1016/j.jad.2024.01.197

⁴⁴ Gard, D. E., Pleet, M. M., Bradley, E. R., Penn, A. D., Gallenstein, M. L., Riley, L. S., ... & Woolley, J. D. (2021). Evaluating the risk of psilocybin for the treatment of bipolar depression: a review of the research literature and published case studies. Journal of Affective Disorders Reports, 6, 100240.

⁴⁵ Honk, L., Stenfors, C. U. D., Goldberg, S. B., Hendricks, P. S., Osika, W., Dourron, H. M., Lebedev, A., Petrovic, P., & Simonsson, O. (2024). Longitudinal associations between psychedelic use and psychotic symptoms in the United States and the United Kingdom. Journal of affective disorders, 351, 194–201. https://doi.org/10.1016/j.jad.2024.01.197

 ⁴⁶ Ford, H., Fraser, C. L., Solly, E., Clough, M., Fielding, J., White, O., & Van Der Walt, A. (2022). Hallucinogenic Persisting Perception Disorder: A Case Series and Review of the Literature. Frontiers in neurology, 13, 878609. https://doi.org/10.3389/fneur.2022.878609
 ⁴⁷ Baggott MJ, Coyle JR, Erowid E, Erowid F, Robertson LC. Abnormal visual experiences in individuals with histories of hallucinogen use: A web-based questionnaire. Drug and Alcohol Dependence. 2011;114: 61–67. pmid:21035275

⁴⁸ Halpern JH, Lerner AG, Passie T. A Review of Hallucinogen Persisting Perception Disorder (HPPD) and an Exploratory Study of Subjects Claiming Symptoms of HPPD. In: Halberstadt AL, Vollenweider FX, Nichols DE, editors. Behavioral Neurobiology of Psychedelic Drugs. Berlin, Heidelberg: Springer; 2018. pp. 333–360. https://doi.org/10.1007/7854_2016_457 pmid:27822679

- episodes. Current clinical trials typically exclude individuals with these conditions or strong family histories.⁴⁹
- b. *Bipolar disorder and history of mania:* Individuals with bipolar disorder may be at risk for mood destabilization or manic episodes following psilocybin exposure, however recent data on psilocybin for treatment of Bipolar Type II indicates some level of safety and efficacy. ^{50,51,52} Case reports document instances of psilocybin triggering manic episodes in previously diagnosed and undiagnosed individuals. There is also evidence that the bipolar medication lithium can have a serious drug interaction with classic psychedelics such as psilocybin which can lead to seizures.
- c. *Cardiovascular conditions:* People with uncontrolled hypertension, history of stroke, myocardial infarction, significant arrhythmias, or severe heart disease may be at increased risk due to psilocybin's temporary effects on blood pressure and heart rate.⁵³
- d. *Seizure disorders:* Individuals with epilepsy or other seizure disorders may face potential risks, as psilocybin lowers the seizure threshold in animal models, though human data remains limited.^{54,55,56}

⁴⁹ Honk, L., Stenfors, C. U. D., Goldberg, S. B., Hendricks, P. S., Osika, W., Dourron, H. M., Lebedev, A., Petrovic, P., & Simonsson, O. (2024). Longitudinal associations between psychedelic use and psychotic symptoms in the United States and the United Kingdom. Journal of affective disorders, 351, 194–201. https://doi.org/10.1016/j.jad.2024.01.197

⁵⁰ Aaronson ST, van der Vaart A, Miller T, et al. Single-Dose Synthetic Psilocybin With Psychotherapy for Treatment-Resistant Bipolar Type II Major Depressive Episodes: A Nonrandomized Open-Label Trial. JAMA Psychiatry. 2024;81(6):555–562. doi:10.1001/jamapsychiatry.2023.4685

⁵¹ Gard, D. E., Pleet, M. M., Bradley, E. R., Penn, A. D., Gallenstein, M. L., Riley, L. S., ... & Woolley, J. D. (2021). Evaluating the risk of psilocybin for the treatment of bipolar depression: a review of the research literature and published case studies. Journal of Affective Disorders Reports, 6, 100240.

⁵² Morton, E., Sakai, K., Ashtari, A., Pleet, M., Michalak, E. E., & Woolley, J. (2023). Risks and benefits of psilocybin use in people with bipolar disorder: An international web-based survey on experiences of 'magic mushroom' consumption. Journal of psychopharmacology (Oxford, England), 37(1), 49–60. https://doi.org/10.1177/02698811221131997

⁵³ Wsół A. (2023). Cardiovascular safety of psychedelic medicine: current status and future directions. Pharmacological reports: PR, 75(6), 1362–1380. https://doi.org/10.1007/s43440-023-00539-4

⁵⁴ Soto-Angona, Ó., Fortea, A., Fortea, L., Martínez-Ramírez, M., Santamarina, E., López, F. J. G., Knudsen, G. M., & Ona, G. (2024). Do classic psychoelics increase the risk of seizures? A scoping review. European neuropsychopharmacology: the journal of the European College of Neuropsychopharmacology, 85, 35–42. https://doi.org/10.1016/j.euroneuro.2024.05.002

⁵⁵ Blond, B. N., & Schindler, E. A. D. (2023). Case report: Psychedelic-induced seizures captured by intracranial electrocorticography. Frontiers in neurology, 14, 1214969. https://doi.org/10.3389/fneur.2023.1214969

⁵⁶ Balabandian, M., Manavi, M. A., Lesani, A., Mohammad Jafari, R., Shafaroodi, H., Heidari, N., Mirnajafi-Zadeh, J., Foroumadi, A., Afrooghe, A., & Dehpour, A. R. (2025). Psilocin, A Psychedelic Drug, Exerts Anticonvulsant Effects Against PTZ- and MES-Induced Seizures in Mice via 5-HT1A and CB1 Receptors: Involvement of Nitrergic, Opioidergic, and Kynurenine Pathways. Pharmacology research & perspectives, 13(2), e70079. https://doi.org/10.1002/prp2.70079

- e. *Personality disorders:* Those with borderline, paranoid, or schizotypal personality disorders may experience symptom exacerbation or particular difficulty integrating intense psychedelic experiences.^{57,58}
- f. *Recent trauma or psychological instability:* Individuals experiencing acute grief, trauma, or psychological crisis may find the intensified emotional states and psychological vulnerability during psilocybin experiences overwhelming, and some vulnerable individuals may have increased suicidality following psychedelic experiences.^{59,60,61}
- g. *Adolescents:* The developing brain may theoretically be particularly vulnerable to the effects of psychoactive substances. ⁶² Neuroplasticity and neurodevelopmental processes continue through adolescence and early adulthood, and the impact of psilocybin on these processes remains understudied. Given that adolescence and young adulthood is the typical onset for psychotic disorders, one risk is destabilization of those with such predisposition without sufficient age for such predisposition to be identified. Most research programs and emerging regulatory frameworks restrict access to adults 21 and older.
- h. *Pregnant women:* Due to ethical limitations on research, effects on fetal development are not well understood, and use during pregnancy is not recommended. Limited animal studies show minimal teratogenicity, but the precautionary principle applies given insufficient human data.⁶³
- B. Individuals on certain medications:

⁵⁷ Marrocu, A., Kettner, H., Weiss, B., Zeifman, R. J., Erritzoe, D., & Carhart-Harris, R. L. (2024). Psychiatric risks for worsened mental health after psychedelic use. Journal of psychopharmacology (Oxford, England), 38(3), 225–235. https://doi.org/10.1177/02698811241232548

⁵⁸ Carrithers, B. M., Roberts, D. E., Weiss, B. M., King, J. D., Carhart-Harris, R. L., Gordon, A. R., Pagni, B. A., Moreau, M., Ross, S., & Zeifman, R. J. (2025). Exploring serotonergic psychedelics as a treatment for personality disorders. Neuropharmacology, 272, 110413. https://doi.org/10.1016/j.neuropharm.2025.110413

⁵⁹ Hendricks, P. S., Johnson, M. W., & Griffiths, R. R. (2015). Psilocybin, psychological distress, and suicidality. Journal of psychopharmacology (Oxford, England), 29(9), 1041–1043. https://doi.org/10.1177/0269881115598338

⁶⁰ Meshkat, S., Malik, T., Zeifman, R., Swainson, J., Zhang, Y., Burback, L., Winkler, O., Greenshaw, A. J., Claire Reichelt, A., Vermetten, E., Erritzoe, D., Jha, M. K., Dunn, W., Jetly, R., Husain, M. I., & Bhat, V. (2025). Psychedelics and Suicide-Related Outcomes: A Systematic Review. Journal of Clinical Medicine, 14(5), 1416. https://doi.org/10.3390/jcm14051416

⁶¹ Zeifman, R. J., Singhal, N., Breslow, L., & Weissman, C. R. (2021). On the Relationship between Classic Psychedelics and Suicidality: A Systematic Review. ACS pharmacology & translational science, 4(2), 436–451. https://doi.org/10.1021/acsptsci.1c00024

⁶² Izmi, N., Carhart-Harris, R. L., & Kettner, H. (2024). Psychological effects of psychedelics in adolescents. Frontiers in child and adolescent psychiatry, 3, 1364617. https://doi.org/10.3389/frcha.2024.1364617

⁶³ Tombari, R. J., Mundy, P. C., Morales, K. M., Dunlap, L. E., Olson, D. E., & Lein, P. J. (2023). Developmental Neurotoxicity Screen of Psychedelics and Other Drugs of Abuse in Larval Zebrafish (Danio rerio). ACS chemical neuroscience, 14(5), 875–884. https://doi.org/10.1021/acschemneuro.2c00642

- a. *Serotonergic antidepressants (SSRIs, SNRIs):* May attenuate psychedelic effects but could theoretically increase serotonin syndrome risk^{64,65}
- b. *Monoamine Oxidase Inhibitors (MAOIs):* May significantly potentiate psychedelic effects and potentially increase life-threatening cardiovascular risks⁶⁶
- c. *Lithium:* Case reports suggest increased seizure risk when combined with psychedelics^{67,68}
- d. *Second Generation Antipsychotics (SGA):* Medications in this class (e.g. risperidone, quetiapine) block the target of psilocybin's effects (serotonin 5HT2A receptors), and as such may have direct pharmacodynamic interactions with psilocybin.^{69,70}
- e. *First Generation Anti-Psychotics (FGA):* Unlike SGA's that block serotonin 5HT2A receptors, FGA's such as haloperidol in particular has been shown to increase the psychotomimetic (psychotic like) effects of psilocybin.⁷¹
- f. *Tramadol and other drugs that lower seizure threshold*: Potentially increased seizure risk⁷²

D. Public Health

a. *Overall level of harm:* Data from the United Kingdom estimated that the total harm to individuals and society attributable to alcohol was one order of magnitude (10.3 times) higher compared to psilocybin mushrooms.⁷³

⁶⁴ Malcolm, B., Thomas, K. Serotonin toxicity of serotonergic psychedelics. Psychopharmacology 239, 1881–1891 (2022). https://doi.org/10.1007/s00213-021-05876-x

⁶⁵ Halman, A., Kong, G., Sarris, J., & Perkins, D. (2024). Drug-drug interactions involving classic psychedelics: A systematic review. Journal of psychopharmacology (Oxford, England), 38(1), 3–18. https://doi.org/10.1177/02698811231211219

⁶⁶ Halman, A., Kong, G., Sarris, J., & Perkins, D. (2024). Drug-drug interactions involving classic psychedelics: A systematic review. Journal of psychopharmacology (Oxford, England), 38(1), 3–18. https://doi.org/10.1177/02698811231211219

⁶⁷ Nayak, S. M., Gukasyan, N., Barrett, F. S., Erowid, E., Erowid, F., & Griffiths, R. R. (2021). Classic Psychedelic Coadministration with Lithium, but Not Lamotrigine, is Associated with Seizures: An Analysis of Online Psychedelic Experience Reports. Pharmacopsychiatry, 54(5), 240–245. https://doi.org/10.1055/a-1524-2794

⁶⁸ Soto-Angona, Ó., Fortea, A., Fortea, L., Martínez-Ramírez, M., Santamarina, E., López, F. J. G., Knudsen, G. M., & Ona, G. (2024). Do classic psychedelics increase the risk of seizures? A scoping review. European neuropsychopharmacology: the journal of the European College of Neuropsychopharmacology, 85, 35–42. https://doi.org/10.1016/j.euroneuro.2024.05.002

⁶⁹ Yates, G., & Melon, E. (2024). Trip-killers: a concerning practice associated with psychedelic drug use. Emergency medicine journal: EMJ, 41(2), 112–113. https://doi.org/10.1136/emermed-2023-213377

⁷⁰ Sarparast, A., Thomas, K., Malcolm, B., & Stauffer, C. S. (2022). Drug-drug interactions between psychiatric medications and MDMA or psilocybin: a systematic review. Psychopharmacology, 239(6), 1945–1976. https://doi.org/10.1007/s00213-022-06083-y

⁷¹ Vollenweider, F. X., Vollenweider-Scherpenhuyzen, M. F., Bäbler, A., Vogel, H., & Hell, D. (1998). Psilocybin induces schizophrenia-like psychosis in humans via a serotonin-2 agonist action. Neuroreport, 9(17), 3897–3902. https://doi.org/10.1097/00001756-199812010-00024

⁷² Pisani, F., Oteri, G., Costa, C. et al. Effects of Psychotropic Drugs on Seizure Threshold. Drug-Safety 25, 91–110 (2002). https://doi.org/10.2165/00002018-200225020-00004

⁷³ Nutt, D. J., King, L. A., Phillips, L. D., & Independent Scientific Committee on Drugs (2010). Drug harms in the UK: a multicriteria decision analysis. Lancet (London, England), 376(9752), 1558–1565. https://doi.org/10.1016/S0140-6736(10)61462-6

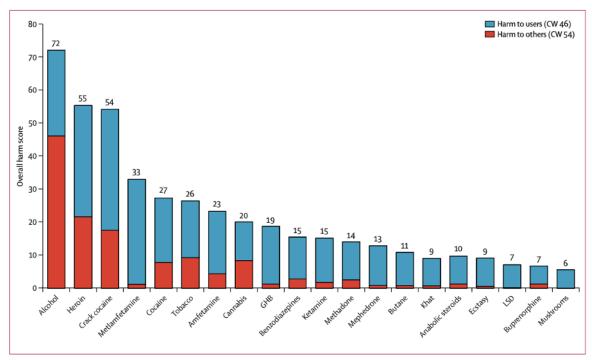


Figure 2: Drugs ordered by their overall harm scores, showing the separate contributions to the overall scores of harms to users and harm to others
The weights after normalisation (0–100) are shown in the key (cumulative in the sense of the sum of all the normalised weights for all the criteria to users, 46; and for all the criteria to others, 54). CW=cumulative weight. GHB=γ hydroxybutyric acid. LSD=lysergic acid diethylamide.

Figure 5. Drugs Ordered By Their Overall Harm Scores. Source: Lancet 2010; 376: 1558-65.

- b. *Prevalence of use:* Unlike people who use cannabis and many other drugs, infrequent users of psychedelics account for most of the total days of use.⁷⁴
 - i. Among psychedelics, use of psilocybin has the highest past-year (3.1%) and past-month (0.9%) prevalence rates for U.S. adults. The past-year prevalence rates for use of all other psychedelic substances are under 1 percent, except MDMA (1.1.%).
 - ii. The total number of use days for psychedelics is two orders of magnitude smaller than it is for cannabis. The past-year and past-month prevalence of cannabis are estimated at roughly 30 percent and 20 percent, respectively.

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⁷⁴ Rockhill, K. M., Black, J. C., Ladka, M. S., Sumbundu, K. B., Olsen, H. A., Jewell, J. S., Hunt, J., Wolf, R. C., Nerurkar, K., Dart, R. C., & Monte, A. A. (2025). The Rise of Psilocybin Use in the United States: A Multisource Observational Study. Annals of internal medicine, 10.7326/ANNALS-24-03145. Advance online publication. https://doi.org/10.7326/ANNALS-24-03145

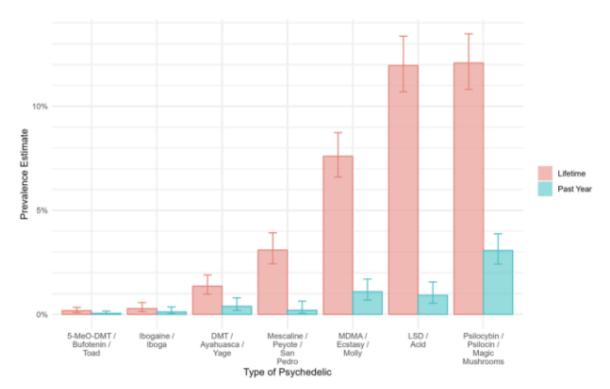


Figure 6. Lifetime and Past-Year Prevalence Rates for Various Psychedelic Substances Among U.S. Adults in 2023. Source: RAND Psychedelic Survey, 2023.

- c. Abuse and dependence potential: Psilocybin has low abuse potential compared to many other psychoactive substances, based on the 8 regulatory criteria in the Controlled Substances Act.⁷⁵ The 2017 Global Drug Survey ranked psilocybin mushrooms as having the lowest emergency medical treatment seeking rate of all substances studied (0.2% of users).⁷⁶ Studies consistently demonstrate:
 - i. Minimal physiological dependence
 - ii. Rapid tolerance development (tachyphylaxis) making frequent use pharmacologically ineffective
 - iii. No evidence of compulsive use patterns typical of addictive substances
 - iv. No documented withdrawal syndrome
- d. *Impaired driving and DUI concerns:* Psilocybin significantly impairs motor coordination, judgment, and perception for 4-6 hours after ingestion and in atypical cases longer,

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⁷⁵ Johnson, M. W., Griffiths, R. R., Hendricks, P. S., & Henningfield, J. E. (2018). The abuse potential of medical psilocybin according to the 8 factors of the Controlled Substances Act. Neuropharmacology, 142, 143–166. https://doi.org/10.1016/j.neuropharm.2018.05.012
⁷⁶ Kopra, E. I., Ferris, J. A., Winstock, A. R., Young, A. H., & Rucker, J. J. (2022). Adverse experiences resulting in emergency medical treatment seeking following the use of magic mushrooms. Journal of psychopharmacology (Oxford, England), 36(8), 965–973.
https://doi.org/10.1177/02698811221084063

rendering driving or operating heavy machinery unsafe. Unlike alcohol, no standardized roadside testing method currently exists, presenting challenges for law enforcement and public safety. Limited data suggests psychedelic-involved traffic incidents are rare compared to alcohol and other substances, likely due to lower prevalence of use and users' recognition of impairment.⁷⁷

- e. *Emergency department visits*: Data from the Drug Abuse Warning Network (DAWN) and similar surveillance systems indicate:
 - i. Psilocybin-related ED visits comprise a small fraction of all drug-related emergency visits
 - ii. Most presentations involve psychological distress rather than medical emergencies
 - iii. Co-ingestion of other substances (particularly alcohol) is present in a majority of cases. Governmental assessments by the Netherlands on decriminalized psilocybin use shows a similar pattern.
 - iv. Most cases resolve with supportive care and without medical sequelae
 - v. Risk of self-harm or harm to others during these episodes is generally low, and this risk is further reduced with proper supervision.
- f. *Pediatric access and exposures:* Accidental pediatric exposures to psilocybin mushrooms are rare but concerning when they occur.⁷⁸ As decriminalization and regulated access expand, considerations include:
 - i. Need for childproof packaging in regulated markets
 - ii. Public education about secure storage
 - iii. Potential confusion with edible non-psychoactive mushrooms (e.g. mushrooms are often blended into chocolate in the illicit market and in decriminalized municipalities).
 - iv. Age verification requirements in jurisdictions with legal access
 - v. Age-appropriate drug education programs
- g. *Hallucinations and violent behavior:* Unlike some substances (e.g., stimulants, synthetic cannabinoids, PCP), psilocybin is not associated with increased aggression or violence in

⁷⁷ Salas-Wright, C. P., Cano, M., Hodges, J., Oh, S., Hai, A. H., & Vaughn, M. G. (2021). Driving while under the influence of hallucinogens: Prevalence, correlates, and risk profiles. Drug and alcohol dependence, 228, 109055. https://doi.org/10.1016/j.drugalcdep.2021.109055

⁷⁸ https://news.virginia.edu/content/magic-mushroom-calls-growing-poison-centers

epidemiological studies. The perception that psychedelics commonly cause violent behavior is not supported by evidence.^{79,80}

- i. A 2016 study of 130,000 US adults found no association between psychedelic use and increased violence
- ii. Population studies show psychedelic users have similar or lower rates of antisocial behavior compared to non-users
- iii. Rare cases of aggression typically involve individuals with pre-existing conditions or co-ingestion of other substances or individuals experiencing delusional symptoms
- h. *Indigenous, sacramental and religious use considerations:* As interest in psilocybin increases, several concerns arise.⁸¹
 - i. Ethno-tourism impact on traditional communities, particularly in Mexico and Central America⁸²
 - ii. Cultural appropriation of indigenous practices without proper context or respect
 - iii. Commercialization threatening the sustainability of traditional practices
 - iv. Need for indigenous representation in developing regulatory frameworks
 - v. Recognition and protection of established religious and traditional use in policy development
- i. *Unregulated use and harm reduction:* In contexts where psilocybin remains illegal or unregulated, there are several points to consider.⁸³
 - i. Users lack access to quality control, accurate dosing information, and harm reduction resources
 - ii. Potential adulteration with other substances, though less common than with manufactured drugs
 - iii. Absence of screening for contraindications and vulnerable populations
 - iv. Limited integration support following challenging experiences

⁷⁹ Sayrafizadeh, N., Ledwos, N., Husain, M. I., & Castle, D. J. (2024). Aggressive behaviours associated with MDMA and psychedelics: a narrative review. Acta neuropsychiatrica, 37, e30. https://doi.org/10.1017/neu.2024.3

⁸⁰ Tomlinson, M. F., Brown, M., & Hoaken, P. N. S. (2016). Recreational drug use and human aggressive behavior: A comprehensive review since 2003. Aggression and Violent Behavior, 27, 9–29. https://doi.org/10.1016/j.avb.2016.02.004

⁸¹ Kuiper, H., Alley, C., Harris, Z., Kuiper Rauch, C., Robbins, M., Rodriguez, P., Tomczak, P., Urrutia, J., & Magar, V. (2024). Psychedelic public health: State of the field and implications for equity. Social science & medicine (1982), 357, 117134. https://doi.org/10.1016/j.socscimed.2024.117134

⁸² Vidriales, Arturo & Ovies, Diego. (2018). Psychedelic tourism in Mexico, a thriving trend. PASOS. Revista de Turismo y Patrimonio Cultural. 16. 1037-1050. 10.25145/j.pasos.2018.16.072.

⁸³ Evans, J., Aixalà, M., Anderson, B. T., Brennan, W., Bremler, R., Breeksema, J. J., Burback, L., Calder, A. E., Carhart-Harris, R. L., Cheung, K., Devenot, N., Gorman, I., Greń, J., Hendricks, P. S., Holoyda, B., Jacobs, E., Krecké, J., Kruger, D. J., Luke, D., Majić, T., ... Yaden, D. B. (2025). On Minimizing Risk and Harm in the Use of Psychedelics. Psychiatric research and clinical practice, 7(1), 4–8. https://doi.org/10.1176/appi.prcp.20240128

- v. The provision of misdemeanors and felonies for psilocybin possession can create lifetime barriers to education, employment, and the ability to raise and support a family. These risks might outweigh the direct risks of psilocybin for some.
- j. *Misidentification:* Foraging for wild mushrooms carries the risk of consuming poisonous species that may resemble psilocybin-containing varieties, potentially resulting in serious hepatotoxicity or nephrotoxicity requiring medical intervention. This risk increases with growing public interest in psychedelic mushrooms.
- k. *Drug interaction risks:* Combining psilocybin with other substances presents various concerns.⁸⁴
 - Alcohol: Increased nausea, disorientation, and impaired judgment
 - Cannabis: Intensified and potentially unpredictable effects⁸⁵
 - Stimulants: Increased cardiovascular stress and anxiety
- Public education and risk communication: As policy landscapes change, accurate public health messaging becomes essential to minimize harm, particularly regarding appropriate dosing and preparation, recognition and management of adverse reactions, contraindications and drug interactions, setting and supervision considerations, and differentiating therapeutic from recreational contexts.
- m. *Risks of unethical facilitation and psychological vulnerability:* The altered state produced by psilocybin creates unique interpersonal dynamics requiring ethical safeguards:
 - i. Facilitator misconduct: Documented cases in clinical trials, underground, and some ceremonial contexts reveal instances of sexual, emotional, and financial abuse of participants during their vulnerable psychedelic states and the aftermath. The heightened suggestibility and emotional openness during psilocybin experiences increases vulnerability to manipulation.^{86,87}

⁸⁴ Halman A, Kong G, Sarris J, Perkins D. Drug-drug interactions involving classic psychedelics: A systematic review. Journal of Psychopharmacology. 2023;38(1):3-18. doi:10.1177/02698811231211219

⁸⁵ Piercey, C.J., Hetelekides, E. & Karoly, H.C. Simultaneous cannabis and psychedelic use among festival and concert attendees in Colorado: characterizing enhancement and adverse reactions using mixed methods. J Cannabis Res 6, 29 (2024). https://doi.org/10.1186/s42238-024-00235-x

⁸⁶ Smith, W. R., & Appelbaum, P. S. (2022). Novel ethical and policy issues in psychiatric uses of psychedelic substances. Neuropharmacology, 216, 109165. https://doi.org/10.1016/j.neuropharm.2022.109165

⁸⁷ Kruger, D. J., Aday, J. S., Fields, C. W., Kolbman, N., Glynos, N., Barron, J., Herberholz, M., & Boehnke, K. F. (2025). Psychedelic Therapist Sexual Misconduct and Other Adverse Experiences Among a Sample of Naturalistic Psychedelic Users. Psychedelic medicine (New Rochelle, N.Y.), 3(1), 41–47. https://doi.org/10.1089/psymed.2024.0011

- ii. Power dynamics: The guide-participant relationship involves inherent power imbalances that can be exploited without proper ethical frameworks and oversight.
- iii. Undue influence: Individuals under the influence of psilocybin may be more susceptible to suggestion and manipulation, potentially enabling coercive behavior or inappropriate influence.⁸⁸
- iv. Cult-like dynamics: Charismatic leadership combined with psychedelic experiences has historically been associated with harmful group dynamics in certain contexts, as seen in some fringe spiritual groups in the 1960s-70s.
- v. Consent considerations: The altered state may compromise capacity for informed consent during the experience, necessitating clear advance directives and boundaries.⁸⁹
- n. *Policy implications:* Emerging regulated models increasingly incorporate ethical guidelines, facilitator screening, training requirements, supervision structures, and grievance mechanisms to address these concerns.⁹⁰
- o. *Microdosing considerations:* The practice of taking sub-psychedelic doses of psilocybin (typically 1/10 to 1/20 of a standard dose) on a regular schedule has gained popularity despite limited research:
 - i. Current evidence: Placebo-controlled studies are still in early phases and show mixed results, with some suggesting claimed benefits for mood, creativity, and focus may be largely attributable to expectancy effects⁹¹
 - ii. Prevalence: Nearly half (47%) of past-year psilocybin users reported microdosing on their last occasion of use.⁹²
 - iii. Methodological challenges: Self-experimentation and variable dosing complicate research interpretation

⁸⁸ Oliver, A., Wong, A., Chen, E., & Raz, A. (2024). Suggestibility and psychedelics: From therapeutics to social context. Psychology of Consciousness: Theory, Research, and Practice. Advance online publication. https://doi.org/10.1037/cns0000412

⁸⁹ Marks M, Brendel RW, Shachar C, Cohen IG. Essentials of Informed Consent to Psychedelic Medicine. JAMA Psychiatry. 2024;81(6):611–617. doi:10.1001/jamapsychiatry.2024.0184

⁹⁰ Belouin, S. J., Averill, L. A., Henningfield, J. E., Xenakis, S. N., Donato, I., Grob, C. S., Berger, A., Magar, V., Danforth, A. L., & Anderson, B. T. (2022). Policy considerations that support equitable access to responsible, accountable, safe, and ethical uses of psychedelic medicines. Neuropharmacology, 219, 109214. https://doi.org/10.1016/j.neuropharm.2022.109214

⁹¹ Savides, I. A., & Outhoff, K. (2024). Less is more? A review of psilocybin microdosing. Journal of psychopharmacology (Oxford, England), 38(10), 846–860.

- iv. Safety profile: While acute toxicity risks are reduced at low doses, the long-term safety of chronic, repeated exposure remains understudied⁹³
- v. Neurobiological effects: Sub-perceptual doses may affect neuroplasticity and receptor sensitivity through different mechanisms than full doses
- vi. Research gaps: Long-term effects on serotonin receptor systems, potential impacts on cardiovascular health (including heart valve disease) with chronic use, and optimal dosing protocols remain uncertain
- vii. Public health significance: Represents a distinct usage pattern requiring separate consideration in policy frameworks
- p. Different forms and preparations: Various preparations of psilocybin present different considerations:
 - i. Natural whole mushrooms: Contain variable concentrations of psilocybin (0.2-2%) and related compounds (psilocin, baeocystin, norbaeocystin) that may contribute to an "entourage effect" 4,95,96
 - ii. Fresh vs. dried mushrooms: Fresh contain higher levels of unstable psilocin but deteriorate rapidly; dried are more stable but lose some psilocin through oxidation. Fresh/dry has huge implications for dosing, as there is an approximately 10-fold difference in weight given that fresh mushrooms have high water content.
 - iii. Synthetic psilocybin: Used in clinical research for precise dosing and quality control; eliminates variability and contamination risks but lacks potentially active secondary compounds
 - iv. Extracts and concentrates: Offer more precise dosing than whole mushrooms but vary in preparation standards; concentrated forms may increase risks of overdosing compared to whole mushrooms
 - v. Psilocybin-infused products: Emerging in some markets with decriminalization; present challenges for dosage standardization and may normalize casual use⁹⁷

⁹³ Rouaud, A., Calder, A. E., & Hasler, G. (2024). Microdosing psychedelics and the risk of cardiac fibrosis and valvulopathy: Comparison to known cardiotoxins. Journal of psychopharmacology (Oxford, England), 38(3), 217–224. https://doi.org/10.1177/02698811231225609

⁹⁴ Sherwood, A. M., Halberstadt, A. L., Klein, A. K., McCorvy, J. D., Kaylo, K. W., Kargbo, R. B., & Meisenheimer, P. (2020). Synthesis and Biological Evaluation of Tryptamines Found in Hallucinogenic Mushrooms: Norbaeocystin, Baeocystin, Norpsilocin, and Aeruginascin. Journal of natural products, 83(2), 461–467. https://doi.org/10.1021/acs.jnatprod.9b01061

⁹⁵ Glatfelter, G. C., Pottie, E., Partilla, J. S., Sherwood, A. M., Kaylo, K., Pham, D. N. K., Naeem, M., Sammeta, V. R., DeBoer, S., Golen, J. A., Hulley, E. B., Stove, C. P., Chadeayne, A. R., Manke, D. R., & Baumann, M. H. (2022). Structure-Activity Relationships for Psilocybin, Baeocystin, Aeruginascin, and Related Analogues to Produce Pharmacological Effects in Mice. ACS pharmacology & translational science, 5(11), 1181–1196. https://doi.org/10.1021/acsptsci.2c00177

⁹⁶ Rakoczy, R. J., Runge, G. N., Sen, A. K., Sandoval, O., Wells, H. G., Nguyen, Q., Roberts, B. R., Sciortino, J. H., Gibbons, W. J. Jr, Friedberg, L. M., Jones, J. A., & McMurray, M. S. (2024). Pharmacological and behavioural effects of tryptamines present in psilocybin-containing mushrooms. British Journal of Pharmacology, 181(19), 3627–3641. https://doi.org/10.1111/bph.16466
⁹⁷ https://time.com/7032706/are-mushroom-edibles-safe-legal/

- vi. Policy implications: Different preparations may warrant different regulatory approaches regarding potency testing, labeling requirements, and access restrictions
- q. *Substance testing protocols:* Quality control and harm reduction through testing present unique considerations:
 - Testing methodologies:^{98,99}
 - Thin-layer chromatography (TLC): Field-deployable but less precise than laboratory methods
 - High-performance liquid chromatography (HPLC): Gold standard for psilocybin/psilocin quantification
 - Mass spectrometry: Essential for identifying adulterants and contaminants
 - Implementation challenges:
 - Limited infrastructure for consumer-accessible testing in most jurisdictions¹⁰⁰
 - Legal barriers to testing services in prohibition contexts
 - Lack of standardized protocols specific to psilocybin-containing mushrooms
 - Misidentification risks: Unlike synthetic compounds, mushroom identification requires mycological knowledge; testing typically confirms the presence of psilocybin but cannot identify toxic look-alikes
 - Testing needs: Unlike substances like MDMA that face significant adulteration risks, psilocybin mushrooms are rarely adulterated but benefit from potency testing due to natural variability
 - Regulatory considerations: States developing legal access programs must establish testing standards, particularly for commercial distribution

Psilocybin controls in Colorado; Decriminalization in Washington, D.C.

• In 2022, Colorado voters approved Proposition 122 to decriminalize certain natural psychedelic plants and fungi for adults 21+ and specifically listed psilocybin among the plant-based substances to be decriminalized.¹⁰¹ The measure also required the state to

https://outsource.contractlaboratory.com/psilocybin-potency-testing-ensuring-quality-and-safety-of-magic-mushrooms/#: \$\$ ``ctext=High \$\$ 2DPerformance \$\$ 20Liquid \$\$ 20Chromatography \$\$ 20(HPLC, Challenges \$\$ 20in \$\$ 20Psilocybin \$\$ 20Potency \$\$ 20Testing \$\$ \$\$ 20In \$\$ 20Psilocybin \$

⁹⁹ https://gentechscientific.com/methods-and-instruments-for-psilocybin-testing/

¹⁰⁰ Siegel, J. S., Daily, J. E., Perry, D. A., & Nicol, G. E. (2023). Psychedelic Drug Legislative Reform and Legalization in the US. JAMA psychiatry, 80(1), 77–83. https://doi.org/10.1001/jamapsychiatry.2022.4101

¹⁰¹ Natural Medicine Health Act of 2022, Colo. Const. art. XVIII, § 12 (2022). https://leg.colorado.gov/sites/default/files/initiative_text_2022_122.pdf

develop a regulated access program for psilocybin and authorizes further study/possible inclusion of other plant medicines. Proposition 122 was superseded and substantially revised by the legislature by S.B. 23-290, (Approved May 23, 2023), (with additional revisions by S.B. 24-198 (Approved June 6, 2024) which created a regulated access program for psilocybin and psilocin. The Department of Revenue (DOR) licenses and regulates natural medicine businesses — healing centers, cultivation entities, manufacturers, and testing facilities, and their owners and employees, pursuant to Colorado Revised Statutes (C.R.S.) Title 44, Article 50. The Department of Regulatory Agencies (DORA) licenses and regulates the facilitators of natural medicine pursuant to C.R.S. Title 12, Article 170. Colorado's program is to "sunset" on September 1, 2032, unless reauthorized (C.R.S. Sec. 44-50-1001).

• **Washington, D.C.** (**Initiative 81, 2020**): Initiative 81 directs local authorities to make enforcement of laws related to entheogenic plants (which explicitly include psilocybin) among their lowest priorities.^[105] Effective on March 16, 2021, this measure has decriminalized non-commercial personal cultivation, possession, and use of entheogenic plants in D.C., though it does not legalize them under federal law.

Conclusion

Psilocybin and psilocin are compounds of significant historical, cultural, and emerging therapeutic importance. Their primary mechanism of action through serotonin receptor agonism produces altered states of consciousness with potential therapeutic applications in mental health treatment. While generally demonstrating favorable physiological safety profiles, psychological risks exist, particularly for vulnerable populations. The regulatory landscape continues to evolve, with several states implementing various forms of decriminalization or regulated access programs. As research continues to expand our understanding of these compounds, evidence-based policy approaches that balance potential benefits with appropriate safeguards will be essential to maximize public health outcomes and minimize potential harms.

¹⁰² Ballotpedia. (2022). Colorado Proposition 122, Decriminalization and Regulated Access Program for Certain Psychedelic Plants and Fungi Initiative (2022). Ballotpedia.

https://ballotpedia.org/Colorado_Proposition_122%2C_Decriminalization_and_Regulated_Access_Program_for_Certain_Psychedelic_Pl ants and Fungi Initiative %282022%29

¹⁰³ https://leg.colorado.gov/sites/default/files/2023a_290_signed.pdf

¹⁰⁴ https://leg.colorado.gov/sites/default/files/2024a_198_signed.pdf

¹⁰⁵ Beaujon, A. (2021, March 15). Magic Mushrooms Are Decriminalized in DC as of Today. Washingtonian; Washingtonian Media Inc. https://www.washingtonian.com/2021/03/15/magic-mushrooms-are-decriminalized-in-dc-as-of-today/

Mescaline Monograph

Executive Summary

Mescaline is a naturally occurring psychedelic compound found primarily in several species of cacti, most famously in species of the *Lophophora* and *Echinopsis* genera. As a "classical" psychedelic, mescaline produces profound alterations in consciousness, perception, and cognition through its primary action as a serotonin receptor agonist. Mescaline has a long history of use in seminal medical contexts and indigenous ceremonial contexts and is one of the oldest hallucinogens with confirmed human consumption. With a relatively high therapeutic index and generally favorable safety profile, mescaline has attracted renewed scientific interest for potential therapeutic applications, albeit at a slower pace than other classical psychedelic compounds. Mescaline is currently designated a Schedule 1 controlled substance by the U.S. federal government, but recent years have seen significant policy reforms at the state level with several jurisdictions decriminalizing or creating regulated access pathways for these substances with varying outcomes. This monograph provides an evidence-based overview of mescaline and its medical, public health, ecological, and ethical considerations and is intended to inform Maryland state-level policy.

Botany/Plant Biology

Mescaline (3,4,5-trimethoxyphenethylamine) is naturally produced by several cacti species, most notably in the *Lophophora* and *Echinopsis* genera, although the exact number of species is unknown.^[106] Mescaline-containing cacti are distributed across North and South America, primarily in Southwestern desert scrub in the US and the Andean Mountains.^[107]

Mescaline concentration in cacti vary widely, with *Lophophora* species ranging between approximately 1% to 6% of dry weight and *Echinopsis* species ranging between 0.2% to 4.7%. ^[108] *Lophophora* species are slow-growing and vulnerable with a limited geographic range and, combined with overharvesting and habitat loss, has severely strained availability. In contrast,

¹⁰⁶ Trout, K. (2014) Cactus chemistry by species. http://sacredcacti.com (accessed August 29, 2025).

¹⁰⁷ Cassels, B. K., & Sáez-Briones, P. (2018). Dark Classics in Chemical Neuroscience: Mescaline. ACS chemical neuroscience, 9(10), 2448–2458. https://doi.org/10.1021/acschemneuro.8b00215

¹⁰⁸ Ogunbodede, O., McCombs, D., Trout, K., Daley, P., & Terry, M. (2010). New mescaline concentrations from 14 taxa/cultivars of Echinopsis spp. (Cactaceae) ("San Pedro") and their relevance to shamanic practice. Journal of ethnopharmacology, 131(2), 356–362. https://doi.org/10.1016/j.jep.2010.07.021

Echinopsis cacti grow more rapidly and are more commonly used in cultivation, presenting less ecological pressure.^[2]

The biosynthesis of mescaline in cacti involves the methylation of dopamine through specific enzymatic pathways. [109] Environmental factors including soil conditions, rainfall, and altitude significantly influence mescaline content, with stressed plants often producing higher concentrations. The compound serves as a natural defense mechanism against herbivores and pathogens. [110]

When mescaline is consumed in whole-cactus preparations, it is commonly accompanied with other bioactive alkaloids that are thought to modulate the experiential effects of mescaline. The companion alkaloids commonly found in *Lophophora* and *Echinopsis* species include pellotine, hordenine, and anhalinine.^[111] These minor alkaloids have heterogeneous pharmacology.

Ethnobotany and Historical Use

The entheogenic use of mescaline-containing cacti dates back millennia. Archaeological evidence reveals *Lophophora* cacti used in ritual contexts in Shumla Cave, Texas, dating between roughly 3780–3660 BCE.^[112] Indigenous communities such as the Huichol, Rarámuri, Tonkawa, Mescalero Apache, and members of the Native American Church have incorporated mescaline-containing cacti into religious and healing rites, often for spiritual communion and as a form of medicine.^[113]

Archaeological and iconographic evidence shows that San Pedro (*Echinopsis/Trichocereus* spp.) has been used ritually in the Andes for at least 3,000 years. ^[2] One of the earliest direct finds is a cactus specimen from the El Paraíso site near Lima, Peru, dated to around 2000 BCE, suggesting ceremonial use in the Late Preceramic period. Depictions in Cupisnique and Chavín art, such as

¹⁰⁹ Berman, P., de Haro, L. A., Cavaco, A. R., Panda, S., Dong, Y., Kuzmich, N., Lichtenstein, G., Peleg, Y., Harat, H., Jozwiak, A., Cai, J., Heinig, U., Meir, S., Rogachev, I., & Aharoni, A. (2024). The biosynthetic pathway of the hallucinogen mescaline and its heterologous reconstruction. Molecular plant, 17(7), 1129–1150. https://doi.org/10.1016/j.molp.2024.05.012

¹¹⁰ Lin, J., Yang, S., Ji, J., Xiang, P., Wu, L., & Chen, H. (2023). Natural or artificial: An example of topographic spatial distribution analysis of mescaline in cactus plants by matrix-assisted laser desorption/ionization mass spectrometry imaging. Frontiers in plant science, 14, 1066595. https://doi.org/10.3389/fpls.2023.1066595

¹¹¹ Vamvakopoulou, I. A., Narine, K. A. D., Campbell, I., Dyck, J. R. B., & Nutt, D. J. (2023). Mescaline: The forgotten psychedelic. Neuropharmacology, 222, 109294. https://doi.org/10.1016/j.neuropharm.2022.109294

¹¹² El-Seedi, H. R., De Smet, P. A., Beck, O., Possnert, G., & Bruhn, J. G. (2005). Prehistoric peyote use: alkaloid analysis and radiocarbon dating of archaeological specimens of Lophophora from Texas. Journal of ethnopharmacology, 101(1-3), 238–242. https://doi.org/10.1016/j.jep.2005.04.022

¹¹³ Jones, P. N. (2007). The Native American Church, Peyote, and Health: Expanding Consciousness for Healing Purposes. Contemporary Justice Review, 10(4), 411–425. https://doi.org/10.1080/10282580701677477

the "Stela of the Cactus Bearer" (~500 BCE), further illustrate the plant's central role in Andean religious traditions.^[114]

The isolation and identification of mescaline began with Arthur Heffter in 1897, who not only isolated the compound but also conducted early self-experiments, pioneering a new era in psychedelic pharmacology. Louis Lewin's taxonomic analysis of peyote (*Anhalonium lewinii*) further advanced botanical and toxicological understanding in the late 19th century. Clinical explorations continued into the early 20th century, including Kurt Beringer's influential monograph *Der Meskalinrausch*, which characterized mescaline intoxication as akin to "experimental psychosis" and informed later phenomenological models. However, psychedelic research was largely halted by mid-20th-century regulatory restrictions (pursuant to enactment of the Drug Abuse Control Amendments of 1965), despite early interest in therapeutic potential.

Mechanism of Action

Mescaline's psychoactive effects largely stem from its agonism at serotonin 5-HT₂A receptors, mirroring the action of other classic psychedelics. Upon ingestion, mescaline induces prolonged alterations in perception, emotional processing, and cognition. The duration in humans averages roughly 11 hours for high doses (e.g., 500 mg).^[119] Mescaline is less potent than psilocybin and DMT in terms of binding affinity to 5-HT₂A receptors, which may contribute to differences in activity profiles.^[120] Pharmacokinetic data indicate mescaline has a half-life of approximately six hours in humans, with mainly renal excretion of unchanged drug and oxidative metabolites.^[14] The temporal dissociation between peak blood levels and psychoactive effects suggests active or psychoactive participation of metabolites.

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¹¹⁴ Torres, C. M. (2008) Chavín's psychoactive pharmacopoeia: The iconographic evidence. In Chavín Art, Architecture and Culture (Conklin, W. J., and Quilter, J., Eds.), pp 237–257, Cotsen Institute of Archaeology, University of California, Los Ángeles, CA.

¹¹⁵ Heffter, A. (1898) Ueber Pellote. Beiträge zur chemischen und pharmakologischen Kenntniss der Cacteen. II. Mittheilung. Naunyn-Schmiedeberg's Arch. Pharmacol. 40, 385– 429, DOI: 10.1007/BF01825267.

¹¹⁶ Jay, M. (2021, April 30). A century of mescaline. Chacruna. https://chacruna.net/century_of_mescaline/

¹¹⁷ Roche, G. T. (1927). Der Meskalinrausch: Seine Geschichte und Erscheinungsweise.

¹¹⁸ Nichols, D. E., & Nichols, C. D. (2025). History of psychedelic drug science and molecular pharmacology. International review of neurobiology, 181, 3–43. https://doi.org/10.1016/bs.irn.2025.02.001

¹¹⁹ Dinis-Oliveira, R. J., Pereira, C. L., & da Silva, D. D. (2019). Pharmacokinetic and Pharmacodynamic Aspects of Peyote and Mescaline: Clinical and Forensic Repercussions. Current molecular pharmacology, 12(3), 184–194. https://doi.org/10.2174/1874467211666181010154139

¹²⁰ Ley, L., Holze, F., Arikci, D. et al. Comparative acute effects of mescaline, lysergic acid diethylamide, and psilocybin in a randomized, double-blind, placebo-controlled cross-over study in healthy participants. Neuropsychopharmacol. 48, 1659–1667 (2023). https://doi.org/10.1038/s41386-023-01607-2

Safety Profile and Public Health Considerations

A. Physical Health

Mescaline has demonstrated a relatively favorable physiological safety profile, similar to other classic serotonergic psychedelic substances, although research remains limited. Common side effects are hallucinations, nausea, emesis (vomiting), dizziness, increased heart rate and blood pressure, pupil dilation, and mild increases in body temperature, along with psychological effects such as anxiety, confusion, and perceptual distortions.^[121] These effects are typically transient and dose-dependent.

Toxicity: Mescaline has a wide safety margin compared to many psychoactive compounds. The estimated median lethal dose (LD₅₀) in humans is ~880 mg/kg (based on extrapolated animal data), meaning a fatal dose would be several hundred times higher than typical recreational or ceremonial use levels (~200–500 mg). [14] Death from mescaline toxicity alone is exceptionally rare, with few verified cases. [122][123] A 2023 double-blind, placebo-controlled safety trial administering up to 800 mg found no life-threatening effects, though participants experienced increasing adverse effects at higher doses (headache, nausea, anxiety). [16] This indicates a high therapeutic index, with toxicity risks mainly arising from misidentification of cactus species or co-ingestion with other substances.

Cardiovascular effects: Mescaline produces transient, dose-dependent increases in blood pressure and heart rate, with mild mydriasis (pupil dilation) and body temperature elevation. In healthy volunteers, systolic blood pressure increases of 10–20 mmHg were typical at doses >300 mg, though values returned to baseline within hours. ^{[16][124]} These effects pose limited risk in otherwise healthy adults but may be clinically significant in individuals with hypertension, arrhythmias, or ischemic heart disease. Unlike MDMA, mescaline does not appear to cause direct cardiotoxicity in human atrial tissue (no pro-arrhythmic or contractility changes). ^[125] However,

¹²¹ Klaiber, A., Humbert-Droz, M., Ley, L., Schmid, Y., & Liechti, M. E. (2024). Safety pharmacology of acute mescaline administration in healthy participants. British journal of clinical pharmacology, 10.1111/bcp.16349. Advance online publication. https://doi.org/10.1111/bcp.16349

¹²² Nolte, K. B., & Zumwalt, R. E. (1999). Fatal peyote ingestion associated with Mallory-Weiss lacerations. The Western journal of medicine, 170(6), 328.

¹²³ Reynolds, P. C., & Jindrich, E. J. (1985). A mescaline associated fatality. Journal of analytical toxicology, 9(4), 183–184. https://doi.org/10.1093/jat/9.4.183

¹²⁴ Speck L. B. (1957). Toxicity and effects of increasing doses of mescaline. The Journal of pharmacology and experimental therapeutics, 119(1), 78–84.

¹²⁵ Neumann, J., Azatsian, K., Höhm, C. et al. Cardiac effects of ephedrine, norephedrine, mescaline, and 3,4-methylenedioxymethamphetamine (MDMA) in mouse and human atrial preparations. Naunyn-Schmiedeberg's Arch Pharmacol 396, 275–287 (2023). https://doi.org/10.1007/s00210-022-02315-2

animal studies show varying cardiopulmonary effects per species, with very high injected doses induced bradycardia and respiratory depression. [19][126][127]

Hepatic effects: Mescaline undergoes oxidative metabolism in the liver, primarily via monoamine oxidase (MAO).^[14] No evidence suggests clinically significant hepatotoxicity or persistent alterations in liver function tests after acute use.^[16] Unlike MDMA or synthetic cathinones, mescaline does not appear to induce hepatocellular injury.

Neurological effects: Mescaline does not appear to be neurotoxic in humans. Preclinical evidence suggests possible modulation of neuroplasticity through serotonin 5-HT₂A receptor signaling, although data are far more limited than for psilocybin or LSD. [128] Literature reviews suggest that classical psychedelics alone (including mescaline) do not increase the risk of seizures. [129]

Teratogenicity and reproductive health: Human data on mescaline in pregnancy or breastfeeding are lacking due to ethical and legal restrictions, though there is some evidence of indigenous cultures including pregnant women, breastfeeding women, and children in mescaline-related rituals. Animal studies at high doses show no consistently measurable teratogenic effects, though fetal growth restriction and altered neurodevelopment have been reported in some rodent models. Although limited, some evidence links mescaline to impaired fertility or reproductive harm.

Gastrointestinal effects: Nausea and vomiting are among the most common acute adverse effects of mescaline, especially in naturalistic "whole-plant" ceremonial settings where ingestion involves fibrous plant material. These effects are partly due to mescaline's serotonergic

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¹²⁶ Orzechowski, R. F., & Goldstein, F. J. (1973). Species variation in blood pressure responses to mescaline: evidence of histamine release. Toxicology and applied pharmacology, 25(4), 525–533. https://doi.org/10.1016/0041-008x(73)90021-5

¹²⁷ De Paul Lynch, V., Clemente, E., & Carson, S. (1967). Effect of mescaline on cardiopulmonary dynamics. Method for determination of right ventricular pressure in the guinea pig. Journal of pharmaceutical sciences, 56(4), 477–483. https://doi.org/10.1002/jps.2600560411

¹²⁸ Agnorelli, C., Spriggs, M., Godfrey, K., Sawicka, G., Bohl, B., Douglass, H., Fagiolini, A., Parastoo, H., Carhart-Harris, R., Nutt, D., & Erritzoe, D. (2025). Neuroplasticity and psychedelics: A comprehensive examination of classic and non-classic compounds in pre and clinical models. Neuroscience and biobehavioral reviews, 172, 106132. https://doi.org/10.1016/j.neubiorev.2025.106132

¹²⁹ Soto-Angona, Ó., Fortea, A., Fortea, L., Martínez-Ramírez, M., Santamarina, E., López, F. J. G., Knudsen, G. M., & Ona, G. (2024). Do classic psychedelics increase the risk of seizures? A scoping review. European neuropsychopharmacology: the journal of the European College of Neuropsychopharmacology, 85, 35–42. https://doi.org/10.1016/j.euroneuro.2024.05.002

¹³⁰ Schaefer, S. (2019, April 18). Beautiful Flowers: Women and Peyote in Indigenous Traditions. Multidisciplinary Association for Psychedelic Studies - MAPS.

https://maps.org/news/bulletin/beautiful-flowers-women-and-peyote-in-indigenous-traditions-spring-2019/

¹³¹ Meyer, S. (2011, May 24). Should I Use Peyote If I Am Pregnant Or Breastfeeding? Native Mothering[TM].

https://nativemothering.com/2011/05/should-i-use-peyote-if-i-am-pregnant-or-breastfeeding/

¹³² Hirsch, K. S., & Fritz, H. I. (1981). Teratogenic effects of mescaline, epinephrine, and norepinephrine in the hamster. Teratology, 23(3), 287–291. https://doi.org/10.1002/tera.1420230302

¹³³ Gilmore H. T. (2001). Peyote use during pregnancy. South Dakota journal of medicine, 54(1), 27–29.

stimulation of the gut as well as bitter alkaloid content in the cactus tissue.^[6] Controlled studies administering pure mescaline also report moderate nausea, though vomiting is less frequent.^[16]

B. Mental Health

The psychological effects of psilocybin present both risks and potential benefits:

Psychological effects: Mescaline reliably produces a range of acute psychological effects (alterations in perception, mood, thought content, and sense of self) that are qualitatively similar to other classic psychedelics but with some distinct features. Visual phenomena are particularly prominent with mescaline; users commonly report intensified colors or altered color perception, geometric form-constants (e.g., "cobweb," spiral, chessboard patterns), complex closed-eye imagery, and synesthesia-like cross-modal experiences (e.g., "seeing" sound or "hearing" color). [6] These perceptual changes often co-occur with enhanced emotionality, introspective insight, and transient changes in time perception and self-boundaries. The intensity and qualitative character of these experiences are dose-dependent and strongly modulated by expectation and context. [134]

Common acute subjective side effects include anxiety, confusion, transient paranoia, and panic during the peak of effects; these typically resolve within hours but can be distressing for some individuals. In naturalistic surveys, many users also report enduring positive changes in well-being, meaning, and psychosocial functioning following mescaline experiences.^[135]

Importance of preparation: Evidence across classic-psychedelic research shows that the person's mindset (set) and the physical and social surroundings (setting) are powerful determinants of psychological outcomes. Structured preparation (including screening for psychiatric risk factors, discussing intentions, and setting expectations) and a supportive environment with trained facilitators markedly reduce the frequency and severity of acute distress and adverse behavioral responses. [136] Research protocols for psychedelic-assisted therapy universally emphasize pre-session preparation, in-session monitoring, and post-session integration to maximize safety and therapeutic value; the same principles apply to mescaline.

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¹³⁴ Uthaug, M. V., Davis, A. K., Haas, T. F., Davis, D., Dolan, S. B., Lancelotta, R., Timmermann, C., & Ramaekers, J. G. (2022). The epidemiology of mescaline use: Pattern of use, motivations for consumption, and perceived consequences, benefits, and acute and enduring subjective effects. Journal of psychopharmacology (Oxford, England), 36(3), 309–320. https://doi.org/10.1177/02698811211013583

Agin-Liebes, G., Haas, T. F., Lancelotta, R., Uthaug, M. V., Ramaekers, J. G., & Davis, A. K. (2021). Naturalistic Use of Mescaline Is Associated with Self-Reported Psychiatric Improvements and Enduring Positive Life Changes. ACS pharmacology & translational science, 4(2), 543–552. https://doi.org/10.1021/acsptsci.1c00018

¹³⁶ Borkel, L. F., Rojas-Hernández, J., Henríquez-Hernández, L. A., Santana Del Pino, Á., & Quintana-Hernández, D. J. (2024). Set and setting predict psychopathology, wellbeing and meaningfulness of psychedelic experiences: a correlational study. Expert review of clinical pharmacology, 17(2), 165–176. https://doi.org/10.1080/17512433.2023.2295997

Conversely, unsupervised use in chaotic or unsafe settings is associated with higher rates of panic, disorientation, and post-use distress.^[137]

Psychosis and psychotic-spectrum risk: Mescaline was among the first psychedelics studied as a pharmacological model for psychosis in the early 20th century, as its perceptual and thought disturbances were seen to resemble acute schizophrenia. Subsequent clinical studies administering mescaline to individuals with schizophrenia generally reported either no improvement or worsening of symptoms, reinforcing the caution against use in this population. Current evidence suggests that persistent psychedelic-induced psychosis is rare in the general population, but case reports confirm that mescaline and related hallucinogens can precipitate prolonged or recurrent psychotic episodes in vulnerable individuals. Accordingly, treatment programs and research protocols exclude people with personal or family histories of schizophrenia, schizoaffective disorder, or related psychotic-spectrum illnesses.

Mania and mood-disorder spectrum considerations: Case reports and observational data indicate that classic psychedelics can precipitate manic episodes in susceptible individuals (e.g., those with bipolar disorder or undiagnosed bipolar spectrum vulnerability). There are few mescaline-specific controlled data. A recent small clinical trial administered a classical psychedelic (psilocybin) to Bipolar II patients without any instigation of manic episodes, and with a significant reduction in depressive symptoms. However, the risk of manic episode instigation by mescaline or other psychedelics cannot be ruled out.

Hallucinogen-Persisting Perception Disorder (HPPD) and "flashbacks": HPPD is a set of persistent, distressing visual disturbances following hallucinogen exposure and remains a recognized but uncommon complication associated with classic and atypical psychedelics.

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¹³⁷ Pilecki, B., Luoma, J. B., Bathje, G. J., Rhea, J., & Narloch, V. F. (2021). Ethical and legal issues in psychedelic harm reduction and integration therapy. Harm reduction journal, 18(1), 40. https://doi.org/10.1186/s12954-021-00489-1

¹³⁸ Hermle, L., Fünfgeld, M., Oepen, G., Botsch, H., Borchardt, D., Gouzoulis, E., Fehrenbach, R. A., & Spitzer, M. (1992). Mescaline-induced psychopathological, neuropsychological, and neurometabolic effects in normal subjects: experimental psychosis as a tool for psychiatric research. Biological psychiatry, 32(11), 976–991. https://doi.org/10.1016/0006-3223(92)90059-9

¹³⁹ Halberstadt, A. L., & Geyer, M. A. (2013). Serotonergic hallucinogens as translational models relevant to schizophrenia. The international journal of neuropsychopharmacology, 16(10), 2165–2180. https://doi.org/10.1017/S1461145713000722 ¹⁴⁰ Denber, H.C.B., Merlis, S. Studies on mescaline I. Action in schizophrenic patients. Psych Quar 29, 421–429 (1955).

¹⁴⁰ Denber, H.C.B., Merlis, S. Studies on mescaline I. Action in schizophrenic patients. Psych Quar 29, 421–429 (1955). https://doi.org/10.1007/BF01567467

¹⁴¹ Sabé, M., Sulstarova, A., Glangetas, A., De Pieri, M., Mallet, L., Curtis, L., Richard-Lepouriel, H., Penzenstadler, L., Seragnoli, F., Thorens, G., Zullino, D., Preller, K., Böge, K., Leucht, S., Correll, C. U., Solmi, M., Kaiser, S., & Kirschner, M. (2025). Reconsidering evidence for psychedelic-induced psychosis: an overview of reviews, a systematic review, and meta-analysis of human studies. Molecular psychiatry, 30(3), 1223–1255. https://doi.org/10.1038/s41380-024-02800-5

¹⁴² Bosch, O. G., Halm, S., & Seifritz, E. (2022). Psychedelics in the treatment of unipolar and bipolar depression. International journal of bipolar disorders, 10(1), 18. https://doi.org/10.1186/s40345-022-00265-5

¹⁴³ Aaronson ST, van der Vaart A, Miller T, et al. Single-Dose Synthetic Psilocybin With Psychotherapy for Treatment-Resistant Bipolar Type II Major Depressive Episodes: A Nonrandomized Open-Label Trial. JAMA Psychiatry. 2024;81(6):555–562. doi:10.1001/jamapsychiatry.2023.4685

Recent surveys and observational studies report a range of transient "flashback" phenomena in a minority of users and estimate clinically significant HPPD at relatively low prevalence (studies vary, with clinically impairing HPPD appearing in a small percentage of lifetime users). [144] Visual symptoms reported include intensified colors, positive afterimages, trailing, and visual snow; anxiety and dissociative symptoms commonly co-occur. [37] A small study showed that a smaller percentage of individuals treated with mescaline experienced "flashbacks" than those who were treated with psilocybin or LSD. [16]

Reviews suggest that repeated heavy use, pre-existing anxiety, and polysubstance use increase risk, although HPPD can follow a single exposure in some cases.^[145] Management is primarily supportive; some pharmacologic interventions have been trialed with limited and variable success.

Potential benefits and clinical research findings: Robust epidemiological, meta-analytic, and randomized controlled trials of mescaline for psychiatric disorders are currently lacking. However, naturalistic survey data and some small open-label trials indicate that many mescaline-experienced users report sustained improvements in depression, anxiety, PTSD symptoms, and problematic alcohol use following ceremonial or therapeutic use. There is also some evidence to suggest that mescaline, like MDMA, has prosocial effects perhaps mediated through increased plasma oxytocin. Contemporary clinical interest has prompted escalating research activity, but high-quality mescaline trials addressing efficacy, optimal psychotherapeutic integration, and safety in clinical populations remain an unmet need. In the Native American Church, there is a widespread view that worship with peyote can support recovery from alcoholism and substance use disorders. The properties are currently lacking.

Possible long-term risks: Long-term adverse outcomes appear to be infrequent but include persistent perceptual disturbances (HPPD), protracted anxiety or mood dysregulation in a minority of users, and, rarely, protracted psychotic syndromes in individuals with underlying vulnerability.^[148] Observational cohort work among sacramental cacti users (e.g., Native American Church members) historically found no evidence of cognitive decline and in some cases noted

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¹⁴⁴ Halpern, J. H., Lerner, A. G., & Passie, T. (2018). A Review of Hallucinogen Persisting Perception Disorder (HPPD) and an Exploratory Study of Subjects Claiming Symptoms of HPPD. Current topics in behavioral neurosciences, 36, 333–360. https://doi.org/10.1007/7854_2016_457

¹⁴⁵ Zhou, K., de Wied, D., Carhart-Harris, R. L., & Kettner, H. (2025). Prediction of hallucinogen persisting perception disorder and thought disturbance symptoms following psychedelic use. PNAS nexus, 4(4), pgae560. https://doi.org/10.1093/pnasnexus/pgae560 ¹⁴⁶ Jones, G., Lipson, J. & Wang, E. Examining associations between MDMA/ecstasy and classic psychedelic use and impairments in social functioning in a U.S. adult sample. Sci Rep 13, 2466 (2023). https://doi.org/10.1038/s41598-023-29763-x

¹⁴⁷ Blum, K., Futterman, S. F. L., & Pascarosa, P. (1977). Peyote, a Potential Ethnopharmacologic Agent for Alcoholism and Other Drug Dependencies: Possible Biochemical Rationale. Clinical Toxicology, 11(4), 459–472. https://doi.org/10.3109/15563657708988210] ¹⁴⁸ Aday, J. S., Mitzkovitz, C. M., Bloesch, E. K., Davoli, C. C., & Davis, A. K. (2020). Long-term effects of psychedelic drugs: A systematic review. Neuroscience and biobehavioral reviews, 113, 179–189. https://doi.org/10.1016/j.neubiorev.2020.03.017

psychosocial benefits.^[149] High-quality, long-term, prospective data for mescaline specifically are limited, but reviews of psychedelics generally suggest enduring positive changes overall.

C. At-Risk Populations

Certain populations may face elevated risks from mescaline use:

Pregnant and lactating individuals: Data on mescaline exposure during pregnancy and lactation are extremely limited and largely observational or anecdotal. Historical and case-report literature has raised concerns about fetal effects associated with mescaline exposure in pregnancy, and clinical guidance advises avoidance due to possible teratogenic or developmental risks and the absence of controlled safety data. [26][24] As with most psychoactive compounds, the prudent recommendation is to avoid mescaline while pregnant or breastfeeding because of potential transfer into breast milk and unknown effects in utero. [150]

Children and adolescents: Adolescents' and children's neurodevelopment render them a vulnerable group for psychoactive drug exposures; classic psychedelics have the potential to influence ongoing neurodevelopmental processes but empirical data on mescaline use in minors are sparse. Neuroplasticity and neurodevelopmental processes continue through adolescence and early adulthood, and the impact of psychedelic compounds, including mescaline, on these processes remains understudied risk.^[151] Current treatment programs and research protocols restrict participants to those who are 18 or 21 years or older.

Older adults: Older adults often have comorbidities and polypharmacy that may increase risk during psychedelic exposure. Emerging prospective cohort and clinical work suggests that older adults may experience attenuated subjective intensity but still face physiologic risks (e.g., cardiovascular) and adverse drug interactions. Conversely, available epidemiological research suggests that older adults may benefit from psychedelic treatment and reap benefits in the domains of mood, attention, and memory. Overall, age alone is not an absolute contraindication, but individualized medical assessment (cardiac, hepatic, renal function; medication review) is essential.

¹⁴⁹ Halpern, J. H., Sherwood, A. R., Hudson, J. I., Yurgelun-Todd, D., & Pope, H. G., Jr (2005). Psychological and cognitive effects of long-term peyote use among Native Americans. Biological psychiatry, 58(8), 624–631. https://doi.org/10.1016/j.biopsych.2005.06.038

¹⁵⁰ Allitt, M. (2025, February 28). Psychedelics and Breastfeeding. Hystelica. https://hystelica.com/psychedelics-breastfeeding

¹⁵¹ Bates, M. L. S., & Trujillo, K. A. (2021). Use and abuse of dissociative and psychedelic drugs in adolescence. Pharmacology, biochemistry, and behavior, 203, 173129. https://doi.org/10.1016/j.pbb.2021.173129

¹⁵² Fearn, K., & Bhattacharyya, K. K. (2024). Is Use of Psychedelic Drugs a Risk or Protective Factor for Late-Life Cognitive Decline?. Gerontology & geriatric medicine, 10, 23337214241250108. https://doi.org/10.1177/23337214241250108

¹⁵³ Kettner, H., Roseman, L., Gazzaley, A., Carhart-Harris, R. L., & Pasquini, L. (2024). Effects of Psychedelics in Older Adults: A Prospective Cohort Study. The American journal of geriatric psychiatry: official journal of the American Association for Geriatric Psychiatry, 32(9), 1047–1059. https://doi.org/10.1016/j.jagp.2024.05.007

People with psychotic-spectrum disorders and/or family history of psychosis: A consistent precaution across psychedelic research is exclusion of individuals with schizophrenia, schizoaffective disorder, or a first-degree family history of psychotic disorders, due to the potential for psychedelics to precipitate or exacerbate psychotic symptoms in vulnerable people. Systematic reviews indicate that persistent psychedelic-induced psychosis is rare at the population level but occurs more often in people with pre-existing vulnerability.^[34] Mescaline has historically been used in experimental psychiatric work to model psychosis, further supporting caution in this group.^[31]

People with certain personality disorders and/or severe emotional dysregulation: People with uncontrolled personality disorders or severe emotional dysregulation may be at higher risk of destabilization after intense psychedelic experiences, particularly when supports for integration are lacking. No studies have investigated the use of mescaline specifically for treating personality disorders, and clinical trials typically exclude individuals with these conditions due to potential risks. However, there is extant historical and observational literature that suggests classical psychedelics, including mescaline, may offer benefits and pose unique risks. 155]

People with seizure disorders or lowered seizure threshold: Systematic reviews of psychedelics and seizures identify a small but non-zero risk; intracranial recording case reports document seizure exacerbation tied to psychedelic use. ^[156] Co-administration with certain drugs (e.g., lithium) may further increase seizure risk. ^[157] Caution is warranted for people with epilepsy or a prior history of unexplained seizures. ^[158]

People with cardiovascular disease or uncontrolled hypertension: Mescaline produces dose-related increases in blood pressure and heart rate; recent controlled human data document systolic and diastolic elevations at doses >100 mg and dose-proportional

¹⁵⁴ Carrithers, B. M., Roberts, D. E., Weiss, B. M., King, J. D., Carhart-Harris, R. L., Gordon, A. R., Pagni, B. A., Moreau, M., Ross, S., & Zeifman, R. J. (2025). Exploring serotonergic psychedelics as a treatment for personality disorders. Neuropharmacology, 272, 110413. https://doi.org/10.1016/j.neuropharm.2025.110413

¹⁵⁵ Blay, M., Benmakhlouf, I., & Speranza, M. (2025). Could psychedelics be useful in the treatment of patients with personality disorder? A case report of psychotherapy with concomitant use of psychedelics. Psychiatry Research Case Reports, 4(1), Article 100245. https://doi.org/10.1016/j.psycr.2025.100245

¹⁵⁶ Blond, B. N., & Schindler, E. A. D. (2023). Case report: Psychedelic-induced seizures captured by intracranial electrocorticography. Frontiers in neurology, 14, 1214969. https://doi.org/10.3389/fneur.2023.1214969

¹⁵⁷ Nayak, S. M., Gukasyan, N., Barrett, F. S., Erowid, E., Erowid, F., & Griffiths, R. R. (2021). Classic Psychedelic Coadministration with Lithium, but Not Lamotrigine, is Associated with Seizures: An Analysis of Online Psychedelic Experience Reports. Pharmacopsychiatry, 54(5), 240–245. https://doi.org/10.1055/a-1524-2794

¹⁵⁸ Freidel, N., Kreuder, L., Rabinovitch, B. S., Chen, F. Y., Huang, R. S. T., & Lewis, E. C. (2024). Psychedelics, epilepsy, and seizures: a review. Frontiers in pharmacology, 14, 1326815. https://doi.org/10.3389/fphar.2023.1326815

tachycardia. [16][159] These hemodynamic effects can pose risks for individuals with ischemic heart disease, significant arrhythmias, recent myocardial infarction, or poorly controlled hypertension. Pre-screening with focused cardiovascular assessment is standard in clinical trial settings.

People taking certain medications (known contraindicated or cautionary drug classes):

- MAOIs (monoamine oxidase inhibitors): Less is known about the combinatory effects of MAOI compounds with mescaline specifically, but users should take special caution given elevated toxicity risk and potentiation of MAOIs with other psychedelics (namely, tryptamines). Whether MAOIs interact with mescaline remains a controversial issue in the scientific community^[14], though there is evidence to suggest that MAOIs combined with other phenethylamines lead to behavioral changes in primates^[160] and that humans have combined MAOI-containing plants with mescaline to produce "peyohuasca" with the intention of producing a synergistic effect. [161] Combining MAOIs with phenethylamines may unpredictably potentiate psychoactive and sympathomimetic effects and increase cardiovascular risk.
- **SSRIs/SNRIs and other serotonergic antidepressants:** Chronic SSRI/SNRI use may blunt acute subjective psychedelic effects and presents theoretical, but rare, risk of serotonin syndrome with polypharmacy. [162] More practically, antidepressant co-use complicates dosing and psychological response; many trial protocols require washout or stabilization.
- **Lithium:** Case reports indicate lithium co-administration with classic psychedelics is associated with serious adverse events, including seizures; concurrent use should be avoided.^[49]
- **Antipsychotics:** These agents (especially those that block 5-HT₂A receptors) will blunt or antagonize psychedelic effects^[56]; some first-generation antipsychotics may paradoxically worsen certain reactions.^[163] Coadministration of mescaline with antipsychotics should generally be avoided given the potential for potentiated effects or exacerbated negative

¹⁵⁹ Klaiber, A., Schmid, Y., Becker, A. M., Straumann, I., Erne, L., Jelusic, A., Thomann, J., Luethi, D., & Liechti, M. E. (2024). Acute dose-dependent effects of mescaline in a double-blind placebo-controlled study in healthy subjects. Translational psychiatry, 14(1), 395. https://doi.org/10.1038/s41398-024-03116-2

¹⁶⁰ Staub, R. A., Gillin, J. C., & Wyatt, R. J. (1980). Monoamine oxidase inhibitors potentiate phenylethylamine effects in rhesus monkeys. Biological psychiatry, 15(3), 429–436.

¹⁶¹ Ott, J. (1996, Summer). Pharmahuasca: On phenethylamines and potentiation. Newsletter of the Multidisciplinary Association for Psychedelic Studies, 6(3), 32–34. https://maps.org/news-letters/v06n3/06332ott.html

Halman, A., Kong, G., Sarris, J., & Perkins, D. (2024). Drug-drug interactions involving classic psychedelics: A systematic review. Journal of psychopharmacology (Oxford, England), 38(1), 3–18. https://doi.org/10.1177/02698811231211219

¹⁶³ Shah, N. S., Jacobs, J. R., Jones, J. T., & Hedden, M. P. (1975). Interaction of mescaline with phenothiazines: effect on behavior, body temperature, and tissue levels of hallucinogen in mice. Biological psychiatry, 10(5), 561–573.

reactions, particularly as antipsychotics target several receptors that overlap with mescaline. [164]

- **Certain analgesics (e.g., tramadol) and drugs that lower seizure threshold:** These may increase seizure risk during psychedelic exposure. [165]
- Alpha blockers/Beta blockers: While there is limited data on combining adrenergic drugs with mescaline, caution is warranted given the potential to modulate the known cardiovascular effects of mescaline. Coadministration could lead to swings in blood pressure, arrhythmias, and/or cardiovascular stress. Early research suggests beta blockers may aid in reducing cardiovascular effects from other psychedelics. [166]
- Sympathomimetics/Stimulants/Drugs that affect cardiovascular system:
 Vasoconstrictors, some cold/allergy meds with sympathomimetic activity, certain
 decongestants, ADHD stimulant medications, and other similar drugs should not be taken
 with mescaline given mescaline's known effects on the cardiovascular system.
 Coadministration of stimulants with psychedelic compounds could lead to dangerous
 elevations in blood pressure including hypertensive crisis, tachycardia, and cardiovascular
 strain.^[167]

D. Public Health

Overall level of harm: Classic serotonergic psychedelics (LSD, psilocybin, mescaline) consistently rank low on indices of physical harm, dependence liability, and social harm compared with alcohol, opioids, and stimulants. [168][169] Mescaline's acute physiological risks in controlled settings appear modest, with recent double-blind trials up to 800 mg in healthy adults showing transient, dose-related increases in heart rate and blood pressure and no serious

¹⁶⁴ Mahmood, D., Alenezi, S. K., Anwar, M. J., Azam, F., Qureshi, K. A., & Jaremko, M. (2022). New Paradigms of Old Psychedelics in Schizophrenia. Pharmaceuticals (Basel, Switzerland), 15(5), 640. https://doi.org/10.3390/ph15050640

¹⁶⁵ Monaco, F., & Cicolin, A. (1999). Interactions between anticonvulsant and psychoactive drugs. Epilepsia, 40 Suppl 10, S71–S76. https://doi.org/10.1111/j.1528-1157.1999.tb00888.x

¹⁶⁶ Kargbo, R. B. (2025). Reducing cardiovascular side effects of DMT using beta-blockers. ACS Medicinal Chemistry Letters, 16(5), 743–745. https://doi.org/10.1021/acsmedchemlett.5c00180

¹⁶⁷ Barnett, B. S., Koons, C. J., Van den Eynde, V., Gillman, P. K., & Bodkin, J. A. (2024). Hypertensive Emergency Secondary to Combining Psilocybin Mushrooms, Extended Release Dextroamphetamine-Amphetamine, and Tranylcypromine. Journal of Psychoactive Drugs, 57(3), 297–303. https://doi.org/10.1080/02791072.2024.2368617

¹⁶⁸ Nutt, D. J., King, L. A., Phillips, L. D., & Independent Scientific Committee on Drugs (2010). Drug harms in the UK: a multicriteria decision analysis. Lancet (London, England), 376(9752), 1558–1565. https://doi.org/10.1016/S0140-6736(10)61462-6

¹⁶⁹ Schlag, A. K., Aday, J., Salam, I., Neill, J. C., & Nutt, D. J. (2022). Adverse effects of psychedelics: From anecdotes and misinformation to systematic science. Journal of psychopharmacology (Oxford, England), 36(3), 258–272. https://doi.org/10.1177/02698811211069100

adverse events; challenging experiences and anxiety were the most common adverse effects reported and typically resolved without medical intervention.^[53]

Prevalence of use: Mescaline use remains uncommon relative to other hallucinogens. A large 2022 international survey of naturalistic mescaline users (N = 452) found most participants had used mescaline fewer than ten times in their lives.^[29] U.S. household data generally aggregate many hallucinogens, but indicate rising hallucinogen use overall since ~2010, with mescaline likely a small fraction of that total.^{[170][171]}

Abuse and dependence potential: Mescaline does not produce physiological withdrawal and rapidly induces tolerance that deters daily use, features linked to low dependence liability.^[29] As with other psychedelics, there is some evidence to suggest that mescaline treatment may reduce alcohol and substance abuse and misuse.^{[172][173]}

Driving impairment and DUI concerns: Like other hallucinogens, mescaline can substantially impair attention, time perception, reaction time, visuospatial processing, and risk appraisal during acute intoxication rendering driving unsafe.^[174]

Emergency department (ED) visits and unintentional ingestion: ED presentations related to classic psychedelics are uncommon relative to alcohol and stimulants but do occur. Most often, ED visits are due to acute anxiety or panic, confusion/disorientation, agitation, tachycardia and/or hypertension, nausea/vomiting, or polysubstance use. Contemporary U.S. claims analyses show rising hallucinogen-related service use since the early 2010s; mescaline-specific counts are small but present in poison-center datasets and observational surveys. Harm reduction (trusted sitter/guide, safe setting, hydration, avoidance of dangerous environments,

¹⁷⁰ Substance Abuse and Mental Health Services Administration (US); Office of the Surgeon General (US). Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health [Internet]. Washington (DC): US Department of Health and Human Services; 2016 Nov. [Table], Mescaline (Peyote) Available from: https://www.ncbi.nlm.nih.gov/books/NBK424847/table/appd.t10/ Shalit, N., Rehm, J., & Lev-Ran, S. (2019). Epidemiology of hallucinogen use in the U.S. results from the National epidemiologic

survey on alcohol and related conditions III. Addictive behaviors, 89, 35–43. https://doi.org/10.1016/j.addbeh.2018.09.020 live Albaugh, B. J., & Anderson, P. O. (1974). Peyote in the treatment of alcoholism among American Indians. The American journal of psychiatry, 131(11), 1247–1250. https://doi.org/10.1176/ajp.131.11.1247

¹⁷³ Calleja-Conde, J., Morales-García, J. A., Echeverry-Alzate, V., Bühler, K. M., Giné, E., & López-Moreno, J. A. (2022). Classic psychedelics and alcohol use disorders: A systematic review of human and animal studies. Addiction biology, 27(6), e13229. https://doi.org/10.1111/adb.13229

¹⁷⁴ Salas-Wright, C. P., Cano, M., Hodges, J., Oh, S., Hai, A. H., & Vaughn, M. G. (2021). Driving while under the influence of hallucinogens: Prevalence, correlates, and risk profiles. Drug and alcohol dependence, 228, 109055. https://doi.org/10.1016/j.drugalcdep.2021.109055

¹⁷⁵ Simon, M. W., Olsen, H. A., Hoyte, C. O., Black, J. C., Reynolds, K. M., Dart, R. C., & Monte, A. A. (2024). Clinical Effects of Psychedelic Substances Reported to United States Poison Centers: 2012 to 2022. Annals of emergency medicine, 84(6), 605–618. https://doi.org/10.1016/j.annemergmed.2024.06.025

¹⁷⁶ Carstairs, S. D., & Cantrell, F. L. (2010). Peyote and mescaline exposures: a 12-year review of a statewide poison center database. Clinical toxicology (Philadelphia, Pa.), 48(4), 350–353. https://doi.org/10.3109/15563650903586745

and avoiding mixing with alcohol/stimulants) reduces ED risk. Public interest in "mescaline cacti" may occasionally lead to misidentification, unsafe foraging, or ingestion of ornamental cacti/unknown plant material. While most cacti are not lethally toxic, mistaken ingestion may cause GI distress or exposure to irritant compounds.

Pediatric access and exposures: Pediatric mescaline consumption is rare; most reported events to poison control centers involve unintentional exposures to peyote or cacti teas or ingestion of plant material at home. Children are likely disincentivized to consume raw plant material to its pronounced bitter taste. Intentional mescaline use among adolescents is also rare and much lower than that of other hallucinogenic drugs. Some children and adolescents in the Native American Church community may take part in religious ceremonies incorporating mescaline-containing cacti, but this is typically done with intention and in early adolescent or pre-teen years. Though uncommon, accidental ingestion is possible and can lead to adverse health effects including gastrointestinal upset and tachycardia; mescaline-containing plant material should be securely stored out of the reach of children.

Mescaline use and aggression or violence: Epidemiologic data do not indicate that classic psychedelic use is associated with elevated interpersonal violence and in fact may have a protective effect.^[181] Population-level analyses also suggest classic psychedelic exposure is not associated with increased criminal violence, and in some analyses correlates with lower odds of certain criminal behaviors, though causality cannot be inferred.^{[182][183]}

(**Recreational**) **drug interaction risks:** Mescaline polypharmacy is less studied than other well-known psychedelic and psychiatric drugs, but coadministration with other illicit substances still pose a theoretical risk:

¹⁷⁷ Bronstein, A. C., Spyker, D. A., Cantilena, L. R., Green, J. L., Rumack, B. H., & Heard, S. E. (2008). 2007 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 25th Annual Report. Clinical Toxicology, 46(10), 927–1057. https://doi.org/10.1080/15563650802559632

¹⁷⁸ Jahn, Z. W., Lopez, J., de la Salle, S., Faber, S., & Williams, M. T. (2021). Racial/ethnic differences in prevalence of hallucinogen use by age cohort: Findings from the 2018 National Survey on Drug Use and Health. Journal of Psychedelic Studies, 5(2), 69-82. https://doi.org/10.1556/2054.2021.00166

¹⁷⁹ Prince, M. A., O'Donnell, M. B., Stanley, L. R., & Swaim, R. C. (2019). Examination of Recreational and Spiritual Peyote Use Among American Indian Youth. Journal of studies on alcohol and drugs, 80(3), 366–370. https://doi.org/10.15288/jsad.2019.80.366

¹⁸⁰ Court: No Peyote For 4-Year-Old. (2003, April 22). CBSnews.com; CBS Interactive Inc. https://www.cbsnews.com/news/court-no-peyote-for-4-year-old/

¹⁸¹ Thiessen, M. S., Walsh, Z., Bird, B. M., & Lafrance, A. (2018). Psychedelic use and intimate partner violence: The role of emotion regulation. Journal of psychopharmacology (Oxford, England), 32(7), 749–755. https://doi.org/10.1177/0269881118771782

¹⁸² Hendricks PS, Crawford MS, Cropsey KL, et al. The relationships of classic psychedelic use with criminal behavior in the United States adult population. Journal of Psychopharmacology. 2017;32(1):37-48. doi:10.1177/0269881117735685

¹⁸³ Viña S. M. (2025). Religion, Psychedelics, Risky Behavior, and Violence. Journal of psychoactive drugs, 57(3), 285–296. https://doi.org/10.1080/02791072.2024.2346132

- **Stimulants (e.g., amphetamines, cocaine):** Has an additive effect on sympathetic nervous system stimulation; increases cardiovascular strain by raising heart rate and blood pressure and increases risk for tachycardia, arrhythmias, and hypertensive crisis.
- **Alcohol**: Increases potential for dehydration, disinhibition, and nausea.
- **Cannabis**: Though not strictly indicated, cannabis may intensify the mescaline experience and increase likelihood of anxiety, panic, paranoia, and challenging experiences. ^{184][185]}
- Harmala alkaloids (Syrian rue, Banisteriopsis caapi): MAOI-containing plant material may dangerously potentiate effects of mescaline and increase risk of serotonin syndrome.
- **2C-O (2,4,5-trimethoxyphenethylamine):** Combining mescaline with other phenethylamines may potentiate its effects. [56]

Risks of unethical facilitation and psychological vulnerability: As interest in underground/retreat settings expands, so do reports of unethical conduct (boundary violations, sexual exploitation, coercion). Ethical analyses in clinical literature call for comprehensive screening, clear consent processes, chaperone policies, transparent grievance routes, and facilitator credentialing to protect vulnerable participants. ^{186]}

Different forms and preparations: Common preparations include (1) brewed teas made from plant material, (2) chewed/dried material, and (3) purified mescaline salts (often sulfate or hydrochloride). Dose predictability is highest with purified salts and lowest with crude plant material, which varies by species, age, and growing conditions. Onset with teas is typically 30–90 min; total duration commonly 8–12 h.^{[5][14][70]}

Substance testing protocols: There are several ways to analyze samples for mescaline content, and these methods can be applied to both plant tissue and biological matrices; more recently, techniques have been developed to test for mescaline in addition to its biometabolites. Below are some of the most commonly used ways of testing for mescaline content, followed by a brief discussion of alternative screening or confirmation approaches.

¹⁸⁴ Kuc, J., Kettner, H., Rosas, F., Erritzoe, D., Haijen, E., Kaelen, M., Nutt, D., & Carhart-Harris, R. L. (2022). Psychedelic experience dose-dependently modulated by cannabis: results of a prospective online survey. Psychopharmacology, 239(5), 1425–1440. https://doi.org/10.1007/s00213-021-05999-1

¹⁸⁵ Piercey, C. J., Hetelekides, E., & Karoly, H. C. (2024). Simultaneous cannabis and psychedelic use among festival and concert attendees in Colorado: characterizing enhancement and adverse reactions using mixed methods. Journal of cannabis research, 6(1), 29. https://doi.org/10.1186/s42238-024-00235-x

¹⁸⁶ Smith, W. R., & Appelbaum, P. S. (2022). Novel ethical and policy issues in psychiatric uses of psychedelic substances. Neuropharmacology, 216, 109165. https://doi.org/10.1016/j.neuropharm.2022.109165

- Gas Chromatography–Mass Spectrometry (GC–MS with derivatization)^{187,188}: This method remains a gold-standard in many forensic laboratories for identifying and quantifying mescaline. Plant samples or extracts are chemically derivatized so that the polar mescaline becomes volatile, then separated by gas chromatography and detected by mass spectrometry. The result is a highly reliable structural identification combined with quantification. Because of the extra derivatization step and requirement for skilled operators, it is somewhat more labor-intensive than other newer methods.
- Liquid Chromatography–Tandem Mass Spectrometry (LC–MS/MS)¹⁸⁹, ¹⁹⁰: This technique is now widely used for both plant and biological samples (e.g., blood or urine) because it does not require derivatization and offers excellent sensitivity and specificity. After simple extraction and cleanup, the sample is separated by liquid chromatography and mescaline is quantified via MS/MS. For many modern labs this has become the preferred method for accurate quantification of mescaline and its metabolites.
- Ultra-High Performance Liquid Chromatography Electrospray Ionisation Tandem Mass Spectrometry (UHPLC-(ESI)MS/MS)¹⁹¹: A very recent validated method (2025) uses UHPLC with electrospray ionisation and MS/MS to quantify mescaline in cactus tissue (specifically the Trichocereus spp.) and screen other cactus varieties. The advantage is faster separation, higher throughput, and improved sensitivity compared to older LC methods. It is emerging as a state-of-the-art approach for plant tissue testing.
- Ambient Ionization High-Resolution Mass Spectrometry (DART-HRMS or equivalent)¹⁹²: For rapid screening of many samples, especially plant tissue, ambient ionization MS methods allow analysis of small pieces of cactus or simple extracts with minimal preparation. These methods deliver results quickly and can handle high throughput, though they may be subject to matrix-interferences and often require confirmatory follow-up by LC or GC methods for definitive quantification.

¹⁸⁷ Gambelunghe, C., Marsili, R., Aroni, K., Bacci, M. and Rossi, R. (2013), GC-MS and GC-MS/MS in PCI Mode Determination of Mescaline in Peyote Tea and in Biological Matrices. J Forensic Sci, 58: 270-278. https://doi.org/10.1111/j.1556-4029.2012.02249.x ¹⁸⁸ United Nations Office on Drugs and Crime. (1989). Recommended methods for testing peyote cactus (mescal buttons)/mescaline and psilocybin mushrooms/psilocybin (ST/NAR/19). https://www.unodc.org/pdf/publications/st-nar-19.pdf

¹⁸⁹ Thomann, J., Ley, L., Klaiber, A., Liechti, M. E., & Duthaler, U. (2022). Development and validation of an LC-MS/MS method for the quantification of mescaline and major metabolites in human plasma. Journal of pharmaceutical and biomedical analysis, 220, 114980. https://doi.org/10.1016/j.jpba.2022.114980

¹⁹⁰ Ogunbodede, O., McCombs, D., Trout, K., Daley, P., & Terry, M. (2010). New mescaline concentrations from 14 taxa/cultivars of Echinopsis spp. (Cactaceae) ("San Pedro") and their relevance to shamanic practice. Journal of ethnopharmacology, 131(2), 356–362. https://doi.org/10.1016/j.jep.2010.07.021

¹⁹¹ Gaur, P., Engel, L., Hall, D., Khoo, C., Sarris, J., Perkins, D., Li, C., & Low, M. (2025). A UHPLC-(ESI)MS/MS method for the determination of the psychedelic secondary metabolite mescaline in San Pedro (Trichocereus spp.) and its applicability for screening mescaline in other cacti varieties. Forensic Chemistry, 44. https://doi.org/10.1016/j.forc.2025.100659

¹⁹² Longo, C. M., & Musah, R. A. (2020). An Efficient Ambient Ionization Mass Spectrometric Approach to Detection and Quantification of the Mescaline Content of Commonly Abused Cacti from the Echinopsis Genus. Journal of forensic sciences, 65(1), 61–66. https://doi.org/10.1111/1556-4029.14134

Alternative methods for screening or confirmation also exist. For example, Thin-Layer
Chromatography (TLC) combined with color-reagent sprays offers a low-cost, rapid
presumptive test for alkaloid-type compounds but cannot reliably distinguish mescaline
from other alkaloids and must be followed by a more specific method for certainty.
Further, when sufficiently pure material is available, structural confirmation using Nuclear
Magnetic Resonance (NMR) or Infrared (IR) spectroscopy provides definitive chemical
identification, but these methods are less practical for complex plant extracts or
low-concentration samples.

Indigenous considerations and ecological implications: Certain mescaline-containing cacti that are culturally sacred to indigenous populations in the US are also ecologically vulnerable, and their threatened status and subsequent diminishing presence affects these populations in the US and Mexico. Wild *Lophophora williamsii* populations in Texas and northern Mexico are at risk by overharvest, habitat loss, and illegal poaching and some local and Indigenous organizations are actively pursuing conservation, cultivation, and legal protections to preserve traditional access for the Native American Church. [193][194] Many reform measures and decriminalization efforts have explicitly excluded peyote (or left peyote subject to federal/state religious protections) in order to protect Indigenous sacramental use and to avoid fueling overharvesting. Recent reporting has highlighted shortages and calls for conservation stewardship, and some data suggests that users of mescaline deprioritize ecological impact of consumption. [195]

State Level Policy and Reconsideration

Federal law (United States)

Mescaline and peyote were not controlled under the federal law until March 18, 1966, (F.R. Doc. 66-2910; Filed Mar. 18, 1966, 8:46 a.m., by James L. Goddard, Commissioner of Food and Drugs; 31 *Federal Register* 4679 - 4680, March 19,1966), pursuant to the Drug Abuse Control Amendments of 1965, P.L. 89-74, 79 STAT. 226 *et seq*. Since the Controlled Substances Act of 1970 (P.L. 91-513, Title II, Oct. 27, 1970, 84 STAT. 1242), the DEA and federal schedules list mescaline (and peyote as "cactus which contains mescaline") as Schedule I substances meaning

¹⁹³ Bharath, D., & Wardarski, J. (2024, December 26). Peyote Sacred to Native Americans Threatened by Psychedelic Renaissance and Development. Ocean State Media.

https://www.ocean statemedia.org/religion/peyote-sacred-to-native-americans-threatened-by-psychedelic-renaissance-and-development

¹⁹⁴ Ermakova, A. O., Terry, M. K., & Trout, K. (2022). Cultivation as a conservation tool for cacti: review of the botanical evidence and a case study of Lophophora williamsii. Bradleya Special, 71–82. https://doi.org/10.25223/brad.sp40.2022.a8

¹⁹⁵ Engel, L., Barratt, M., Ferris, J., Puljevic, C., & Winstock, A. (2023). Mescaline, Peyote and San Pedro: Is sustainability important for cacti consumers?. Journal of Psychedelic Studies, 7(2), 135-142. https://doi.org/10.1556/2054.2023.00252

they are legally classified as having no currently accepted medical use and a high potential for abuse under federal law (P.L. 91-513, Sec. 202(c): Schedule I(c)(11) and (12), 84 STAT. 1249; (21 U.S.C 812(c): Schedule I(c)(11) and (12), (2025). Possession, manufacture, or distribution of mescaline or mescaline-containing preparations is therefore unlawful under federal statute except where an explicit exemption applies or where federal prosecutorial discretion is exercised.

Religious exemptions

The federal accommodation for bona fide religious use of mescaline-containing cacti by "members of the Native American Church" (NAC) was an integral part of the regulation controlling peyote and mescaline in 1966.¹⁹⁷ Prior to enactment of the American Indian Religious Freedom Act Amendments Act of 1994 (AIRFA), P.L. 103-344, 42 U.S.C. 1996a, some States did not recognize a religious use exemption for the use of Peyote. The 1994 Amendments extended this protection to all states and territories. Other rulings, such as U.S. v. Boyll, ¹⁹⁸ provided that there is no racial limitation on membership in the Native American Church, noting that the tradition of the Church did not have a racial restriction (although one branch of the Native American Church, known as the Native American Church of North America, does have such restrictions). Memoranda of the Office of Legal Counsel of the U.S. Department of Justice also describe this exemption. ^[199] These legal protections are narrowly framed (centering on recognized religious practice) and do not create a broad legalization for use outside those religious contexts.

Research-use and clinical investigations

Because mescaline is Schedule I, researchers wishing to conduct clinical or nonclinical studies involving mescaline must comply with both DEA and FDA processes. Typical research pathways include: (1) Institutional Review Board (IRB) approval; (2) an IND (Investigational New Drug) application or similar FDA interaction for clinical efficacy/safety trials when investigational treatment is involved; and (3) DEA Schedule I research registration and secure storage/handling authorization.^[200]

¹⁹⁶ DEA Diversion Control. (2025, September 19). Controlled Substances: Alphabetical Order.

https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf

¹⁹⁷ (Now found at Title 21 Code of Federal Regulations (CFR) Section 1307.31;

https://www.ecfr.gov/current/title-21/chapter-II/part-1307/subject-group-ECFR68c82f2ca866120/section-1307.31)

¹⁹⁸ 774 F.Supp. 1333 (D.N.M. 1991) https://law.justia.com/cases/federal/district-courts/FSupp/774/1333/1426009/)

¹⁹⁹ United States Department of Justice, Office of Legal Counsel. (1981, December 22). Peyote Exemption for Native American Church [Memorandum Opinion for the Chief Counsel, Drug Enforcement Administration]. Office of Legal Counsel. https://www.justice.gov/olc/opinion/peyote-exemption-native-american-church

²⁰⁰ Drug Enforcement Administration, Diversion Control Division. (2022, June 15). Researcher's Manual (2022 edition) (DEA-DC-057, EO-DEA217). https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-057)(EO-DEA217)_Researchers_Manual_Final_signed.pdf

In recent years the FDA has issued draft guidance clarifying expectations for psychedelic clinical trials (study design, safety monitoring, chemistry/manufacturing controls), and the DEA has published materials to support Schedule I research registration. ^[201] These processes are feasible but carry regulatory complexity (DEA researcher registration, security plans, and IND/IRB oversight).

State and local policy landscape

Many state and local reforms in the U.S. focus on plant-based entheogens (i.e., naturally occurring psychedelics) rather than on all synthetic Schedule I drugs. The map is rapidly changing; below are the most salient, current examples that pertain to mescaline-containing cacti or entheogens more broadly:

• Colorado (statewide — Proposition 122, 2022): Proposition 122 decriminalized certain natural psychedelic plants and fungi for adults 21+ and specifically listed mescaline among the plant-based substances that were to be decriminalized. [202] The measure also requires the state to develop a regulated access program for psilocybin and authorizes further study/possible inclusion of other plant medicines. [203] Mescaline (excluding peyote) may be included in the program after June 1, 2026 if recommended by the State Natural Medicine Advisory Board and approved by the Director of the Division of Occupations and Professions and the Executive Director of the State Licensing Authority (the Division of Natural Medicine under the Department of Revenue). Proposition 122 was superseded and the groundwork for its implementation laid by the legislature in S.B. 23-290, (Approved May 23, 2023), 204 with additional revisions by S.B. 24-198 (Approved June 6, 2024).²⁰⁵ Those laws created the regulated access program for psilocybin and psilocin. Colorado's program is to "sunset" on September 1, 2032, unless reauthorized (C.R.S. Sec. 44-50-1001). In addition, S.B. 23-290 specifically expressed concern that "considerable harm may occur to Federally recognized American tribes and indigenous people, communities, culture and religions if natural medicine is overly commodified, commercialized, and exploited; and if facilitators, healing centers, and other natural medicine licensees with minimal or no connection to traditional use of natural medicine

²⁰¹ U.S. Food and Drug Administration. (2023, June 23). Psychedelic drugs: Considerations for clinical investigations [Draft guidance for industry]. https://www.fda.gov/news-events/press-announcements/fda-issues-first-draft-guidance-clinical-trials-psychedelic-drugs ²⁰² Natural Medicine Health Act of 2022, Colo. Const. art. XVIII, § 12 (2022).

https://leg.colorado.gov/sites/default/files/initiative_text_2022_122.pdf

²⁰³ Ballotpedia. (2022). Colorado Proposition 122, Decriminalization and Regulated Access Program for Certain Psychedelic Plants and Fungi Initiative (2022). Ballotpedia.

https://ballotpedia.org/Colorado_Proposition_122%2C_Decriminalization_and_Regulated_Access_Program_for_Certain_Psychedelic_Plants_and_Fungi_Initiative_%282022%29

²⁰⁴ https://leg.colorado.gov/sites/default/files/2023a_290_signed.pdf

²⁰⁵ https://leg.colorado.gov/sites/default/files/2024a_198_signed.pdf

misappropriate or exploit tribal and indigenous cultures and religions." (S.B. 23-290, Sec. 1).

- Washington, D.C. (Initiative 81, 2020): Initiative 81 directs local authorities to make enforcement of laws related to entheogenic plants (which explicitly include mescaline-containing cacti) among their lowest priorities. [206] Effective on March 16, 2021, the initiative effectively decriminalized non-commercial personal cultivation, possession, and use of entheogenic plants in D.C., though it does not legalize them under federal law.
- Municipal decriminalization/deprioritization (select examples): Several U.S. cities have enacted resolutions or ordinances that deprioritize enforcement of laws against entheogenic plants and fungi. These local policies typically mention cacti and other plant-based entheogens alongside psilocybin. Examples (non-exhaustive) include:
 - o Oakland, CA (city council resolution, 2019) decriminalized entheogenic plants (including cacti). [207]
 - o Santa Cruz, CA; San Francisco, CA; Berkeley, CA; Arcata, CA; and other California municipalities have adopted similar measures or resolutions at the city level. Many are framed as "lowest law-enforcement priority" policies rather than full legalization. [208][209][210]
 - o Ann Arbor, MI; Washtenaw County, MI; Detroit, MI; and other Michigan localities have adopted decriminalization resolutions or ballot initiatives that include entheogenic plants (some mention cacti explicitly). [211][212] These are local prosecutorial or legislative policies that reduce enforcement but do not override state or federal law.

²⁰⁶ Beaujon, A. (2021, March 15). Magic Mushrooms Are Decriminalized in DC as of Today. Washingtonian; Washingtonian Media Inc. https://www.washingtonian.com/2021/03/15/magic-mushrooms-are-decriminalized-in-dc-as-of-today/

²⁰⁷ Levin, S. (2019, June 5). "These are healing plants": Oakland decriminalizes magic mushrooms. The Guardian; The Guardian. https://www.theguardian.com/us-news/2019/jun/05/oakland-magic-mushrooms-decriminalize

²⁰⁸ Lara Nava, R. (2021, December 12). Arcata legalizes the use of psychedelics. El Leñador Bilingual Newspaper. https://www.ellenadornews.com/2021/12/12/arcata-legalizes-the-use-of-psychedelics

²⁰⁹ Kaur, H. (2020, February 3). Santa Cruz decriminalizes magic mushrooms and other natural psychedelics, making it the third US city to take such a step. CNN. https://www.cnn.com/2020/01/30/us/santa-cruz-mushrooms-psychedelics-trnd

²¹⁰ Gecan, A. (2023, July 12). Berkeley says "yes" to psychedelics — with limits. Berkeleyside; Cityside Journalism. https://www.berkeleyside.org/2023/07/12/berkeley-psychedelics-decriminalization

²¹¹ Kai-Hwa Wang, F. (2021, November 3). Detroit just decriminalized psychedelics and "magic mushrooms." Here's what that means. PBS News; NewsHour Productions LLC.

https://www.pbs.org/newshour/politics/detroit-just-decriminalized-psychedelics-and-magic-mushrooms-heres-what-that-means ²¹² Prosecutor's Office Washtenaw County. (n.d.). Policy 2021-06: Policy regarding entheogenic plants. Www.washtenaw.org. https://www.washtenaw.org/3298/Entheogenic-Plants-Policy

Synthetic mescaline vs. natural cacti: legal distinctions

Federal law mainly targets the active compound (mescaline) as well as some (but not all) species of cacti as Schedule I substances. Some state/local reforms focus on natural entheogens (plant/fungi preparations) rather than purified synthetic molecules; others (like Colorado) included natural mescaline while expressly excluding endangered species of cacti. [89] In practice, possession of purified mescaline salts remains illegal at the federal level and in most states unless expressly decriminalized or covered by narrow local policies. [84]

Final Summary

Mescaline is a classic psychedelic with historical, medical, and cultural significance, most notably in Indigenous and religious contexts, and growing contemporary interest in its potential therapeutic applications. Its physiological risk profile is generally low in healthy individuals, though transient cardiovascular changes, nausea, and emesis are common, and vulnerable populations such as those with cardiovascular disease, psychotic-spectrum or mood disorders, or those taking contraindicated medications may face elevated risks. While prevalence of use in clinical research trials and among the general population remains relatively low, public and medical interest is increasing, with early findings suggesting possible lasting benefits for mood, substance use, and quality of life. Legally, mescaline remains a Schedule I substance under U.S. federal law, with narrow exemptions for some species of cacti in Indigenous religious use, though several states and municipalities have begun decriminalizing or deprioritizing enforcement for natural entheogens more broadly. Moving forward, balanced, evidence-informed policy approaches will be necessary to honor Indigenous stewardship, safeguard public health, and responsibly explore mescaline's potential contributions to mental health while minimizing potential harms.

DMT (*N*, *N*-Dimethyltryptamine) Monograph

Executive Summary

N,N-Dimethyltryptamine (DMT) is a commonly-occurring, natural psychoactive. This compound can be found in a wide range of plant and animal species. There is archeological evidence that DMT-containing plants, including *Psychotria viridis*, have been ritually consumed among indigenous tribes in South America for thousands of years. DMT is a "classic psychedelic," binding to and agonizing 5HT2A serotonin receptors. As with other serotonergic psychedelics (e.g. psilocybin, mescaline), DMT produces intense psychedelic experiences often described as immersive and otherworldly. DMT is currently under investigation as a therapeutic agent in mental health treatment for depression and anxiety. DMT is generally considered safe, possessing low physiological toxicity and addiction potential. Nonetheless, like other psychedelics, DMT can cause significant harm for individuals with some medical and psychiatric conditions. Though a unanimous 2006 U.S. Supreme Court case protected the rights of religious communities to use DMT-containing preparations as a sacrament in religious ceremonies, at present, DMT is a Schedule I controlled substance in the United States, and is illegal to grow, import, possess, distribute, or sell.

Botanical and Chemical Background

N,N-Dimethyltryptamine (DMT) is a naturally occurring indolealkylamine that is a substituted tryptamine structurally related to serotonin and melatonin, which explains its high affinity for serotonin receptors and its broad neuropsychological effect.²¹³ DMT has been identified in more than fifty plant and animal species, including humans, where it can be found in trace concentrations.²¹⁴ ²¹⁵ Its role in physiology is unclear; however, there is some speculation that it

²¹³ Cameron, L. P., & Olson, D. E. (2018). Dark classics in chemical neuroscience: N,N-dimethyltryptamine (DMT). ACS Chemical Neuroscience, 9(10), 2344–2357. https://doi.org/10.1021/acschemneuro.8b00101

²¹⁴ Barker, S. A. (2018). N,N-Dimethyltryptamine (DMT): An endogenous hallucinogen. Metabolites, 8(3), 58. https://doi.org/10.3390/metabo8030058

Dean, J. G., Liu, T., Huff, S., Sheler, B., Barker, S. A., Strassman, R. J., & Wang, M. M. (2019). Biosynthesis and extracellular concentrations of N,N-dimethyltryptamine (DMT) in mammalian brain. Scientific Reports, 9(1), 9333. https://doi.org/10.1038/s41598-019-45812-w

may play a role in central nervous system functioning and stress response. ²¹⁶ ²¹⁷ DMT is rapidly deaminated by monoamine oxidase (MAO), an enzyme found throughout the human body, explaining its brief effects when smoked/vaporized or injected. ²¹⁸ When it is co-administered with MAOIs (e.g., β -carbolines in *Banisteriopsis caapi*, a liana used as a part of ayahuasca brews), its metabolism is delayed, producing more prolonged effects. ²¹⁹

Ethnobotanical and Historical Use

DMT has been isolated in numerous plant species from around the world, including *Psychotria viridis* (Amazon river basin), *Diplopterys cabrerana* (Amazon river basin), *Desmodium gangeticum* (India and the Himalayas), and *Mimosa hostilis* (northeastern Brazil, southern Mexico, Colombia, Venezuela, and El Salvador). It is the primary psychoactive alkaloid in at least three different plants used in ayahuasca brews, where it has been employed ceremonially by Indigenous Amazonian cultures for centuries.²²⁰ The ayahuasca brew, a decoction²²¹, combines a DMT-containing plant (e.g., *Psychotria viridis*) with an MAOI-containing liana (e.g., *Banisteriopsis caapi*), allowing oral DMT activity by preventing first-pass MAO degradation in the gut.^{222,223} This ceremonial beverage has been used to facilitate healing, divination, and spiritual insight in the cultures where it is used. While ayahuasca is often portrayed as a millennia-old tradition, archaeological and ethnographic analyses suggest that its use in its modern, decocted form may be comparatively recent, possibly only several hundred years old.^{224 225}

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²¹⁶ Callaway JC, McKenna DJ, Grob CS, Brito GS, Raymon LP, Poland RE, Andrade EN, Andrade EO, Mash DC. Pharmacokinetics of Hoasca alkaloids in healthy humans. J Ethnopharmacol. 1999 Jun;65(3):243-56. doi: 10.1016/s0378-8741(98)00168-8. PMID: 10404423. ²¹⁷ Fontanilla, D., Johannessen, M., Hajipour, A. R., Cozzi, N. V., Jackson, M. B., & Ruoho, A. E. (2009). The hallucinogen

N,N-dimethyltryptamine (DMT) is an endogenous sigma-1 receptor regulator. Science, 323(5916), 934–937. https://doi.org/10.1126/science.1166127

²¹⁸ Riba, J., Valle, M., Urbano, G., Yritia, M., Morte, A., & Barbanoj, M. J. (2003). Human pharmacology of ayahuasca: Subjective and cardiovascular effects, monoamine metabolite excretion, and pharmacokinetics. Journal of Pharmacology and Experimental Therapeutics, 306(1), 73–83. https://doi.org/10.1124/jpet.103.049882

²¹⁹ McKenna, D. J., & Riba, J. (2015). New world tryptamine hallucinogens and the neuroscience of ayahuasca. Current Topics in Behavioral Neurosciences, 36, 283–311. https://doi.org/10.1007/7854_2015_5002

²²⁰ Riba, J., Valle, M., Urbano, G., Yritia, M., Morte, A., & Barbanoj, M. J. (2003). Human pharmacology of ayahuasca: Subjective and cardiovascular effects, monoamine metabolite excretion, and pharmacokinetics. Journal of Pharmacology and Experimental Therapeutics, 306(1), 73–83. https://doi.org/10.1124/jpet.103.049882

²²¹ A strong herbal "tea" made by simmering tough plant parts, including roots, bark, or seeds, in water to extract their constituent compounds. This process can take hours when preparing an ayahuasca brew.

²²² McKenna, D. J., & Riba, J. (2015). New world tryptamine hallucinogens and the neuroscience of ayahuasca. Current Topics in Behavioral Neurosciences, 36, 283–311. https://doi.org/10.1007/7854_2015_5002

²²³ Callaway, J. C., McKenna, D. J., Grob, C. S., et al. (1999). Pharmacokinetics of hoasca alkaloids in healthy humans. Journal of Ethnopharmacology, 65(3), 243–256. https://doi.org/10.1016/S0378-8741(98)00168-8

²²⁴ Fotiou, E. (2016). The globalization of ayahuasca shamanism and the erasure of Indigenous shamanism. Anthropology of Consciousness, 27(2), 151–179. https://doi.org/10.1111/anoc.12056

²²⁵ Torres, C. M., Repke, D. B., Chan, K., & McKenna, D. J. (1991). Snuff powders from pre-Hispanic San Pedro de Atacama: Chemical and contextual analysis. Current Anthropology, 32(5), 640–649. https://doi.org/10.1086/203999

Beyond ayahuasca, other Indigenous South American groups have prepared DMT-containing snuffs, such as yopo (from *Anadenanthera peregrina* seeds) and vilca (from *Anadenanthera colubrina*), administered via hollow tubes in ritual contexts. Archaeological finds of snuff trays and related paraphernalia in the Andes dating back over 4,000 years attest to longstanding traditions of inhaled tryptamine practices.²²⁶ ²²⁷

The ayahuasca experience is typically characterized by intense visionary and introspective effects alongside a marked purgative component, often involving vomiting or diarrhea. These somatic effects are largely attributed to β -carboline alkaloids in *Banisteriopsis caapii* that act as MAOIs and are often interpreted within Indigenous traditions as a cleansing or spiritually significant aspect of the ceremony. ²²⁸ ²²⁹

In recent decades, ayahuasca has spread globally, becoming central to syncretic religions such as Santo Daime and União do Vegetal (UDV) and circulating in "neo-shamanic" and underground settings. ^{230,231} In the United States, religious use has been recognized under freedom-of-religion protections, most notably by the U.S. Supreme Court (*Gonzales v. O Centro Espírita Beneficente União do Vegetal, 546 U.S. 418* (2006), with detailed legal analyses documenting these precedents. ^{232,233} Meanwhile, ayahuasca and DMT have also entered ultra-modern spaces, including underground communities in New York and technology hubs like Silicon Valley, sparking what has been described as an "ayahuasca boom" in the U.S. ²³⁴

Western scientific engagement with DMT began in the mid-20th century: Hungarian psychiatrist Stephen Szára published the first clinical studies of injected DMT in the 1950s, documenting

²²⁶ Miller, M. J., Albarracín-Jordan, J., Moore, C., & Capriles, J. M. (2019). Chemical evidence for the use of multiple psychotropic plants in a 1,000-year-old ritual bundle from South America. Proceedings of the National Academy of Sciences, 116(23), 11207–11212. https://doi.org/10.1073/pnas.1902174116

Barbosa, P. C. R., Giglio, J. S., & Dalgalarrondo, P. (2005). Altered states of consciousness and short-term psychological after-effects induced by the first time ritual use of ayahuasca in an urban context in Brazil. Journal of Psychoactive Drugs, 37(2), 193–201. https://doi.org/10.1080/02791072.2005.10399798

²²⁸ Labate, B. C., & MacRae, E. (2016). Ayahuasca, ritual and religion in Brazil. Routledge.

²²⁹ Gonzales v. O Centro Espírita Beneficente União do Vegetal, 546 U.S. 418 (2006).

²³⁰ Fotiou, E. (2016). The globalization of ayahuasca shamanism and the erasure of Indigenous shamanism. Anthropology of Consciousness, 27(2), 151–179. https://doi.org/10.1111/anoc.12056

²³¹ Gonzales v. O Centro Espírita Beneficente União do Vegetal, 546 U.S. 418 (2006).

²³² Bronfman, J. (2011). The legal case of the União do Vegetal vs. the U.S. government. In B. C. Labate & H. Jungaberle (Eds.), The internationalization of ayahuasca (pp. 287–301). LIT Verlag.

²³³ Tupper, K. W. (2009). Ayahuasca healing beyond the Amazon: The globalization of a traditional Indigenous entheogen. Global Networks, 9(1), 117–136. https://doi.org/10.1111/j.1471-0374.2009.00245.x

²³⁴ Szára, S. (1956). Dimethyltryptamin: its metabolism in man; the relation to its psychotic effect to the serotonin metabolism. Experientia. 1956 Nov 15;12(11):441-2. doi: 10.1007/BF02157378. PMID: 13384414.

profound psychoactive effects in humans.^{235,236} Modern clinical work was substantially advanced by Rick Strassman, M.D., in the 1990s with controlled intravenous DMT studies, followed by his comprehensive monograph synthesizing those findings. 237,238

Mechanism of Action

DMT is a potent partial agonist at the 5-HT₂A receptor, like the other "classic psychedelics," including psilocybin, LSD, and mescaline. 239 It also has high binding affinity for 5-HT₁A and 5-HT₂C receptors and sigma-1 receptors, where it may act as an endogenous ligand with potential neuroprotective effects.²⁴⁰ Additionally, DMT interacts with trace amine-associated receptors (TAARs), suggesting a complex pharmacological profile beyond the serotonergic system.²⁴¹

Its unusually fast onset is due to rapid absorption and its ability to cross the blood-brain barrier within seconds when inhaled or injected.²²²⁴² Its brief duration, however, is primarily attributable to rapid metabolism by monoamine oxidase (MAO) enzymes and redistribution in the body.²⁴³ ²⁴⁴ Inhaled or injected, DMT produces effects that peak quickly and consistently resolve within 20-30 minutes.²⁴⁵ By contrast, when DMT is taken orally together with an MAOI (as in the ayahuasca brew), MAO degradation is inhibited, resulting in slower onset (30–60 minutes), longer duration (2-6 hours), and a more sustained experiential arc. 246

²³⁵ Szára S. (1957). The comparison of the psychotic effect of tryptamine derivatives with the effects of mescaline and LSD-25 in self-experiments. In Psychotropic Drugs (pp. 460–467). Elsevier, Amsterdam.

²³⁶ Strassman, R. J., Qualls, C. R., Uhlenhuth, E. H., & Kellner, R. (1994). Dose–response study of N,N-dimethyltryptamine in humans: II. Subjective effects. Archives of General Psychiatry, 51(2), 98-108. https://doi.org/10.1001/archpsyc.1994.03950020022002 ²³⁷ McKenna, D. J., & Riba, J. (2015). New world tryptamine hallucinogens and the neuroscience of ayahuasca. Current Topics in

Behavioral Neurosciences, 36, 283-311.

²³⁸ Strassman, R. J. (2001). DMT: The spirit molecule. Park Street Press.

²³⁹ Szára S. (1957). The comparison of the psychotic effect of tryptamine derivatives with the effects of mescaline and LSD-25 in self-experiments. In Psychotropic Drugs (pp. 460–467). Elsevier, Amsterdam.

²⁴⁰ Strassman, R. J., Qualls, C. R., Uhlenhuth, E. H., & Kellner, R. (1994). Dose–response study of N,N-dimethyltryptamine in humans: II. Subjective effects. Archives of General Psychiatry, 51(2), 98-108. https://doi.org/10.1001/archpsyc.1994.03950020022002 ²⁴¹ Strassman, R. J. (2001). DMT: The spirit molecule. Park Street Press.

²⁴² Nichols, D. E. (2016). Psychedelics. Pharmacological Reviews, 68(2), 264–355. https://doi.org/10.1124/pr.115.011478

²⁴³ Szabo, A., Kovacs, A., Frecska, E., & Rajnavolgyi, E. (2016). Psychedelic N,N-dimethyltryptamine and sigma-1 receptor activation: A novel therapeutic approach for neuroinflammation and neurodegeneration. Frontiers in Neuroscience, 10, 423. https://doi.org/10.3389/fnins.2016.00423

²⁴⁴ Strassman, R. J., & Qualls, C. R. (1994). Dose–response study of N,N-dimethyltryptamine in humans: I. Neuroendocrine, autonomic, and cardiovascular effects. Archives of General Psychiatry, 51(2), 85–97. https://doi.org/10.1001/archpsyc.1994.03950020009001 ²⁴⁵ Strassman, R. J., & Qualls, C. R. (1994). Dose–response study of N,N-dimethyltryptamine in humans: I. Neuroendocrine, autonomic, and cardiovascular effects. Archives of General Psychiatry, 51(2), 85-97. https://doi.org/10.1001/archpsyc.1994.03950020009001 ²⁴⁶ Vogt, S.B., Ley, L., Erne, L. et al. Acute effects of intravenous DMT in a randomized placebo-controlled study in healthy participants. Transl Psychiatry 13, 172 (2023). https://doi.org/10.1038/s41398-023-02477-4

Preparation and Administration Forms

Freebase DMT (smoked/vaporized): DMT in its freebase form produces rapid onset, very short duration, and intense peak effects. Vaporized DMT is typically prepared by extracting the alkaloid from plant material, most commonly *Mimosa tenuiflora* (syn. *Mimosa hostilis*) root bark, using a nonpolar solvent such as naphtha in illicit contexts. ²⁴⁷ ²⁴⁸ The resulting freebase crystals can be smoked in a pipe, vaporized using specialized devices, or infused into vape cartridges. Recently, pre-filled vape pens containing DMT have appeared in underground markets, often with variable concentrations and purity levels, raising concerns about dosing accuracy and adulteration. ²⁴⁹

Ayahuasca (oral): Ayahuasca is a decoction combining a DMT-containing plant (e.g., *Psychotria viridis*) with an MAOI-containing vine (*Banisteriopsis caapi*), brewed over several hours. ²⁵⁰ Orally, the presence of MAOIs allows DMT to become active, producing longer lasting and more gradual effects compared to inhaled DMT. In the United States, DMT is classified as a Schedule I controlled substance, though religious exemptions for groups such as União do Vegetal (UDV) and Santo Daime have been recognized in federal court. ²⁵¹ Outside of sanctioned religious contexts, both the plants and the finished brew may be considered illegal under federal law.

Pharmahuasca (DMT + synthetic MAOI): This preparation involves synthetic DMT combined with pharmaceutical MAOIs such as harmaline or moclobemide, producing effects similar to ayahuasca but under controlled conditions. While primarily used in research or specialized psychonaut communities, possession and use remain criminalized under U.S. federal law.²⁵²

Injection (IV/IM): DMT has been administered intravenously and intramuscularly in clinical research for precision dosing. Early studies by Stephen Szára in the 1950s demonstrated the psychoactive profile of injected DMT,²⁵³ and later work by Rick Strassman in the 1990s

self-experiments. In Psychotropic Drugs (pp. 460-467). Elsevier, Amsterdam.

²⁴⁷ Torres, C. M., Repke, D. B., Chan, K., & McKenna, D. J. (1991). Snuff powders from pre-Hispanic San Pedro de Atacama: Chemical and contextual analysis. Current Anthropology, 32(5), 640–649. https://doi.org/10.1086/203999

²⁴⁸ Krebs, T. S., & Johansen, P. Ø. (2013). Psychedelics and mental health: A population study. PLoS ONE, 8(8), e63972. https://doi.org/10.1371/journal.pone.0063972

²⁴⁹ Johnson, M. W., & Griffiths, R. R. (2017). Potential therapeutic effects of classic hallucinogens: A review of human clinical studies. Neurotherapeutics, 14(3), 734–740. https://doi.org/10.1007/s13311-017-0542-y

²⁵⁰ Vogt, S.B., Ley, L., Erne, L. et al. Acute effects of intravenous DMT in a randomized placebo-controlled study in healthy participants. Transl Psychiatry 13, 172 (2023). https://doi.org/10.1038/s41398-023-02477-4

²⁵¹ Bronfman, J. (2011). The legal case of the União do Vegetal vs. the U.S. government. In B. C. Labate & H. Jungaberle (Eds.), The internationalization of ayahuasca (pp. 287–301). LIT Verlag.

²⁵² Bouso, J. C., & Sánchez-Avilés, C. (2020). Traditional healing practices involving ayahuasca and related plants: Ethnographic and epidemiological perspectives. Journal of Psychedelic Studies, 4(3), 137–147. https://doi.org/10.1556/2054.2020.00159 ²⁵³ Szára S. (1957). The comparison of the psychotic effect of tryptamine derivatives with the effects of mescaline and LSD-25 in

systematically investigated dose–response effects in humans.²⁵⁴ This route is rare outside research contexts.

Illicit preparation and precursors: In the United States, underground production often begins with bulk imports of *Mimosa tenuiflora* root bark, which contains high concentrations of DMT.²⁵⁵ Extraction typically follows an acid–base process involving solvents such as naphtha or heptane. While the chemistry is relatively straightforward, possession of raw plant material and associated solvents with intent to extract DMT may carry criminal penalties under federal drug laws.²⁵⁶

Safety Profile and Health Risk Assessment

A. Physical Health

General Effects and Side Effects: At psychoactive doses, DMT induces intense perceptual and cognitive changes, often accompanied by physical effects such as dilated pupils, elevated blood pressure, increased heart rate, dizziness, agitation, and nausea. When administered intravenously, common short-term side effects include heart palpitations, nausea, fatigue, unease, and thirst.²⁵⁷ ²⁵⁸ ²⁵⁹

Toxicity: DMT has a high safety threshold and wide therapeutic index. Typical psychoactive doses in humans are 20–50 mg when smoked or vaporized, and 0.1–0.4 mg/kg intravenously, while ayahuasca preparations usually deliver 25–35 mg of DMT per session, depending on concentration and brewing methods. Animal studies have estimated the median lethal dose (LD_{50}) of DMT to be approximately 110 mg/kg intravenously in mice, or approximately 20 times

²⁵⁴ Strassman, R. J., Qualls, C. R., Uhlenhuth, E. H., & Kellner, R. (1994). Dose–response study of N,N-dimethyltryptamine in humans: II. Subjective effects. Archives of General Psychiatry, 51(2), 98–108. https://doi.org/10.1001/archpsyc.1994.03950020022002

²⁵⁵ Krebs, T. S., & Johansen, P. Ø. (2013). Psychedelics and mental health: A population study. PLoS ONE, 8(8), e63972. https://doi.org/10.1371/journal.pone.0063972

²⁵⁶ U.S. Department of Justice, Drug Enforcement Administration. (2023). Controlled substances: Chemical control of precursor chemicals for illicit drug manufacture. Federal Register. Retrieved from https://www.deadiversion.usdoj.gov/

²⁵⁷ Strassman, R. J., Qualls, C. R., Uhlenhuth, E. H., & Kellner, R. (1994). Dose–response study of N,N-dimethyltryptamine in humans: II. Subjective effects. Archives of General Psychiatry, 51(2), 98–108. https://doi.org/10.1001/archpsyc.1994.03950020022002

²⁵⁸ Strassman, R. J., & Qualls, C. R. (1994). Dose–response study of N,N-dimethyltryptamine in humans: I. Neuroendocrine, autonomic, and cardiovascular effects. Archives of General Psychiatry, 51(2), 85–97. https://doi.org/10.1001/archpsyc.1994.03950020009001 ²⁵⁹ Vogt, S.B., Ley, L., Erne, L. et al. Acute effects of intravenous DMT in a randomized placebo-controlled study in healthy participants. Transl Psychiatry 13, 172 (2023). https://doi.org/10.1038/s41398-023-02477-4

²⁶⁰ Riba, J., Rodríguez-Fornells, A., Urbano, G., Antonijoan, R., Montero, M., & Barbanoj, M. J. (2001). Subjective effects and tolerability of ayahuasca in healthy volunteers. Psychopharmacology, 154(1), 85–95. https://doi.org/10.1007/s002130000606

²⁶¹ Gable, R. S. (2007). Risk assessment of ritual use of oral dimethyltryptamine (DMT) and harmala alkaloids. Addiction, 102(1), 24–34 https://doi.org/10.1111/j.1360-0443.2006.01652.x

higher than the active human dose when scaled across species.²⁶² ²⁶³ Human fatalities at psychoactive doses have not been documented when DMT is used in isolation.²⁶⁴

Cardiovascular Effects: DMT reliably increases heart rate and blood pressure via $5-HT_2A$ receptor activity. These effects are typically mild and transient in healthy individuals but may pose a risk to those with underlying cardiovascular disease. ²⁶⁵ ²⁶⁶ ²⁶⁷

Hepatic Effects: When taken with MAOIs, as in ayahuasca, liver enzyme activity can be altered. While DMT itself does not appear hepatotoxic, repeated ayahuasca use may modestly affect liver enzymes, warranting caution in individuals with hepatic impairment.²⁶⁸

Neurological Considerations: There is no evidence that DMT causes neurotoxicity or structural brain damage at typical psychoactive doses. Concerns about excitotoxicity remain theoretical and unsubstantiated.²⁶⁹ Interestingly, some preclinical studies suggest that DMT may actually exert neuroprotective effects via sigma-1 receptor activity, which is implicated in cellular stress regulation and neuroplasticity.²⁷⁰ ²⁷¹ ²⁷² While these findings are preliminary, they have raised interest in DMT's potential role in promoting resilience and repair in neural tissue.

Gastrointestinal Effects: Unlike other common psychedelics, smoked or injected DMT rarely produces significant gastrointestinal side effects.²⁷³ However, when DMT is consumed orally in combination with MAOIs, nausea, vomiting, and diarrhea are frequently reported. These effects are believed to arise from serotonergic activation of the gastrointestinal tract and stimulation of

²⁶² Halberstadt, A. L. (2016). Behavioral and pharmacokinetic interactions between MAOIs and DMT in rodents. Psychopharmacology, 233(24), 4593–4602. https://doi.org/10.1007/s00213-016-4420-1

²⁶³ Nagai, F., Nonaka, R., & Kamimura, K. (2007). The effects of non-medically used psychoactive drugs on monoamine neurotransmission in rat brain. European Journal of Pharmacology, 559(2–3), 132–137. https://doi.org/10.1016/j.ejphar.2006.12.063 ²⁶⁴ Halpern, J. H., & Pope, H. G. (1999). Do hallucinogens cause residual neuropsychological toxicity? Drug and Alcohol Dependence, 53(3), 247–256. https://doi.org/10.1016/S0376-8716(98)00129-X

²⁶⁵ Nichols, D. E. (2016). Psychedelics. Pharmacological Reviews, 68(2), 264–355. https://doi.org/10.1124/pr.115.011478

²⁶⁶ Strassman, R. J., & Qualls, C. R. (1994). Dose–response study of N,N-dimethyltryptamine in humans: I. Neuroendocrine, autonomic, and cardiovascular effects. Archives of General Psychiatry, 51(2), 85–97. https://doi.org/10.1001/archpsyc.1994.03950020009001

²⁶⁷ Carbonaro, T. M., & Gatch, M. B. (2016). Neuropharmacology of N,N-dimethyltryptamine. Brain Research Bulletin, 126, 74–88. https://doi.org/10.1016/j.brainresbull.2016.04.016

²⁶⁸ Dos Santos, R. G., Bouso, J. C., Alcázar-Córcoles, M. Á., & Hallak, J. E. (2017). Efficacy, tolerability, and safety of ayahuasca in humans: A systematic literature review. Journal of Psychopharmacology, 31(1), 1–20. https://doi.org/10.1177/0269881116676103

²⁶⁹ Halpern, J. H., & Pope, H. G. (1999). Do hallucinogens cause residual neuropsychological toxicity? Drug and Alcohol Dependence, 53(3), 247–256. https://doi.org/10.1016/S0376-8716(98)00129-X

²⁷⁰ Szabo, A., Kovacs, A., Frecska, E., & Rajnavolgyi, E. (2016). Psychedelic N,N-dimethyltryptamine and sigma-1 receptor activation: A novel therapeutic approach for neuroinflammation and neurodegeneration. Frontiers in Neuroscience, 10, 423. https://doi.org/10.3389/fnins.2016.00423

²⁷¹ Szabo, A., Kovacs, A., Frecska, E., & Rajnavolgyi, E. (2016). Psychedelic DMT and sigma-1 receptor activation: A novel therapeutic approach for neuroinflammation and neurodegeneration. Frontiers in Neuroscience, 10, 423. https://doi.org/10.3389/fnins.2016.00423

Ly, C., Greb, A. C., Cameron, L. P., Wong, J. M., et al. (2018). Psychedelics promote structural and functional neural plasticity. Cell Reports, 23(11), 3170–3182. https://doi.org/10.1016/j.celrep.2018.05.022

²⁷³ Fotiou, E., & Gearin, A. K. (2019). Purging and the body in the therapeutic use of ayahuasca. Social Science & Medicine, 239, 112532. https://doi.org/10.1016/j.socscimed.2019.112532

the brainstem's area postrema.²⁷⁴ While such purging is prominent in ayahuasca rituals as a method of catharsis, it is minimal or absent with isolated DMT administration.

Teratogenicity & Reproductive Health: Human safety data are lacking, but animal studies at high doses suggest potential abortifacient and teratogenic effects.²⁷⁵ In light of these findings and the absence of reliable human research, DMT use during pregnancy and breastfeeding is strongly discouraged due to unknown risks.

B. Mental Health

Acute psychological distress: DMT experiences are often extremely intense, with rapid immersion into altered states of consciousness that can provoke anxiety, fear, or disorientation—particularly in individuals who are unprepared or in unsupportive environments. Although these adverse experiences are usually short-lived due to DMT's rapid metabolism, they may nonetheless be deeply distressing. ²⁷⁶ ²⁷⁷ ²⁷⁸ ²⁷⁹ Proper preparation, safe settings, and supportive guidance substantially reduce the likelihood and severity of such reactions. ²⁸⁰ **Hallucinations and perceptual changes:** DMT is potent in producing immersive visual, auditory, and somatic hallucinations, frequently described as "breakthrough" experiences that feel as though the user has entered an alternate realm or encountered autonomous entities. ²⁸¹ ²⁸² ²⁸³ While these experiences are often interpreted positively as mystical or spiritually meaningful, they can also provoke confusion, panic, or paranoia in certain individuals. ²⁸⁴

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²⁷⁴ Dos Santos, R. G., Hallak, J. E. C., Palhano-Fontes, F., Oliveira, J. P. M., & Bouso, J. C. (2024). Reproductive toxicity of ayahuasca and DMT: Evidence from animal models. International Journal of Toxicology, 43(1), 45–56. https://doi.org/10.1177/10915818241230916 ²⁷⁵ Johnson, M. W., Richards, W. A., & Griffiths, R. R. (2008). Human hallucinogen research: Guidelines for safety. Journal of Psychopharmacology, 22(6), 603–620. https://doi.org/10.1177/0269881108093587

²⁷⁶ Tupper, K. W. (2009). Ayahuasca healing beyond the Amazon: The globalization of a traditional Indigenous entheogen. Global Networks, 9(1), 117–136. https://doi.org/10.1111/j.1471-0374.2009.00245.x

²⁷⁷ Strassman, R. J., Qualls, C. R., Uhlenhuth, E. H., & Kellner, R. (1994). Dose-response study of N,N-dimethyltryptamine in humans: II. Subjective effects. Archives of General Psychiatry, 51(2), 98–108. https://doi.org/10.1001/archpsyc.1994.03950020022002

²⁷⁸ Strassman, R. J., & Qualls, C. R. (1994). Dose–response study of N,N-dimethyltryptamine in humans: I. Neuroendocrine, autonomic, and cardiovascular effects. Archives of General Psychiatry, 51(2), 85–97. https://doi.org/10.1001/archpsyc.1994.03950020009001
²⁷⁹ Vogt, S.B., Ley, L., Erne, L. et al. Acute effects of intravenous DMT in a randomized placebo-controlled study in healthy participants. Transl Psychiatry 13, 172 (2023). https://doi.org/10.1038/s41398-023-02477-4

²⁸⁰ Martinotti, G., Santacroce, R., Pettorruso, M., et al. (2018). Hallucinogen persisting perception disorder: Etiology, clinical features, and therapeutic perspectives. Brain Sciences, 8(3), 47. https://doi.org/10.3390/brainsci8030047

²⁸¹ Tupper, K. W. (2009). Ayahuasca healing beyond the Amazon: The globalization of a traditional Indigenous entheogen. Global Networks, 9(1), 117–136. https://doi.org/10.1111/j.1471-0374.2009.00245.x

²⁸² Szára, S. (1956). Dimethyltryptamin: its metabolism in man; the relation to its psychotic effect to the serotonin metabolism. Experientia. 1956 Nov 15;12(11):441-2. doi: 10.1007/BF02157378. PMID: 13384414.

²⁸³ Strassman, R. J., Qualls, C. R., Uhlenhuth, E. H., & Kellner, R. (1994). Dose–response study of N,N-dimethyltryptamine in humans: II. Subjective effects. Archives of General Psychiatry, 51(2), 98–108. https://doi.org/10.1001/archpsyc.1994.03950020022002
²⁸⁴ Krebs, T. S., & Johansen, P. Ø. (2013). Psychedelics and mental health: A population study. PLoS ONE, 8(8), e63972.
https://doi.org/10.1371/journal.pone.0063972

Psychosis and mood instability: As with other serotonergic psychedelics, DMT can unmask latent psychotic disorders or trigger mania in individuals with bipolar spectrum conditions.²⁸⁵ There remains insufficient data on outcomes in populations with bipolar disorder or schizophrenia, and current clinical studies typically exclude individuals with personal or family histories of psychosis.²⁸⁶ For this reason, careful screening and monitoring are necessary in research and therapeutic settings.

Hallucinogen Persisting Perception Disorder (HPPD): While rare, there are isolated case reports of HPPD following DMT use. This condition involves persistent visual disturbances, such as visual snow, halos, or tracers, and is more commonly documented with LSD or psilocybin. To date, no large-scale epidemiological studies have specifically evaluated HPPD risk in DMT users.²⁸⁷

C. Therapeutic Potential

Clinical interest: Clinical interest in DMT has grown considerably in recent years, with early-stage trials exploring its applications in psychiatry. A recent Phase 2a clinical trial of inhaled DMT in patients with treatment-resistant depression (TRD) demonstrated safety, tolerability, and rapid antidepressant effects: 85.7% of participants showed clinical response and 57.1% achieved remission one week after dosing. Notably, reductions in depressive symptoms were maintained for up to three months, and suicidal ideation decreased significantly immediately following treatment.²⁸⁸

PTSD and related disorders: Beyond depression, DMT has also been investigated for post-traumatic stress disorder (PTSD). Preliminary clinical research, supported by observational studies of ayahuasca ceremonies, suggests that DMT-containing preparations may reduce PTSD symptoms, substance misuse, and suicidality.²⁸⁹ These therapeutic effects are hypothesized to relate to DMT's capacity to facilitate emotional processing of traumatic memories, enhance

²⁸⁵ Krebs, T. S., & Johansen, P. Ø. (2013). Psychedelics and mental health: A population study. PLoS ONE, 8(8), e63972. https://doi.org/10.1371/journal.pone.0063972

²⁸⁶ Schifano, F., Orsolini, L., Papanti, G. D., & Corkery, J. M. (2015). Novel psychoactive substances of interest for psychiatry. World Psychiatry, 14(1), 15–26. https://doi.org/10.1002/wps.2017

²⁸⁷ Halpern, J. H., & Pope, H. G. (1999). Do hallucinogens cause residual neuropsychological toxicity? Drug and Alcohol Dependence, 53(3), 247–256. https://doi.org/10.1016/S0376-8716(98)00129-X

²⁸⁸ Falchi-Carvalho M, Wießner I, Silva SRB, O Maia L, Barros H, Laborde S, Arichelle F, Tullman S, Silva-Costa N, Assunção A, Almeida R, Pantrigo ÉJ, Bolcont R, Costa-Macedo JV, Arcoverde E, Galvão-Coelho N, Araujo DB, Palhano-Fontes F. Safety and tolerability of inhaled N,N-Dimethyltryptamine (BMND01 candidate): A phase I clinical trial. Eur Neuropsychopharmacol. 2024 Mar;80:27-35. doi: 10.1016/j.euroneuro.2023.12.006. Epub 2023 Dec 22. PMID: 38141403.

²⁸⁹ Rodrigues, L. S., Rossi, G. N., Rocha, J. M., & Osório, F. L. (2021). Effects of ayahuasca and its alkaloids on substance use disorder: An updated (2016–2020) systematic review of preclinical and human studies. European Archives of Psychiatry and Clinical Neuroscience, 271(1), 57–71. https://doi.org/10.1007/s00406-021-01209-2

psychological flexibility, and temporarily dissolve rigid ego structures that sustain psychopathology.

Mechanistic studies: Mechanistic studies provide converging support for these observations. DMT and other serotonergic psychedelics promote neuroplasticity through 5-HT₂A receptor activation, upregulation of brain-derived neurotrophic factor (BDNF), and stimulation of synaptogenesis.²⁹⁰ These molecular and cellular changes may underlie the enduring psychological benefits observed in both naturalistic and clinical contexts.

Pharmacokinetics and scalability: Finally, DMT's pharmacokinetic profile distinguishes it from other classic psychedelics. Its short duration of action, typically 20–30 minutes when inhaled or injected, contrasts with psilocybin (4–6 hours) and LSD (8–12 hours). ²⁹² ²⁹³ ²⁹⁴ This brevity could make DMT a uniquely scalable candidate for clinical deployment, enabling shorter therapy sessions while retaining therapeutic depth, thereby reducing cost and accessibility barriers compared to longer-acting psychedelics.

Potential At-Risk Populations

https://doi.org/10.3389/fnins.2016.00423

Individuals with psychotic disorders or predispositions: DMT and other psychedelics are generally contraindicated in individuals with schizophrenia or familial psychosis due to risks of precipitating or exacerbating psychotic episodes. A 2024 meta-analysis found that while the overall incidence of psychedelic-induced psychosis is low (0.002–0.6%), in uncontrolled trials that included individuals with schizophrenia, 3.8% of participants reported persistent psychotic symptoms and, of those with psychedelic-induced psychosis, 13.1% later developed symptoms consistent with the diagnosis of schizophrenia, supporting the rationale for exclusion in clinical studies.²⁹⁵

²⁹⁰ Szabo, A., Kovacs, A., Frecska, E., & Rajnavolgyi, E. (2016). Psychedelic N,N-dimethyltryptamine and sigma-1 receptor activation: A novel therapeutic approach for neuroinflammation and neurodegeneration. Frontiers in Neuroscience, 10, 423.

²⁹¹ Ly, C., Greb, A. C., Cameron, L. P., Wong, J. M., et al. (2018). Psychedelics promote structural and functional neural plasticity. Cell Reports, 23(11), 3170–3182. https://doi.org/10.1016/j.celrep.2018.05.022

²⁹² Szára S. (1957). The comparison of the psychotic effect of tryptamine derivatives with the effects of mescaline and LSD-25 in self-experiments. In Psychotropic Drugs (pp. 460–467). Elsevier, Amsterdam.

²⁹³ Strassman, R. J., Qualls, C. R., Uhlenhuth, E. H., & Kellner, R. (1994). Dose–response study of N,N-dimethyltryptamine in humans: II. Subjective effects. Archives of General Psychiatry, 51(2), 98–108. https://doi.org/10.1001/archpsyc.1994.03950020022002

²⁹⁴ Carhart-Harris, R. L., & Goodwin, G. M. (2017). The therapeutic potential of psychedelic drugs: Past, present, and future. Neuropsychopharmacology, 42(11), 2105–2113. https://doi.org/10.1038/npp.2017.84

²⁹⁵ Dos Santos, R. G., Bouso, J. C., & Hallak, J. E. C. (2024). Psychedelics and psychosis: Systematic review and meta-analysis of clinical and epidemiological data. Psychological Medicine. https://doi.org/10.1017/S0033291724001234

People with uncontrolled hypertension or cardiac disease: DMT transiently elevates blood pressure and heart rate, posing risks for individuals with underlying cardiovascular conditions. Clinical guidelines recommend avoiding psychedelic use in individuals with uncontrolled hypertension or serious cardiac disease.²⁹⁶²⁹⁷

Pregnant or breastfeeding individuals: Rigorous human safety data are lacking, and animal studies suggest potential reproductive toxicity at high doses. Accordingly, DMT use during pregnancy and breastfeeding is strongly discouraged.²⁹⁸²⁹⁹

Those on serotonergic medications or MAOIs: Combining DMT with medications that alter serotonin signaling increases the risk of serotonin syndrome:

- SSRIs/SNRIs/TCAs: Potentiate serotonergic signaling, raising risks of serotonergic toxicity when combined with DMT.³⁰⁰
- MAOIs (e.g., phenelzine, tranylcypromine): Prevent DMT metabolism, dramatically prolonging and intensifying its effects; preclinical reports confirm potentiation and risk of serotonin toxicity with irreversible MAOIs.³⁰¹
- Other serotonergic agents (e.g., buspirone, triptans, MDMA): May amplify serotonin effects and unpredictably interact with DMT, increasing toxicity risk.³⁰²

Individuals with seizure disorders: While seizures following DMT use are rare, case reports suggest heightened vulnerability in individuals with epilepsy or lowered seizure threshold. Co-administration with serotonergic or stimulant medications may further increase seizure risk.³⁰³

²⁹⁶ Carbonaro, T. M., & Gatch, M. B. (2016). Neuropharmacology of N,N-dimethyltryptamine. Brain Research Bulletin, 126, 74–88. https://doi.org/10.1016/j.brainresbull.2016.04.016

²⁹⁷ Johnson, M. W., Griffiths, R. R., & Hendricks, P. S. (2019). The abuse potential of medical psilocybin according to the 8 factors of the Controlled Substances Act. Neuropharmacology, 142, 143–166. https://doi.org/10.1016/j.neuropharm.2018.05.012

²⁹⁸ Johnson, M. W., Richards, W. A., & Griffiths, R. R. (2008). Human hallucinogen research: Guidelines for safety. Journal of Psychopharmacology, 22(6), 603–620. https://doi.org/10.1177/0269881108093587

²⁹⁹ Dos Santos, R. G., Hallak, J. E. C., Palhano-Fontes, F., Oliveira, J. P. M., & Bouso, J. C. (2024). Reproductive toxicity of ayahuasca and DMT: Evidence from animal models. International Journal of Toxicology, 43(1), 45–56. https://doi.org/10.1177/10915818241230916 ³⁰⁰ Gillman, P. K. (2010). Tricyclic antidepressant pharmacology and therapeutic drug interactions updated. British Journal of Pharmacology, 161(4), 751–764. https://doi.org/10.1111/j.1476-5381.2010.00974.x

³⁰¹ Halberstadt, A. L. (2016). Behavioral and pharmacokinetic interactions between MAOIs and DMT in rodents. Psychopharmacology, 233(24), 4593–4602. https://doi.org/10.1007/s00213-016-4420-1

³⁰² Schifano, F., Orsolini, L., Papanti, G. D., & Corkery, J. M. (2015). Novel psychoactive substances of interest for psychiatry. World Psychiatry, 14(1), 15–26. https://doi.org/10.1002/wps.20174

³⁰³ Kuypers, K. P. C., & Ramaekers, J. G. (2007). Acute, dose-related effects of MDMA on memory and prospective memory. Psychopharmacology, 192(4), 571–582. https://doi.org/10.1007/s00213-007-0764-2

Patterns of Use and Drug Interaction Risks

Prevalence: DMT use remains relatively rare compared to other psychedelics. National survey data indicate that past-year prevalence among U.S. adults is well under 1%. Ayahuasca use is more common in ceremonial and religious contexts, particularly within syncretic religious groups and underground communities. 305

Abuse and dependence potential: DMT is not associated with physiological dependence, compulsive use, or significant withdrawal symptoms.³⁰⁶ Tolerance develops rapidly (tachyphylaxis) and diminishes motivation for frequent use, a pattern consistent with other classic serotonergic psychedelics.³⁰⁷

Recreational Drug Interactions

General guidance: Evidence on polydrug use with DMT or ayahuasca is limited; where data are lacking, best practice follows human hallucinogen research safety guidelines: avoid combining classic psychedelics with other psychoactive substances, particularly serotonergic, stimulant, or depressant agents (e.g., alcohol). Acute agitation may be managed clinically with non-synergistic agents, such as benzodiazepines.³⁰⁸

Serotonergic agents (high risk): SSRIs, SNRIs, TCAs, MDMA, tramadol, and certain opioids (e.g., meperidine). Combining these with DMT may raise serotonin to toxic levels and has been linked to serotonin syndrome in case reports.³⁰⁹ ³¹⁰

MAOI-stimulant combinations (contraindicated): Cocaine, amphetamines, methylphenidate, and sympathomimetics (including common decongestants). With MAOIs, these combinations can precipitate hypertensive crisis and hyperpyrexia; they are contraindicated.³¹¹

³⁰⁴ Yockey, R. A., Vidourek, R. A., & King, K. A. (2020). Trends in DMT and other tryptamine use among US adults, 2007–2014. Journal of Psychoactive Drugs, 52(3), 243–250. https://doi.org/10.1080/02791072.2020.1718256

³⁰⁵ Labate, B. C., & Cavnar, C. (2014). Ayahuasca shamanism in the Amazon and beyond. Oxford University Press.

³⁰⁶ Nichols, D. E. (2016). Psychedelics. Pharmacological Reviews, 68(2), 264–355. https://doi.org/10.1124/pr.115.011478

³⁰⁷ Griffiths, R. R., Richards, W. A., Johnson, M. W., McCann, U., & Jesse, R. (2008). Mystical-type experiences in psilocybin research: Immediate and persisting effects. Psychopharmacology, 187(3), 268–283. https://doi.org/10.1007/s00213-007-0358-7

³⁰⁸ Gillman, P. K. (2010). Tricyclic antidepressant pharmacology and therapeutic drug interactions updated. British Journal of Pharmacology, 161(4), 751–764. https://doi.org/10.1111/j.1476-5381.2010.00974.x

³⁰⁹ Schifano, F., Orsolini, L., Papanti, G. D., & Corkery, J. M. (2015). Novel psychoactive substances of interest for psychiatry. World Psychiatry, 14(1), 15–26. https://doi.org/10.1002/wps.20174

³¹⁰ Malcolm B, Thomas K. Serotonin toxicity of serotonergic psychedelics. Psychopharmacology (Berl). 2022 Jun;239(6):1881-1891. doi: 10.1007/s00213-021-05876-x. Epub 2021 Jul 12. PMID: 34251464.

³¹¹ Gillman, P. K. (2011). CNS stimulant/MAOI interactions: Implications for clinical practice. British Journal of Clinical Pharmacology, 72(4), 578–590. https://doi.org/10.1111/j.1365-2125.2011.04029.x

Lithium (high risk): Co-administration with psychedelics has been associated with an increased incidence of seizures in survey and case data.³¹²

Other classic psychedelics (unknown to high risk): Combining DMT/ayahuasca with psilocybin, LSD, or mescaline may amplify cardiovascular strain and intensify psychological effects. Controlled data are sparse, so concurrent use is not recommended.³¹³

Ketamine (caution): Limited evidence exists on direct interactions. Both ketamine and serotonergic psychedelics elevate blood pressure/heart rate and alter consciousness; co-use may elevate cardiovascular and psychological risks.³¹⁴

Alcohol (caution/avoid): Increases dehydration, risk of vomiting/aspiration, and impairs judgment during altered states. Psychedelic safety guidelines recommend against co-use.³¹⁵

Benzodiazepines (situational/clinical use): Not a recreational "combo," but benzodiazepines are clinically used to attenuate acute anxiety or agitation during psychedelic crises, though they also blunt psychedelic effects.³¹⁶

Cannabis: Systematic interaction data are lacking. Anecdotal reports suggest it may intensify perceptual effects and anxiety; intentional co-use should be avoided outside of controlled or clinical settings.³¹⁷

³¹² Schenberg, E. E. (2018). Psychedelics and seizures: A review of the available evidence. Epilepsy & Behavior, 88, 102–110. https://doi.org/10.1016/j.yebeh.2018.09.024

³¹³ Johnson, M. W., & Griffiths, R. R. (2017). Potential therapeutic effects of classic hallucinogens: A review of human clinical studies. Neurotherapeutics, 14(3), 734–740. https://doi.org/10.1007/s13311-017-0542-y

³¹⁴ Niciu, M. J., Luckenbaugh, D. A., & Zarate, C. A. (2014). The role of ketamine in psychiatric disorders: Recent findings and future directions. Harvard Review of Psychiatry, 22(6), 354–364. https://doi.org/10.1097/HRP.0000000000000045

³¹⁵ Gillman, P. K. (2010). Tricyclic antidepressant pharmacology and therapeutic drug interactions updated. British Journal of Pharmacology, 161(4), 751–764. https://doi.org/10.1111/j.1476-5381.2010.00974.x

³¹⁶ Gillman, P. K. (2010). Tricyclic antidepressant pharmacology and therapeutic drug interactions updated. British Journal of Pharmacology, 161(4), 751–764. https://doi.org/10.1111/j.1476-5381.2010.00974.x

³¹⁷ Schifano, F., & Deluca, P. (2020). Poly-substance use involving psychedelics: Epidemiological trends and health consequences. Drug and Alcohol Dependence, 212, 108–118. https://doi.org/10.1016/j.drugalcdep.2020.108118

Public Safety Considerations

Driving impairment: DMT produces acute perceptual, cognitive, and motor impairment. Because its effects are brief, residual impairment is unlikely beyond one hour post-use. However, driving or operating machinery during or immediately after administration is unsafe.³¹⁸

Emergency visits: Emergency department visits specifically attributed to DMT are rare. When they occur, they typically involve acute psychological distress, confusion, or panic rather than physiological toxicity. Such cases are generally resolved with reassurance, a calm environment, or short-term benzodiazepine use.³¹⁹

Pediatric risk: Though rare, case reports of accidental ayahuasca ingestion in pediatric populations highlight the need for secure storage and childproof packaging in contexts where ceremonial or legal use occurs.³²⁰ Within Indigenous traditions, adolescents have occasionally participated in ayahuasca rituals under supervision, though this practice is culturally specific and remains controversial in biomedical ethics.³²¹

Violence and aggression: There is no evidence linking DMT to heightened aggression or violence. On the contrary, users generally describe peaceful, introspective, or mystical states. Instances of harmful behavior typically involve poly-substance use or pre-existing psychiatric conditions.³²²

Indigenous and Religious Considerations

DMT has deep cultural and spiritual significance in Amazonian Indigenous traditions, particularly through ayahuasca ceremonies led by shamans (curanderos). These rituals are framed as forms of healing, divination, and spiritual communion, and are embedded within broader cosmologies

³¹⁸ Kuypers, K. P. C., Riba, J., de la Fuente Revenga, M., Barker, S., Theunissen, E. L., & Ramaekers, J. G. (2019). Ayahuasca enhances creative divergent thinking while decreasing conventional convergent thinking. Psychopharmacology, 236(2), 581–593. https://doi.org/10.1007/s00213-018-5119-x

³¹⁹ Malcolm B, Thomas K. Serotonin toxicity of serotonergic psychedelics. Psychopharmacology (Berl). 2022 Jun;239(6):1881-1891. doi: 10.1007/s00213-021-05876-x. Epub 2021 Jul 12. PMID: 34251464.

³²⁰ Dos Santos, R. G., Bouso, J. C., & Hallak, J. E. (2017). Ayahuasca, dimethyltryptamine, and psychosis: A systematic review of human studies. Therapeutic Advances in Psychopharmacology, 7(4), 141–157. https://doi.org/10.1177/2045125316689030

³²¹ Labate, B. C., & Cavnar, C. (2014). Ayahuasca shamanism in the Amazon and beyond. Oxford University Press.

³²² Bouso, J. C., & Sánchez-Avilés, C. (2020). Traditional healing practices involving ayahuasca and related plants: Ethnographic and epidemiological perspectives. Journal of Psychedelic Studies, 4(3), 137–147. https://doi.org/10.1556/2054.2020.00159

that connect human health to ecological and spiritual balance.³²³ Beyond ayahuasca, other Indigenous groups in South America have long used DMT-containing snuffs, such as yopo (from *Anadenanthera peregrina*) and vilca (from *Anadenanthera colubrina*), administered through hollow tubes in collective ritual contexts. Archaeological evidence of snuff trays and paraphernalia in the Andes dates back over 4,000 years, highlighting the antiquity of some DMT-related practices.³²⁴

In Brazil, ayahuasca became central to the emergence of syncretic religious movements such as Santo Daime and União do Vegetal (UDV), which integrate Christianity, Indigenous cosmologies, and Afro-Brazilian spiritual practices. These movements, now with global reach, use ayahuasca as a sacrament and organize ceremonies that have spread to North America, Europe, and beyond. In the United States, religious use of ayahuasca has been recognized under freedom of religion protections, most notably in the 2006 U.S. Supreme Court case, *Gonzales* v. *O Centro Espírita Beneficente União do Vegetal*, 546 U.S. 418, which unanimously upheld the UDV's right to use ayahuasca sacramentally. Santo Daime has similarly received federal court-recognized religious exemptions. These precedents highlight the legal and ethical imperatives of balancing religious freedom with drug control laws.

Today, ayahuasca ceremonies are not only practiced in their original cultural and religious contexts but also increasingly adopted in underground or "neo-shamanic" circles in the U.S. and Europe. This globalization raises significant ethical challenges: risks of cultural appropriation, commercialization of sacred traditions, and biopiracy of Indigenous plant knowledge. At the same time, Indigenous leaders and scholars emphasize the importance of respecting traditional intellectual property, ensuring that policy development meaningfully includes Indigenous voices, and safeguarding ceremonial practices from exploitation. For religious communities, the sincere use of these substances as a sacred and ceremonial practice is entitled to the complete legal protection that all religious practices obtain under the Maryland and U.S. Constitutions.

³²³ Labate, B. C., & Cavnar, C. (2014). Ayahuasca shamanism in the Amazon and beyond. Oxford University Press.

³²⁴ Torres, C. M., Repke, D. B., Chan, K., & McKenna, D. J. (1991). Snuff powders from pre-Hispanic San Pedro de Atacama: Chemical and contextual analysis. Current Anthropology, 32(5), 640–649. https://doi.org/10.1086/203999

³²⁵ Johnson, M. W., & Griffiths, R. R. (2017). Potential therapeutic effects of classic hallucinogens: A review of human clinical studies. Neurotherapeutics, 14(3), 734–740. https://doi.org/10.1007/s13311-017-0542-y

³²⁶ Gonzales v. O Centro Espírita Beneficente União do Vegetal, 546 U.S. 418 (2006).

Niciu, M. J., Luckenbaugh, D. A., & Zarate, C. A. (2014). The role of ketamine in psychiatric disorders: Recent findings and future directions. Harvard Review of Psychiatry, 22(6), 354–364. https://doi.org/10.1097/HRP.0000000000000045

³²⁸ Schifano, F., & Deluca, P. (2020). Poly-substance use involving psychedelics: Epidemiological trends and health consequences. Drug and Alcohol Dependence, 212, 108–118. https://doi.org/10.1016/j.drugalcdep.2020.108118

³²⁹ Labate, B. C., & Cavnar, C. (2014). Ayahuasca shamanism in the Amazon and beyond. Oxford University Press.

Substance Testing and Regulation

Testing methods: Analytical techniques such as gas chromatography–mass spectrometry (GC–MS) and high-performance liquid chromatography (HPLC) are the gold standards for identifying and quantifying DMT in biological samples and plant preparations.³³⁰ These methods are widely used in forensic toxicology, clinical research, and quality control of botanical preparations. By contrast, simple reagent tests (e.g., Ehrlich's reagent) have limited specificity, as they may yield false positives due to cross-reactivity with other indole-containing tryptamines.³³¹

Legal Status

Federal Classification: DMT remains a Schedule I substance under the Controlled Substances Act, indicating high abuse potential, no accepted medical use, and no safety under medical supervision.³³²

Religious Exemptions: In Gonzales v. O Centro Espírita Beneficente União do Vegetal (546 U.S. 418, 2006), the U.S. Supreme Court upheld the União do Vegetal's sacramental use of ayahuasca under the Religious Freedom Restoration Act.³³³ Similarly, federal injunctions have protected Santo Daime's ceremonial use.³³⁴

Local Decriminalization.

- Oakland, California (2019): The City Council unanimously decriminalized entheogenic plants and fungi—including ayahuasca components—by making enforcement of related offenses among the lowest police priorities.³³⁵
- Washington, D.C. (2020): Initiative 81 directs law enforcement to treat non-commercial engagement with entheogenic plants and fungi as their "lowest enforcement priorities."³³⁶

³³⁰ Maurer, H. H. (2010). Advances in analytical toxicology: The current role of liquid chromatography–mass spectrometry in drug analysis. Therapeutic Drug Monitoring, 32(3), 324–329. https://doi.org/10.1097/FTD.0b013e3181d36f5c

³³¹ Cole, M. D. (2016). The analysis of hallucinogenic mushrooms for indole alkaloids by HPLC and simple colorimetric reagents. Forensic Science International, 262, 87–92. https://doi.org/10.1016/j.forsciint.2016.03.019

³³² U.S. Drug Enforcement Administration. (2023). Controlled Substances Act: Schedule I hallucinogens. Federal Register. https://www.deadiversion.usdoj.gov/schedules/

³³³ Gonzales v. O Centro Espírita Beneficente União do Vegetal, 546 U.S. 418 (2006).

Labate, B. C., & Feeney, K. (2012). Ayahuasca and the process of regulation in Brazil and internationally: Implications and challenges. International Journal of Drug Policy, 23(2), 154–161. https://doi.org/10.1016/j.drugpo.2011.06.006

³³⁵ City of Oakland. (2019). Resolution: Decriminalize Nature Oakland – Entheogenic Plant Practices. Oakland City Council Records.

³³⁶ District of Columbia Board of Elections. (2020). Initiative 81 – Entheogenic Plant and Fungus Policy Act of 2020. Washington, D.C. Board of Elections.

State-Level Reform.

 Colorado (2022): Proposition 122 decriminalized personal possession, growth, and sharing of DMT and several other plant-based psychedelics for adults 21 and older. It also establishes a regulated framework for "healing centers" under state oversight, with DMT potentially included starting in 2026.³³⁷

Conclusion

DMT is a powerful psychedelic compound with unique properties and significant cultural, therapeutic, and spiritual relevance. While it demonstrates a favorable safety profile under controlled or ceremonial conditions, it presents acute psychological risks for some users and contraindications for vulnerable populations. Its short duration and non-compulsive nature make it distinct among classic psychedelics. As interest in therapeutic and ceremonial use expands, regulation must balance potential benefits, safety, and cultural respect, supporting research and harm reduction.

³³⁷ Colorado Secretary of State. (2022). Proposition 122: Access to natural psychedelic substances. Colorado State Ballot Initiatives.

Section II. Natural Psychedelic Substances in Context

Psychedelic Use Practices

Much information is available regarding current and naturalistic psychedelic use practices, including use trends, prevalence across jurisdictions, dosing and supportive practices, and common use motivations. The Task Force believes that representing the full range of psychedelic practices happening currently-in absence of a state-level regulated framework-is critically important in advising the Maryland General Assembly as per its mandate: "The Task Force shall: study: existing... practices relating to the use of natural psychedelic substances;... opportunities to maximize public benefits... opportunities to mitigate potential risks of access to and use of natural psychedelic substances."

Use of Psychedelics is Increasing

Recent survey data suggest that the use of psychedelics is both more common than previously understood and increasingly mainstream. RAND found that **Psilocybin is the most commonly used** psychedelic substance among adults in the United States: 12.1% of U.S. adults—approximately **31.7 million people—reported lifetime use of psilocybin**, with 3.1% (8.1 million) having used it in the past year.³³⁸

³³⁸ Kilmer, B., Priest, M., Ramchand, R., Rogers, R. C., Senator, B., & Palmer, K. (2024). Considering alternatives to psychedelic drug prohibition. RAND Corporation. https://www.rand.org/pubs/research_reports/RRA2825-1.html

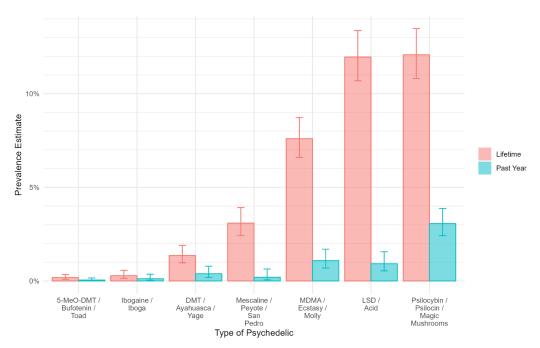


Figure 7. Lifetime and Past-Year Prevalence Rates for Various Psychedelic Substances Among U.S. Adults in 2023. Source: Considering alternatives to psychedelic drug prohibition, RAND Corporation.

These findings are consistent with the Berkeley Psychedelics Survey, a representative sample of registered U.S. voters repeated in 2023 and 2025, with a margin of error of ± 2.5%. In 2025, a majority of voters (55%) reported that they or someone close to them have used psychedelics at some point in their lives. Between 2023 and 2025, proximity to psychedelic use among self-identified conservatives increased from 43% to 50%. Among liberals, proximity remained relatively stable, rising slightly from 64% to 65%. Proximity also rose among older age groups. In those aged 65 to 74, it rose from 41% to 51%, and among those over 74, from 23% to 38%. The largest increase was reported by Black voters, whose proximity grew from 26% to 42% over the two-year period.

³³⁹ UC Berkeley Center for the Science of Psychedelics. (2025, June 17). UC Berkeley Center for the Science of Psychedelics releases new findings from Second Berkeley Psychedelics Survey [Press release]. https://psychedelics.berkeley.edu/uc-berkeley-bcsp-second-psychedelic-survey-results/

Keeping in mind that this survey is confidential – to the best of your knowledge, have you or has someone close to you ever used a psychedelic?

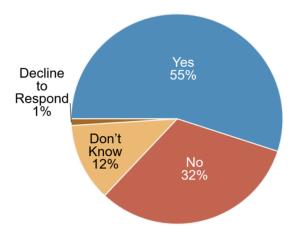


Figure 8. Lifetime History of Use of Psychedelics Among U.S. Registered Voters, 2025. Source: Second Berkeley Psychedelics Survey, UC Berkeley Center for the Science of Psychedelics.

Prevalence Across Regulated and Unregulated Settings

Among states with legal psychedelic access models, psychedelic use has accelerated.

Monte et. al. (2024) found that from 2019-2020 to 2021-2023, Oregon and Colorado saw an increase in past-year psychedelic use from 3.28% to 5.44% (a 65.9% increase). Meanwhile, rates in US states without psychedelic reform increased from 2.4% to 2.84% (an 18.3% increase). Regarding past-year initiation of psychedelic use, from 2019-2020 to 2021-2023 Oregon and Colorado rates rose from 1.5% to 2.14% (a 43% increase), compared to other US states where values rose from 1.44% to 1.65% (a 15% increase). The overall trend suggests that policy changes toward more permissive regulation correlate with uptake in psychedelic consumption. This rise is not uniform: some substances show steeper increases than others, and demographic factors (e.g. age, local awareness, media coverage) seem to moderate these trends. Other factors, such as the COVID-19 pandemic and national media attention, likely also contributed to the observed increase, suggesting broader shifts in public attitudes.

³⁴⁰ Monte AA, Schow NS, Black JC, Bemis EA, Rockhill KM, Dart RC. The Rise of Psychedelic Drug Use Associated With Legalization/Decriminalization: An Assessment With the Nonmedical Use of Prescription Drugs Survey. Ann Emerg Med. 2024 Mar;83(3):283-285. doi: 10.1016/j.annemergmed.2023.11.003. Epub 2023 Dec 22. PMID: 38142372.

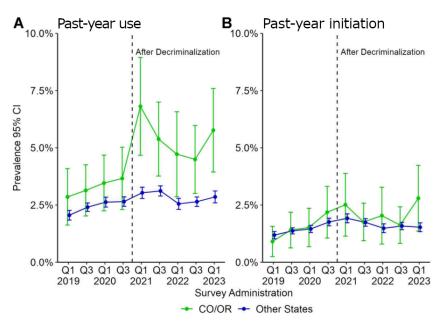


Figure 9. Past-Year Use (A), and Past-Year Initiation (B) of Psychedelic Substances in Oregon/Colorado versus other US states. Source: Psychedelic Drug Use Associated With Legalization/Decriminalization, Monte et. al.

While Oregon and Colorado have implemented state-level facilitated access programs for psilocybin–and New Mexico is in the process of developing its own–a majority of psychedelic use still occurs outside of regulated settings. Of the 8.1 million American adults who used psilocybin in 2023, only 715 were served in Oregon³⁴¹–the only state-level regulated psychedelic access program active in that year. Although precise estimates of clinical trial enrollment are difficult to obtain due to the decentralized nature of data collection, a recent review reported that 39 psychedelic clinical trials conducted between 2017 and 2024 enrolled a total of 1,393 participants. These numbers indicate that a vast majority of psilocybin use occurred outside of regulated settings, even after accounting for clinical trials that occurred during the same year. With an estimated 8,000 participants served by Oregon in 2024, the state-led program shows increases in access, but ultimately leaves a vast majority of American users unaccounted for within regulated settings.

³⁴¹ Acker, L. (2023, December 22). Over 700 people have used psychedelic mushrooms under Oregon's program in 2023. The Oregonian.

https://www.oregonlive.com/health/2023/12/over-700-people-have-used-psychedelic-mushrooms-under-oregons-program-in-2023.ht ml

³⁴² Hughes ME, Garcia-Romeu A. Ethnoracial inclusion in clinical trials of psychedelics: a systematic review. EClinicalMedicine. 2024 Jul 3;74:102711. doi: 10.1016/j.eclinm.2024.102711. PMID: 39050106; PMCID: PMC11268117.

³⁴³ McInally, M. (2024, December 13). Psilocybin industry will focus on fine-tuning first-in-the-nation program in 2025. Oregon Capital Chronicle.

https://oregoncapitalchronicle.com/2024/12/13/psilocybin-industry-will-focus-on-fine-tuning-first-in-the-nation-program-in-2025/

Differences Between Psychedelic, Alcohol, and Cannabis Use

Use of psychedelics differs greatly from both alcohol and cannabis. RAND found that lifetime use of psilocybin/psilocin (12.1%), dimethyltryptamine (1.4%), and mescaline (3.1%) are significantly lower than that of alcohol (85.9%) or cannabis (56%).³⁴⁴ Past-year and past-month use are also significantly lower, with only 0.9% of users reporting past-month use of psilocybin, compared to 55.2% for alcohol, and 20.2% for cannabis.

Table 2.1. Lifetime, Past-Year, and Past-Month Prevalence of Various Psychedelics from the 2023 RPS

	Lifetime		Past Year		Past Month	
Substance	%	95% CI	%	95% CI	%	95% CI
Alcohol	85.9%	(84.1, 87.5)	68.3%	(66.2, 70.3)	55.2%	(53.0, 57.3)
Cannabis	56.0%	(53.8, 58.1)	29.8%	(27.9, 31.8)	20.2%	(18.5, 22.0)
Psychedelics						
Psilocybin/psilocin/magic mushrooms	12.1%	(10.8, 13.5)	3.1%	(2.4, 3.9)	0.9%	(0.5, 1.4)
LSD/acid	12.0%	(10.7, 13.4)	0.9%	(0.5, 1.6)	0.2%	(0.1, 0.4)
MDMA/ecstasy/Molly	7.6%	(6.6, 8.7)	1.1%	(0.7, 1.7)	0.2%	(0.1, 0.4)
Mescaline/peyote/San Pedro	3.1%	(2.4, 3.9)	0.2%	(0.1, 0.6)	0.2%	(0.1, 0.6)
DMT/ayahuasca/yagé	1.4%	(1.0, 1.9)	0.4%	(0.2, 0.8)	0.1%	(0.0, 0.4)
Ibogaine/iboga	0.3%	(0.1, 0.6)	0.1%	(0.0, 0.4)	0.0%	(0.0, 0.2)
5-MeO-DMT/bufotenin/toad	0.2%	(0.1, 0.3)	0.0%	(0.0, 0.2)	0.0%	(0.0, 0.1)

NOTE: CI = confidence interval.

Figure 10. Lifetime, Past-Year, and Past-Month Prevalence of Various Psychedelics Among U.S. Adults in 2023. Source: Considering alternatives to psychedelic drug prohibition, RAND Corporation.

Unlike users of cannabis and many other drugs, infrequent users of psychedelics drive the psychedelic market, accounting for most of the total days of use. **About 60% of psychedelic users reported using them on "five or fewer days" within a month**, compared to only 5% of cannabis users reporting that frequency.

³⁴⁴ Kilmer, B., Priest, M., Ramchand, R., Rogers, R. C., Senator, B., & Palmer, K. (2024). Considering alternatives to psychedelic drug prohibition. RAND Corporation.

A Variety of Psychedelic Dosing Practices

Among psychedelic users, various dose ranges and practices have been documented. These dosing practices are broadly categorized below, in order of ascending quantity:

"Microdosing" involves ingesting a very small dose, called a "microdose," usually between one tenth and one twentieth of a typical recreational dose. This is often referred to as "sub-perceptual," meaning that users should take a dose so low that they cannot identify any acute drug effects, nor experience functional impairment. However, clinical laboratory research suggests that doses typical of microdosing do, in fact, cause acute subjective effects.³⁴⁵ This is done "usually for the purpose of improving wellbeing, cognition, mood, or interpersonal processes."³⁴⁶ Unlike other forms of psychedelic use, microdosers typically consume such small amounts of psychedelic substances regularly or semi-regularly, on a predetermined schedule, for prolonged periods of time. One common schedule is to consume a microdose once daily for 4 days, followed by no dose for 3 days, and so on. This might be **compared more** closely to typical consumption of an antidepressant medication, or a vitamin. Over the past five years, the popularity of microdosing has increased rapidly, now positively discussed in mainstream news stories, documentaries, books, movies, and entertainment television. UC Berkeley found that psychedelic use characterized as "microdosing" rose sharply from 22% of psychedelic use 6-10 years ago, to 41% within the last 5 years. A majority of research into psychedelics involves "high dose" ranges, and researchers face emerging questions about the degree to which microdosing outcomes are related to expectation or placebo, with some research suggesting that therapeutic-type effects for psychiatric disorders (e.g., improved attention or other cognitive enhancements) might be completely driven by expectation. 347,348 However, relatively little research with microdoses has been conducted in patient populations, so therapeutic efficacy in psychiatric disorders remains an open scientific question. Among the 8.1 million US adults who reported past-year use of psilocybin, nearly half reported that their most recent use involved microdosing (RAND Corporation, 2024).

³⁴⁵ Bershad AK, Schepers ST, Bremmer MP, Lee R, de Wit H. Acute Subjective and Behavioral Effects of Microdoses of Lysergic Acid Diethylamide in Healthy Human Volunteers. Biol Psychiatry. 2019 Nov 15;86(10):792-800. doi: 10.1016/j.biopsych.2019.05.019. Epub 2019 Jun 3. PMID: 31331617; PMCID: PMC6814527.

³⁴⁶ Vince Polito, Paul Liknaitzky, The emerging science of microdosing: A systematic review of research on low dose psychedelics (1955–2021) and recommendations for the field, Neuroscience & Biobehavioral Reviews, Volume 139, 2022, 104706, ISSN 0149-7634, https://doi.org/10.1016/j.neubiorev.2022.104706.

³⁴⁷ Szigeti B, Kartner L, Blemings A, Rosas F, Feilding A, Nutt DJ, Carhart-Harris RL, Erritzoe D. Self-blinding citizen science to explore psychedelic microdosing. Elife. 2021 Mar 2;10:e62878. doi: 10.7554/eLife.62878. PMID: 33648632; PMCID: PMC7925122.

³⁴⁸ Bershad AK, Schepers ST, Bremmer MP, Lee R, de Wit H. Acute Subjective and Behavioral Effects of Microdoses of Lysergic Acid Diethylamide in Healthy Human Volunteers. Biol Psychiatry. 2019 Nov 15;86(10):792-800. doi: 10.1016/j.biopsych.2019.05.019. Epub 2019 Jun 3. PMID: 31331617; PMCID: PMC6814527.

Table 1. Plausible dose ranges for microdoses of various substances.

Compound	Typical recreational or therapeutic dose range	Intoxication threshold dose range	Plausible microdose dose range
Psilocybe cubensis dried mushroom: PO	3–5g	0.5-1.5 g	0.1-0.5g
Psilocybin synthetic: PO	17-30mg ^a	3–8 mg ^b	0.8–5 mg ^c

Figure 11. Plausible Dose Ranges for Psilocybin. Source: The emerging science of microdosing, Polito & Liknaitzky. Note: Psilocybin itself (typically measured in milligrams) constitutes a very small percentage of the mass of mushrooms (typically measured in grams), accounting for common errors when comparing the dose of psilocybin used in clinical research versus the doses of mushrooms used by the public outside of scientific trials.

"Low Dose" (sometimes called "mesodose" or "sub-hallucinogenic dose", or, colloquially, as a "museum dose" or "concert dose") is the dose range whereby the user might feel some effects, but not a distinctly hallucinogenic experience. Relating to psilocybin, a sub-hallucinogenic dose may be found between 0.5-1.5 grams dried psilocybin mushrooms, consumed orally. This range represents an intermediate range where an individual might feel a subtle, but perceptible mental and even physical effect " (mood shift, heightened body sensitivity, etc.), without reaching the threshold of becoming overstimulating or dissociative. Exploratory studies show benefits of sub-hallucinogenic doses as utilizing a "pulse regimen" protocol for reducing cluster headache frequency in chronic patients. 349 As mentioned above, however, clinical research investigating therapeutic effects for psychiatric disorders is inconclusive.

"Regular Dose" (sometimes "macrodose," "high dose," or "treatment dose") is the dose range whereby the user might experience profound changes in mood, thought, self-experience, altered perception of time and space, sensory hallucinations (e.g. tasting colors, etc.), and often mystical or transcendent experiences (colloquially, "a trip"). Relating to psilocybin, a regular dose may be found between 1.5-5 grams dried psilocybin mushrooms, consumed orally, with higher doses involving more hallucinatory effects. A majority of research into clinical applications of psychedelic substances utilize this dose range.

³⁴⁹ Schindler EAD, Sewell RA, Gottschalk CH, Flynn LT, Zhu Y, Pittman BP, Cozzi NV, D'Souza DC. Psilocybin pulse regimen reduces cluster headache attack frequency in the blinded extension phase of a randomized controlled trial. J Neurol Sci. 2024 May 15;460:122993. doi: 10.1016/j.jns.2024.122993. Epub 2024 Apr 2. PMID: 38581739.

According to the Global Psychedelic Survey, psychedelic users (72.8%) engage in both "regular" and "microdose" practices, with more individuals reporting these "dual-dose" practices in US/Canada compared to other regions.³⁵⁰ Very few use (1.8%) psychedelics only in "microdoses." The reader should note, the Global Psychedelic Survey faces scrutiny for methodological limitations, including its reliance on a self-selected, non-representative sample and the use of self-reported data, which introduces selection bias and limits the generalizability and verifiable accuracy of the findings.

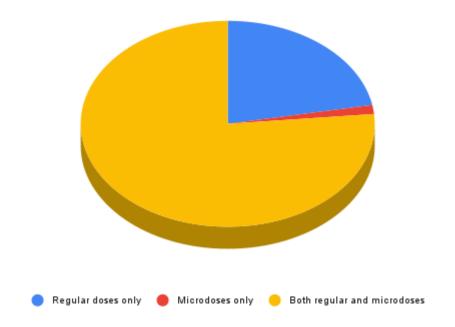


Figure 12. Regular, Microdosing, and Dual-Dose Practices Among Psychedelic Users. Source: The Global Psychedelic Survey

Triphasic and Supportive Psychedelic Practices

Within both regulated and unregulated settings, psychedelic users seeking psychosociospiritual gains (e.g. improvements to mental health, psychological insight, spiritual connection, etc.) often engage in three stages. Within the psychedelic-assisted therapy (P-AT) context, these stages are often titled: preparation, dosing, and integration. The Yale Manual for Psilocybin-Assisted Therapy of Depression (using Acceptance and Commitment Therapy as a Therapeutic Frame) details this:³⁵¹

³⁵⁰ Lake S, Lucas P. The Global Psychedelic Survey: Consumer characteristics, patterns of use, and access in primarily anglophone regions around the world. Int J Drug Policy. 2024 Aug;130:104507. doi: 10.1016/j.drugpo.2024.104507. Epub 2024 Jun 26. PMID: 38936219.

³⁵¹ Sloshower, Jordan & Guss, Jeffrey & Krause, Robert. (2020). The Yale Manual for Psilocybin-Assisted Therapy of Depression (using Acceptance and Commitment Therapy as a Therapeutic Frame). 10.31234/osf.io/u6v9y.

- Preparation: "Preparatory sessions, occurring prior to the medication session, aim to
 accomplish several important tasks. Therapists must develop therapeutic rapport with the
 participant, gather information about the participant and their history, and provide
 psychoeducation regarding the psychedelic experience, the therapeutic approach to be
 used, and expectations of the participant's active collaboration in the process.
 Additionally, the sessions seek to clarify the participant's expectations of the medication
 session."
- **Dosing:** During the psychedelic-dose phase, therapists "generally encourage participants to focus their mind inward [...] provide emotional support and encourage the participant to engage with difficult thoughts, sensations, or memories that arise. They also assist the participant by meeting any immediate needs for comfort or safety."
- **Integration:** "The integration phase usually begins the day after the dosing session; it involves reviewing the participant's experience during the dosing session thoroughly and, in some cases, applying therapeutic techniques to reinforce particular aspects of the experience so they foster sustained desirable patterns of thought and behavior. In other words, integration continues the therapeutic process that began during preparation sessions, and intensified during a psychedelic experience."

This relevance of facilitated support and supervision at the time of ingesting the substance is seen also in naturalistic community settings where self-medicating individuals seek out "gray-market" "guides" or "trip-sitters;" and also within spiritual or indigenous practices where psychedelic dosing sessions occur in group settings under facilitation of "shaman" or "spiritual guides." Importantly, the triphasic approach is not relevant to all therapeutic psychedelic modalities. For example, microdosers seek gains to well-being and cognition, but typically do not engage in a preparation or integration phase to the degree detailed above. As another example, facilitated support during the regular low-dose/sub-hallucinogenic treatment of cluster headache may be unnecessary and cost-prohibitive to patients in urgent need of relief.

Psychedelic Use Motives

Among psychedelic users, a broad range of motives for use have been documented-more broad than intentions for alcohol or cannabis use. The Task Force recognizes challenges in identifying motives as distinct categories. In the same way a person might exercise with the intention of self-improvement but nonetheless also experience joy, a person might use psychedelic substances with the intention of mental health improvement but nonetheless also experience pleasure-or vice versa. Below represents this Task Force's conceptualization of psychedelic use motives, roughly in order of descending goal-directness. This categorization draws from three

studies: the The Global Psychedelic Survey,³⁵² the UC Berkeley Psychedelics Survey,³⁵³ and a publication by RAND.³⁵⁴ These studies utilized national data among US adults, as this Task Force was not able to locate Maryland-specific population data on this topic. Still, even if nationwide samples vary from Maryland-specific numbers, we might assume that they are at least representative of the Maryland population in regard to breadth of use motivation. All three of these studies invited participants to "check all that apply," reflecting how these categories are not mutually exclusive, but rather aimed toward illustrating the breadth of intentions for psychedelic use:

Self-Medication (Health, and/or Therapeutic Use)

This category encompasses self-medication with the intention of attaining mental or physical health improvements, or reductions in symptoms. According to input received via public listening sessions, community engagement, and psychedelic use surveys, users self-medicate for mental health conditions such as depression, anxiety, PTSD, substance use problems, or others. Another subset of individuals reports self-medicating for migraine, cluster headache, fibromyalgia, and long COVID. Stakeholder input to the Task Force highlighted the use of psilocybin and DMT for cluster headaches—described as among the most effective treatments available, though largely inaccessible in regulated therapeutic models. These users might participate in any of the dosing or facilitation practices listed above: peer-supported infrequent "regular dose" practices intending to approximate clinical trial settings may be more prevalent around community members seeking reduction in mental health symptoms, whereby solo semi-regular "low dose" practices (a "pulse regimen") may be more prevalent among those seeking reduction in chronic pain conditions.

In the studied surveys where participants were invited to check all the use motives that applied, 39% reported "therapeutic" use in the UC Berkeley study, 48.8% reported "mental health" use in the RAND study, and 42.1% reported "medical/therapeutic" use in the Global Psychedelic Survey study. These numbers represent a not-insignificant quantity of psychedelic self-medication motivated toward therapeutic gains. UC Berkeley found that psychedelic use characterized as "therapeutic" rose from 21% of psychedelic use more than 10 years ago, to 48% 6-10 years ago,

³⁵² Lake S, Lucas P. The Global Psychedelic Survey: Consumer characteristics, patterns of use, and access in primarily anglophone regions around the world. Int J Drug Policy. 2024 Aug;130:104507. doi: 10.1016/j.drugpo.2024.104507. Epub 2024 Jun 26. PMID: 38936219.

³⁵³ UC Berkeley Center for the Science of Psychedelics. (2025, June 17). UC Berkeley Center for the Science of Psychedelics releases new findings from Second Berkeley Psychedelics Survey [Press release].

https://psychedelics.berkeley.edu/uc-berkeley-bcsp-second-psychedelic-survey-results/

³⁵⁴ Kilmer, B., Priest, M., Ramchand, R., Rogers, R. C., Senator, B., & Palmer, K. (2024). Considering alternatives to psychedelic drug prohibition. RAND Corporation. https://www.rand.org/pubs/research_reports/RRA2825-1.html

and to finally 53% within the last 5 years–indicating the increasing prevalence of "therapeutic" use. This may likely be attributed to shifting public perceptions and growing media coverage on the potential benefits of psychedelic substances, and people being eager to explore alternative health options accessible to them despite absence of FDA approval.

Given the absence of any regulated psychedelic access framework in Maryland, all use for medicinal benefits would be categorized as "self-medication," regardless of the presence of a formal diagnosis. Maryland residents do not have any option to seek legal supervision or guidance in use of the substances they have access to through "gray market" (semi-legal) channels such as DC. Similarly, licensed healthcare providers who may be trained on benefit-maximization and/or risk-mitigation strategies via available training programs (California Institute of Integral Studies, Integrative Psychiatry Institute, Fluence, etc.) are not legally permitted to provide advice or guidance.

Some cross-sectional surveys of naturalistic psychedelic use (self-medicating outside regulated settings) have partially replicated clinical findings of psychedelic-assisted therapy. Naturalistic users have reported decreases in depression and anxiety symptoms³⁵⁵ as well as decreases in the use of addictive substances including tobacco smoking^{356,357} (Garcia-Romeu et al., 2020; Johnson et al., 2017; Nygart et al., 2022). Meta-analysis of 104 studies reports naturalistic use of psilocybin, LSD, MDMA, mescaline, and 5-MeO-DMT is associated with reductions in depression, anxiety, PTSD, substance use disorders, interpersonal violence, and suicidality, alongside gains in emotional well-being, social connectedness, spirituality, nature relatedness, psychological flexibility, and physical health.³⁵⁸ While self-reported benefits often mirror those observed in research, the absence of screening, supervision, and integration support introduces risks of adverse effects, particularly among people with psychiatric vulnerabilities. The following sections provide a summary of clinical research, as well as a more detailed exploration of opportunities to maximize public benefits and mitigate public risks.

Well-Being (Personal Growth, Enhancement, and/or Artistic Use)

This category encompasses psychedelic use with the intention of improving oneself outside the scope of mental or physical health diagnoses. According to input received via public listening

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³⁵⁵ Nygart, V. A., Pommerencke, L. M., Haijen, E., Kettner, H., Kaelen, M., Mortensen, E. L., ... & Erritzoe, D. (2022). Antidepressant effects of a psychedelic experience in a large prospective naturalistic sample. Journal of Psychopharmacology, 36(8), 932-942 356 Johnson, M. W., Garcia-Romeu, A., Johnson, P. S., & Griffiths, R. R. (2017). An online survey of tobacco smoking cessation associated with naturalistic psychedelic use. Journal of psychopharmacology, 31(7), 841-850.

³⁵⁷ Garcia-Romeu, A., Davis, A. K., Erowid, E., Erowid, F., Griffiths, R. R., & Johnson, M. W. (2020). Persisting reductions in cannabis, opioid, and stimulant misuse after naturalistic psychedelic use: An online survey. Frontiers in psychiatry, 10, 955.

³⁵⁸ Haden, M., Paschall, S. A., & Woods, B. (2025). Beyond prohibition: A public health analysis of naturalistic psychedelic use. Journal of Psychedelic Studies (published online ahead of print 2025).

sessions, community engagement, and psychedelic use surveys, users consume psychedelic substances for existential exploration, personal growth, self-awareness, heightened creativity, enhanced performance, creativity, problem solving, or general well-being. These users might participate in any of the dosing or facilitation practices listed above: peer-supported infrequent "regular dose" practices may be more prevalent around community members (colloquially referred to as "psychonauts") seeking to explore consciousness, whereby "microdosing" may be more prevalent among those seeking enhanced performance at school, work, etc.

In the studied surveys where participants were invited to check all the use motives that applied, 25% reported "artistic" use in the UC Berkeley study, 45.2% reported "personal development" use in the RAND study, and 83.9% reported "personal growth" use in the Global Psychedelic Survey study. This was the highest chosen motive in the Global Psychedelic Survey. While significantly variable–likely due to sample populations and varying options among the different surveys–these numbers represent a not-insignificant quantity of psychedelic use motivated toward some form of personal improvement outside the scope of diagnosable conditions. UC Berkeley found that psychedelic use characterized as "artistic" rose mildly from 14% of psychedelic use more than 10 years ago, to 22% 6-10 years ago.

Spiritual and/or Religious Use

This category encompasses psychedelic use with the intention of achieving greater connection with nature or the sacred. Dosing practices are not standardized, and ceremonial practices vary. 359,360,361

In the studied surveys where participants were invited to check all the use motives that applied, 32% reported "spiritual" use in the UC Berkeley study, 41.3% reported "spiritual growth" use in the RAND study, and 50.7% reported "religious/spiritual purposes" use in the Global Psychedelic Survey study.

Indigenous communities have long incorporated naturally occurring psychedelics into their cultural and spiritual practices, operating entirely outside of regulated commercial markets. Substances like ayahuasca from the Amazonian vine, peyote (a cactus containing mescaline), or

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³⁵⁹ Spiers, Nicholas & Labate, Beatriz & Ermakova, Anna & Farrell, Patrick & Romero, Osiris & Gabriell, Ibrahim & Olvera, Nidia. (2024). Indigenous psilocybin mushroom practices: An annotated bibliography. Journal of Psychedelic Studies. 8. 10.1556/2054.2023.00297. ³⁶⁰ Ruffell SGD, Crosland-Wood M, Palmer R, Netzband N, Tsang W, Weiss B, Gandy S, Cowley-Court T, Halman A, McHerron D, Jong A, Kennedy T, White E, Perkins D, Terhune DB, Sarris J. Ayahuasca: A review of historical, pharmacological, and therapeutic aspects. PCN Rep. 2023 Oct 2;2(4):e146. doi: 10.1002/pcn5.146. PMID: 38868739; PMCID: PMC11114307.

³⁶¹ Doesburg-van Kleffens, Marjolein & Zimmermann-Klemd, Amy & Gründemann, Carsten. (2023). An Overview on the Hallucinogenic Peyote and Its Alkaloid Mescaline: The Importance of Context, Ceremony and Culture. Molecules. 28. 7942. 10.3390/molecules28247942.

psilocybin mushrooms are often gathered and prepared by shamans or elders according to traditional methods passed down through generations. Their use is not for recreational purposes but is deeply embedded in cultural rituals, healing ceremonies, and rites of passage, with the belief that they facilitate communication with the spiritual world and provide profound insights. Participants in these ceremonies frequently report a heightened sense of connection to their heritage and community, which helps to alleviate feelings of isolation and loneliness. This traditional use stands apart from the modern, regulated approaches to psychedelics, representing a continuous stream of culturally significant consumption.

Contemporary religious use of psychedelics, exemplified by groups like the Santo Daime Church, contrasts sharply with traditional indigenous practices. While both use psychoactive substances like ayahuasca for spiritual purposes, their origins, theology, and cultural context are fundamentally different. The Santo Daime Church is a modern, syncretic religion founded in Brazil in the 20th century. Its theology blends elements from various traditions, including indigenous shamanism, Afro-Brazilian animism, Catholicism, and Kardecist Spiritism. During stakeholder engagement, this Task Force has identified at least two "non-indigenous" religious organizations practicing in Maryland.

People engaging in solitary psychedelic use for spiritual reasons often cultivate a personal ritual to foster connection with nature and the sacred. For example, they may intentionally seek a natural setting, like a quiet forest or personal garden, for a semi-regular session of "prayer" or introspection. This autonomous practice allows them, in their view, to commune with their higher power and the natural world on their own terms, outside of organized communal or institutional frameworks.

Adult (Recreational, Curiosity, Fun, and/or Social) Use

This category encompasses psychedelic use with the intention of attaining a sense of joy, pleasure, play, sensory delight, or break from the routine of daily life. This encompasses interpersonal or community bonding, connecting with a friend, family, community, or social group. This motive also encompasses curiosity: consuming a psychedelic substance to witness whatever unfolds, with no particular goal or aim. This motive is distinct from the above in that it is not aimed at effecting an outcome of productivity or industriousness, but rather a receptive experience of joy and/or connection. Use in this type might occur at a party, music venue, or a private gathering where the environment is carefully curated to be safe and enjoyable. These users might participate in any of the dosing or facilitation practices listed above, though "microdose" or unfacilitated infrequent "low dose" practices may be more conducive to enhancing an art museum, music concert, or social gathering without risking sensory overwhelm.

Recreational use inherently constitutes a wide landscape, ranging from carefully curated environments with safety mechanisms in place, on one end, to much riskier use, sometimes involving co-use of other substances such as alcohol, on the other end.

In the studied surveys where participants were invited to check all the use motives that applied, 73% reported "recreational" use in the UC Berkeley study, 59.1% reported "fun" use in the RAND study, and 59.4% reported "recreation" use in the Global Psychedelic Survey study. These were the highest chosen motives in the UC Berkeley and RAND studies, and the second-highest in the Global Psychedelic Survey. Interestingly, the high rates indicate some necessary overlap between participants who selected "recreational" and "therapeutic," "fun" and "improved mental health"–perhaps challenging the societal assumption of mutual exclusivity between some of these intentions. UC Berkeley found that psychedelic use characterized as "recreational" declined mildly from 76% of psychedelic use more than 10 years ago, to 71% within the last 5 years. This may be due to increases in attribution to other use types as "therapeutic," "microdosing," and other uses rose.

Psychedelic use in last five years significantly more likely to be characterized as therapeutic, microdosing

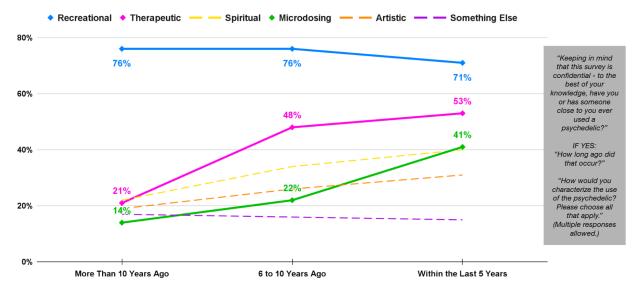


Figure 13. Psychedelic Use Motivations (Check all that apply) by Recency. Source: UC Berkeley Psychedelics Survey

Table 2.8. Intentions for Using Psilocybin at Last Use Among Individuals Who Used in the Past Year

Intention	%	95% CI
Fun (e.g., for a sense of joy, pleasure, or play, including at a party or other social gathering)	59.1%	(47.0, 70.3)
Improved mental health (e.g., to decrease symptoms of a mental health condition, such as depression or PTSD, or a substance use problem	48.8%	(37.1, 60.7)
Personal development (e.g., existential exploration, personal growth, self-awareness)	45.2%	(33.6, 57.4)
Curiosity (e.g., to witness whatever unfolds with no particular goal or aim	42.9%	(32.0, 54.6)
Spiritual growth (e.g., greater connection with nature or the sacred)	41.3%	(30.0, 53.7)
Cognitive enhancement (e.g., heightened creativity, performance, or problem solving)	41.2%	(29.7, 53.7)
Interpersonal bonding (e.g., to connect with a friend, family member, or romantic partner) ^a	24.0%	(15.8, 34.8)
Community bonding (e.g., to connect with your family, community, or social group)	15.0%	(8.8, 24.4)
Improved physical health (e.g., to decrease symptoms of a physical ailment or enhance physical performance)	14.9%	(8.9, 23.9)
Escapism (e.g., to avoid feelings of pain or discomfort)	10.4%	(5.7, 18.4)
Other	0.7%	(0.1, 5.0)

 $^{^{\}circ}$ Denotes p < 0.05 in weighted logistic regression models between those who microdosed the last time they used and those who did not. Respondents were asked to check all that apply.

Figure 14. Psilocybin Use Motivations (Check all that apply) at Last Use. Source: Considering alternatives to psychedelic drug prohibition, RAND Corporation

Summary of Psychedelic Research

Below is a summary of current research into psychedelics for the treatment of mental health indications (including substance use disorders), chronic pain conditions, and other conditions. This section presents most notable highlights, and is not intended to represent a comprehensive review of all research.

Mental Health Conditions

The research into natural psychedelic substances for the treatment of mental health conditions is one of the most rapidly evolving areas of modern medicine. Results are highly promising, but still preliminary, with a strong focus on addressing conditions that are resistant to conventional treatments.

Major Depressive Disorder (MDD)

Recent clinical research consistently shows that psilocybin-assisted therapy produces rapid and clinically significant reductions in depressive symptoms for adults with Major Depressive Disorder (MDD). Multiple randomized controlled trials (RCTs) demonstrate that one or two doses of psilocybin, paired with psychological support, yield clinically significant and often persistent antidepressant effects, with some studies reporting effect sizes exceeding those of conventional antidepressants, and improvements in well-being lasting weeks to months after one or two sessions. 362,363,364

One example is the Usona Institute sponsored Phase II randomized controlled trial at Johns Hopkins University and NYU with 27 participants with major depressive disorder.³⁶⁵ Two

³⁶² Carhart-Harris, R. L., Giribaldi, B., Watts, R., Baker-Jones, M., Murphy-Beiner, A., Murphy, R., ... & Nutt, D. J. (2021). Trial of psilocybin versus escitalopram for depression. The New England Journal of Medicine, 384(15), 1402-1411. DOI: 10.1056/NEJMoa2032994

³⁶³ Raison CL, Sanacora G, Woolley J, Heinzerling K, Dunlop BW, Brown RT, Kakar R, Hassman M, Trivedi RP, Robison R, Gukasyan N, Nayak SM, Hu X, O'Donnell KC, Kelmendi B, Sloshower J, Penn AD, Bradley E, Kelly DF, Mletzko T, Nicholas CR, Hutson PR, Tarpley G, Utzinger M, Lenoch K, Warchol K, Gapasin T, Davis MC, Nelson-Douthit C, Wilson S, Brown C, Linton W, Ross S, Griffiths RR. Single-Dose Psilocybin Treatment for Major Depressive Disorder: A Randomized Clinical Trial. JAMA. 2023 Sep 5;330(9):843-853. doi: 10.1001/jama.2023.14530. Erratum in: JAMA. 2024 Feb 27;331(8):710. doi: 10.1001/jama.2024.0828. PMID: 37651119; PMCID: PMC10472268

³⁶⁴ Gukasyan N, Davis AK, Barrett FS, Cosimano MP, Sepeda ND, Johnson MW, Griffiths RR. Efficacy and safety of psilocybin-assisted treatment for major depressive disorder: Prospective 12-month follow-up. J Psychopharmacol. 2022 Feb;36(2):151-158. doi: 10.1177/02698811211073759. PMID: 35166158; PMCID: PMC8864328.

³⁶⁵ Davis, A. K., Barrett, F. S., May, D. G., Cosimano, M. P., Sepeda, N. D., Johnson, M. W., & Griffiths, R. R. (2021). Effects of psilocybin-assisted therapy on major depressive disorder: A randomized clinical trial. JAMA Psychiatry, 78(5), 481–489. https://doi.org/10.1001/jamapsychiatry.2020.3285

psilocybin sessions (20–30 mg/70kg) combined with psychotherapy produced rapid and sustained reductions in depression scores, with about 70% of participants achieving a clinical response at four weeks.

The durability of these effects and their performance relative to established treatments are still under investigation. Research is often constrained by small sample sizes and short follow-up periods. One conflicting meta-analysis suggests that psilocybin's antidepressant efficacy is overestimated compared with that of SSRIs and esketamine. Concerns have been raised that high rates of functional unblinding in combination with trial participants expectations might bias treatment outcomes.

Treatment-Resistant Depression (TRD)

In patients with Treatment-Resistant Depression (TRD), large multi-site randomized trials have found that a single high-dose psilocybin session, delivered with psychological support, can produce significant reductions in depressive symptoms, with effects persisting for several weeks in a subset of participants. These results suggest that psilocybin may have rapid-acting antidepressant properties even in populations that have not responded to conventional treatments.

The most substantial data come from a multi-site Phase IIb randomized controlled trial led by COMPASS Pathways, which enrolled 233 participants with TRD across 22 European and North American sites. A single 25 mg psilocybin dose produced significantly greater symptom reductions at three weeks than 1 mg or 10 mg comparators, though effects diminished over time. A smaller open-label study (Carhart-Harris et al., Lancet Psychiatry 2016, Imperial College London) with 12 TRD patients found similar rapid decreases in depression scores. These trials suggest that psilocybin can produce short-term improvements in otherwise treatment-resistant populations.

³⁶⁶ Madden K, Flood B, Young Shing D, et al. Psilocybin for clinical indications: A scoping review. Journal of Psychopharmacology. 2024;38(10):839-845. doi:10.1177/02698811241269751

³⁶⁷ Hieronymus F, López E, Werin Sjögren H, Lundberg J. Control Group Outcomes in Trials of Psilocybin, SSRIs, or Esketamine for Depression: A Meta-Analysis. JAMA Netw Open. 2025 Jul 1;8(7):e2524119. doi: 10.1001/jamanetworkopen.2025.24119. Erratum in: JAMA Netw Open. 2025 Sep 2;8(9):e2536707. doi: 10.1001/jamanetworkopen.2025.36707. PMID: 40736734; PMCID: PMC12311713. ³⁶⁸ Guy M. Goodwin, Megan Croal, Lindsey Marwood, Ekaterina Malievskaia, Unblinding and demand characteristics in the treatment of depression, Journal of Affective Disorders, Volume 328, 2023, Pages 1-5, ISSN 0165-0327,

characteristics in the treatment of depression, Journal of Affective Disorders, Volume 328, 2023, Pages 1-5, ISSN 0165-0327, https://doi.org/10.1016/j.jad.2023.02.030.

³⁶⁹ Goodwin, G. M., Aaronson, S. T., Alvarez, O., Arden, P. C., Baker, A., Bennett, J. C., Bird, C., & Malievskaia, E. (2022). Single-dose psilocybin for a treatment-resistant episode of major depression. New England Journal of Medicine, 387(18), 1637–1648. https://doi.org/10.1056/NEJMoa2206443

³⁷⁰ Carhart-Harris, R. L., et al. (2016). Psilocybin with psychological support for treatment-resistant anxiety and depression: Open-label feasibility study. The Lancet Psychiatry, 3(7), 642–650. https://doi.org/10.1016/S2215-0366(16)30065-7

The durability of these effects remains under investigation. Evidence is largely limited to short-term follow-up, leaving the durability of effects and the optimal dosing schedule (single vs. multiple sessions) uncertain.

Early studies using ayahuasca (DMT) have also reported reductions in depressive symptoms within days of administration, though the evidence base remains limited and sample sizes are small. A randomized placebo-controlled trial at the Federal University of Rio Grande do Norte, Brazil enrolled 29 TRD participants and found significant reductions in depression severity within 24 hours of a single ayahuasca dose, with effects persisting for seven days.³⁷¹ These findings are promising but remain based on small sample sizes and single-dose designs.

Cancer-Related Anxiety, Depression, and Suicidal Ideation

Psilocybin-assisted therapy has demonstrated **substantial promise in rapidly and effectively alleviating depression and anxiety** in patients with **life-threatening cancer diagnoses**.

Two pivotal randomized cross-over trials were conducted at Johns Hopkins University³⁷² and NYU.³⁷³ Both used a single high-dose psilocybin session (22–30 mg/70kg) in patients with life-threatening cancer and documented rapid, large reductions in anxiety and depression scores, with many effects persisting for six months or longer. One observational (post-blinding) study for one of these trials suggested substantial improvement an average of 4.5 years after treatment.³⁷⁴ In these studies, a high percentage of participants achieved clinical response or remission, with the intervention significantly outperforming active placebos. These studies are small and single-site but have been influential in shaping subsequent clinical development programs.

In a randomized controlled trial of psilocybin-assisted therapy, participants with advanced cancer found rapid and sustained improvements in depression, demoralization, and hopelessness,

³⁷¹ Palhano-Fontes, F., Barreto, D., Onias, H., Andrade, K. C., Novaes, M. M., Pessoa, J. A., ... de Araujo, D. B. (2019). Rapid antidepressant effects of the psychedelic ayahuasca in treatment-resistant depression: A randomized placebo-controlled trial. Psychological Medicine, 49(4), 655–663. https://doi.org/10.1017/S0033291718001356

³⁷² Griffiths, R. R., Johnson, M. W., Carducci, M. A., Umbricht, A., Richards, W. A., Richards, B. D., Cosimano, M. P., & Klinedinst, M. A. (2016). Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: A randomized double-blind trial. Journal of Psychopharmacology, 30(12), 1181–1197. https://doi.org/10.1177/0269881116675513
³⁷³ Ross, S., Bossis, A., Guss, J., Agin-Liebes, G., Malone, T., Cohen, B., Mennenga, S. E., Belser, A., Kalliontzi, K., Babb, J., Su, Z., Corby, P., & Schmidt, B. L. (2016). Rapid and sustained symptom reduction following psilocybin treatment for anxiety and depression in patients with life-threatening cancer: A randomized controlled trial. Journal of Psychopharmacology, 30(12), 1165–1180. https://doi.org/10.1177/0269881116675512

Agin-Liebes GI, Malone T, Yalch MM, Mennenga SE, Ponté KL, Guss J, Bossis AP, Grigsby J, Fischer S, Ross S. Long-term follow-up of psilocybin-assisted psychotherapy for psychiatric and existential distress in patients with life-threatening cancer. J Psychopharmacol. 2020 Feb;34(2):155-166. doi: 10.1177/0269881119897615. Epub 2020 Jan 9. PMID: 31916890.

suggesting a potential antisuicidal effect.³⁷⁵ Secondary analysis found psilocybin-assisted therapy was associated with reductions in suicidal ideation as early as 8 hours and persisted over 6 months following the dose session. Psilocybin-assisted therapy also produced reductions in "Loss of Meaning" (which predicts suicidal ideation in this population) apparent 2 weeks after treatment, and remained significant though the 4.5 year follow-ups, suggesting psilocybin-assisted therapy as an antisuicidal intervention.

Current research is limited by generalizability across diverse terminal illness or other populations.

Post-Traumatic Stress Disorder (PTSD)

Emerging research demonstrates promising outcomes for psychedelic treatment of PTSD, with psilocybin showing particular potential through mechanisms including promoting neuroplasticity via brain-derived neurotrophic factor (BDNF) signaling, reducing amygdala hyperactivity, facilitating emotional processing, and enhancing fear extinction.³⁷⁶ Clinical trials examining psilocybin for depression typically employ 20-30mg/70kg or fixed 25mg dosing paradigms that inform potential PTSD protocols. Psilocybin reduces default mode network brain communication activity associated with rumination and rigid thought patterns, directly addressing core PTSD pathophysiology. 377 A 2024 study examining psychedelics in naturalistic veteran retreat settings found 44% of veterans with likely PTSD at baseline no longer met criteria post-retreat, with large effect size symptom reductions.³⁷⁸ Veterans reported profound experiences of self-compassion, spiritual connection, and recontextualization of traumatic events. The VA's National Center for PTSD reports that psychedelic-assisted therapy shows promise in helping patients access traumatic memories with reduced avoidance.³⁷⁹ Veterans often present with moral injury, psychological distress from actions transgressing deeply held beliefs, where traditional treatments show limited effectiveness while psilocybin experiences appear to facilitate meaning-making and self-forgiveness.³⁸⁰

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³⁷⁵ Agin-Liebes, E., Haas, T., Gukasyan, N., Davis, A. K., & Griffiths, R. R. (2021). Acute and sustained reductions in loss of meaning and suicidal ideation following psilocybin-assisted psychotherapy for psychiatric and existential distress in life-threatening cancer. Journal of Affective Disorders, 285, 1–7. https://doi.org/10.1016/j.jad.2021.01.077

³⁷⁶Krediet E., et al. (2020). Reviewing the Potential of Psychedelics for the Treatment of PTSD. Int J Neuropsychopharmacol. 2020 Jun 24;23(6):385-400. doi: 10.1093/ijnp/pyaa018. PMID: 32170326; PMCID: PMC7311646

³⁷⁷ Carhart-Harris, R. L., et al. (2017). Neural correlates of the psychedelic state as determined by fMRI studies with psilocybin. Proceedings of the National Academy of Sciences, 109(6), 2138-2143.

³⁷⁸ Calnan, M., et al(2025). Exploring the Therapeutic Effects of Psychedelics Administered to Military Veterans in Naturalistic Retreat Settings." *Brain and behavior* vol. 15,7: e70660. doi:10.1002/brb3.70660 https://pmc.ncbi.nlm.nih.gov/articles/PMC12230355/ ³⁷⁹ VA National Center for PTSD. (2024). Psychedelics-Assisted Therapy for PTSD.

https://www.ptsd.va.gov/professional/treat/txessentials/psychedelics_assisted_therapy.asp

³⁸⁰Calnan, M., et al(2025). Exploring the Therapeutic Effects of Psychedelics Administered to Military Veterans in Naturalistic Retreat Settings." *Brain and behavior* vol. 15,7: e70660. doi:10.1002/brb3.70660 https://pmc.ncbi.nlm.nih.gov/articles/PMC12230355/

Researchers have provided rationale for the potential benefits of ayahuasca for PTSD treatment, though standardized protocols remain underdeveloped.³⁸¹ Studies found significant veteran PTSD symptom reductions though MAOI components create medication interaction concerns, particularly with VA-prescribed antidepressants, necessitating careful screening.

Despite promising evidence, substantial gaps remain. Mescaline research remains limited, though naturalistic surveys show self-reported improvements. Research faces challenges including peyote's endangered status and varying concentrations in sustainable alternatives.

Alcohol Use Disorder (AUD)

Evidence suggests that psilocybin-assisted therapy has potential utility as an adjunctive intervention for treating Alcohol Use Disorder (AUD) by reducing alcohol misuse and promoting abstinence.

A multisite double-blind RCT led by NYU and the University of New Mexico enrolled 93 participants with alcohol use disorder.³⁸² Two psilocybin-assisted psychotherapy sessions produced 83%reductions in heavy drinking days for up to 32 weeks, compared with an active placebo. Participants also showed improvements in measures of craving and self-efficacy. This represents the largest controlled trial of psilocybin for any substance use disorder to date.

Research is limited by a small number of modern trials, and a lack of long-term data beyond. Longer follow-up and replication, especially across more diverse populations, are needed.

Ayahuasca observational studies report significant reductions in alcohol consumption, with participants describing facilitated insight into addiction patterns.³⁸³

Tobacco Use Disorder (TUD)

Early pilot studies and ongoing clinical trials indicate that psilocybin-assisted therapy holds potential for treating Tobacco Use Disorder (TUD). Currently a large Randomized Controlled Trial (RCT) is underway comparing psilocybin with nicotine replacement therapy, however no completed RCTs for TUD have yet been peer-reviewed and/or published.

³⁸¹ Calnan M, Blest-Hopley G, Busch C, Adams M, Ruffell SGD, Piper T, Roseman L, Kettner H, Carhart-Harris R. Exploring the Therapeutic Effects of Psychedelics Administered to Military Veterans in Naturalistic Retreat Settings. Brain Behav. 2025 Jul;15(7):e70660. doi: 10.1002/brb3.70660. PMID: 40619953; PMCID: PMC12230355.

³⁸² Bogenschutz, M. P., Ross, S., Bhatt, S., Baron, T., Forcehimes, A. A., Mennenga, S. E., ... Umbricht, A. (2022). Psilocybin-assisted treatment for alcohol use disorder: A randomized clinical trial. JAMA Psychiatry, 79(10), 953–962. https://doi.org/10.1001/jamapsychiatry.2022.2096

³⁸³ Oliveira-Lima, A. J., et al. (2021). Effects of ayahuasca on the development of ethanol-induced behavioral sensitization and on a post-sensitization treatment in mice. Physiology & Behavior, 235, 113376. https://doi.org/10.1016/j.physbeh.2021.113376

An open-label pilot study combined moderate and high doses of psilocybin with cognitive behavioral therapy (CBT) in 15 participants, achieving an 80% biologically confirmed abstinence rate at six months, which is substantially higher than conventional treatments. This high quit rate was largely sustained at 67% after one year and 60% after 2.5 years. A recently completed but yet unpublished randomized comparative efficacy study found significantly higher biologically confirmed tobacco abstinence rates compared to nicotine patch treatment when both treatments were combined with CBT. Veterans reported reduced tobacco cravings and successful smoking cessation, though systematic research specifically examining veterans with TUD remains limited. Survey research collected accounts of individuals having claimed cessation or reduction of tobacco smoking following ingestion of psilocybin or other classic psychedelics such as LSD or ayahuasca. Respondents reported substantially less emotion-related withdrawal such as depressive symptoms compared to other times they tried to quit smoking.

Current evidence remains limited to small pilot studies. Larger studies with more robust controls are needed to confirm efficacy, safety, and optimal treatment models.

Obsessive-Compulsive Disorder (OCD)

One foundational pilot study suggests the potential for efficacy of psilocybin for Obsessive-Compulsive Disorder (OCD).

In the first modern clinical investigation of psilocybin for OCD, nine participants with treatment-resistant OCD were administered in an open-label setting.³⁸⁸ Participants received up to four doses of psilocybin, ranging from 25 micrograms/kg (sub-hallucinogenic) to 300 micrograms/kg (hallucinogenic). Testing days were separated by at least 1 week. Results showed acute reductions in OCD scores ranging from 23%-100%. Acute symptom reduction was similar between the higher doses and the very low dose intended to serve as an active placebo, suggesting the possibility that results may have been the product of expectation. One participant

³⁸⁴ Johnson, M. W., Garcia-Romeu, A., & Griffiths, R. R. (2014). Pilot study of the 5-HT2AR agonist psilocybin in the treatment of tobacco addiction. Journal of Psychopharmacology, 28(11), 983–992. https://doi.org/10.1177/0269881114548296

³⁸⁵ "Clinical Trial Comparing Psilocybin to Nicotine Patch for Tobacco Addiction" International Society for Research on Psychedelics. New Orleans, LA. February, 2024

³⁸⁶ Davis, A. K., et al. (2025). Exploring the Therapeutic Effects of Psychedelics Administered to Military Veterans in Naturalistic Retreat Settings. PMC, Article PMC12230355.

³⁸⁷ Johnson MW, Garcia-Romeu A, Johnson PS, Griffiths RR. An online survey of tobacco smoking cessation associated with naturalistic psychedelic use. J Psychopharmacol. 2017 Jul;31(7):841-850. doi: 10.1177/0269881116684335. Epub 2017 Jan 18. PMID: 28095732; PMCID: PMC6753943.

³⁸⁸ Moreno, F., et al. (2006). Safety, tolerability, and efficacy of psilocybin in 9 patients with obsessive-compulsive disorder. Journal of Clinical Psychiatry, 67(11), 1735–1740. https://doi.org/10.4088/JCP.v67n1110

continued to be in remission at 6-month follow-up. More recent research corroborates these findings: a 2022 case series of three patients with treatment-refractory OCD who received psilocybin-assisted therapy showed marked symptom improvement, with Yale-Brown Obsessive Compulsive Scale (Y-BOCS) scores decreasing by 25-50% and sustained improvements at 6-month follow-up.³⁸⁹

A 2021 systematic review examining psychedelics for OCD noted that beyond psilocybin, ayahuasca has shown promise in case reports, with patients reporting reduced obsessive thoughts and compulsive rituals following ceremonial use.³⁹⁰

Although encouraging, research into psilocybin for OCD is in early stages. One randomized active-placebo-controlled, double-blind study at Yale University (NCT03356483) led by Dr. Benjamin Kelmendi was recently completed, but results have not yet been published.³⁹¹

Anorexia Nervosa (AN)

Psilocybin is in early stages of exploration for treatment of Anorexia Nervosa (AN), with current research suggesting that psilocybin alone may not be sufficient for treating core symptoms.

A Phase 1 feasibility study at the University of California, San Diego, investigated psilocybin-assisted therapy for 10 adult women with anorexia nervosa (AN). ³⁹² A single 25-mg dose of synthetic psilocybin was administered in conjunction with psychological support. Psilocybin was found to be well-tolerated, with variable improvements in psychological flexibility and eating disorder psychopathology at four weeks: some participants reported clinically meaningful improvements, while others saw limited change. It should also be noted that no significant changes in body mass index (BMI) were observed, suggesting that future treatments may need enhanced treatment protocols for behavior change (including potentially repeated dosing) if these early suggestive findings of psychological improvements are to be translated to robust treatment results. Additional research is exploring ayahuasca's potential for eating disorders. Preliminary observational studies suggest ayahuasca ceremonies may help address underlying psychological factors including perfectionism, body image distortion, and trauma that

Barber, G. S., Rosenblat, J. D., Meshkat, S., Pong, J. C., Komaricevic, M., & McIntyre, R. S. (2022). Psilocybin-assisted therapy for treatment-resistant obsessive-compulsive disorder: A case series of three patients. Frontiers in Psychiatry, 13, 933321.

³⁹⁰ Szmulewicz, A. G., Valerio, M. P., & Smith, J. M. (2021). Psychedelics in the treatment of obsessive-compulsive disorder. General Hospital Psychiatry, 73, 64-7

³⁹¹ Yale University. (2024). Efficacy of psilocybin in OCD: A double-blind, placebo-controlled study. ClinicalTrials.gov. Retrieved from https://www.clinicaltrials.gov/study/NCT03356483

Peck, K., (et al.). (2023). Psilocybin therapy for females with anorexia nervosa: A phase 1, open-label feasibility study. American Journal of Psychiatry, 180(9), 741–752. https://doi.org/10.1176/appi.ajp.20230005

contribute to AN. Participants have reported insights into the emotional roots of disordered eating and shifts in self-compassion, though systematic research remains extremely limited.

Research is limited by small, open-label samples and short-term data.

Body Dysmorphic Disorder (BDD)

Early research suggests psilocybin may hold therapeutic promise for individuals with Body Dysmorphic Disorder (BDD), especially those unresponsive to standard medication.

An open-label pilot study at Columbia University tested psilocybin-assisted therapy in 12 adult individuals with SSRI-nonresponsive moderate-to-severe, treatment-resistant body dysmorphic disorder.³⁹³ The study found that a single oral dose of 25 mg psilocybin, administered with psychological support, was well-tolerated and produced significant reductions in BDD symptoms. Secondary efficacy measures of BDD symptoms, conviction of belief, negative affect, and disability also improved significantly.

Evidence base in psilocybin-assisted therapy for the treatment of BDD is extremely limited, as studies are preliminary and uncontrolled.

Chronic Pain Conditions

Emerging evidence from early-phase clinical trials, case series, and observational studies suggests potential benefit of natural psychedelic substances for some chronic pain conditions.

Cluster Headache

Small randomized controlled trials and open-label studies indicate that psilocybin may reduce chronic cluster headache attack frequency, with effect sizes suggesting clinical relevance and a favorable safety profile in the short term.

One exploratory randomized, double-blind, placebo-controlled study investigated the effects of psilocybin in cluster headache in 14 participants.³⁹⁴ Participants were randomly assigned to receive placebo or low doses of psilocybin (0.143 mg/kg) in a "pulse" of three doses, each ~5 days

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³⁹³ Schneier, F. R., et al. (2023). Pilot study of single-dose psilocybin for serotonin reuptake-refractory body dysmorphic disorder. Journal of Psychiatric Research, 170, 1–9. https://doi.org/10.1016/j.jpsychires.2023.02.011

³⁹⁴ Schindler, E. A. D., Sewell, R. A., Gottschalk, C. H., Luddy, C., Flynn, L. T., Zhu, Y., Lindsey, H., Pittman, B., Cozzi, N., & D'Souza, D. C. (2022). Exploratory investigation of a patient-informed low-dose psilocybin pulse regimen in the suppression of cluster headache: Results from a randomized, double-blind, placebo-controlled trial. Headache: The Journal of Head and Face Pain, 62(10), 1383–1394. https://doi.org/10.1111/head.14420

apart. Participants also maintained headache diaries starting 2 weeks before and continuing through 8 weeks after the first drug session. Psilocybin was found to be well-tolerated, and with a small effect in episodic participants, but a large effect in chronic participants, as compared to placebo. Improvements remained over the entire 8-week period measured.

In a blinded extension phase (follow-up study), 10 participants returned to receive a psilocybin pulse at least 6 months following their first round of participation.³⁹⁵ In the three weeks after the start of the pulse, cluster attack frequency was significantly reduced from baseline, and reduction of approximately 50% was seen regardless of individual response to psilocybin in the first round. The results indicated that multiple rounds of treatment with psilocybin may increase the efficacy of the treatment. In a foundational survey that interviewed 53 cluster headache patients, 22 of 26 psilocybin users reported that psilocybin aborted attacks, 18 of 19 reported remission period extension.³⁹⁶

Research is limited by small sample sizes and the need for replication. An ongoing randomized controlled trial at Yale University (NCT03341689) is testing single-dose psilocybin versus placebo for both migraine and cluster headache, with results not yet published.³⁹⁷

Migraine

Small studies suggest there may be enduring therapeutic effects in migraine headache after a single administration of psilocybin.

At Yale School of Medicine, a double-blind, placebo-controlled pilot study with 10 participants found that a single low-dose psilocybin session significantly reduced weekly migraine frequency for two weeks.³⁹⁸ Psilocybin was well-tolerated, with no serious adverse events.

Despite encouraging findings, research is limited by small sample sizes, reliance on survey data, and absence of large-scale randomized controlled trials with long-term follow-up. The field also lacks controlled comparative data evaluating psilocybin against established headache treatments. An ongoing randomized controlled trial at Yale University (NCT03341689) is testing

³⁹⁵ Schindler, E. A. D., Sewell, R. A., Gottschalk, C. H., Flynn, L. T., Zhu, Y., Pittman, B. P., Cozzi, N. V., & D'Souza, D. C. (2024). Psilocybin pulse regimen reduces cluster headache attack frequency in the blinded extension phase of a randomized controlled trial. Journal of the Neurological Sciences, 460, 122993. https://doi.org/10.1016/j.jns.2024.122993

³⁹⁶ Sewell RA, Halpern JH, Pope HG Jr. Response of cluster headache to psilocybin and LSD. Neurology. 2006 Jun 27;66(12):1920-2. doi: 10.1212/01.wnl.0000219761.05466.43. PMID: 16801660.

³⁹⁷ Yale University. (2023). Psilocybin for the treatment of migraine headache. ClinicalTrials.gov. Retrieved from https://clinicaltrials.gov/study/NCT03341689

³⁹⁸ Schindler, E. A. D., Sewell, R. A., Gottschalk, C. H., Luddy, C., Flynn, L. T., Lindsey, H., Pittman, B. P., Cozzi, N. V., & D'Souza, D. C. (2021). Exploratory controlled study of the migraine-suppressing effects of psilocybin. Neurotherapeutics, 18(1), 534–543. https://doi.org/10.1007/s13311-020-00962-y

single-dose psilocybin versus placebo for both migraine and cluster headache, with results not yet published.³⁹⁹

Fibromyalgia

In an open-label pilot clinical trial for fibromyalgia patients, recruitment was halted early due to "concerns about generalizability and changes in FDA guidance for psychedelic clinical trials." The 5 participants recruited, received two doses of oral psilocybin (15mg and 25mg) delivered two weeks apart, in conjunction with two preparatory and four integration psychotherapy sessions. Results showed psilocybin was well-tolerated with no serious adverse events. Compared to baseline, participants reported clinically meaningful improvements in pain severity, pain interference, and sleep disturbance, one month following their second psilocybin dose. One participant reported their symptoms "very much improved," two reported "much improved," and two reported "minimally improved."

Evidence remains generally limited by sample sizes, or to surveys which rely on self-reports. No large-scale high-quality randomized controlled trials have yet established efficacy or optimal dosing. Ongoing phase 2a research is investigating an oral psilocybin formulation paired with psychotherapy for treatment of fibromyalgia, with results pending.⁴⁰¹

Neuropathic Pain, Including Phantom Limb Pain

Preliminary data and one case study which involved a military veteran with traumatic arm amputation who experienced complete resolution of phantom limb pain, this suggests that a single dose of psilocybin, paired with mirror-visual-feedback, may safely lead to a significant and sustained reduction in chronic phantom limb pain.⁴⁰²

An ongoing double-blind placebo-controlled pilot study is investigating whether psilocybin can be safely administered to people with chronic phantom limb pain (PLP) in a supportive setting, and its effects on pain symptoms and other moods, attitudes, and behaviors, with results pending.⁴⁰³

³⁹⁹ Yale University. (2023). Psilocybin for the treatment of migraine headache. ClinicalTrials.gov. Retrieved from https://clinicaltrials.gov/study/NCT03341689

Aday, J. S., McAfee, J., Conroy, D. A., Van Dyck, N. N., Lavertu, A. L., Loria, L., Carhart-Harris, R. L., & Ajroud-Driss, S. (2025). Preliminary safety and effectiveness of psilocybin-assisted therapy in adults with fibromyalgia: an open-label pilot clinical trial. Frontiers in Pain Research, 6, 1527783.

⁴⁰¹ https://cdn.clinicaltrials.gov/large-docs/62/NCT05128162/Prot_SAP_001.pdf

⁴⁰² Lin, A. Y.-M., Zeme, S. K., & Ramachandran, V. S. (2018). Relief from intractable phantom pain by combining psilocybin and mirror visual-feedback (MVF). Neurocase, 24(2), 105–110. https://doi.org/10.1080/13554794.2018.1468469

⁴⁰³ University of California San Diego. (2023). Psilocybin-assisted therapy for phantom limb pain (ClinicalTrials.gov Identifier No. NCT05224336). ClinicalTrials.gov. Retrieved from https://www.clinicaltrials.gov/study/NCT05224336

Additionally, a randomized control double-blinded active-placebo trial plans to explore the feasibility of psilocybin for alleviating pain in chronic neuropathic pain, but results are not yet available.404

Inflammatory and Metabolic Conditions

Emerging research suggests that natural psychedelic substances may hold significant promise as anti-inflammatory compounds, with potential therapeutic applications across a range of inflammation-related conditions. These substances are posited to represent a new class of small molecule, highly bioavailable, and efficacious at sub-behavioral levels, useful for treating and preventing a variety of inflammatory-related diseases and conditions, such asthma, atherosclerosis, cardiovascular disease, and/or inflammatory bowel disease. 405 Anti-inflammatory potential also intersects with metabolic diseases like type 2 diabetes. 406

Evidence has been demonstrated in several cell and tissue types across several species. No clinical studies in humans have yet been published.

Neurodegenerative Conditions (Alzheimer's, Parkinson's, etc.)

Research into natural psychedelic substances for neurodegenerative and aging-related conditions is at its earliest stages. Current evidence is limited to preclinical studies, mechanistic reviews, and early-phase clinical trials. Preclinical and translational research demonstrates that psilocybin and its metabolite psilocin promote neuroplasticity, neurogenesis, and synaptic remodeling, primarily via 5-HT2A receptor agonism. These effects may counteract neuroinflammatory and neurodegenerative processes. These mechanisms are hypothesized to be relevant for counteracting neuroinflammatory and neurodegenerative processes, but have not been validated in large human studies.

⁴⁰⁴ Unity Health Toronto. (2025). Psilocybin for enhanced analgesia in chronic neuropathic pain (PEACE-PAIN) (ClinicalTrials.gov Identifier No. NCT06731335). ClinicalTrials.gov. Retrieved from https://www.clinicaltrials.gov/study/NCT06731335

⁴⁰⁵ Charles D. Nichols, Psychedelics as potent anti-inflammatory therapeutics, Neuropharmacology, Volume 219, 2022, 109232, ISSN 0028-3908, https://doi.org/10.1016/j.neuropharm.2022.109232.

⁽https://www.sciencedirect.com/science/article/pii/S002839082200291X)

⁴⁰⁶ Gojani, E. G., Wang, B., Li, D.-P., Kovalchuk, O., & Kovalchuk, I. (2024). The Impact of Psilocybin on High Glucose/Lipid-Induced Changes in INS-1 Cell Viability and Dedifferentiation. Genes, 15(2), 183. https://doi.org/10.3390/genes15020183

Preclinical studies in Alzheimer's mouse models suggest DMT may affect neuroinflammatory and neuroplasticity pathways, with the potential to serve as a novel preventive and therapeutic agent against Alzheimer's disease.⁴⁰⁷

An open-label pilot study examined the feasibility of psilocybin-assisted therapy among people with mild to moderate stage Parkinson's disease plus depression and/or anxiety among 12 participants. The study found no worsening of Parkins's disease symptomology. Non-motor and motor symptoms, and performance in select cognitive domains, improved post-treatment for at least one month following drug exposure, suggesting that more study into effects on Parkinson's disease may be warranted.

No large-scale efficacy trials in human neurodegenerative disease populations have yet been published. Most clinical trials have excluded patients with significant comorbidities or advanced neurodegenerative disease.

Other Conditions

General Well-Being

Findings show potential for high-dose natural psychedelic substances to support well-being beyond the scope of diagnosable disorders.

A landmark double-blind study by Griffiths and colleagues administered 2-3 individual 8-hour sessions of 30mg/70kg psilocybin to 30 healthy, psychedelic-naive participants encouraged to "close their eyes and direct their attention inward." Griffiths found at 2 months, participants rated the experience as having "substantial personal meaning and spiritual significance" related to positive changes in attitudes and behavior changes. Another study found that participants who had "mystical experiences" during their psilocybin experience had significant increases in

⁴⁰⁷ Cheng D, Lei ZG, Chu K, Lam OJH, Chiang CY, Zhang ZJ. N, N-Dimethyltryptamine, a natural hallucinogen, ameliorates Alzheimer's disease by restoring neuronal Sigma-1 receptor-mediated endoplasmic reticulum-mitochondria crosstalk. Alzheimers Res Ther. 2024 May 1;16(1):95. doi: 10.1186/s13195-024-01462-3. PMID: 38693554; PMCID: PMC11061967.

⁴⁰⁸ Bradley ER, Sakai K, Fernandes-Osterhold G, Szigeti B, Ludwig C, Ostrem JL, Tanner CM, Bock MA, Llerena K, Finley PR, O'Donovan A, Zuzuarregui JRP, Busby Z, McKernan A, Penn AD, Wang ACC, Rosen RC, Woolley JD. Psilocybin therapy for mood dysfunction in Parkinson's disease: an open-label pilot trial. Neuropsychopharmacology. 2025 Jul;50(8):1200-1209. doi: 10.1038/s41386-025-02097-0. Epub 2025 Apr 9. PMID: 40205013; PMCID: PMC12170852.

⁴⁰⁹ Griffiths, R. R., Richards, W. A., McCann, U. D., & Jesse, R. (2006). Psilocybin can occasion mystical-type experiences having substantial and sustained personal meaning and spiritual significance. Psychopharmacology, 187(3), 268–283. https://doi.org/10.1007/s00213-006-0457-5

the personality domain of "openness" 1 year after their session, suggesting the role for psilocybin and mystical experiences in adult personality change.⁴¹⁰

A large-scale general population online study investigated relationship between psilocybin, mescaline, and other classic psychedelic substances, finding that--after controlling for other psychoactive substances and common personality traits--psychedelic experience uniquely predicted self-reported engagement in pro-environmental behaviors (e.g. saving water, recycling). Another study found correlations between lifetime psychedelic use, nature-relatedness, and psychological well-being. These studies potentially suggest relevance for psychedelic treatment and ecological health.

Microdosing

Anecdotal reports suggest that microdosing enhances well-being and cognition, including improvements to mood, energy, creativity, etc. Modern studies find that effects are often not significantly different from placebo groups, and are potentially biased by user expectations.

One foundational, large-scale study tracked the experiences of 98 microdosing participants across a 6 week period with a battery of psychometric measures. Analysis found general increases in reported psychological functioning on dosing days, but limited evidence of residual effect on non-dosing days; reductions in reported levels of depression, stress, distractability; increased absorption, neuroticism. In a follow-up round, the study found a lack of consistency between effects observed versus effects believed most likely to change. Another study examined effects of microdosing on two creativity-related problem-solving tasks among non-blinded participants, finding quantitative differences in convergent and divergent thinking between microdose versus non-microdose groups. It should be noted that the open-label (non-blinded) nature of these studies allow for the possibility that expectation may have driven positive effects.

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⁴¹⁰ MacLean, K. A., Johnson, M. W., & Griffiths, R. R. (2011). Mystical experiences occasioned by the hallucinogen psilocybin lead to increases in the personality domain of openness. Journal of Psychopharmacology, 25(11), 1453–1461. https://doi.org/10.1177/0269881111420188

⁴¹¹ Forstmann M, Sagioglou C. Lifetime experience with (classic) psychedelics predicts pro-environmental behavior through an increase in nature relatedness. J Psychopharmacol. 2017 Aug;31(8):975-988. doi: 10.1177/0269881117714049. Epub 2017 Jun 20. PMID: 28631526.

⁴¹² Kettner H, Gandy S, Haijen ECHM, Carhart-Harris RL. From Egoism to Ecoism: Psychedelics Increase Nature Relatedness in a State-Mediated and Context-Dependent Manner. Int J Environ Res Public Health. 2019 Dec 16;16(24):5147. doi: 10.3390/ijerph16245147. PMID: 31888300; PMCID: PMC6949937.

⁴¹³ Polito, V., & Stevenson, R. J. (2019). A systematic study of microdosing psychedelics. PLOS One, 14(2), e0211023. https://doi.org/10.1371/journal.pone.0211023

⁴¹⁴ Prochazkova L, Lippelt DP, Colzato LS, Kuchar M, Sjoerds Z, Hommel B. Exploring the effect of microdosing psychedelics on creativity in an open-label natural setting. Psychopharmacology (Berl). 2018 Dec;235(12):3401-3413. doi: 10.1007/s00213-018-5049-7. Epub 2018 Oct 25. PMID: 30357434; PMCID: PMC6267140.

Among the most methodically rigorous research to date, one double-blind placebo-controlled study administered psilocybin or placebo to 34 participants. This study found greater effects to subjective experience, behavior, creativity, perception, and cognition among the microdose group versus the placebo group, but only for participants who correctly identified their experimental condition (microdose versus placebo), suggesting that expectation underlies at least some of the benefits attributed to microdosing. Another study used a placebo-controlled, self-blinding, citizen-science design with 191 participants. The study found that all psychological outcomes improved significantly from baseline to after the 4 weeks long dose period, with no significant differences observed between the microdose versus placebo group.

Rapid-Acting Applications

DMT has been studied primarily in early-phase safety and pharmacology trials, including intravenous studies at Imperial College London and Columbia University (Timmermann et al., Front Psychiatry 2019; n=13 healthy volunteers). These have established dosing parameters and tolerability but not efficacy. Ayahuasca, which contains DMT, has been evaluated in the Brazilian TRD trial noted above. Several industry-sponsored trials of IV DMT (e.g. Small Pharma's SPL026 program in MDD) are ongoing but not yet published.

Summary

Research into psychedelic substances for indications ranging from treatment-resistant depression and PTSD to chronic pain represents a profound and rapidly accelerating area of study. While the body of evidence is undoubtedly growing, the regulatory journey clearly indicates it has not yet reached the level of sufficient evidence required for widespread clinical adoption. The recent decision by the FDA to reject the New Drug Application for MDMA-assisted therapy, driven by concerns over trial design including insufficient assessment of abuse-related or positive adverse effects, insufficient data on durability, and patient selection-bias) underscores the heightened rigor and unique challenges facing this new psychedelic-assisted therapeutic paradigm. It has also been speculated that therapist sexual misconduct that had occurred in early Phase 2 research may have influenced the decision. Similarly, despite receiving Breakthrough Therapy designations for depression, psilocybin has no FDA approval to date.

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⁴¹⁵ Cavanna F, Muller S, de la Fuente LA, Zamberlan F, Palmucci M, Janeckova L, Kuchar M, Pallavicini C, Tagliazucchi E. Microdosing with psilocybin mushrooms: a double-blind placebo-controlled study. Transl Psychiatry. 2022 Aug 2;12(1):307. doi: 10.1038/s41398-022-02039-0. PMID: 35918311; PMCID: PMC9346139.

⁴¹⁶ Szigeti, F., Kartner, L., Blemings, A., Rosas, F., Feilding, A., Girn, M., & Carhart-Harris, R. L. (2021). Self-blinding citizen science to explore psychedelic microdosing. eLife, 10, e62878. https://doi.org/10.7554/eLife.62878

⁴¹⁷ Complete Response, NDA 215455. US Food and Drug Administration. August 8, 2024. Accessed September 5, 2025. https://psychedelicalpha.com/wp-content/uploads/2025/09/CRL_NDA215455_20240808.pdf

Nevertheless, given the significant unmet needs for treatment-resistant conditions and the promising, rapid, and durable effects suggested by current data, the potential therapeutic benefit is immense. While a careful, methodical "work-in-process" approach is essential to generate robust, transparent, and reproducible data, the risks of the substances themselves—at least when administered in controlled medical settings or other supervised settings—do not justify the imposition of additional, restrictive research limitations that would unnecessarily impede the development of a potentially transformative class of medicine.

Psychedelic Law Enforcement Data

Psychedelic substances are not well tracked in national or state law enforcement data systems. According to a 2024 RAND Corporation report, "official national figures for the number of arrests involving psychedelics do not exist." Based on data from 13,293 law enforcement agencies contributing to the FBI's National Incident-Based Reporting System (NIBRS), RAND estimated that psychedelic-related arrests in 2022 were likely "in the low double-digit thousands," accounting for no more than 2% of total drug arrests nationwide. Similarly, the National Forensic Laboratory Information System (NFLIS) 2022 Annual Report found that psilocybin accounted for just 0.84% of drug reports submitted for laboratory analysis. Dimethyltryptamine (DMT) and mescaline were not listed in the available data set.

Maryland-specific data mirrors these national trends in underreporting. According to the Drug Enforcement Administration's 2022 list of the most frequently identified drugs in Maryland, psilocybin/psilocin ranked 16th with 149 detections—just ahead of caffeine (145). By comparison, cocaine (4,967), fentanyl (3,206), and cannabis/THC (1,368) were far more prevalent. DMT and mescaline were not identified in this dataset.

Leveraging connections of the Task Force's own law enforcement expert, the Task Force was able to obtain substance-specific data for one county. According to the Montgomery County Forensic Chemistry Unit, which tracks drug types submitted as evidence, 647 exhibits were analyzed in 2024, of which 17 exhibits (2.6%) involved psilocybin/psilocin mushrooms, 2 exhibits (0.3%) involved dimethyltryptamine, and 0 exhibits (0%) involved mescaline. This corresponds with other findings that, where data is available, **incidents of crime associated with natural psychedelic substances appear uncommon.**

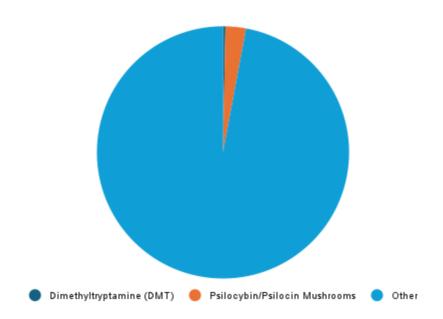


Figure 15. Natural Psychedelic Substances Analyzed by Montgomery County Crime Lab, 2024

The Maryland Uniform Crime Report for 2022 also provides limited insight. **Psychedelics are not categorized separately in statewide arrest data.** One dataset groups drugs into "Opium/Cocaine," "Marijuana," "Synthetic," and "Other." It is presumed that substances such as psilocybin and DMT fall under "Other," which accounted for just 10 of 262 drug arrests (3.8%) for sale/manufacture and 175 of 1,855 arrests (9.4%) for possession. However, this category likely also includes substances unrelated to this Task Force's mandate, such as PCP, prescription stimulants or sedatives, or inhalants. This lack of specificity makes it difficult to assess the true scope of law enforcement activity related to natural psychedelics.

A second dataset within the same report tracked demographic characteristics of hallucinogen-related seizures. Here, the "hallucinogens" category is undefined and may include LSD, ketamine, PCP, or other unrelated substances. One Prince George's County police officer and the Task Force's own former Montgomery County law enforcement expert anecdotally reported that a majority of hallucinogen-related cases involve PCP, not the substances under this task force's purview. County-level seizures ranged from 1 in Garrett County to 122 in Prince George's County (31.4% of the statewide total). Demographic breakdowns show that 67% of hallucinogen seizures involved Black individuals, compared to 30% involving White individuals. Most seizures involved people identified as Non-Hispanic (71%) and male (81%). These data highlight persistent inequities in how drug laws are applied across different communities.

Unlike more commonly tracked substances such as cannabis, offenses involving natural psychedelic substances are typically recorded by law enforcement without sufficient detail. For example, the Montgomery County Crime Lab combines "hallucinogens and stimulants" into a single category, grouping natural psychedelics alongside unrelated substances such as LSD, MDMA, ketamine, and methamphetamine—many of which are synthetic or not considered psychedelics. The Drug Enforcement Administration (DEA) does list psilocybin, psilocin, and psilocybin/psilocin as separate identifiers, but does not report separate counts for dimethyltryptamine (DMT) or mescaline. However, based on the limited data available and anecdotal input from law enforcement personnel which this Task Force was able to obtain, organized criminal involvement with these substances appears to be minimal.

Absence of State-Level Poison Data

This Task Force was unable to locate any relevant state-level poison data. The Maryland Poison Center 2023 Annual Report made no mention of the substances studied by this Task Force. Among drug-substances involved in poisonings, 4.3% were attributed to "Stimulants and Street Drugs," and 19.8% were attributed to "Others." It is unclear which, if any, category might encompass natural psychedelic substances. The Maryland Department of Health (MDH) Unintentional Drug and Alcohol-Related Intoxication Deaths 2023 Annual Report and Data-Informed Overdose Risk Mitigation (DORM) 2023 Annual Report both made no mention of the substances studied by this Task Force. This is consistent with the Task Force's findings that no fatal dose of these substances has been determined. State-level data from the Maryland Youth Risk Behavior Survey/Youth Tobacco Survey (YRBS/YTS) 2022-2023 Trend Analysis Report assessed use of alcohol, cannabis, MDMA, and other substances, but made no mention of the substances studied by this Task Force.

Public Perceptions of Psychedelics

Over the past decade, public perceptions of psychedelic substances have shifted considerably. Once previously synonymous with counterculture or recreational excess, **psychedelics are now increasingly viewed as potential sources of medical advances, mental health innovation, and cultural healing**. This shift, however, is neither uniform nor uncontested. Substantial skepticism and resistance remain, reflecting divergent beliefs about safety, efficacy, morality, and social risk. This section examines these evolving attitudes, highlighting both the data that reflect increasing public acceptance and the cultural, legal, and political forces that sustain opposition.

Growing Public Interest and Support

There is broad public backing and interest for specific legal uses of psychedelics, and this support grew between 2023 and 2025. In 2025 alone there were over 3 dozen psychedelic related bills introduced throughout the US, signaling a resurgence of interest in psychedelics for a variety of therapeutic applications. In recent months, momentum for psychedelic policy reform has accelerated nationwide. In October 2025, California Governor Gavin Newsom signed Assembly Bill 1103, a veteran-backed bill directing the California Health and Human Services Agency to expedite study of psychedelics for PTSD and mental health treatment, with specific focus on psilocybin and MDMA research for veteran populations (AB 1103, 2025). Meanwhile, Louisiana created the Task Force on Alternative Therapies for Veterans through Senate Resolution 186 in 2025, specifically responding to the state's veteran suicide rate exceeding the national average in 2022. The nine-member task force will tentatively begin conducting public hearings In October 2025. A recent survey conducted by UC Berkeley showed a large majority of respondents supported easing access to psychedelic substances for scientific research (81%), legalizing therapeutic use (72%), gaining federal approval to permit prescription access (66%), and eliminating criminal penalties for personal possession (51%. Support is lower for personal spiritual use (48%) and for use within organized religion (43%).

Dyamacal	Total Support		
Proposal	2023	2025	Difference
Allowing therapeutic use of psychedelics to be legal	61%	72%	+11%
Obtaining FDA approval so that people can access them as prescription medicines	56%	66%	+10%
Allowing the personal use of psychedelics for spiritual purposes	44%	48%	+4%
Making it easier for scientists to study psychedelics	78%	81%	+3%
Removing criminal penalties for personal use possession of psychedelics	49%	51%	+2%
Allowing the use of psychedelics as part of an organized religious practice	44%	43%	-1%

Figure 16. Support For Specific Uses of Psychedelics Among U.S. Registered Voters, 2023 and 2025. Source: Second Berkeley Psychedelics Survey, UC Berkeley Center for the Science of Psychedelics.

More than half of registered U.S. voters support regulated therapeutic access to psychedelics for specific groups (light blue in Figure 8): people with depression (61%), military Veterans (56%), and individuals with addiction (55%). A little fewer than half support psychedelic access for people in end-of-life care (48%) or for all adults aged 21 and over (38%). Support for removing criminal penalties is generally lower (dark blue in Figure 8). While 38% support removing criminal penalties for end-of-life care patients who use psychedelics, 11% support doing so for individuals with addiction. Overall, respondents were most permissive toward those in end-of-life care, with 86% supporting decriminalization or regulated therapeutic access, compared with 78% for military Veterans and 77% for people with depression.

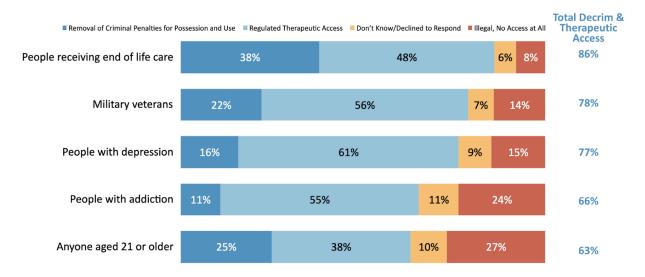


Figure 17. Support For Access to Psychedelics for Specific Groups Among U.S. Registered Voters, 2025. Source: Second Berkeley Psychedelics Survey, UC Berkeley Center for the Science of Psychedelics.

The VA's National Center for PTSD now formally acknowledges psychedelic-assisted therapy shows promise for helping patients access traumatic memories with reduced avoidance (VA National Center for PTSD, 2024), a significant shift for an institution historically conservative about alternative treatments.

Perspectives of Healthcare Professionals

A 2023–2024 survey conducted by the University of Maryland School of Social Work explored the attitudes, practices, knowledge, and training needs of social workers and nurses related to psychedelic-assisted therapies. The findings show broad support for therapeutic use: **75% of respondents believe psychedelics hold promise for treating psychiatric disorders**, and 57% see potential for treating substance use disorders. Nearly two-thirds **(64%) agree that psychedelic-assisted therapy is a reasonable treatment approach**, and **76% support legalization for therapeutic purposes**.

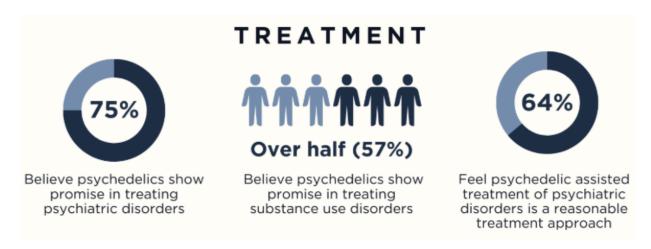


Figure 18. Perspectives of Social Workers and Nurses on Psychedelic Assisted Therapies, 2023-2024, University of Maryland, Baltimore School of Social Work.

Despite these positive perceptions of psychedelic therapy, only 34% of nurses and social workers endorse legalization of psychedelics for recreational use. A strong majority (85%) believe that any future legal psychedelic treatments should be tightly regulated and delivered in controlled settings following standardized protocols. Meanwhile, 61% reported discomfort discussing psychedelics with patients, and 46% expressed interest in learning more about psychedelic therapy. While based on a modest sample of 152 respondents, these findings suggest growing professional interest alongside caution and a desire for structured guidance.

A 2024 survey by Johns Hopkins researchers assessed knowledge, attitudes, and concerns about psilocybin and MDMA among U.S. healthcare professionals, based on responses from 879 professionals, including nurses and physicians. In this national survey, respondents demonstrated strong belief in the therapeutic potential of both substances . Specifically, **93% of respondents believed that psilocybin can be administered safely in clinical settings**, while 76% felt the same about MDMA. However, objective knowledge about pharmacology, therapeutic use, and risks was notably lower, highlighting a clear gap between enthusiasm and understanding.

The primary concerns among healthcare professionals included a lack of trained providers, the financial cost of treatment, and medical contraindications. Factors associated with greater openness to clinical use included prior personal psychedelic use, higher self-rated knowledge, and younger age; in contrast, physicians reported lower openness than nurses and other providers. These findings point to the urgent need for formal education,

professional training programs, and infrastructure development if psychedelic-assisted therapies are to be safely and equitably integrated into healthcare.

Concerns About Access to Psychedelics

Even many who support policy change still hold negative perceptions. In the 2023 Berkeley Psychedelics Survey, nearly half of registered voters supporting policy change express concerns about psychedelics. Of the 61% of respondents who support regulated therapeutic use, 47% agree that psychedelics are not "good for society," 56% agree that psychedelics are not "something I am interested in learning more about," and 63% agree that psychedelics are not "something for people like me." These findings may suggest that public support reflects tolerance for psychedelic policy changes aimed at mental health benefits for certain groups, not broad cultural approval.

Based on our analysis of media reports of failed psychedelic policy initiatives and consultations with experts, objections to legal psychedelic therapy fall into four primary categories: legal and regulatory, scientific and medical, moral and social, and practical and operational. From a legal standpoint, **critics often cite federal illegality and the absence of FDA approval**. In response, states may regulate substances under state law, **as we have seen successfully with cannabis**, and can contribute meaningfully to evidence development through well-designed pilot programs. Issues around licensure and scope of practice can be addressed with provisional guidance, as currently practiced with ketamine used for mental health conditions and chronic pain.

Table 6. Summary of Objections to Legalizing Psychedelic Therapy

	Objection	Counterpoint
Legal and Regulatory	Federally illegal	States can regulate under state law; cannabis sets precedent.
	No authority to override federal law	State public health policy is often a precursor to federal reform. States are responsible for regulating the health and safety of their citizens.
	Not FDA-approved	States can create pilot programs and contribute to data collection, which may inform Federal reforms
	Licensure conflicts	Boards can issue provisional guidance; precedent exists with ketamine.
Scientific and Medical	Insufficient long-term data	Ongoing trials show positive outcomes; pilot programs can manage risk.
	Risk to vulnerable populations	Evidence-based screening criteria and exclusion protocols reduce this risk.
	Risk of psychosis or trauma	Screening, preparation, supervision, and integration support minimize these outcomes.
Moral and Social	Sends wrong message	Clear public education distinguishes therapeutic from recreational use.
	Morally wrong	Ground policy in compassion, harm reduction, saving lives, not punishment.
	Politically unpopular	Polling shows support; aligns with mental health, chronic pain, and Veterans' needs.
Practical and Operational	No infrastructure	Build on Maryland's existing academic/clinical hubs; establish facilitation centers; scale with feedback.
	Unsafe providers	Train and certify facilitators; define scope of practice; review complaints.

Scientific and medical concerns center on the perceived lack of long-term safety data and the potential for adverse reactions in vulnerable individuals. However, the growing body of positive clinical trial outcomes and risk mitigation strategies, such as rigorous screening, preparation, and supervised use, attempt to proactively address these concerns.

Scientific concerns may also relate to new evidence that past Randomized Controlled Trials (RCTs) included methodological limitations, including participant selection bias, positive expectancy effects among both participants and investigators, and failures to maintain double-blinding, as seen with the failed FDA application for midomafetamine (MDMA) with therapy. While MDMA is not currently under the scope of this Task Force's study or recommendations, there remains concern that similar methodological limitations may be found in studies for natural psychedelic substances. One 2025 meta-analysis found less significant differences between psilocybin and control groups, suggesting that psilocybin's antidepressant efficacy may be overstated. 418 In 2022, the American Psychiatric Association released a position statement: "There is currently inadequate scientific evidence for endorsing the use of psychedelics to treat any psychiatric disorder except within the context of approved investigational studies. APA supports continued research and therapeutic discovery into psychedelic agents with the same scientific integrity and regulatory standards applied to other promising therapies in medicine."419 Regulated access models that embed necessary scientific rigor can address issues that challenge traditional RTC design, while collecting real-world comparisons to traditional medical interventions.

Moral and social objections, including fears that psychedelic legalization sends the wrong message or is inherently immoral, are countered by grounding policy in compassion and public health rather than criminalization. Public education can also help people distinguish between therapeutic and recreational contexts, and public polling indicates substantial support when policies focus on mental health and Veteran populations. Conversely, it may be framed as morally wrong to prohibit in particular Veterans with treatment resistant PTSD and others with severe mental illness access to potentially life saving treatment.

Finally, operational challenges such as lack of infrastructure or unsafe practitioners can be addressed by starting with trusted clinical and academic institutions creating a foundation and

⁴¹⁸ Hieronymus F, López E, Werin Sjögren H, Lundberg J. Control Group Outcomes in Trials of Psilocybin, SSRIs, or Esketamine for Depression: A Meta-Analysis. JAMA Netw Open. 2025 Jul 1;8(7):e2524119. doi: 10.1001/jamanetworkopen.2025.24119. Erratum in: JAMA Netw Open. 2025 Sep 2;8(9):e2536707. doi: 10.1001/jamanetworkopen.2025.36707. PMID: 40736734; PMCID: PMC12311713. ⁴¹⁹ American Psychiatric Association. (2022). Position statement on the use of psychedelic and empathogenic agents for mental health

conditions. American Psychiatric Association. https://www.psychiatry.org/getattachment/d5c13619-ca1f-491f-a7a8-b7141c800904/Position-Use-of-Psychedelic-Empathogenic-Agen ts.pdf

building regulatory frameworks to ensure safe, competent facilitation, when appropriate. Through phased implementation and thoughtful regulation, these concerns can be responsibly managed.

Table 7. Summary of Objections to Decriminalization of Psychedelics

Category	Objection	Counterpoint
Legal and Regulatory	Conflict with federal law	States have leeway; decriminalization deprioritizes enforcement, not full legalization.
	No regulatory framework	Develop clear local or statewide guidelines and enforcement boundaries.
Scientific and Medical	Increased unsupervised use	Provide harm reduction tools and public education.
	Impaired driving risk	Include penalties and prevention programs modeled on cannabis and alcohol.
Moral and Social	Normalizes drug use	Reframe as a public health and liberty issue, not moral judgment.
	Appropriation of traditions	Protect ceremonial use through exemptions and Indigenous involvement.
Political and Institutional	Public confusion	Pair policy with outreach and community education.
Practical and Operational	No standards for dosing/packaging	Consider a regulated adult-use model with product labeling and safety protocols.
	Cannot control underground markets	Decriminalization plus legal access reduces illicit activity and improves transparency.

Opposition to decriminalization or legal adult use of psychedelics spans several key areas, including legal concerns, scientific and medical risks, moral objections, political messaging, and operational readiness. Legally, critics worry about conflict with federal drug laws and the absence of a regulatory framework. These concerns can be addressed by clarifying that decriminalization or deprioritization decrease enforcement without creating legal markets, and by implementing local or state-level guidelines to set clear boundaries for enforcement.

From a medical standpoint, increased unsupervised use and the potential for impaired driving are cited as risks. These can be mitigated by incorporating harm reduction messaging, making

educational materials widely available, and establishing penalties and prevention programs based on cannabis and alcohol policy models.

Moral and cultural objections include fears that legalization will normalize drug use and disrespect sacred Indigenous practices. These issues can be addressed by emphasizing a public health and personal liberty framing, and by creating clear exemptions and protections for traditional ceremonial use, in collaboration with Indigenous leadership.

On the political and institutional front, public confusion is a real concern, but one that can be offset through robust educational programs, community engagement and clear, transparent communication with the public. Finally, practical challenges like lack of standards for packaging or dosing, and concerns about underground markets, point to the need for careful attention to the sequence in which access models are introduced. By combining decriminalization with thoughtfully designed legal access pathways, states might reduce illicit trade, enhance product safety, and support responsible adult use.

Section III. Maryland Legacy and Opportunities

Opportunities to Maximize Public Benefit

In a statewide community survey conducted by the Maryland Department of Health released in 2024, the **number one important issue selected was "Mental Health"**, **selected by 58.2% of Marylanders.** Respondents described the mental health crisis as multifactorial—driven by poverty, COVID-19, isolation, and physical health challenges—and made worse by limited access to timely, high-quality care. This was followed closely by Access to Care (56.0%), and Chronic Diseases at #4 (33.6%).

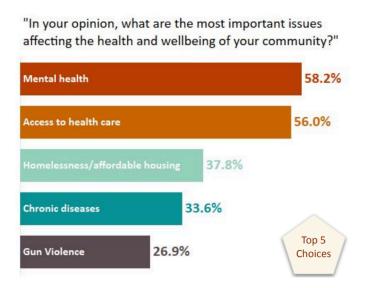


Figure 19. Factors that Affect the Health of Maryland Resident's Communities Source: Maryland State Health Assessment

An environmental scan of local community health assessments across 22 of Maryland's 24 jurisdictions similarly found that, **among 92 community-identified priorities**, **Cancer & Chronic Conditions accounted for 33.7%**, **and Behavioral Health accounted for 30.4%**–with key concerns including **mental illness (57%)**, **substance use (36%)**, **and suicide (7%)**.

⁴²⁰ Maryland Department of Health. (2024). Building a healthier Maryland: State health assessment. https://health.maryland.gov/pha/Documents/PHAB%20documents/BAHM%20State%20Health%20Assessment%202024%20(1).pdf

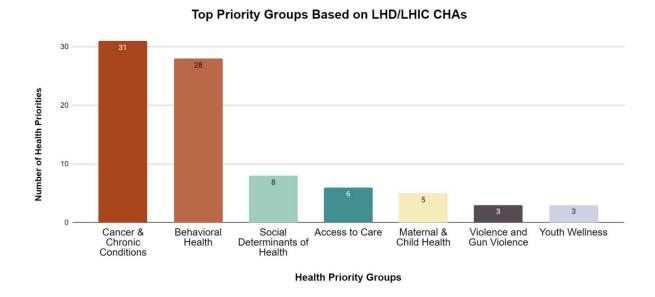


Figure 20. Health Priorities Identified in Environmental Scan of Local Health Department and Local Health Improvement Coalition Community Health Assessments, 2024. Source: Maryland State Health Assessment.

Urgent Behavioral Health Needs

Each year, about one in five adults experiences a mental illness, and an estimated 781,000 Maryland adults are living with a mental health condition–over nineteen times the population of Annapolis. 421 More than a quarter of Maryland adults (27.3%) report symptoms of anxiety or depression. 422 In 2020, Maryland lost 650 lives to suicide, and 188,000 adults reported having thoughts of suicide. 423

Adverse Childhood Experiences

The impact of **Adverse Childhood Experiences (ACEs)** is particularly notable. Adverse Childhood Experiences (ACEs)—such as abuse, neglect, household dysfunction, or exposure to violence—are strongly associated with long-term impacts on both mental and physical health.

⁴²¹ National Alliance on Mental Illness. (2021). Mental health in Maryland fact sheet. https://www.nami.org/wp-content/uploads/2023/07/MarylandStateFactSheet.pdf

⁴²² Kaiser Family Foundation. (2025). Mental health and substance use state fact sheets: Maryland. KFF.

https://www.kff.org/interactive/mental-health-and-substance-use-state-fact-sheets/maryland

⁴²³ National Alliance on Mental Illness. (2021). Mental health in Maryland fact sheet. https://www.nami.org/wp-content/uploads/2023/07/MarylandStateFactSheet.pdf

Individuals with high ACE scores face significantly increased risks of depression, anxiety, substance use disorders, and post-traumatic stress disorder (PTSD), as well as chronic medical conditions like heart disease, diabetes, and cancer. ACEs can disrupt brain development, stress response systems, and health behaviors, contributing to poor health outcomes and reduced life expectancy if unaddressed. Early intervention and trauma-informed care are critical to breaking this cycle and promoting resilience.

- 37% of Maryland children have experienced at least one ACE.
- More than 60% of adults report at least one ACE, with 22% reporting 3 or more.
- Baltimore City and Cecil County carry the highest adult ACE burden, where nearly one-third report high ACE scores.⁴²⁴

Suicide and Suicidal Ideation

Suicide also remains a critical concern:

- Male suicide rates are nearly four times higher than female rates in Maryland.
- The most common means of suicide is with a firearm.
- Among **high school students, 20.6% reported suicidal ideation** in 2021, with significantly higher rates among females (26.7%) than males (14%).

⁴²⁴ Maryland Department of Health. (2024). Building a healthier Maryland: State health assessment. https://health.maryland.gov/pha/Documents/PHAB%20documents/BAHM%20State%20Health%20Assessment%202024%20(1).pdf

Female Male 50 40.6 40 28.6 Deaths per 100,000 30 22.7 21.4 20.9 20.4 18.2 20 15:2 10 3.1 6.3 5.2 5.5 5 4.8 4.2 15-24 25-34 35-44 45-54 55-64 65-74 75-84 85+ years years years years years years years years

Suicide Rate by Age and Sex, Maryland, 2016 - 2020 Average

Figure 21. Suicide Rate in Maryland, by Age and Sex, 2016-2020. Source: Maryland State Health Assessment.

Burden of Untreated Mental Health

Mental health disorders impose a tremendous burden, extending beyond the direct costs of treatment. In 2019, U.S. medical expenditures for mental health conditions totaled approximately \$106.5 billion, encompassing outpatient visits, inpatient care, and prescription medications.⁴²⁵

Indirect economic impact, stemming from lost productivity, unemployment, disability, and reduced participation in the labor force, is also significant. A macroeconomic analysis by Yale University researchers estimated that mental illness costs the U.S. economy roughly \$282 billion annually, or 1.7% of gross domestic product (GDP), when considering these broader economic consequences. Earlier data from Kessler et al. (2008) similarly found that serious mental illness

⁴²⁵ Agency for Healthcare Research and Quality. (2022). Expenditures for mental disorders among adults age 18 and older, 2019: Estimates for the U.S. civilian noninstitutionalized population (MEPS Statistical Brief #539). U.S. Department of Health and Human Services. https://meps.ahrq.gov/data_files/publications/st539/stat539.pdf

⁴²⁶ Yale News. (2024, April 22). Novel study quantifies immense economic costs of mental illness in the U.S. https://news.yale.edu/2024/04/22/novel-study-quantifies-immense-economic-costs-mental-illness-us

alone accounted for \$193.2 billion in lost earnings in 2002, reflecting both the personal and societal toll of untreated or undertreated mental health conditions.⁴²⁷

Barriers to accessing in-network behavioral health services force many residents into higher-cost, out-of-network care, compounding financial strain for both patients and insurers. The Mental Health Association of Maryland (2024) also reports that individuals with behavioral health conditions consistently incur higher overall healthcare costs than those without such conditions, amplifying the fiscal pressures on state systems. Moreover, in 2024 the Maryland's Department of Budget and Management projected more than \$227 million in upcoming expenditures to expand certified community behavioral health clinics, illustrating the scale of public investment required to meet the demand for mental health services.

Psychedelic-Assisted Mental Health Therapies

Emerging economic analyses suggest that psychedelic-assisted therapies may offer meaningful cost benefits compared to conventional mental health treatments. A recent decision-analytic model estimated that psilocybin-assisted therapy for treatment-resistant depression could be cost-effective if total treatment costs remain near or below \$5,000 per patient, yielding an incremental cost-effectiveness ratio (ICER) of about \$117,517 per quality-adjusted life year (QALY) gained—well within accepted thresholds for many healthcare systems. Lower treatment costs further enhance economic viability, while even modest clinical improvements can lead to substantial societal savings by reducing healthcare utilization, lost productivity, and long-term disability. Population data has suggested an association between psychedelic use and reduced psychological distress and suicidality. Together, these findings indicate that responsibly implemented psychedelic therapies could represent both a clinically and economically sustainable strategy toward addressing the mental health crisis.

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⁴²⁷ Kessler, R. C., Heeringa, S., Lakoma, M. D., Petukhova, M., Rupp, A. E., Schoenbaum, M., Wang, P. S., & Zaslavsky, A. M. (2008). Individual- and societal-level effects of mental disorders on earnings in the United States: Results from the National Comorbidity Survey Replication. American Journal of Psychiatry, 165(6), 703–711. https://doi.org/10.1176/appi.ajp.2008.08010126

⁴²⁸ Maryland Matters. (2024, April 17). Patients less likely to get behavioral health covered by insurance than other needs. https://marylandmatters.org/2024/04/17/report-patients-less-likely-to-get-behavioral-health-covered-by-insurance-than-other-needs/ despertition of Maryland. (2024). New study finds continuing pervasive disparities in access to in-network mental health and substance use care.

https://www.mhamd.org/news/new-study-finds-continuing-pervasive-disparities-in-access-to-in-network-mental-health-and-substance-use-care/

⁴³⁰ Maryland Department of Budget and Management. (2024). Fiscal year 2026 operating budget testimony: Maryland Department of Health, Behavioral Health Administration. https://dbm.maryland.gov/budget/FY2026Testimony/M00L.pdf

⁴³¹ Reuter, A. C., Doblin, R., & Nichols, D. E. (2025). Cost-effectiveness of psilocybin-assisted therapy for treatment-resistant depression in the United States: A decision analytic model. JAMA Network Open, 8(2), e2410247. https://pubmed.ncbi.nlm.nih.gov/40883271/

⁴³² Serrano, P. A., & Reiff, C. M. (2023). Scaling psychedelic-assisted psychotherapy: Workforce and access challenges. Frontiers in Psychiatry, 14, 1293243. https://doi.org/10.3389/fpsyt.2023.1293243

⁴³³ Hendricks, P. S., Thorne, C. B., Clark, C. B., Coombs, D. W., & Johnson, M. W. (2015). Classic psychedelic use is associated with reduced psychological distress and suicidality in the United States adult population. Journal of Psychopharmacology, 29(3), 280–288. https://doi.org/10.1177/0269881114565653

Substance Use Disorders

Maryland continues to experience high rates of drug and alcohol-related deaths, with a growing number of fatalities involving both alcohol and opioids. **Between 2010 and 2020, Maryland's drug-induced death rate quadrupled**, and in 2020 alone, more than 2,800 residents died from overdose—nearly 90% of them between ages 25 and 64. The vast majority of drug-related deaths are the result of opioids/fentanyl.⁴³⁴

Drug-Induced Death Rate by Age Group, Maryland, 2000 - 2020

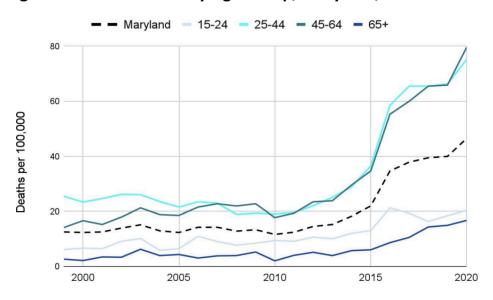


Figure 22. Death Rate Associated with Use of Non-Prescription Drugs, by Age Group, 2000-2020. Source: Maryland State Health Assessment.

Burden of Untreated Substance Use Disorders

Nationally, the annual attributable medical cost of Substance Use Disorder (SUDs) among individuals with employer-sponsored insurance (ESI) has been estimated at **\$15,640 per affected enrollee**, with total spending exceeding **\$35.3 billion in 2018**.⁴³⁵ Beyond medical care,

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⁴³⁴ Maryland Department of Health. (2024). Building a healthier Maryland: State health assessment. https://health.maryland.gov/pha/Documents/PHAB%20documents/BAHM%20State%20Health%20Assessment%202024%20(1).pdf ⁴³⁵ Li M, Peterson C, Xu L, Mikosz CA, Luo F. Medical Costs of Substance Use Disorders in the US Employer-Sponsored Insurance Population. JAMA Netw Open. 2023 Jan 3;6(1):e2252378. doi: 10.1001/jamanetworkopen.2022.52378. PMID: 36692881; PMCID: PMC9972180.

the societal costs of SUDs—including productivity loss, criminal justice expenditures, and social services—raise the total annual U.S. economic burden to hundreds of billions of dollars. Hospital expenditures alone related to substance use are estimated to total **\$13.2 billion annually**, underscoring the extensive strain on acute-care systems. State and federal analyses of the opioid epidemic indicate that Maryland has faced one of the highest per-capita combined costs of opioid use disorder and fatal opioid overdoses.

Psychedelic-Assisted Addiction Treatment

Growing research suggests that natural psychedelic substances may offer both life-saving and cost-saving benefits in the treatment of substance use disorders. Clinical studies show promising efficacy across multiple forms of addiction. A randomized controlled trial found that psilocybin-assisted psychotherapy significantly reduced heavy drinking days compared to standard treatment in individuals with alcohol use disorder. In a pilot study for tobacco addiction, 80% of participants remained abstinent at 26 weeks and 67% at one year after only two psilocybin sessions combined with behavioral support. If psychedelic therapies can maintain long-term abstinence after limited dosing, they could reduce healthcare expenditures related to hospitalization, overdose, and chronic comorbidities, as well as societal costs from lost productivity. Together, these findings indicate that psychedelic therapies could provide both clinical and economic value in addressing the persistent and costly burden of substance use disorders.

Chronic Pain Conditions

Chronic pain is a major public-health issue, with The National Center for Health Statistics (NCHS) estimating, in 2023, 24.3% of U.S. adults had chronic pain, and 8.5% had high-impact chronic

⁴³⁶ Florence C, Luo F, Rice K. The economic burden of opioid use disorder and fatal opioid overdose in the United States, 2017. Drug Alcohol Depend. 2021 Jan 1;218:108350. doi: 10.1016/j.drugalcdep.2020.108350. Epub 2020 Oct 27. PMID: 33121867; PMCID: PMC8091480.

⁴³⁷ Shah N, Velez FF, Colman S, Kauffman L, Ruetsch C, Anastassopoulos K, Maricich Y. Real-World Reductions in Healthcare Resource Utilization over 6 Months in Patients with Substance Use Disorders Treated with a Prescription Digital Therapeutic. Adv Ther. 2022 Sep;39(9):4146-4156. doi: 10.1007/s12325-022-02215-0. Epub 2022 Jul 12. PMID: 35819569; PMCID: PMC9273919.

⁴³⁸ Luo, F., Li, M., & Florence, C. (2021). State-level economic costs of opioid use disorder and fatal opioid overdose—United States, 2017. MMWR. Morbidity and Mortality Weekly Report, 70(15), 541–546. https://www.cdc.gov/mmwr/volumes/70/wr/mm7015a1.htm

⁴³⁹ Bogenschutz, M. P., Ross, S., Bhatt, S., Baron, T., Forcehimes, A. A., Laska, E., Mennenga, S. E., O'Donnell, K., Owens, L. T., Podrebarac, S. K., Pudiak, C. M., Smith, E. B., Tonigan, J. S., & Newberg, A. (2022). Psilocybin-assisted treatment for alcohol dependence: A randomized clinical trial. JAMA Psychiatry, 79(10), 953–962. https://doi.org/10.1001/jamapsychiatry.2022.2096

⁴⁴⁰ Johnson, M. W., Garcia-Romeu, A., Cosimano, M. P., & Griffiths, R. R. (2014). Pilot study of the 5-HT2AR agonist psilocybin in the treatment of tobacco addiction. Journal of Psychopharmacology, 28(11), 983–992. https://doi.org/10.1177/0269881114548296

⁴⁴¹ Marseille, E., Kahn, J. G., & Yazar-Klosinski, B. (2022). Cost-effectiveness of psychedelic-assisted therapies: A systematic review and research agenda. Frontiers in Psychiatry, 13, 976068. https://doi.org/10.3389/fpsyt.2022.976068

pain. 442 Maryland-specific data is difficult to obtain, however. The Maryland State Advisory Council on Pain's 2005 report explicitly acknowledged the lack of systematic state-level surveillance at the time. 443 The Maryland Behavioral Risk Factor Surveillance System Questionnaire (BRFSS) intermittently asks about arthritis/joint pain but does not consistently include an overall chronic-pain item, so it cannot produce a current statewide estimate. 444

Headache and Migraine

Headache and migraine–a subset of chronic pain conditions–also have a notable impact on society. Headache disorders affect more than 40 million Americans, or 1 in 6 adults. In Maryland, an estimated 924,699 people are living with migraines. Migraine is one of the world's top causes of years lived with disability across all age groups and the leading cause among women aged 15-49. Despite the prevalence and impact of headache and migraine, there are limited treatment options, and headache disorders receive just 0.2% of NIH funding.

Challenges Accessing Relief

Conventional chronic pain treatment options often fail to provide adequate or sustained relief.⁴⁴⁹ Standard medical management—typically involving analgesic medications, physical therapy, and behavioral interventions—offers modest benefit for many patients and is frequently limited by side effects, cost, or accessibility. Opioid analgesics, once the cornerstone of moderate-to-severe pain treatment, have been increasingly restricted due to risks of misuse, dependence, and overdose, leaving many patients with few effective alternatives.⁴⁵⁰ Non-opioid medications such

⁴⁴² Zelaya, C. E., Feinstein, M. J., Simile, C., & Ward, B. W. (2024). Chronic pain and high-impact chronic pain in U.S. adults, 2021–2023 (NCHS Data Brief No. 518). National Center for Health Statistics.

⁴⁴³ Maryland State Advisory Council on Pain. (2005). Report on pain management in Maryland. Maryland Department of Health and Mental Hygiene.

⁴⁴⁴ Maryland Department of Health. (2021). 2021 Maryland Behavioral Risk Factor Surveillance System Questionnaire. https://health.maryland.gov/phpa/ccdpc/Reports/Documents/MD-BRFSS/MD_BRFSS_Questionnaire_2021.pdf

⁴⁴⁵ Burch, Rebecca C., Paul Rizzoli, and Elizabeth W. Loder. "The Prevalence and Impact of Migraine and Severe Headache in the United States: Figures and Trends from Government Health Studies." Headache: The Journal of Head and Face Pain, vol. 58, no. 4, 2018, pp. 496–505. https://doi.org/10.1111/head.13281.

⁴⁴⁶ Flags for Headache. (n.d.). State statistics. Retrieved October 17, 2025, from https://flagsforheadache.org/map/

⁴⁴⁷ Steiner, T. J., L. J. Stovner, R. Jensen, D. Uluduz, and Z. Katsarava. "Migraine Remains Second among the World's Causes of Disability, and First among Young Women: Findings from GBD2019." The Journal of Headache and Pain, vol. 21, 2020, article 137, BioMed Central, https://doi.org/10.1186/s10194-020-01208-0

⁴⁴⁸ National Institutes of Health. "Funding for Various Research, Condition, and Disease Categories (RCDC), FY2008–FY2024." NIH Report, U.S. Department of Health and Human Services, 17 June 2025, https://report.nih.gov/funding/categorical-spending. Accessed 18 Sept. 2025.

⁴⁴⁹ Dahlhamer, J., Lucas, J., Zelaya, C., Nahin, R., Mackey, S., DeBar, L., Kerns, R., Von Korff, M., Porter, L., & Helmick, C. (2018). Prevalence of chronic pain and high-impact chronic pain among adults — United States, 2016. Morbidity and Mortality Weekly Report, 67(36), 1001–1006. https://doi.org/10.15585/mmwr.mm6736a2

⁴⁵⁰ Dowell, D., Ragan, K. R., Jones, C. M., Baldwin, G. T., Chou, R., & CDC Opioid Workgroup. (2022). CDC clinical practice guideline for prescribing opioids for pain — United States, 2022. Morbidity and Mortality Weekly Report, 71(3), 1–95. https://doi.org/10.15585/mmwr.rr7103a1

as NSAIDs, anticonvulsants, or antidepressants often provide only partial relief, and are ineffective or poorly tolerated for many individuals with complex pain syndromes.⁴⁵¹

Beyond pharmacological limitations, many people with chronic pain struggle to access multidisciplinary care that addresses the physical, psychological, and social dimensions of pain. Insurance coverage for integrative and nonpharmacologic therapies (e.g., acupuncture, cognitive-behavioral therapy, mindfulness, or physical rehabilitation) remains inconsistent, contributing to inequities in care and patient dissatisfaction. Moreover, stigma surrounding chronic pain—especially among patients who no longer respond to standard therapies—often results in undertreatment or patient dismissal. As a result, millions live with persistent pain, diminished quality of life, and elevated risk for depression, anxiety, and disability.

Burden of Untreated Chronic Pain Conditions

Nationally, the economic burden of pain has been estimated at **\$560-\$635 billion annually** in health-care costs and lost productivity, implying substantial consequences for Maryland's workforce and public programs.⁴⁵³ Recent analyses indicate direct health care expenditures for individuals with migraine averaged about **\$22,364 per person per year** (versus \$15,697 for individuals without migraine), with additional associated indirect costs, such as those for absenteeism.⁴⁵⁴ A comprehensive review of U.S. health care utilization data indicates that the annual cost burden of migraine (direct plus indirect) exceeds **\$56 billion**.⁴⁵⁵

Psychedelic Treatment of Chronic Pain Conditions

Emerging research suggests that psychedelics may be appropriate to treat many chronic pain conditions. Multiple surveys and anecdotal reports suggest that a notable proportion of naturalistic psychedelic users use these substances to manage physical pain.^{456,457} In a cross-sectional survey of adults with fibromyalgia, a small subset specifically used psychedelics to

⁴⁵¹ Gaskin, D. J., & Richard, P. (2012). The economic costs of pain in the United States. The Journal of Pain, 13(8), 715–724. https://doi.org/10.1016/j.jpain.2012.03.009

⁴⁵² National Academies of Sciences, Engineering, and Medicine. (2020). Framing opioid prescribing guidelines for acute pain: Developing the evidence. The National Academies Press. https://doi.org/10.17226/25679

⁴⁵³ Gaskin DJ, Richard P. The economic costs of pain in the United States. J Pain. 2012 Aug;13(8):715-24. doi: 10.1016/j.jpain.2012.03.009. Epub 2012 May 16. PMID: 22607834.

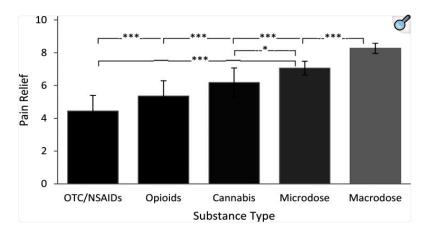
⁴⁵⁴ Bonafede, M., Sapra, S., Shah, N., Tepper, S., Cappell, K., Desai, P. (2018). Direct and indirect healthcare resource utilization and costs among migraine patients in the United States. Headache, 58(5). As cited in "Estimating the Economic Burden of Migraine on US Employers." The American Journal of Managed Care, etc. AJMC

⁴⁵⁵ Guy GP Jr, Miller GF, Legha JK, Rikard SM, Strahan AE, Mikosz C, Florence CS. Economic Costs of Chronic Pain-United States, 2021. Med Care. 2025 Sep 1;63(9):679-685. doi: 10.1097/MLR.000000000002181. Epub 2025 Jul 3. PMID: 40730349.

⁴⁵⁶ Clusterbusters. (2022). Clusterbusters: The cluster headache advocacy group. Retrieved October 17, 2025, from https://clusterbusters.org/

⁴⁵⁷ Psychedelics & Pain Association. (2025). Searchable databases. Psychedelics & Pain Association. https://psychedelicsandpain.org/research-resources/searchable-databases/

treat chronic pain and reported perceived symptom improvement. Another study conducted among individuals with chronic pain and prior psychedelic experience found that the majority reported meaningful reductions in pain following use. In one international survey, 78.8% of participants reported that psychedelics were effective in managing physical health conditions, with chronic pain, migraines, and sleep disorders being the most frequently targeted. While these findings are based on self-reported data from non-representative samples, they highlight a growing trend of self-medicating with psychedelics for pain management.



Comparison between perceived pain relief (0 = no pain relief, 10 = complete pain relief) achieved using microdosing and macrodosing, and the three most frequently reported conventional medications: over-the-counter (OTC)/NSAIDs, opioids and cannabis. Statistically significant differences between groups are denoted by ***(<0.001), **(<0.01) and *(<0.05). Error bars indicate standard error.

Figure 23. Perceived Pain Relief Across Microdosing, Macrodosing, and Conventional Medications. Source: Analgesic Potential of Macrodoses and Microdoses, A Population Survey⁴⁶¹

Conclusion

In addition to the conditions highlighted above, psychedelics are in early stages of investigation for their potential to address a wide range of unmet health needs, including neurodegenerative

⁴⁵⁸ Uthaug, M. V., Erritzoe, D., Carhart-Harris, R. L., & Kaelen, M. (2023). Scoping review: The role of psychedelics in the management of chronic pain. Journal of Pain Research, 16, 1423–1437. https://doi.org/10.2147/JPR.S404816

⁴⁵⁹ Mason, N. L., Kuypers, K. P. C., Reckweg, J. T., Müller, F., Tse, D. H. Y., Toennes, S. W., Hutten, N. R. P. W., & Ramaekers, J. G. (2022). Analgesic potential of macrodoses and microdoses of classic psychedelics in chronic pain patients and healthy volunteers: A mixed-methods study. Maastricht University.

https://cris.maastrichtuniversity.nl/files/105335894/Mason 2022 Analgesic potential of macrodoses and.pdf

⁴⁶⁰ Psychiatry Advisor. (2023, January 31). Psychedelics may improve chronic pain, reduce substance use.

https://www.psychiatryadvisor.com/news/psychedelics-may-improve-chronic-pain-reduce-substance-use/

⁴⁶¹ Bonnelle V, Smith WJ, Mason NL, Cavarra M, Kryskow P, Kuypers KP, Ramaekers JG, Feilding A. Analgesic potential of macrodoses and microdoses of classical psychedelics in chronic pain sufferers: a population survey. Br J Pain. 2022 Dec;16(6):619-631. doi: 10.1177/20494637221114962. Epub 2022 Jul 14. PMID: 36452124; PMCID: PMC9703241.

and cognitive disorders, inflammatory and immune-mediated diseases, traumatic brain injury, and other social and behavioral health challenges.

While psychedelic substances are certainly not a universal solution, these findings point to a public health opportunity. Expanding safe and equitable access to a variety of psychedelic therapies and use modalities could help relieve some burdens associated with behavioral health conditions, substance use disorders, and chronic pain conditions in Maryland. Current treatment options are insufficient for many individuals, and the need for new tools is urgent. When implemented with appropriate safeguards and integrated into multidisciplinary care, natural psychedelic substances may provide innovative and cost-effective approaches within a broader continuum of care.

Even modest improvements at the population level could yield profound societal benefits. For instance, findings suggest a 10% reduction in adverse childhood experience (ACE) prevalence across Europe and North America could equate to annual savings of 3 million DALYs or \$105 billion. Similarly, the responsible implementation of psychedelic-assisted interventions could generate meaningful health and economic gains, contributing to a more resilient and compassionate public health system.

Among Maryland residents already seeking health improvements from natural psychedelic substances, their products and services are obtained via illegal channels or abroad in D.C., Oregon, Mexico, Jamaica, etc. If these services were within a legal access framework in Maryland, revenues could be captured and redirected toward public education or other services that provide public benefit.

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⁴⁶² Bellis MA, Hughes K, Ford K, Ramos Rodriguez G, Sethi D, Passmore J. Life course health consequences and associated annual costs of adverse childhood experiences across Europe and North America: a systematic review and meta-analysis. Lancet Public Health. 2019 Oct;4(10):e517-e528. doi: 10.1016/S2468-2667(19)30145-8. Epub 2019 Sep 3. PMID: 31492648; PMCID: PMC7098477.

Opportunities to Mitigate Public Risks

Maryland has multiple opportunities to mitigate public risks through establishment of consumer protections that compete with unregulated sales, moderating difficult psychedelic experiences by targeting "set and setting" factors, enabling support through existing resources, and utilizing public health education campaigns.

Consumer Protections

Given Maryland's unique geographic positioning directly adjacent to Washington D.C.-where psilocybin/psilocin, mescaline, and DMT are lowest law-enforcement priority–Maryland residents are readily able to purchase unregulated psychedelic products without any standard consumer protections (e.g. testing for contaminants, packaging requirements, potency labeling, etc.).

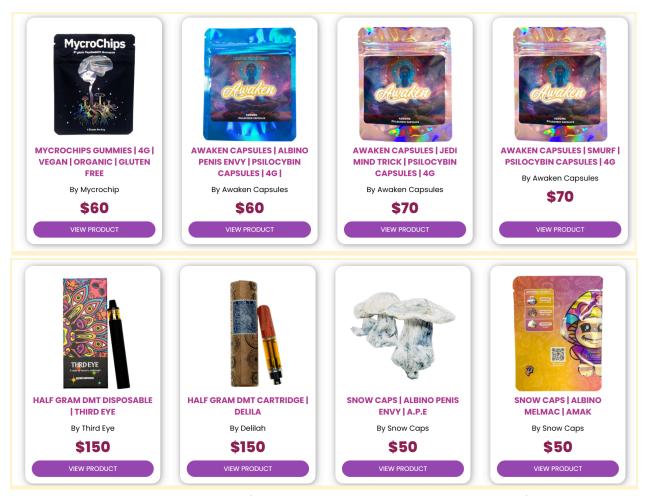


Figure 24. Products Available via Leaf Dreams Weed Delivery DC. Source: leafdreamsdc.com

Recent investigations have demonstrated that many mushroom-based edibles marketed as containing psychoactive compounds do not accurately reflect their labeling. A CDC investigation into Diamond Shruumz products identified inconsistent psychoactive contents, including O-acetylpsilocin, and muscimol, while advertised ingredients were often absent. The CDC also found severe illness potentially associated with consuming Diamond Shruumz brand chocolate bars, cones, and gummies, reporting 180 total illnesses, 73 hospitalizations, and 3 potentially associated deaths as of October 2024. These findings highlight the unreliability of product labeling and the potential risks associated with consuming unidentified compounds.

⁴⁶³ Centers for Disease Control and Prevention. (2024, November 14). Severe illness potentially associated with consuming Diamond Shruumz[™] brand chocolate bars, cones, and gummies.

https://www.cdc.gov/environmental-health-studies/outbreak-investigation-diamond-shruumz-products/index.html



Figure 25. "Diamond Shruumz" Products Potentially Associated with Severe Illness.

Mislabeling increases the risk of acute adverse events and prevents consumers from making informed decisions. Establishing transparency, education, quality control standards, and accountability within a regulated marketplace could reduce risks, even outside of clinical or research contexts.

Moderation of Difficult Experiences

Research indicates that difficult or distressing psychedelic experiences are not uncommon but not universal, and they are not typically associated with lasting harm. The most commonly reported experiences during difficult psychedelic-induced states include fear, grief, paranoia, feelings of isolation, and physical discomfort. While these episodes can be intense in the moment, many participants later describe the experiences as meaningful and sometimes associated with long-term psychological benefit. Global data also suggest that even challenging experiences can be associated with increased insight and long-term psychological

⁴⁶⁴ Barrett, F. S., Bradstreet, M. P., Leoutsakos, J.-M. S., Johnson, M. W., & Griffiths, R. R. (2016). The Challenging Experience Questionnaire: Characterization of challenging experiences with psilocybin mushrooms. Journal of Psychopharmacology, 30(12), 1279–1295. https://doi.org/10.1177/0269881116678781

⁴⁶⁵ Carbonaro, T. M., Bradstreet, M. P., Barrett, F. S., MacLean, K. A., Jesse, R., Johnson, M. W., & Griffiths, R. R. (2016). Survey study of challenging experiences after ingesting psilocybin mushrooms: Acute and enduring positive and negative consequences. Journal of Psychopharmacology, 30(12), 1268–1278. https://doi.org/10.1177/0269881116662634

⁴⁶⁶ Davis, A. K., Barrett, F. S., & Griffiths, R. R. (2020). Psychological flexibility mediates the relations between acute psychedelic experiences and subjective decreases in depression and anxiety. Journal of Contextual Behavioral Science, 15, 39–45. https://doi.org/10.1016/j.jcbs.2019.11.004

growth.⁴⁶⁷ In a representative U.S. sample, approximately 60% of lifetime psychedelic users reported never experiencing a difficult or distressing experience.⁴⁶⁸ In the Global Psychedelic Survey, 41.7% of participants from the United States and Canada described their most intense experience as "a mix of positive and negative," and 7.2% reported their most intense experience was "largely negative/challenging.⁴⁶⁹ Among those who did experience distress, about 9% reported functional impairment lasting more than one day, and few sought medical assistance.

Difficult experiences are more likely when psychedelics are used without preparation, in unsafe environments, during negative psychological states, or at unusually high doses. Conversely, harm reduction strategies, safe dosing education, psychological preparation, supportive environments during the dosing experience, and access to trained peer or professional support (e.g., Zendo Project, Fireside Project), have been associated with reductions in both the frequency and intensity of difficult experiences. The likelihood and severity of difficult experiences are posited to be effects are strongly influenced by modifiable non-pharmacological contextual factors: "set and setting"

- "Set" refers to the internal mindset of the individual, including their mood, intentions, expectations, culture, worldview, physical health, mental preparation, etc.
- "Setting" refers to the individual's external environment in which the psychedelic experience takes place, including physical (e.g. room, lighting, temperature, music, etc), social (e.g. presence of social support, therapist, guide, etc.), and other elements.

Existing evidence indicates that harm reduction strategies can be implemented effectively and with minimal resources. A scoping review of harm reduction practices found that some users in naturalistic contexts already adopt strategies such as dose moderation, preparation of safe and comfortable environments, the presence of trusted companions, and post-experience integration.⁴⁷³ Palmer and Maynard (2022) found that individuals who engaged in harm reduction

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⁴⁶⁷ Schmid, Y., Liechti, M. E., & Lang, U. E. (2021). Global Psychedelic Survey: Exploring the link between difficult experiences and long-term mental health outcomes. Frontiers in Psychiatry, 12, 730047. https://doi.org/10.3389/fpsyt.2021.730047

⁴⁶⁸ Simonsson, O., Sexton, J. D., Cooper, A. J., Anderson, C. T., & Goldberg, S. B. (2023). Prevalence and associations of challenging, difficult or distressing experiences using classic psychedelics. Journal of Affective Disorders, 326, 105–110. https://doi.org/10.1016/j.jad.2023.01.073

⁴⁶⁹ Lake S, Lucas P. The Global Psychedelic Survey: Consumer characteristics, patterns of use, and access in primarily anglophone regions around the world, International Journal of Drug Policy, Volume 130, 2024,104507, ISSN 0955-3959, https://doi.org/10.1016/j.drugpo.2024.104507.

⁴⁷⁰ Johnson, M. W., Richards, W. A., & Griffiths, R. R. (2008). Human hallucinogen research: Guidelines for safety. Journal of Psychopharmacology, 22(6), 603–620. https://doi.org/10.1177/0269881108093587

⁴⁷¹ Pilecki, B., Luoma, J. B., Bathje, G. J., Rhea, J., & Narloch, V. F. (2021). Ethical and legal issues in psychedelic harm reduction and integration therapy. Harm Reduction Journal, 18(1), 40. https://doi.org/10.1186/s12954-021-00489-1

⁴⁷² Evans, J., Nichols, C. D., & Johnson, M. W. (2025). On minimizing risk and harm in the use of psychedelics. Psychiatric Research and Clinical Practice, 7(1), 5–13. https://doi.org/10.1176/appi.prcp.20240128

⁴⁷³ Klein, A., Yates, K., & Sessa, B. (2025). Harm reduction practices for users of psychedelic drugs: A scoping review. Harm Reduction Journal, 22(14), 1–18. https://doi.org/10.1186/s12954-025-01264-2

behaviors before and during psychedelic experiences reported fewer adverse outcomes and more positive effects. ⁴⁷⁴ Guidance focused on mindset, environment, and aftercare was identified as an effective approach to risk reduction; informal education and peer-to-peer knowledge exchange were also found to normalize safety practices within user communities. These grassroots practices demonstrate that individuals can reduce risk through basic, accessible measures.

The Fireside Project provides a model for scalable harm reduction. Established in 2021, Fireside operates a free, nationwide peer support hotline for individuals during or after psychedelic experiences. Volunteers offer nonjudgmental, real-time support via phone or text, assisting callers in managing distress and integrating their experiences. An evaluation found that 65% of callers reported decreased distress and 57% reported increased meaning following contact with the hotline. This program demonstrates how accessible, confidential, peer-led support can enhance safety and improve outcomes outside of clinical environments.

Overall, difficult psychedelic experiences are an established phenomenon, but their risks can be largely moderated through education, harm reduction strategies, and other interventions targeting modifiable "set and setting" factors. These mitigation efforts are more feasible in contexts where decriminalization and public education campaigns enable open discussion and guidance.

Support Resources

Simonsson et al. (2023) found that 98% of participants did not seek help during their most challenging psychedelic experience. This is posited to be associated fear and stigma maintained by criminalization status. Pilecki et al. (2021) observed that the illegality of psychedelics complicates harm reduction efforts by creating uncertainty among therapists regarding how to legally support clients. This can lead to avoidance behaviors, with some providers declining to discuss or treat patients who disclose psychedelic use.

⁴⁷⁴ Palmer, M., & Maynard, O. M. (2022). Are you tripping comfortably? Investigating the relationship between harm reduction and the psychedelic experience. Harm Reduction Journal, 19(81), 1–12. https://doi.org/10.1186/s12954-022-00662-0

Williams, M. T., Perkins, D., & Rhead, R. (2022). A hotline for psychedelic harm reduction: Evaluating the first year of the Fireside Project. Journal of Psychedelic Studies, 6(3), 145–156. https://doi.org/10.1556/2054.2022.00202

⁴⁷⁶ Simonsson, O., Sexton, J. D., Cooper, A. J., Anderson, C. T., & Goldberg, S. B. (2023). Prevalence and associations of challenging, difficult or distressing experiences using classic psychedelics. Journal of Affective Disorders, 326, 105–110. https://doi.org/10.1016/j.jad.2023.01.073

⁴⁷⁷ Pilecki, Brian & Luoma, Jason & Bathje, Geoff & Rhea, Joseph & Narloch, Vilmarie. (2021). Ethical and legal issues in psychedelic harm reduction and integration therapy. Harm Reduction Journal. 18. 10.1186/s12954-021-00489-1.

Conversely, decriminalization may reduce fear and stigma associated with seeking assistance and improve both community and institutional responses to individuals experiencing distress. Even without a legal access framework, decriminalization may enable healthcare providers to offer better support to patients who use psychedelics obtained outside of regulated settings, and to offer adjunctive therapies available when appropriate and necessary.

Denver provides a real-world example of a jurisdiction where a low-enforcement environment has allowed the development of formal training for first responders in managing psychedelic crises. Although research on the effectiveness of these programs remains limited, early evidence suggests that decriminalized environments enable communities and institutions to provide more structured support. Under such conditions, first responders, clinicians, and peer-support volunteers can be trained in crisis intervention and culturally informed care without legal constraints, thereby enhancing emergency response and ongoing support. 478

Public Health Education

Comprehensive public health education regarding psychedelic use is an immediate need, particularly given rising public interest and usage outside regulated frameworks. Although full legalization and FDA approval have not been achieved, public use of psychedelics is increasing, driven by both media attention and emerging scientific research. Any psychedelic use within Maryland is by definition unregulated, whether motivated by self-medication, wellness, spirituality, or recreation.

Education can help address gaps in awareness regarding individual risk factors, such as underlying mental health conditions or family history, which may predispose some individuals to adverse outcomes including psychosis or suicidal ideation. Education can also inform the public about areas that need further study, and factors like "set and setting" that moderate distressing experiences. Balanced, evidence-based communication can promote informed decision-making and encourage adoption strategies that maximize benefits and mitigate risks.

A public health approach that emphasizes balanced information supports multiple objectives: it helps individuals and families reduce preventable harm, protects the integrity of ongoing scientific research, ensures that self-medicating individuals have access to reliable guidance, upholds informed consent principles, and maintains public trust in drug policy reform efforts. Public health education campaigns have successfully shifted public perception about many

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⁴⁷⁸ Axios Denver. (2024, March 13). Denver to launch psychedelic crisis training program for first responders. Axios. https://www.axios.com/local/denver/2024/03/13/psychedelic-crisis-training-program-first-responders

life-saving behaviors (e.g. condom use, designated drivers, etc.), and could be effectively applied to psychedelic use toward mitigating public risk.

Maryland's Positioning

Maryland stands at the intersection of historical precedent, scientific leadership, and policy innovation.

A Legacy of Religious Freedom

From its founding, Maryland has held a unique role in protecting religious freedom. The **Maryland Toleration Act of 1649** was the earliest law in colonial America granting religious liberty. Although it initially applied only to Christians and was repealed and reinstated multiple times, it modeled the separation of Church and State enshrined in the U.S. Constitution. Today, that legacy resonates as sincere religious groups face legal and bureaucratic barriers to the sacramental use of psychedelic substances—even under the federal **Religious Freedom Restoration Act (RFRA) of 1993**.

A Historic Role in Psychedelic Science

Maryland also has deep roots in the scientific study of psychedelics. **Spring Grove Hospital Center in Catonsville** was once the country's leading institution conducting psychedelic research. Beginning in the early 1950s and, after a brief hiatus, resuming from 1963 until 1976—when research was outlawed nationally—Spring Grove researchers explored therapeutic uses of LSD and psilocybin in psychiatric care. These early studies focused on schizophrenia, alcohol use disorder, depression, OCD, and end of life care for cancer. Researchers at Spring Grove established routines still used in clinical trials today, laying groundwork for exploring scientific questions that are now being revisited with modern tools and ethical standards.

That foundation was revitalized by the late Dr. Roland Griffiths, a pioneering neuroscientist at the **Johns Hopkins Center for Psychedelic and Consciousness Research**, which he founded. In 2001, Dr. Griffiths received the first federal grant for psychedelic treatment research in 50 years. His group soon published a landmark study showing that a single high dose of psilocybin could reliably induce profound, spiritually meaningful experiences in healthy volunteers. These findings helped restore scientific credibility to the field after decades of stigma and prohibition and paved the way for the return of federally funded research into psychedelics. His subsequent research demonstrated psilocybin's potential to treat depression, addiction, anxiety, and end-of-life distress. Until his death in 2023, Dr. Griffiths remained a leading voice in psychedelic science,

committed to exploring not only therapeutic benefits but also the deeper human questions of meaning, mortality, and transcendence.

A Hub for Research and Clinical Innovation

Maryland is now home to multiple leading institutions in psychedelic science and therapy.

- **Johns Hopkins** Center for Psychedelic and Consciousness Research, backed by \$55 million in funding, remains a global leader in clinical research on psychedelics for both illness and wellness.
- **Sheppard Pratt** Institute for Advanced Diagnostics and Therapeutics investigates uses for psychedelic medications across a wide range of psychiatric illnesses.
- **Sunstone Therapies**, based at the Aquilino Cancer Center in Rockville, conducts clinical trials on psychedelic-assisted therapy.
- **CBH Health**, a psychiatric clinical research site in Gaithersburg, features an inpatient observation unit and has conducted multiple psychedelic trials.
- Walter Reed National Military Medical Center, in Bethesda, in 2025 received one of two \$4.9 million grants from the Department of Defense to fund a study of psychedelic therapy for active-duty service members.
- **National Institutes of Health**, a federal agency headquartered in Bethesda, administers extramural grants to outside researchers and sponsors pivotal intramural research on the use of ketamine for difficult-to-treat depression.
- Food and Drug Administration, a federal agency headquartered in White Oak, has
 designated 3 psychedelic medications psilocybin, MDMA, and LSD as breakthrough
 therapies. Approval of psychedelic therapy by the FDA would likely retrigger rescheduling
 of the approved substance under federal law, paving the way for legal access through the
 mainstream healthcare system.
- BrainFutures, a non-profit launched by the Mental Health Association of Maryland, dedicated to advancing access to evidence-based innovations in brain health and optimizing learning and performance across the lifespan. It produces white papers, evidence reviews, and policy guidance that help set the evolving standard of care for psychedelic assisted psychotherapy.

These organizations, together with Maryland's broader academic and clinical communities, provide a uniquely robust ecosystem for advancing safe, effective, and ethical access to psychedelic treatments.

Innovation in Health Care Financing

Maryland's leadership extends beyond research to health policy. As the only state with an all-payer rate-setting system for hospitals, Maryland has long prioritized innovation in health care financing. That tradition continues with the forthcoming implementation of the **AHEAD** (Advancing Health Equity and Access to Care Transformation) Model in 2026. AHEAD enables states to align payment models across Medicare, Medicaid, and commercial insurers—creating opportunities to integrate emerging treatments like psychedelic therapy into value-based care models where appropriate.

Psychedelic therapy could also help advance **Maryland's State Health Improvement Plan (SHIP)**, particularly in its **focus on behavioral health**. By addressing conditions such as PTSD, depression, and substance use disorders, psychedelic-assisted therapies may serve as important tools supporting SHIP's population-level strategies for mental health promotion and disease prevention.

Maryland's Phased Evolution of Cannabis Policy

Maryland's journey toward responsible **cannabis regulation has evolved through an incremental approach in parallel with public sentiment**. It began with Senate Bill 364 (2014), when Governor Martin O'Malley signed legislation decriminalizing possession of under 10 grams of cannabis—transforming it into a civil infraction enforcing modest fines and drug education rather than criminal punishment. That same year, House Bill 881 established the Natalie M. LaPrade Medical Cannabis Commission, which launched Maryland's regulated medical cannabis program in 2017.

Expanding on these foundations, voters approved Question 4 in November 2022, mandating adult-use legalization. Meanwhile, the legislature passed HB 837 (2022) to legalize possession of up to 1.5 ounces and home cultivation of two plants, while creating the Cannabis Public Health Advisory Council, a dedicated fund for public health initiatives, and social equity licensing provisions. HB 556/SB 516 (2023) laid out a phased licensing framework, a graduated excise tax structure, and measures to automatically expunge eligible criminal records. This exemplifies Maryland's history of tiered drug policy reform, with complimentary goals attained across distinct "multi-model" regulatory programs.

These policy milestones illustrate Maryland's consistent approach: incremental reforms informed by scientific and fiscal analysis, paired with health safeguards such as youth prevention programs, potency limits, and funding for impacted communities. While **critical differences exist between natural psychedelic substances and cannabis** (see Table 11, p. 77), this adaptive strategy sets a precedent for how Maryland might expand access to psychedelics.

Cannabis Expungement and Clemency

Maryland's cannabis policy evolution has been accompanied by deliberate efforts to repair the harms of "the War on Drugs." In 2025, the General Assembly passed SB 432, **The Expungement Reform Act**, expanding eligibility for expungement and opening new paths to work, wages, and wealth for thousands of Marylanders who have served their time and fulfilled their rehabilitation requirements. Governor Wes Moore championed this legislation as part of a broader agenda to dismantle structural barriers created by prior criminal convictions. The law helps alleviate the long-lasting impacts of criminal records on access to employment, housing, education, and licensure.

The Expungement Reform Act builds on **Governor Moore's Executive Clemency Order**, which in June 2024 pardoned more than 175,000 cannabis possession convictions, which was then the largest pardon in the country for misdemeanor cannabis offenses. In June 2025, Governor Moore added nearly 7,000 pardons for cannabis convictions. Together, these actions signal a clear commitment that Maryland's approach to drug policy must not only reflect current science and social norms but also acknowledge and undo the enduring consequences of past laws.

Maryland-DC Policy Divide

Maryland, with its lack of a regulated psychedelic access program, is geographically positioned directly next to Washington D.C., a jurisdiction where psychedelics have been decriminalized and are readily accessible. In D.C., since the passage of Initiative 81, police have been directed to treat the non-commercial possession, cultivation, and use of entheogenic plants and fungi-including psilocybin/psilocin, DMT, and mescaline-as among their lowest law enforcement priorities. While these substances remain technically illegal, **D.C. has in practice flourished into a thriving "gray market,"** with psychedelic storefront shops mimicking commercial access. **Maryland residents are able to purchase unregulated psychedelic products under the guise of "gifting," without any standard consumer protections** (e.g. testing for contaminants, packaging requirements, potency labeling, etc.). This creates a unique and complex dynamic for

Maryland residents, whereby the status quo involves easy access to a different enforcement approach and an unregulated market, just a few miles away.

Special Populations of Interest

Serving Those Who Served

Maryland is home to over 324,000 military Veterans, accounting for approximately 6.6% of the state's population. In Maryland, 25% of Veterans have a disability, compared with 13.2% of non-veterans. Over 23% of Veterans live with post-traumatic stress disorder (PTSD), and many others live with depression and other mental health conditions that have not responded to traditional therapies. Veterans are five times more likely to experience major depression than civilians, and 3 in 10 veterans with traumatic brain injury have depression. The Department of Veterans Affairs estimates \$25,684 annual cost of PTSD per veteran for health care, disability, unemployment, and other costs, representing a staggering economic burden of Veterans suffering.⁴⁷⁹

Veterans are at 72% higher risk of suicide than those who haven't served. Among Veterans who died by suicide in 2022, the prevalence of depression was 38.6%, anxiety 26.1%, and PTSD 24.9%, according to data from the Veteran's Health Administration. In 2022, the most frequently identified risk factors for veteran suicide were pain (53.8%), sleep problems (51.4%), increased health problems (42.5%), recent declines in physical ability (34.3%), relationship problems (33.1%), and hopelessness (30.4%).⁴⁸⁰ In 2022, there were 6,407 suicides among Veterans and 41,484 among non-Veteran U.S. adults. Among all U.S. adults in 2022, there were, on average, 131.2 suicides per day, with 17.6 Veteran suicides per day.

Chronic pain is highly prevalent among U.S. military veterans, affecting a majority of this population. National data indicate that nearly two-thirds of veterans experience some level of pain, and about 9% report severe, activity-limiting pain, rates significantly higher than those seen in nonveteran populations (National Center for Complementary and Integrative Health [NCCIH], 2020).

⁴⁷⁹ Davis, L. L., Schein, J., Cloutier, M., Gagnon-Sanschagrin, P., Maitland, J., Urganus, A., Guerin, A., Lefebvre, P., & Houle, C. R. (2022). The economic burden of posttraumatic stress disorder in the United States from a societal perspective. The Journal of Clinical Psychiatry, 83(3). https://doi.org/10.4088/JCP.21m14116

⁴⁸⁰ U.S. Department of Veterans Affairs, Office of Suicide Prevention. (2024, December). National Veteran Suicide Prevention Annual Report (Part 2 of 2). U.S. Department of Veterans Affairs.

https://www.mentalhealth.va.gov/docs/data-sheets/2024/2024-Annual-Report-Part-2-of-2_508.pdf

In recognition of the urgent need for new treatment options, the Maryland General Assembly passed Senate Bill 709 in 2022, establishing a psychedelic treatment fund for Veterans with PTSD. This bill passed unanimously in May 2022 and was enacted without Gov. Hogan's signature via "pocket approval." The law allocated state funding to support clinical research on psychedelic-assisted therapy and enabled qualified Veterans to access treatment under approved research protocols. The Maryland Department of Health (MDH), Behavioral Health Administration, issued a Request for Applications (RFA) which closed on August 9th, 2024. According to leading advocates of the bill and public record, the funding was never allocated, and the mandated report was never submitted. Despite this setback, this initiative positioned Maryland as one of the first states in the country to invest public funds specifically to explore psychedelic therapies for Veterans.

Duty to Law Enforcement and First Responders

In addition to military Veterans, there are over **16,000 sworn law enforcement officers in**Maryland and on the order of **10,000** career firefighters and **24,000 volunteer firefighters**and emergency medical responders, as well as thousands of retirees. While about 6% of U.S. adults are diagnosed with PTSD, this figure can increase to as high as **11% in the public**safety community, which includes police officers, firefighters, EMS personnel, and public safety telecommunications workers. This significant rise may help explain the higher suicide rate among first responders compared to civilians. Many of these men and women who are also exposed to trauma in their work lives have the potential to benefit from psychedelic-assisted therapy, which has shown promise in studies of Veterans and First Responders.

Section IV. Existing Psychedelic Policy

The Federal Policy Landscape

Between 2015 and 2025, the federal policy landscape around psychedelics evolved from near-total prohibition toward greater institutional openness, driven largely by scientific research, advocacy for Veterans' mental health, and bipartisan legislative efforts. Some key federal milestones from the past decade are listed in Figure 11.

- 2017-2019: FDA grants breakthrough therapy status to MDMA and psilocybin
- **2019:** First congressional psychedelic amendment introduced by Rep. Alexandria Ocasio-Cortez (D-NY) failed but established precedent
- **2021:** Second psychedelic amendment introduced by Rep. Ocasio-Cortez shows growing support (+49 votes)
- 2022: First dedicated psychedelic bill (Breakthrough Therapies Act) introduced
- 2022: Congressional Psychedelics Caucus formed
- **2024:** First enacted federal psychedelic legislation (NDAA provisions)
- 2025: Multiple bipartisan bills pending for expanded research and VA programs

Figure 11. Key Federal Milestones in Psychedelic Policy and Regulation, 2017 to 2025

A number of important psychedelic regulatory actions have advanced in recent years. The FDA granted Breakthrough Therapy designations to MDMA (in 2017) and psilocybin (in 2018 and 2019) for treatment-resistant mental health conditions including PTSD and major depressive disorder. These designations accelerated clinical trials and created a policy foothold for future regulatory change, even though they do not guarantee rescheduling. In December 2023, Lykos Therapeutics submitted the first-ever New Drug Application for a psychedelic-assisted therapy (MDMA for PTSD), which received Priority Review status in 2024. The FDA declined to approve Lykos's application in 2024, requesting an additional Phase 3 trial. The U.S. Department of Veterans Affairs has requested \$1.5 million for further study into MDMA. Meanwhile, the DEA increased its manufacturing quotas for research purposes.

Table 8. Federal Psychedelics Regulatory Actions, 2015 to 2025

Year	Action	Agency/ Authority	Туре	Status	Overview	
2017	MDMA Breakthrough Therapy Designation	FDA	Regulatory designation	☑ Granted	FDA designated MDMA-assisted therapy as breakthrough therapy for PTSD treatment	
2018	Psilocybin Breakthrough Therapy Designation	FDA	Regulatory designation	☑ Granted	FDA designated psilocybin-assisted therapy as breakthrough therapy for treatment-resistant depression	
2019	Psilocybin Breakthrough Therapy Designation	FDA	Regulatory designation	☑ Granted	FDA designated psilocybin-assisted therapy as breakthrough therapy for major depressive disorder, not limited to treatment-resistant depression	
2023	Increased Production Quotas for Psychedelics	DEA	Manufacturing quotas	Implemented	DEA significantly increased 2023 aggregate production quotas for MDMA, psilocin, 5-MeO-DMT, MDA, LSD for research purposes	
2024	Committee Report H. Rept. 118-647	House Appropriations Committee	Congressional guidance	✓ Adopted	Advises VA should include FDA-approved psychedelics in formulary for Veterans (PTSD, suicidal ideation); requests report to Congress	

On the legislative front, several bills were introduced in Congress over this period. Most focused on creating protections for state-regulated psychedelic programs or improving access for terminally ill patients under Right to Try laws. Key bills included the VISIONS Act (to block federal interference in state-legal psilocybin programs), and the Breakthrough Therapies Act, which aimed to facilitate access to Schedule I drugs with FDA breakthrough designations. In 2024, the National Defense Authorization Act included funding for psychedelic research for Veterans and active-duty service members, marking a significant policy milestone. The growing visibility of

these issues led to the formation of congressional working groups and bipartisan support from lawmakers interested in Veterans' health and mental health innovation.

The Congressional Psychedelics Advancing Therapies (PATH) Caucus, relaunched in the 118th Congress (2023–2024), is a bipartisan group co-chaired by Representatives Lou Correa (D-CA) and Jack Bergman (R-MI). Its mission is to elevate and support rigorous clinical research into therapeutic uses of psychedelics such as psilocybin and MDMA, with a special focus on mental health conditions like PTSD, depression, anxiety, and substance use disorders. Since its relaunch, the caucus has held regular briefings on Capitol Hill and issued public requests for stakeholder and public input to inform federal policy on supervised psychedelic therapy programs.

Table 9. Federal Psychedelics Legislation, 2015 to 2025

Year	Bill/Act	Sponsors	Туре	Status	Overview	
2019	AOC Amendment #1	Rep. Alexandria Ocasio-Cortez (D-NY), Rep. Lou Correa (D-CA), Rep. Ro Khanna (D-CA), Rep. Matt Gaetz (R-FL)	Research barrier removal amendment	X Failed (91-331)	First federal amendment to remove 1996 rider prohibiting federal funds for Schedule I drug legalization advocacy; would have enabled psychedelic research	
2021	AOC Amendment #2	Rep. Alexandria Ocasio-Cortez (D-NY), Rep. Lou Correa (D-CA), Rep. Ro Khanna (D-CA), Rep. Matt Gaetz (R-FL)	Research barrier removal amendment	X Failed (140-285)	Second attempt to remove research barriers gained significant suppor (+49 votes from 2019)	
2022	Breakthrough Therapies Act (Original)	Sen. Cory Booker (D-NJ), Sen. Rand Paul (R-KY)	Rescheduling legislation	Referred to Senate Judiciary Committee	Original bill to reschedule FDA breakthrough therapies from Schedule I to Schedule II; would have streamlined research registration	
2023	H.R. 3684 - Douglas Mike Day Psychedelic Therapy to Save Lives Act	Rep. Dan Crenshaw (R-TX)	DOD research grants	X Stalled in House Armed Services Committee	Directs Department of Defense to award grants for psychedelic therapy research for active-duty Armed Forces with PTSD/TBI	

Year	Bill/Act	Sponsors	Туре	Status	Overview	
2023	Breakthrough Therapies Act (Revised)	Sen. Cory Booker (D-NJ), Sen. Rand Paul (R-KY), Rep. Madeleine Dean (D-PA), Rep. Nancy Mace (R-SC)	Rescheduling X Introduced legislation		Updated version removing research registration sections; focuses on rescheduling breakthrough therapies and FDCA waiver drugs	
2023	Validating Independence for State Initiatives on Organic Natural Substances (VISIONS) Act	Rep. Robert Garcia (D-CA)	Federal "safe harbor"	Referred to the House Energy and Commerce Committee and the Judiciary Committee	Prohibits use of federal funds to interfere with state or local psilocybin laws, covering use, distribution, possession, cultivation, and research	
2024	National Defense Authorization Act (NDAA) - Psychedelics Provisions	Rep. Dan Crenshaw (R-TX), Rep. Jack Bergman (R-MI), Rep. Morgan Luttrell (R-TX), Rep. Ro Khanna (D-CA)	Military research funding	Passed & Enacted	Requires DOD to establish \$10M clinical trial grant program for psychedelic- assisted PTSD and TBI research; 180-day implementation	
2025	Innovative Therapies Centers of Excellence Act	Rep. Lou Correa (D-CA), Rep. Jack Bergman (R-MI), Rep. Morgan Luttrell (R-TX), Rep. Ro Khanna (D-CA), Rep. Dan Crenshaw (R-TX)	VA research centers	Pending	Directs VA to create at least 5 Centers of Excellence for psychedelic research (MDMA, psilocybin, ibogaine, ketamine) for PTSD, chronic pain, SUD, Parkinson's	
2025	Breakthrough Therapies Act (Revised)	Sen. Rand Paul (R-KY), Sen. Cory Booker (D-NJ)	Automatic rescheduling	Pending	Would automatically reschedule any FDA-designated "Breakthrough Therapy" (MDMA, psilocybin) to Schedule II	
2025	HALT Fentanyl Act (Halt All Lethal Trafficking of Fentanyl Act)	Sen. Bill Cassidy (R-LA), Sen. Martin Heinrich (D-NM), Rep. Morgan Griffith (R-VA), Rep. Bob Latta (R-OH)	Fentanyl criminalization + Schedule l research provisions	Passed	Permanently criminalizes fentanyl analogues as Schedule I but includes provisions removing barriers to Schedule I research including marijuana, psychedelics; expedites research applications (30-45 day review), eliminates duplicative registrations	

Year	Bill/Act	Sponsors	Туре	Status	Overview
					for research teams

The State Policy Landscape

The state-level psychedelic policy landscape is expanding rapidly, with **38 states introducing over 220 bills of psychedelic-related legislation since 2020**. Most state efforts have followed one of three pathways: task forces or working groups to study policy options (e.g., 13 enacted, including Maryland, Georgia, Minnesota, Nevada, Vermont, Washington), clinical trial or pilot program bills (e.g., enacted in Arizona, Indiana, North Carolina, Maryland, Connecticut, Utah, and elsewhere), or decriminalization or legal adult use proposals, often via ballot initiatives (e.g., enacted in New Jersey). While 68 of these bills remained in progress as of April 2025, at least 29 have passed, signaling a shift in public and political attitudes, especially around the therapeutic potential of psychedelic substances.

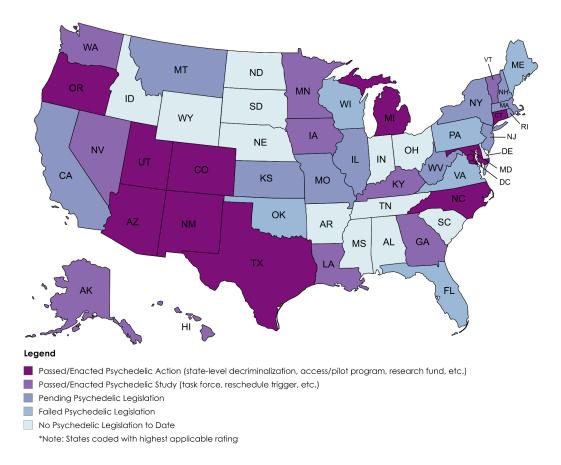


Figure 26. National Psychedelic Legislative Activity as of July 2025

Several states appear "ripe" for meaningful policy change in the next legislative cycle.

Nevada and Texas have established state-sanctioned psychedelic research programs with bipartisan support and significant participation from Veterans' advocates. Illinois, Missouri, and Indiana are showing early signs of legislative interest, often through Republican-sponsored bills aimed at medical access, particularly for PTSD and difficult-to-treat depression. These states are politically diverse, but share a common emphasis on incremental policy that centers Veterans, First Responders, and clinical settings rather than broader adult-use frameworks.

In more progressive states like California, Massachusetts, and New York, the psychedelic movement has followed a **broader and more complex trajectory**. **California's statewide decriminalization bills have faced repeated setbacks**, despite the City of San Francisco and others adopting local deprioritization. Meanwhile, activists are moving forward with a 2026 ballot

initiative that would legalize regulated adult use of psilocybin and establish a state agency to oversee access. Massachusetts had both a well-supported task force process and a 2024 ballot initiative, narrowly defeated at 57% to 43%, that would have legalized possession, cultivation, and licensed-facilitator administration of psilocybin and established a regulatory commission. New York has introduced several bills to permit medical access or protect religious and ceremonial use, with strong grassroots support and some bipartisan interest.

Connecticut and Arizona also stand out. Connecticut passed legislation in 2021 to fund psilocybin therapy pilot programs for Veterans and First Responders. The program is overseen by the state's Department of Mental Health and Addiction Services and aims to align with federal regulatory processes. Arizona, meanwhile, has created a \$5 million psychedelic research grant program, reflecting rising interest in the therapeutic potential of psychedelics even in historically conservative states. Both states may serve as bellwethers for how early clinical research efforts can evolve into broader legal frameworks.

Overall, the outlook is one of cautious expansion. States are exploring different models that reflect their political cultures, healthcare infrastructure, and public opinion. States adopting deliberate, data-informed strategies—like Oregon's regulatory adult-use system and Colorado's hybrid framework—are shaping the policy conversation nationally. As more states move from research and task force stages into implementation, the next few years will be critical in defining safe, equitable, and scalable approaches to legal psychedelic access. We offer a summary of our lessons learned from our study of key states of interest below. A detailed listing of state and local legislation from 2015 to 2025 appears in Appendix 3. For a comprehensive review of the federal and state policy environment, we refer the reader to the National Psychedelic Landscape Assessment presented by the Center for Psychedelic Policy (2025).

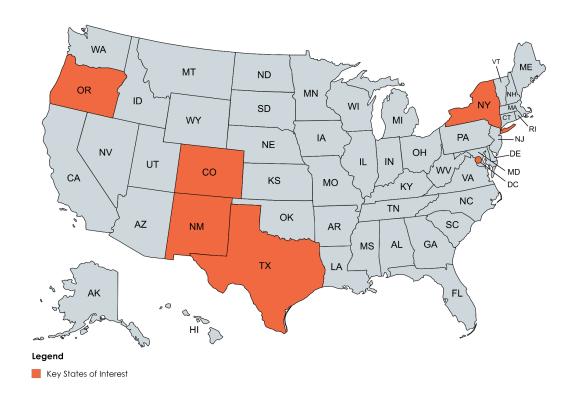


Figure 27. Key States of Interest for Psychedelic Policy Activity in 2025-2027

Oregon

Oregon stands as the pioneer of state-level psychedelic legalization, having implemented the most comprehensive and mature regulatory framework in the United States. Measure 109 passed in 2020 with 56% support, making Oregon the first state to legalize supervised adult use of psilocybin at licensed service centers with licensed facilitators since 2023. Measure 110, passed simultaneously, decriminalized possession of small amounts of all drugs including LSD and MDMA, redirecting cannabis tax revenue to treatment services, although this was partially reversed in 2024. Oregon's psilocybin program requires extensive facilitator training, state licensing, and operation at least 1,000 feet from schools, with all products cultivated and tested by licensed businesses. The state has faced implementation challenges, including numerous local opt-outs by cities and counties that have blocked service centers, and ongoing legislative refinements through bills like HB 2387 (2025) that enhance facilitator protections and update licensing requirements. Affordability remains a central concern, as costs per session in Oregon range from \$400 to over \$3,000, depending upon the dosage consumed and whether clients are participating in individual or group sessions. Oregon rules require licensees to submit a social equity plan that identifies ways that licensees will support

social equity. Many licensees are subsidizing psilocybin services with donations, offering reduced rates for certain individuals, or providing scholarships to clients. While **approximately 10,000 or more sessions have occurred under Oregon's framework in the first two years**, this number suggests that the majority of psychedelic use may still be happening outside legal access models. In summary, Oregon's real-world experience with regulated psychedelic services provides crucial data and lessons for other states.

Colorado

Colorado represents one of the most progressive psychedelic policy landscapes in the United States, building from grassroots efforts to comprehensive state regulation. Denver made history in 2019 as the first U.S. city to decriminalize psilocybin via Initiative 301, establishing the foundation for statewide reform. Proposition 122 passed in 2022 with 54% voter support, making Colorado the second state after Oregon to establish supervised adult use of psychedelics. Proposition 122 created a comprehensive "Natural Medicine Health Act" that immediately decriminalized personal possession and use of psilocybin, mescaline (excluding peyote), DMT, and Ibogaine for adults 21 and older, while establishing a phased rollout of licensed healing centers, cultivation facilities, manufacturing facilities and testing laboratories which began serving clients in June 2025. Like Oregon, Colorado's program requires training and licensing of facilitators; however Colorado offers several facilitator licenses, depending on previous qualifications and licensure as well as lived experience. Notably, the Clinical Facilitator license allows medical and mental health professionals to integrate psilocybin care into their pre-existing professional practices. Colorado's 2025 legislation included SB 25-297 which required data collection from psilocybin programs starting July 2026 to monitor both positive and adverse outcomes. Colorado also passed complementary psilocybin-centric legislation unrelated to the regulatory program, HB25-1063, which is a "trigger law" allowing medical professionals to prescribe crystalline polymorph psilocybin (synthetic, vs. natural) statewide once federally rescheduled by the FDA. There are key differences between Colorado's implementation and Oregon's earlier program. Colorado's regulations created a category of micro-licenses for manufacturing facilities and healing centers. Micro-healing centers, added on to existing medical practices or wellness centers, make program participation more accessible for facilitators who will only conduct a few psilocybin sessions each month. These micro-centers have less elaborate security requirements and lower costs of operation, in exchange for less natural medicine and natural medicine products kept on premise. Colorado's framework allows regulation of time, place and manner of healing center operations, but unlike Oregon's county opt-out provisions, it prevents local jurisdictions from banning healing centers, ensuring statewide access to regulated psychedelic services. Additionally, pursuant to SB 23-290, Colorado

regulators **commissioned a report from a working group of Federally Recognized American Tribes and Indigenous Communities** to inform its implementation of the Natural Medicine
Health Act and an annual report from the Department of Revenue regarding the program.

New Mexico

New Mexico achieved a historic milestone as the **first state to pass comprehensive** psychedelic legislation through the legislative process, establishing a framework that prioritizes equity and medical access. After 11 years of advocacy and collaboration between lawmakers and state agencies, SB 219 became law in 2025, making New Mexico the first state where psychedelic legalization was accomplished through legislative action rather than citizen initiatives. The legislation establishes a medical psilocybin advisory board to oversee rulemaking and clinical program development, with therapy access required to begin by the end of 2027. New Mexico's model is **limited initially to people with qualifying diagnoses and to psilocybin** therapy, creating a more conservative regulatory framework compared to Colorado and Oregon's broader adult-use models. The state's legislation represents a significant geographic expansion of psychedelic reform into the Southwest, potentially influencing neighboring states and demonstrating that legislative rather than ballot-driven reform is viable. New Mexico's success shows how psychedelic policy can advance through traditional governmental processes, where experienced leadership and effective collaboration between state **agencies exist**, offering a pathway for states such as Maryland where ballot initiatives are not possible or where lawmakers prefer to guide policy development and implementation timelines.

Texas

Texas has emerged as an unexpected leader in psychedelic research and Veteran-focused therapy, driven primarily by Republican lawmakers advocating for military mental health solutions. HB 1802 in 2021 made Texas the first state to enact psychedelic research legislation, requiring partnership with Baylor College of Medicine to study psilocybin for Veteran PTSD. The state's commitment escalated dramatically in 2025 with HB 4561 and SB 2308, which authorized an unprecedented \$50 million in state-backed matched funding for FDA-approved ibogaine clinical trials. Texas's approach uniquely focuses on both psilocybin and ibogaine research, targeting opioid use disorder, PTSD, and TBI through public-private partnerships that allow the state to retain intellectual property stakes and revenue sharing. The legislation establishes consortiums including public universities, hospitals, and drug developers, with specific provisions for Veteran-focused funding. This Republican-led initiative demonstrates how psychedelic reform has become a genuinely bipartisan issue, particularly when framed around Veteran healthcare and addiction treatment.

New York

New York has positioned itself as a major East Coast hub for psychedelic policy innovation, with an unprecedented volume of legislative activity and research initiatives spanning Veteran care to comprehensive regulation. The state currently has six distinct psychedelic bills pending in **2025,** including S 1801/A 3845 for **Veteran and first-responder psilocybin pilots**, A 3375 for clinically supervised naturally grown psilocybin with \$5 million in grants, and A 2142/S 5303 establishing a **regulated permit system for adult non-commercial use**. New York's approach uniquely emphasizes in-home psilocybin use under clinical supervision, distinguishing it from facility-based models in Oregon and Colorado. The state's legislation includes comprehensive ibogaine research programs (S 1817/A 1522 and S 4664) specifically targeting addiction treatment and PTSD, reflecting the state's focus on evidence-based policy development. New York lawmakers have designed their framework to mirror successful structures from other states while adding innovative elements like **permit-based cultivation** systems that would allow adults to grow psilocybin for personal use after completing health screenings and educational requirements. The state's multiple legislative approaches suggest a comprehensive strategy to address both therapeutic access and broader decriminalization goals.

District of Columbia

The District of Columbia achieved one of the most decisive victories in psychedelic decriminalization history, establishing itself as a model for urban entheogenic plant and fungi policy reform. Initiative 81 passed in November 2020 with an overwhelming 76% voter approval, making enforcement of laws against natural psychedelics (psilocybin, ayahuasca, ibogaine, DMT, mescaline) among the lowest police priorities. The "Entheogenic Plant and Fungus Policy Act of 2020" covers a broad spectrum of naturally occurring psychedelics, specifically focusing on plant and fungal sources rather than synthetic compounds. D.C.'s policy represents one of the most comprehensive local deprioritization measures in the United States, going beyond psilocybin-only initiatives to include traditional medicines like ayahuasca and ibogaine. The initiative's success in the nation's capital carries significant symbolic weight, demonstrating urban acceptance of psychedelic policy reform and potentially influencing federal conversations about drug policy. Unlike state-level legalization efforts, D.C.'s approach focuses purely on enforcement deprioritization, avoiding the complex regulatory frameworks required for legal therapeutic markets while still providing meaningful protection for adult users of entheogenic plants and fungi.

Outlook, Trends and Key Drivers for 2026 and Beyond

Looking ahead to 2026 and beyond, several powerful forces are likely to accelerate psychedelic policy reform across the United States. Veteran-led mental health advocacy continues to **provide compelling bipartisan support**, especially for clinical access to MDMA, a synthetic psychedelic, and psilocybin, the naturally occurring psychedelic with the largest body of research to date. These efforts have helped destigmatize psychedelic research and created political momentum in both conservative and progressive jurisdictions. A major potential inflection point is the anticipated FDA approval of MDMA-assisted therapy, possibly in 2027 or 2028. Such approval could trigger a cascade of state-level rescheduling actions and catalyze broader access to one form of psychedelic therapy through traditional healthcare systems. Meanwhile, results from early access models and pilot programs in Connecticut, Texas, Colorado, and Oregon are expected to shape policymaking by offering concrete, localized evidence on program design, safety, and efficacy. Economic and biotech interests will also play a decisive role, as states such as Texas and Indiana position themselves as hubs for biotech or psychedelic **therapy innovation and job creation**. These converging trends suggest that the next wave of psychedelic policy may be shaped by competition between states within a growing field of medical and economic transformation, in addition to public health and criminal justice priorities.

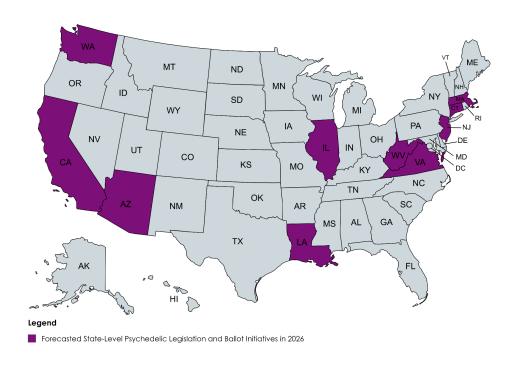


Figure 28. Forecasted State-Level Psychedelic Legislation and Ballot Initiatives in 2026

Table 10. Outlook for State-Level Psychedelic Legislation and Ballot Initiatives in 2026

State	Trend	Possible Outcome
Arizona	Local momentum for decriminalization	Could prompt legislative action
California	Significant public pressure, growing Veteran support, multiple cities passing decrim bills	Pilot programs for veterans/first responders; expanded psychedelic-assisted therapy licensing
		Possession decriminalization and study bill likely refiled and passed
Illinois	HB 1143 sponsors plan to refile; coalition support growing	Revised psilocybin therapy bill with new regulatory guardrails
Louisiana	Veterans task force report expected Feb 2026	Could prompt pilot or access bill in late 2026
Massachusetts	Narrowly failed ballot initiative in 2024 strong grassroots effort	Another ballot initiative (therapy and decriminalization) likely in 2026; new pilot bills in legislature
New Jersey	S 2283 already drafted and held; increasing legislative support	Psilocybin therapy and research legalization
Virginia	Bipartisan support for psychedelics research exists	Rescheduling and advisory board bill could pass with minor edits
Washington	Task force already studying access issues	Narrow access bills (clinical and tribal exemptions) may be refiled
West Virginia	Research bills got House support	Ibogaine/psilocybin studies could return with broader legislative backing

Comparison of State and Federal Pathways for Psychedelic Policy Reform

As Maryland considers a range of options for responsible access to natural psychedelic substances, a critical question emerges: **Should reform efforts align with federal timelines for FDA approval, or proceed through state-level legislative or regulatory initiatives?** Each path presents distinct advantages and trade-offs in terms of safety, speed, equity, innovation, and accessibility.

Federal Pathway: FDA Approval Route

Pursuing reform through the FDA approval process ensures a high level of medical legitimacy and scientific rigor. Treatments approved by the FDA undergo extensive clinical trials to establish safety, efficacy, dosage, and long-term effects, creating standardized protocols that are broadly accepted across the healthcare system. This route also opens the door to eventual insurance coverage, which is a reliable pathway to provide for widespread access to patients with qualifying health conditions. Clinicians and researchers may also benefit from reduced legal risk, as FDA approval provides clearer protection under federal law.

However, the federal route comes with considerable limitations. It is often slow—sometimes taking a decade or more to bring new treatments to market—delaying access for individuals with urgent mental health needs. The FDA's preference for highly standardized clinical models may exclude community-based, ceremonial, or culturally rooted practices. Additionally, existing disparities in clinical trial participation mean that approved protocols may not be well-suited to people of color, LGBTQ+ individuals, those from low-income backgrounds, or persons who have been underrepresented in clinical research in the U.S. and abroad. Even when treatments are covered by insurance, high deductibles or limited networks can make access unaffordable, particularly in the face of recent cuts to Medicaid and Medicare reimbursement.

State Pathway: Legislative or Regulatory Reform

State-level action—through legislation, ballot measures, or administrative rulemaking—offers a more flexible and timely approach, which could be implemented significantly sooner than a federally driven model. States like Oregon, Colorado, and New Mexico have already adopted access models that allow broader experimentation with supervised adult use, peer support, and ceremonial access. This creates opportunities for Maryland to center community-led models that are culturally responsive and accessible outside of clinical settings. State policy can

also be structured around reparative justice—incorporating expungement, equity-focused licensing, and reinvestment in communities impacted by criminalization. A state-level approach could serve as a **"laboratory of democracy," testing various approaches to access, training, and integration** outside of a top-down federal system that may leave less room for flexibility.

Yet, state-led reform also entails significant risks and limitations. Psychedelics such as psilocybin remain classified as Schedule I substances under federal law, which places providers and patients in potential legal jeopardy despite state-level protections. Without federal oversight, states must develop their own safety standards, product testing protocols, and training requirements for facilitators—an expensive and complex undertaking. Furthermore, services offered outside the medical model are unlikely to be covered by health insurance, placing a high initial financial burden on individuals seeking care and exacerbating existing inequities in access.

Conclusion

The choice between state and federal pathways is not binary. **Many advocates envision a complementary approach in which states take early steps to pilot culturally responsive and equitable access models, while continuing to monitor federal developments.** Maryland is uniquely positioned to do both: it has a legacy of innovation in psychedelic science and a strong track record in public health leadership. By learning from other states and contributing its own data, Maryland can shape national policy while also addressing local needs through thoughtful, phased, and inclusive reform.

Overview of Access Models

The Task Force identified a spectrum of policy options based on our review of scientific literature, expert consultation, and efforts in other states. **These definitions below are distinct and not mutually exclusive, such that multiple options may be implemented in a parallel or complementary fashion.** Each model has specific precedents and real-world examples, allowing for clear delineation and elaboration of their respective pros and cons. They also carry distinct economic implications.

Table 11. Comparison of Access Models for Natural Psychedelic Substances. Source: M. Macis, Johns Hopkins University

	Commercial Sales	Supervised Adult Use	Medical / Therapeutic Use	Non-Commercial Peer Sharing	Deprioritization / Decriminalization	•	FDA-Approved Use
Examples	Maryland cannabis dispensaries	Oregon (originally)	New Mexico	Colorado "Grow and Give"	Washington, D.C.	Native American Church	No state-level action; Esketamine
State involvement	High	High	Moderate/High	Moderate	Low/Moderate	Low	Lowest
State revenue potential	High	Moderate to High	Moderate	Low	Low	Low	Lowest
Policy lead time	Moderate	Slow (2+ years)	Slow (2+ years)	Fast	Fastest	Fast	Slowest (3+ years)
Regulated market and supply chain	Yes	Yes	Yes	No; "Gift economy"	No; "Gray market"	No; Church donations	Yes
Breadth of access	Broad	Broad	Moderate	Broad/Moderate	Broad/Moderate	Narrow	Narrow
Health screening	Maybe (via user permitting)	Yes	Yes	Maybe (via user permitting)	No	No	Yes
Required supervised use	No	Yes	Yes	No	No	Probably	Probably
Cost to Consumer	Moderate	Moderate/High	High	Low	Moderate	Lowest	High
Provider barriers to entry	Low/Moderate	High	Moderate	Low	Lowest	Low/Moderate	High

Above models are organized left-to-right from highest-to-lowest state involvement, based on the analysis and guidance of external economic advisors from Johns Hopkins University.

Commercial Sales

In the commercial sales model, licensed private businesses are authorized to cultivate, manufacture, and sell natural psychedelic substances through a regulated marketplace. This model most closely mirrors adult-use cannabis systems and includes oversight for safety testing, packaging, labeling, advertising, and taxation. Maryland's own cannabis dispensaries, along with proposals like New York's A2142 Personal Psilocybin Permit bill, serve as key examples. In one variation, consumers complete a screening process and an educational module to obtain a personal use permit, allowing them to purchase taxed psychedelic products from licensed providers and self-administer independently or with optional facilitation. This model could be limited to require sales only to those with medical authorization or who are working with a licensed professional.

State Involvement: High. This model requires a comprehensive regulatory structure encompassing licensing, quality control, zoning, tax collection, compliance monitoring, and enforcement.

State Revenue Potential: High. Revenues would stem from licensing fees, retail and excise taxes, and economic spillover effects such as tourism and job creation.

Costs:

- State: Investment in infrastructure for regulation, public education, and enforcement.
- Private Sector: High startup costs, compliance burdens, and reputational risk.
- Society: Potential for commercialization-driven inequities, normalization without sufficient guardrails, and risk of exploitative marketing.

Benefits:

- State: Predictable revenue streams, economic stimulation, job growth, potential for public health reinvestment.
- Private Sector: Large and scalable market opportunities with potential for innovation.
- Society: Expanded access, normalized discourse, and safe and tested product choice for diverse consumers.

Supervised Adult Use

Under the supervised adult use model, sometimes referred to as "regulated access," adults 21 and older may legally access psychedelics through trained, state-licensed facilitators in non-medical settings such as wellness centers or retreat environments. Unlike medical models, this approach does not require a clinical diagnosis or that a clinical practitioner administers the

medicine—just professionals trained in facilitation as regulated by the state. Oregon was the first state to implement this model, and Colorado has since adopted similar frameworks. Emphasis is placed on participant screening, session safety, facilitator training, and facility licensure to minimize risks and maintain public trust.

State Involvement: High. Requires robust infrastructure for licensing facilitators, certifying training programs, approving service centers, and ensuring quality and compliance.

State Revenue Potential: Moderate to High. Revenue derives from licensing fees for facilitators and facilities, as well as taxation on service provision.

Costs:

- State: Regulatory and compliance development, enforcement, and administrative oversight.
- Private Sector: High barriers to entry due to required training and infrastructure; limited scalability due to long session durations.
- Society: High out-of-pocket costs restrict access, particularly for low-income populations. These cost barriers have been well documented in both Oregon and Colorado.

Benefits:

- State: Generates licensing revenue while supporting public health objectives.
- Private Sector: Creates space for innovation in service delivery, retreat design, facilitator training, and supportive technologies.
- Society: Offers broad access without requiring a medical gatekeeper. Establishes strong safety, screening, and training standards that reduce harm and professionalize care delivery. Enables large-scale data collection for future research and policy refinement. Broad accessibility supports inclusion of historically marginalized communities and respects diverse motivations for use, if special care is taken to avoid structural and cultural barriers. Creates accountability for potentially bad actors.

Medical / Therapeutic Use

This model restricts access to psychedelics to patients with qualifying diagnoses under the care of licensed healthcare providers. Medical access programs are rooted in clinical trial protocols and aim to align with insurance and healthcare delivery systems. Examples include amended provisions in Oregon and Colorado, as well as New Mexico's Senate Bill 0219. Access is typically granted to individuals with PTSD, depression, anxiety, chronic pain, or substance use disorders.

State-approved practitioners, such as psychiatrists, physicians, and licensed therapists, deliver services in regulated settings.

State Involvement: Moderate to High. Requires regulatory oversight for clinical protocols, facility standards, and professional licensure.

State Revenue Potential: Moderate. Derived from licensing, clinic permits, and limited taxation on services.

Costs:

- State: Requires alignment with insurance programs and oversight of clinical safety protocols. Potential need for public subsidies.
- Private Sector: High entry costs and unclear legal protections may discourage provider participation.
- Society: Access is limited to those with diagnoses or the means to pay out-of-pocket. Implementation is slowed by institutional resistance and high service costs.

Benefits:

- State: May reduce downstream healthcare costs, including hospitalizations and pharmaceuticals.
- Private Sector: Expands opportunities in clinical training and therapeutic service delivery.
- Society: Legitimizes use through integration into established healthcare systems. Offers relief for treatment-resistant conditions. Establishes a strong evidentiary base, builds public trust, and creates pathways for eventual insurance reimbursement.

Other Considerations: Establishing licensure and regulatory systems for psychedelic facilitators is complex and time-intensive. Legal uncertainties may deter clinician involvement unless explicit statutory protections are enacted. Without financial assistance or insurance alignment, participation is likely to remain limited. Sustainable program success will require dedicated funding, public education, limited sales for off-site use, and continuing adaptation.

Non-Commercial Peer Sharing

This model allows adults to grow psychedelic-containing plants or fungi and share them with others without compensation. The statutory framework for this approach—exemplified by Colorado's "Grow and Give" law (CO Rev. Stat. 18-18-434(5)(a))—permits cultivation and gifting of natural psychedelics while explicitly prohibiting sales or advertising. It promotes personal autonomy, mutual aid, and community-based healing outside of formal healthcare or

commercial systems. In some proposed versions, individuals could apply for a personal psychedelic use permit following education or health screening, but this is not a requirement in most peer sharing laws. Penalties for unauthorized possession are replaced by civil fines or warnings, reducing criminalization while still deterring misuse.

State Involvement: Moderate. Requires clear legal definitions, limitations on advertising or sales, and oversight of public safety concerns.

State Revenue Potential: Low. Minimal revenue may be generated through permit fees, or the testing of products through state-licensed testing facilities. No tax revenue is associated with non-commercial transactions.

Costs:

- State: Complex-to-enforce boundaries between gifting and illicit "disguised" sales, although this is similar to current criminalization schemes where a law enforcement agent has to examine each case to distinguish between possession, intent to distribute, and trafficking.
- Private Sector: Limited to voluntary testing for potency and purity.
- Society: Quality control is limited; safety risks may emerge from untested or improperly prepared substances. Need to invest in public education.

Benefits:

- State: Relatively low administrative burden and enforcement costs compared to commercial systems. State-provided testing of non-regulated products allows for monitoring trends in substance use, which may inform future regulation and policy discussions.
- Private Sector: May indirectly support ancillary markets, such as cultivation supplies, harm reduction education, or integration coaching.
- Society: Expands access with minimal financial barriers. Supports community care and decriminalization efforts while minimizing reliance on commercial or medical institutions. Avoids commercial influence on public health regulations. Avoids commercial pressure to expand use via advertising and promotion.

Deprioritization / Decriminalization

This model involves either the formal removal of criminal penalties or a shift in law enforcement priorities for personal use, possession, cultivation, or gifting of psychedelic substances. Examples include Washington, D.C.'s 2020 ballot initiative concerning "entheogenic plants and fungi," which

made enforcement the lowest priority for local police. Under "deprioritization," psychedelic substances remain illegal but are rarely prosecuted, while "decriminalization" statutorily removes criminal penalties and often replaces them with civil fines or health assessments.

Decriminalization legislation may include language that provides for non-commercial peer sharing. Neither model establishes legal protections for facilitators or regulated access systems.

Table 12. Comparison of Deprioritization and Decriminalization

	Deprioritization	Decriminalization
Legal Status	Substance remains technically illegal	Removes criminal penalties and sometimes civil penalties as well
Law Change	A shift in enforcement policy/priority	Requires a change in law/statute
Consequences	Reduced likelihood of arrest/prosecution by police	Fines (which could lead to criminalization if unpaid), health assessments, no criminal record (although arrest and conviction records prior to decriminalization must be cleared)
Enforcement Risk	Still at risk from state or federal authorities	Lower risk from local authorities

State Involvement: Low to Moderate. Requires policy changes or legislative action but little in the way of regulatory infrastructure.

State Revenue Potential: Low. These models generate no tax revenue but may reduce costs associated with criminal enforcement.

Costs:

- State: No regulatory income; does not leverage healthcare or economic systems.
- Private Sector: No legitimate market or formal investment opportunities.
- Society: Underground use continues without state-run product testing or facilitator standards. Unregulated storefront sales may increase, provoking local backlash.

Benefits:

- State: Cost savings on enforcement and incarceration. Politically easier to implement and generally avoids federal interference.
- Private Sector: Advocacy and education markets may expand. Decriminalization may signal policy momentum.

Society: Reduces stigma and incarceration risks. Increases affordability and access
through gray markets, even if informally. Enables community-based harm reduction, such
as education on risk-reduction practices, drug testing, or safe supply promotion.
Encourages broader public discourse and may pave the way for future reforms. Provides
victims of abuse a legal pathway to hold unscrupulous actors accountable through the
criminal and civil courts.

Other Considerations: Lack of national public health data limits the ability to rebut concerns about safety. Ethical risks remain for seekers interacting with guides and individuals who may take advantage of novices or individuals who have not gained knowledge of psychedelics. Policymakers often worry about increased youth access, product contamination, and the potential for disorganized or unsafe use. Whereas, criminalization doesn't remove these concerns and may actually exacerbate safety issues (e.g., people reluctant to go take a friend to the hospital or call for an ambulance because the substances they've ingested are illegal).

Denver remains the only city to have published an official report on the effects of decriminalization (2019–2021). Briefly, Psilocybin-related criminal cases decreased by roughly two-thirds in the three years following deprioritization. While poison control reports increased up to three-fold among adults and more than seven-fold among children, hospital or emergency department admissions for psilocybin-related incidents remained minimal. There was no evidence of increased youth exposure, public disturbances, or destabilized social behavior tied to psilocybin.

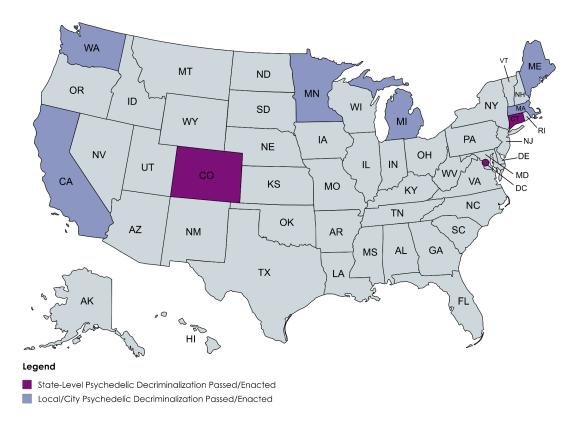


Figure 29. Psychedelic Decriminalization Legislation Passed or Enacted as of July 2025

Religious Use

Religious use models recognize the sacramental use of psychedelics by specific faith communities. The Native American Church, which uses peyote in its worship, operates legally under the protection of the American Indian Religious Freedom Act Amendments of 1994 (P.L.103-344). Groups such as the União do Vegetal (which uses Hoasca® or ayahuasca sacramentally) have won legal protection from Federal law enforcement for ceremonial use under the Religious Freedom Restoration Act of 1993 (RFRA) (P.L. 103-141). RFRA does not apply to the States (*City Of Boerne*, v. *P.F. Flores*, *Archbishop of San Antonio*, *and United States*, <u>521 U.S.</u> <u>507</u>, 117 S.Ct. 2157, 138 L.Ed.2d 624 (1997). These exemptions are narrow, tied to specific lineages and practices, and do not permit general public access.

State Involvement: Low. Minimal state role unless legal or public concerns arise. Oversight tends to be reactive rather than proactive.

State Revenue Potential: Low. These models generate no significant direct revenue.

Costs:

- State: Legal oversight of religious exemptions.
- Private Sector: No market access or commercialization allowed.
- Society: Very narrow eligibility and limited public health integration.

Benefits:

- State: Simple to administer and respectful of constitutional rights.
- Private Sector: None directly.
- Society: Preserves cultural practices and provides a legal pathway for spiritual or religious use. May lead to beneficial health and societal impacts downstream. May integrate uniquely well with public health due to its organized, community-based, and collective nature.

FDA-Approved Use

This approach maintains the status quo, "wait and see." The federal process leads, and Maryland would integrate through providers and payers. Psilocybin and MDMA are currently in late-stage trials, and federal rescheduling could occur within a few years. States taking this path avoid legal and regulatory conflict but offer no interim relief or access. It is the most cautious model, prioritizing federal alignment over innovation, public health urgency, and an approach tailored to the unique needs of the Marylanders.

State Involvement: Low. Integration into existing healthcare and insurance systems. Federal approval limits state effort to integration and monitoring.

State Revenue Potential: Low. Indirect via general economic activity; negligible direct revenue.

Costs:

- State: Initial implementation challenges (education, regulation), Delays in availability.
- Private Sector: High investment for R&D and trials, Limited to few players with IP and capital.
- Society: Limited competition may keep prices high. Slower adoption, resulting in more
 people with treatment-resistant mental health needs either have to continue to suffer or
 travel to other states that have already decriminalized or allow for supervised adult
 access or a medical model. This approach also results in the most people, of all the listed
 approaches, continuing to be involved in the criminal legal system.

Benefits:

- State: Long-term integration with insurance systems, Reduces enforcement burden.
- Private Sector: Federal legitimacy, Broad market once reimbursable, Pharma and biotech opportunities.
- Society: Standardized quality, Potential widespread insurance coverage, Clinical oversight, based on high-quality evidence of efficacy and safety. Broadly accepted framework for medical care, Highly trained medical professionals and facilities, Extensive and rigorous randomized controlled trial data clearly establishing the extended efficacy.

Other Concerns: MAPS/Lykos MDMA-Assisted Psychotherapy was delayed by the FDA in 2024, with earliest projected FDA approval now in 2027 or beyond. One 3-dose course of treatment is projected to cost \$30,000. It is unknown what type of an ICER (Institute for Clinical and Economic Review) value assessment this treatment will receive or what level of insurance coverage will be adopted. If costs remain high, it is widely expected that insurance coverage will start low/limited and involve extensive prior authorization requirements, co-pays, and cost-sharing expenses, even among those well-insured. The limited number of certified therapists who can legally administer treatment will contribute to bottlenecks and access delays upon launch.

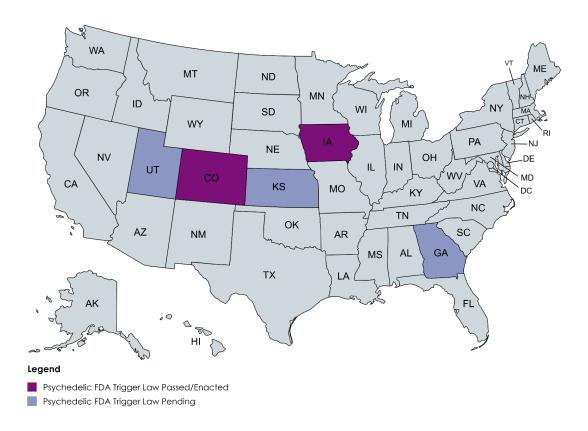


Figure 30. Psychedelic "Trigger Laws" Enacted as of July 2025

Section V. Task Force Recommendations

Below are the results of the Modified Delphi process. These results are presented in two forms, for the General Assembly's consideration:

- First, the Proposition by Proposition Summary details each of the 90 policy propositions, including the grade of recommendation, relevant stakeholder input, and implementation considerations. Grades are as follows: A=Strongly Recommended, B=Moderately Recommended, C= Conditionally Recommend, NFS=Needs Further Study, I= Insufficient Consensus, and finally No Grade. Propositions which received a grade A received significantly stronger consensus than grade B, and so forth. For detailed discussion of the Modified Delphi methodology, please refer to Appendix 2.
- Second, the Ensemble Model details this Task Force's recommendations for combining the most strongly recommended of the 90 policy propositions, toward establishing a unique multi-pathway model of psychedelic access that involves the strongest public benefit maximization and risk mitigation strategies from models seen in other jurisdictions.

The Task Force recommends the Ensemble Model as presented. The Task Force also respects the role of law-makers in crafting legislation. Should the General Assembly wish to reconsider alternative combinations of the most strongly recommended policy propositions, the deconstructed Proposition by Proposition Summary captures considerations on an itemized level. The Proposition by Proposition Summary may also provide guidance should the General Assembly wish to revisit propositions with weaker support or incomplete consensus.

Proposition by Proposition Summary

Cross-Model Propositions (001-023)

Proposition 001 (Grade A - Strongly Recommended)

Access models should initially focus on psilocybin (natural, not synthetic), with potential expansion to other natural psychedelic substances once initial programs are successfully established.

The Task Force recognized psilocybin's extensive research base, established safety profile, and growing clinical evidence as compelling reasons to begin with this substance. The focus on natural rather than synthetic psilocybin respects traditional usage patterns and may face less regulatory resistance than synthetic alternatives, while providing a solid foundation for program development and public acceptance This phased approach allows Maryland to learn from initial implementation with psilocybin before expanding to substances like mescaline or DMT, which have less research supporting their therapeutic use. The strategy aligns with successful policy rollouts in other jurisdictions and provides a framework for systematic expansion based on demonstrated safety and efficacy. .

Proposition 002 (Grade A - Strongly Recommended)

Maryland should implement multiple complementary access models (e.g., deprioritization and medical/therapeutic use) in its initial legislation for natural psychedelic substances.

The Task Force strongly endorsed a comprehensive approach recognizing that no single access model can meet all legitimate needs for psychedelic substances. One stakeholder emphasized: "I believe it is important for us to emphasize in our report that natural psychedelic medicines are effectively used in different ways, under different circumstances. The Maryland Assembly should not consider its job 'done' after implementing one, or even several, access pathways. This is because no one pathway can effectively satisfy the needs of all who could benefit from natural psychedelic substances." Another noted: "We should not fear being comprehensive...

Presentation of multiple models of access reflects that we have been sophisticated in our analysis." The multi-model approach acknowledges diverse use patterns from medical treatment

to public health, personal growth, spiritual practices, and harm reduction. By implementing complementary models simultaneously, Maryland can create a robust framework serving different populations while maintaining appropriate safety measures and preventing policy gaps that might drive users toward unregulated markets.

Proposition 003 (Grade I - Insufficient)

Use of natural psychedelic substances should be limited to adult residents of Maryland who have a formal qualifying medical or psychiatric diagnosis from a licensed health care provider.

This proposition received insufficient consensus, reflecting significant Task Force disagreement about restricting access to medically diagnosed individuals. Critics argued this limitation would exclude legitimate non-medical uses including personal growth, spiritual practices, and general wellness applications. One stakeholder noted: "While it would be feasible to limit access to individuals with a formal qualifying medical or psychiatric diagnosis, it is to me highly undesirable, because there are important and legitimate uses of these substances that lie outside of the narrow medical model." Another expressed concern: "If legal use is limited to medical/psychiatric diagnoses, the majority of users will not be provided screening, education, safety standards, nor participation in a taxable revenue-generating above-ground market. Those 'well' individuals will continue to seek 'personal growth' via illegal channels." The medical gatekeeping approach could create access barriers, particularly for marginalized communities lacking regular healthcare contact. One stakeholder raised the consideration of limiting psychedelic use to individuals found with absence of exclusionary criteria or disqualifying diagnoses, rather than presence of inclusionary criteria. This was supported by another "I think it's really important that people are pre-screened, not that they have to have a specific diagnosis, but just that they're pre-screened for their health and safety in the case that they might be a high risk for having an adverse event with a psychedelic." The insufficient grade indicates the diagnostic restriction may be too narrow for initial implementation, though medical pathways remain important components of broader access frameworks.

Proposition 004 (Grade A - Strongly Recommended)

Individuals who wish to access (grow, forage, commercially purchase, etc.) natural psychedelic substances outside of a regulated setting should first obtain a permit/license for use.

The permitting system received strong support as a mechanism balancing personal autonomy with public safety. This consideration was derived from New York State's pending legislation Assembly Bill A2142. Stakeholders highlighted that permitting "solves the issue of differentiating"

between religious versus secular use" while ensuring all users receive appropriate education and screening. The system addresses the reality that most psychedelic use occurs outside clinical settings. As one stakeholder noted: "In 2023, eight million Americans used psilocybin, but only 700 of them did so in Oregon" and "The most common motive is for personal growth, which, as we know, is not a medical diagnosis or disorder." Permitting provides a "step up in terms of safety and education" for the majority of users who will continue self-administering regardless of policy. The system allows quality control, harm reduction education, and basic screening while preserving individual choice about use context. Implementation should balance accessibility with meaningful safety measures to avoid creating barriers that drive users toward unregulated alternatives.

Proposition 005 (Grade C - Conditionally Recommended)

Individuals who wish to obtain a permit/license for use of natural psychedelic substances should first undergo an appropriate medical and psychiatric screening by a licensed health professional (e.g., similar to a Medical Examiner's Certificate for a Commercial Driver's License or a Medical Cannabis Registration).

This conditional recommendation requires careful implementation to avoid creating barriers while ensuring safety. One stakeholder emphasized: "Natural psychedelic medicines are more powerful and have significantly more potential side effects and complications compared to cannabis, or other commonly used substances such as caffeine and alcohol... medical professionals can help discourage individuals at high risk of medical or psychiatric complications from accessing models that do not provide sufficient support." Medical organizations recommended: "requiring comprehensive psychiatric evaluations performed by licensed physicians or psychiatrists prior to administration, particularly outside of FDA-approved uses." The conditions for implementation should include: evidence-based screening criteria focused on genuine contraindications rather than subjective judgments; affordable fee structures with sliding scales or state subsidies; geographically distributed screening providers; streamlined processes avoiding excessive bureaucracy; appeals mechanisms for denied applications; and cultural competency training for providers. Screening should assess for absence of exclusion criteria-identifying specific safety concerns like drug interactions, psychiatric vulnerabilities, or medical contraindications-rather than assessing for inclusion criteria in a general gatekeeping fashion. Success depends on developing protocols that are medically sound but not unnecessarily restrictive, ensuring the requirement enhances safety without becoming a tool for limiting access through burdensome or biased implementation.

Proposition 006 (Grade C - Conditionally Recommended)

Individuals who wish to obtain a permit/license for use of natural psychedelic substances should complete a mandatory education course and pass an exam.

Educational requirements received conditional support contingent on accessible, high-quality programming. Implementation conditions should include: state-provided low-cost online training options; content covering harm reduction, drug interactions, contraindications, and integration practices; culturally responsive materials; multiple language options; accommodations for different learning styles and abilities; and reasonable passing standards focused on safety rather than exclusion. The education should emphasize practical harm reduction rather than abstinence-based approaches, with content that is evidence-based and regularly updated as research evolves. Fee structures must not create economic barriers, requiring sliding scales or state subsidies as needed. The exam should test practical safety knowledge rather than creating arbitrary hurdles. Ensuring that education/examination remain low-cost and feasible in regard to time commitment is critical, as challenges in attainability may inadvertently drive individuals to underground markets. Stakeholders emphasized the importance of meaningful education: education requirements should ensure users understand set and setting, potential interactions, and when to seek help. One stakeholder raised the consideration of whether permitting/licensing should require completion of a supervised practicum with mandatory hours requirement. Success requires balancing comprehensive education with accessibility, ensuring the requirement enhances safety without becoming a tool for limiting access through burdensome or biased implementation.

Proposition 007 (Grade B - Moderately Recommended)

Any access programs for natural psychedelic substances should be implemented in a way that is Maryland State revenue-neutral or Maryland State revenue-generating across all programs (i.e., losses from one or more programs may be offset by surpluses from others).

Revenue sustainability received moderate support with recognition of implementation challenges. Stakeholders noted: "Supporting this proposition sends an important message to lawmakers that it is desirable for multiple access models to co-exist and that there are likely 'positive externalities' - benefits to society - that may accrue outside of the obvious impacts to the state budget." Others emphasized: "We need to show full economic impact - like the new committee that was formed. It's not just 'dollars in', but reduction of dollars spent in other areas of healthcare and lost productivity." However, concerns were raised: "I think there may be start-up costs to developing the system that are not cost neutral or generating, and I think

making the system sustainable from day one will have a large impact on access/equity - since user fees/taxes will have to be high. I do think long term sustainability (within 3-5 years is achievable) but initially that may not be possible." Implementation should phase in revenue targets, allowing initial subsidization before transitioning to self-sustaining models while accounting for broader fiscal benefits including reduced criminal justice and healthcare costs.

Proposition 008 (Grade A - Strongly Recommended)

Maryland should clarify that lawful personal use or possession of natural psychedelic substances in and of itself is not grounds for child abuse/neglect proceedings.

This protection received strong support as essential for preventing discriminatory enforcement and family separation based solely on legal substance use. The clarification parallels existing protections for legal substances and medical cannabis use, establishing that lawful adult behavior should not automatically trigger child welfare investigations. However, implementation must carefully distinguish between possession/use and impaired caregiving or child endangerment. The protection should not prevent intervention in cases of actual neglect or abuse but prevents automatic family disruption based on legal adult behavior. Clear guidelines should distinguish between responsible adult use and situations genuinely threatening child welfare. Training for child protective services, family courts, and law enforcement will be essential to ensure proper implementation. The protection addresses legitimate concerns about prosecutorial overreach while maintaining child safety as the primary concern. This safeguard is fundamental to preventing stigma-based discrimination against lawful users and ensuring that legal psychedelic use receives the same protections as other legal substances.

Proposition 009 (Grade B - Moderately Recommended)

Maryland should protect individuals from discrimination in employment or housing based on their lawful personal use of natural psychedelic substances.

Employment and housing discrimination protections received moderate support while acknowledging implementation challenges. As one stakeholder noted: "Maryland should protect people against discrimination housing and employment that is based on prejudice, ignorance and unwarranted fear as a general matter. We already protect against employment discrimination 'because of that person's race, color, religion, sex (including pregnancy), age, national origin, marital status, sexual orientation, gender identity, genetic information, military status, or disability." However, complications exist with federal programs: "My rating is actually lower more like a 1, as many housing programs for low income individuals are subjective [sic.] to

federal laws therefore I think it would be hard to change some of the language around use for those who use housing vouchers. This would essentially make a psychedelic treatment modality unusable or very risky for someone who utilizes a housing voucher." Implementation should examine how similar protections function for medical cannabis users and apply successful approaches. The protection should cover off-duty legal use while allowing employers to maintain workplace safety standards, requiring careful balance between anti-discrimination goals and practical implementation challenges.

Proposition 010 (Grade A - Strongly Recommended)

Maryland should establish an advisory board with representatives from diverse stakeholders to monitor any permitted access model for natural psychedelic substances.

Stakeholder oversight received strong support as essential for responsive policy implementation and public accountability. The advisory board should include healthcare professionals, law enforcement, community representatives, equity advocates, religious leaders, and affected communities. Diverse representation ensures multiple perspectives inform ongoing policy refinement and prevents capture by narrow interests. As stakeholders noted, the board could "encourage Department of Health and Behavioral Health Administration planning to support the clinical services that currently serve public sector patients, to develop policy and environmental, staffing and work-flow modifications that will be needed for implementation into practice." The board should focus on "Monitoring for market monopolies" and "Establishing oversight mechanisms to prevent monopolistic practices" to ensure "affordability and access to psilocybin products for the broader community." The board-or potentially a separate council to avoid conflicts of interest-should also monitor impacts of psychedelic access on public health measures, and advise regulatory agencies of any public health oriented interventions, as done with Maryland's Cannabis Public Health Advisory Council. Regular reporting requirements ensure accountability to the legislature and public, while the board provides a mechanism for addressing implementation challenges, incorporating new research, and maintaining community input in policy evolution. Success depends on meaningful diverse representation and clear authority to influence policy direction.

Proposition 011 (Grade A - Strongly Recommended)

Maryland should establish whistleblower protections for reporting violations in any permitted psychedelic access model.

Whistleblower protections received strong support as essential for maintaining program integrity and public trust. While some questioned practical necessity, noting "I don't have any experience in whistleblower protections at the state level - it feels like bad actors can be reported regardless of whistleblower protections," others emphasized their importance: "I believe that this is essential to build public trust and to limit risk to the population." Protections should cover employees, contractors, participants, and community members reporting violations including supply diversion to illicit markets, safety violations, discriminatory practices, or regulatory non-compliance. The system should provide confidential reporting mechanisms, legal protections against retaliation, and investigative procedures for reported violations. Implementation should establish clear reporting channels, protection procedures, and enforcement mechanisms. Regular training should ensure stakeholders understand reporting procedures and protection availability. The system builds public confidence by creating accountability mechanisms and encouraging internal compliance monitoring. Success requires robust protection enforcement and visible consequences for retaliatory actions.

Proposition 012 (Grade A - Strongly Recommended)

Public education campaigns about safer use of natural psychedelic substances should be implemented in any approved psychedelic access model.

Public education received unanimous strong support as fundamental to successful implementation and harm reduction. Public education campaigns have successfully shifted public perception about many life-saving behaviors (e.g. condom use, designated drivers, etc.), pointing to the familiarity and efficacy of education-based interventions. Campaigns should provide evidence-based information about safe use practices, potential risks, drug interactions, contraindications, and when to seek help. Content must be culturally responsive, accessible across different populations, and available in multiple languages. Education should address both potential benefits and risks without promoting or discouraging use. Materials should counter misinformation while providing practical safety guidance. Distribution channels should include healthcare providers, community organizations, online platforms, and direct outreach to relevant populations. Regular updates ensure information reflects evolving research and practice. The education complements individual training requirements by creating broader community awareness and reducing stigma. Stakeholders emphasized the importance of comprehensive public education to prevent the problems seen with cannabis implementation, with "insufficient consumer education, often resulting in misuse and negative experiences for users that could have been avoided." Examples include, education through the Maryland Department of Health's "Be Cannabis Smart" campaign and psychedelic civic education such as Stanford Medicine's "SafetyFirst" campaign, or the Coalition for Psychedelic Safety and Education's "Before You Trip"

campaign. The "Before You Trip" Campaign reached 860,000 young adults, generated 5.2 million impressions, and more than doubled knowledge on safe use--a compelling indication of both the need and effectiveness of a social media education campaign. Success requires adequate funding, professional development expertise, and ongoing evaluation of campaign effectiveness and reach across diverse Maryland communities.

Proposition 013 (Grade A - Strongly Recommended)

Educational materials emphasizing harm reduction should be provided to anyone receiving natural psychedelic substances through any approved access model at the time substances are received.

Point-of-access education received strong support as a final safety checkpoint ensuring all users receive current harm reduction information. Materials should cover immediate safety concerns including dosing guidelines, contraindications, drug interactions, set and setting considerations, and emergency procedures. Content should be concise, practical, and actionable rather than a comprehensive curriculum. Multiple formats should accommodate different learning preferences and literacy levels. Regular updates ensure materials reflect current evidence and emerging safety concerns. Distribution systems should track provision to ensure universal coverage and compliance monitoring. Integration with broader education requirements creates layered safety approaches combining general knowledge with immediate practical guidance. The requirement acknowledges that even educated users benefit from current safety reminders and ensures consistent minimum safety information across all access pathways. Implementation success requires standardized materials, provider training, and compliance monitoring systems that verify all users receive appropriate materials without creating burdensome paperwork that impedes access.

Proposition 014 (Grade A - Strongly Recommended)

A comprehensive data collection and monitoring system should be established to track costs; revenues; prevalence, frequency, quantity, and mode of use; safety; efficacy; equity impact; and other outcomes across all approved models.

Comprehensive monitoring received unanimous support as essential for evidence-based policy refinement and public accountability. The system should track multiple outcome measures including public health impacts, economic effects, utilization patterns, safety events, and equity indicators. Data collection must balance comprehensive monitoring with privacy protection and should be integrated across all access models for complete assessment. Regular analysis and reporting ensure policymakers, providers, and the public have current information about

program performance. The monitoring system should identify emerging trends, safety concerns, and implementation challenges requiring policy response. Integration with national databases could provide broader context and comparative analysis. The system provides the foundation for evidence-based policy evolution and demonstrates Maryland's commitment to responsible implementation. Success requires adequate funding, technical infrastructure, standardized data collection protocols, and qualified analytical staff capable of producing meaningful reports that inform policy decisions and public understanding of program outcomes.

Proposition 015 (Grade A - Strongly Recommended)

Any statewide monitoring system should exclude personally identifiable information about consumers of natural psychedelic substances.

Privacy protection received unanimous support as fundamental to monitoring system design and public trust. De-identification protects individual privacy while enabling population-level analysis and policy evaluation. Technical safeguards should prevent re-identification while preserving analytical utility. Clear data governance policies should specify access controls, use limitations, and security requirements. Regular audits should ensure compliance with privacy protections and identify potential vulnerabilities. The protection encourages participation and reporting by reducing privacy concerns that might otherwise limit data quality. Implementation requires technical expertise in privacy-preserving data analysis and robust cybersecurity measures. Legal frameworks should specify penalties for unauthorized access or misuse. The approach balances public health monitoring needs with individual privacy rights, building trust essential for successful program implementation and community acceptance. Given the stigma and legal complexities surrounding psychedelic use, strong privacy protections are essential for encouraging honest reporting and participation in monitoring efforts.

Proposition 016 (Grade A - Strongly Recommended)

De-identified data from the statewide data collection and monitoring system for natural psychedelic substances should be made readily available to the public.

Public data access received strong support as essential for transparency, accountability, and research advancement. Open data policies should provide regular public reporting with analysis of trends, outcomes, and policy impacts. Data formats should be accessible to researchers, policymakers, and community organizations for independent analysis. Regular reporting schedules ensure consistent public information flow and timely identification of emerging issues. Technical infrastructure should support data access while maintaining privacy protections and

preventing system abuse. Documentation should explain methodologies, limitations, and appropriate interpretation guidelines. Public access promotes accountability by enabling independent verification of official reports and analysis. The transparency builds public trust and supports evidence-based policy discourse. Access should be user-friendly with clear interfaces and adequate technical support. Success requires balancing open access with data security, providing meaningful data while protecting privacy and preventing misuse. Notable examples of publicly accessible outlets for statewide data include the Maryland Cannabis Administration Medical and Adult-Use Cannabis Data Dashboard, and the Oregon Psilocybin Services Data Dashboard . The public availability of data enables independent research, policy analysis, and community oversight essential for maintaining program accountability and continuous improvement.

Proposition 017 (Grade A - Strongly Recommended)

Environmental sustainability requirements should be established for cultivation and production of natural psychedelic substances.

Environmental protections received strong support recognizing cultivation impacts and Maryland's environmental commitments. Requirements should address energy use, water consumption, waste management, pesticide use, and ecosystem protection. Standards should promote sustainable cultivation practices including organic methods, renewable energy use, and waste reduction. Implementation should learn from cannabis industry environmental challenges and best practices. Requirements might include environmental impact assessments, sustainability reporting, and incentives for exceeding minimum standards. Enforcement mechanisms should include compliance monitoring and penalties for violations. The approach balances environmental protection with industry viability through reasonable standards and technical assistance. Given Maryland's environmental priorities and the potential scale of psychedelic cultivation, establishing sustainability requirements from the beginning prevents environmental degradation and promotes responsible industry development. Stakeholders differentiated between cultivation of cannabis versus psilocybin mushrooms, with the latter having more variability among strains and species, and being subject to distinct pathogens, pests, and contaminants-all of which impact potency, palatability, safety, and other traits. One stakeholder raised the consideration of establishing a breeding license-which does not exist in the cannabis industry-within the natural psychedelic industry, to support development of new genetics (GMO), pest resistance, and potency. Others countered with concerns about gamification, as seen within the cannabis industry's race to escalate THC content, preferring to restrict cultivation to specific and unmodified species. Success requires clear regulatory

frameworks, industry guidance, ongoing monitoring of environmental impacts and compliance rates, and coordination with existing environmental protection agencies and regulations.

Proposition 018 (Grade A - Strongly Recommended)

Maryland should take measures to ensure diverse participation in psychedelic industries and services (e.g., prioritizing applicants representing groups disproportionately impacted by drug policies enacted from 1973 to 2023).

Equity measures received strong support acknowledging historical drug policy harms and the need for restorative justice. Diversity should be defined to include race, religion, ability, education, economic resources, geographic location, etc., as many intersecting demographic factors may impact one's participation in industry or access to health care. Programs should prioritize licensing for individuals and communities disproportionately affected by prohibition enforcement. Measures might include application fee waivers, technical assistance, mentorship programs, and preferential licensing. Some stakeholders suggested: "a merit-based application process, similar to the initial medical cannabis licensing round in 2016-2017, would be most effective for ensuring safety and capable handling in psychedelic operations." Stakeholders also expressed shortcomings within the cannabis industry, which witnessed the acceleration of licenses granted to large multi-state operators (MSOs), often sidelining local, Maryland-based applicants and stifling local entrepreneurship." Community reinvestment should direct program revenues toward affected communities through education, healthcare, or economic development. Implementation requires careful definition of eligible populations and effective outreach to ensure broad participation. Success depends on adequate funding for equity programs and meaningful preferences that create real opportunities rather than token gestures. Regular monitoring should track diversity outcomes and program effectiveness. The approach recognizes that equitable implementation requires proactive measures beyond non-discrimination policies. Community engagement ensures equity programs address actual needs and priorities of affected populations. Given the documented disparities in drug law enforcement, equity provisions are essential for ensuring that the benefits of legalization reach communities most harmed by prohibition.

Proposition 019 (Grade A - Strongly Recommended)

Maryland should offer a low-cost online training option that satisfies requirements for any access program that mandates training for providers, facilitators, users, or any other participants.

Accessible training received unanimous support as essential for removing economic barriers to participation. State-provided options should meet all program training requirements while remaining affordable or free. Online delivery increases accessibility across geographic and scheduling constraints. Existing infrastructure, such as the University of Maryland or Maryland OneStop portal may be leveraged. Content quality should match expensive private alternatives while maintaining lower costs through state support. Multiple language options and accessibility accommodations ensure broad usability. Regular updates should incorporate new research and best practices. The approach prevents training requirements from becoming exclusionary barriers that favor wealthy participants. Implementation requires adequate initial investment and ongoing maintenance funding. Success depends on user-friendly technology, quality content development, and technical support systems. The training option supports both equity goals and program quality by ensuring universal access to high-quality education. Given stakeholder concerns about economic accessibility - as one noted: "Natural psychedelics must be available to everyone, not just people of means" - providing affordable training options is essential for equitable implementation.

Proposition 020 (Grade A - Strongly Recommended)

Maryland should implement a regular policy review process (e.g., annually) to adapt regulations for natural psychedelic substances based on emerging evidence.

Regular policy review received strong support recognizing the need for responsive policy adaptation in a rapidly evolving field. Annual reviews should examine emerging research, implementation outcomes, stakeholder feedback, and developments in other jurisdictions. Review processes should include diverse stakeholder input and transparent public participation. Adaptation mechanisms should allow timely policy updates without requiring full legislative processes for minor adjustments. Reviews should consider both expanding and restricting policies based on evidence rather than assuming unidirectional change. Implementation requires adequate staffing, technical expertise, and structured review procedures. Success depends on maintaining flexibility while ensuring appropriate deliberation and stakeholder input. The process demonstrates Maryland's commitment to evidence-based policy and responsiveness to changing conditions and knowledge. Given the rapid pace of psychedelic research and policy development nationwide, regular review ensures Maryland's policies remain current with best practices and emerging evidence while maintaining stability for program participants and providers.

Proposition 021 (Grade C - Conditionally Recommended)

All new psychedelic access programs should include a sunset provision requiring reauthorization after a specified period (e.g., 5 years) based on evidence of safety, efficacy, and equity impacts.

Sunset provisions received conditional support requiring careful design to avoid program instability while ensuring accountability. Stakeholders expressed mixed views: "I think sunset provisions do not make sense in this setting since we want to create a policy environment for private actors to participate (cultivators, facilitators, education institutions). Without certainty that a market will exist I don't believe people will invest and participate." Another noted: "A sunset clause seems drastic. It may make more sense to recommend a review period of five years to fine-tune regulations, but if changes need to be made to models of access, new legislation can be introduced." Implementation conditions should include: clear evaluation criteria focusing on objective outcomes rather than subjective preferences; adequate time periods allowing meaningful program development and assessment; streamlined reauthorization processes for successful programs; and protection mechanisms preventing arbitrary program termination. Five-year cycles may provide sufficient time for initial implementation and outcome assessment while maintaining accountability pressure. Evaluation criteria should emphasize safety, public health impacts, equity outcomes, and fiscal performance rather than ideological preferences. Success requires clear evaluation frameworks, adequate funding for assessment activities, and political commitment to evidence-based reauthorization decisions.

Proposition 022 (Grade I - Insufficient)

Local jurisdictions should be allowed to opt out of access models for natural psychedelic substances.

This proposition received insufficient consensus, reflecting deep tensions between local control and statewide policy coherence. Supporters emphasized local democratic control and community values, arguing that municipalities should have autonomy over policies affecting their residents. However, opponents worried about creating patchwork systems that could limit access and complicate implementation across Maryland. One stakeholder compared approaches applied in other jurisdictions: "Oregon's measure allowed for this, which resulted in 27 of Oregon's 36 counties, as well as 115 towns, voting on whether to allow psilocybin access at the local level in the 2022 election... Colorado's psilocybin measure did not allow individual jurisdictions to opt out entirely. Colorado requires healing centers be at least 1,000 feet from schools and childcare centers and allows local jurisdictions to regulate the "time, place, and manner" of how natural psychedelic businesses operate." Opt-out provisions might create

geographic inequities where access depends on zip code rather than individual need, potentially undermining program viability if major jurisdictions withdraw. Such fragmentation could also increase costs and administrative complexity for state agencies managing multiple regulatory schemes. Conversely, forced implementation in unwilling communities might generate political backlash and enforcement problems. The insufficient grade suggests this issue requires additional consideration of alternative approaches such as local input in implementation details rather than complete opt-out authority. Other options might include graduated local control, requirements for public processes before opt-out decisions, or sunset provisions on local opt-outs. Resolution requires balancing local autonomy with program coherence and equitable access across Maryland communities.

Proposition 023 (Grade S - Needs Further Study)

Consumption of natural psychedelic substances should be allowed in approved sites (e.g., an outdoor music venue with an appropriate permit, other sites specified by access models), but not in public spaces.

This proposition received consensus around desirability, but not feasibility. The "Needs Further Study" grade signals that additional study is required to develop appropriate frameworks balancing public safety with practical access needs. The distinction between "approved sites" and "public spaces" needs clarification, as does the approval process for consumption venues. Potential approved sites might include licensed facilities, private residences, religious institutions, or specially permitted venues for events or retreats. Public space restrictions should consider safety concerns, community impact, and enforcement practicality while avoiding overly restrictive policies that drive use underground. Implementation challenges include defining regulatory categories, establishing approval criteria for consumption sites, and creating enforcement mechanisms that distinguish between appropriate and inappropriate venues. The framework should accommodate diverse use contexts including medical, spiritual, recreational, and therapeutic applications while maintaining community safety and acceptance. Study should examine approaches in other jurisdictions, stakeholder input on appropriate venues and restrictions, and law enforcement perspectives on implementation feasibility. Success requires balancing individual autonomy, public safety, community acceptance, and practical enforcement considerations.

Deprioritization Propositions (024-033)

Proposition 024 (Grade A - Strongly Recommended)

Arrests for simple possession (no intent to sell, no property damage, etc.) should be the lowest law enforcement priority.

This foundational deprioritization policy proposition received strong support as an essential first step toward reducing criminalization harms while maintaining public safety focus on serious crimes. The recommendation establishes clear guidance for law enforcement resource allocation, directing attention away from low-level possession toward trafficking, violence, and other public safety priorities. Simple possession cases often involve individuals who would benefit more from health interventions than criminal sanctions. Deprioritization reduces incarceration costs, criminal justice system burden, and collateral consequences for individuals while preserving law enforcement discretion for cases involving genuine public safety concerns. Implementation requires clear definitions of "simple possession" versus distribution or trafficking, training for law enforcement on new priorities, and monitoring systems to ensure consistent application across different communities. The policy should include exceptions for cases involving minors, impaired driving, or other aggravating circumstances. Success depends on comprehensive law enforcement training, clear policy guidance, and regular evaluation of implementation outcomes.

Proposition 025 (Grade I - Insufficient)

Maryland should establish clear quantity thresholds defining personal use amounts of natural psychedelic substances.

This proposition received insufficient consensus despite widespread recognition of the need to accurately distinguish between personal use from potential distribution. One stakeholder asserted: "In current drug law, this is called 'possession with the intent to distribute (PWID).' Typically this offense is a felony punished very harshly – at the same level as distribution... The establishment of maximum possession amounts provides law enforcement with an evidentiary shortcut to establishing a felony-level offense with a legal presumption of an intent to illicitly distribute based only on quantity. Indeed, even in the complete absence of any evidence of illicit distribution, the mere possession of the excess quantity allows for the inference or presumption of intent to distribute to attach. In the absence of evidence of distribution, this presumption is a shortcut that offends the principle of proof beyond a reasonable doubt. Because the punishment for felony drug distribution is so severe, once the possession quantity is exceeded, it creates

enormous pressure on the possessor to plead guilty to a felony in exchange for a less than maximum sentence. Creating unwarranted pressure to plead guilty undermines competent and thorough law enforcement." Even among supporters of quantity thresholds, disagreement reflected technical challenges in establishing appropriate quantities across different substances and preparation methods. Psilocybin mushrooms, for example, vary significantly in potency by species and growing conditions, complicating simple weight-based thresholds. Fresh versus dried preparations create additional complexity. Stakeholders disagreed on whether thresholds should be conservative to minimize diversion risk or generous to avoid criminalizing legitimate personal use including storage for multiple sessions. Implementation challenges include scientific basis for threshold determination, consideration of different consumption patterns (microdosing versus full doses), and enforcement practicality. Resolution requires expert consultation on appropriate quantities, consideration of approaches in other jurisdictions, and stakeholder input on balancing access with diversion prevention. Clear thresholds are ultimately necessary for effective deprioritization implementation, requiring additional work to achieve consensus on specific amounts.

Proposition 026 (Grade B - Moderately Recommended)

Maryland should establish harm reduction services for natural psychedelic substances (e.g., designated safe spaces for use of natural psychedelic substances, psychedelic first aid, and access to home test kits for purity and potency, hotlines/websites for adverse events and abuse).

Harm reduction services received moderate support as valuable public health interventions that reduce risks associated with psychedelic use regardless of legal status. Services should include drug checking programs to identify adulterants and verify potency, crisis intervention services for adverse experiences, safe use education, and integration support resources. Testing services are particularly important given variability in natural psychedelic potency and potential contamination risks. Crisis hotlines and trained responders can provide immediate support for difficult experiences, reducing emergency room visits and improving outcomes. Notable examples of hotlines include the Fireside Project's Psychedelic Peer Support Line, or those in place for alcohol and tobacco. Safe spaces might include supervised consumption sites or peer support venues where individuals can use substances in supportive environments. Implementation requires training programs for harm reduction workers, funding for testing equipment and facilities, and coordination with healthcare systems for severe adverse events. Success depends on accessibility across Maryland communities, adequate funding, trained staff, and integration with existing substance abuse treatment and mental health services. The approach acknowledges that some use will occur regardless of legal status and focuses on minimizing associated harms.

Proposition 027 (Grade A - Strongly Recommended)

Arrests for personal cultivation (as defined by production limits, grow space limits, quantity limits, etc.) should be the lowest law enforcement priority.

Personal cultivation deprioritization received strong support as logical extension of possession deprioritization that recognizes individual autonomy and reduces criminalization of non-commercial activity. Home cultivation for personal use avoids many risks associated with illicit markets including adulteration, unpredictable potency, and supporting criminal organizations. The recommendation requires clear limits on cultivation scale to distinguish personal from commercial production, including plant/fungi counts and growing space restrictions. Implementation should establish reasonable cultivation limits that accommodate legitimate personal use including storage for extended periods. Enforcement should focus on commercial-scale operations while deprioritizing small personal grows. Training for law enforcement should include recognition of personal versus commercial cultivation indicators. The policy should address security requirements to prevent theft and diversion while avoiding burdensome regulations that discourage compliance. Success requires clear regulatory guidelines, law enforcement training, and monitoring to ensure consistent implementation across jurisdictions while preventing diversion to illicit markets.

Proposition 028 (Grade A - Strongly Recommended)

Law enforcement officers should receive specific training on deprioritization policies for natural psychedelic substances.

Training received strong support as essential for effective and consistent policy implementation across Maryland law enforcement agencies. Despite some stakeholder concern that "any additional law enforcement training may be difficult to justify," comprehensive training ensures officers understand new priorities, legal requirements, and appropriate responses to psychedelic-related encounters. Training should cover legal framework changes, identification of personal versus commercial quantities, differentiation between deprioritized offenses (e.g. simple possession) versus other illegal activity, crisis intervention techniques for individuals experiencing adverse effects, and referral pathways to health and social services. Content should emphasize public safety focus while reducing unnecessary criminalization and should address officer safety considerations and de-escalation techniques. Training should be mandatory for all officers with regular refresher sessions as policies evolve. Implementation requires collaboration between state training academies, local departments, and subject matter experts. Evaluation should track training completion rates, policy compliance, and outcomes including arrest

patterns and officer confidence. Success depends on adequate funding, quality curriculum development, and ongoing support for departments implementing new approaches.

Proposition 029 (Grade B - Moderately Recommended)

Law enforcement should update DUI protocols with available testing methods for psychedelic impairment.

DUI protocol updates received moderate support while acknowledging significant technical and implementation challenges. One stakeholder noted: "A DUI prosecution and conviction can be devastating to the defendant. I am not sure what kinds of objective tools are available to accurately measure impairment. It is important that this be done, but I don't know that the science and engineering capacity is up to the task of creating tools to objectively measure impairment due to psychedelic ingestion." Another emphasized contextual considerations: "If used strictly in a medical setting, this might be excessive. If used more broadly, this is essential." Current testing technology for psychedelic impairment lags behind that available for alcohol or other substances, raising concerns about false positives and prosecution of individuals who are not actually impaired. Implementation requires development of scientifically valid testing methods, training for officers on impairment recognition, and legal frameworks that account for testing limitations. Protocols should emphasize behavioral indicators of impairment rather than relying solely on chemical tests. Success depends on technological advancement, scientific validation of testing methods, and careful legal framework development that protects against wrongful prosecution while maintaining road safety.

Proposition 030 (Grade A - Strongly Recommended)

If deprioritization of natural psychedelic substances is enacted, public education campaigns should clarify that deprioritization does not equal legalization.

Public education received strong support as essential for preventing misunderstanding about policy changes and their implications. Deprioritization policies create nuanced legal situations where substances remain illegal but enforcement priorities change, potentially confusing the public about what behaviors are actually permitted, as seen in other jurisdictions. Several stakeholders raised the consideration of expanding the scope of this policy proposition: "I think it would be worthwhile, whatever model we end up choosing, to expand this wider to be able to explain to people what is legal and what is not." Education campaigns should clearly explain the differences between deprioritization and legalization, emphasizing that substances remain controlled and that certain activities may still result in arrest. Materials should address workplace

policies, federal law implications, driving restrictions, and potential consequences for violations. Education should target multiple audiences including potential users, employers, parents, and community organizations. Campaigns should emphasize continued risks and safety considerations while explaining reduced enforcement priorities. Implementation requires coordinated messaging across state agencies, collaboration with media outlets, and culturally appropriate materials for diverse communities. Success depends on clear, consistent messaging that reduces confusion while providing accurate information about legal status and potential consequences. The education helps ensure policy implementation proceeds smoothly without creating false expectations about complete legalization.

Proposition 031 (Grade A - Strongly Recommended)

Penalties for simple possession and personal cultivation of natural psychedelic substances should be reduced to civil infractions rather than criminal charges.

Civil infraction penalties received strong support as an important step toward reducing criminalization while maintaining a legal framework for regulation. Converting criminal penalties to civil infractions eliminates incarceration risk, reduces criminal justice system burden, and avoids creating criminal records that impact employment, housing, and other opportunities. Civil penalties can include fines, required education, or community service while maintaining a legal framework for addressing violations. Implementation should establish reasonable fine levels that are not punitive while providing compliance incentives. Procedures should include appeal processes and ability to perform community service instead of paying fines to avoid creating financial barriers for low-income individuals. The approach maintains legal status as controlled substances while reducing enforcement harshness and social consequences. Success requires clear enforcement guidelines, training for law enforcement and court personnel, and monitoring to ensure consistent implementation. The policy represents a middle ground between full criminalization and complete legalization that may be more politically feasible while achieving primary harm reduction goals.

Proposition 032 (Grade A - Strongly Recommended)

Penalties for possession and personal cultivation of "personal use" amounts of natural psychedelic substances should include protection from asset forfeiture.

Asset forfeiture protections received strong support as essential safeguards against disproportionate enforcement consequences that can devastate individuals and families. Civil asset forfeiture allows seizure of property allegedly connected to drug crimes even without

criminal convictions, creating potential for abuse and disproportionate punishment for minor offenses. Protecting personal use amounts from forfeiture ensures penalties remain proportionate to the offense severity and prevents loss of homes, vehicles, or other essential property for minor violations. Implementation should clearly define personal use quantities eligible for protection and establish procedures for challenging any attempted forfeitures. Protections should extend to related property like cultivation equipment for personal use. The policy recognizes that asset forfeiture is designed to combat major trafficking operations rather than personal use and prevents enforcement overreach that could cause more harm than the underlying violation. Success requires clear legal frameworks, training for law enforcement on forfeiture limitations, and mechanisms for individuals to recover improperly seized property.

Proposition 033 (Grade A - Strongly Recommended)

Convictions under current Maryland law for only simple possession of natural psychedelic substances should be expunged.

Expungement received strong support as an essential restorative justice measure addressing past enforcement harms and removing barriers to opportunity. Criminal records for simple possession create lasting consequences including employment discrimination, housing denial, educational barriers, and other collateral consequences that often exceed the severity of the original offense. As one stakeholder noted: "Expungement of previous criminal convictions and charges is important to me. Non violent offenses like this are a barrier to employment." Automatic and retroactive expungement for simple possession ensures individuals benefit from policy changes without requiring individual petitions that may be burdensome or inaccessible. One notable example of such expungement is Maryland's Expungement Reform Act (SB 432) of 2025. Implementation should include convictions from all Maryland courts and establish streamlined processes for record clearing. The policy should address both convictions and arrests that did not result in conviction. Success requires coordination between courts, law enforcement agencies, and background check systems to ensure complete record clearing. Regular monitoring should verify that expunged records do not appear in background checks and that individuals receive full benefits of record clearing.

Non-Commercial Peer Sharing Propositions (034-040)

Proposition 034 (Grade B - Moderately Recommended)

Qualified adults should be allowed to cultivate and gift small, specified quantities of natural psychedelic substances to other qualified adults without financial compensation, non-financial compensation, or bartering.

Peer sharing received moderate support while acknowledging significant implementation challenges based on experiences in other jurisdictions. One stakeholder warned: "'Grow and give' is allowed in Colorado, but commercial sales is not. The spirit of the law is meant to prevent businesses from providing natural psychedelic substances and related services in an unregulated market. Nonetheless, businesses are currently exploiting loopholes in Colorado law in order to operate much like cannabis dispensaries, by charging 'consulting fees' in lieu of sales." They emphasized that "based on the early experience in Colorado, we can expect that implementation of non-commercial peer sharing instead of commercial sales will result in profit motivated individuals exploiting any available loopholes, without the public benefiting from enhanced safety offered by commercial sales." Other stakeholders compared peer sharing with other access models: "Having commercial sales is an important buffer if you want to have both a medical market and a home grow to provide a safer viable alternative to an unregulated market." Implementation requires careful legal drafting to prevent commercial exploitation while preserving genuine peer sharing, clear quantity limits, and robust enforcement mechanisms.

Proposition 035 (Grade A - Strongly Recommended)

Sharing of cultivation knowledge and techniques for natural psychedelic substances to groups or individuals eligible to participate in peer sharing should be explicitly protected from state prosecution.

Knowledge sharing protections received strong support as essential for safe cultivation practices and harm reduction. Educational information about cultivation techniques, safety practices, contamination prevention, and quality assessment helps ensure safer production and reduces risks associated with inexperience or misinformation. Protecting cultivation education prevents prosecuting individuals for sharing safety information that benefits public health. The protection should cover written materials, online resources, workshop instruction, and peer-to-peer education among qualified individuals. Implementation should clearly distinguish between educational activities and commercial promotion or facilitation of illegal activity. Protections should extend to harm reduction organizations, researchers, and individuals sharing safety information. Success requires clear legal frameworks that protect legitimate education while

preventing exploitation for commercial purposes. The approach recognizes that education about safe practices serves public health interests regardless of legal status and that criminalizing information sharing drives practices underground where they may be less safe.

Proposition 036 (Grade I - Insufficient)

Peer sharing should be allowed only for specific species of natural psychedelic substances (e.g., Psilocybe cubensis), not broad categories (e.g., psilocybin-producing mushrooms).

Species restrictions received insufficient consensus despite recognition of significant potency variations among different psilocybin-containing species. One stakeholder explained: "Individual strains of psilocybin mushroom vary by potency from 4mg psilocybin per gram of dry mushroom, to well over 20mg per gram. By limiting access to certain species and strains, and providing a registration process for additional species and strains, consumers will be better able to predict the strength of the products they are ingesting, which can prevent many adverse experiences associated with psychedelic use." The Task Force noted that "the concentration of different strains of psilocybin mushroom can vary by like a couple of orders of magnitude" and "it might not be sufficient to sort of say, you can have psychedelic mushrooms. We may want to be very specific about saying certain species are allowed." However, others argued: "I cannot see what the benefit of this proposal would be. It seems like it is a limitation without a reason" and "This distinction sounds extremely hard to enforce." The insufficient grade reflects tension between safety benefits of predictable potency and enforcement challenges of species-specific restrictions.

Proposition 037 (Grade I - Insufficient)

Non-commercial cultivation and sharing of natural psychedelic substances should be limited to members of community-based organizations (e.g., member owned co-operatives) licensed by the state.

Community-based organization limitations received insufficient consensus, reflecting uncertainty about this novel regulatory approach and its practical implications. One supporter referenced international models: "In Spain and Belgium, cannabis social clubs operate as non-profit cooperatives where adult members collectively grow and distribute cannabis for personal use. These clubs are self-regulated, with membership limits, internal rules, and closed-loop distribution to prevent diversion to the broader market." However, critics argued: "These recommendations unnecessarily limit an individual's ability to share a small amount of psychedelics with other members of their community. This restriction will likely have the unintended consequence of people continuing to access underground markets rather than being

able to share substances with an individual they trust. This is because there will likely be only a limited number of CBOs throughout the state with the proper documentation permitting them to cultivate and/or share." The insufficient grade indicates the need for further study of community-based organization models before implementation.

Proposition 038 (Grade C - Conditionally Recommended)

Peer sharing by community-based organizations should require documentation of the provenance and purity of natural psychedelic substances.

Documentation requirements received conditional support contingent on practical implementation that avoids excessive bureaucracy while enhancing safety. One stakeholder noted: "The costs may be prohibitive. Also if it is psilocybin mushrooms, they are relatively easy to cultivate and there is less concern about soil condition compared to plants cultivated in the group. While there is a chance that some may want to pick wild mushrooms and there is change of contamination (e.g. fecal matter) and misidentification, I think a better strategy is to require cultivation and forbid wild harvesting for sharing." However, others emphasized environmental and safety considerations: "I think this is essential to protect indigenous communities and their natural environments. I think it should be woven into provisions that protect the environment and indigenous populations." Implementation conditions should include: reasonable documentation standards that don't create excessive paperwork; focus on source verification rather than comprehensive testing for small-scale sharing; cost-effective testing options available through state-licensed facilities; clear guidelines on what documentation is required; and appeals processes for organizations unable to meet requirements. The requirement should balance safety benefits with accessibility, ensuring documentation enhances rather than impedes legitimate peer sharing. Success depends on developing practical standards that improve safety without creating barriers that drive activity underground or make participation prohibitively expensive for community organizations.

Proposition 039 (Grade B - Moderately Recommended)

Community-based organizations facilitating peer sharing of natural psychedelic substances should be granted limited liability protections.

Limited liability protections received moderate support while acknowledging significant implementation concerns and the need for careful balance between protection and accountability. One stakeholder emphasized conditional support: "I think limited liability is OK if we set a regulator framework for them to operate within. If the CBOs want to operate on their

own with state regulation (which I imagine some would prefer) I don't think we should extend limited liability." Others raised fundamental concerns: "I am concerned about the fact that without liability there may be little incentive for being careful" and "Why should ANYONE not have liability if they act negligently or recklessly or intentionally in ways that injure people?" Supporters noted the value of community-based psychedelic experiences: "I think that there is value in some psychedelic retreats, which are not always religious-based, that are community-based." Implementation should establish clear standards for liability protection including mandatory safety protocols, insurance requirements, compliance with state regulations, and exceptions for negligent or reckless conduct. Protections should encourage responsible community-based organizations while maintaining accountability for participant safety.

Proposition 040 (Grade S - Needs Further Study)

Any individuals or entities engaging in peer sharing natural psychedelic substances should be prohibited from making therapeutic or health claims.

Health claims restrictions received consensus around desirability, but not feasibility. The "Needs Further Study" grade signals that additional study is required to balance consumer protection with free speech rights and practical enforcement challenges. Stakeholders noted: "Supporting this proposition signals that lawmakers should specifically protect consumers of natural psychedelic substances from unscrupulous providers who might otherwise use unfounded and exploitative messages to market psychedelic products. This proposition does not limit anyone from discussing scientific findings, where they exist. Also, this proposition does not limit the exercise of free speech, in the same way that the First Amendment does not allow someone to yell 'Fire!' in a crowded theater." However, others emphasized First Amendment concerns: "They have a First Amendment right to share their thoughts based on research or anecdotal experiences. They are sharing, not engaged in commerce." Implementation challenges include distinguishing between prohibited health claims and permitted sharing of experiences or research information, enforcement mechanisms for non-commercial contexts, and coordination with FDA regulations on health claims. Study should examine approaches used for dietary supplements and other regulated products, stakeholder input on appropriate boundaries, and legal analysis of First Amendment implications for restricting speech in non-commercial peer sharing contexts.

Commercial Sales Propositions (041-053)

Proposition 041 (Grade A - Strongly Recommended)

Maryland should establish a regulated market for commercial sales of natural psychedelic substances.

Commercial sales regulation received strong support as providing the most comprehensive framework for quality control, safety oversight, and consumer protection. A regulated market enables systematic product testing, standardized packaging and labeling, licensed provider training, and comprehensive monitoring of use patterns and outcomes. Commercial regulation can generate state revenue through licensing fees and taxes while creating legal employment opportunities and legitimate business development. The framework allows implementation of robust safety measures including mandatory testing, product recalls when necessary, and professional oversight of the entire supply chain. Implementation requires comprehensive regulatory structure encompassing licensing procedures, facility standards, product requirements, testing protocols, taxation systems, and enforcement mechanisms. Success depends on learning from cannabis regulatory experiences while adapting to unique characteristics of psychedelic substances. A regulated market provides the foundation for ensuring product quality, preventing diversion, tracking use patterns, and maintaining public safety while serving legitimate consumer demand through legal channels rather than illicit markets.

Proposition 042 (Grade I - Insufficient)

Commercial sales of natural psychedelic substances should be allowed exclusively in person at state-owned outlets (e.g., a "state monopoly" like Alcohol Beverage Services in Montgomery County).

State monopoly distribution received insufficient consensus, reflecting disagreement about the optimal balance between state control and private enterprise. Stakeholders expressed mixed views on feasibility and desirability of state-operated retail systems. State monopolies can provide maximum government oversight and revenue capture while eliminating private profit motives that might encourage inappropriate marketing or sales practices. However, state operation may be less efficient than private enterprise and could face political opposition from businesses seeking participation in the regulated market. State monopolies might also limit accessibility by reducing the number of retail locations and limiting operating hours compared to private dispensaries. Implementation challenges include startup costs for state facilities, hiring and training state employees, inventory management systems, and ongoing operational oversight. The insufficient grade suggests the need for additional analysis comparing state

versus private retail models, examination of outcomes in jurisdictions using different approaches, and consideration of hybrid models that might combine state oversight with private operation.

Proposition 043 (Grade A - Strongly Recommended)

Commercial sales of natural psychedelic substances should be allowed exclusively via state-licensed dispensaries.

State-licensed dispensaries received strong support as the preferred commercial distribution model, building on Maryland's experience with cannabis dispensaries and providing comprehensive regulatory oversight. Licensed dispensaries enable standardized safety protocols, product quality assurance, trained staff, and consistent consumer protection measures. The model allows state oversight of retail operations while utilizing private sector efficiency and expertise. Licensed dispensaries can implement age verification systems, product tracking from cultivation to sale, and consumer education programs. Implementation requires comprehensive licensing procedures including background checks, financial requirements, facility standards, staff training mandates, and ongoing compliance monitoring. Dispensaries should be required to maintain detailed transaction records, implement robust security measures, and follow standardized operating procedures. The model provides foundation for tax collection, regulatory compliance, and consumer protection while creating legitimate business opportunities. One stakeholder raised considerations from prior industry rollout: "To safeguard early investments and encourage responsible growth, we recommend a limited number of initial licenses (10-20)...Establishing caps on licensing ensures that the market does not become oversaturated prematurely, allowing for measured growth responsive to demand and performance metrics...A strategic plan will facilitate gradual license expansions contingent upon market performance evaluations and community needs assessments." Success depends on reasonable licensing requirements that encourage participation while maintaining appropriate oversight, learning from cannabis implementation experiences, and ensuring geographic distribution provides reasonable access across Maryland communities.

Proposition 044 (Grade A - Strongly Recommended)

Commercial sales should be allowed only for natural psychedelic substances cultivated by state-licensed commercial growers.

Licensed cultivation requirements received strong support as essential for ensuring product quality, safety, and supply chain integrity. State licensing enables oversight of cultivation

practices, product testing, contamination prevention, and compliance with environmental and safety standards. Licensed growers must meet facility requirements, implement quality control measures, maintain detailed production records, and submit to regular inspections. One stakeholder noted: "I am particularly worried about psychedelics being treated like cannabis where the intensity is amped up by the growers to make the effects way too intense." This concern emphasizes the need for cultivation standards that prioritize safety and consistency over maximum potency. Implementation requires comprehensive cultivation licensing including facility inspections, growing practice standards, testing requirements, security measures, and environmental compliance. Licensed growers should be required to track products from cultivation through distribution, implement contamination prevention protocols, and maintain standardized growing practices. The system provides a foundation for quality assurance, consumer protection, and regulatory compliance while preventing contaminated or adulterated products from reaching consumers.

Proposition 045 (Grade A - Strongly Recommended)

Commercial sales should be allowed only to eligible adult Maryland residents who maintain an active license to use natural psychedelic substances.

Purchase licensing requirements received strong support as a mechanism for ensuring informed use and regulatory compliance. One stakeholder noted: "Commercial sellers are going to be regulated regarding supply, who they can sell to, as well as avoiding selling to people who are not eligible. I think a license of some kind allows the supply chain to be monitored especially in the case of adverse outcomes." However, concerns about access barriers were raised: "I am uncomfortable with this. I believe a license for use, which will invariably involve a fee, is a barrier to access. It is unfair and elitist." One stakeholder raised the consideration of removing the residency requirement, allowing all eligible adults to seek participation in the commercial market. Implementation should ensure licensing requirements enhance safety without creating insurmountable barriers through affordable fees, accessible application processes, and reasonable qualification criteria and/or minimal exclusionary criteria. The licensing system should coordinate with broader permitting requirements (Proposition 004 - Grade A) and screening provisions (Proposition 005 - Grade C) to create a coherent regulatory framework. Success requires balancing consumer protection with accessibility, ensuring fees don't exclude low-income individuals, and providing clear application procedures. The system enables tracking use patterns, ensuring consumer education, and maintaining compliance with safety requirements while serving legitimate demand through regulated channels.

Proposition 046 (Grade A - Strongly Recommended)

All commercially sold natural psychedelic substances should undergo mandatory testing at state-licensed laboratories.

Mandatory testing received strong support as a fundamental consumer protection measure ensuring product safety, potency accuracy, and contamination prevention. Testing should include potency verification, contamination screening for pesticides and heavy metals, microbiological testing for harmful bacteria and fungi, and adulterant detection. State-licensed laboratories ensure testing quality, standardization, and independence from commercial interests. Implementation requires laboratory licensing standards, testing protocol development, quality assurance procedures, and result reporting requirements. Testing should be required before products reach retail markets with clear labeling of results including potency levels and safety certifications. Failed products should be removed from distribution with mandatory reporting of safety issues. The system prevents consumers from unknowingly purchasing contaminated or mislabeled products while providing valuable data on product quality trends. Stakeholders noted lessons to improve upon cannabis implementation: "The cannabis sector has historically suffered from a lack of genetic control, resulting in significant variability in potency and terpene profiles. This inconsistency can jeopardize patient safety and confidence in the product." Organizations involved in testing psychedelic substances in other jurisdictions also provided detailed implementation considerations beyond the scope of this Task Force's current expertise, including: "state-licensed genetics bank," "microbial contaminant tests," and "quantitative polymerase chain reaction (qPCR) assay to simultaneously confirm that the spore is actually Psilocybe cubensis and rule out the presence of any look alike." Success depends on adequate laboratory capacity, reasonable testing costs that don't create excessive price barriers, and standardized testing protocols that ensure consistent results across facilities. The requirement builds consumer confidence and supports public health while enabling quality-based market differentiation.

Proposition 047 (Grade A - Strongly Recommended)

Marketing practices that target minors should not be allowed for natural psychedelic substances.

Youth marketing restrictions received strong support as essential protection against inappropriate targeting of vulnerable populations. Restrictions should prohibit advertising in youth-oriented media, marketing near schools and youth facilities, use of cartoon characters or youth-appealing imagery, and promotional activities at youth events. One stakeholder noted the challenge: "given the colorfulness of artwork/iconography of psychedelics in general."

Implementation should establish clear advertising standards, enforcement mechanisms, and penalties for violations. Marketing restrictions should apply across all media including digital platforms, print advertising, and promotional materials. The approach parallels existing restrictions for alcohol, tobacco, and cannabis while recognizing unique characteristics of psychedelic substances. Compliance monitoring should track advertising content, placement, and targeting to ensure protection effectiveness. Violations should result in licensing consequences and financial penalties sufficient to deter inappropriate marketing. Success requires comprehensive advertising standards, active enforcement, and regular policy updates addressing new marketing channels and techniques. The protection demonstrates commitment to responsible implementation while preventing normalization among minors and addressing legitimate parental and community concerns about youth exposure.

Proposition 048 (Grade A - Strongly Recommended)

Commercial psychedelic packaging should include standardized warning labels.

Standardized warning labels received strong support as essential consumer information and safety measures. Labels should include dosage guidelines, contraindication warnings, drug interaction alerts, and emergency contact information. Warning content should be evidence-based, regularly updated, and accessible to diverse populations through multiple languages and clear formatting. Standardization ensures consistent safety information across products and prevents misleading or inadequate warnings. Implementation requires development of warning content, label design standards, compliance monitoring, and regular updates reflecting emerging safety information. Labels should be prominent, readable, and resistant to removal or alteration. Content should address common risks including medication interactions, driving impairment, and contraindicated health conditions, including use in pregnancy and while breastfeeding, specifically. The system provides last-line safety information for consumers while demonstrating industry commitment to responsible practices. Success depends on evidence-based warning content, effective design that captures attention, and enforcement ensuring compliance across all commercial products. Standardized warnings build consumer confidence and support informed decision-making while reducing liability risks for businesses and state agencies.

This Task Force consulted with co-designers of the International Intoxicating Cannabinoid Product Symbol (IICPS) (ASTM D8441), Doctors for Drug Policy Reform, who shared an International Psychedelics Product Symbol (IPPS) compliant with ISO 3864 and ANSI Z535 standards, featured below. Stakeholders reported that the symbol may be reproduced, distributed, and used for any legal purpose, as long as the symbol itself is not modified.

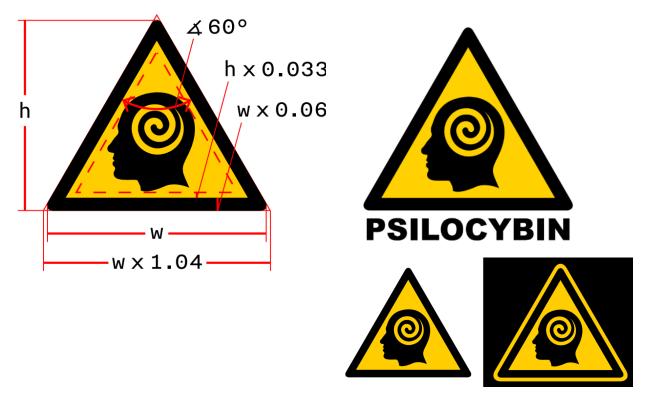


Figure 31. International Psychedelics Product Symbol (IPPS)

Proposition 049 (Grade A - Strongly Recommended)

Natural psychedelic substances should be packaged and sold in single-dose quantities, in child/pet-proof containers, clearly labeled for potency (i.e., to prevent consumers from inadvertently taking higher than expected amounts).

Single-dose packaging with child-resistant containers received strong support as a critical safety measure preventing accidental ingestion and dosing errors. One stakeholder emphasized: "Packaging has to be tamper-proof. A lot of cannabis products do not offer this." Single-dose packaging eliminates guesswork about appropriate amounts while child-resistant containers prevent accidental access by minors and pets. Clear potency labeling enables informed consumption decisions and reduces risk of unintentional overdose. One stakeholder raised implementation considerations based on the variety of psychedelic use practices: "microdosing or low doses [should] be packaged in blister packs or something similar that still separates out each dose but allows a user to leave with a reasonable amount of the natural medicine to limit frequency of visits to weekly (or monthly)." Implementation requires packaging standards development, testing procedures for child-resistance, and labeling requirements for potency information. Packaging should be environmentally responsible while maintaining safety features and should accommodate different product forms and dosing approaches. The requirement addresses significant safety concerns about accidental ingestion while supporting responsible use through accurate dosing information. Success depends on effective packaging design that balances safety with practicality, reasonable cost impacts that don't create excessive price barriers, and compliance monitoring ensuring consistent implementation. The approach demonstrates commitment to public safety while enabling informed consumer choice.

Proposition 050 (Grade A - Strongly Recommended)

Commercial vendors should be prohibited from making therapeutic or health claims.

Health claims restrictions received strong support as a consumer protection measure preventing misleading marketing and unauthorized medical advice. One stakeholder affirmed: "Absolutely - if not an approved indication by the FDA." Restrictions should prohibit claims about treating specific conditions, curing diseases, or providing medical benefits without FDA approval. The approach parallels existing regulations for dietary supplements and other health products while recognizing unique regulatory status of psychedelic substances. Implementation requires clear guidelines distinguishing prohibited health claims from permitted general information, enforcement mechanisms through licensing consequences, and coordination with FDA regulatory authority. Vendors should be allowed to provide general safety information, research

summaries, and harm reduction guidance without making specific therapeutic claims. Violations should result in licensing consequences and financial penalties. The restriction prevents consumer deception while allowing businesses to operate responsibly within legal boundaries. Success requires clear regulatory guidance, consistent enforcement, and regular updates addressing new marketing approaches and emerging research claims.

Proposition 051 (Grade A - Strongly Recommended)

Maryland should establish production quotas for commercial producers of natural psychedelic substances.

Production quotas received strong support as a mechanism for preventing overproduction and maintaining market stability. One stakeholder explained: "One shipping container-sized cultivation setup for mushrooms can produce up to 1 US ton per year, which represents between 25,000 higher doses and 250,000 microdoses. Much of this production capacity can be redirected towards producing culinary mushrooms. Production quotas can help prevent overproduction of psychedelic mushrooms, which could otherwise easily occur." However, concerns were raised: "I worry a production quota could put unnecessary stress or burden on the commercial producers -- sometimes stress like that can inadvertently reduce the quality of the product." Another noted existing federal precedent: "The DEA has an ARCOS database that collects data on all controlled substances (maybe just C2-4 drugs?) that determines how much has been sold and then sets up quotas for production from various manufacturers (to spread the wealth, presumably). So, there is an infrastructure already in place to determine how many producers are needed based on the amount of consumption." Implementation should establish quotas based on market demand assessment, provide flexibility for market growth, and include appeals processes for quota adjustments. The system should prevent oversupply that could lead to diversion while ensuring adequate supply for legitimate demand.

Proposition 052 (Grade A - Strongly Recommended)

Commercial vendors of natural psychedelic substances should be required to maintain detailed sales records.

Detailed sales records received strong support as essential for regulatory compliance, safety monitoring, and diversion prevention. Records should track product movement from cultivation through final sale, including customer information, product details, quantities sold, and transaction dates. Record-keeping enables investigation of adverse events, monitoring of use patterns, and detection of potential diversion or abuse. Implementation requires standardized

record-keeping systems, data security protocols, and reporting requirements to state agencies. Records should be maintained for specified periods and made available for regulatory inspections. The system should integrate with broader tracking requirements creating comprehensive oversight of the entire supply chain. Electronic record-keeping systems can improve efficiency while ensuring accuracy and accessibility. Success depends on reasonable record-keeping requirements that provide meaningful oversight without creating excessive administrative burdens, adequate data security protecting consumer privacy, and integration with statewide monitoring systems (Proposition 014 - Grade A). The requirement enables evidence-based policy refinement while supporting public safety and regulatory compliance.

Proposition 053 (Grade A - Strongly Recommended)

Maryland businesses related to natural psychedelic substances should have state income tax deductions for qualified business expenses (e.g., as Maryland has done with cannabis businesses).

State tax deductions received strong support as a mechanism for supporting legitimate business development while federal tax restrictions remain in place. One stakeholder explained: "Section 280E of the Internal Revenue Code prevents businesses from deducting standard expenses related to the sale of Schedule I or II substances, apart from the Cost of Goods Sold. As cannabis remains a Schedule I drug, this provision applies even to state-legal cannabis businesses. This penalty results in effective tax rates in excess of 80% and sometimes approaching gross revenue of the business. While awaiting rescheduling of natural psychedelic substances by the DEA or changes to federal law, Maryland can provide relief to psychedelic businesses to support their financial viability." Implementation should allow deductions for ordinary business expenses including rent, utilities, payroll, and professional services while maintaining appropriate documentation requirements. The policy supports business viability and job creation while demonstrating state commitment to successful program implementation. Success requires clear guidelines for eligible expenses, coordination with existing cannabis tax provisions, and monitoring to ensure benefits support legitimate business development rather than creating inappropriate tax advantages.

Religious Use Propositions (054-062)

Proposition 054 (Grade I - Insufficient)

Maryland should take no specific action at this time to expand access to natural psychedelic substances for religious use, awaiting updates by the DEA to the petition process for religious exemptions from the Controlled Substances Act (CSA) under the Religious Freedom Restoration Act (RFRA).

The Task Force did not achieve consensus on taking no action to expand access to natural psychedelic substances for religious use. The insufficient consensus reflects disagreement about whether Maryland should proactively protect religious use or defer to federal developments. Supporters emphasized avoiding conflicts with federal law and noted existing DEA processes for religious exemptions under RFRA. However, critics argued that waiting indefinitely could deny legitimate religious practitioners their constitutional rights while federal processes remain slow and uncertain. The current federal process to protect religious practices that include the use of natural psychedelic substances was criticized in an 80-page study by the Government Accountability Office, "DEA Should Improve its Religious Exemptions Petition Process for Psilocybin (Mushrooms) and Other Controlled Substances," (GAO 24-106630, May 2024). 481 Of 24 applications to DEA for a religious exemption submitted since 2016, none have been granted; two have been denied, eight were ultimately withdrawn, and the remainder are in limbo. (Fig. 5, p.40). The no-action approach conflicts with stakeholder input advocating to "Consider proactively providing religious organizations protected rights to use natural medicine as sacraments under state law." Another stakeholder asserted: "The DEA's current exemption process fails the public interest because, in addition to requiring extensive legal services, it requires a church to have fixed, articulated religious practices regarding controlled substances, even though it's obvious to any scholar of religion that practices and beliefs evolve over time. The DEA would ask us to present these tender beliefs and practices for public scrutiny even though it's outside the DEA's mandate and competence to discern sincere religious exercise... Asserted religious rights should be presumed, not permitted, and not unreasonably denied or delayed." Some religious practitioners expressed urgency: "This is a part of my religious belief. I'd have to risk a felony by bringing Ayahuasca into the country to practice my religion." The insufficient grade reflects tension between federal law compliance and state constitutional obligations to protect religious freedom. Implementation would require monitoring federal developments while possibly disadvantaging sincere religious practitioners during extended waiting periods.

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⁴⁸¹ https://www.gao.gov/assets/gao-24-106630.pdf

Alternative approaches might include conditional protections that activate upon federal changes or regulatory frameworks that provide some protection while acknowledging federal limitations.

One task force member noted that the entirety of the religious use propositions reflected ambiguity that was perhaps shaped by the drafting of this proposition. Several propositions for implementing religious use had Grade A consensus. It is important to note that the very presentation of religious use propositions implicitly affirms that there is sincere religious use of natural psychedelic substances. Natural psychedelic substances are being used for religious purposes in conformity with the U.S. Constitution as affirmed by a unanimous opinion of the United States Supreme Court (*Gonzales v. O Centro Espirita Beneficente Uniao Do Vegetal*, 546 U.S. 418, 2006, upholding the use of ayahuasca by members of the O Centro Espirita Beneficente Uniao Do Vegetal (UDV) church), and by federal statute (American Indian Religious Freedom Act Amendments Act of 1994, P.L. 103-344, 108 STAT. 3125, 42 U.S.C. 1996a, protecting the right of members of the Native American Church to use peyote). In fact, of all the uses of natural psychedelic substances considered by the Task Force, the *only* uses that are guaranteed by the U.S. and Maryland Constitutions are the religious uses.

Proposition 055 (Grade B - Moderately Recommended)

Maryland should recognize religious use of natural psychedelic substances as a practice protected under Article 36 of the Declaration of Rights of the Maryland Constitution.

Constitutional protection received moderate support as recognition of fundamental religious freedom rights under Maryland law. Article 36 provides that "no person ought by any law to be molested in his person or estate, on account of his religious persuasion, or profession, or for his religious practice." Implementation would establish a state constitutional basis for religious use protection while acknowledging potential conflicts with federal law. The approach recognizes legitimate religious practices and provides a legal foundation for defending practitioners against state prosecution. However, federal law enforcement could still pursue violations regardless of state constitutional protections. Of course, Maryland has created an extensive cannabis industry, in which all participants – growers, processors, dispensaries, transporters and customers – are in violation of the federal Controlled Substances Act. Implementation of a religious freedom pathway requires legal framework development addressing scope of protection, qualifying religious practices, and coordination with federal authorities. Such protection would vindicate state commitment to religious liberty while acknowledging regulatory enforcement challenges. Success depends on clear criteria for protected religious use, and coordination with law enforcement agencies. The approach provides a foundation for religious freedom in contrast with the hypothetical federal-only protections for sincere religious practices.

Proposition 056 (Grade B - Moderately Recommended)

Production and cultivation of natural psychedelic substances should be allowed for Religious Organizations for use as sacraments.

Religious cultivation received moderate support while acknowledging implementation challenges and authenticity concerns. Stakeholders noted: "It would be difficult to differentiate between legitimate well-intentioned spiritual/religious practices versus bad actors falsely claiming religious protections as a guise for irresponsible use or diversion." Congress, in enacting Internal Revenue Code section 501(c)(3) (26 U.S.C. 501(c)(3)) exempted from federal taxation organizations that are "organized and operated exclusively for religious . . . purposes." According to the Internal Revenue Service, "Churches that meet the requirements of IRC Section 501(c)(3) are automatically considered tax exempt and are not required to apply for and obtain recognition of tax-exempt status from the IRS."482 While implementation requires oversight mechanisms preventing diversion and cultivation limits appropriate for sacramental use, it is not clear that a process for determining sincerity of beliefs is necessary. Religious cultivation should be limited to amounts necessary for genuine religious practice with security requirements preventing theft or distribution outside religious contexts. The approach enables religious autonomy over sacrament preparation while maintaining appropriate oversight. Implementation challenges might include establishing authenticity criteria for religious organizations, preventing commercial exploitation of religious exemptions, or coordinating with federal authorities. Success requires clear guidelines distinguishing legitimate religious cultivation from commercial or recreational production, appropriate security and tracking requirements, and ongoing monitoring ensuring compliance with religious use limitations. The policy respects religious autonomy while maintaining public safety protections.

Proposition 057 (Grade A - Strongly Recommended)

Religious organizations should implement safety protocols for ceremonies involving natural psychedelic substances.

Safety protocols received strong support as essential protection for participants in religious ceremonies. One stakeholder noted: "Spiritual use is good for humanity. I don't interfere in other religions, so why do I have to explain why psychedelics are important to my relationship with God?" However, safety remains paramount regardless of religious context. Protocols should include participant screening for contraindications, preparation and integration support, qualified ceremony leaders, emergency response procedures, and appropriate supervision ratios. Implementation should respect religious autonomy while ensuring participant safety through evidence-based guidelines. Safety protocols should address medical emergencies,

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⁴⁸² "Tax Guide for Religious and Other Organizations," IRS Publication 1828 (https://www.irs.gov/pub/irs-pdf/p1828.pdf, accessed Oct. 14, 2025, emphasis added

psychological crises, and participant preparation while accommodating diverse religious traditions and practices. The requirement demonstrates that religious freedom includes responsibility for participant welfare. Success requires collaboration between religious communities and health professionals, flexible guidelines accommodating different traditions, and training resources for religious leaders. The approach balances religious autonomy with participant protection while supporting responsible ceremonial practices.

Proposition 058 (Grade I - Insufficient)

Maryland should establish regulations and certification for religious leaders who will administer natural psychedelic substances as sacraments.

Religious leader certification received insufficient consensus due to fundamental First Amendment concerns about state interference in religious practice. One stakeholder declared: "Absolutely not. This is a First Amendment issue." Others noted: "It's a constitutional right. And I don't think it's our place to determine what is part of a religious tradition and what's part of a religious right or service." However, some argued for safety oversight: "These regulations would be subject to the high-level of scrutiny governing the protection against state-imposed burdens upon the free exercise of religion. Maryland would have to prove that it has a 'compelling interest' in this regulation and certification AND that this approach was the 'least' burdensome way of accomplishing that compelling state interest." The insufficient grade reflects tension between public safety interests and religious freedom protections. Any certification requirements would face strict constitutional scrutiny requiring compelling state interest and least restrictive means. Alternative approaches might include voluntary certification programs, safety training resources, or collaboration with religious communities on best practices rather than mandatory state certification.

Proposition 059 (Grade A - Strongly Recommended)

Maryland should implement a regulatory process for exemption from criminal liability for individual and/or community religious use of natural psychedelic substances.

Criminal liability exemptions received strong support as essential protection for sincere religious practitioners. One stakeholder emphasized: "A state-issued license for spiritual psychedelic use aligns with the First Amendment and federal law: RFRA Compliance: Licensing satisfies the 'least restrictive means' test under the Religious Freedom Restoration Act... It ensures safety without prohibiting sincere religious practice. I personally know many Marylanders who possess a bona fide spiritual connection to these psychedelic substances, and their access should be allowed."

Implementation should establish clear criteria for religious exemptions, application procedures for individuals and communities, and oversight mechanisms ensuring legitimate religious use. The process should require demonstration of sincere religious belief, appropriate safety measures, and compliance with reasonable regulations. Exemptions should protect both individual practitioners and religious communities while maintaining accountability for safe practices. Success requires clear application procedures, reasonable criteria for religious sincerity, and coordination with law enforcement agencies. The approach provides practical protection for religious freedom while maintaining appropriate oversight and preventing abuse of religious exemptions.

Proposition 060 (Grade I - Insufficient)

Minors should be allowed to participate in ceremonies involving natural psychedelic substances with parental consent.

Minor participation received insufficient consensus due to fundamental safety and ethical concerns despite arguments about religious freedom. One stakeholder noted: "Catholic churches allow children to consume wine, which is illegal, but it's part of their religious rite." However, others raised serious concerns: "This raises so many ethical and safety questions that my mind cannot contain them all. Given how our society conceptualizes childhood/minorhood, I do not think that there can be any provisions allowing for parents to permit their children to use these substances, period. It would be equivalent to a parent authorizing that their child could get highly intoxicated as part of a religious ceremony." The insufficient grade reflects tension between religious freedom and child protection. Even supporters suggested restrictions: "With parent and doctor consent maybe" and emphasized the need for "safety protocols that I think religious use needs to have standards." The approach raises complex issues about parental rights, religious freedom, child welfare, and substance effects on developing brains. Resolution requires careful consideration of child protection laws, religious freedom precedents, and medical evidence about developmental impacts.

Proposition 061 (Grade I - Insufficient)

Religious use of natural psychedelic substances should be allowed only in designated worship spaces.

Worship space restrictions received insufficient consensus due to conflicts with religious freedom and practical worship needs. One stakeholder argued: "The idea that worship has to be limited to some fixed or enclosed location is an anathema" and referenced the Native American Church: "Typically, this worship takes place in a teepee that is erected for the purpose of the

worship. Worshippers sit on the ground. This can take place anywhere that is appropriate to the organizers and participants." Another noted: "This would imply that religious use can only fall under a church or temple. I can have religious or, to be more accurate, spiritual practices that do not require a designated building or location." The restriction conflicts with diverse religious traditions that conduct ceremonies in natural settings, temporary structures, or non-traditional worship spaces. Implementation would require defining "designated worship spaces" while accommodating various religious practices and traditions. The insufficient grade reflects tension between regulatory control and religious autonomy over worship practices and locations.

Proposition 062 (Grade A - Strongly Recommended)

Religious organizations should maintain records of any adverse events related to natural psychedelic substances.

Adverse event reporting received strong support as an essential safety measure that protects participants while providing valuable data for improving practices. Record-keeping should include documentation of any negative physical or psychological reactions, emergency responses, and follow-up care provided. The requirement supports participant safety through systematic attention to potential problems while contributing to broader understanding of risks and safety measures. Implementation should respect religious privacy while ensuring adequate documentation for safety analysis and improvement. Records should be confidential and used primarily for internal safety improvement with aggregate data potentially shared for broader safety analysis. The approach demonstrates religious community commitment to participant welfare while supporting evidence-based safety improvements. Success requires clear guidelines for reportable events, confidentiality protections respecting religious privacy, and systems for analyzing trends to improve safety practices. The requirement balances participant protection with religious autonomy while contributing to responsible ceremonial practices.

Supervised Adult Use Propositions (063-076)

Proposition 063 (Grade A - Strongly Recommended)

Licensed facilities should be established where adults can consume natural psychedelic substances under supervision by licensed facilitators.

Supervised consumption facilities received strong support as providing safe, controlled environments for psychedelic use with professional oversight. One stakeholder remarked optimistically on Maryland's positioning: "Since starting psychedelic services in Jan 2023, over 10,000 individuals have accessed psilocybin at licensed service centers. 7 of 35 service centers in Oregon have already closed, and this is not alarming, given that many startup businesses fail. Rather than lead us to question the feasibility of this model, this information should inspire us to better prepare Maryland psychedelic businesses to succeed, based on earlier experiences in Oregon, Colorado and New Mexico." Implementation requires comprehensive facility licensing including safety protocols, staff training requirements, emergency response procedures, and oversight mechanisms. Facilities should provide controlled environments with appropriate supervision, emergency medical support, and integration resources. The model serves individuals seeking psychedelic experiences in safe settings while generating valuable data on use patterns and outcomes. Success depends on reasonable licensing requirements encouraging facility development, adequate safety protocols protecting participants, and geographic distribution ensuring accessibility across Maryland communities.

Proposition 064 (Grade A - Strongly Recommended)

Supervised use facilities for natural psychedelic substances should be mandatorily staffed by licensed facilitators.

Licensed facilitator staffing received strong support as a fundamental safety requirement ensuring professional supervision during psychedelic sessions. One stakeholder expressed concern while recognizing the safety necessity: "I see the value in this, but I am wary about any government process to license facilitators." Licensed facilitators provide trained oversight during vulnerable periods, emergency response capabilities, and professional guidance throughout the experience. Mandatory staffing ensures consistent supervision standards across all facilities while building public confidence in facility safety. Implementation requires facilitator licensing standards, training requirements, continuing education mandates, and supervision protocols. Facilities should maintain adequate staffing ratios with trained professionals present during all sessions. The requirement addresses legitimate safety concerns while creating professional

standards for the emerging field. Success depends on reasonable licensing requirements that don't create excessive barriers to qualified individuals, adequate training programs, and ongoing oversight ensuring competency maintenance. The approach demonstrates commitment to participant safety while supporting professional development in psychedelic facilitation.

Proposition 065 (Grade A - Strongly Recommended)

Maryland should establish training and certification requirements for supervised use facilitators of natural psychedelic substances.

Training and certification requirements received strong support as essential for ensuring facilitator competency and participant safety. Medical organizations urged Maryland to: "establish clear and enforceable standards of training and oversight for licensed facilitators." Stakeholders emphasized: "[Maryland] should establish equitable and sustainable training programs and certification requirements else we will see a repeat of Oregon and Colorado (most of these programs historically have been \$10,000+ this doesn't include the additional costs of practicum and then the license itself)." Others noted resources available: "Utilizing Maryland's robust college and university systems to provide education for licensed clinicians and clinicians-in-training on psychedelic-assisted therapy" and "The Beckley Academy produced an open source review of competencies addressed by existing training programs: A Psychedelic-Assisted Therapy Learning Framework." Concerns about access were raised: "We risk leaving out people with lived experiences and people serving communities that look like they do." Implementation should include: comprehensive curriculum covering safety protocols, emergency response, ethics, and cultural competency; practical training components with supervised experience; affordable programs accessible to diverse candidates; recognition of existing expertise and legacy practitioners; and ongoing continuing education requirements. Success requires balancing rigorous training standards with accessibility, ensuring programs prepare competent facilitators while not creating insurmountable barriers to qualified individuals from diverse backgrounds.

Proposition 066 (Grade A - Strongly Recommended)

Requirements for supervised use facilitators of natural psychedelic substances should allow participation by licensed health care providers acting within the scope of their professional training.

Healthcare provider participation received strong support while acknowledging scope-of-practice complexities. Stakeholders noted concerns: "Scope of professional training for these things doesn't really exist." Medical organizations shared: "MedChi is concerned that this could lead to

confusion regarding scope of practice, legal liability, and the role distinctions between licensed medical providers and non-clinical facilitators" and urged that Maryland "establish clear and enforceable standards of training and oversight for licensed facilitators, and to exercise caution in treating non-medical use environments as therapeutic without physician involvement." However, others argued for inclusivity: "I'm also advocating these are not just licensed healthcare providers (this feels like gatekeeping). This should also include adults (21+) with at least a high school diploma and indigenous lineage carriers." Stakeholders advocated for the involvement of social workers: "Social workers provide the majority of mental health services in the country more than psychiatrists, psychologists and psychiatric nurses combined... Embedded throughout service systems (community clinics, hospitals, hospice, VA, nursing homes, employee assistance etc.). Work with the most marginalized (those below federal poverty line, Medicaid eligible, those needing assistance with daily living.) We are affordable and diverse." Implementation should clarify scope of practice boundaries, establish role definitions distinguishing medical from facilitation services, and coordinate with professional licensing boards. Examples include Colorado's multiple license types ("Facilitator License" vs "Clinical Facilitator License"), 483 or Oregon's provisions for Licensed Psilocybin Facilitators who also hold board-regulated professional licenses. 484 Healthcare providers bring valuable medical training while potentially expanding the qualified facilitator pool. The approach should prevent scope confusion while enabling appropriate professional participation. Success requires clear guidelines defining healthcare provider roles, coordination with existing professional licensing requirements, and training that addresses unique aspects of psychedelic facilitation distinct from traditional medical practice.

Proposition 067 (Grade A - Strongly Recommended)

Consumers should undergo medical and psychiatric screening by a licensed health professional before participation at supervised use facilities for natural psychedelic substances.

Pre-participation screening received strong support as an essential safety measure identifying potential contraindications and risk factors. Screening should identify medical conditions, psychiatric vulnerabilities, medication interactions, and other factors requiring special consideration or exclusion. Medical organizations recommended: "requiring comprehensive psychiatric evaluations performed by licensed physicians or psychiatrists prior to administration, particularly outside of FDA-approved uses." The process ensures appropriate care planning and

⁴⁸³ Natural Medicine Licensure Rules and Regulations, 4 CCR 755-1 (2024). Retrieved from https://www.sos.state.co.us/CCR/GenerateRulePdf.do?ruleVersionId=11610&fileName=4%20CCR.

⁴⁸⁴ Relating to psilocybin; and declaring an emergency, HB 2387 Enrolled (2025). Retrieved from https://olis.oregonlegislature.gov/liz/2025R1/Measures/Overview/HB2387

risk mitigation while connecting high-risk individuals to more intensive medical supervision when needed. Implementation requires standardized screening protocols, qualified screening providers, and referral pathways for identified concerns. Screening should be affordable and accessible while maintaining professional standards. The approach coordinates with broader permitting requirements (Proposition 005 - Grade C) while specifically addressing supervised facility contexts. Success depends on evidence-based screening criteria focused on genuine safety concerns, adequate provider network ensuring accessibility, and coordination with medical systems for identified issues. The requirement demonstrates commitment to participant safety while enabling informed decision-making about appropriate levels of supervision and support.

Proposition 068 (Grade A - Strongly Recommended)

Consumers should be required to attend preparation sessions before supervised use of natural psychedelic substances.

Preparation sessions received strong support as a fundamental safety and efficacy measure ensuring participants understand the experience and develop appropriate mindset and expectations. Preparation should cover session structure, potential effects, coping strategies, safety protocols, and integration planning. Sessions help identify concerns, establish therapeutic goals, and build rapport with facilitators. Implementation requires standardized preparation curricula, qualified preparation providers, and adequate session time for comprehensive preparation. Preparation should be culturally responsive and accessible to diverse participants. The requirement recognizes that psychedelic experiences are significantly influenced by preparation quality and participant readiness. Success depends on evidence-based preparation protocols, trained providers delivering consistent programming, and integration with broader education requirements. The approach enhances both safety and therapeutic potential while demonstrating professional standards in psychedelic services.

Proposition 069 (Grade A - Strongly Recommended)

Supervised use facilities should offer integration support after use of natural psychedelic substances.

Integration support received strong support as an essential component maximizing therapeutic benefits and processing difficult experiences. One stakeholder emphasized broader context: "I want to highlight a broader cultural issue: the integration process. Our society's pace—saturated with screens, traffic, and constant demands—makes it difficult for people to fully absorb the insights that emerge from psychedelic work. I believe policy should not only ensure safety but

also encourage models that give people adequate time and space for reflection after their sessions." Integration support helps participants process experiences, develop insights, and implement positive changes in their lives. Implementation requires trained integration providers, standardized support protocols, and follow-up scheduling systems. Support should be culturally responsive and accessible to all participants. The requirement recognizes that integration is crucial for realizing psychedelic benefits and preventing adverse outcomes. Success depends on qualified integration providers, evidence-based support methods, and adequate time allocation for meaningful processing.

Proposition 070 (Grade A - Strongly Recommended)

Supervised use facilities for natural psychedelic substances should maintain specific staff-to-consumer ratios.

Staff-to-consumer ratios received strong support as a critical safety measure ensuring adequate supervision during vulnerable periods. Stakeholder input suggested: "Consider saying minimum staff-to-consumer ratios" to provide flexibility while maintaining safety standards. Appropriate ratios ensure facilitators can provide individual attention, monitor safety, and respond to emergencies effectively. Ratios should vary based on session type, participant risk factors, and facility design while maintaining minimum safety standards. Implementation requires evidence-based ratio determination, staff qualification requirements, and monitoring systems ensuring compliance. Ratios should account for different supervision needs including preparation, active sessions, and integration periods. The requirement addresses safety concerns while providing operational guidance for facilities. Success depends on ratios that ensure safety without creating unnecessary operational burdens, qualified staff meeting supervision requirements, and flexibility accommodating different service models while maintaining participant protection.

Proposition 071 (Grade A - Strongly Recommended)

Group sessions at supervised use facilities for natural psychedelic substances should have maximum participant limits.

Group session limits received strong support as a safety measure ensuring manageable supervision and emergency response capabilities. Stakeholder input suggested considering "or establish a reasonable participant-to-facilitator ratio" as an alternative framework. Maximum limits should ensure facilitators can monitor all participants effectively, provide individual attention when needed, and coordinate emergency responses. Limits should consider session

intensity, participant risk factors, facility design, and staffing levels. One stakeholder asked: "Psychedelics for therapy should not be limited to just medical facilities. What about group therapy?" Implementation requires evidence-based limit determination, facility capacity assessment, and emergency response planning. Limits should balance safety with program accessibility and operational viability. The requirement ensures facilitators can maintain safety oversight while enabling group experiences that may enhance therapeutic outcomes. Success depends on limits that ensure safety without unnecessarily restricting access, adequate emergency protocols for group situations, and trained staff capable of managing group dynamics during psychedelic sessions.

Proposition 072 (Grade A - Strongly Recommended)

Supervised use facilities administering natural psychedelic substances should have specific safety equipment and protocols in place.

Safety equipment and protocols received strong support as fundamental requirements for emergency preparedness and participant protection. Equipment should include medical emergency supplies, communication systems, monitoring devices, and safety restraints if needed. Protocols should address medical emergencies, psychiatric crises, facility security, and adverse event response. Facilitators should understand the potential adverse effects and possess the knowledge, skills, and abilities to initiate treatment while awaiting emergency services, as needed. Implementation requires comprehensive safety planning, staff training on emergency procedures, equipment maintenance requirements, and regular protocol updates. Safety measures should be evidence-based and regularly reviewed for effectiveness. The requirement ensures facilities can respond appropriately to emergencies while maintaining participant safety throughout sessions. Success depends on adequate equipment specifications based on facility size and services, comprehensive emergency protocols covering likely scenarios, and regular training ensuring staff competency in emergency response. The approach demonstrates commitment to participant safety while providing clear operational guidance for facilities.

Proposition 073 (Grade A - Strongly Recommended)

Supervised use facilities should maintain detailed records of natural psychedelic substances administered and adverse events.

Record-keeping requirements received strong support as essential for safety monitoring, quality improvement, and regulatory compliance. Records should track substances administered,

dosages, participant responses, adverse events, and emergency interventions. Documentation enables investigation of problems, identification of safety trends, and evidence-based practice improvement. Implementation requires standardized record-keeping systems, data security protocols, and reporting requirements to regulatory authorities. Records should be maintained for specified periods and made available for safety investigations while protecting participant privacy. The requirement supports continuous safety improvement while enabling accountability and oversight. Success depends on comprehensive record-keeping standards that capture meaningful safety information, adequate data security protecting participant confidentiality, and analysis systems enabling trend identification and practice improvement. The approach enables evidence-based safety enhancement while supporting regulatory oversight and quality assurance.

Proposition 074 (Grade A - Strongly Recommended)

Supervised use facilities for natural psychedelic substances should be required/incentivised to offer affordable options of care (e.g., facilitators could receive discounted training/certification/licensing fees in exchange for offering sliding scale fees or a patient discount program).

Affordable care options received strong support as an essential equity measure preventing economic barriers to access. Stakeholders emphasized: "Natural psychedelics must be available to everyone, not just people of means" and "I don't want the mental health facilities taking over the use of psychedelics and then charging huge fees to get access. Big Pharma already does this." One noted implementation considerations: "facilitators could receive discounts on training, certification, and licensing fees in exchange for offering a patient discount program." Implementation should include sliding scale fee requirements, state subsidies for training costs, scholarship programs, and tax incentives for facilities serving low-income populations. The approach ensures economic accessibility while maintaining service quality and provider sustainability. Success requires adequate funding mechanisms supporting affordable care, clear guidelines for sliding scale implementation, and monitoring ensuring meaningful access for low-income individuals. The requirement demonstrates commitment to equitable access while addressing legitimate concerns about psychedelic services becoming available only to wealthy populations.

Proposition 075 (Grade A - Strongly Recommended)

Supervised use facilities of natural psychedelic substances should be subject to regular inspections (provided these inspections do not disrupt provision of care).

Regular inspections received strong support as an essential oversight mechanism ensuring compliance with safety standards and regulatory requirements. Inspections should verify facility safety, staff qualifications, record-keeping compliance, and adherence to operational protocols. The caveat about not disrupting care demonstrates recognition that inspections must balance oversight with service continuity. Implementation requires inspection scheduling systems, qualified inspection staff, standardized inspection protocols, and enforcement mechanisms for violations. Inspections should be announced when possible to minimize disruption while maintaining thorough oversight. The requirement ensures ongoing compliance while building public confidence in facility operations. Success depends on reasonable inspection frequencies that ensure adequate oversight without excessive burden, qualified inspectors understanding facility operations, and efficient inspection processes minimizing operational disruption. The approach balances regulatory oversight with operational practicality while maintaining participant safety and service quality.

Proposition 076 (Grade A - Strongly Recommended)

Supervised use facilities of natural psychedelic substances should be prohibited from making therapeutic or medical claims.

Medical claims restrictions received strong support as a consumer protection measure preventing misleading marketing and unauthorized therapeutic promises. Similar to Proposition 050 (Grade A) for commercial vendors, this restriction prevents facilities from claiming to treat specific conditions without appropriate medical authorization. MedChi, the state medical society, urged Maryland to "exercise caution in treating non-medical use environments as therapeutic without physician involvement." The prohibition should allow general wellness and personal growth descriptions while preventing specific medical or therapeutic claims. Implementation requires clear guidelines distinguishing prohibited claims from permitted descriptions, enforcement mechanisms through licensing consequences, and coordination with healthcare regulations. Facilities should be able to describe services and potential experiences without making unauthorized medical claims. The restriction protects consumers from deceptive marketing while maintaining appropriate boundaries between facilitated experiences and medical treatment. Success requires clear regulatory guidance, consistent enforcement, and regular updates addressing new marketing approaches. Final recommendations should include enforcement mechanisms, such as licensing consequences or civil penalties for facilities that engage in unauthorized medical marketing, as well as guidance for facilities to use non-clinical, educational language when describing potential effects.

Medical/Therapeutic Use Propositions (077-083)

Proposition 077 (Grade A - Strongly Recommended)

Licensed healthcare providers should be allowed by Maryland to administer natural psychedelic substances for therapeutic purposes.

Healthcare provider administration received strong support as essential for legitimate medical practice and patient care. However, stakeholders noted challenges: "Might be problematic in terms of regulation. Might put practitioners in violation of federal law" and "The cost to providers to get training and certification, and to get malpractice has proven onerous making access to NPS in localities that use this MOA/Access point challenging." Stakeholders also expressed implementation considerations: "Maryland should petition the relevant healthcare licensing boards to remove penalties, reprimands, or denial of licensure for approved providers offering natural psychedelic substances within therapeutic, regulated models." Medical organizations emphasized protection needs: "MedChi urges the inclusion of explicit guidance from licensing boards and the establishment of safe harbor provisions within Maryland law to protect licensed providers acting in good faith and in accordance with approved standards." Implementation requires clear scope of practice guidelines, professional liability protections, training requirements, and coordination with medical licensing boards. The approach enables legitimate medical practice while addressing federal law conflicts and professional protection needs. Success depends on clear legal protections for providers, accessible training programs, and reasonable malpractice insurance availability. The recommendation recognizes healthcare providers as appropriate practitioners while acknowledging implementation challenges requiring careful legal and regulatory framework development.

Proposition 078 (Grade C - Conditionally Recommended)

Medical use of natural psychedelic substances should require a formal diagnosis from a qualified healthcare provider.

Formal diagnosis requirements received conditional support requiring careful implementation to avoid excluding legitimate uses while ensuring medical oversight. One stakeholder expounded: "I have lots of issues with the need for a formal diagnosis to allow a person to access an NPS. First, what is a diagnosis anyway...especially within the mental health setting. Second, who are the people authorized to diagnose? Ostensibly, it should be mental health practitioners who do (at least for mental health conditions), but that would create more barriers... Third, what is the purpose of a diagnosis (in Mental health)? Is it to give a suffering person something that they can

use to explain why they suffer? Is it a tool used by insurance companies to categorize people for actuarial purposes? Is it something that can accurately point to a coherent plan for healing? I don't think that diagnoses in the mental health space have enough explanatory weight to necessitate that they be used when determining whether someone is permitted to have a NPS. All that said, if we are going to recommend a medical model, we are going to need to have a diagnosis to 'justify medical necessity.' Though imperfect, it might be necessary." Implementation conditions should include: broad diagnostic categories encompassing various conditions where psychedelics may be beneficial; recognition of off-label medical uses; consideration of pain management applications; flexible criteria avoiding overly restrictive medical gatekeeping; and appeals processes for denied applications. One stakeholder articulated the need for clearly defining "qualified healthcare provider": I agree if a psychiatrist or clinical psychologist is required that is an undue burden on an extreme shortage specialty. On the other hand, we need to explicitly limit and prosecute those individuals who will come out of the woodwork to prey on veterans to make unsubstantiated diagnoses in order to profit." The requirement should balance medical oversight with access to legitimate therapeutic uses including mental health, chronic pain, and other qualifying conditions. Success depends on establishing reasonable diagnostic criteria that enable appropriate medical use without creating excessive barriers, training providers on psychedelic therapeutic applications, and coordination with medical professional standards. The approach should recognize diverse therapeutic applications while maintaining medical professional oversight.

Proposition 079 (Grade A - Strongly Recommended)

Approved use of natural psychedelic substances for consumers at high risk of medical or psychiatric complications should be restricted to the medical/therapeutic use model.

High-risk population protections received strong support as an essential safety measure ensuring vulnerable individuals receive appropriate medical supervision. One stakeholder noted technical considerations regarding this policy proposition: "I believe the intent is that high risk consumers should be required to be supervised by medical staff." High-risk populations include those with psychiatric disorders, cardiovascular conditions, seizure disorders, and medication interactions. Medical supervision provides immediate medical response capabilities, professional oversight, and appropriate screening protocols. Implementation requires clear criteria defining high-risk populations, assessment protocols identifying vulnerable individuals, and referral systems connecting high-risk users to medical programs. The approach ensures appropriate care levels while protecting vulnerable populations from inadequate supervision. Success depends on evidence-based risk criteria, accessible medical programs serving high-risk populations, and coordination between different access models for appropriate triage. The requirement

demonstrates commitment to population-specific safety while recognizing that some individuals require enhanced medical oversight regardless of access model preferences.

Proposition 080 (Grade A - Strongly Recommended)

Licensed health care providers should document an informed consent process including the risks, benefits, and alternatives prior to initiating therapy with natural psychedelic substances.

Informed consent documentation received strong support as a fundamental medical practice requirement ensuring patient understanding and provider protection. However, stakeholders noted unique challenges: "psychedelics create a predicament where people are asked to agree to accept a risk that they cannot possibly understand... it is impossible for a person without a child (or more colorfully, a person who is not a vampire) to have enough information to make an informed decision about whether to have children (or become [a] vampire)." Despite these philosophical challenges, informed consent remains essential for medical practice. Medical organizations urged: "strong informed consent requirements and clear delineation of liability responsibilities among stakeholders involved in psychedelic care." Implementation requires standardized consent procedures, comprehensive risk disclosure, alternative treatment discussion, and documentation requirements. Consent should address unique psychedelic risks, potential benefits, and patient questions while acknowledging limitations in predicting individual responses. The requirement aligns with medical professional standards while addressing unique characteristics of psychedelic therapy. Success depends on comprehensive consent protocols addressing psychedelic-specific considerations, provider training on consent procedures, and legal frameworks protecting both patients and providers through appropriate documentation.

Proposition 081 (Grade A - Strongly Recommended)

Protocols for medical use of natural psychedelic substances should require preparation, administration, and integration sessions.

Comprehensive session protocols received strong support as an evidence-based practice standard ensuring optimal outcomes and safety. However, stakeholders noted important limitations: "To include facilitated preparation, dosing, and integration sessions doesn't take into account psychedelics for uses outside of mental health conditions. There are many medical uses for psychedelics that do not require P-AT [psychedelic-assisted therapy], for example, cluster headache. In fact, P-AT for cluster headache wouldn't be feasible, accessible, or useful. Pain patients use psychedelics differently than mental health patients, and a medical model should include consideration for those patients... It's important not to miss these patients and just focus

on mental health. A medical model is the most comfortable for many, and that is well understood, but doctor recommendation followed by home use will be accessible for people with chronic pain." Implementation should include flexible protocols accommodating different medical applications, modified requirements for conditions not requiring intensive psychotherapy, and alternative approaches for pain management and other non-psychiatric uses. The requirement should ensure appropriate support while avoiding unnecessary barriers for legitimate medical uses that may not require full psychotherapy protocols. Success depends on evidence-based protocols adapted to different medical conditions, flexible implementation allowing appropriate modifications, and provider training on various therapeutic approaches.

Proposition 082 (Grade A - Strongly Recommended)

Lawful administration of natural psychedelic substances should not constitute sole grounds for disciplinary action by professional licensing boards in Maryland.

Professional licensing protection received strong support as essential provider protection enabling legitimate medical practice. One stakeholder noted concern: "I already serve as a psychedelic facilitator and I am concerned that the state will tell me what I can and can't do, even though I have thirty years of experience." Medical organizations emphasized: "MedChi urges the inclusion of explicit guidance from licensing boards and the establishment of safe harbor provisions within Maryland law to protect licensed providers acting in good faith and in accordance with approved standards." Implementation requires coordination with professional licensing boards, clear practice guidelines, and explicit statutory protection for lawful practice. The protection should cover providers operating within approved frameworks while maintaining accountability for professional misconduct unrelated to lawful psychedelic administration. Success depends on clear statutory language protecting lawful practice, coordination with licensing boards ensuring consistent interpretation, and ongoing guidance helping providers understand protected activities. The approach enables professional participation while maintaining appropriate oversight and accountability.

Proposition 083 (Grade A - Strongly Recommended)

Maryland should create a state-wide no-fault alternative to lawsuits related to lawful administration of natural psychedelic substances by authorized health care providers or facilitators (e.g., the Florida Birth-Related Neurological Injury Compensation Association aka. NICA).

No-fault compensation received strong support as an innovative approach addressing liability concerns while protecting patients and providers. One stakeholder noted: "There is a similar

program in Virginia" and emphasized: "This, or something like this, is necessary if we make the recommendation of a medical model for NPS." Medical organizations stressed: "MedChi emphasizes the need for robust informed consent protocols and cautions against transferring liability to clinicians without defined care pathways and legal safeguards." Implementation requires comprehensive compensation fund development, claim assessment procedures, provider participation requirements, and coordination with existing malpractice systems. The program should provide timely compensation for legitimate injuries while protecting providers from frivolous litigation. Success depends on adequate funding mechanisms, fair claim assessment procedures, and provider confidence in the protection offered. The approach addresses legitimate liability concerns that might otherwise deter provider participation while ensuring patient protection through alternative compensation mechanisms.

FDA-Approved Use Propositions (084-085)

Proposition 084 (Grade A - Strongly Recommended)

Maryland should automatically permit access to any FDA-approved exemptions (psychedelic therapies, etc.) once rescheduled by the DEA, on a provisional basis, pending the Maryland Department of Health's annual update and republishing of the state controlled substances schedule.

Automatic FDA approval adoption received strong support as a mechanism ensuring rapid access to federally approved therapies without bureaucratic delays. Stakeholders noted considerations: "maybe - would need public education" and "Risks of cultural appropriation/environmental degradation should be considered and plan [sic.] for mitigation should be conducted before automatic adoption of these substances." Implementation requires coordination with federal approval processes, provisional approval mechanisms, and state regulatory update procedures. The approach ensures Maryland residents can access federally approved therapies promptly while maintaining state oversight through regular review processes. Automatic adoption prevents delays that might deny patients access to approved treatments while enabling state modifications through annual review cycles. Success depends on coordination systems tracking federal approvals, provisional approval procedures enabling rapid access, and oversight mechanisms ensuring appropriate state review and adaptation. The approach balances rapid access with appropriate state oversight while recognizing federal regulatory authority over therapeutic approvals.

Proposition 085 (No Grade)

Maryland should take no specific action at this time to expand access to natural psychedelic substances for Maryland Residents, awaiting review of ongoing studies by the FDA and rescheduling of natural psychedelic substances by the DEA.

The no-action alternative represents the status quo option rather than a policy recommendation, and it received no grade, reflecting uniformly low desirability ratings and a lack of consensus on feasibility. This approach would maintain current prohibition while waiting for federal developments. Supporters might emphasize avoiding conflicts with federal law and allowing federal processes to proceed before state action. However, this approach conflicts with the Task Force's mandate to develop recommendations for psychedelic access and would deny Maryland residents potential public benefits and public risk mitigation while federal processes remain slow and uncertain. The option serves as a baseline comparison against active policy recommendations but does not provide the proactive policy framework that the Task Force was

established to develop. Implementation would require no new legislation or regulatory development but would maintain current legal barriers and enforcement approaches. The approach acknowledges federal regulatory authority while potentially disadvantageous to Maryland residents who might benefit from state-level policy innovation and expanded access opportunities.

Additional Propositions (086-090)

Proposition 086 (Supported, Grade Unavailable)

For any Maryland individuals currently incarcerated solely for a conviction for simple possession of natural psychedelic substances, the prosecuting office should file a motion with the appropriate court to vacate the sentence and to order the immediate release of the individual.

This proposition was addressed during a "Live Delphi" round during the Open Meeting on September 25th, 2025. The level of participation (13 of 19, less than 75% of Task Force members present) made consensus calculations unstable, therefore no grade can be assigned. Collective dispositions toward this policy proposition, on scales of both desirability and feasibility, are illustrated with the "Mentimeter" reading below:

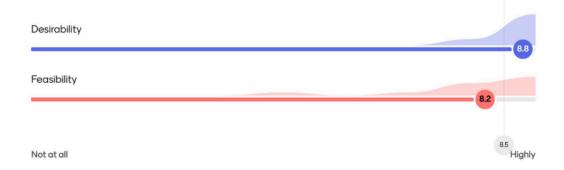


Figure 32. Live Delphi Measure for Proposition 086

Proposition 087 (Supported, Grade Unavailable)

Maryland should encourage the comparative study of psychedelic use across traditional/natural versus Western-medicine contexts (e.g. blood pressure changes resulting from psychedelic use in a clinic versus in nature; effects of synthesized psilocybin versus whole mushroom, etc.)

This proposition was addressed during a "Live Delphi" round during the Open Meeting on September 25th, 2025. The level of participation (13 of 19, less than 75% of Task Force members

present) made consensus calculations unstable, therefore no grade can be assigned. Collective dispositions toward this policy proposition, on scales of both desirability and feasibility, are illustrated with the "Mentimeter" reading below:

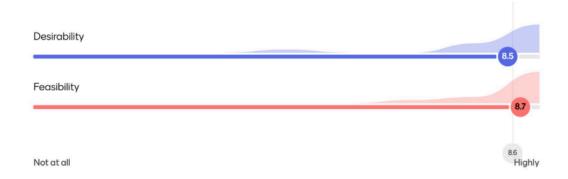


Figure 33. Live Delphi Measure for Proposition 087

Proposition 088 (Supported, Grade Unavailable)

All penalties (including civil penalties, fines, etc.) for possession and personal cultivation of natural psychedelic substances should be removed.

This proposition was addressed during a "Live Delphi" round during the Open Meeting on September 25th, 2025. The level of participation (13 of 19, less than 75% of Task Force members present) made consensus calculations unstable, therefore no grade can be assigned. Collective dispositions toward this policy proposition, on scales of both desirability and feasibility, are illustrated with the "Mentimeter" reading below:

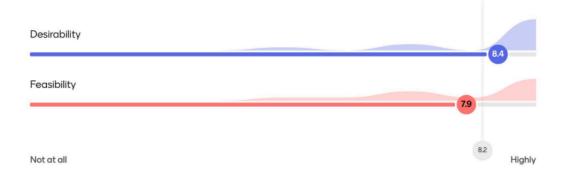


Figure 34. Live Delphi Measure for Proposition 088

Proposition 089 (Supported, Grade Unavailable)

Maryland should create a regulated pathway to support access for individuals with disabilities, those receiving palliative care, and patients with chronic pain (e.g. mobile and home-based psychedelic treatment options, etc.).

This proposition was addressed during a "Live Delphi" round during the Open Meeting on September 25th, 2025. The level of participation (13 of 19, less than 75% of Task Force members present) made consensus calculations unstable, therefore no grade can be assigned. Collective dispositions toward this policy proposition, on scales of both desirability and feasibility, are illustrated with the "Mentimeter" reading below:

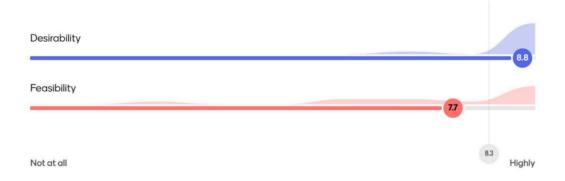


Figure 35. Live Delphi Measure for Proposition 089

Proposition 090 (Supported, Grade Unavailable)

Maryland law enforcement should track with more granularity the substances associated with arrests and crimes, at minimum differentiating natural psychedelic substances (psilocybin/psilocin, dimethyltryptamine, and mescaline, etc.) from synthetic (Ketamine, PCP, etc.)

This proposition was addressed during a "Live Delphi" round during the Open Meeting on September 25th, 2025. The level of participation (13 of 19, less than 75% of Task Force members present) made consensus calculations unstable, therefore no grade can be assigned. Collective

dispositions toward this policy proposition, on scales of both desirability and feasibility, are illustrated with the "Mentimeter" reading below:

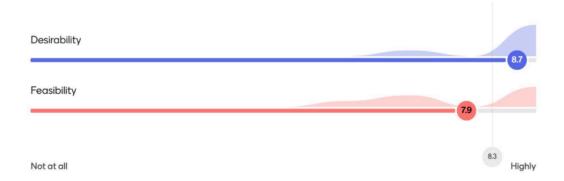


Figure 36. Live Delphi Measure for Proposition 090

Maryland Ensemble Model for Natural Psychedelic Substances Access Programs

Comprehensive Framework

The Maryland Task Force on Responsible Use of Natural Psychedelic Substances has developed and recommends an innovative psychedelics access model for Maryland that represents a fundamental shift in how states can approach psychedelic policy. The proposed comprehensive framework thoughtfully combines multiple access models to meet the diverse needs of Maryland residents seeking safe use of natural psychedelic substances for a range of purposes, rather than forcing all users through a single, potentially restrictive pathway. By implementing complementary access models simultaneously, Maryland can create a robust framework serving different populations while maintaining appropriate safety measures and preventing policy gaps that might drive users toward unregulated markets. This integrated strategy and foundation of the ensemble model received strong Grade A recommendation consensus through **Proposition 002** that "Maryland should implement multiple complementary access models (e.g., deprioritization and medical/therapeutic use) in its initial legislation for natural psychedelic substances."

Initial Focus on Psilocybin with Potential Expansion

The Task Force came to a Grade A consensus on **Proposition 001** that access models should initially focus on psilocybin (natural, not synthetic), with potential expansion to other natural psychedelic substances once initial programs are successfully established. This foundational recommendation establishes a cautious, evidence-based approach to psychedelic policy

implementation that allows Maryland to learn from experience while building toward more comprehensive access.

The Task Force strongly recommends that Maryland's framework be designed from the outset to accommodate expansion to other natural psychedelic substances such as DMT and Mescaline, once the psilocybin program demonstrates success.

The Task Force emphasizes that this phased approach to substance inclusion should not be interpreted as a limitation on the ultimate scope of Maryland's psychedelic policy. Rather, it represents a responsible implementation strategy that allows the state to develop expertise, refine regulatory systems, and build public confidence before expanding to substances with complex regulatory considerations. A systematic expansion based on demonstrated success ensures that Maryland's psychedelic policy evolves through evidence rather than speculation, while maintaining the flexibility to incorporate additional substances as research and implementation experience warrant. This approach positions Maryland as a leader in evidence-based psychedelic policy while respecting the diverse traditional and contemporary uses of natural psychedelic substances. The Task Force affirms the importance of bona fide religious access to natural psychedelic substances. However, the Task Force desires to take more time to develop more nuanced recommendations for a fifth pathway to reflect the balance between Constitutional imperatives, protection of Indigenous rights and practices and sources of sacramental materials, and public safety. The Task Force will address these matters in a subsequent report.

Core Components of the Ensemble Model Framework

The ensemble model weaves together essential components to create a robust and flexible access system, each addressing different population needs and use contexts:

1.) Deprioritization with Civil Penalties and Expungement

This component addresses the immediate harm caused by continued criminalization while other access systems develop. This component ensures that individuals are not penalized for personal use while other components of the comprehensive framework are implemented, and it addresses past injustices through expungement of prior convictions for simple possession. This pathway serves individuals who are engaged in informal community-based approaches, those seeking alternatives to medicalized or commercial systems, and provides a bridge during the transition to regulated access. As stakeholders noted, deprioritization addresses immediate harms from prohibition that include incarceration, criminal records, and family disruption, while

supporting peer networks and traditional practices. Law enforcement agencies would treat personal possession and cultivation as lowest priority (**Proposition 024**, **Grade A**). Civil infractions would replace criminal charges for unauthorized uses (**Proposition 031**, **Grade A**) protections against asset forfeiture (**Proposition 032**, **Grade A**) as well as expungement of prior convictions (**Proposition 033**, **Grade A**).

However, as multiple stakeholders emphasized, "deprioritization alone may not solve problems with illicit/gray markets, questionable safety of unregulated substances, mitigation of public risk through education, abuse by 'bad actors,' etc." Other states and/or jurisdictions prior experience demonstrates that deprioritization can "embolden unscrupulous merchants to sell counterfeit and potentially dangerous products marketed as psilocybin." This limitation underscores the need for complementary pathways that provide regulated access with safety protections.

Expungement: The Task Force strongly recommends expungement of convictions under current Maryland law for simple possession (**Proposition 033 - Grade A**), addressing the accumulated harms of prohibition while supporting the transition to deprioritized enforcement. Expungement received strong support as an essential restorative justice measure addressing past enforcement harms and removing barriers to opportunity. Criminal records for simple possession create lasting consequences including employment discrimination, housing denial, educational barriers, and other collateral consequences that often exceed the severity of the original offense.

Law Enforcement Priority and Training: The Task Force strongly recommends that arrests for simple possession should be the lowest law enforcement priority (**Proposition 024 - Grade A**), with similar protections for personal cultivation (**Proposition 027 - Grade A**). These changes need to be accompanied by comprehensive training (**Proposition 028 - Grade A**) to ensure consistent implementation across Maryland's 23 counties and Baltimore City.

Immediate Justice Measures: For Maryland individuals currently incarcerated solely for simple possession convictions, prosecuting offices should file motions to vacate sentences and order immediate release **(Proposition 086, Supported, Grade Unavailable)**. This ensures individuals don't remain imprisoned for conduct Maryland no longer prioritizes for enforcement.

Complete Penalty Removal: While civil infractions represent the current recommendation, **Proposition 088 (Supported, Grade Unavailable)** recognizes the desirability of removing all penalties (including civil penalties and fines) for possession and personal cultivation. Though initial Task Force feasibility ratings appear mixed, this represents the aspirational goal as implementation matures and demonstrates safety.

Enhanced Data Collection: Maryland law enforcement should track substances with greater granularity (**Proposition 90, Supported, Grade Unavailable**), differentiating natural psychedelic substances (psilocybin, DMT, mescaline) from synthetic substances (ketamine, PCP, LSD). This improved tracking, highly desirable with moderate to high feasibility, enables evidence-based policy decisions and prevents conflation of different substance categories in enforcement statistics. For the same reasons, as a corollary Maryland health authorities should much more specifically track the public health incidents regarding these substances. Current testing and reporting at hospitals, emergency departments, poison control centers, etc. do not adequately differentiate the different substances and different means of administration.

Asset Forfeiture Protections: The Task Force strongly recommends protection from asset forfeiture for possession and personal cultivation of "personal use" amounts **(Proposition 032 - Grade A)**, preventing the seizure of homes, vehicles, or other assets based solely on personal use activities.

Harm Reduction Services: The Task Force recommends establishing harm reduction services (Proposition 026 - Grade B), such as psychedelic first aid training, access to home test kits for purity and potency, and hotlines/websites for adverse events. Harm reduction services are seen by the Task Force as highly desirable public health interventions that reduce risks associated with psychedelic use regardless of legal status. The Task Force also recommends that services should include drug checking programs to identify adulterants and verify potency, crisis intervention services for immediately and appropriately addressing adverse experiences, safe use education, and integration support resources. Testing services are particularly important given variability in natural psychedelic potency and potential contamination risks. Crisis hotlines and trained responders can provide immediate support for difficult experiences, reduce emergency room visits and improve outcomes. Implementation requires training programs for harm reduction workers, funding for testing equipment and facilities, and coordination with healthcare systems for severe adverse events. Success depends on accessibility across Maryland communities, adequate funding, trained staff, and integration with existing substance abuse treatment and mental health services. The approach acknowledges that some use will occur regardless of legal status and focuses on minimizing associated harms.

Public Education: The Task Force strongly recommends that if deprioritization is enacted, public education campaigns should clarify that deprioritization does not equal legalization (**Proposition 030 - Grade A**), addressing confusion observed in other jurisdictions.

2.) The Medical/Therapeutic Use Pathway

This component is a clinically-integrated approach that provides structured clinical supervision and medical expertise for individuals with qualifying conditions and/or who would benefit from professional guidance and monitoring (**Propositions 074-077**, **and 079 - Grade A**).³ This pathway builds on Maryland's existing healthcare infrastructure and incorporates evidence-based therapeutic practices. Ideally, this will also serve as infrastructure to rapidly implement therapeutic approaches that receive FDA approval in the future (**Proposition 084 - Grade A automatic permit access for FDA approved exemptions or rescheduling**).

Provider Authorization and Protection: Licensed healthcare providers would be explicitly authorized to administer natural psychedelic substances (**Proposition 077 - Grade A**). Crucially, lawful administration would not constitute sole grounds for professional licensing discipline (**Proposition 082 - Grade A**), addressing provider liability concerns. The need for clear scope of practice guidelines, explicit guidance from licensing boards, professional liability protections, and safe harbor provisions must be addressed before providers can confidently participate.

No-Fault Compensation System: Maryland would establish a state-wide no-fault alternative to lawsuits (**Proposition 083 - Grade A**), modeled after Florida's NICA program (Neurological Injury Compensation Association, http://nica.com.) This would provide financial protection for both providers and patients while reducing litigation risks that could discourage provider participation.

Clinical Protocols: Comprehensive protocols require preparation, administration, and integration sessions. However, protecting flexibility in the application of the protocols by healthcare providers is essential.

Informed Consent: Licensed healthcare providers must document comprehensive informed consent processes (**Proposition 080 - Grade A**), that set forth the risks, benefits, and alternatives prior to initiating therapy with natural psychedelic substances. Informed consent documentation received strong support as a fundamental medical practice requirement ensuring patient understanding and provider protection.

High-Risk Protection: Restricting individuals at high risk of medical/psychiatric complications to this model **(Proposition 079, Grade A)** ensures vulnerable populations receive appropriate supervision. Veterans are a particularly important vulnerable population given higher rates of PTSD, traumatic brain injury (TBI), chronic pain, and suicide risk. The medical pathway's clinical oversight provides essential protections for veterans with complex trauma histories, polytrauma, and potential medication interactions from VA-prescribed pharmaceuticals. Protection of

high-risk populations received strong support in the Task Force as essential safety measures. Medical supervision provides immediate medical response capabilities, professional oversight, and appropriate screening protocols.

To serve persons with diverse therapeutic needs, Maryland should create regulated pathways for individuals with disabilities, those receiving palliative care, and chronic pain patients through mobile and home-based treatment options (**Proposition 89, Supported, Grade Unavailable**). While assessed as moderately to minimally feasible, given safety infrastructure requirements, this recommendation addresses critical access barriers for populations unable to travel to facilities.

3.) The Supervised Adult Use Pathway

This component creates safe, regulated environments through the use of licensed facilities staffed with licensed facilitators, where adults can access natural psychedelic substances with appropriate safeguards and support systems in place that balances broad accessibility with comprehensive safety measures. (**Proposition 063 - Grade A**). These facilities would provide education, harm reduction resources, and supervised settings for those who prefer structured support without the medical model requirements. Under this framework, adults 21 and older would be able to legally access natural psychedelic substances through state-licensed facilities staffed by trained facilitators (**Proposition 063 - Grade A**). Unlike medical models that require clinical diagnoses or prescriptions, this approach creates wellness-oriented spaces where individuals can explore psychedelics in controlled, supportive environments (**Proposition 064 - Grade A**).

The development of supervised adult use facilities presents its own challenges, requiring establishment of new professional categories, training standards, and safety protocols that must be clearly distinguished from medical practice while maintaining appropriate oversight and emergency response capabilities. The Task Force recognizes that these facilities will need to coordinate with medical systems for participant screening and crisis intervention while operating within their own regulatory framework.

The supervised use framework offers a middle ground between highly medicalized approaches and unregulated personal use, providing professional oversight without requiring medical gatekeeping. Facilities would be subject to regular inspections to ensure compliance with safety standards (**Proposition 075 - Grade A**), while being explicitly prohibited from making therapeutic or medical claims about their services (**Proposition 076 - Grade A**).

Facility Requirements: Facilities must be staffed by licensed facilitators at all times (**Proposition 064 - Grade A**), maintaining specific staff-to-consumer ratios (**Proposition 070 - Grade A**) and maximum participant limits for group sessions (**Proposition 071 - Grade A**). Safety protocols would include emergency medical supplies, communication systems, and comfortable spaces for challenging reactions (**Proposition 072 - Grade A**). Regular inspections would ensure ongoing compliance (**Proposition 075 - Grade A**).

Facilitator Training and Certification: The establishment of comprehensive training and certification requirements (Proposition 065 - Grade A) is a cornerstone of the supervised use model. Maryland would need to develop robust educational programs that balance theoretical knowledge with practical skills. Healthcare providers could participate within their scope of practice (Proposition 066 - Grade A), while non-medical facilitators would require specialized training. Requirements for supervised use facilitators of natural psychedelic substances should allow participation by licensed health care providers acting within the scope of their professional training and practice. Healthcare provider participation received strong support while acknowledging scope-of-practice complexities. This highlights the need for inclusive credentialing pathways that recognize both formal education and experiential knowledge, supported by low-cost online training options (Proposition 019 - Grade A) as well as incorporation of the aforementioned provider protections. Success requires clear guidelines defining healthcare provider roles, coordination with existing professional licensing requirements, and training that addresses unique aspects of psychedelic facilitation distinct from traditional medical practice.

Implementation should clarify scope of practice boundaries, establish role definitions distinguishing medical from facilitation services, and coordinate with professional licensing boards. Healthcare providers bring valuable medical training while potentially expanding the qualified facilitator pool.

Consumer Screening and Preparation: Comprehensive screening by licensed health professionals (**Proposition 067 - Grade A**) would help identify individuals at higher risk for adverse reactions.

Following screening, mandatory preparation sessions (**Proposition 068 - Grade A**) would educate participants, establish trust with facilitators, set intentions, and develop coping strategies.

Integration Support: Facilities would be required to offer integration support **(Proposition 069 - Grade A)**, helping consumers process experiences and translate insights into meaningful life changes. Research demonstrates that integration significantly impacts long-term outcomes.

Affordability Measures: A persistent challenge involves cost barriers limiting access to affluent individuals, with Oregon session costs ranging from \$400 to over \$3,000. Facilities would be required or incentivized to offer affordable options (**Proposition 074 - Grade A**), including sliding scale fees or patient discount programs. Natural psychedelics must be affordable and available to everyone, not just people of means.

Accessibility for Vulnerable Populations: To serve diverse therapeutic needs the Task Force recommends that Maryland should create regulated pathways supporting access for individuals with disabilities, those receiving palliative care, and chronic pain patients through mobile and home-based treatment options (Proposition 89, Supported, Grade Unavailable). While highly desirable, moderate to low feasibility reflects challenges of maintaining safety standards outside fixed facilities. This flexibility particularly serves populations for whom facility-based care creates insurmountable barriers.

Prohibition on Medical Claims: Facilities would be explicitly prohibited from making therapeutic or medical claims (**Proposition 076 - Grade A**), maintaining clear boundaries between supervised adult use and medical treatment while allowing descriptions of services in terms of personal growth, wellness, or spiritual exploration.

4.) The Commercial Sales Pathway

This component creates a regulated marketplace that provides quality-controlled products while generating revenue to support public education, equity programs, and system monitoring (Propositions 041-044 - Grade A for commercial sales). Under this framework, Maryland would create a comprehensive regulatory system that allows licensed businesses to cultivate, test, and sell natural psychedelic substances to qualified adult residents (Proposition 041 - Grade A). This component and pathway recognize that many adults prefer the autonomy and convenience of purchasing products for personal use, similar to other regulated substances. The Task Force believes that with the education, harm reduction, and licensing features, this component meets the requirements of public safety and protection. Integration with other access pathways would be essential for program success. Consumers with licenses obtained for commercial purchase might also want to access therapeutic services or participate in religious ceremonies, requiring coordination between different regulatory frameworks. The advisory board monitoring system (Proposition 010 - Grade A) would play a crucial role in ensuring the commercial model operates harmoniously with other access pathways.

Regulatory Structure: Maryland would establish state-licensed private dispensaries **(Proposition 043 - Grade A)**, allowing market competition while maintaining strict oversight.

While state-owned outlets were considered, this approach received insufficient support (**Proposition 042 - Grade I**).

Individuals wishing to access psychedelic substances outside of regulated settings (e.g. supervised use facilities) would be permitted/licensed (**Proposition 004 - Grade A**). The permitting/licensing process may require appropriate medical and psychiatric screening by a licensed health professional (e.g. Medical Cannabis Registration) (Proposition 005 - Grade C) and/or completion of a mandatory course and exam (Proposition 006 - Grade C).

The commercial model would incorporate participation requirements (**Proposition 018 - Grade A**), prioritizing applicants from groups disproportionately impacted by drug policies from 1973 to 2023, and remaining inclusive of individuals across race, religion, ability, education, economic resources, geographic location, and other demographic factors which impact participation in industry or access to health care

Product Safety and Quality Assurance: Consumer safety stands at the forefront of the commercial sales model through multiple layers of protection. All commercially sold substances would undergo mandatory testing (**Proposition 046 - Grade A**) for potency, contamination, and adulterants. Commercial psychedelic packaging should include standardized warning labels (**Proposition 048 - Grade A**),- Products must be packaged in single-dose quantities within child and pet-proof containers, clearly labeled for potency (**Proposition 049 - Grade A**), addressing critical safety concerns about preventing accidental ingestion.

Production Controls: Maryland would establish production quotas (**Proposition 051 - Grade A**) to prevent oversupply and maintain market equilibrium.

Marketing Restrictions: Marketing targeting minors would be explicitly prohibited **(Proposition 047 - Grade A)**, and commercial vendors would be prohibited from making therapeutic or health claims **(Proposition 050 - Grade A)**, preventing misleading advertising while maintaining clear distinctions between commercial and medical/therapeutic access models.

Record-Keeping: Commercial vendors would maintain detailed sales records (**Proposition 052 - Grade A**), contributing to the statewide data collection system while protecting personally identifiable information.

Revenue: The commercial model would be revenue-neutral or revenue-generating (**Proposition 007 - Grade B**), with tax revenues potentially offsetting costs of other programs and supporting public education. Maryland businesses would have access to state income tax deductions for qualified business expenses (**Proposition 053 - Grade A**), ensuring fair tax treatment.

Equity: Participation requirements prioritize applicants from communities disproportionately impacted by drug policies and encourage inclusion of individuals across race, religion, ability, education, economic resources, geographic location, and other demographic factors which impact participation in industry or access to health care. **(Proposition 018, Grade A).**

The Philosophy Behind the "Ensemble" Approach

The "ensemble" model is a paradigm shift from the traditional single-pathway approaches that have characterized most drug policy reforms. This multi-faceted framework acknowledges the reality that Marylanders seeking access to natural psychedelic substances come from vastly different backgrounds, have varying needs and circumstances, and hold diverse preferences for how they wish to engage with these substances. Some individuals may benefit significantly from clinical supervision and medical expertise, particularly those dealing with treatment-resistant mental health conditions. Others may be seeking personal growth, spiritual exploration, or relief from specific conditions like PTSD, cluster headaches, or chronic pain, and have a need for accessible and flexible pathways. No single access model can meet all legitimate needs and responsible uses of psychedelic substances.

The rationale for this comprehensive approach became particularly clear through public stakeholder input and illustrated why **a one-size-fits-all approach would fail to serve many Marylanders** who could benefit from these substances. The ensemble approach acknowledges diverse use practices from medical treatment to personal growth, spiritual practices, and harm reduction.

The Task Force explicitly rejected the alternative of taking no action while awaiting federal developments. **Proposition 085**, which suggested Maryland should take no specific action to expand access to natural psychedelic substances while awaiting review of ongoing FDA studies and DEA rescheduling, received no consensus grade. This approach would maintain current prohibition and deny Maryland residents potential benefits while federal processes remain slow and uncertain. The Task Force determined that proactive state-level policy development better serves Maryland residents while federal policy evolves, positioning the state to integrate federal changes when they occur rather than remaining passive.

The Task Force's approach and recommendations have emerged from extensive stakeholder engagement and careful consideration of real-world needs. Over the course of 8 months, the Task Force conducted comprehensive public hearings, received written testimony from diverse stakeholders including healthcare providers, researchers, patients, religious practitioners, harm

reduction specialists, policy experts, and community advocates. The Task Force also reviewed evidence from other jurisdictions implementing psychedelic access programs, consulted with subject matter experts on clinical applications and safety protocols, and analyzed current research on therapeutic applications, risks, and best practices. This deliberative process involved grading each proposition through a rigorous consensus methodology, with recommendations categorized as Grade A (strongly recommended), Grade B (moderately recommended), Grade C (conditionally recommended), Grade I (insufficient consensus), or Grade S (needs further study).

Integration of Conditional Recommendations

The ensemble model's strength lies in its thoughtful integration of conditionally recommended propositions (Grade C) where specific implementation conditions can address stakeholder concerns while advancing policy goals. For example, medical screening requirements for permits (Proposition 005 - Grade C) are included with explicit conditions ensuring accessibility, affordability, and appeals processes. Similarly, mandatory education requirements (Proposition 006 - Grade C) are incorporated with conditions guaranteeing state-provided low-cost options, cultural responsiveness, and reasonable standards.

This approach demonstrates that the ensemble model embraces nuanced policy solutions rather than rejecting complex issues that require careful implementation. By specifying the conditions necessary for successful implementation of moderately and conditionally supported propositions, Maryland can address legitimate concerns while maintaining comprehensive access options.

Phased Implementation Strategy

The Task Force recommends that the Maryland General Assembly consider a carefully structured phased approach to implementing the ensemble model, recognizing that the complexity of establishing multiple complementary access pathways requires strategic coordination of diverse stakeholders, regulatory systems, and professional frameworks. This phased approach operationalizes the strong **Grade A consensus in Proposition 002** that "Maryland should implement multiple complementary access models (e.g., deprioritization and medical/therapeutic use) in its initial legislation for natural psychedelic substances" by ensuring that all pathways can be launched in a coordinated manner once essential infrastructure is established.

The Task Force recognizes that implementing such a comprehensive framework requires careful sequencing and coordination, with particular attention to scope of practice issues that may significantly affect the viability and safety of different pathways. However, the order of implementation must carefully consider professional regulatory frameworks and safety concerns raised by medical organizations and health care providers.

The Task Force's recommendation for simultaneous implementation of multiple pathways does not mean that all components must activate on the exact same day, but rather that Maryland should avoid the sequential approach seen in other jurisdictions where implementing one pathway causes others to "languish,"and/or bolster black and gray markets. Instead, the phased strategy establishes foundational systems that support all pathways equally, followed by a coordinated launch of medical, supervised adult use, and deprioritization pathways, with commercial sales following once product safety systems are operational.

The Task Force's analysis reveals that implementation sequencing will significantly impact both program success and long-term sustainability. The intersection of healthcare regulation, professional licensing requirements, liability frameworks, and public safety considerations creates a complex implementation environment requiring careful navigation. Healthcare providers have expressed the need for clear guidance about their roles, legal protections, and scope of practice before participating in any psychedelic access program.

Professional medical organizations have raised substantive concerns about scope of practice delineation, professional liability protections, informed consent requirements, and the need for explicit regulatory guidance from licensing boards. These concerns are particularly acute given the novel nature of psychedelic facilitation and its relationship to traditional medical practice but also extend beyond simple administrative matters to fundamental questions about boundaries between medical practice and facilitation services, adequacy of screening protocols conducted by non-physicians, and establishment of appropriate liability frameworks that protect both providers and participants while enabling program operation.

Patient and participant safety emerges as the overarching consideration that must be addressed across all access pathways. This includes developing comprehensive screening and evaluation processes that can identify contraindications and risk factors while maintaining program accessibility for appropriate candidates. The integration of medical oversight with various access models presents both opportunities and challenges that may influence implementation timing to ensure adequate support systems and emergency response capabilities are established.

The Task Force also recognizes that successful implementation requires coordination with existing state regulatory systems whose experience with regulated substance programs provides

valuable institutional knowledge for avoiding common implementation pitfalls while adapting proven regulatory approaches to the unique characteristics of psychedelic substances.

The Task Force recommends the following phased implementation strategy that honors the simultaneous pathway approach while ensuring adequate preparation:

Phase 1: Regulatory Infrastructure, Professional Framework Development and Restorative Justice Measures

- Establish comprehensive advisory board with medical and legal expertise (Proposition 010 - Grade A)
- Develop clear scope of practice guidelines distinguishing medical and facilitation roles
- Create professional licensing protections and safe harbor provisions (Proposition 082 -Grade A)
- Implement liability protection frameworks including no-fault compensation systems (Proposition 083 Grade A)
- Launch public education programs and monitoring systems (Propositions 012, 014 -Grade A)
- Develop training and certification programs for facilitators (**Proposition 065 Grade A**)
- Establish testing laboratory licensing and protocols (**Proposition 046 Grade A**)
- Create law enforcement training programs on deprioritization policies (Proposition 028 -Grade A)
- Begin expungement of convictions under current Maryland law for simple possession (**Proposition 033 Grade A**),
- including immediate release motions for those incarcerated solely for simple possession (**Proposition 086, Supported, Grade Unavailable**)
- Consider transitioning from civil infractions to complete penalty removal for personal amounts (**Proposition 088, Supported, Grade Unavailable**)

Phase 2: Coordinated Pathway Launch with Medical Oversight

- Implement deprioritization measures to prevent continued criminalization (Propositions 024, 031 - Grade A)
- Launch medical pathway with clear scope of practice protections for providers (Propositions 077-082 Grade A)
- Begin supervised adult use facilities with medical screening requirements (Propositions 063-076 - Grade A)

- Activate personal cultivation permits with education requirements (Propositions 004-006)
- Initiate comparative research programs examining traditional versus Western-medicine contexts (**Proposition 087, Supported, Grade Unavailable**)
- Implement regular policy review processes (Proposition 020 Grade A)

This coordinated launch ensures that medical, supervised adult use, and deprioritization pathways all become operational within the same general timeframe, fulfilling the simultaneous implementation vision while ensuring each pathway has adequate support systems.

Phase 3: Full System Operation and Expansion

- Activate commercial sales once testing and quality control systems are operational (Propositions 041-053 - Grade A)
- Expand access based on demonstrated safety outcomes and provider confidence
- Evaluate readiness for expanding to additional natural psychedelic substances (**Proposition 001 Grade A**)

This approach addresses scope of practice concerns by ensuring clear professional frameworks are established before implementation, while maintaining the ensemble model's commitment to multiple access pathways launching in close coordination rather than years apart. The distinction between Phase 1 (preparation) and Phase 2 (coordinated launch) operationalizes Proposition 002's call for simultaneous implementation by creating the conditions necessary for multiple pathways to succeed together.

Success depends on establishing clear professional frameworks, comprehensive liability protections, and robust safety protocols before implementation begins, recognizing that professional confidence and regulatory clarity are prerequisites for sustainable program operation across all access pathways within the ensemble model.

Access Structure

The ensemble model creates multiple regulated sources to ensure quality and safety across all pathways. Licensed commercial cultivators and retailers serve the commercial marketplace, operating under strict quality control and testing requirements. The Task Force emphasized that "all commercially sold natural psychedelic substances should undergo mandatory testing at

state-licensed laboratories" **(Proposition 046 - Grade A)** to ensure "product safety, potency accuracy, and contamination prevention."

Medical and therapeutic providers maintain quality-controlled supplies specifically for clinical use, ensuring appropriate potency and purity where precise dosing and consistent effects are crucial for treatment outcomes. Supervised adult use facilities source from licensed suppliers while maintaining their own quality assurance protocols. Under deprioritization, personal cultivation within defined limits provides the most autonomous access option while maintaining some regulatory oversight.

Access criteria vary by pathway, reflecting different safety needs and policy goals. The permitting system (**Proposition 004 - Grade A**) received strong support as a mechanism "balancing personal autonomy with public safety." The Task Force noted that permitting "solves the issue of differentiating between religious versus secular use" while ensuring users receive appropriate education and screening.

Medical pathway access requires qualifying diagnoses, this proposition received conditional support requiring careful implementation to avoid excluding legitimate uses while ensuring medical and clinical oversight, particularly for high-risk populations (**Proposition 079 - Grade A**). Supervised adult use requires medical screening (**Proposition 067 - Grade A**) but not formal diagnoses, balancing safety with accessibility. Commercial sales require active use licenses (**Proposition 045 - Grade A**), coordinating with educational and potentially screening requirements. Deprioritization provides the lowest barrier to access, though civil penalties may apply for unlicensed use.

However, stakeholders raised important considerations about screening requirements. While **Proposition 005 received conditional (Grade C)** support for medical screening, implementation risk must avoid creating barriers. Implementation conditions should include evidence-based screening criteria, affordable fee structures, and appeals mechanisms.

The model designates appropriate locations for different types of use, recognizing that setting plays a crucial role in psychedelic experiences and safety outcomes. Licensed therapeutic facilities provide clinical environments with medical supervision, trained staff, and emergency protocols tailored to psychedelic experiences. Supervised adult use facilities offer safe, supportive settings with trained facilitators and harm reduction resources. Commercial sales through dispensaries ensure product quality while providing point-of-sale education. Private residences remain available for permitted personal use under both commercial and deprioritization pathways, acknowledging that many individuals prefer familiar environments.

Safety, Equity, and Oversight Measures

Central to the success of the recommended integrated model are the implementation of comprehensive safety measures that apply across all access pathways. Mandatory public education campaigns would ensure that all Marylanders have access to evidence-based information about risks, benefits, and safe use practices (**Proposition 012 - Grade A**). Harm reduction materials would be provided at all points of access (**Proposition 013 - Grade A**) giving users the information and resources they need to minimize risks and maximize benefits.

Under deprioritization, harm reduction services (**Proposition 026 - Grade B**) would include designated safe spaces, psychedelic first aid, access to test kits, and hotlines for adverse events. Marketing targeting minors would be explicitly prohibited All commercially sold substances would undergo mandatory testing for potency, contamination, and adulterants. All packaging should include standardized warning labels, are in single dose quantities, and are child and pet resistant Products must be packaged in single-dose quantities within child and pet-proof containers, clearly labeled for potency addressing critical safety concerns about preventing accidental ingestion (**Proposition 046, 047, 048, 049 - Grade A**).

Public education becomes particularly crucial under deprioritization, where the Task Force strongly recommends that campaigns clarify that deprioritization does not equal legalization (**Proposition 030 - Grade A**). Public education should also communicate risk factors, such as personal contextual factors which impact likelihood of adverse events and risk-reduction strategies (**Proposition 012 - Grade A**). Like past successful public health campaigns (e.g. designated driving), public education can fill critical gaps in public knowledge toward informed decision-making, reductions in avoidable harms, and wide adoption of safer practices.

The framework establishes robust data collection and monitoring systems to track outcomes across all pathways, measuring costs, revenues, prevalence of use, adverse incidents, efficacy, and equity impacts (**Proposition 014 - Grade A**). This comprehensive monitoring system, supported will enable evidence-based policy adjustments and help identify what works best for different populations and purposes. The Task Force emphasized that monitoring should track multiple outcome measures including public health impacts, economic effects, utilization patterns, safety events, and equity indicators while maintaining strict privacy protections through **Proposition 015 - Grade A**, which received unanimous support for excluding personally identifiable information. Maryland would need innovative approaches to track prevalence and safety through emergency department data, law enforcement statistics, and voluntary surveys. The monitoring system provides essential data for the regular policy review process (**Proposition 020 - Grade A**) and potential sunset provisions (**Proposition 021 - Grade C**).

An advisory board with representatives from diverse stakeholder groups would provide ongoing oversight and recommend adjustments based on real-world outcomes and emerging evidence (**Proposition 010 - Grade A**). The Task Force noted that diverse representation ensures multiple perspectives inform ongoing policy refinement and prevents capture by narrow interests. The board could encourage the planning to support clinical services, develop policy modifications needed for implementation, and monitor for market monopolies to ensure affordability and access.

Environmental sustainability requirements for cultivation operations ensure responsible industry development (**Proposition 017 - Grade A**).

Equity considerations are woven throughout the ensemble model, reflecting the task force's Grade A recommendation of **Proposition 018** that "Maryland should take measures to ensure diverse participation in psychedelic industries and services, prioritizing applicants representing groups disproportionately impacted by drug policies enacted from 1973 to 2023." This includes priority licensing for affected communities, environmental sustainability requirements for cultivation operations (**Proposition 017 - Grade A**), and low-cost training options to reduce barriers to participation in the emerging industry (**Proposition 019 - Grade A**) ensuring economic circumstances don't prevent qualified individuals from entering the industry or accessing educational resources. The expungement recommendation directly addresses historical harms from prohibition. (**Proposition 088 - Supported, Grade Unavailable**)

Legal Protections and Social Safeguards

The ensemble model incorporates important protections for lawful users across all pathways, recognizing that responsible adult use should not result in collateral consequences that harm individuals or families. **Proposition 008 -** Grade A ensures that "lawful personal use or possession of natural psychedelic substances in and of itself is not grounds for child abuse/neglect proceedings," protecting families from unnecessary interventions based solely on legal substance use. Adoption of these safeguards recognizes that responsible adult use should not result in collateral consequences that harm individuals or families.

Additionally, **Proposition 009 - Grade B** provides moderate protection from "discrimination in employment or housing based on their lawful personal use," acknowledging that while full protections may take time to develop, basic safeguards against discrimination are essential for successful implementation.

Additional protections include whistleblower safeguards for those reporting safety concerns (**Proposition 011 - Grade A**).

For medical providers, **Proposition 082 - Grade A** ensures lawful administration would not constitute grounds for professional licensing discipline, addressing critical provider participation concerns. The no-fault compensation system **(Proposition 083 - Grade A)** provides additional liability protection essential for enabling provider participation.

Financial Sustainability and Long-term Viability

The ensemble model addresses financial sustainability through a revenue-neutral or revenue-generating approach that leverages income from commercial sales and licensing fees to support public education, monitoring, equity programs, and system administration (**Proposition 007 - Grade B**). This self-sustaining financial model reduces the burden on general state revenues while ensuring adequate funding for all components of the framework. By establishing diverse revenue streams-including facility licensing fees, practitioner certifications, product testing charges, and sales-based assessments- the psilocybin system creates a robust financial foundation that can scale with market growth while maintaining regulatory oversight.

The precedent established by Maryland's cannabis reform demonstrates the viability of this revenue-generation model for emerging therapeutic and wellness substances. Despite critical differences from cannabis in agricultural needs, facilitated support, use practices, market drivers, etc., psilocybin represents another substance transitioning from prohibition to regulated access, requiring initial infrastructure investment that can be recouped through ongoing operational revenues. Both substances necessitate comprehensive regulatory frameworks encompassing licensing, testing, education, and equity initiatives-all of which require sustained funding. The cannabis model has shown that appropriately structured fee schedules and revenue allocations can support robust regulatory programs without requiring ongoing general fund appropriations, a principle directly applicable to psilocybin implementation.

Furthermore, both cannabis and psilocybin share common regulatory needs that inform financial planning: quality control and product testing infrastructure, consumer education campaigns, workforce training and certification systems, social equity program administration, public health monitoring and research, and enforcement and compliance mechanisms. The financial architecture developed for cannabis-balancing accessibility through reasonable fee structures while generating sufficient revenue for comprehensive oversight- provides a tested template for psilocybin's fiscal framework. This parallel approach allows Maryland to leverage institutional

knowledge and administrative efficiencies while establishing psilocybin's financial independence from the outset.

The task force incorporated lessons learned from Maryland's experience with regulated substance markets, recognizing that successful long-term viability requires financial models that adapt to market maturation. The comprehensive data collection system (**Proposition 014** - **Grade A**) will enable evidence-based policy adjustments and help identify what works best for different populations and purposes, while also informing financial forecasting and fee structure optimization. Real-time tracking of licensing volumes, service utilization patterns, revenue generation, and program costs will allow for dynamic budget adjustments that maintain fiscal stability across varying market conditions.

Looking toward the future, the ensemble model includes provisions for regular review and reauthorization based on demonstrated outcomes (**Proposition 020 - Grade A**) for regular policy review).²² This commitment to systematic evaluation extends beyond regulatory compliance to encompass financial sustainability metrics, ensuring that revenue generation keeps pace with programmatic needs and that fee structures remain equitable as the market matures. Annual financial audits, multi-year budget projections, and cost-benefit analyses will be integrated into the review process, providing transparency and accountability to stakeholders and policymakers.

Sunset provisions as suggested in **Proposition 021 - Grade C** would require legislative reauthorization after a specified period "based on evidence of safety, efficacy, and equity impacts," ensuring that the framework evolves based on real-world evidence rather than initial assumptions. These provisions create natural checkpoints for evaluating whether the financial model is achieving its intended goals: supporting comprehensive regulation without creating barriers to access, adequately funding equity initiatives, enabling quality research and monitoring, and maintaining administrative efficiency. This periodic reauthorization process also provides opportunities to benchmark Maryland's approach against other jurisdictions, incorporating innovations and best practices as the national landscape for psilocybin policy develops.

This adaptive approach positions Maryland to be a leader in evidence-based psychedelic policy while maintaining the flexibility to adjust course as new information emerges. Financial sustainability is not viewed as a static achievement but as an ongoing optimization process that responds to market dynamics, public health data, equity outcomes, and stakeholder feedback. This iterative model ensures that Maryland's psilocybin framework remains financially viable across the full spectrum of implementation phases-from initial infrastructure development

through market stabilization and eventual maturation-while preserving the core commitment to public health, safety, and equitable access that defines the ensemble approach.

Basic Functions of the Maryland Model

Where substances come from:

- Licensed commercial cultivators and retailers for commercial sales
- Medical/Therapeutic providers with quality-controlled supplies for medical use, and potentially
- Personal cultivation for permit holders for personal cultivation with appropriate permits
- **Who uses it:** Adult Maryland residents who meet criteria depending on their chosen pathway:
 - Those with qualifying medical conditions accessing medical/therapeutic providers with quality-controlled supplies (**Propositions 074-079 - Grade A**) for medical use and/or therapeutic services
 - o Personal use for Adults 21 and over (**Propositions 004-006 Grades A and C**)

• Where it is used:

- Licensed therapeutic facilities (Proposition 074 Grade A)
- Licensed supervised adult use facilities (Proposition 063 Grade A)
- Private residences for permitted personal use (Proposition 009 Grade B)

Safety measures:

- Supervised use facilities:
 - Should be adequately staffed by trained licensed facilitators and/or licensed health care providers (**Proposition 067-073,075 Grade A**).
 - Medical and psychiatric screening, required preparation sessions, integration support, staffing ratios, on-hand safety equipment, and maintain adequate records to track adverse events (Proposition 063-066 -Grade A).
- Mandatory public education campaigns (Proposition 012 Grade A).
- Harm reduction materials provided at point of access (**Proposition 013 Grade A**).
- Comprehensive data collection and monitoring (Proposition 014 Grade A).

• Whistleblower protections (**Proposition 011 - Grade A**).

Environmental and equity safeguards:

- Environmental sustainability requirements for cultivation (Proposition 017 -Grade A).
- Measures to ensure diverse industry participation (**Proposition 018 Grade A**).
- Low-cost online training options to reduce barriers (**Proposition 019 Grade A**).
- Incentives to offer affordable options for care (i.e. reduced fees and licensing permits for providers that offer low cost and sliding scale options) (**Proposition 074 - Grade A**)

• Legal protections:

- Lawful personal use cannot be grounds for child abuse/neglect proceedings (Proposition 008 - Grade A).
- Protection from employment and housing discrimination for lawful use
 (Proposition 009 Grade B).
- Oversight through diverse stakeholder advisory boards (Proposition 010 Grade A).

• Financial sustainability:

- Revenue-neutral or revenue-generating implementation across all programs (Proposition 007 - Grade B).
- Regular policy reviews (**Proposition 020 Grade A**).
- Potential sunset provisions requiring reauthorization based on evidence (Proposition 021 - Grade C).

Access Models Requiring Further Development

Religious Use

The approach of taking "no specific action at this time to expand access to natural psychedelic substances for religious use, awaiting updates by the DEA to the petition process for religious exemptions from the Controlled Substances Act (CSA) under the Religious Freedom Restoration Act (RFRA)" (**Proposition 54**) received insufficient consensus, reflecting the complex constitutional and practical considerations surrounding state regulation of religious practice.

Important progress was made in identifying key components of potential religious protections. The propositions that "Maryland should proactively provide established religious organizations protected rights to use natural psychedelic substances as sacraments under state law" (**Proposition 55**) and "Production and cultivation of natural psychedelic substances should be allowed for Religious Organizations for use as sacraments" (**Proposition 56**) both achieved Grade B status as moderately recommended. This moderate support indicates viable pathways forward once implementation details are resolved.

Significantly, there was **strong Grade A** consensus on three essential features of a religious pathway: (1) the implementation of "safety protocols for ceremonies" (**Proposition 57**), (2) organizational "registration" with state authorities (**Proposition 59**), and (3) requirements to "maintain records of any adverse effects" (**Proposition 62**). These elements provide a foundation for responsible religious use that prioritizes participant safety while respecting religious autonomy.

Reservations about structuring the religious use pathway were found in the insufficient consensus regarding (1) "regulation and certification of religious leaders who would administer" the sacramental materials (**Proposition 58**), (2) the participation of minors with parental consent (**Proposition 60**), and (3) requirements that ceremonies be restricted to "designated worship spaces" (**Proposition 61**). These areas of disagreement reflect unresolved tensions between potential state safety concerns and bedrock constitutional religious freedom protection.

The Task Force received substantial input from organizations and individuals currently using natural psychedelic substances in worship and ceremonial practice, many noting the three and one-half century history of robust protection of the free exercise of religion in Maryland. This historical context emphasizes the importance of resolving the tension between strong Grade A consensus on certain safety features of a religious pathway, coupled with moderate consensus on propositions "protecting" and "allowing" religious organizations.

This unresolved tension suggests that religious use protections may develop through separate legal and regulatory processes rather than as an integrated component of the initial ensemble implementation. The strong consensus on safety protocols and registration processes provides a framework that could be activated when constitutional and practical implementation issues are resolved, whether through federal policy changes, court decisions, or additional stakeholder engagement and legal analysis involving religious law experts, constitutional scholars, and traditional practice holders.

Peer Sharing and Non-Commercial Distribution

The Task Force encountered significant challenges achieving consensus on peer sharing frameworks for natural psychedelic substances. **Proposition 034 (Grade B)** moderately recommended allowing qualified adults to cultivate and gift small quantities to other qualified adults without compensation as well as limited liability protections for community based organizations (**Proposition 039, Grade B**),

The tension between protecting genuine peer sharing while preventing commercial exploitation created implementation complexities. **Proposition 037 (Grade I)** received insufficient consensus on limiting non-commercial cultivation and sharing to state-licensed community-based organizations.

Related propositions on documentation requirements for community-based organizations (**Proposition 038, Grade C**), and health claims prohibitions (Proposition 040, Grade S) all received conditional or insufficient support. The Task Force recognized that while peer sharing serves important community functions and traditional practices, preventing commercial exploitation through definitional loopholes remains a critical challenge requiring additional legal analysis, stakeholder input, and potentially learning from other states' experiences.

Protection for sharing cultivation knowledge and techniques received strong support (**Proposition 035**, **Grade A**), recognizing that educational information about safe cultivation practices serves public health interests. However, the broader peer sharing framework may develop separately from initial ensemble implementation, potentially through later legislative refinement once commercial and regulated pathways are established and lessons learned about preventing gray market exploitation.

Areas Requiring Further Study

Two propositions received "Grade S - Needs Further Study" designations, indicating areas where the Task Force recognized importance but determined that additional research and analysis were necessary before making definitive recommendations. **Proposition 023**, addressing consumption in approved sites versus public spaces, requires additional study to develop appropriate frameworks balancing public safety with practical access needs. The complex distinction between "approved sites" and "public spaces" and the development of approval processes for consumption venues need further stakeholder input and legal analysis.

Proposition 040, concerning prohibitions on therapeutic or health claims in peer sharing contexts, needs further study to balance consumer protection with free speech rights and practical enforcement challenges. The intersection of First Amendment protections with consumer safety in non-commercial contexts requires additional legal analysis and stakeholder engagement to develop appropriate frameworks.

These areas of continuing study would benefit significantly from the expanded expertise recommended above, particularly input from legal scholars specializing in First Amendment issues, public health professionals experienced with venue-based interventions, community advocates familiar with peer support models, and policy experts from the Medical Cannabis Administration who have navigated similar regulatory challenges in cannabis implementation.

Looking Forward

This ensemble model is more than simply a policy framework - it embodies Maryland's commitment to evidence-based governance, social equity, and individual autonomy. Simultaneously implementing multiple access pathways rather than sequential rollouts, allows Maryland to avoid the pitfall of having an early-implemented model *crowd out* other necessary approaches. The comprehensive data collection and monitoring systems will generate invaluable evidence for other jurisdictions considering similar reforms.

The phased implementation strategy acknowledges the complexity of launching such a comprehensive system while ensuring that essential safety and oversight mechanisms are established from the beginning. The financial sustainability model, drawing revenue from commercial operations to fund public education, equity programs, and system monitoring, creates a self-sustaining framework that reduces burden on general state resources.

Perhaps most importantly, the ensemble model recognizes the fundamental dignity and autonomy of adult citizens while maintaining appropriate safeguards for public health and safety. Whether someone seeks relief from cluster headaches through home-based micro-dosing protocols, therapeutic support for treatment-resistant PTSD, or personal growth through supervised ceremonial use, the framework provides appropriate pathways with corresponding protections and support systems.

The Maryland Task Force is recommending a model that other states can adapt to their own circumstances and values. By prioritizing evidence over ideology, equity over exclusion, and flexibility over rigid adherence to single approaches, Maryland is positioned to demonstrate that

thoughtful, comprehensive drug policy reform can enhance both individual wellbeing and community safety. The ensemble model stands as a testament to what becomes possible when policymakers engage earnestly with stakeholders, follow the evidence, and design systems that serve real human needs rather than abstract policy preferences.

Expanding Expertise for Implementation Success

As Maryland moves toward implementing this comprehensive ensemble model, the Task Force recognizes the critical importance of expanding its membership and/or the continuance of establishing ongoing official collaboration with agencies and professionals whose specialized expertise will be essential for creating robust and viable access pathways to natural psychedelic substances. The complexity and novelty of psychedelic policy implementation requires expertise that extends beyond the current Task Force composition to ensure successful program development and operation.

The Task Force particularly recommends leveraging the expertise of policy professionals from existing Maryland agencies, such as the Maryland Cannabis Administration (MCA), whose experience implementing and managing Maryland's medical cannabis program provides invaluable insights directly applicable to psychedelic policy development. The MCA's institutional knowledge of regulated substance programs, including licensing procedures, facility inspections, product testing protocols, patient registration systems, and regulatory compliance monitoring, offers a proven foundation for adapting successful regulatory frameworks to psychedelic substances.

Policy experts from the MCA can provide crucial guidance on avoiding implementation pitfalls encountered during cannabis program development, streamlining regulatory processes for efficiency and accessibility, adapting existing testing and quality control protocols for psychedelic substances, and integrating psychedelic programs with existing medical cannabis infrastructure where appropriate. Their experience with stakeholder engagement, public education campaigns, and ongoing program refinement will be particularly valuable for psychedelic program implementation. Additionally, their insights into regulatory compliance, product handling, security protocols, consumer education, inventory tracking, and retail operations can help avoid implementation pitfalls while building on successful regulatory frameworks already established in Maryland.

The Task Force also recommends expanding collaboration to include specialized professionals such as mycologists who can provide essential expertise on cultivation standards, species

identification, contamination prevention, and quality control protocols specific to psilocybin-containing mushrooms. Their knowledge will be particularly valuable for developing safety standards for personal cultivation permits, establishing commercial cultivation licensing requirements, and creating testing protocols that ensure product safety and potency consistency.

The Task Force recommends expanding collaboration to include economists with expertise in analyzing public health impact, toward conducting evidence-based cost-benefit analysis, improving resource allocation, and evaluating healthcare issues and outcomes.

The Task Force also recommends establishing formal collaboration structures with medical organizations and/or healthcare professionals specializing in psychedelic therapy, including psychiatrists, psychologists, and other mental health professionals who are developing expertise in psychedelic-assisted treatment. Their input will be crucial for developing medical pathway protocols, training requirements for therapeutic providers, and safety standards for clinical psychedelic administration.

The Task Force recommends further differentiating between religious and traditional/indigenous use, which exist with different use practices and cultural contexts, yet are erroneously represented by one individual seat among the Task Force membership. The addition of another seat, and separating the roles of "one representative of a Native American tribe with experience in the spiritual use of psychedelic substances" and "one individual with expertise in religious use of psychedelic substances" would provide representation consistent with the authorizing bill's intention. Additionally, the inclusion of a constitutional lawyer could provide needed expertise into issues of free exercise of religion, First Amendment violations, disputes impacting religious organizations, and navigation of complex federal laws such as the Religious Freedom Restoration Act (RFRA).

Additionally, ongoing collaboration with traditional and indigenous knowledge holders, religious leaders from communities with established psychedelic traditions, harm reduction specialists, public education specialists, law enforcement professionals experienced with drug policy implementation, and community advocates representing populations disproportionately impacted by drug prohibition or different access to care will ensure that implementation serves diverse community needs while maintaining cultural sensitivity and social equity.

The Task Force further recommends establishing technical advisory groups that can provide specialized input on areas such as laboratory testing protocols, facility design and safety requirements, product packaging and labeling standards, environmental sustainability practices, and data collection and analysis systems. These collaborative structures should include

representatives from relevant state agencies including the Department of Health, the Medical Cannabis Administration, the Department of Commerce, and other regulatory bodies, as well as academic institutions, professional organizations, and community groups to ensure comprehensive expertise and stakeholder representation.

This expanded collaborative approach recognizes that successful psychedelic policy implementation builds upon Maryland's existing regulatory expertise while incorporating the specialized knowledge necessary for this emerging field. By leveraging proven administrative capabilities and established regulatory frameworks, Maryland can implement psychedelic access programs more efficiently and effectively while maintaining the high standards of safety, quality, and public accountability that characterize the state's approach to regulated substance programs.

Conclusion - National Leadership and Replication

The Maryland Task Force on Responsible Use of Natural Psychedelic Substances has developed a groundbreaking "ensemble" system to serve the diverse needs of Maryland residents while maintaining rigorous safety and equity standards. This comprehensive framework is a significant departure from the traditional single-pathway approach of other states and will establish Maryland as the national leader in evidence-based psychedelic policy reform.

The financial sustainability model, drawing revenue from commercial operations to fund public education, equity programs, and system monitoring, creates a self-sustaining framework that reduces burden on general state resources while demonstrating fiscal responsibility. This approach, combined with the comprehensive monitoring and regular review processes, positions Maryland to generate robust evidence about policy outcomes that can inform implementation in other jurisdictions.

The expanded expertise and ongoing collaboration structures recommended by the Task Force will be essential for maintaining Maryland's leadership position in evidence-based psychedelic policy development. By creating formal mechanisms for incorporating specialized knowledge from existing state agencies like the Medical Cannabis Administration and adapting to emerging research and practice innovations, Maryland can continue to refine and improve its ensemble model while sharing lessons learned with other jurisdictions considering similar reforms.

Perhaps most importantly, the ensemble model recognizes the fundamental dignity and autonomy of adult citizens while maintaining appropriate safeguards for public health and

safety. Whether someone seeks relief from cluster headaches through home-based micro-dosing protocols, therapeutic support for treatment-resistant PTSD, personal growth through supervised ceremonial use, or spiritual connection through religious practice, the framework provides or anticipates appropriate pathways with corresponding protections and support systems.

The Maryland Task Force has created a model that other states can adapt to their own circumstances and values. By prioritizing evidence over ideology, equity over exclusion, and flexibility over rigid adherence to single approaches, Maryland is positioned to demonstrate that thoughtful, comprehensive drug policy reform can enhance both individual wellbeing and community safety. The ensemble model stands as a testament to what becomes possible when policymakers engage earnestly with stakeholders, follow the evidence, and design systems that serve real human needs while acknowledging the complexities and unresolved tensions that require ongoing attention and development.

The framework's adaptive design, with built-in review processes and flexibility for incorporating new evidence and resolving implementation challenges, ensures that Maryland's psychedelic policy can evolve responsibly while maintaining its commitment to safety, equity, and individual autonomy. This approach, supported by expanded expertise and collaborative structures that leverage Maryland's existing regulatory capabilities, provides a foundation for continued policy development that can address currently unresolved issues while maintaining the comprehensive, evidence-based approach that characterizes the ensemble model.

Summary of Key Recommendations

The task force's recommendations have been developed through a rigorous consensus process building on the expertise of all the members of the task force. The highest-priority Grade A recommendations are the foundation of the ensemble model:

Framework Structure: Maryland should implement multiple complementary access models focusing initially on psilocybin (**Propositions 001-002**), creating a comprehensive system rather than forcing all users through a single pathway of access.

Access Pathways: The model encompasses four core components - medical/therapeutic use (**Propositions 074-079**), supervised adult use (**Proposition 063**), *decriminalization* with expungement (**Propositions 030-033**), and commercial sales (**Propositions 041-044**) - each serving different population needs and preferences.

Safety and Oversight: Comprehensive protections across all access pathways include mandatory public education (**Proposition 012**), harm reduction resources (**Proposition 013**), robust data collection (**Proposition 014**), advisory board oversight (**Proposition 010**), and whistleblower protections (**Proposition 011**).

Equity and Inclusion: Strong measures ensure diverse industry participation (**Proposition 018**), environmental sustainability (**Proposition 017**), accessible training opportunities (**Proposition 019**), and protection from discrimination for lawful users (**Propositions 008-009**).

Personal Cultivation and Access: Adult residents can access substances through personal cultivation permits (**Proposition 004**) and education-based permitting systems (**Propositions 004-006**), providing autonomous options within the regulated framework.

The Complete Framework

The ensemble model's operational success depends on its integrated approach across all essential components:

Multiple Supply Sources ensure quality and safety through licensed commercial operations, medical providers, and regulated personal cultivation, creating redundant pathways that prevent supply disruptions while maintaining strict quality standards.

Broad User Populations can access appropriate pathways based on their specific circumstances, from medical patients seeking therapeutic intervention to adults pursuing personal growth through education-based permits, and across a range of geographic, demographic, and economic backgrounds. This ensures the system serves varied community needs.

Appropriate Usage Locations provide safe environments for different types of experiences, whether clinical settings for therapeutic use, supervised facilities for adult use, or private residences for personal cultivation participants, with ongoing research informing public consumption policies.

Comprehensive Safety Infrastructure protects all participants through mandatory education, harm reduction resources, robust monitoring, and oversight mechanisms that can quickly identify and address emerging issues across all pathways.

Strong Equity Safeguards ensure that communities historically harmed by drug prohibition benefit from the emerging industry, while environmental protections and accessible training create sustainable, inclusive participation opportunities.

Robust Legal Protections shield lawful users from discrimination and collateral consequences, while advisory board oversight ensures diverse community voices guide policy implementation and evolution.

Sustainable Financial Model generates revenue to support all program components while reducing burden on state resources, creating a self-sustaining framework that can adapt and expand based on evidence and community needs.

Conclusion

The work of the *Maryland Task Force on Responsible Use of Natural Psychedelic Substances* represents a historic collaboration across disciplines and stakeholder groups. Over the past year, thousands of hours of volunteer service have been devoted to careful study, dialogue, and consensus-building. The resulting recommendations—embodied in the Ensemble Model—reflect both scientific rigor and civic imagination: a pragmatic yet visionary roadmap for ensuring that Marylanders can access natural psychedelic substances safely, ethically, and equitably. This work demonstrates that meaningful reform need not be rushed or partisan. It can emerge instead through open inquiry, compassion, and the shared belief that public policy should serve the well-being of all residents.

Maryland now stands at a threshold. The state's long history of medical innovation, public health leadership, and commitment to religious and civil freedom provide a strong foundation to lead the nation in psychedelic policy reform. The Task Force's findings and the independent analysis from researchers at Johns Hopkins University make clear that a regulated, evidence-based approach is both achievable and beneficial. By acting with foresight, Maryland can balance personal liberty with collective safety, expand therapeutic options for those in need, and build systems that reflect the highest standards of accountability, equity, and care.

Call to Action

The Task Force calls upon the Maryland General Assembly to take up this work in the coming legislative sessions. The time has come to translate evidence into action by establishing a *Maryland Natural Psychedelic Substance Access Program* rooted in the principles of the Ensemble Model. Doing so will position the state as a national leader in public health innovation, prevent harm by replacing unregulated underground use with safe and transparent pathways, and uphold Maryland's tradition of compassion and pragmatism. The recommendations contained in this report are not speculative—they are grounded in data, community input, and the experience of other states. With continued partnership among legislators, regulators, health professionals, researchers, and community stakeholders, Maryland can move beyond prohibition toward a responsible, equitable framework that embodies both scientific integrity and human dignity.

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Appendix 1. Full Text of Authorizing Legislation for the Task Force

Chapters 792 & 793 of 2024

AN ACT concerning

Task Force on Responsible Use of Natural Psychedelic Substances

FOR the purpose of establishing the Task Force on Responsible Use of Natural Psychedelic Substances to study and make recommendations related to the use of natural psychedelic substances; and generally relating to the Task Force on Responsible Use of Natural Psychedelic Substances.

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That:

- (a) (1) In this section, "natural psychedelic substances" includes naturally derived psilocybin, psilocin, dimethyltryptamine, mescaline, and any other substance determined by the Task Force to be a natural psychedelic substance.
 - (2) "Natural psychedelic substances" does not include peyote.
- (b) There is a Task Force on Responsible Use of Natural Psychedelic Substances.
- (c) The Task Force consists of the following members:
 - (1) one member of the Senate of Maryland who shall be appointed by the President of the Senate;
 - (2) one member of the House of Delegates who shall be appointed by the Speaker of the House;
 - (3) the Secretary of Health, or the Secretary's designee;
 - (4) the Secretary of Disabilities, or the Secretary's designee;
 - (5) the Secretary of Veterans Affairs, or the Secretary's designee;
 - (6) the Director of the Maryland Cannabis Administration, or the Director's designee; and
 - (7) the following members, appointed by the Governor:

- (i) one representative of the University System of Maryland, the Johns Hopkins University's Center for Psychedelic and Consciousness Research, or Sheppard Pratt;
- (ii) one representative of a Native American tribe with experience in the religious and spiritual use of psychedelic substances;
- (iii) one individual with expertise in behavioral health;
- (iv) one individual with expertise in the treatment of substance use disorders;
- (v) one individual with expertise in the treatment of chronic pain;
- (vi) one individual with expertise in psychedelic-assisted psychotherapy;
- (vii) one individual with expertise in psychedelic research;
- (viii) one individual with expertise in access to care in underserved communities;
- (ix) one individual with expertise in drug policy reform;
- (x) one individual with expertise as a member of law enforcement;
- (xi) one individual who is a patient with conditions that can be treated with psychedelic substances;
- (xii) one individual with experience with the pharmacology of natural psychedelic substances; and
- (xiii) one physician with experience with the appropriate use of psychedelic substances and other integrative medical practices.
- (d) To the extent practicable, the membership of the Task Force shall reflect the socioeconomic, ethnic, and geographic diversity of the State.
- (e) The Governor shall designate the chair of the Task Force.
- (f) The Maryland Cannabis Administration shall provide staff for the Task Force.
- (g) A member of the Task Force:
 - (1) may not receive compensation as a member of the Task Force; but

- (2) is entitled to reimbursement for expenses under the Standard State Travel Regulations, as provided in the State budget.
- (h) The Task Force shall:
 - (1) study:
 - (i) existing laws, policies, and practices relating to the use of natural psychedelic substances;
 - (ii) the best available science and data on public benefits of responsible access to and use of natural psychedelic substances;
 - (iii) opportunities to maximize public benefits of responsible access to and use of natural psychedelic substances;
 - (iv) the best available data on potential risks of access to and use of natural psychedelic substances;
 - (v) opportunities to mitigate potential risks of access to and use of natural psychedelic substances; and
 - (vi) barriers health care practitioners and facilitators may encounter relating to natural psychedelic substances, including barriers relating to insurance, restrictions by licensing and credentialing entities, zoning, advertising, and financial services;
 - (2) make recommendations regarding any changes to State law, policy, and practices needed to create a Maryland Natural Psychedelic Substance Access Program that enables broad, equitable, and affordable access to psychedelic substances, including:
 - (i) permitting requirements, including requirements regarding education and safety;
 - (ii) access to treatment and regulated support; and
 - (iii) production of natural psychedelic substances; and

- (3) make recommendations to transition from criminalizing conduct involving natural psychedelic substances, including:
 - (i) punishing with civil penalties nonviolent infractions involving the planting, cultivating, purchasing, transporting, distributing, or possessing of or other engagement with natural psychedelic substances;
 - (ii) expunging the records of Marylanders with convictions for nonviolent criminal offenses relating to natural psychedelic substances; and
 - (iii) releasing Marylanders incarcerated for nonviolent criminal offenses relating to natural psychedelic substances.
- (i) The Task Force may consult with experts and stakeholders in conducting its duties.
- (j) On or before July 31, 2025, the Task Force shall submit a report of its findings and recommendations to the Governor and, in accordance with § 2–1257 of the State Government Article, the General Assembly.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect July 1, 2024. It shall remain effective for a period of 2 years and 6 months and, at the end of December 31, 2026, this Act, with no further action required by the General Assembly shall be abrogated and of no further force and effect.

Approved by the Governor, May 16, 2024.

Appendix 2. Membership of the Task Force

	Professional Affiliations	Task Force Role
Substances Committee		
Ben Bregman, MD	Associate Clinical Professor of Medicine, Department of Psychiatry and Behavioral Health, George Washington University. Owner of Washington Integrative Mental Health Services, PLLC Contractor at Sunstone Therapies PC Contractor at Avesta Mental Health, LLC	Behavioral Health Expertise
Cynthia Macri, MD	Senior VP and Chief Medical Officer, EagleForce Health; U.S. Navy Captain (ret), Medical Corps; Executive Council, Japanese American Veterans Association; Steering Committee, Asian American Health Initiative, Montgomery County, Asst. Clinical Professor, George Washington University School of Medicine	Designee of the Maryland Department of Veterans Affairs
Manish Agrawal, MD	CEO and Co-Founder, Sunstone Therapies	Physician with Experience with Appropriate Use of Psychedelic Substances
Dr. Matthew Johnson	Senior Researcher, Institute for Advanced Diagnostics and Therapeutics, Sheppard Pratt	University System of Maryland/Johns Hopkins University Center for Psychedelic and Consciousness Research/Sheppard Pratt
Models of Access		
Candace Oglesby-Adepoju (she/her), LCPC	Owner/Founder of Jurnee Mental Health Consulting. Supervisor at Prism Wellness. Psychedelic Clinical Trial Trainer and Educator at Fluence Training. Contractor and Clinical Psychedelic Researcher	Access to Care in Underserved Communities Expertise
Kirsten Bosak	Director, Health and Behavioral Health Policy, Department of Disabilities	Designee of the Maryland Department of Disabilities
Mark White	Montgomery County Police (ret)	Law Enforcement Expertise
David Jun Selleh, LCPC, LPC	Ketamine-Assisted Psychotherapist with Expand Your Self Wellness. Psychotherapist with TheraHeal Group. Advisor with PsiloHealth	Psychedelic-Assisted Psychotherapy Expertise
Shane Norte Public Education and	Founder of The Church of the People for Creator and Mother Earth	Representative of a Native American tribe with experience in the religious and spiritual use of psychedelic substances
Legislature Support		
Timothy Hamilton	Business and Marketing Manager for the Maryland Park Service	Patient with Conditions Treated by Psychedelic Substances

	Professional Affiliations	Task Force Role
Sen. Brian Feldman	Maryland General Assembly	Appointed by the President of the Senate
Del. Ashanti Martinez	Member of Maryland House of Delegates	Appointed by the Speaker of the House
Laura Barrett	Founder, Ask Nurse Laura Executive Director, National Clinical Director Consortium Clinical Director, Connor Sheffield Foundation Chair, Cannabis Nurse Task Force, Univ. of Miami Adjunct Faculty, Univ. of Maryland & NYU	Chronic Pain Treatment Expertise
Andrew Coop, PhD	Professor and Associate Dean for Students, University of Maryland School of Pharmacy	Governor Appointed Chair; Pharmacology of Natural Psychedelic Substances Expertise
Regulations and Governance		
Shanetha Lewis, MS	Executive Director of Veterans Initiative 22	Psychedelic Research Expertise
Khadyne Augustine, JD	Senior Policy Analyst, Maryland Cannabis Administration	Designee of the Maryland Cannabis Administration
Nishant Shah, MD, MPH	Maryland Department of Health and Behavioral Health Administration	Designee of the Maryland Department of Health
Eric Edward Sterling, JD	Eric E. Sterling, J.D., has been professionally involved in drug policy since 1980. Assistant Counsel, U.S. House of Representatives, Committee on the Judiciary, Subcommittee on Crime (1979-1989). Executive Director, Criminal Justice Policy Foundation (1989-2020). State of Maryland Natalie M. LaPrade Medical Marijuana Commission, Chair of Policy Committee (2013-2017). American Bar Association, Standing Committee on Substance Abuse for over 20 years. Montgomery County, Maryland, Alcohol and Other Drug Abuse Advisory Council (10 years including 3 as Chair). Montgomery County, Maryland, Advisory Commission in Policing (2020-2024; Chair 2022-2024). Facilitator, Native American Religious Freedom Project, 1990. Pacific Symposium on Psychedelic Drugs, 1994, 1995. Advisory Boards: Law Enforcement Action Network; Students for Sensible Drug Policy. Lifetime Achievement Award, National Organization for the Reform of Marijuana Policy (2015).	Drug Policy Reform Expertise
Economic Impact	\ <i>p</i>	
Joey Nichols, MD, MPH, FAAFP	Canopy Family Care, Takoma Park, MD. Health Policy Scholar, Ethical Legal Implications of Psychedelics in Society (ELIPSIS) Program, Baylor College of Medicine.	Substance Use Disorder Treatment Expertise

Appendix 3. Delphi Process Methodology

Purpose

This appendix outlines the specific methodology of the Delphi process used by the Maryland Task Force on the Responsible Use of Natural Psychedelic Substances. "[A] Delphi study is practical in problematic areas where either statistical model-based evidence is not available, knowledge is uncertain and incomplete, and human expert judgment is better than individual opinion." (Nasa P., Jain R., Juneja D., "Delphi methodology in healthcare research: How to decide its appropriateness," 2021, World J. Methodol. doi. https://doi.org/10.5662/wjm.v11.i4.116 citing Linstone HA, Turoff M., "The Delphi Method: Techniques and Applications," 1975. Available from: https://web.njit.edu/~turoff/pubs/delphibook/ch1.html). "In modern times, this forecasting tool has evolved into a statistical methodology to collate individual opinions and converge them into statistically generated consensus with collective intelligence. A constant theme is observed across all domains with vital elements like anonymity, iteration, controlled feedback, and group response (or consensus)." (Ibid).

Through the systematic Delphi consensus-building process, the Task Force evaluated policy propositions across seven access models: Deprioritization, Non-Commercial Peer Sharing, Commercial Sales, Religious Use, Supervised Adult Use, Medical/Therapeutic Use, and FDA-Approved Use.

Study Design

Modified Delphi Method

To generate evidence-based policy recommendations regarding access to natural psychedelic substances, the Task Force employed a modified Delphi technique. We selected this technique as a tool to efficiently reach consensus, not as a research methodology. We make no claims that our findings generalize beyond the scope of our authorizing legislation. This method was selected because it:

- Allows for anonymous evaluation of policy propositions
- Minimizes the influence of dominant voices
- Enables structured feedback between rounds
- Provides a systematic approach to measuring consensus
- Supports both quantitative and qualitative data collection
- Results in specific, graded policy recommendations

Panel Composition

The panel for this Delphi process consisted of the 19 appointed members of the Task Force. Task Force membership was determined by the authorizing legislation and appointment by the Governor or Cabinet Secretaries, and all Task Force members were invited and encouraged to participate. Studies employing the modified Delphi technique routinely require much larger sample sizes in order for the results to be considered generalizable. However, since we are not employing the modified Delphi technique as a research method, it is not appropriate to compare our sample size with research norms.

Proposition Generation

Based on comprehensive literature reviews and stakeholder input, 120 policy propositions were developed across the seven access models identified by Task Force members. These initial 120 propositions were sorted by themes and prioritized. Redundant and low priority items were dropped, resulting in 85 propositions. Each proposition describes a potential policy feature that could be encoded into Maryland law.

Rating Dimensions

Each proposition was rated on two dimensions:

- 1. Desirability: The extent to which implementing the proposition would be beneficial for Maryland (1 = Not at all desirable, 9 = Extremely desirable)
- 2. Feasibility: The likelihood that the proposition could be successfully implemented within the next 5 years (1 = Not at all feasible, 9 = Extremely feasible)

Panelists were also asked to complete an importance allocation task, distributing 100 points across various factors (e.g. political viability, financial sustainability, equity, etc.) to indicate which criteria most influenced their feasibility and desirability judgments.

The Delphi survey was administered electronically using a secure online platform. Each panelist was permitted to complete the survey multiple times, with the option to revise their earlier responses based on written comments provided anonymously by other panelists.

Response Rate and Participation Goal

The target response rate was set a priori at 75% rounded to the nearest whole number (i.e., at least 14 of 19 members). Reminders and follow-up communications were used to maximize

participation while maintaining voluntary and anonymous responses. [We need to include the actual number of respondents for each round here.]

Survey Administration

The Delphi process consisted of four rounds.

Round 1: Task Force members rated all propositions on both dimensions (desirability and feasibility) using the 9-point Likert scales and optionally provided qualitative feedback for ratings in the neutral (i.e. 4-6) range. This round was conducted asynchronously through the electronic survey platform.

Round 2: This round featured structured deliberation conducted via videoconferencing. Propositions were prioritized for discussion based on the level of consensus reached in Round 1, with particular focus on:

- Propositions with emerging but incomplete consensus, defined as:
 - 50-79% of ratings in either the 7-9 range (emerging positive consensus) or 1-3 range (emerging negative consensus)
- Propositions with high desirability but varied feasibility ratings, defined as:
 - ≥75% of desirability ratings in the 7-9 range AND <50% of feasibility ratings within any single tertile range (i.e. 1-3, 4-6, or 7-9)
- Propositions with significant polarization in responses, defined as:
 - ≥25% of ratings in the 1-3 range AND ≥25% of ratings in the 7-9 range AND IQR ≥ 4

During these deliberation sessions, Task Force members engaged in moderated discussions of selected propositions. During each discussion, members used an interactive presentation software (Mentimeter) to anonymously re-rate propositions. Visualizations of the live rating distributions were shared with the group in real time to illustrate emerging patterns of consensus. This approach allowed for meaningful dialogue while preserving the benefits of anonymous rating to minimize groupthink or social pressure.

Round 3: Following the deliberation sessions, panelists completed a final asynchronous survey to review and refine their ratings of all propositions based on further reflection. Panelists were required to provide justifications for any ratings outside of the consensus position of the group at the start of the round. This round focused on solidifying consensus for the final recommendations.

Round 4: Following solidified consensus for the original 85 propositions, a fourth round was utilized to capture initial Task Force dispositions to an additional 5 propositions. These additional

propositions were intended to capture recurring feedback from stakeholders which were not reflected in the original set of 85. Round 4 occurred during a "Live Delphi" deliberation and survey process during the Open Meeting on September 25th, 2025. The level of participation (13 of 19, less than 75% of Task Force members present) made consensus calculations unstable, therefore no grade could be assigned. Still, collective dispositions toward these additional 5 policy propositions were captured, and could be subject to ongoing exploration at the General Assembly's request.

Between-Round Analysis and Feedback

Between rounds, the research team:

- Calculated descriptive statistics for all ratings
- Identified emerging consensus patterns
- Summarized qualitative justifications
- Highlighted areas of agreement and disagreement
- Prepared visualizations to aid interpretation

This information was shared with Task Force members to inform subsequent rounds of rating.

Analysis Plan

Quantitative Analysis

- Median and intertertile range for each proposition
- Percentage of ratings in each tertile range (i.e. 1-3, 4-6, 7-9)
- Assignment of consensus level based on the thresholds above
- Sensitivity analysis to assess the impact of weighting schemes from the importance allocation task or Task Force member attributes

Qualitative Analysis

- Thematic and content analysis of justifications for outlier ratings
- Identification of recurring concerns or opportunities
- Analysis of proposed modifications to improve proposition acceptability
- Grouping of consensus positions into "constellations" of mutually reinforcing recommendations

Consensus Definitions

Consensus definitions and thresholds were specified a priori as follows. Thresholds for panelist counts were rounded up or down to the nearest whole number. At target levels of participation, the magnitude of the threshold between moderate and strong consensus ranged between 2 and 3 panelists.

Strong Consensus:

- ≥80% of panelists rating the proposition in the 7-9 range (for positive consensus) OR 1-3 range (for negative consensus)
- AND Median score \geq 7 (for positive consensus) or \leq 3 (for negative consensus)
- AND Intertertile range (ITR) ≤2

Moderate Consensus:

- <80% and ≥65% of panelists rating the proposition in the 7-9 range (for positive consensus) or 1-3 range (for negative consensus)
- AND Median score ≥7 (positive) or ≤3 (negative)
- AND ITR ≤3

No Consensus:

- <65% agreement in either the 7-9 or 1-3 ranges
- OR median in the 4-6 range
- OR ITR >3

Translation to Recommendation Grades

Final consensus ratings were translated into recommendation grades as follows. Results were synthesized in a format to enable legislators and stakeholders to evaluate the most promising elements of psychedelic policy for Maryland.

- Grade A (Strongly Recommended): Strong consensus on both desirability AND feasibility
- Grade B (Moderately Recommend): Strong consensus on desirability AND moderate consensus on feasibility
- Grade C (Conditionally Recommended): Moderate consensus on desirability AND any consensus on feasibility
- Grade S (Needs Further Study): Any consensus on desirability AND no consensus on feasibility

- Grade L (Long Shots): Any consensus on desirability AND any consensus on infeasibility
- Grade W (Warning): Any consensus on undesirability AND feasibility
- Grade X (Not Recommended): Any consensus on undesirability AND infeasibility
- Grade I (Insufficient): No consensus on desirability

Task Force members were, on the whole, very pleased with the Delphi process. It expeditiously enabled identification of critical areas of consensus. One criticism of the process was that by not having conversations about the propositions before they were ranked, there may have been a lack of agreement of what a proposition meant. This problem was exhibited during the live round of ranking. After a conversation about the meaning of the proposition, consensus was quickly achieved. A similar criticism was specifically directed at Proposition 54 which instead of proposing an action, proposed taking no action. Another criticism is that in many instances, forecasts of the feasibility of various propositions may have exceeded the expertise of panel members.

Appendix 4. Summary of Public Listening Session Feedback

A PowerPoint presentation was developed to educate the general public about natural psychedelics, including their types, effects, current laws across the country, potential models of access in Maryland, and emerging scientific research. This presentation was delivered during the first half of public meetings held throughout the state. The second half of each meeting was reserved for open discussion and public feedback, with participants encouraged to share both supportive and opposing views.

Outreach and promotion of the meetings included postings on the Task Force website, targeted announcements in relevant regional subreddits, graphic posts shared on high-traffic Facebook pages in each host area, and press releases distributed to local media outlets. In addition, direct notice was provided to local psychedelic community groups, including the Baltimore Psychedelic Society, Montgomery County Psychedelic Society, and the D.C. Psychedelic Society. Both the press materials and social graphics made clear that input was welcomed from all members of the public, regardless of their stance on psychedelics.

During the public comment portion of the meetings, the following feedback was shared. Below represents the breadth of feedback received, grouped thematically for the reader's convenience:

- Natural psychedelics must be available to everyone, not just people of means.
- Expungement of previous criminal convictions and charges is important to me. Non violent offenses like this are a barrier to employment.
- Psychedelics for therapy should not be limited to just medical facilities. What about group therapy?
- Spiritual use is good for humanity. I don't interfere in other religions, so why do I have to explain why psychedelics are important to my relationship with god?
- I am worried about the commercialization aspect. What issues does this bring up? I am particularly worried about psychedelics being treated like cannabis where the intensity is amped up by the growers to make the effects way too intense.
- What about the Feds? Will they trump the state regulations so that I think that I'm okay to use them, but then I'm arrested and get fired from my job?
- Why only natural psychedelics? What about LSD?
- The employees at the dispensary need to be trained properly about the different varieties and their effects? I feel like the cannabis dispensaries are not doing a good job with this.
- Distributors should pay into a fund that would be directed towards research.

- There should be protocols for safely walking people down from SSRIs before taking the psychedelics. They just can't stop taking them one day. And there needs to be public education about safety.
- I don't want the mental health facilities taking over the use of psychedelics and then charging huge fees to get access. Big Pharma already does this.
- Baltimore is supposed to be the big hub of research activity, but the University of Maryland, and even Johns Hopkins, isn't doing enough, and we are losing researchers to other states.
- How do I as a social worker get training and accredited? I want to research and ask people who may know, but I don't want to set off any red flags and lose my job.
- I already serve as a psychedelic facilitator and I am concerned that the state will tell me what I can and can't do, even though I have thirty years of experience.
- We have to make sure that people have a controlled and safe environment.
- What about Bufo? That is a natural psychedelic. What about Ibogaine?
- Packaging has to be tamper-proof. A lot of cannabis products do not offer this.
- Decriminalization is the way to go. And people need the option to use at home rather than a facility. End-of-life care should be offered at home. This was left out of the Oregon bill.
- This is a part of my religious belief. I'd have to risk a felony by bringing Ayahuasca into the country to practice my religion.
- What about San Pedro cacti?
- Go for broke with this bill. Ask for everything. When it is voted down, then you know what you can reasonably include the next year. There was vehement disagreement in the room regarding this comment.

At the conclusion of the presentation portion of each meeting, two QR codes were displayed on screen for the remainder of the session. One directs attendees to a Google Form for submitting anonymous comments and feedback; the other links to an application to present directly to the Task Force or one of its committees. Both forms are also accessible via the Task Force website.

Appendix 5: State and Local Psychedelic Reforms, 2015 to 2025

Jurisdiction	Year	Measure / Bill	Туре	Status	Overview
Alaska	2024	HB 228 / SB 166	Alaska Mental Health and Psychedelic Medicine Task Force	Became Law (September 19, 2024)	Task force to study licensing and regulation of psychedelic-assisted therapy in anticipation of federal FDA approval; report due January 31, 2025
Arizona	2023	HB 2486	Psilocybin research grants and advisory council	➤ Died in committee	Proposed \$30 million from state budget for psilocybin research grants and establishment of psilocybin research advisory council
Arizona	2024	SB 1570	Psilocybin therapeutic services regulatory framework	Passed Legislature / X Vetoed by Gov. Hobbs	Would have created regulatory framework for facilitated on-site psilocybin services, Arizona Psilocybin Advisory Board, and Psilocybin Control and Regulation Fund; vetoed due to concerns about premature clinical expansion and financial implications
Arizona	2025	HB 2871	Ibogaine clinical study funding	Passed House (36-22)	Initially \$10M, amended to \$5M + \$5M matching for ibogaine clinical study to treat TBI and PTSD; pending Senate consideration
Arizona	2025	SB 1555	Psilocybin advisory board	In committee	Refiling of 2024's Oregon-style psilocybin services; committee-revised to create psilocybin advisory board with annual safety/efficacy reports

California	2021	SB 519	Psychedelic decriminalization	Died in Assembly Appropriations Committee (November 30, 2022)	Would have removed criminal penalties for possession and social sharing of psilocybin, psilocin, MDMA, LSD, DMT, ibogaine, and mescaline (excluding peyote); passed Senate 21-16 on June 1, 2021, but stalled in Assembly
California	2022	SB 58	Psychedelic decriminalization (revised)	Vetoed by Gov. Newsom (October 7, 2023)	Would have legalized possession, transportation, preparation of psilocybin, psilocin, DMT, ibogaine, and mescaline (excluding peyote) for adults 21+; passed Senate 21-16 on May 24, 2023
California	2023	AB 941	End Veteran Suicide Act	In committee (as of July 1, 2024	Would authorize licensed clinical counselors to administer controlled substances to combat veterans; requires minimum 30 sessions with 12-hour duration sessions and 2-3 counselors present per patient
California	2025	AB 1103	VA psychedelics research exemption	Passed Unanimously (October 2025)	Exempts VA-run psychedelics research from delays by California's Research Advisory Panel if DEA-registered
California	2025	SB 751	Veterans/First Responders Psilocybin Pilot	Pending	Up to five counties to launch pilot partnered with UC system and mental health providers, funded by state special fund
California - Arcata	2021	Resolution No. 212-17	Local entheogen decriminalization	Passed Unanimously (October 2021)	City council voted unanimously to deprioritize enforcement of entheogen prohibition
California - Berkeley	2023	City Council Resolution	Local decriminalization	✓ Passed	Resolution deprioritizing enforcement against natural psychedelic use and possession

California - Eureka	2023	City Council Resolution	Local entheogen decriminalization	Passed unanimously (October 17, 2023)	Followed neighboring Arcata; decriminalized psilocybin and other natural entheogens; allows people to reach out to medical/mental health professionals without fear of reprisal
California - Oakland	2019	Resolution No. 87731 CMS	Local entheogen decriminalization	Passed (June 2019)	Second city in U.S. to decriminalize; resolution decriminalizes all "entheogenic plants" including psilocybin, ayahuasca, and peyote
California - Oakland	2020	Resolution No. 88464 CMS	State decriminalization advocacy	Passed unanimously (December 2020)	Urges state legislature to decriminalize entheogenic plants/fungi and allow local jurisdictions to authorize community-based healing ceremonies; supports Oakland Community Healing Initiative (OCHI)
California - Santa Cruz	2020	Resolution No. NS-29,867	Local entheogen decriminalization	Passed (January 2020)	Decriminalized personal possession and cultivation of entheogenic plants and fungi
California - San Francisco	2022	Board of Supervisors Resolution	Local entheogen decriminalization	V Passed	Citywide resolution urging decriminalization and support for plant medicine access and education
Colorado	2022	Proposition 122 (Natural Medicine Health Act)	Natural medicine therapy + decriminalization	Passed (54%)	Legalized regulated adult use of psilocybin and other natural psychedelics with phased licensing; immediate decriminalization of personal possession and use
Colorado	2025	HB 1063	Psilocybin "trigger law"	✓ Passed	Allows licensed medical professionals to prescribe psilocybin statewide once federally rescheduled by the FDA
Colorado	2025	SB 76	Product restrictions	Filed	Allowed domestication conditional on FDA approval

Colorado	2025	SB 25-297	Data collection for psilocybin program	✓ Passed	Establishes data-collection requirement for Colorado's psilocybin access program starting July 2026; requires demographic and health outcome reporting
Colorado - Denver	2019	Initiative 301	Local psilocybin decriminalization	✓ Passed (May 7, 2019)	First city in U.S. to decriminalize psilocybin; made possession and use lowest law enforcement priority for adults 21+
Connecticut	2021	SB 1083	Psilocybin health benefits study	Signed into law (June 2021)	Calls upon Department of Mental Health and Addiction Services to convene working group to study health benefits of psilocybin and examine therapeutic use under healthcare provider direction; report due January 1, 2022
Connecticut	2022	HB 5506	State budget with psychedelic therapy funding	Signed into law (May 2022)	Budget earmarked funds for psychedelic-assisted therapy pilot program for veterans, retired first responders, and healthcare workers using psilocybin/MDMA at FDA-approved sites; establishes Connecticut Psychedelic Treatment Advisory Board
Connecticut	2023	HB 5102	Medicinal psilocybin use	Referred to Joint Committee on Public Health	Would allow psilocybin use for medicinal and therapeutic purposes including physical, mental, behavioral healthcare
Connecticut	2023	HB 6146	Psychedelic assisted therapy pilot program	Referred to Appropriations Committee	Would implement psychedelic assisted therapy pilot program with General Fund appropriation

Connecticut	2023	HB 6734	Psilocybin	✓ Passed	Eliminates criminal penalty
			possession decriminalization	House (May 10, 2023)	for possessing less than ½ ounce of psilocybin; requires temporary license loss for over ½ ounce when under 21; effective October 1, 2023
Connecticut	2025	HB 7065	Psilocybin possession decriminalization	Passed House	Decriminalizes possession of less than ½ ounce psilocybin; passed House, pending Senate Judiciary action
Connecticut	2025	HB 5456 / HB 6380	Therapy pilot + decriminalization proposal	Filed, in committee	Mirror of NY structures; under review
District of Columbia	2020	Initiative 81	Entheogenic plant decriminalization	✓ Passed (76%)	Made enforcement of laws against natural psychedelics (psilocybin, ayahuasca, ibogaine) the lowest police priority
Florida	2021	HB 725	Collateral Consequences of Convictions and Decriminalization of Cannabis and All Drugs Act	➤ Died in committee (March 2022)	Decriminalize personal use/possession of controlled substances in favor of civil fines and drug rehabilitation referral
Florida	2022	SB 348 / HB 193	Using Alternative Therapies to Treat Mental Health and Other Medical Conditions	➤ Died in committee (March 2022)	Would require study of therapeutic efficacy of MDMA, psilocybin, ketamine for depression, anxiety, PTSD, bipolar, chronic pain, migraines; modeled on Texas HB 1802
Georgia	2022	HR 896	House Study Committee on Alternative PTSD Treatment for Veterans	➤ Died in committee	Bipartisan proposal to create 5-member committee studying psilocybin-assisted therapy for veterans with PTSD, depression, and addiction
Georgia	2025	HB 382	COMP-360 trigger law	Pending	Trigger law rescheduling crystalline psilocybin to mirror federal status upon FDA approval

Georgia	2025	HB 717	Licensed psychedelic clinics	X Stalled in committee	Establishes licensed clinics for FDA-approved psychedelic-assisted treatments
Hawaii	2021	SB 738	Psilocybin therapy centers	➤ Deferred by Judiciary Committee	Would remove psilocybin/psilocin from Schedule I and establish designated treatment centers for therapeutic administration
Hawaii	2021	HCR 174 / SCR 208	Therapeutic Psilocybin Working Group	Adopted (March 31, 2021)	Calls for Health Department working group to study psilocybin laws, research, and develop strategic plan for safe, accessible therapeutic psilocybin for adults 21+
Hawaii	2022	SB 2575	Psilocybin therapy legalization + review panel	➤ Died in committee	Remove psilocybin/psilocin from Schedule I, establish treatment centers, and create psilocybin review panel with annual reports until 2027
Hawaii	2022	SB 3160	Therapeutic psilocybin working group	Passed Senate unanimously	DOH to create working group examining medicinal effects and developing strategic plan for therapeutic psilocybin access
Hawaii	2022	SCR 100 / SR 88	Therapeutic psilocybin working group resolutions	Approved (amended)	Senate resolutions requesting DOH convene therapeutic psilocybin working group; amended to make access dependent on FDA approval
Hawaii	2023	HB 1340 / SB 1531	Breakthrough Therapy Advisory Council	Recommended by committees	Establish Temporary Breakthrough Therapy Designation Advisory Council within 3 months of FDA breakthrough therapy approvals

Hawaii	2023	SCR 69	Beneficial Treatments Advisory Council	X Deferred	Requesting DOH establish advisory council for safe, accessible therapeutic psilocybin, psilocybin-based products, and MDMA for adults 21+
Hawaii	2023-202	SB 1042	Mental Health Emerging Therapies Pilot Program	Passed Senate / X Pending House	2-year pilot program for public-private partnerships funding Phase 3 trials of FDA Breakthrough Therapy candidates including psychedelics
Illinois	2023	HB 0001 / HB 1143	Illinois CURE (Compassionate Use and Research of Entheogens) Act	Re-referred to Rules Committee (April 5, 2024)	Proposal to remove psilocybin/psilocin from Schedule I, provide for record expungement, and allow licensing of manufacturers, service centers, and facilitators
Illinois	2023	SB 2353	Psilocybin research authorization	X Status unclear	Would authorize Department of Financial and Professional Regulation to distribute psilocybin for medical, psychological, and scientific studies despite Schedule I status
Illinois	2025	HB 1143	The Compassionate Use and Research of Entheogens Act (refiled)	Pending	Third year filing by Rep. LaShawn Ford (D); would establish Illinois Psilocybin Advisory Board and allow lawful manufacturing, delivery, possession, and sales of psilocybin products with restrictions
Illinois	2025	HB 2992	Psilocybin-assisted therapy pilot	Under committee review	Sets up pilot program including regulatory board, cultivation standards, and licensing framework

Illinois - Chicago	2020	R2019-735	Expression of support for adult use of entheogenic plants	➤ Heard but not passed	Chicago's Committee on Health and Human Relations resolution calling for hearings on feasibility of entheogenic plants as alternative treatment options
Illinois - Evanston	2020	Evanston decriminalizati on proposal	Local entheogen decriminalization	➤ Proposed but status unclear	Council member Devon Reid announced intentions to sponsor legislation decriminalizing entheogenic plants with civil fines up to \$100 or waived with rehabilitation/public service
Indiana	2023	HB 1166	Psilocybin research funding	X Introduced only	Did not pass committee
Indiana	2024	SB 139	Therapeutic psilocybin research fund	Referred to Ways and Means Committee	Establishes psilocybin research fund administered by Indiana Department of Health to provide financial assistance to research institutions studying psilocybin for mental health and medical conditions
Indiana	2025	HB 1166	Psilocybin research program funding	Pending	Republican-sponsored appropriations bill allocating up to \$600,000 over 2025-2026 to fund existing psilocybin research program signed into law by Gov. Holcomb (R) in March 2024;
lowa	2021	HF 480	Terminal illness psychedelic decriminalization	Referred to Human Resources	Proposes decriminalizing DMT, LSD, peyote, psilocybin, psilocin, and MDMA for patients with terminal illness or life-threatening conditions

lowa	2021	HF 636	Psilocybin Services Act	Referred to House Public Safety Committee	Creates regulated psilocybin administration for adults 21+; deprioritizes prosecution of noncommercial entheogenic activities including ibogaine, DMT, mescaline, peyote, psilocybin
lowa	2021	HF 459	Psilocybin/psilocin rescheduling	➤ Indefinitely postponed	Aimed to remove psilocybin and psilocin from Schedule I controlled substances
lowa	2023	HF 240	Psilocybin/psilocin rescheduling	Recommended by subcommittee (April 11, 2023)	Would remove psilocybin and psilocin from Schedule I controlled substances list
lowa	2025	HF 351	Psilocybin rescheduling	Pending	Removes psilocybin/psilocyn from Schedule I entirely
lowa	2025	HF 609	Religious freedom for psychedelics	Pending	Expands religious freedom protections to include psychedelics (psilocybin, peyote) in religious ceremonies
lowa	2025	HF 620	PTSD psilocybin system	Pending	Creates state-legal system for PTSD use of psilocybin including cultivation, testing, provider protections; capped at 5,000 participants
lowa	2025	Compass Trigger Law	COMP-360 rescheduling	Passed both chambers unanimously	Automatically reschedules COMP-360 upon FDA approval
Kansas	2021	HB 2288	Psilocybin cultivation/possess ion penalty reduction	X Failed	Aimed to reduce penalties for small quantities of psilocybin cultivation and possession
Kansas	2022	HB 2465	Legalized Homegrown Psilocybin Mushroom Act	➤ Died in committee (May 23, 2022)	Aimed at reducing penalties for individuals cultivating or possessing small quantities of psilocybin or psilocin; similar to failed 2021 HB 2288

Kansas	2025	HB 2218	COMP-360 rescheduling	Pending	Reschedules COMP-360 (crystalline psilocybin) to Schedule IV
Kentucky	2025	SB 240	lbogaine research fund	Pending	Declares ibogaine worthy of clinical research, establishes Ibogaine Research Fund for opioid dependence and mental health treatment
Louisiana	2025	Senate Resolution (McMath)	Task Force on Alternative Therapies for Veterans	Enacted (June 12, 2025)	9-member task force to study psychedelic therapies for veterans, focusing on psilocybin, MDMA, ibogaine, and ketamine; report due February 1, 2026
Maine	2021	HP 713 (LD 967)	Drug possession civil penalty	X Failed Senate (14-18, June 30, 2021)	Would have made possession of scheduled drugs for personal use merely a civil penalty; passed House 77-62 but rejected by Senate
Maine	2021-202	SP 496 (LD 1582)	Maine Psilocybin Services Act	X Failed House after Senate passage	Aimed to legalize facilitated psilocybin use at licensed service centers; voted down 8-3 by Health and Human Services Committee in February 2022, but Senate later passed it in April 2022 before House declined to advance
Maine	2024	LD 1914	Maine Psilocybin Health Access Act	Carried over to special session	Act allowing licensed psilocybin administration at service centers and decriminalizing personal possession/growing for adults 21+; passed House in April 2024, Senate carried over to special session May 10, 2024
Maine	2025	LD 1034	Psilocybin possession decriminalization	Carried over	Aims to decriminalize personal possession of one ounce or less of psilocybin for adults

Maine - Portland	2023	City Council Resolution	Local entheogen decriminalization	Passed (October 3, 2023)	City Council voted to deprioritize local enforcement of laws against psychedelic plants and fungi
Maryland	2022	SB 709	Veterans psychedelic pilot program	☑ Enacted	Created a \$1 million grant program for qualified researchers to provide psychedelic-assisted therapy to veterans with PTSD and TBI
Maryland	2024	HB 548 / SB 1009	Task Force on Responsible Use of Natural Psychedelic Substances	Enacted (May 16, 2024)	17-member task force overseen by Maryland Cannabis Administration to study "broad, equitable, and affordable access" to psilocybin, DMT, mescaline; report due 2025
Massachusetts	2021	HD 1494	Entheogenic plants task force	Referred to House Rules Committee (June 9, 2022)	Establish interagency task force to study public health and social justice implications of legalizing possession, consumption, transportation, and distribution of naturally cultivated entheogenic plants and fungi
Massachusetts	2021	HD 1450 / SD 949	Personal use decriminalization	Referred to Joint Committee on Judiciary (February 16, 2023)	Would remove penalties for adults to possess, ingest, obtain, grow, and give away up to 2 grams of psilocybin, psilocin, DMT, ibogaine, and mescaline
Massachusetts	2023	HD 3574	MDMA treatment service pricing	Referred to Committee for Public Health (April 13, 2023)	Would establish maximum charge of \$5,000 per MDMA treatment service unit for all registered MDMA service providers

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Massachusetts	2023	HB 3605	Psilocybin facilitator licensing	Referred to Committee for Public Health (March 30, 2023)	Committee for Public Health (March 30, 2023)Would require Department of Public Health to establish procedures for granting psilocybin facilitator licenses with 20-300 hours of training including 21 hours in-person practicum
Massachusetts	2024	Question 4	Legalization + home grow + decriminalization	X Failed (57% No)	Proposed regulation and decriminalization of multiple psychedelics
Massachusetts	2025	HD 4017	Licensed psilocybin therapy centers	Pending	Grassroots co-drafted bill for licensed therapy centers with clinician facilitators
Massachusetts	2025	HD 4196	Medical practitioner psilocybin pilot	Pending	Medical practitioner-led psilocybin pilot program
Massachusetts	2025	SD 1624	Broad-spectrum psychedelics pilot	Pending	Comprehensive pilot program covering multiple psychedelic substances
Massachusetts	2025	HD 3895	"No Harm No Foul" possession	Pending	Automatic dismissal for non-harmful psilocybin possession by adults
Massachusetts	2025	SD 870	Decriminalization with community support	Pending	Decriminalization framework with community support systems
Massachusetts	2025	HD 3368	Personal therapeutic access	Pending	Personal therapeutic access for qualifying medical conditions, up to 2g, until federal rescheduling
Massachusetts	2025	HD 4243	Equitable access task force	Pending	Task force on equitable access to psilocybin and entheogens
Massachusetts	2025	HD 4017, HD 188, SD 323, HD 4243, HD 1003, etc.	Therapy pilots, decriminalization, task force	All pending or filed	Multiple bills varying by local advocates

Massachusetts	2021	City Council	Local	✓ Passed	Official resolution directing
- Cambridge	2021	Resolution	decriminalization	i usseu	police to make psilocybin and entheogen possession the lowest enforcement priority
Massachusetts - Somerville	2021	City Council Resolution	Local decriminalization	✓ Passed	Non-binding resolution passed unanimously, similar to Cambridge
Massachusetts - Northampton	2021	City Council Resolution	Local decriminalization	✓ Passed	Non-binding resolution expressing city support for decriminalization of entheogenic plants
Massachusetts - Amherst	2022	City Council Resolution	Local decriminalization	Passed (June 2022)	Joined other Massachusetts cities in decriminalizing entheogenic plants and fungi
Massachusetts - Salem	2023	City Council Resolution	Local decriminalization	Passed (May 11, 2023)	City Council voted to end arrests involving psilocybin and other entheogenic substances
Massachusetts - Easthampton	2021	City Council Resolution	Local decriminalization	Passed (October 2021)	Voted 7-0 on resolution to support ending arrests for growing entheogenic plants and fungi
Massachusetts - Medford	2023	City Council Resolution	Local decriminalization	✓ Passed	Decriminalized personal possession of entheogenic plants and fungi
Massachusetts - Provincetown	2023	City Council Resolution	Local decriminalization	✓ Passed	Added to growing list of Massachusetts cities decriminalizing entheogens
Michigan	2021	SB 631	Entheogenic plant and fungus decriminalization	Referred to committee	Would decriminalize manufacture, creation, delivery, and possession of entheogenic plants/fungi including DMT, ibogaine, mescaline, and psilocybin; prohibits commercial sales but permits reasonable fees for counseling/spiritual guidance services

Michigan	2022	Ballot Initiative	Comprehensive drug law overhaul	Deferred to 2024	Would decriminalize possession of Schedule 1 and 2 substances and legalize cultivation, possession, use, and gifting of psilocybin, psilocin, ibogaine, peyote, and DMT for adults 18+; includes regulated sale and treatment system through hospital-designated entities
Michigan	2023	House Concurrent Resolution No. 5	Veterans psychedelic treatment support	XIntroduced	Urges Congress, DoD, and VA to invest in non-technology treatment options including psychedelics in clinical settings for servicemembers and veterans with psychological trauma
Michigan - Ann Arbor	2020	City Council Resolution	Local entheogen decriminalization	Passed (September 21, 2020)	First Michigan city; unanimously decriminalized entheogenic plants and fungi, making enforcement lowest priority
Michigan - Detroit	2021	Proposal E	Local entheogen decriminalization	✓ Passed (61%)	Approved by voters; deprioritized enforcement of laws prohibiting natural entheogen use and possession
Michigan - Hazel Park	2022	City Council Resolution	Local entheogen decriminalization	Passed (March 22, 2022)	Third Michigan city; unanimously voted for decriminalization and prohibited use of city funds for enforcement
Michigan - Ferndale	2023	City Council Resolution	Local entheogen decriminalization	Passed (February 27, 2023)	Fourth Michigan city to decriminalize entheogenic plants and fungi
Michigan - Washtenaw County	2021	County Resolution	County-level entheogen decriminalization	✓ Passed	County-level decriminalization of entheogenic plants and fungi

Minnesota	2023	HF 1884 / SF 1954	Psychedelic Medicine Task Force	Signed into law by Gov. Walz	Establishes 23-member task force to study and advise on legalizing psilocybin, LSD, and MDMA; included in omnibus health bill; initial report delivered February 1, 2024, final report due January 1, 2025
Minnesota	2025	HF 2699	Psilocybin personal use decriminalization	Pending	Eliminates criminal and civil penalties for personal psilocybin use/possession by adults 21+; allows personal cultivation, transportation, and non-remunerative exchange; establishes Psychedelic Medicine Board and public health education programs
Minnesota - Minneapolis	2023	Executive Order	Local entheogen decriminalization	Passed (July 23, 2023)	Mayor issued executive order making entheogens lowest law enforcement priority
Missouri	2021 - 2022	HB 1176 / HB 2429	Right to Try expansion	Referred to committee	Expand Missouri's Right to Try Act to allow terminal patients to use MDMA, psilocybin, LSD, DMT, mescaline, or ibogaine with doctor's recommendation; also reduces penalties for low-level possession
Missouri	2022	HB 2469	Multi-substance possession decriminalization	Referred to Crime Prevention Committee	would create three-tiered penalty system reducing possession penalties for small amounts of MDMA, LSD, and psilocybin to infractions with \$100 fines
Missouri	2022	HB 2850	Natural medicine legalization	X Public hearings completed	Would legalize ibogaine, plant/fungus-derived psilocybin, DMT, and non-peyote mescaline for medical conditions; provides healthcare provider immunity

Missouri	2023	HB 869	Psilocybin affirmative defense	X Not considered by committee	Would allow psilocybin use for treatment-resistant depression, PTSD, or terminal illness at approved locations with affirmative defense against prosecution
Missouri	2023	HB 1154	Psilocybin research program	➤ Placed on informal perfection calendar	Approved by House Veterans Committee 11-0; requires Department of Health to conduct USDA-approved psilocybin trials for PTSD, depression, substance abuse, and end-of-life care
Missouri	2023	HB 951 / SB 90	Veteran-focused research and pilot bill	X Stalled (no hearing before adjourn)	Proposed psilocybin pilot research framework
Montana	2022 - 2023	LC 2311	Interim study on psilocybin for mental illness treatment	➤ Died in process (May 2, 2023)	Interim study bill on psilocybin for mental illness treatment; placed on hold December 12, 2022
Montana	2023	LC 1208	Psilocybin treatment legalization	Died in committee (May 2, 2023)	Would have legalized psilocybin use for certain mental health conditions including PTSD; would have established guidelines for cultivation, manufacturing/packaging, and administration
Nevada	2023	SB 242	Psychedelic Medicines Working Group	✓ Enacted (June 2023)	Directed Nevada Department of Health to establish working group to study therapeutic use of hallucinogens like psilocybin
Nevada	2025	SJR 10	Federal rescheduling resolution	Pending committee review	Joint Resolution urging federal rescheduling and research support
New Hampshire	2022	HB 1349-FN	Psilocybin possession decriminalization	★Tabled (March 31, 2022)	Aimed to decriminalize possession or use of certain amount of psilocybin mushrooms by persons 18+ years old; referred to Criminal Justice and Public Safety committee

New Hampshire	2023	HB 328-FN	Multi-substance legalization	Inexpedient to legislate (March 16, 2023)	Would have legalized possession and use of LSD, mescaline, psilocybin, and peyote for persons 21+
New Hampshire	2023	HB 216-FN Bills to remove DMT/etc.	State decriminalization proposals	X Failed / tabled	DMT removal repealed; traffic penalty amendment stalled in Senate
New Hampshire	2025	HB 528	Adult-use psilocybin legalization	Pending	Legalizes psilocybin possession/use for adults 21+; under Criminal Justice & Public Safety Committee review
New Jersey	2021	S3256	Psilocybin possession penalty reduction	Passed (February 2021)	Reduced psilocybin possession penalty: one ounce or less now disorderly persons offense with up to 6 months imprisonment and \$1,000 fine (previously third-degree crime with 3-5 years imprisonment and up to \$35,000 fine)
New Jersey	2022	S2934	Psilocybin Behavioral Health Access and Services Act	Referred to Senate Health Committee (June 2022)	Would authorize production and use of psilocybin for health and wellness; would decriminalize and expunge past offenses involving psilocybin production, possession, use, and distribution
New Jersey	2024	S2283	Psilocybin Behavioral Health Access and Services Act (amended)	Approved by Senate Budget Committee	Introduced January 2024; amended to create only regulated facilitated access model for psilocybin after being approved by Senate Health and Human Services Committee

New Mexico	2023	HB 393	Psilocybin Advisory Group study	X Postponed indefinitely	Would have created advisory group to study feasibility of psilocybin treatment program for mental health and substance use disorders, establish treatment guidelines, and monitor similar programs in other states
New Mexico	2025	SB 219	Medical psilocybin access act	✓ Passed	Established a medical psilocybin advisory board to oversee rulemaking and clinical program development; therapy access slated to begin by end of 2027
New Mexico	2025	SB 410	Crystalline polymorph psilocybin trigger law	Tabled indefinitely (February 19, 2025)	COMP-360 trigger law bill
New Mexico	2025	HM 58	Department of Health psilocybin study request	Pending	Requests Department of Health study psilocybin-based treatment implementation including training requirements standardization, testing protocols, regulatory/legal barriers, and implementation frameworks
New York	2020	A10299	Psilocybin decriminalization	X Did not leave Health Committe	
New York	2021	A7928	Public psychedelic research institute	Referred to Health Committee	Would establish public psychedelic research institute and psychedelic substances therapeutic research programs

New York	2021 - 22	A6065	Natural hallucinogen legalization	X Status unclear	Would have legalized adult possession and use of certain natural plant or fungus-based hallucinogens, remove prohibitions on possession, use, cultivation of DMT, ibogaine, mescaline, psilocybin, psilocin by adults 21+; includes supervision/guidance services and prevents state cooperation with federal CSA enforcement
New York	2021	A8569	Medical psilocybin training system	X Status unclear	Would enable medical professionals to receive training for psilocybin therapy administration, creating Oregon-style medical use system
New York	2023	A00114	Natural hallucinogen legalization with protections	Referred to Health Committee	legalizes adult possession/use of psilocybin, psilocin, DMT, ibogaine, and non-peyote mescaline; includes employment, licensing, and child custody protections
New York	2023 - 2024	S 3520	Medical psilocybin grant program	Re-referred to Finance Committee (January 3, 2024)	Relates to medical use of psilocybin and establishes psilocybin assisted therapy grant program; amended December 20, 2023
New York	2024	A10375	Regulated adult psilocybin use	X Status unclear	Would allow growth, cultivation, and regulated adult use of psilocybin for treatment of certain health conditions; provides for certification of support service providers and licensure of cultivators
New York	2025	S 495	State-supervised psilocybin therapy program	Pending	Would create state-supervised program permitting licensed facilitators to provide psilocybin-assisted therapy to eligible patients

New York	2025	S 628	Natural hallucinogen legalization	Pending	Would legalize adult possession and use of DMT, psilocybin, mescaline, ibogaine, and psilocin
New York	2025	S 1801 / A 3845	Veteran/first responder psilocybin pilot	Pending	Pilot program for veteran and first-responder psilocybin therapy
New York	2025	A 3375	Clinically supervised psilocybin pilot	Pending	Naturally grown psilocybin pilot including in-home use with \$5M grants
New York	2025	A 2142 / S 5303	Regulated permit system	Pending	Regulated permit/licensing system for adult non-commercial psilocybin use and cultivation
New York	2025	S 1817 / A 1522	Ibogaine addiction research	Pending	Office-led research into ibogaine for addiction treatment
New York	2025	S 4664	PTSD ibogaine study commission	Pending	Commission PTSD ibogaine study with report within one year
North Carolina	2023	HB 727	Breakthrough Therapies Research Grant Fund	Re-referred to Appropriations Committee (May 16, 2023)	Would establish \$5 million grant fund (plus \$400,000 administrative costs) for MDMA research on PTSD in veterans, first responders, healthcare professionals, and domestic violence/sexual assault victims; psilocybin research on anxiety/depressive disorders with pain outcome measures
North Carolina	2025	SB 568	Mental health and psychedelic medicine task force	Pending	Would establish bipartisan task force to consider implementation barriers and recommend licensing/insurance requirements for practitioners upon FDA approval; final report due December 1, 2026

Oregon	2020	Measure 109	Psilocybin therapy legalization	Passed (55.8%)	First state to legalize adult-use psilocybin therapy. Established licensing, facilitator training, and two-year rulemaking process culminating in 2023 program launch
Oregon	2020	Measure 110	Drug decriminalization	Passed (58.5%)	Decriminalized possession of small amounts of all drugs including LSD, MDMA; reclassified offenses and redirected cannabis tax revenue to treatment services
Oregon	2022-24	Local opt-outs (various cities/counties)	Local bans on psilocybin centers	Mixed (most passed opt-out)	Cities blocked therapy centers locally
Oregon	2025	HB 2387	Psilocybin program updates	✓ Passed	Refined facilitator licensing, client consent, and safety protocols within the Oregon Psilocybin Services program
Oregon	2025	SB 907	Regulatory improvements to existing program	× Filed	Updated licensing, board composition
Oregon	2025	HB 3817	VA-linked ibogaine PTSD access	Pending	VA-linked ibogaine PTSD access pathway including cardiac screening and controlled administration
Pennsylvania	2021	НВ 1959	The Public Health Benefits of Psilocybin Act	Referred to Health Committee	Introduced by Rep. Tracy Pennycuick (R) with 20 co-sponsors; would authorize clinical study of psilocybin-assisted therapy for PTSD, TBI, and mental health conditions with priority for veterans, first responders, and families; would authorize limited cultivation under state law; modeled after Texas HB 1802

Pennsylvania	2022	HB 2421	Psilocybin Data Act	Presumed dead (not reintroduced 2023-24)	Introduced by Rep. Tracy Pennycuick (R), referred to Health Committee; provides framework for research and clinical studies of psilocybin and psilocybin-assisted therapy to optimize public health benefits; renamed version of HB 1959
Rhode Island	2022	HB 7715	Psilocybin and buprenorphine decriminalization with therapeutic use	Held for further study (April 13, 2022)	Would decriminalize possession of up to one ounce of psilocybin and buprenorphine (no civil penalty, unlike marijuana's \$150 fine); would allow practitioners to prescribe/dispense psilocybin therapeutically with Health Director empowered to promulgate rules
Rhode Island	2023	HB 5923 / S 0806	Uniform Controlled Substances Act amendment	Passed House Judiciary Committee (12-2) / Passed House / Referred to Senate Judiciary	Would permit possession of less than one ounce of psilocybin and secure cultivation at residence for personal use; includes FDA rescheduling trigger provisions for Department of Health to establish cultivation, distribution, and medical prescription rules; amended with sunset clause for July 1, 2
Rhode Island	2025	HB 5186	Personal legalization + therapeutic access	➤ Held for further study	Personal/cultivation legalization plus FDA-dependent therapeutic access program
Texas	2021	HB 1802	Psychedelic research (veterans)	✓ Passed	Required the state to study psilocybin for PTSD among veterans in partnership with Baylor College of Medicine
Texas	2023	НВ 4288	Alternative PTSD therapies study	Referred to Public Health Committee (March 21, 2023)	Would conduct studies on MDMA, psilocybin, and ketamine for PTSD in veteran population

Texas	2023	HB 4423	Psilocybin research council	X Status unclear	Would conduct studies on MDMA, psilocybin, and ketamine for PTSD in veteran populations
Texas	2025	SB 2308	Ibogaine clinical trials funding	Pending	Authorizes \$50M in state-backed matched funding for FDA-approved ibogaine clinical trials; establishes consortium with IP stake and veteran-focused funds
Texas	2025	HB 4561	lbogaine clinical research pilot	✓ Signed	Gov. Abbott signed bill to fund and facilitate ibogaine research for opioid use disorder; aims to advance to clinical trials
Utah	2023	SB 200	Psilocybin therapy legalization	Filed as "bills not passed" (March 3, 2023)	Would have legalized psilocybin therapy for adults 21+ with certain psychiatric diagnoses; would have provided state regulation of psilocybin production and therapy
Utah	2024	SB 266	MDMA and psilocybin pilot program	✓ Became law (March 2024	Creates pilot program for two healthcare systems (Intermountain Health and University of Utah Health) to offer MDMA and psilocybin treatments; program has yet to come to fruition
Utah	2025	SB 248	Crystalline psilocybin trigger law	Pending	Trigger law for crystalline psilocybin plus provider authority to offer psilocybin/MDMA therapy in clinical settings
Vermont	2021	H 309	Entheogenic plant and fungi decriminalization	Referred to Judiciary Committee	Would decriminalize compounds found in plants and fungi used for medicinal, spiritual, religious, or entheogenic purposes, including psilocybin, psilocin, mescaline, peyote, DMT, and ibogaine

Vermont	2023	H 371	Psilocybin decriminalization with therapeutic workgroup	Heard by House Judiciary Committee (February 24, 2023)	Would decriminalize psilocybin possession and distribution and establish workgroup to investigate therapeutic potential
Vermont	2023	H 439	Plant and fungi compound decriminalization	Referred to Judiciary Committee (March 1, 2023	would remove mescaline, peyote, psilocybin, psilocin, ibogaine, DMT, and containing plants/fungi from "Hallucinogenic Drugs" and "Regulated Drug" definitions; proposed effective date July 1, 2023
Vermont	2023	S 114	Psychedelic Therapy Advisory Working Group	Signed into law by Governor (May 29, 2024)	Establishes working group to examine psychedelic use for physical/mental health improvement and make recommendations for state therapeutic program similar to Connecticut, Colorado, or Oregon; report due November 15, 2024
Vermont	2025	H 189	Advisory board for personal-use benchmarks	Pending	Establishes advisory board for personal-use benchmarks (LSD, psilocybin); under-limit possession becomes harm-reduction
Vermont	2025	HB 452	Psilocybin decriminalization and therapeutic program	Pending	Would decriminalize possession, cultivation, and noncommercial personal use of psilocybin mushrooms by adults; would establish state-licensed "Psilocybin Therapeutic Consultation Program"
Virginia	2022	SB 262	Psilocybin possession decriminalization	Passed by indefinitely (January 31, 2022)	Would reduce psilocybin/psilocin possession penalty to civil fine of max \$100 for adults 21+; Senate Judiciary Committee voted to pass by indefinitely

Virginia	2022	HB 898	Multi-substance possession decriminalization	X Shelved (January 24, 2022)	Would reduce penalties for psilocybin, psilocin, ibogaine, and peyote possession from Class 5 felony to civil offense with max \$100 fine for adults 21+
Virginia	2023	HB 1513	Medical psilocybin prescription	Left in Courts of Justice Committee	Would allow psilocybin possession with valid prescription for refractory depression, PTSD, or end-of-life anxiety; would prohibit prosecution of healthcare practitioners and pharmacists
Virginia	2023	SB 932	Virginia Psilocybin Advisory Board	Passed Senate (25-15, February 7, 2023) / X Status unclear in House	Would establish 12-member advisory board, reclassify psilocybin from Schedule I to Schedule III, and develop strategic plan for therapeutic access
Virginia	2024	SB 229	Breakthrough Therapies for Veteran Suicide Prevention Act	Passed Senate / X Failed House	Earlier version of psychedelic therapy bill for veterans; passed Senate but didn't make it out of House
Virginia	2025	SB 1101	Breakthrough Therapies for Veteran Suicide Prevention Act	Passed Senate (40-0) / X Killed in House (18-0)	Established 6-member state advisory council to study FDA breakthrough therapies (psilocybin, MDMA) for veterans; Senate unanimous approval but House Rules Committee killed bill
Virginia	2025	SB 1135	COMP-360 crystalline psilocybin trigger law	Passed Legislature / X Vetoed by Gov. Youngkin (March 24, 2025)	Would direct Virginia Board of Pharmacy to promulgate regulations for prescribing, dispensing, possessing, and using crystalline polymorph psilocybin (COMP-360) upon FDA approval and DEA rescheduling; Youngkin vetoed as "premature," saying state should wait for federal action

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Washington	2025	SB 5201	State-licensed psilocybin therapy services	Pending/Stalle d	State-licensed psilocybin therapy services for adults 21+; sponsored by Sen. Salomon with co-sponsors
Washington	2025	HB 1281	Pilot psilocybin therapy for veterans/first responders	Pending	Pilot psilocybin therapy pathway for veterans and first responders via medical professionals
Washington	2025	HB 1433	Regulated psychedelic access with equity focus	Pending	Regulated access bill emphasizing cost equity and insurance inclusion
Washington	2025	HB 5204	University of Washington ibogaine study	Pending	UW-led ibogaine study for opioid use disorder in partnership with licensed Mexican clinic; sponsored by Salomon, Trudeau, Nobles
Washington - Seattle	2021	Resolution	Local entheogen decriminalization	Passed (October 4, 2021)	Largest U.S. city to decriminalize psychedelics; made enforcement of laws against natural psychedelics the lowest police priority
Washington - Port Townsend	2021	Resolution	Local entheogen decriminalization	Passed (December 20, 2021)	Made investigation, arrest, and prosecution of adults engaging in entheogen-related activities a low enforcement priority
Washington - Jefferson County	2023	Resolution	County-level entheogen decriminalization	Passed (May 2023)	County commissioners unanimously approved resolution to make psychedelics enforcement among lowest priorities
Washington - Olympia	2024	Resolution	Local entheogen decriminalization	Passed (August 13, 2024)	State capital city unanimously approved resolution declaring entheogen enforcement as lowest law enforcement priority
Washington - Tacoma	2025	Resolution	Local entheogen decriminalization	Passed (January 28, 2025)	Third largest city in Washington; unanimously approved resolution to deprioritize enforcement and support statewide decriminalization

West Virginia	2021	HB 3113	Psilocybin rescheduling	X Stalled in committee	Proposed removing psilocybin and other substances from Schedule I; reached Health and Human Resources committee before Legislature adjourned without scheduling
West Virginia	2023	HB 2951	Multi-substance rescheduling	X Stalled in committee	Proposed removing Schedule I status of THC and psilocybin from West Virginia Code
West Virginia	2025	HB 3344	lbogaine clinical trials grant program	Passed House / X Pending Senate	Establishes grant program to fund ibogaine clinical trials for FDA approval
West Virginia	2025	НВ 3343	COMP-360 crystalline psilocybin trigger law	Passed House / X Pending Senate	Compass Pathways-backed trigger law to reschedule crystalline polymorph psilocybin upon FDA approval

Appendix 6: Psychedelic Economics and Policy Evaluation

Psychedelic Policy for Maryland: An Independent Report offered to the Task Force on Responsible Use of Natural Psychedelic Substances

October 8 2025

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Executive Summary

Overview: This independent report, prepared for the Maryland Task Force on Responsible Use of Natural Psychedelic Substances, offers insights to support informed decision-making as Maryland considers a variety of regulatory pathways and policy options for psychedelics. These insights are derived from an integration of various sources of evidence described in detail in this report, including existing clinical evidence, economic considerations, lessons from cannabis regulation, and lessons from early state psychedelic policy initiatives. Psychedelics (notably, psilocybin and MDMA) have shown promise in treating a variety of mental health conditions, including treatment-resistant depression, post-traumatic stress disorder, and substance use disorders. Federal approvals remain limited, but interest is growing—not only for clinical treatment, but also for spiritual and personal growth, while also acknowledging the need to respect Indigenous use.

Options and Approach: We consider the following, non-mutually exclusive policy options: (1) FDA-approved use; (2) religious use; (3) decriminalization; (4) non-commercial peer sharing; (5) state-authorized medical/therapeutic use; (6) supervised adult use; (7) commercial sales; (8) (not emphasized) state monopoly sales. Distinct potential benefits and risks, including considerations of safety, equity, public health, and accessibility, accompany each option. We do not conduct new head-to-head cost-effectiveness analyses due to the limited availability of real-world data. We draw on the available clinical, economic, and policy evidence to assess each regulatory option on two key axes: 1) its ability to unlock potential benefits (both medical and non-medical) and 2) its safeguards against potential risks. Given the very limited evidence base, many of our estimates are necessarily provisional and should be interpreted with considerable caution.

Key Insights:

Existing evidence & Oregon's experience. Psychedelic treatments can be cost-effective, but results hinge on the durability of benefit, drug costs, and therapist hours. Clinical benefits are promising but still emerging; risks appear manageable with robust screening, supervision, product testing, clear consent/boundary policies, and regular safety checks. Non-medical settings, therefore, need robust safeguards. From Oregon's supervised adultuse rollout, we observe that the bottleneck is service centers, fee-only funding is fragile, siting rules and 280E raise costs and limit growth, and clear adverse event definitions/monitoring are essential. Together, these factors constrain throughput, keep prices high, and skew access toward higher-income users.

Match policy to purpose. For clinical goals under strong safety controls, prioritize a state-authorized medical/therapeutic track (and FDA-approved use when available) to deliver trial-aligned benefits with supervision and data reporting. When the aim includes non-medical well-being-related goals (e.g. personal growth) for those without a medical diagnosis, consider a tightly regulated, supervised adult-use pilot with screening, on-site dosing, and integration support. Where the objective is rapid justice and harm reduction, consider decriminalization, recognizing that it does not create, by itself, a clinical pathway. If expanding access is a goal and the state accepts weaker point-of-use safeguards, consider regulated commercial channels—as complements rather than substitutes—paired with strong testing, labeling, marketing limits, and monitoring. In mixed-goal settings, pilot in parallel or sequentially—starting with medical/therapeutic and supervised adult-use—then tune levers (screening, supervision, testing/labeling, pricing/coverage, equity targets, data/monitoring) and iterate using evaluation results.

Demand and Scale. Under a medical/therapeutic model, Maryland should plan for low-thousands of patients annually. A supervised adult-use model scaled from Oregon suggests modest early volumes (hundreds to a few thousand clients over initial years). If commercial sales are ever authorized, past-year prevalence would plausibly rise; however, both use-days and consumer spending for psilocybin would remain small fractions of Maryland's cannabis use-days and sales. All the figures we report are based on strong assumptions and should be treated as tentative and provisional.

Evaluation-first data & implementation. Build reliable, standardized, timely data from day one to measure benefits (clinical improvement, well-being, access, equity) and risks (e.g., adverse events). Design for comparative evaluation against alternatives and integrate data with CRISP. Use staggered rollouts, transparent thresholds, equity-weighted lotteries, and pilot-first (stepped-wedge) designs; collect data on participants and non-participants to enable quasi-experimental methods. Track exposure/market conditions, direct and indirect outcomes, and report via public dashboards to support tighten/relax/scale decisions.

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1. Introduction

1.1 Background and context

Clinical trials and observational studies suggest that psychedelics¹ such as psilocybin, methylenedioxymethamphetamine (MDMA), and lysergic acid diethylamide (LSD) may offer significant therapeutic benefits for a number of mental health conditions, including treatment-resistant depression (TRD), post-traumatic stress disorder (PTSD), anxiety disorders, certain types of substance use disorders, and end-of-life anxiety and distress. Reflecting this promise, the U.S. regulatory system that has the potential to open the door to market access to these therapies has cracked the door. The Food and Drug Administration (FDA) granted Breakthrough Therapy designation to MDMA-assisted therapy for PTSD in 2017, to psilocybin in 2018 (for treatment-resistant depression) and in 2019 (for major depressive disorder), and to an LSD formula in 2024 for generalized anxiety disorder. However, broader FDA approvals and a looser federal regulatory environment have yet to occur. For example, in 2024, the FDA declined to approve MDMA-assisted therapy. The Advisory Committee that reviewed the trials primarily raised concerns tied to the quality of evidence collection (i.e., study design, functional unblinding, safety monitoring, and data integrity). The agency subsequently issued a Complete Response Letter requesting that additional evidence be collected (including another Phase 3 trial).

Meanwhile, the prevalence of mental illness in the United States continues to rise. As of 2022, approximately 23.1 percent of U.S. adults were estimated to experience any mental illness (AMI) (NIMH, 2025), and 6 percent experienced serious mental illness (SMI). New data also show that the prevalence of depression among adolescents and adults increased by 60 percent over the past decade (Brody & Hughes, 2025).

The growing demand for policy change in this area reflects a convergence of forces: rising public concern over the inadequacy of existing mental health treatments, increased awareness of promising research, and advocacy by patients, clinicians, and veterans' groups seeking access to new options. The fact that interest is expanding despite decades of stigma and prohibition suggests a shifting social landscape in which the urgency of addressing mental illness is starting to outweigh long-standing reservations. At the same time, it is important to acknowledge that certain communities, including many Indigenous communities, have histories of using psychedelic substances such as peyote, ayahuasca, and psilocybin-containing mushrooms in ceremonial, healing, and spiritual contexts. These traditions demonstrate that psychedelics have deep cultural and religious significance in some societies, and they provide valuable perspectives for contemporary policy discussions (including the importance of respectful engagement and protections for sacramental use)².

At the state level, discussions on psychedelics include safety and legal rules as well as how a growing public health crisis should be addressed using therapies that are promising but not yet proven. At the federal level, psychedelics such as psilocybin, LSD, and MDMA remain classified as Schedule I controlled substances under the Controlled Substances Act, meaning they are deemed to have a high potential for abuse, no currently accepted medical use, and a lack of accepted safety for use under medical supervision. Nonetheless, state and local policies have become increasingly diverse. As of early 2025, three states have established legal pathways for the use of psilocybin and other psychedelic substances: Oregon (via voter-approved Measure 109 in 2020), Colorado (through Proposition 122 in 2022), and New Mexico, which enacted a legislatively passed Medical Psilocybin Act in 2025. At the local level, a number of jurisdictions—including the District of Columbia (Initiative 81, effective March 2021), Oakland, San Francisco, Seattle, Ann Arbor, Minneapolis, and Portland (Maine)—have decriminalized or deprioritized enforcement of certain psychedelic-related offenses.

¹In this report, psychedelics refers broadly to classic psychedelics (such as psilocybin, lysergic acid diethylamide) and other substances with similar psychoactive effects, such as non-classic psychedelics like MDMA.

² Two recent reports provide up-to-date tracking of enacted laws, ballot measures, and pending psychedelic policy initiatives across U.S. jurisdictions: Kilmer, B., Priest, M., Ramchand, R., Rogers, R. C., Senator, B., & Palmer, K. (2024). Considering alternatives to psychedelic drug prohibition. RAND. Retrieved August 20, 2025, from https://www.rand.org/pubs/research_reports/RRA2825-1.html; and Center for Psychedelic Policy. (2025). National Psychedelic Landscape Assessment (NPLA) 2025. Retrieved August 20, 2025, from https://www.cppolicy.org/download-report

1.2 Policy Options

Maryland has several non-mutually exclusive regulatory paths available; they can be sequenced (e.g., decriminalizing first, then piloting supervised services later), layered (e.g., medical use alongside religious protections), or piloted regionally before scaling up. Table 1 below briefly describes each option.

Table 1: Policy Options

FDA-approved use

- Use of psychedelic-derived products that have completed FDA approval, delivered under the federal label, and any Risk Evaluation and Mitigation Strategies (REMS) requirements within ordinary medical practice. Patients who meet FDA criteria receive care from credentialed prescribers in certified settings; the state mainly integrates the product into existing licensing and coverage systems and may adopt an automatic-rescheduling trigger to align state schedules with DEA actions.
- Example: Esketamine (sold under Spravato).

Religious use

- Sacramental use within a bona fide religious organization operating under federal protections (e.g., Religious Freedom Restoration Act (RFRA) or court orders). Participation follows the faith's internal rules; ceremonies are led by clergy or designated facilitators. The state generally defers to federal protections and intervenes only for public-safety or child-protection concerns.
- Examples: Peyote in the Native American Church; ayahuasca exemptions for União do Vegetal and Santo Daime.

Deprioritization/decriminalization

- Removes or sharply reduces criminal penalties for adult possession and personal use of small, noncommercial amounts. No legal retail supply is created; sourcing typically occurs via home cultivation or informal networks.
- Examples: Washington, D.C.'s Initiative 81; Denver's 2019 psilocybin decriminalization.

Non-commercial peer sharing

- Allows eligible adults to grow and possess natural psychedelics for personal use and to gift them to other
 adults without payment (no sales, bartering, or advertising). There is no licensed supply chain; statute defines
 possession/cultivation limits and the boundary between gifting and illegal sales.
- Example: Colorado's "grow-and-give" allowance under its Natural Medicine program.

Medical/therapeutic use

- State-authorized clinical use of non-FDA-approved psychedelics for patients with qualifying diagnoses (e.g., treatment-resistant depression (TRD), PTSD, end-of-life distress), administered in regulated healthcare or psychotherapy settings with required screening, supervised dosing, integration, and data reporting. The health department licenses clinics and training, sets protocols, and oversees safety and outcomes.
- Example: New Mexico's Medical Psilocybin Act (2025) for physician-supervised psilocybin.

Supervised adult use

- Non-medical pathway where any eligible adult consumes psychedelics on-site at a licensed service center under a trained facilitator's supervision. Required preparation, on-site administration, observation, and postsession integration are delivered in a regulated system that also licenses manufacturers and labs.
- Example: Oregon's Psilocybin Services program (Measure 109).

Commercial sales

- For-profit market in which licensed private firms cultivate, manufacture, test, distribute, and retail psychedelic products to adults. The state operates a cannabis-style regulatory apparatus (licensing, seed-tosale tracking, testing, labeling, marketing limits, taxation) and pairs it with public-health monitoring.
- Example: No U.S. jurisdiction has legalized over-the-counter psychedelic retail; the analogue is Maryland's adult-use cannabis program.

State monopoly sales

- The state owns and operates production, testing, distribution, and retail, excluding private licensees; adults purchase limited quantities from state-run outlets (stores or online); the state sets product formats, potencies, prices, and consumer-education standards and bears both operational and regulatory responsibility.
- Examples: No U.S. jurisdiction currently uses a state monopoly for psychedelics, and none operates a government monopoly over cannabis retail—though state or local monopolies do exist for alcohol in parts of the United States (e.g., Montgomery County Alcohol Beverage Services for spirits wholesale/retail) and for lottery products (e.g., Maryland Lottery & Gaming)³. We do not focus on this model in this report. The RAND report, Considering Alternatives to Psychedelic Drug Prohibition (Kilmer et al., 2024), does consider it—describing state monopoly sales as "a middle ground alternative to supply prohibition that cautious jurisdictions could try for a few years before deciding whether to allow profit-maximizing firms to enter the retail markets."

1.3 Report Approach

With such a variety of regulatory options for states and emerging evidence on state experiences experimenting with these options, there is an opportunity for states, such as Maryland, to weigh the evidence to support decision-making.

This report offers insights to support informed decision-making. We take an explicitly comparative, evaluationfirst approach. We combine economic considerations with insights from clinical research, public health, and comparative policy experiences to map the likely costs and benefits of different regulatory models. We analyze each policy's impact on individuals, providers, and the state, considering direct costs and broader social effects, to clarify trade-offs.

We evaluate each policy option by how well it unlocks potential benefits while mitigating risks (a judgment made harder by the still-developing evidence base for medical benefits). Benefits may be medical (clinical improvement, reduced symptom burden, remission) and non-medical (well-being, meaning/spiritual growth, social connectedness), with potential overlap between the two categories. Risks span clinical and psychological harms (acute distress, adverse events), public-health risks (impaired driving, unsafe products), professional/ethical risks (boundary violations, poor supervision), and equity risks (unequal access, predatory marketing). Each regulatory model uses different levers—eligibility and screening, supervision and setting,

product quality/testing, education and labeling, data/monitoring, accountability/complaints, and cost/coverage—and thus differs in its potential to enable benefits while safeguarding against harms. Because psychedelic care is episodic and front-loaded, value will hinge on durability of benefit and retreatment rates; evaluation should therefore track outcomes over time and compare them to alternative programs competing for the same public dollars.

Our intent is to provide a framework to aid decision-makers in matching policy to purpose. We specify standard economic endpoints to enable apples-to-apples comparisons with realistic alternatives. We recommend building data and implementation to support credible quasi-experimental evaluation and leveraging existing data infrastructure for privacy-protective linkage to clinical and public-health data.

1.4 Key Takeaways

- Match policy to purpose—so long as the goal is explicit. If the state's primary objective is clinical outcomes (remission, reduced symptom burden) with strong safety controls, the medical/therapeutic or FDA-approved routes are generally the most consistent with that aim. State initiatives can also move faster than federal pathways and, if designed with standardized reporting, can generate valuable real-world evidence that can complement evidence from clinical trials; in particular, state-authorized medical/therapeutic pilots best position Maryland to test and deliver clinical benefits more quickly. If the priority is broad non-medical benefits (well-being, meaningfulness) with structured guardrails, supervised adult use may be more appropriate. Peer sharing, as allowed in some states, offers another non-commercial access model, though it provides little oversight and uneven safeguards. If the goal is a rapid reduction of criminal-justice harms with minimal state build-out, deprioritization/decriminalization may be the more direct lever; however, because it offers very limited safety safeguards, it is better suited to substances with well-established safety profiles. If scale and potential revenue are central—and the state is prepared to accept weaker supervision at the point of use—commercial sales are a plausible but higher-risk option; however, expected sales volumes are likely well below cannabis, given a smaller addressable market and slower/less frequent use. Several levers—screening rules, supervision, testing/labeling, pricing/coverage, equity targets, and data/monitoring—can be tuned to shift each model along the benefit—risk frontier. Finally, where goals are mixed (e.g., "maximize access and protect high-risk patients"), the framework points to layered, evaluation-first approaches—for example, piloting medical/therapeutic use and supervised adult use in parallel (potentially time-limited or regional), with eligibility and safety screens, and embedding evaluation so Maryland can iterate as evidence accrues. Decriminalization and, where authorized, carefully regulated commercialization can function as complementary levers to the clinical and supervised pathways if paired with strong safeguards and ongoing monitoring.
- Evidence base: limited and evolving—necessitating evaluation-first design. Because psychedelics remain federally Schedule I and only a few jurisdictions have recent experience with psychedelics (with Oregon providing the most data to date), the evidence base is limited and evolving. We therefore pair emerging psychedelic research with lessons from cannabis policy evaluation and use transparent, order-of-magnitude assumptions (e.g., per-capita scaling) that are updated as new data accrue. The evidence base is further restricted by the fact that jurisdictions outside the U.S. that have enacted policies for access to psychedelics (e.g. Australia, Switzerland) have generally not mandated data collection, limiting evaluation opportunities (Langlitz, 2025). This makes it especially important for Maryland to build an evaluation-first program that can inform both state and national policy.
- Projected Demand and Market Scale Across Pathways. Our tentative estimates suggest planning for low-thousands of patients per year under a medical/therapeutic model at modest uptake (5–15%). A supervised adult-use track, scaled from Oregon, implies on the order of 2,500–9,000 clients per year, depending on access (≈2,700/year under a partial-access scenario; ≈8,800/year with full statewide access) during the early years. If commercial sales are authorized, the prevalence of psilocybin use (at least once in the past year) could plausibly rise, implying ~\$10–\$20M in annual consumer spending—only a few percent of Maryland's adult-use cannabis sales—and total psilocybin use-days of roughly ~1.4 million at baseline, rising to ~2.0–2.7 million under commercial-uptake scenarios. For comparison, cannabis use-days are on

- the order of ~112 million annually in Maryland (sensitivity ~86–137 million). All figures are tentative and heavily assumption-dependent.
- Implementation and measurement: how Maryland can generate credible, decision-relevant evidence. Given these constraints—namely, a limited and evolving evidence base, sparse mandated data collection in many places, and the generalizability limits of randomized controlled trials for psychedelics—state initiatives can expand the evidence base if they are designed from the start for measurement and evaluation. While randomized clinical trials remain the gold standard, they face distinctive challenges for psychedelics (e.g., imperfect blinding). Modern quasi-experimental tools in econometrics (e.g., differencein-differences, synthetic control, regression discontinuity) enable credible causal inference from real-world rollouts. We propose a statewide data and evaluation plan—leveraging CRISP, Maryland's health information exchange—to enable continuous monitoring, equity tracking, and evidence-based course correction. Core indicators should include standardized clinical outcomes and safety events—including emergency department visits and hospitalizations related to psychedelics—alongside adverse event reports and, where feasible, poison-center calls and impaired-driving signals. Design choices should facilitate headto-head or parallel evaluations (e.g., sites offering psychedelic-assisted care versus sites offering digital cognitive behavioral therapy (CBT) or enhanced usual care) to compare effectiveness, uptake, persistence, harms, and costs. We recommend pre-specifying decision rules (e.g., cost-effectiveness or safety thresholds) and publishing public dashboards with shared data standards to support transparency and timely course correction. Whatever path Maryland chooses, we advocate for an evaluation-first policy approach: explicit goals are set, standardized and privacy-protective reporting is required, public dashboards are published, de-identified data access for independent analyses is provided, and mechanisms are built in to adjust rules as evidence accumulates.

1.5 Report Structure

The rest of this report is organized as follows.

- Section 2 synthesizes the existing evidence on clinical outcomes and safety; summarizes the small but growing cost-effectiveness literature; presents a scoping review of psilocybin economics and policy impacts; identifies the key cost drivers and implementation levers that shape prices, access, and program viability across policy models; synthesizes the literature on psychedelic policy evaluation, in addition to summarizing the relevant literature from cannabis policy evaluations; and briefly reviews select state-led mental and behavioral health initiatives to provide comparison points for policymaking.
- Section 3 summarizes operational and early-outcome lessons from Oregon's psilocybin program—workforce and licensing, utilization and client mix, safety reporting, equity, and finances.
- Section 4 provides tentative estimates of Maryland's potential clinical need under a medical/therapeutic model (TRD and chronic/severe PTSD) and potential market size under a supervised adult-use model and a commercial sales model, with uptake scenarios and implications for service capacity and coverage.
- Section 5 then uses this evidence base to compare the models side-by-side on operational profiles, benefits, costs, and risks.
- Section 6 proposes data standards and an evaluation plan for continuous monitoring, equity tracking, and evidence-based course correction.
- Section 7 summarizes our conclusions.

2. Clinical Evidence, Cost-Effectiveness, Psilocybin Economics, and Policy Evaluation 2.1 Clinical Evidence and Cost-Effectiveness Studies

Snapshot of the evidence on psychedelics as mental health treatments: Psilocybin, along with other psychedelic substances, has recently been the focus of a growing number of clinical studies for a variety of conditions. These include, in terms of psilocybin, for major depressive disorder (von Rotz et al., 2023; Raison et al., 2023; Goodwin et al., 2022; Davis et al., 2021), alcohol-use disorder (Rieser et al., 2025; Bogenschutz et al., 2022), smoking cessation (Johnson et al., 2014), end-of-life anxiety (Ross et al., 2016; Ross et al., 2025), posttraumatic stress disorder (PTSD) (Davis et al., 2023), and obsessive compulsive disorder (Moreno et al., 2006). Psilocybin, typically administered alongside some form of psychosocial support, has been shown to significantly reduce symptoms of depression and anxiety. With regard to substance use disorders, studies involving psilocybin have shown encouraging results. It has been used with cognitive behavioral therapy for smoking cessation, showing long-term abstinence effects (Johnson et al., 2014). Other studies have demonstrated robust reductions in heavy drinking with psilocybin (Bogenschutz et al., 2022; van der Meer et al., 2023). Other classic psychedelics, like lysergic acid diethylamide (LSD) and ayahuasca (comprised of the classic psychedelic DMT and a monoamine oxidase inhibitors (MAOI)), have also been investigated, with ayahuasca showing antidepressant effects (Osorio et al., 2015) and LSD alleviating anxiety (Gasser et al., 2014). LSD's significant short-term and medium-term effects on alcohol use disorder have been revealed through a metaanalysis (Krebs, 2012). Other non-classic psychedelics like methylenedioxymethamphetamine (MDMA) have been examined as well, with MDMA reducing PTSD symptoms (Mitchell et al., 2021), as well as demonstrating reduced alcohol consumption (Nicholas et al., 2022).

Safety and Adverse Events: In clinical settings, psychedelics (referring here to classic or serotonergic psychedelics) have been shown to trigger unpredictable psychological effects like anxiety or paranoia (Breeksema et al., 2022; Bremler et al., 2023; Bender & Hellerstein, 2022), especially in those predisposed to mental health issues (Bremler et al., 2023; Bender & Hellerstein, 2022). Physical risks may include cardiovascular issues (Ghuran, Wieker & Nolan, 2001), headaches and nausea. With regard to research settings, a recent systematic review of studies examining classic psychedelics (n=114 studies) found no serious adverse events (SAEs) reported for healthy participants, and in approximately 4% of participants with pre-existing neuropsychiatric disorders (Hinkle et al., 2024). The absence of standardized dosing and risk of misuse in nonmedical settings could add complications. Use without professional guidance can result in adverse psychological reactions (Carbonaro et al., 2016), dangerous substance interactions (Nayak et al., 2021), or acute toxicity. Even though serotonergic psychedelics appear to have low abuse potential, their risks outside carefully controlled trials are not well understood (Jones, Herrmann, Wang, 2023). As recreational use has increased, adult emergency department visits related to psychedelic use and poison control centers related to psychedelic use by both adolescents and adults have also increased (Farah et al., 2024; Simon et al., 2024). Moreover, recent lab analyses of "magic mushroom" edibles sold outside regulated channels found that many contained no psilocybin and instead muscimol (from Amanita muscaria), synthetic tryptamines, or other adulterants highlighting mislabeling risks and the need for verified product testing and clear labeling (van Breemen et al., 2025).

Some Limitations of Existing Clinical Trials: Clinical trials for psychedelic substances have several limitations, with many of these issues present in clinical studies in other areas of medicine. One prominent issue that has been discussed is the presence of functional unblinding in many psychedelic studies: given the distinct acute subjective effects of psychedelics, psychedelic substances are difficult to blind, meaning that participants and study staff may guess which treatment arm participants were assigned to (Elk & Fried, 2023). Other concerns that have been raised are the small sample sizes of many psychedelic clinical studies and lack of representativeness, limiting generalizability. Moreover, study durations tend to be fairly short (Elk & Fried, 2023). The quality of adverse event monitoring also differs significantly between studies: only 23.5% of studies published after 2005 reported systematic methods for ascertaining and reporting adverse events, raising worries about the under-detection of adverse events. However, the percentage of psychedelic studies reporting adverse events (53.3%) is higher than the median in other fields (46% in clinical trials of health interventions), pointing

to the need for improvement in reporting across all fields (Hinkle et al., 2024).

Effect on other types of substance use patterns: Evidence from cannabis policy is mixed, with some studies suggesting legalization increased polysubstance use and some suggesting a potential "substitution effect," where legal availability of cannabis reduced the consumption of other substances (Miller & Seo, 2021; Crost & Guerrero, 2012; Nguyen et al., 2023). Yet, psychedelics differ from cannabis in their drug use patterns, pharmacodynamics and user experiences. High-dose psychedelic use is not repeated at the frequency of cannabis or alcohol and has been shown to have a low potential for addiction (Johnson & Griffiths, 2017). Moreover, the potential therapeutic properties of psychedelics in treating substance use disorders (Sharma et al., 2023) may possibly reduce the consumption of other addictive substances. A recent survey of current psychedelic users reported psychedelic use was associated with decreased alcohol and stimulant use but increased opioid and cannabis use (Glynos et al., 2024). However, data from the National Survey on Drug Use and Health suggests that cannabis use disorder is associated with the use of psychedelic substances (Zech, Yaden & Jones, 2025).

Cost-Effectiveness Studies: A small but growing set of analyses suggests that psychedelic-assisted therapies can be cost-effective under specific assumptions, though results are sensitive to staffing intensity, drug price, and the durability of the benefits achieved. Across studies, clinician time is the dominant cost driver (≈90% for MDMA-AT in one model). Importantly, psychedelic-assisted therapy differs economically from "standard care." Most conventional treatments (e.g., daily medication plus ongoing psychotherapy) are continuous and potentially indefinite, so costs and clinician time accumulate month after month. By contrast, psychedelic care is episodic and front-loaded—preparation, one or a few dosing sessions, and limited integration—so value turns on the durability of benefit and retreatment frequency. This also has budgeting implications (episode-based payments vs. maintenance care) and capacity implications (meeting peak supervised-session demand vs. steady-state clinic visits). Moreover, we note that models for MDMA-assisted therapy and for psilocybin-assisted therapy also differ substantially, with MDMA models being significantly more time- and resource-intensive due to the psychotherapy that is provided during the drug administration session— in contrast, the psychosocial support that has been provided for psilocybin administration in clinical trials generally is non-directive. Broadly:

- MDMA-assisted therapy for PTSD is generally cost-effective—and often near cost-saving—under most scenarios, with favorable ICERs that remain robust unless treatment benefits dissipate within a year.
- Psilocybin-assisted therapy for treatment-resistant depression looks borderline at current prices and staffing, but can become cost-effective if therapist hours are reduced (e.g., through the use of group formats, hybrid staffing, digital integration tools) and drug costs are low.
- Conclusions hinge on time horizon and benefit durability (12-month vs. multi-year), perspective (payer vs. societal), and jurisdictional thresholds (e.g., US willingness-to-pay ~\$100k-\$150k per QALY vs. UK £20k-£30k).

These findings point to practical levers Maryland can control in program design (staffing models, group services, training/credentialing requirements, data-guided protocol choices) that materially influence affordability without presuming specific drug prices.

Table 2: Summary of cost-effectiveness studies		
Psilocybin- assisted therapy for treatment- resistant depression	McCrone et al. (2023) evaluated the cost-effectiveness of psilocybin-assisted therapy (PAT) for treatment-resistant depression compared with conventional medication, cognitive behavioral therapy (CBT) and the combination of conventional medication and CBT. Costs for PAT were estimated to range from £6132 to £7652 (dependent upon the cost of psilocybin).	
depression	They found that PAT may be cost-effective if therapist support was reduced by 50%, and the psilocybin price was reduced to £400-800 per person. The incremental cost-effectiveness ratio (ICER) for PAT was above £30,000 for all ranges of psilocybin costs.	

Psilocybin-assisted therapy for treatment- resistant depression	Avanceña and colleagues (2025) evaluated the cost-effectiveness for psilocybin-assisted therapy (PAT) for major depressive disorder compared to the standard of care (SOC), which they characterized as the use of second-generation antidepressants in conjunction with psychotherapy. They estimated the total cost of PAT to be \$5000, with \$3500 for the therapists and \$1500 for the psilocybin. Overall, Avanceña et al. reported that one-time, single-dose dose may be cost-effective compared to the current SOC. They found that with a 9% remission rate, the mean benefit of PAT was 0.031 QALYs over 12 months. The expected incremental cost-effectiveness ratio (ICER) of PAT (the ratio of incremental mean costs and incremental mean health effects between PAT and SOC) was \$117,517. PAT was found to be cost-effective when its cost was \$5000 or less.
MDMA-assisted therapy for post- traumatic stress disorder	Marseille and colleagues (2022) evaluated the cost-effectiveness of MDMA-assisted therapy (MDMA-AT) for post-traumatic stress disorder (PTSD) compared to standard care. They estimated the cost of MDMA-AT to be \$11,537 per patient, 90.7% of which is clinician compensation. Marseille et al. reported the incremental cost-effectiveness ratio (ICER) for MDMA-AT to be \$2,384 per QALY gained (assuming no savings in healthcare costs) and found MDMA-AT to be better and cheaper than standard care, except in scenarios where benefits ceased after one year.

2.2 Evidence on Psilocybin Economics and Policy Impacts

To inform our review of psychedelic regulatory pathways, we conducted a scoping review of expected costs and revenues for psilocybin policy options across three groups: providers, the state, and consumers/patients. A scoping review methodology was chosen as this type of review aims to clarify and identify key ideas in a field, in addition to searching for knowledge gaps (Munn et al., 2018; Arksey & O'Malley, 2005) (for an in-depth description of our methodology, see Appendix 1). Our scoping review comprises two parts: Part 1 focuses on identifying evidence on psilocybin economics and impacts of psilocybin policies in other states, while Part 2 aims to identify the key cost drivers of various psilocybin policy options.

2.2.1 Psilocybin Economics Review

We reviewed the peer-reviewed and grey literature on psilocybin economics in the U.S. Our search identified articles that examined, amongst other topics, the impact of drug decriminalization (including psilocybin) in Oregon, characteristics of psilocybin facilitators in Oregon, and retreat organizations present in the U.S. From the grey literature, our search identified a legislative report and reports from policy organizations. We briefly summarize these results below in Table 3.

Table 3: Summary of psilocybin economics studies		
Survey of psilocybin facilitators (Oregon).	In a survey of 106 psilocybin facilitators in Oregon, Luoma and colleagues (2025) found that there were 16 active training programs, and the average cost of tuition was \$9,359. 79% of respondents reported that the cost of tuition was a moderate strain on their finances. Regarding licensure, 57% reported that they had a healthcare license (e.g. professional counsellor, acupuncturist, psychologist).	

Decriminalizatio
n's near-term
system impacts
(Oregon).

In 2020, Measure 110 was passed in Oregon, which decriminalized the non-commercial possession of all drugs. Smiley-McDonald et al. (2024) and Spencer (2023) examined the impact of this measure on criminal system engagement by people who use drugs (PWUD) and unintentional drug overdose deaths, respectively. Smiley-McDonald and colleagues found that, in a survey of 468 PWUD, 74% reported past-year criminal legal system engagement. Among those who had been found to possess drugs by law enforcement (n=110), 77% had their drugs seized at least once. Knowledge of Measure 110 and the fact that all drugs had been decriminalized was low amongst the respondents (Smiley-McDonald et al., 2024). Using a synthetic control method, Spencer found that after Measure 110 was passed, 182 additional unintentional overdose deaths occurred in Oregon in 2021 (Spencer, 2023).

Retreat market characteristics and pricing.

Neitzke-Spruill and colleagues assessed the characteristics of 298 psychedelic retreat organizations and found that the vast majority were focused on general wellness. A small proportion of organizations identified as religious organizations. 28.2% of organizations had operations based in the U.S. The type of psychedelic substance offered varied between organizations, with most organizations offering ayahuasca (73.8%), while 25.5% offered psilocybin. The price for participation ranged from 20 USD – 150,000 USD (Neitzke-Spruill et al., 2025).

Implementation finance lessons from a legislative review.

Our search identified a legislative report prepared by the Psychedelic Medicine Task Force in Minnesota (Psychedelic Medicine Task Force, 2025). The report highlighted several suggestions from regulators in Oregon and Colorado for future psychedelic policy initiatives, such as

"making sure to get prior authorization from licensing boards related to dual licensure for facilitators, and to keep costs down by not restricting access to facilitated services to service centers that also need to be licensed for such purposes, or requiring that the program be funded entirely by licensing fees."

The report also notes that

"Oregon has had to allocate funds from tax-payer dollars to offset the costs until the program can be self-funded through licensing fees, and it would be financially more sustainable for the state to allocate funding to set up the program to get ahead of startup costs, so they don't get passed onto providers or potential clients."

Additional policy-report signals.

Our search identified reports from RAND-a policy think tank— and BrainFutures, a nonprofit focused on producing assessments of brain-based interventions. RAND's report, "Considering Alternatives to Psychedelic Drug Prohibition", highlights the financial inaccessibility of psilocybin services in Oregon and notes that since the beginning of the program, one service center has closed due to an insufficient number of clients. The authors additionally provide some data on spending on psilocybin by adults. In a survey of adults who report having used psilocybin in the last month, the average past-month spending on psilocybin products was \$44.56 (Kilmer et al., 2024).

BrainFutures' report, "Expediting Psychedelic Assisted Therapy Adoption in Clinical Settings", provides an assessment of facilitators' training costs, with tuition ranging from approximately \$6,000 to \$21,500. When combined with the lost income stemming from time spent away from their practice, the authors found facilitators may encounter costs of \$18,000 to \$143,000 in order to be trained to provide psychedelic treatments. The report additionally estimates that the psychotherapy component of psychedelic-assisted treatments will cost patients between \$5,300 and \$7,500 (Davis & Lampert, 2022).

The literature suggests that legal change without robust education and service access can leave outcomes unimproved—or even worsen some metrics. Workforce training and opportunity costs are major price drivers, while facility requirements and financing choices (fee-only versus early public investment) strongly influence affordability and program viability. In addition, markets tend to segment sharply by setting and price, making policy design choices—such as group sessions and equity supports—critical for ensuring access.

2.2.2 Cost Drivers and Implementation Levers Across Models

Part 2 of our scoping review identified the main cost drivers for seven psilocybin policy options—(1) FDA-approved use, (2) Religious use exemptions, (3) Deprioritization/decriminalization, (4) Non-commercial peer sharing, (5) Medical/therapeutic use, (6) Supervised adult use, and (7) Commercial sales. We group the findings into cross-cutting drivers (relevant to multiple models) and model-specific drivers.

Cross-cutting drivers. Some inputs shape costs across all policy models—regardless of who delivers services or how tightly the market is regulated. Most notably, (i) the production pathway and molecule and (ii) the drug's duration and dose drive large swings in unit and service costs.

Costs of producing synthetic versus natural psychedelics	A number of papers suggested that the production cost of psychedelics is likely to depend upon whether natural or synthetic psychedelics are made, with natural psychedelics likely to be relatively cheaper (Kilmer et al., 2024; McGuire et al., 2023; Gibbons, 2021).
Costs associated with the type of psychedelic and dosage	The type of psychedelic used is likely to also determine the costs associated with policy models like Medical/Therapeutic Use and Supervised Adult Use. Shorter-acting psychedelics, like dimethyltryptamine (DMT), may present a lower-cost alternative to classic psychedelics like psilocybin and lysergic acid diethylamide (LSD), which have a longer acute subjective experience, or "trip", and therefore require a higher number of facilitator hours for supervision.
	The potential development of non-hallucinogenic psychedelics, or psychedelics "without the trip" (also known as "non-hallucinogenic psychoplastogens"), may also be a promising avenue to reduce costs, as supervision by facilitators for the duration of the drug administration session may not be required (Aday et al., 2024). However, we note that it is still an open empirical question as to whether non-hallucinogenic psychedelics would have the same therapeutic impact as hallucinogenic ones (Olson, 2020; Yaden & Griffiths, 2020), and that their development is still in early stages.
	Regarding dosage, the microdosing model—the administration of psychedelics as sub-hallucinogenic doses— also presents a potentially lower cost alternative due to reduced supervision needs (Andrews & Wright, 2022).

FDA-approved use. We found no state-specific cost studies on FDA-approved psychedelic products; the available literature is national/global. The table below therefore maps the main cost centers across the product life cycle—from pre-approval development under Schedule I controls, to post-approval safety obligations, to point-of-care delivery—so Maryland can anticipate where costs arise even without local estimates.

Costs associated with clinical trials	The costs of conducting clinical trials with psychedelics may be driven up by the current Schedule I placement of psychedelics, which then increases costs associated with the manufacture, storage and administration of psychedelics (Al-Khaled, 2022; Marks, 2018). More generally, the largest cost associated with drug approval are Phase III trials (Rodgers et al., 2024).	
Costs associated with regulatory compliance	The cost of running a pharmacovigilance program, such as a Risk Evaluation and Mitigation Strategies (REMS), was mentioned as a major cost of labeling new indications (Rodgers et al., 2024)	

Religious-use exemptions. Entities must petition the DEA for an exemption from the Controlled Substances Act under RFRA/case law. This process can generate (1) legal fees for counsel to prepare the petition and supporting evidence; (2) lost income while ceremonies are paused or restricted during review; and (3) potential litigation costs to defend or clarify an exemption once granted (Litman, 2024; GAO, 2024). Ongoing costs may also include maintaining documentation to demonstrate bona fide religious practice, safety screening and ceremony protocols, risk management/insurance, and supply logistics (e.g., sourcing sacramental materials, import paperwork where applicable). Because ceremonies are typically donation-based, there is no retail revenue to offset these outlays, so even modest legal or compliance expenses can be material.

Costs related to obtaining the exemption	To obtain a religious use exemption for psychedelics, entities are required to petition the Drug Enforcement Administration for an exemption from the Controlled Substances Act. Potential costs associated with this process include: 1) legal fees from attorneys hired to navigate the exemption process and prepare the application, 2) the loss of income associated with an inability to generate income related to prayer ceremonies, and 3) litigation to defend the religious use exemption (Litman, 2024; GAO, 2024).
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Deprioritization/decriminalization. We did not find explicit cost drivers in the psychedelic literature for this model beyond general public-health communication costs. That said, jurisdictions typically face implementation expenses such as: drafting and disseminating enforcement guidance; training for police, prosecutors, and courts; public education and multilingual harm-reduction campaigns; building light-touch surveillance (poison-center signal monitoring, ED/EMS dashboards); modest data and evaluation capacity; community partnership grants for hotlines/peer support; and, where included, record relief (expungement/resentencing) administration. Some costs can be offset by reduced arrests, bookings, lab testing, and prosecutions, though savings may materialize gradually and can be partially reallocated to health outreach and monitoring.

Non-commercial peer sharing. With no licensed market, state costs center on policy clarity and enforcement (defining "no remuneration," distinguishing gifting from trafficking, addressing advertising/solicitation violations). User costs are mainly cultivation supplies and optional testing/integration services. We did not find literature that explicitly estimates these costs for psychedelics; however, jurisdictions should anticipate modest outlays for statutory guidance, law-enforcement and judicial training, public education on safe use and the gifting boundary, light-touch signal surveillance (e.g., poison-center/emergency department trends), and periodic evaluations—costs that are generally far lower than those associated with building a full licensing and retail apparatus.

Medical/therapeutic use. In clinical or therapeutic models, labor is the primary cost driver: day-long dosing sessions (often ~8 hours for psilocybin) plus preparation and integration multiply facilitator hours, which rise further with stricter credentialing. Additional costs come from facility needs (dedicated rooms, staffing requirements, emergency equipment), quality assurance (e.g., video recording/review), regulatory compliance (storage/REMS/chain-of-custody), and caregiver time (transport/monitoring). Cost-mitigation levers include group administration/integration, lighter-touch psychological support if appropriate (nothing that this is likely to be substance dependent as well), digital tools for parts of integration, and hybrid staffing (in-room + remote supervision)—all requiring clear rules and safety guardrails.

Labor costs	In contemporary psychedelic clinical trials, two facilitators are usually present for the duration of the drug administration session. This session can be fairly lengthy, lasting around eight hours for psilocybin. Drug administration sessions are bookended by preparation and integration sessions, which also requires a therapist or facilitator. Accordingly, many have suggested that a major cost driver associated with the provision of psychedelic treatments will be the facilitator hours required for preparation, integration and drug administration sessions (Lamkin, 2022; Andrews & Wright, 2022; Hayes et al., 2022) – increasing the number of required sessions for integration and preparation will increase costs (Smith & Appelbaum, 2022; Hutson, 2025; dos Santos et al., 2021). Costs are also likely to be elevated if greater licensure requirements are imposed on facilitators (Adams et al., 2024; Hatfield et al., 2024; McGuire et al., 2024; Belouin et al., 2022). One estimate from BrainFutures places the cost of psychotherapy alone for one round of psychedelic-assisted treatment at \$5,300–\$7,500 (Davis & Lampert, 2022).
	Potential methods to lower costs include conducting group drug administration sessions (which allows facilitators to supervise multiple clients simultaneously), permitting group therapy for integration (Magar et al., 2023; Wolfgang & Hoge, 2023), and providing psychological support (a more limited form of psychosocial support) in lieu of psychotherapy for some psychedelic treatments if appropriate and safe. The use of digital apps for integration may also be a cost-saving method (Hatfield et al., 2024). Another potential method to lower costs may be to have one facilitator in the drug administration room, while another supervises via video, which allows the second facilitator to supervise multiple sessions at once (Jacobs et al., 2024).
	Another identified cost driver is the cost associated with reviewing video recordings. Many contemporary clinical trials record drug administration sessions as a safety procedure, as recordings help furnish evidence in the case of boundary violations by the facilitator (Rajwani, 2023). However, reviewing these recordings for violations will be a costly practice (Hatfield et al., 2024).
Facility costs	As the drug administration session generally requires a private space, one cost driver is the capital costs associated with dedicating a room for this purpose (Barber & Dike, 2023). Costs will also be raised if overnight supervision at a facility post-drug administration session is mandated as part of the model (Hatfield et al., 2024).
Costs associated with legal/regulatory compliance	Costs mentioned in the literature include those stemming from a need to comply with a REMS, if required by the FDA, and storage costs stemming from the Schedule I status of psychedelics (Davis & Lampert, 2022).
Miscellaneous costs	Some other cost drivers of the therapeutic use model mentioned in the literature include costs related to caregiving, as there may be a potential increase in the burden placed on care partners due to the need for monitoring post-drug administration and accompaniment to and from sessions (Otsuka, 2024).

Supervised adult use. In supervised adult-use systems, costs are driven by labor/training, regulatory/facility build-out (multi-tier licensure, brick-and-mortar sites, security/recordkeeping), tax/finance frictions (IRC 280E, limited banking), and data/insurance overhead. Liability insurance can also be a major operating expense (e.g., reports of ≈\$12,000/year for psilocybin service providers in Oregon—substantially higher than average psychiatric malpractice premiums), which increases pressure on pricing and access. Local zoning/opt-outs can push up rents and client travel. Cost levers include group sessions, shared facilities, right-sized training, and streamlined reporting that preserves safety.

Labor costs	A number of articles referred to the high cost of training for facilitators as a cost driver, with current training programs for facilitators in Oregon costing on average \$9,359 (Luoma et al., 2025). Some trainees that hold other healthcare licenses also incur an opportunity cost when training, as time is spent away from their practice (Davis & Lampert, 2022).
Costs associated with legal/regulatory compliance	Cost drivers stemming from legal and regulatory compliance include the potential need to obtain state licensure and state required security systems (Aday et al., 2024). In Oregon, some have argued that costs are high due to staffing requirements, and the mandate that psilocybin be administered in a dedicated brick-and-mortar location (Psychedelic Medicine Task Force, 2025). Businesses involved in producing or selling psilocybin products are also subject to Internal Revenue Code 280E, which prohibits taxpayers who work with Schedule I substances from deducting expenses under the "ordinary and necessary" standard: this imposes a significant federal tax penalty on psilocybin businesses. Concerns have also been raised about the costs associated with data monitoring programs, if mandated, as service center in Oregon are required to develop their own systems for data collection (Smith, Sisti & Appelbaum, 2024).
Miscellaneous costs	The cost of obtaining liability insurance has been mentioned as one cost driver, with one report finding that it cost a psilocybin service provider in Oregon \$12,000 (Ferenstein, 2024) ⁴ .

Commercial sales. In competitive retail, consumer prices are driven by outlet density/license caps, wholesale/retail markups, and taxes/fees; more density and lower excise generally push prices down, tight caps/high taxes push them up (Kilmer et al., 2024). State costs come from building/running a cannabis-style regulatory apparatus; industry bears compliance/testing that flows through to prices.

2.3 Insights from Selected Research on Psychedelic Policy Evaluation

We identified a focused set of research contributions that make concrete, actionable suggestions for how to measure psychedelic services and their impacts across policy settings. As summarized in the table, Korthuis and colleagues offer a ready-made minimum dataset for supervised services with clearly specified process, outcome, and structure measures, paired with facilitator and client safety checklists and defined follow-up intervals which can anchor licensing requirements and routine reporting. Haden, Paschall, and Woods extend the lens beyond clinics to naturalistic use, showing why any population monitoring must record context including mindset, environment, and dose alongside age and experience, and must track salutary effects (well-being, social connection) as rigorously as adverse events, with special attention to youth and other higher-risk groups. Haden, Emerson, and Tupper supply the governance scaffolding—an oversight commission and a college for supervisors—that implies collecting system-level data on supervisor training, facility accreditation, protocols (especially around touch and referral), complaint handling, and product supply chains, including sustainability. Black and co-authors set the template for a fit-for-purpose postmarket "mosaic" that links point-of-care registries, patient-reported outcomes, administrative data, and community surveys; they emphasize product-specific identifiers, validated effectiveness measures (not only safety), the need to distinguish intended psychoactive effects from adverse events, and the importance of equity analyses at small geographic scales.

Finally, Ostrovsky and Barnett show how newly issued Category III CPT codes (0820T–0822T) can give immediate visibility into session duration, staffing, and setting for monitored psychedelic therapy, while also revealing current coding gaps for preparation and integration that policy makers should close to avoid fragmented evidence and inequitable access.

Korthuis et al. (2024)

- Three-round e-Delphi defined a core dataset for supervised psilocybin services: 11 process, 11 outcome, 17 structure measures (Donabedian framework).
- Priority items: informed consent; explicit touch/sexual-boundary policies; medication & mental-health screening; dose documentation; brief follow-ups at 1–2 weeks, 6 months, 12 months; paired facilitator/client safety checklists within 24 hours/7 days.
- Insight: States/providers can adopt this as a ready-made minimal dataset for licensing, audits, and outcome tracking without overburdening community settings.

Haden, Paschall & Woods (2025)

- Public-health synthesis of naturalistic psychedelic use: associations with improved mental health, social connectedness, reduced substance misuse.
- Flags concentrated risks: youth, high doses, psychological vulnerability, poor set/setting.
- Advocates legalization/regulation plus evidence-informed education centered on set, setting, and dosage.
- Insight: Surveillance should routinely capture context variables (mindset, environment, dose), brief well-being/function metrics, and age/experience stratifiers to target harm reduction.

Haden, Emerson & Tupper (2016)

- Regulatory blueprint proposing: a Psychoactive Substances Commission (supply stewardship, plain packaging, sustainability) and a College of Psychedelic Supervisors (train, license/certify, inspect, handle complaints).
- Details youth-access rules (mature-minor pathways), preparation/integration expectations, continuous monitoring.
- Insight: Policy data must extend beyond patients to systems—track supervisor credentials, facility standards, referrals/escalations, complaints (especially boundary violations), and product/batch flows.

Black et al. (2024)

- Calls for a purpose-built "mosaic" post-market surveillance linking point-of-care registries, patient-reported outcomes, community surveys, and administrative data.
- Priorities: measure effectiveness (not just safety) with validated scales; separate intended psychoactive effects from adverse events; use product-specific coding to avoid conflating regulated vs. illicit exposures; account for facilitator training, setting, and co-medications.
- Insight: Build harmonized instruments/identifiers now (drug, dose, protocol, setting, provider) and design analyses for small-area equity monitoring.

Ostrovsky & Barnett (2024)

- New AMA Category III CPT codes 0820T–0822T ("continuous in-person monitoring and intervention during psychedelic medication therapy") enable standardized claims on session duration, staffing mix, and supervision—pre- and post-FDA approvals.
- Expose gaps (e.g., no universal 90-minute preparation/integration psychotherapy code); urge adoption across systems, payers, and community clinics to study access, cost, and safety (including Medicaid/Medicare).
- Insight: Require these codes where applicable to create a national, analyzable trail of service delivery and enable real-time comparisons of care models and equity.

2.4 Insights from Cannabis Policy Evaluation

Although cannabis and psilocybin differ in important ways, evidence from cannabis offers a clear template for what to measure and how to measure it when a jurisdiction changes drug policy.

We conducted a review of the literature on policy evaluations for cannabis legalization, excluding articles that were published before 2010 for relevance. Below is a summary of our results. The reviewed articles examined the impact of cannabis legalization on a variety of outcomes. These can be roughly grouped thematically into two broad categories: 1) public health outcomes, and 2) economic outcomes.

Table 4: Summary of policy outcomes		
Category		Outcomes
Public Health	Consumption Patterns	 Per capita alcohol consumption (Veligati et al., 2020) Per capita tobacco consumption (Veligati et al., 2020)
	Morbidity and Mortality	 Drug-related deaths (Brown, Cohen & Felix, 2018) Overdose injuries (Delling et al., 2019) Drug-related hospitalizations (Brown, Cohen & Felix, 2018) Chronic pain hospital admissions (Delling et al., 2019)
	Healthcare Utilization	 Substance abuse treatment admissions (Brown, Cohen & Felix, 2018) Use of prescription drugs for which cannabis could serve as a clinical alternative (Bradford & Bradford, 2018)
	Occupational Health	 Number of worker compensation claims (Abouk et al., 2021) Incidence of work-limiting disabilities (Abouk et al., 2021) Non-traumatic workplace injury rates (Abouk et al., 2021)
	Road safety	 Number of traffic accidents and fatalities (Gonzalez-Sala et al., 2023) Number of risk behaviors related to driving after consumption (Gonzalez-Sala et al., 2023)
	Crime	 Number of crimes and arrests for property crime (Freisthler et al., 2016) Number of crimes and arrests for violent crime (Freisthler et al., 2016)
Economic	Employment and Productivity	 Wages among working-age adults (Sabia & Nguyen, 2018) Reported weekly hours worked (Nicholas & Maclean, 2019) Reported absences due to sickness (Ullman, 2016) Unemployment rate (Chakraborty, Doremus & Stith, 2021)
	Housing	Housing prices (Cheng et al., 2018; Burkhardt & Flyr, 2019; Conklin, Diop & Li, 2020)

	Tourism	 Hotel occupancy (Meehan et al., 2020) Number of rooms rented (Meehan et al., 2020)
	Financial Sector	Audit fees incurred by banks in legalized states (Brushwood et al., 2020)
	Macroecono mic indicators	 Gross Domestic Product (GDP) (Brown, Cohen & Felix, 2018) Income per capita (Brown, Cohen & Felix, 2018) Wages per capita (Brown, Cohen & Felix, 2018)

Anderson & Rees (2023) synthesize empirical evaluations of cannabis policy and report that researchers track consumption through large, repeated surveys (Monitoring the Future, NSDUH, YRBS) and arrest-based proxies from the FBI's Uniform Crime Reports; market conditions via prices; and downstream outcomes spanning youth use, use of alcohol, opioids, and tobacco (self-reports, sales data, Medicare/Medicaid prescribing, overdose mortality), mental health (suicide, BRFSS "poor mental health" days, validated screening tools), traffic safety (crashes and fatalities, including alcohol involvement), workplace outcomes (absenteeism, injuries, labor supply, workers' compensation, SSDI/SSI), and crime (violent and property offenses, drug arrests, neighborhood-level patterns near dispensaries, marijuana-specific offenses). French et al. (2022) reinforce this breadth in a systematic review, documenting parallel measurement across adolescent use, opioid outcomes, alcohol and tobacco use, illicit cultivation incidents, employment and academic performance, public risk perceptions, road safety, sexual behavior and births, crime, and suicide, drawing on population surveys, health-care claims and hospital records, vital statistics, education and labor datasets, traffic safety databases, and law-enforcement statistics.

Two complementary papers translate those empirical practices into explicit monitoring frameworks. Hall & Lynskey (2016) recommend a policy evaluation backbone that includes general-population and school surveys of use; retail metrics such as sales volumes, legal plant counts, and THC potency; car-crash fatalities and injuries; emergency-department presentations; presentations to addiction treatment; and targeted surveillance of regular use among youth in mental-health and criminal-justice settings. Fischer et al. (2019) propose a concise, standardized indicator set—prevalence and age of initiation, patterns and modes of use, potency, product source, impaired driving and injuries, hospitalizations and poisonings (including poison-center calls), cannabis use disorders, use and mortality from other risky substances, and harms to others—with harmonized definitions and routine public reporting.

Together, these evaluations show that rigorous policy assessment rests on three pillars: 1) consistent measurement of exposure and market conditions (who is using, what they are using, and at what strength and price), 2) comprehensive outcome surveillance across health, safety, labor, and justice domains, and 3) standardized indicators that allow comparison over time and across jurisdictions. Crucially, both direct and indirect effects must be tracked—for example, direct effects such as acute adverse events, emergency department presentations, and changes in frequency/potency of use, and indirect effects such as substitution or complementarity with alcohol/opioids, traffic crashes and DUIs, labor-market outcomes, crime and victimization patterns, and shifts in health-care utilization and costs.

Anderson & Rees (2023) — Review of empirical cannabis-policy evaluations and what they measure.

- Outcome domains commonly used: use/prevalence (MTF, NSDUH, YRBS), arrests, prices; youth use; substitution/complementarity with alcohol (self-reports, sales, hospital admissions, alcohol-involved fatalities), opioids (Part D/Medicaid prescribing, mortality), and tobacco (prices/taxes, consumption); mental health (suicide rates, BRFSS "not good" days, campus screens); traffic safety (crashes/fatalities); workplace outcomes (absenteeism, injuries, labor supply, SSDI/SSI); and crime (violent/property, marijuana offenses, dispensary-area crime).
- Insight: For psychedelics, build a parallel indicator set: prevalence/intent, substitution with alcohol/opiates, mental-health and functioning markers, traffic injuries, and neighborhood crime, so Maryland can compare across policy regimes.

French et al. (2022) — Systematic review (113 studies) cataloging societal-cost/benefit metrics used for medical/recreational marijuana laws.

- Measures span: adolescent use; opioid prescriptions/overdoses/mortality; alcohol/tobacco use; illicit cultivation; employment/workplace metrics (hours worked, health absences, workers' comp); academic achievement/time use; crime (violent/property, arrests); perceived harmfulness; road safety; sexual behavior and birth outcomes; and suicide.
- Insight: Use this as a menu for a psychedelic evaluation plan: include adolescent exposure perception, workforce/education impacts, perceived risk, and sentinel health outcomes, then reduce to a lean, Maryland-feasible core.

Hall & Lynskey (2016) — Monitoring framework for recreational legalization.

- Recommends routine: household/school surveys on use; market indicators (sales, production counts, potency/THC); and harm indicators (traffic fatalities/injuries, ED presentations, treatment entries, prevalence of regular use among youth in mental-health/criminal-justice settings).
- Insight: Translate to psychedelics by substituting product/setting indicators (batch/lot, dose categories, service-center volume) and harm markers (ED/EMS calls, poison-center reports), plus targeted surveillance in youth/behavioral-health systems.

Fischer et al. (2019) — Ten core public-health indicators and a composite index concept.

- Core indicators: prevalence/age of initiation; patterns (frequency/intensity); modes (e.g., smoking/edibles—analog: oral/tea/capsule); potency; product source; impaired driving/injuries; hospitalizations/poisonings (incl. poison-center data); use disorders; co-use/mortality with other risky substances; and harms to others.
- Insight: Adapt the "ten-indicator" approach for psychedelics (e.g., add set/setting, facilitator supervision, and contraindicated co-medications) and consider an index for Maryland's dashboards to track net public-health movement over time.

2.5 Select State-Led Initiatives to Improve Mental Health

States across the U.S. have implemented a variety of initiatives focused on mental and behavioral health. Below, we provide a select summary of state-led efforts against which some psychedelic policy models may be compared and contrasted. These state initiatives include expanding telehealth access to mental health services, increasing access to mental health screenings, and improving the provision of culturally competent care (NAMI, 2022).

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Expansion of access to underserved populations	A number of bills have been introduced that expand access to mental health services to underserved populations. California SB 141, for example, proposes expanding funding for LGBTQ behavioral health concerns. LD 1848 in Maine proposes to increase the availability of assertive community treatment by removing the requirement that a licensed practical nurse may be included on an ACT team in lieu of a registered nurse only if the prescriber is not a certified nurse practitioner.
Mental health insurance parity	One potential method to improve access to mental health care services is to introduce state parity laws, which require health insurance plans to provide equivalent coverage for mental health services as for medical care.
	A growing number of states have enacted some form of mental health parity statute (for example, the 2022 Mental Health Parity and Addiction Equity Act in Maryland).
Telehealth services	Several states have introduced or enacted bills to codify telehealth access to mental health services (e.g. HB 1069 in Washington), which can be an effective way to provide mental health care when patients and providers are geographically distant and helps to improve continuity of care. For example, SB 1179 in South Carolina proposes allowing social workers, other therapists, and counselors to provide behavioral telehealth services.
Sharing of information about mental health supports	Some states have also considered bills that require institutions to provide information to students about available mental health support, through methods such as printing resources on student identification cards and live presentations. For example, New York A 1139 proposes, alongside other measures, to require institutions to provide incoming and current students with information about depression and suicide prevention.
Mental health screenings	A small number of states have improved access to mental health screenings (an assessment of whether an individual shows mental health symptoms) through legislation, which may then lead to improved access to behavioral health services. For example, HB 303 in Delaware requires insurance coverage of annual behavioral health wellness checks.
Provision of culturally competent care	A number of states have introduced bills that support the provision of culturally competent mental health services, which may then allow mental health services to be more sensitive to the needs of diverse populations (Guarnaccia & Rodriguez, 1996). For example, SB 22-148 in Colorado proposes the creation of a grant program to support improvements to tribal behavioral health facilities for Indigenous individuals.
Veterans' mental health	Some states have focused on the improvement of veterans' mental health through legislation. For example, HB 1181 in Washington proposes the establishment of measures to prevent suicide among veterans.
Improving access to medication	Bills have been introduced in a number of states that propose improving access to medication. For example, SB 140 in Kentucky proposes changes to the step therapy reform law to provide a way for physicians to override step therapy protocols in certain cases.

Improving mental health workforce shortages	A number of states have focused on the problem of mental health workforce shortages. Addressing workforce shortages is one potential method to improve access to mental health care services, and to meet the growing need for mental health care in the US (Belz et al., 2024). For example, HF 2725 in Minnesota proposes the creation of a grant program for mental health providers who have at least 25% of clients on public insurance, or who serve underrepresented communities.
Peer support workers	A small number of states have introduced bills that aim to better integrate the use of peer support workers in mental health services, which may then help improve social support for patients and patient satisfaction (Eddie et al., 2019). For example, SB 282 in Florida proposes recognizing the role of peer specialist as an essential element in a coordinated system of care, and requires reimbursement for qualified peer specialists.

3. The Oregon Experience

Oregon created a non-medical, licensed psilocybin services program under ORS 475A, with supervised dosing at service centers, trained facilitators, and a 15% tax on psilocybin products. Service provision began in 2023. By early 2025 the state had licensed several hundred facilitators but far fewer centers, and service volume remained modest. Safety events reported to the health authority have been rare, though monitoring continues. Finances are tight: fee revenue has not yet covered program costs, start-up subsidies were needed, and businesses face insurance, banking, zoning, and federal tax burdens (IRC 280E). Clients skew higher income and many travel from out of state, raising access and equity concerns.

3.1 Overview of the Psilocybin Services Act

The Oregon Psilocybin Services Act –or Ballot Measure 109– was voted into law in November 2020 by Oregonians, making Oregon the first state in the U.S. to create a regulatory framework for the provision of psilocybin. It is codified as Oregon Revised Statutes Chapter (ORS) 475A. The program was developed between 2021 and 2022, and service provision began in 2023. When passing Ballot Measure 109, it was estimated that the program would cost \$3.1 million a year to run, with the goal of being wholly funded by licensing fees generated by the program.

ORS 475A, hereafter referred to as the Act, authorizes psilocybin administration at licensed service centers with trained facilitators under a non-medical model. Clients do not need a medical diagnosis, facilitators need not be health professionals, and consent materials state that services are not clinical treatment. Moreover, the Act originally required facilitators who held other healthcare licenses to not utilize their healthcare expertise in integration and preparation sessions. However, House Bill 2387, passed in 2025, amended ORS 475A to permit facilitators who hold both a psilocybin facilitator license and other specific healthcare licenses to provide preparation and integration sessions under both licenses. Professions included under this amendment are: the Oregon Board of Licensed Professional Counselors and Therapists; Oregon Board of Naturopathic Medicine; Oregon Board of Psychology; Oregon Medical Board; Oregon State Board of Nursing; State Board of Licensed Social Workers; and the State Board of Pharmacy.

The Act also mandated the establishment of the Oregon Psilocybin Advisory Board, which advises Oregon Health Authority—which governs psilocybin services—on the implementation of the Act. Oregon Health Authority has written and adopted a set of rules (OAR 333-333) that sets out requirements for, amongst other things: facilitator training programs, product testing, the manufacture of psilocybin, packaging, the locations of service centers, and safety and emergency plans. A sales tax of 15% is placed on the sale of the psilocybin product, but not on the accompanying services offered (e.g. preparation, integration). Manufacturers, psilocybin facilitators, service centers and laboratories must all be licensed. Service centers must also have a social equity plan in place, submitted with their license application, that describes how diversity, equity, justice and inclusion principles will be applied to their center's operations, and how performance will be measured.

To obtain a psilocybin facilitator license, applicants must be 21 years of age or older, and have a high school diploma (or its equivalent). Individuals must have taken an approved training program and have passed an examination. OAR 333-333 mandates that training curricula must cover the following topics, with a minimum number of hours dedicated to each module: history of psilocybin, cultural equity, safety and ethics, science, facilitation skills, preparation and orientation, administration, integration and group facilitation. 40 hours of practicum training at a service center is also required.

For clients to obtain psilocybin services, they must undergo a preparation session with a facilitator, during which the informed consent document is reviewed, along with the client Bill of Rights (whose content is set out by OAR 333-333), and the client's willingness and comfort with the use of touch during the drug administration session. The client is also screened for conditions that warrant exclusion from receiving psilocybin services. These are: 1) having taken lithium in the past 30 days, 2) active suicidal ideation, and 3) having been diagnosed or treated for active psychosis. During the drug administration session, the client must be continuously supervised by a facilitator. Facilitators are required to maintain a non-directive approach to facilitation and integration. After the session, the facilitator must offer the client an integration session, but the client is not required to undergo it.

Finally, Senate Bill 303, which was passed in 2023 and is now codified in ORS 475A, directs service centers to collect certain data from clients. These include race and ethnicity, preferred spoken language, disability status, gender identity, sex, household income, age, and reasons for requesting psilocybin services. These data are deidentified and published by the Oregon Health Authority on their website, as well as shared with <u>Oregon Health and Science University</u>.

3.2 Current Status of the Program

Psilocybin services have now been provided in Oregon for roughly two years. Regarding licensing, as of August 2025, licenses have been approved for: 372 facilitators, 1 laboratory, 11 manufacturers, 24 service centers, and 872 workers (individuals permitted to perform work on behalf of a licensee). 18 training programs are currently active. Since January 2023, 30,029 psilocybin products have been sold, and 13 emergency service reports have been made.

In Q1 (January - March) of 2025, 1509 clients received psilocybin services. 1368 of these sessions were individual sessions, and 197 sessions were group administration. The average product dose was 24.44 mg. Two severe behavioral reactions have occurred in Q1 (defined as a client's behavioral reaction that required transport to a hospital), and three adverse medical reactions have occurred (defined as a client's medical reaction that required contacting emergency services or receiving care from a medical provider that occurred during an administration session). One 72-hour post-session reaction has occurred in Q1 (defined as a medical/behavioral action that occurred within 72 hours of a client's release from a dosing session that was likely related to psilocybin consumption and resulted in contact with emergency services or the receipt of care from a medical provider).

With regard to client demographics, the average income of clients accessing psilocybin services in Q1 was approximately \$136,000, and average client age was 44.5 years old. Approximately half of the clients served were from Oregon, and while the rest travelled from out-of-state.

Clients reported having sought out psilocybin services for a variety of reasons spanning medical and non-medical motivations, including for: general health and wellness, enhanced creativity, a change in perspective and motivation, expanded consciousness, mental and physical exhaustion, depression, chronic pain, PTSD, or domestic violence related trauma.

3.3 Progress and Experience Thus Far

Since starting service provision in 2023, it is estimated that the program has served over 10,000 clients.

One significant concern that has been raised thus far is the financial sustainability of the program. While the program was designed to be funded entirely by license fees, it has not yet generated enough revenue to do so. For the 2023-2025 period, the program received state-allocated funds to help start-up the program (Oregon Psilocybin Services, 2025).

Licensing fees have not yet covered the program's administrative costs for several reasons. One such is that the industry has seen slower growth than expected, partly due to the challenges faced by applicants in obtaining licenses. Local government ordinances (the Act permits local governments to adopt ordinances that prohibit psilocybin businesses) and zoning restrictions have created hurdles for applicants. Currently, only 11 out of the 36 counties in Oregon permit psilocybin businesses. Licensees also face high costs related to insurance, banking and tax filing, which further threatens the financial sustainability of psilocybin service centers. Concerns have also been raised about the costs related to the data monitoring requirement imposed by Senate Bill 303, as service centers are required to develop and maintain their own data collection systems. Moreover, psilocybin businesses are subject to Internal Revenue Code 280E, which prohibits businesses that work with Schedule I or II substances under the Controlled Substances Act from deducting expenses under the "ordinary and necessary" standard. This imposes a substantial federal tax penalty on psilocybin businesses. Since 2023, a number of psilocybin service centers have closed (Oregon Psilocybin Services, 2025; Effinger, 2025).

Due to the high cost of operating, the price of psilocybin services is high for clients, with many voicing worries about the subsequent inaccessibility of psilocybin services (Oregon Psilocybin Services, 2025). One center has been quoted as charging \$1000 per session (Effinger, 2025). Other financial concerns include the cost of facilitator training programs. The cost of training was reported to be a financial strain for facilitators (Luoma et al., 2025), with tuition costs averaging \$9,359. Some providers also incur an opportunity cost during training, as time is spent away from their primary practices. One facilitator stated that

"That's kind of the problem: the people who are making the money right now in this are the schools. The service centers are not; the licensing fees for them are very high. The facilitators are not ... we're breaking even, and most of us are not doing it for the money," (Domurat & DePaola, 2025)

Compounding this financial burden, one media article has reported that there may be an over-supply of facilitators, with limited opportunities for facilitators to work at service centers (Stringer, 2024).

Finally, some have raised concerns about the current safeguards in place for clients, with some arguing that there exists insufficient oversight, while others suggest that the safety and effectiveness of psilocybin services have been demonstrated over the past two years. Smith, Sisti and Appelbaum have previously argued for oversight by mental health professionals, given the current evidence base on psilocybin's safety and effectiveness (Smith, Sisti & Appelbaum, 2024). In contrast, others point to the low rate of emergency service calls and adverse medical events as evidence that current safety protocols may be adequate or excessive (although the criteria for reporting adverse events under the Act is much higher than in psychedelic clinical trials) (Oregon Psilocybin Services, 2025).

In sum, Oregon's experience shows that a non-medical model can operate safely at modest scale with trained facilitators and supervised dosing, but service centers—not facilitators—are the main bottleneck. Fee-only funding has proven unstable in the early years, making a start-up subsidy or backup appropriation important. Local siting rules and federal tax treatment further constrain growth and raise prices, while the client mix has skewed toward higher-income and out-of-state users unless prices fall or subsidies are introduced. Although adverse events reported so far have been rare, continued monitoring and clear definitions remain essential. Finally, data standards such as those required under Senate Bill 303 strengthen evaluation but add costs that must be anticipated and budgeted.

4. Assessing Potential Demand in Maryland

4.1 Potential Demand Under a Medical/Therapeutic Use Model

Approach and key assumptions

We use a prevalence-to-uptake framework grounded in two qualifying groups commonly cited for early clinical deployment for psychedelic therapy: treatment-resistant depression (TRD) and post-traumatic stress disorder (PTSD) with persistent impairment despite standard care. We focus on adults, as existing clinical trials have primarily enrolled adults and pediatric evidence remains limited. For sizing, we set the Maryland population to ~6.18M, with ~4.82M adults (78%) (Source: Maryland Dept. of Planning's statewide 2020 Census profile, derived from U.S. Census Bureau DHC).

Treatment-resistant depression (TRD)

Rab, Raison, and Marseille (2025) estimate that, nationally, ~2.7 million patients meet TRD criteria among ~9 million treated for major depressive disorder (MDD). Applying clinical eligibility screens for psilocybin-assisted therapy (PSIL-AT), they report three bands for TRD eligibility: a strict lower-bound (24%) that mirrors randomized-trial exclusions (e.g., psychotic or manic disorders; suicide attempt in the past year; certain personality disorders; moderate—severe hepatic impairment; alcohol or drug dependence; specified cardiovascular risks; pregnancy; inability to taper SSRIs or pause psychotherapy; recent ECT/TMS; recent/high lifetime psychedelic use; first-degree family history of psychosis/bipolar); a mid-range (56%) that relaxes exclusions unlikely to hold in routine care such as removing alcohol and substance use disorders while retaining safety-critical contraindications such as active psychosis/mania, acute suicidality, and serious hepatic/cardiovascular disease; and an upper-bound (62%) that further adjusts for double-counting across comorbid conditions (e.g., overlapping psychosis/suicidality and cardiovascular clusters). Their uncertainty analysis yields a 95% range of 1.4–1.9 million nationally eligible TRD patients.

To translate these figures to Maryland adults, we scale by the adult population share (MD adults \approx 4.82M vs. U.S. \approx 250.6M; share \approx 1.92%). This implies an eligible TRD pool of roughly \sim 11,544 (lower-bound), \sim 28,860 (mid-range), and \sim 32,708 (upper-bound), with a sensitivity band of \sim 26,945–36,603. Converting that stock into annual treatment volumes requires an uptake assumption. Using annual uptake rates of 5%, 15%, and 30% (reflecting constraints from coverage, provider capacity, and patient preference) yields:

Maryland TRD eligibility (scaled to MD adults)	Eligible TRD patients (MD)	5% annual uptake	15% annual uptake	30% annual uptake
Lower-bound eligibility (24%)	~11,544	~577	~1,732	~3,463
Mid-range eligibility (56%)	~28,860	~1,443	~4,329	~8,658
Upper-bound eligibility (62%)	~32,708	~1,635	~4,906	~9,812
Sensitivity band (95% CI → MD share)	~26,945–36,603	~1,347–1,830	~4,042–5,490	~8,084–10,981

Notes: Eligibility bands (24%/56%/62%) and 95% CI from Rab, Raison, & Marseille (2025); Maryland counts are per-capita scaling using the MD/U.S. adult share (~1.92%). Uptake rates (5%, 15%, 30%) are illustrative annual participation among the eligible adult pool; figures exclude off-label use and spill-in and are rounded.

These are order-of-magnitude planning figures. They assume Maryland's TRD prevalence, comorbidity mix, and clinical eligibility profile mirror national patterns. Actual effective demand will depend on out-of-pocket affordability / any state subsidy mechanisms, clinic capacity, and how Maryland codifies inclusion/exclusion criteria in regulation. Moreover, the figures exclude any off-label use, any uptake among currently untreated patients with MDD, and any spill-in from neighboring states.

Post-Traumatic Stress Disorder (PTSD)

Avanceña, Kahn, and Marseille (2022) estimate adult past-year PTSD prevalence at 3.6% nationally (≈9.0M adults), with about half (≈50%) experiencing chronic and severe forms. Applying the Phase 3 MDMA-assisted therapy (MDMA-AT) trial's inclusion/exclusion criteria, they assume 21.9% of the chronic-severe group would be ineligible because of psychiatric or medical comorbidities (e.g., current substance use disorder, primary psychotic or bipolar disorder), yielding an eligible national pool of ≈3.52M adults (range: 2.11M–4.74M, reflecting uncertainty in chronic-severe prevalence and exclusion rates).

To translate these figures to Maryland adults, we scale by the adult population share (MD adults \approx 4.82M vs. U.S. adults \approx 250.6M; share \approx 1.92%). This implies an eligible Maryland PTSD pool of \approx 67,800 (base case), with a plausible range of \approx 40,600– \approx 91,100. Converting that stock into annual treatment volumes requires an uptake assumption. Using annual uptake rates of 5%, 15%, and 30% (reflecting constraints from coverage, provider capacity, and patient preference) yields the following:

Maryland PTSD eligibility (scaled to MD adults)	Eligible PTSD patients (MD)	5% annual uptake	15% annual uptake	30% annual uptake
Base-case eligibility (50% chronic-severe; 21.9% ineligible)	~67,800	~3,390	~10,170	~20,330
Low-end eligibility (study range)	~40,600	~2,030	~6,090	~12,180
High-end eligibility (study range)	~91,100	~4,555	~13,665	~27,330

Notes: Eligibility counts and parameters from Avanceña, Kahn, & Marseille (2022); Maryland figures are percapita scaling using MD/U.S. adult share (~1.92%). Uptake percentages are illustrative annual participation rates among the eligible pool.

These are order-of-magnitude planning figures. They assume Maryland's PTSD prevalence, chronic-severe share, and clinical-eligibility profile mirror national patterns. Actual effective demand will depend primarily on out-of-pocket affordability and any state subsidy mechanisms (because while psilocybin remains Schedule I and not FDA-approved, Medicaid/Medicare and most commercial plans are unlikely to cover the drug or supervised dosing), as well as on clinic capacity, and how Maryland codifies inclusion/exclusion criteria in regulation. As with the TRD analysis, these exclude any off-label use, any uptake among currently untreated PTSD patients, and any spill-in from neighboring states.

4.2 Potential Size of a Supervised Adult Use Market

Oregon's Measure 109 created a supervised adult-use model for psilocybin: only licensed service centers may administer psilocybin on-site under state-licensed facilitators; products must be produced by licensed manufacturers and tested in a licensed lab; and local jurisdictions can opt out. As of the latest reporting, 11 of 36 counties permit services. Point-in-time (stock) totals as of August 2025 are: 24 service centers, 374 facilitators, 10 manufacturers, 1 testing lab, 860 worker licenses, and 18 training programs. Service-volume metrics annualized from Q1 2025 run rates are approximately 6,036 clients served (1,509 in 2025 Q1 × 4), 5,472 individual sessions (1,368 × 4), and 788 group sessions (197 × 4) per year. We omit product sales dollars and unit counts because they are incomplete (excluding service-fee spending) and not directly comparable to annualized service volumes.

Our methodology scales Oregon's observed psilocybin program to Maryland using simple per-capita ratios, keeping assumptions to a minimum. Specifically, we use Oregon's total counts—including out-of-state clients—convert them to per-resident (or per-1,000) rates and apply those rates to Maryland's population. This implicitly carries over Oregon's cross-border inflow as part of the baseline; we make no additional inflow/outflow adjustments for Maryland. To reflect possible geographic limits on access, we present two scenarios: first, Maryland permits services in the same share of counties as Oregon, using county share as a proxy for population share; second, all Maryland counties permit services. We omit product sales dollars and unit counts because they exclude service-fee spending, are reported cumulatively (not directly comparable to the annualized service volumes we project). We also do not adjust for demographic differences, noting only that Maryland and Oregon are broadly comparable on age and education, while Maryland's higher income could plausibly raise demand. Finally, structural counts (centers, workforce, training programs) are treated as point-intime stocks as of August 2025, while service-volume metrics (clients served, individual and group sessions) are annualized from Oregon's Q1 2025 run rate.

Projected Maryland Market: Two Access Scenarios

Under a simple per-capita scaling of Oregon's program—treating service-volume metrics as annualized flows from Oregon's Q1-2025 run rate and structural counts as point-in-time stocks as of August 2025—Maryland's full-access scenario (all counties allow services) would serve ~8,800 clients per year, with ~7,976 individual sessions per year and ~1,160 group sessions per year. The corresponding ecosystem would include roughly 35 service centers, ~545 facilitators, ~15 manufacturers, 1–2 labs, ~1,250 licensed workers, and ~26 training programs. In the partial-access scenario (matching Oregon's participating-county share), results scale to approximately ~2,688 clients per year, ~2,436 individual sessions per year, ~360 group sessions per year, ~11 service centers, ~167 facilitators, 4–5 manufacturers, 0–1 labs, ~383 workers, and ~8 training programs. These projections embed Oregon's observed cross-border draw (because Oregon's totals include non-resident clients) and keep assumptions minimal; they offer a transparent baseline for Maryland.

Maryland psilocybin market projections under two access scenarios (Scaled from Oregon baseline; service-volume metrics (clients served, individual and group sessions) annualized from Q1 2025 run rates; structural counts (centers, facilitators, etc.) reflect point-in-time totals as of August 2025.)

Metric	Туре	Oregon (baseline)	Maryland – Scenario 1 (≈ 30.6 % counties)	Maryland – Scenario 2 (all counties)	
Clients served (per year)	Annualized (flow)	6,036	2,688	8,800	
Individual sessions (per year)	Annualized (flow)	5,472	2,436	7,976	
Group sessions (per year)	Annualized (flow)	788	360	1,160	
Service centers	Stock (as of Aug 2025)	24	11	35	
Facilitators	Stock	374	167	545	
Manufacturers	Stock	10	~4–5	~15	
Laboratories	Stock	1	~0-1	~1–2	
Workers (licensed)	Stock	860	383	1,254	
Training programs	Stock	18	8	26	

Notes: Oregon data source: OHA Psilocybin Data Dashboard. Figures are simple per-capita scalings from Oregon to Maryland (population MD \approx 6.18M; OR \approx 4.24M). Service-volume metrics (clients served, individual and group sessions) are annualized from Q1 2025 run rates (\times 4); structural counts (service centers, facilitators, manufacturers, labs, licensed workers, training programs) are point-in-time stocks as of August 2025. Scenario 1 applies Oregon's participating-county share ($11/36 \approx 30.56\%$) as an access proxy; Scenario 2 assumes all Maryland counties permit services. Oregon totals include non-resident clients; the cross-border effect is carried implicitly without further adjustment.

Several caveats qualify these estimates. We omit product-sales dollars and unit counts because they exclude service-fee spending, and are reported cumulatively (not directly comparable to our annualized service volumes). Because we use Oregon's totals that include non-residents, Maryland's estimates embed an assumed cross-border draw similar to Oregon's; if Maryland attracts more out-of-state clients—given proximity to DC, VA, PA, and DE—the true figures would be higher. In addition, Oregon's per-capita baseline is calculated using the entire state population even though only 11 of 36 counties permit services; this "dilutes" utilization observed in participating counties and therefore makes our Maryland projections conservative. A less conservative alternative would re-estimate using the population of Oregon's participating counties rather than the simple county share. Finally, service volumes are annualized from Oregon's Q1-2025 run rate; seasonality or ramp-up effects could make realized annual totals differ from these projections.

Maryland's Oregon-style program could create multiple entry points for small businesses, with the most immediate opportunities in service delivery rather than product manufacturing. Under full access, our scaling implies roughly 35 service centers and ~545 licensed facilitators; even the partial-access scenario supports ~11 centers and ~167 facilitators (stocks as of an equivalent program maturity). Using illustrative session prices of \$800–\$2,500 per client episode and our annualized client projections, annual service revenue is approximately \$7.0–\$22.0 million under full access (~8,800 clients/year) and \$2.15–\$6.72 million under partial access (~2,688 clients/year). Spread across centers, that equates to roughly ~251 clients per center per year and ~\$201k–\$628k in top-line annual service revenue per center in full access (before costs), and ~244 clients per center per year with ~\$196k–\$611k per center in partial access.

Upstream opportunities also exist. A full-access Maryland market scaled from Oregon would support on the order of ~15 manufacturers and 1–2 testing labs; these activities are more capital- and compliance-intensive and may suit a few specialized firms or incumbents repurposing cannabis or clinical-lab capabilities. By contrast, training and education scale to roughly 26 programs in Maryland under full access (from Oregon's baseline of 18), a natural lane for universities, nonprofits, and boutique providers. Ancillary services—compliance consulting, intake/preparation/integration software, harm-reduction education, insurance brokerage, and professional-supervision networks—are also natural footholds for small firms. Given Maryland's higher median income and education levels, plus proximity to DC/VA/PA/DE, centers near the Baltimore–Washington corridor could reasonably expect a cross-border client share similar to Oregon's, supporting wellness-oriented offerings and group sessions that improve affordability and margins.

Policy design will shape how much of this space small businesses can realistically occupy. Licensing fees scaled to small operators, transparent curricula and exams for facilitators, clear scope-of-practice rules, and zoning that allows modest centers in medical or mixed-use corridors would lower barriers to entry. A basic procurement market for training and continuing education, plus pathways for existing behavioral-health practices to add supervised psychedelic services, can broaden participation.

Notes: Client volumes are annualized flows (from Oregon's Q1-2025 run rate, scaled per capita); provider counts are stocks. Revenue figures are illustrative order-of-magnitude.

4.3 Potential Demand Under a Commercial Sales Model

Here, we estimate potential demand under a commercial sales model, focusing on psilocybin. Because no U.S. state has retail (over-the-counter) psychedelic sales yet, any demand estimate is necessarily provisional. We therefore present a transparent baseline that can be updated as real data arrive; realized demand will depend on Maryland's design choices (e.g., potency caps, \$/mg taxes or minimum pricing, outlet density, marketing limits) and market evolution.

Using data from the National Survey Investigating Hallucinogenic Trends (NSIHT), we take the South-region past-year psilocybin prevalence of 1.8% as Maryland's baseline, and project how prevalence might change under a commercial sales model by applying Monte et al. (2024)'s estimated increase for Oregon and Colorado—a 65.9% rise in psychedelic use prevalence after policy change (95% CI: 41.2%–90.2%). However, it is important to note that the policy changes in Oregon and Colorado did not include a commercial sales model, so these increases may not accurately reflect the potential magnitude of change under a retail framework. Multiplying the 1.8% baseline by these factors yields a point estimate of 2.99% with bounds 2.54%–3.42%. Using an adult population of ~4.82 million, the implied counts range from ~122k to ~165k, with a point estimate of ~144k (see Table 5, Panel A).

The RAND "Considering Alternatives to Psychedelic Drug Prohibition" report (2024) provides national-level estimates of the number of use days. Using the RAND Psychedelics Survey (RPS) 2023—RAND's nationally fielded survey on psychedelic use patterns—(Table 2.4), we estimate an overall average of ≈16.1 psilocybin usedays per past-year user per year (constructed from past-month frequency category midpoints, the share of past-year users active in the past month, and annualization). Applying that constant to the Maryland headcounts from the prevalence paragraph above yields the implied total use-days shown in Table 5, Panel B. It is useful to compare these figures with cannabis use days in Maryland: Based on 2023 data from the Maryland Behavioral Risk Factor Surveillance System (BRFSS), approximately 3.6% of adults reported using cannabis on 1–4 days per month, 2.3% on 5–10 days, 1.9% on 11–20 days, and 5.4% on 21–30 days. Using category midpoints to represent frequency (2.5, 7.5, 15.5, and 25.5 days per 30 days), an adult population of roughly 4.82 million, and assuming consistent use throughout the year, we estimate around 112 million annual cannabis use-days in Maryland (range: 86–137 million depending on bin assumptions). This provides a useful benchmark: even at the upper end of psilocybin uptake under a commercial model, total psilocybin use-days would represent a small fraction of cannabis use intensity in the state. These figures are approximate and rely on self-reported frequency bins that may not capture seasonality or multiple product modes.

In addition to use-days, estimating market size requires knowing how much psilocybin people consume per use—something major surveys don't currently capture. The RAND 2024 report notes that the RPS 2023 do not ask about quantity, and that actual psilocybin content varies widely across mushroom species and even specimens. To anchor quantities, RAND summarizes dose ranges from clinical and review sources: "typical" recreational/therapeutic dried-mushroom doses around 3–5 g (with 3.5 g often cited), and microdoses roughly 0.1–0.5 g; for synthetic psilocybin, ~17–30 mg is a typical full dose (Thomas et al., 2023; Polito & Liknaitzky, 2022). RAND also reports that microdosing is common—about 47% of past-year users and 66% of past-month users said they microdosed at last use—which implies a substantial share of use-days involve sub-gram amounts. Together, these points underscore that translating use-days into total grams (or "units") is highly sensitive to the distribution between microdosing and full-dose days and to actual product potency. For credible Maryland estimates, future data collection should record purchase weight, labeled potency, and whether a session was a microdose or full dose, so use-day counts can be converted into quantities with far fewer assumptions.

Using RAND (2024) RPS spending data, we construct an order-of-magnitude estimate of Maryland's annual consumer spending on psilocybin under the baseline and commercial-uptake scenarios. We begin with Maryland's adult population (~4.82M) and the NSIHT South-region past-year prevalence (baseline 1.8%). For the commercial model, we scale prevalence by Monte et al. (2024)'s estimated post-policy increases for Oregon/Colorado (+41.2% lower bound, +65.9% point, +90.2% upper). We assume, per RPS, that 28.1% of past-year users used in the past month, and we apply RAND's mean expenditures: \$23.77 per month among past-month users (annualized by ×12) and \$36.13 per year among past-year-but-not-past-month users. Summing across these two groups yields the totals below. These figures are a transparent baseline—actual spending in a legal retail market could differ with prices, taxes, product mix, and shifts in the share of users who pay versus receive for free.

Table 5: Projected Psilocybin Prevalence, Use-Days, and Consumer Spending in Maryland (Order-of-Magnitude)

Panel A — Prevalence (Adults 18+)

Scenario	Past-Year Prevalence	Implied Past-Year Users (≈4.82M adults)
Baseline (NSIHT – South)	1.80%	~86,800
Commercial – Lower (Monte et al.+41.2%)	2.54%	~122,500
Commercial – Point (Monte et al. +65.9%)	2.99%	~143,900
Commercial – Upper (Monte et al.+90.2%)	3.42%	~165,000

Panel B — Annual Use-Days (per past-year users × ≈16.1 days/year)

Scenario	Implied Past-Year Users	Implied Annual Use Days
Baseline (1.80%)	~86,800	~1.40M
Commercial – Lower (2.54%)	~122,500	~1.97M
Commercial – Point (2.99%)	~143,900	~2.32M
Commercial – Upper (3.42%)	~165,000	~2.66M

Panel C — Estimated Annual Consumer Spending (RPS means; order-of-magnitude)

Scenario	Implied Past-Year Users	Annual Spend
Baseline (1.80%)	~86,800	~\$9.2M
Commercial – Lower (2.54%)	~122,500	~\$13.0M
Commercial – Point (2.99%)	~143,900	~\$15.3M
Commercial – Upper (3.42%)	~165,000	~\$17.5M

Notes: Maryland adult population \approx 4.82M. Baseline prevalence 1.80% from NSIHT (South census region). Commercial scenarios apply Monte et al. (2024) post-policy increases (+41.2%, +65.9%, +90.2%) to the 1.80% baseline. Annual use-days use a planning average of \approx 16.1 days per past-year user (from RPS 2023 Table 2.4 construction). Spending uses RPS mean expenditures: \$23.77/month among past-month users (annualized) and \$36.13/year among past-year-only users, with a 28.1% / 71.9% split between past-month and past-year-only users. All figures rounded; intended for tentative, updateable planning—not revenue forecasting.

Using Maryland's Q1–Q3 2025 cannabis tax receipts (\$53.4M) and the 9% rate (sales \approx tax \div 0.09) implies \sim \$593.5M in taxable adult-use sales over those three quarters. Annualizing at the same pace yields \sim \$71.2M in receipts and \sim \$791M in 2025 sales. By comparison, our psilocybin consumer-spending baseline is \sim \$9.2M (1.8% past-year prevalence, NSIHT South), rising to \sim \$13.0M–\$17.5M under the Monte et al. commercial-uptake scenarios. Even at the upper bound, psilocybin spending would be only \sim 1–2% of Maryland's projected adult-use cannabis sales. The gap reflects far fewer psilocybin use-days and less frequent consumption. These are planning estimates—not revenue forecasts—and actual totals will depend on legality, pricing, product mix, and regulatory design.

Key caveats to interpret Table 5. These figures rest on strong external validity assumptions: inputs mix region-specific and national sources (e.g., baseline past-year prevalence from NSIHT's South census region; post-policy multipliers from Oregon/Colorado via Monte et al.; average use-days and spending splits from the national RPS 2023 survey). Monte et al.'s post-policy prevalence increase may not translate to Maryland's demographics, enforcement, outlet density, or pricing/tax structure; moreover, the policy changes in Oregon and Colorado did not include a commercial sales model, making their prevalence effects an imperfect analogue for Maryland's potential retail scenario. The RPS inputs are self-reported and cross-sectional, with wide confidence intervals; our 16.1 use-days/year also assumes a "typical month" and stable behavior over time. Market design will move these numbers: potency caps, \$/mg taxes, minimum pricing, retailer spacing, local optouts, and 280E/frictions (or relief thereof) can shift both participation and paid vs. free acquisition. Legalization can induce substitution and complementarity (e.g., with alcohol/cannabis or clinical/supervised channels), alter the microdose/full-dose mix, and change the share who pay—so spending could diverge materially from RPS patterns drawn from an illicit/gray market. The illegal market response (price undercutting, product variety), cross-border flows, and equity supports also affect realized demand. Finally, these are order-of-magnitude planning estimates, not revenue forecasts; they should be updated with Marylandspecific data on purchases, potency, and outcomes once any program launches.

Finally, we note that if Maryland ever authorizes commercial sales, retailers could take several forms. One option is co-location with licensed supervised adult-use centers, allowing "retail + supervised dosing" under one roof with shared testing, intake education, and adverse-event reporting—though guardrails would be needed to avoid steering high-risk clients to unsupervised use. A second option is a stand-alone psychedelics-only retailer (analogous to cannabis dispensaries) operating under potency caps, plain packaging, density limits, and strict marketing rules; this model simplifies oversight but separates sales from facilitation. A third path is a hybrid network in which a subset of supervised centers obtains retail endorsements while independent retailers operate elsewhere, paired with mandatory referral pathways to facilitators and an adverse events hotline. Finally, if Maryland wishes to emphasize medical integration, it could consider limited retail endorsements for health-system—affiliated sites (e.g., hospital outpatient pharmacies or behavioral-health clinics) for specific formats, recognizing that this is more restrictive and would require clear separation from clinical billing and prescribing. Equity licensing, conflict-of-interest rules (e.g., separating product branding from facilitation), and active compliance monitoring would be essential under any footprint.

5. Comparing Policy Models: Operational Profiles, Benefits and Risks

This section pulls together the evidence from Sections 2, 3, and 4—clinical outcomes, cost-effectiveness, and policy evaluations (Section 2), Oregon's operational experience (Section 3), and Maryland-specific demand sizing (Section 4)—to compare Maryland's policy options side by side. We assess each model—FDA-approved use, medical/therapeutic use, supervised adult use, religious use, deprioritization/decriminalization, and commercial sales—on what it can plausibly deliver and what it might risk for individuals, providers, and the state.

Our lens is consistent with the report's overall approach: weigh potential benefits (clinical improvement, reduced symptom burden, remission; well-being, meaning, social connection) against risks (clinical and psychological harms, public-health concerns such as impaired driving and unsafe products, professional/ethical issues including boundary violations and supervision quality, and equity impacts). We pay particular attention to operational feasibility and costs, drawing on observed constraints in Oregon and the cost drivers identified in Section 2.

Because each model relies on different levers—eligibility and screening, supervision and setting, product quality/testing, education and labeling, data/monitoring, accountability/complaints, and cost/coverage—we indicate how those levers can be tuned to move a model toward Maryland's objectives. The goal is to help decision-makers match policy to purpose and to highlight where layered, evaluation-first approaches (e.g., piloting medical/therapeutic and supervised adult use in parallel with clear safety screens) may be most appropriate given current uncertainties.

Table 6 shows a side-by-side comparison of seven access models for natural psychedelic substances—ranging from FDA-approved use to commercial sales—using concrete examples for each. It summarizes expected benefits (clinical and non-medical), key safeguards (health screening and whether supervision is required), access scope (who can participate), consumer costs, and the state's role (regulatory intensity, revenue potential, and lead time). It also flags whether each model entails a regulated supply chain and the barriers to entry for providers.

Below, we expand on each option—drawing on the evidence from Sections 2—4—to highlight what benefits it can realistically unlock (and for whom), where the main risks lie, and which implementation levers Maryland can tune (screening, supervision, product standards, pricing/equity supports, and data reporting). The goal is to translate the table's snapshot into brief, decision-oriented profiles for each model.

Table 6: Comparison of Policy Options for Natural Psychedelic Substance Non-Deprioritization / Supervised Adult Medical / Therapeutic FDA-Approved Use Commercial Sales Religious Use Commercial Decriminalization Use Use **Peer Sharing** Colorado "Grow Maryland cannabis Example Esketamine Native American Church Washington, D.C. New Mexico Oregon (originally) dispensaries and Give" Limited/indirect Yes — patients — personal use Yes — patients with No (by design) — any Minimal — retail Medical meeting FDA No - no clinical may be paired Limited-nonclinical gains are incidental qualifying diagnoses in stateaccess without clinical indications in certified pathway or supervision with private clinical pathway benefits to the sacrament regulated clinics care therapy, but not clinical settings built in Limited — secondary **Yes** — members/guests Yes — adults 21+ Yes — adults 21+ Yes (broad/variable) Yes — adults avoid Limited — well-being as a with prep, on-site - wide access; quality well-being gains in faith ceremonies who can grow/gift Non-medical criminal penalties; secondary outcome in clinical experience, benefits among treated (spiritual, communal or receive from varies by informal access care patients benefits) integration seller/product peers Yes — basic intake per Yes — REMS/label-Yes — mandated clinical Yes — facilitator Maybe — age check Health No — no mandated Maybe — via based medical & ceremony rules; not screening & screening per program & label warnings; no screening screening user permitting clinical care contraindications exclusionary criteria clinical screen psychiatric screening Probably - in-clinic Probably — on-site No — Required **Yes** — supervised dosing Yes — on-site at No — take-home ceremony with supervised dosing & observation No — personal use personal/home licensed centers retail sessions clergy/facilitator typical use use **Broad/Moderate** Narrow/Moderate **Broad** — any eligible Breadth of Narrow — faith **Moderate** — adults -- adults 21+ Moderate — qualifying — labeled adult under program **Broad** — 21+ members/guests within grow/gift diagnoses & capacity with possession limits access indications/eligibility rules limits

Cost to consumer	High — specialty drug + monitored visits; insurance- dependent	Lowest — donation-based; no clinical fees	Moderate — illicit/DIY prices; no supervision costs	Low — homegrow/input costs	High — cash-pay unless federally approved; subsidies could help (episode-based, front-loaded costs; generally cash-pay until federal approval).	Moderate to High — service/facilitator fees; no insurance coverage	Moderate to High — retail price + taxes; no clinical services
State involvement	Lowest — existing boards/REMS oversight	Low — limited oversight	Low/Moderate — policing guidance & public education	Moderate — define/monitor gifting boundary	High — license clinics/training, protocols, data	High — multi-tier licensing (centers, facilitators, manufacturers, labs)	High — cannabis- style regulator, licensing, testing, tax, data
State revenue potential	Lowest	Low	Low — no licensing/excise; minimal fines	Low — minimal fees; no retail tax	Moderate — clinic/training licenses	Low-Moderate — fee revenue often insufficient at start; early subsidy may be needed (as in OR)	Moderate (likely lower than cannabis given smaller addressable market & slower use).
Policy lead time	Slowest (3+ years) — depends on FDA/DEA actions	Variable — fast if operating under established exemptions; slow if new petition/litigation required.	Fastest — statutory change & training	Fast — statutory change & guidance	Slow (2+ years) — build rules, workforce, sites	Slow (2+ years) — stand up full system	Moderate — rulemaking + market buildout
Regulated market & supply chain	Yes	No	No — informal supply	No — personal cultivation/giftin	Yes — regulated clinical sourcing/chain-of-custody	Yes — licensed manufacturers, labs, centers	Yes — seed-to-sale tracking, testing, labeling
Provider barriers to entry	High — REMS certification, space, protocols	Low/Moderate — governance, safety protocols, legal counsel	High to prohibitive — no license to possess; sales illegal	Low — no license; must follow limits	Moderate — license, training, facility standards	High — licensing, dedicated site, security, facilitator training	Low/Moderate — capital, licenses, testing compliance
Expected early scale (first 2 years)	Depends on labeled indication & adoption	Small; congregation-based	Unknown (untracked)	Unknown; diffuse	Low-Moderate; capacity-limited, cash-pay	Low; Oregon percapita scaling suggests modest volumes	Unknown; below cannabis per capita

In the pages that follow, we take each policy model in turn and summarize what it can plausibly deliver, the risks it poses, and how it might be adapted to Maryland's needs. Building on the evidence reviewed in earlier sections, we emphasize the trade-offs between benefits and safeguards and point to the operational levers—such as eligibility rules, supervision, product standards, cost supports, and data systems—that can be adjusted to shape outcomes. The aim is to move from the table's high-level comparison to clear, decision-oriented profiles.

1. **FDA-approved use**:

Unlocks high-confidence medical benefits for narrowly defined, labeled indications (e.g., TRD if approved), delivered in certified clinical settings. Policy lead time is the slowest—access depends on FDA approval, DEA scheduling, product launch, and payer coverage decisions before Maryland can fully implement. Access for the target clinical populations can be good where payers cover care. Safeguards are strong by design—cGMP (current Good Manufacturing Practice) product quality, REMS (Risk Evaluation and Mitigation Strategies) screening and monitoring if required, supervised dosing, documentation, and pharmacovigilance—though these protections raise episode costs and demand trained prescribers and space for monitored sessions.

2. Religious use:

Unlocks non-medical benefits (spiritual/communal/well-being) for small, self-selected congregations; it is not oriented to clinical diagnoses like TRD/PTSD and typically does not target those populations. Access can be low-cost (donation-based) but is limited to bona fide groups and their guests. Safeguards vary by tradition: many employ intake questions, set/setting rituals, and community norms; however, product quality, screening rigor, and data reporting are not state-standardized, so risk controls and transparency are uneven.

3. Deprioritization / decriminalization:

Primarily unlocks justice benefits (fewer arrests and collateral harms and reduces stigma; it does not create a structured pathway to therapeutic or high-quality wellness services. Access to substances may expand informally, but those with the greatest clinical need still lack screening, supervision, or reliable products. Safeguards are minimal; risk reduction depends on voluntary education and public-health messaging (e.g., saferuse guidance, warning signs, when to seek help). Light, low-burden surveillance (poison-center/emergency department signals, community surveys) can monitor population risk.

4. Non-commercial peer sharing:

Unlocks wider non-medical access than decriminalization (home grow + gifting), which can improve affordability and participation in supportive peer contexts; it does not ensure clinical benefits. Safeguards remain light: the state can define "no remuneration," set possession/cultivation limits, enable optional testing access, and fund harm-reduction education—yet there is no mandated screening, supervision, or quality assurance, so risks (misidentification, dose variability, contraindicated co-medications) persist, especially for vulnerable users.

5. Medical / therapeutic use (state-authorized):

Targets medical benefits for screened patients (e.g., TRD, chronic/severe PTSD, end-of-life distress) in regulated clinics. This model can be shaped for those most likely to benefit via clear inclusion/exclusion criteria, supervised dosing, integration support, and adverse-event reporting. Safeguards are strong and adjustable: licensed sites, trained clinicians/facilitators, product testing, consent/boundary rules, rapid safety checks, and standardized outcomes. The trade-offs are cost and capacity: while federally unapproved, care is largely cashpay; early provider bandwidth and facility build-out constrain access. Equity improves if Maryland pairs this model with group formats, right-sized staffing, and targeted subsidies.

6. Supervised adult use:

Unlocks broad non-medical benefits (well-being, meaning, personal growth) without requiring a diagnosis, and may incidentally help some with unmet needs. Safeguards can be moderate-to-strong when well designed: licensed centers and facilitators, on-site administration, product testing (van Breemen et al., 2025), informed-consent and boundary policies, rapid post-session checks, and routine data reporting. The main constraint is price: Oregon's experience suggests fees can be high, drawing higher-income and out-of-state clients unless equity supports or group sessions reduce costs. Without those supports, the model is less accessible to lower-income residents who might benefit. Oregon also shows business sustainability challenges—modest volumes, high fixed costs, 280E tax exposure, banking limits, and local opt-outs have pressured centers (with some closures) and created a center bottleneck alongside facilitator oversupply.

7. Commercial sales:

In principle, it maximizes non-medical access and convenience and can lower prices over time through competition; it is not geared to clinical populations or supervised care. Safeguards are policy-dependent: product testing (the need for which is demonstrated by recent findings that many unregulated products marketed as containing psilocybin often instead contain other substances, see van Breemen et al., 2025), labeling, age checks, marketing limits, potency caps, and retailer licensing can reduce product risks, but the absence of screening/supervision raises the likelihood of misuse, contraindicated co-use, and inequities (e.g., outlet clustering, aggressive promotion). Public-health education, strong enforcement, and robust data systems are essential if this route is considered.

Bottom line: No single model optimizes all goals. FDA-approved pathways are the slowest (they hinge on federal timelines) but, once available, offer a high-safeguard route to delivering trial-based clinical benefits. State initiatives can move faster and, if designed with standardized reporting, can also accumulate new real-world evidence; among these, state-authorized medical/therapeutic pilots best position Maryland to test and deliver clinical benefits at pace. Models that broaden non-medical access (supervised adult use, commercial sales, peer sharing) can support well-being, but generally don't let the state evaluate or extend trial-based medical benefits without extra data requirements, and they need strong guardrails and equity supports. Deprioritization quickly reduces justice harms but does not create a path to assess clinical benefits and still requires education and monitoring. Layered approaches can mix strengths—e.g., a clinical track for evidence and access alongside a supervised adult-use track for non-medical goals—while mitigating weaknesses. In that spirit, decriminalization and, where authorized, tightly regulated commercial channels can serve as complementary tools to the clinical and supervised pathways—reducing justice harms and expanding access—so long as they are paired with robust safeguards, transparent data reporting, and ongoing evaluation.

6. A Roadmap for Data Collection and Policy Evaluation

Reliable, standardized, and timely data are the foundation of rigorous policy evaluation, and they must be tailored to the setting. Implementation should also be designed to enable credible quasi-experimental evaluation, thereby complementing evidence from randomized clinical trials. To inform the suggestions below, we draw on (a) psychedelic-specific research that offers concrete, actionable guidance for measuring services and impacts across policy settings, and (b) insights from policy evaluation of cannabis legalization, noting that although cannabis and psychedelics differ in important ways, the cannabis literature highlights the need to track both direct effects (e.g., adverse events, patterns of use, emergency department visits and hospitalizations related to psychedelics) and indirect effects (e.g., substitution or complementarity with alcohol/opioids, traffic injuries, crime, workplace and educational outcomes). Details of these sources are summarized in Section 2. Consistent with our conclusions, we recommend designing data and implementation to enable comparative evaluation, i.e., whether psychedelic policies outperform realistic alternatives on health outcomes and societal value.

6.1 Data Collection

A data collection plan that accompanies a new psychedelic policy should map directly to an evaluation's objectives:

- 1. enable measurement of potential benefits (clinical improvement, well-being, access, and equity) and
- 2. enable measurement of risks, including standardized adverse-event (AE) reporting and explicit tracking of emergency department visits and inpatient hospitalizations related to psychedelics, boundary violations, impaired driving, unsafe products (e.g., mislabeled products or products with inaccurate dosages; see van Breemen et al., 2025).

It should also make de-identified data publicly available, or available to researchers, so independent evaluations can complement the state's periodic reports. In addition, the plan should support economic evaluation by collecting standardized cost and utilization data to estimate QALYs, incremental cost per QALY, net economic benefit, and program budget impact—so Maryland can assess opportunity cost relative to alternative interventions.

With the above in mind, Table 7 below details data that we recommend should be collected in three streams—medical/therapeutic care, supervised adult use, and commercial sales. All streams should use the same data dictionary (shared IDs for facility, facilitator/supervisor, product/batch/lot, and session/protocol) and validated outcome tools. Data should be de-identified for analysis with strong privacy safeguards and tiered access (e.g., the public sees only aggregate, anonymized dashboards; approved researchers/regulators can access de-identified, record-level data under agreements; and a small, authorized group can view identifiable information for specific safety/complaint investigations). The table also notes integration with existing state infrastructure (e.g., CRISP) to streamline reporting while maximizing usefulness. Where feasible, mirror data elements across comparison programs (e.g., digital CBT rollouts, enhanced usual care) to enable head-to-head analyses using the same outcomes and economic endpoints.

Table 7: Data Elements by Regulatory Model: Medical/Therapeutic, Supervised Adult Use, and Commercial Sales

Item	Therapeutic (medical/clinical)	Supervised adult use	Commercial sales
Who reports	Licensed clinics/hospitals	Licensed service centers	Licensed manufacturers/retailers
Core IDs	Facility, facilitator, client, session, batch/lot, time	Center, facilitator, client, session, batch/lot, time	Retailer, transaction, product SKU, batch/lot, time
Screening / eligibility	Demographics, insurance, clinical screen	Brief health screen; age eligibility	Age check; standard warnings acknowledgment
Product / testing	Drug/formulation; dose	Drug/varietal; dose	Product type; labeled potency; lab test result
Safety monitoring	AE flags; ED visit ≤72h and subsequent hospitalizations; complaints	AE flags; 24–72h safety check; ED/hospital presentation if occurs; complaints	AE/complaints; recalls; lab verification; buyer-reported ED/hospital encounters via opt- in surveys or sentinel pharmacies
Outcomes	Standardized clinical tools (e.g., PHQ-9, PCL-5, AEs)	Brief well-being + AEs	Market/harms indicators; optional opt-in surveys
Access & equity	Wait time; travel; demographics/ZIP	Wait time; travel; demographics/ZIP	Outlet density; prices/discounts; purchaser ZIP mix
Costs/charges	Itemized fees; subsidies; out-of-pocket	Total charges; sliding scale; out- of-pocket	Retail price/taxes; discount use
Reporting cadence	Encounter-level; quarterly dashboard; annual report	Session-level; quarterly dashboard; annual report	Transaction-level; quarterly dashboard; annual report
Linkages	CRISP; ED/poison/injury/workforce (de-identified)	Same as therapeutic	Retail + lab data; poison/ED/injury/recall (de- identified)

External data linkages (secure, de-identified). Link program records to: (i) hospital ED/visit data and poison-center calls (AE corroboration, trend detection); (ii) Medicaid and state-employee health plans for downstream utilization, access, and costs of non-psychedelic services; (iii) traffic-injury/safety surveillance (rare but monitor suspected impairment); (iv) law-enforcement complaints involving licensed sites; (v) workforce licensing and complaint registries; and (vi) periodic community surveys on use, motivations, perceived risk, and access barriers. For comparative evaluation, also link to records from alternative programs (e.g., state-subsidized digital CBT) capturing the same core outcomes and costs to enable ICER and budget-impact analyses.

Governance, privacy, and transparency. House the program under a state commission and establish a College of Supervisors/Facilitators to set training standards, license/inspect sites, and handle complaints. Participation in the data program is a condition of licensure. De-identify records at collection; collect only what is necessary; use clear consent for any follow-ups; keep service access separate from research participation; and offer simple opt-out options. Publish quarterly dashboards (use, outcomes, adverse events, equity), including counts and rates of ED visits and hospitalizations related to psychedelics, an annual methods report, and rapid advisories when early-warning signals appear (e.g., adverse event clusters tied to a product batch). Pre-specify decision rules (e.g., safety triggers; minimum clinically important differences; cost-effectiveness thresholds) to guide tighten/relax/scale decisions and publish them for transparency.

This approach distinguishes regulated from unregulated outcomes, tracks effectiveness and safety, and captures the context that shapes risk and benefit. Standardized IDs and lightweight, validated measures keep reporting feasible while enabling licensing oversight, complaint resolution, clinical quality improvement, and independent policy evaluation.

6.2 Implementation Designed to Enable Policy Evaluation

How Maryland rolls out any new policy is as important as what it measures. Evidence from randomized clinical trials is essential, but RCTs often have limited generalizability to real-world service delivery, given standardized settings, tightly selected participants, and protocolized care (Deaton and Cartwright, 2018). Moreover, in psychedelics specifically, they face added challenges such as functional unblinding and expectancy effects, intensive therapist/setting requirements that constrain scale, exclusion of common comorbidities, and typically short follow-up.

Thoughtful implementation can generate quasi-experimental evidence that complements trials, producing credible, policy-relevant causal estimates using real-world data (McGinty et al. 2024). What follows are practical implementation recommendations and concrete examples to make such quasi-experimental evaluation feasible from day one. Where possible and appropriate, structure implementation to allow *head-to-head* or *parallel* comparisons between psychedelic pathways and leading alternatives (e.g., digital CBT or enhanced usual care) using identical outcome and cost measures.

- Phase access to create comparison groups. Use staggered rollouts across regions, provider types, or facility cohorts. Clearly document go-live dates, eligibility rules, and protocols at each site. This enables difference-in-differences and event-study analyses with pre-trend checks, and—when comparing statewide launches—synthetic-control comparisons to suitable external benchmarks.
- Leverage transparent thresholds. Publish simple, preannounced eligibility or prioritization cutoffs (e.g., PHQ-9 ≥ X, PCL-5 ≥ Y, age ≥ 21, ZIP-code equity tiers). These support regression-discontinuity and regression-kink designs that identify causal effects near the threshold while also making access rules fair and auditable.
- Allocate scarce capacity fairly and informatively. When demand exceeds supply, use lotteries or randomized waitlist sequencing with public rules. Lotteries can be equity-weighted (e.g., higher draw weights for Medicaid/uninsured, rural residents, or veterans) to avoid exacerbating disparities while still preserving internal validity.

- Collect data for participants *and* non-participants. For credible evaluation, capture baseline characteristics and subsequent outcomes on both treated and appropriate comparison groups:
 - Screened-but-not-treated cohorts (e.g., capacity limits, lottery non-winners, not-yet-eligible due to thresholds) with the same baseline measures (demographics, ZIP, insurance, PHQ-9/GAD-7/PCL-5, C-SSRS, co-medications) and the same follow-up cadence (1–2 weeks, 6 and 12 months) as participants.
 - Geographic comparators from regions scheduled for later rollout.
- Consider "pilot-first" rollouts. Start with stepped-wedge (cluster) pilots that deliberately vary along policy-relevant dimensions. For example: group vs. individual dosing/integration; one- vs. two-facilitator staffing (with remote co-supervision if appropriate); etc. Where appropriate and feasible, consider including parallel pilot arms that deliver comparator services (e.g., digital cognitive behavioural therapy, collaborative care), using identical outcome instruments and micro-costing templates to enable ICER estimation.
- Ethics, equity, and transparency. Treat the rollout as a learning health policy initiative with IRB review where needed, and clearly separate access to services from research participation. Commit to publishing prespecified analysis plans and periodic public dashboards of both clinical and economic endpoints to support timely course correction.
- **Safety signal plan.** Predefine thresholds for ED/hospitalization rates (overall and by product batch/facility) that trigger rapid review, temporary holds, or targeted outreach.

7. Conclusions

Here we summarize what the report has built step-by-step into a few actionable takeaways. Our approach combined (i) clinical safety and effectiveness evidence and early cost-effectiveness studies, (ii) a scoping review of psilocybin economics and cost drivers, (iii) Oregon's operational experience to date, and (iv) order-of-magnitude demand estimates for Maryland adults (adults being the population most studied in clinical trials). We then compared seven policy models on benefits, risks, access, costs, and state capacity, and specified a data/evaluation plan to support course correction. The conclusions below synthesize those strands into guidance on aligning policy choice with purpose, what the evidence supports, what Oregon's experience counsels, and how Maryland can right-size capacity and affordability while building evaluation in from day one.

- 1) Match policy to purpose. The "right" pathway depends on Maryland's explicit goal. If the aim is to realize potential clinical benefits while keeping safety controls strong, a state-authorized medical/therapeutic track is the most direct fit. If the goal also includes non-medical well-being (meaning, personal growth) without requiring a diagnosis, a supervised adult-use track implemented within a tightly regulated framework specifically to put safeguards against risks in place can complement clinical care. Taken together—and sequenced or piloted regionally—these two models offer the clearest route to unlock benefits while mitigating risks through screening, supervised dosing, product testing, informed-consent and boundary rules, rapid post-session checks, and routine reporting. Deprioritization/decriminalization reduces justice harms quickly but does not, on its own, create a pathway to evaluate or expand clinical benefits; commercial retail maximizes access but weakens point-of-use safeguards. That said, deprioritization/decriminalization and, where authorized, tightly regulated commercial sales can complement the medical/therapeutic and supervised adult-use pathways—reducing justice harms and expanding access—provided strong safeguards and ongoing evaluation are put in place.
- 2) Lessons from existing evidence. Clinical studies suggest meaningful but still emerging benefits for adults with conditions such as TRD and PTSD, alongside predictable risks that can be managed with screening, supervision, and clear protocols. Given the scale and severity of treatment-resistant mental health needs, psychedelics warrant policy attention even while cost-effectiveness evidence remains thin—because they may offer meaningful improvement where current options are limited. However, evaluation should be explicitly comparative rather than standalone: for instance, if Maryland subsidized digital CBT for major depressive disorder, that program would also generate benefits at some public cost; the question is whether psychedelic access yields greater net health benefit (e.g., lower or acceptable incremental cost per QALY and favorable budget impact) than leading alternatives such as digital CBT, collaborative-care enhancements, or medication optimization. Trials face limitations (functional unblinding, small/selected samples, short follow-up), underscoring the need for careful real-world evaluation with head-to-head or parallel rollouts where feasible. Cost-effectiveness analyses are encouraging but conditional: MDMA-assisted therapy for PTSD is generally cost-effective, while psilocybin-assisted therapy for TRD becomes cost-effective when therapist time and drug costs are lower and benefits persist. Economically, psychedelic care is episodic and front-loaded (prep, one/few dosing sessions, brief integration), unlike ongoing "standard care," so value hinges on durability of benefit and retreatment rates—variables Maryland can partly influence via program design (group formats, hybrid staffing, clear inclusion/exclusion rules) and should benchmark against the performance of those alternative interventions.
- 3) Lessons from Oregon. Oregon's supervised adult-use program demonstrates that a regulated non-medical model can operate safely at a modest scale with trained facilitators and on-site dosing. However, centers (not facilitators) are the bottleneck, early volumes are small, and fee-only funding has not covered start-up and operating costs. Local opt-outs and zoning limit access; federal tax rules (IRC 280E), banking/insurance frictions, and data/reporting obligations raise operating costs; and prices have skewed the client mix toward higher-income and out-of-state users, highlighting equity challenges. Safety events reported to the state have been rare, but continued monitoring and clear definitions remain essential. These realities argue for pragmatic expectations, targeted equity supports, and an early-year state backstop for program administration if Maryland chooses a supervised adult-use track.

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- 4) Right-size capacity, affordability, and market expectations. Section 4 suggests planning for low-thousands of adults from the TRD/PTSD pools at 5–15% uptake, with near-term access largely cash-pay—so pair launch with sliding scales, group options, and travel/fee assistance. Stand up dozens of sites and hundreds of clinicians/facilitators, with fees/zoning calibrated for small/community providers. For supervised adult use, plan for roughly 2,700 clients/year under a partial-access scenario and about 8,800 clients/year with full statewide access; consider a temporary state backstop for program administration. If commercial sales are considered, set expectations low: our scenarios imply ~\$10–\$20M in annual consumer spending (only a few percent of Maryland's cannabis sales) and total psilocybin use-days on the order of ~1.4 million at baseline, rising to ~2.0–2.7 million under commercial-uptake scenarios—a small fraction of Maryland's ~112 million annual cannabis use-days (sensitivity ~86–137 million). Any footprint should include strong safeguards and standardized data reporting. General caveats. These are rough planning estimates, not forecasts; they assume external effects generalize to Maryland and rely on self-reported data with wide confidence intervals. Results will vary with pricing/taxes, potency caps, local opt-outs, cross-border flows, substitution with alcohol/cannabis, the paid-vs-free mix, eligibility rules, workforce capacity, and subsidies.
- 5) Build evaluation from day one. Whatever policy Maryland adopts, success depends on standardized, privacy-protective data collection that is tailored to the setting. Design the evaluation to compare psychedelics against realistic policy alternatives (e.g., subsidized digital CBT, collaborative-care optimization), not just to baseline. Design implementation with evaluation in mind so causal impacts can be credibly estimated using rigorous quasi-experimental methods—for example, staggered rollouts across regions or facilities, randomized waitlist lotteries when capacity is limited, and pre-specified eligibility thresholds that enable regressiondiscontinuity and difference-in-differences analyses. These designs create credible comparison groups without denying access. For the medical/therapeutic track—and specifically in settings where the state subsidizes care consider embedding parallel program arms (e.g., sites offering psychedelic-assisted care versus sites offering digital CBT or enhanced usual care) to enable head-to-head comparisons of effectiveness, uptake, persistence, and harms. A single statewide program with coordinated streams (medical/therapeutic care; supervised adultuse; and, if applicable, commercial sales) should use a shared data dictionary (facility, facilitator, product/batch, session/protocol IDs), brief validated and standardized outcome tools (e.g., PHQ-9, PCL-5, and standardized adverse-event [AE] reporting), and core safety indicators that explicitly track emergency department visits and hospitalizations related to psychedelics, along with public dashboards with de-identified, small-area equity reporting where feasible. Integration with CRISP can minimize the burden and maximize analytic value; external linkages (including ED and poison-center data, as well as hospital discharge data to capture inpatient stays) and traffic injury surveillance, de-identified law enforcement, and workforce licensing data enable early warning and accountability. Track common economic endpoints (e.g., QALYs, incremental cost per QALY) so Maryland can assess opportunity cost relative to alternatives. Pre-specify decision rules (e.g., thresholds for costeffectiveness or safety signals) to guide tightening, relaxing, or scaling choices. With these pieces in place, Maryland can iterate—tightening or relaxing rules, targeting equity supports, and scaling what works—as the evidence base grows.

8. References

Abouk, R., Ghimire, K. M., Maclean, J. C., & Powell, D. (2021). Does marijuana legalization affect work capacity? Evidence from workers' compensation benefits (No. w28471). National Bureau of Economic Research.

Aday, J. S., Boehnke, K. F., Herberholz, M., & Kruger, D. J. (2024). Attitudes of psychedelic users regarding cost of treatment and non-hallucinogenic alternatives. Journal of Psychedelic Studies, 8(3), 380–383.

Adams, D. R., Allen, H., Nicol, G. E., & Cabassa, L. J. (2024). Moving psychedelic-assisted therapies from promising research into routine clinical practice: Lessons from the field of implementation science. Translational Behavioral Medicine, 14(12), 744–752.

Al-Khaled, N. (2021). MDMA and psilocybin for mental health: Deconstructing the Controlled Substances Act's usage of "currently accepted medical use." Washington University Law Review, 99, 1023–1053.

Anderson, D. M., & Rees, D. I. (2023). The public health effects of legalizing marijuana. Journal of Economic Literature, 61(1), 86–143.

Andrews, T., & Wright, K. (2022). The frontiers of new psychedelic therapies: A survey of sociological themes and issues. Sociology Compass, 16(2), e12959.

Arksey, H., & O'Malley, L. (2005). Scoping studies: Towards a methodological framework. International Journal of Social Research Methodology, 8(1), 19–32.

Askariyan, K., Joghataei, M. T., Dehghan, S., Nohesara, S., Rihipour, L., Mohammadi, M. H., & Ahmadirad, N. (2025). An overview of psilocybin, LSD, MDMA, and ketamine in revitalizing psychedelic-assisted therapy: Insights, limitations and future directions. Progress in Neuro-Psychopharmacology and Biological Psychiatry, 111461.

Avanceña, A. L., Vuong, L., Kahn, J. G., & Marseille, E. (2025). Psilocybin-assisted therapy for treatment-resistant depression in the US: A model-based cost-effectiveness analysis. Translational Psychiatry, 15(1), 330.

Barber, G. S., & Dike, C. C. (2023). Ethical and practical considerations for the use of psychedelics in psychiatry. Psychiatric Services, 74(8), 838–846.

Belouin, S. J., Averill, L. A., Henningfield, J. E., Xenakis, S. N., Donato, I., Grob, C. S., ... & Anderson, B. T. (2022). Policy considerations that support equitable access to responsible, accountable, safe, and ethical uses of psychedelic medicines. Neuropharmacology, 219, 109214.

Belz, F. F., Vega Potler, N. J., Johnson, I. N., & Wolthusen, R. P. (2024). Lessons from low-and middle-income countries: Alleviating the behavioral health workforce shortage in the United States. Psychiatric Services, 75(7), 699-702.

Bender, D., & Hellerstein, D. J. (2022). Assessing the risk-benefit profile of classical psychedelics: A clinical review of second-wave psychedelic research. Psychopharmacology, 239(6), 1907–1932.

Black, J. C., Monte, A. A., Dasgupta, N., Jewell, J. S., Rockhill, K. M., Olson, R. A., & Dart, R. C. (2024). Optimizing real-world benefit and risk of new psychedelic medications: The need for innovative postmarket surveillance. Nature Mental Health, 2(5), 469–477.

Bogenschutz, M. P., Ross, S., Bhatt, S., Baron, T., Forcehimes, A. A., Laska, E., ... & Worth, L. (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.

Bradford, A. C., & Bradford, W. D. (2018). The impact of medical cannabis legalization on prescription medication use and costs under Medicare Part D. Journal of Law and Economics, 61(3), 461–487.

Breeksema, J. J., Kuin, B. W., Kamphuis, J., van den Brink, W., Vermetten, E., & Schoevers, R. A. (2022). Adverse events in clinical treatments with serotonergic psychedelics and MDMA: A mixed-methods systematic review. Journal of Psychopharmacology, 36(10), 1100–1117.

van Breemen, R. B, Simchuk, D, Fritzsche, B, Huson, D, Kuzdzal, S. A, Ferguson, J. (2025) Active constituents of psilocybin mushroom edibles. JAMA Network Open, 8(9): e2531345.

Bremler, R., Katati, N., Shergil, P., Erritzoe, D., & Carhart-Harris, R. (2023). Focusing on the negative: Cases of long-term negative psychological responses to psychedelics. Scientific Reports, 13, 15998.

Brody DJ, Hughes JP. Depression prevalence in adolescents and adults: United States, August 2021–August 2023. 2025 Apr; (527)1–11

Brown, J., Cohen, E., & Felix, R. A. (2023). Economic benefits and social costs of legalizing recreational marijuana (Working Paper No. 23-10). Federal Reserve Bank of Kansas City.

Brushwood, J. D., Hall, C. M., & Rapley, E. T. (2020). Unintended costs of a dual regulatory environment: Evidence from state-level cannabis legalization and bank audit fees. Journal of Accounting and Public Policy, 39(3), 106736.

Burkhardt, J., & Flyr, M. (2019). The effect of marijuana dispensary openings on housing prices. Contemporary Economic Policy, 37(3), 462–475.

Carbonaro, T. M., Bradstreet, M. P., Barrett, F. S., MacLean, K. A., Jesse, R., Johnson, M. W., ... & Griffiths, R. R. (2016). Survey study of challenging experiences after ingesting psilocybin mushrooms: Acute and enduring positive and negative consequences. Journal of Psychopharmacology, 30(12), 1268–1278.

Celidwen, Y., Redvers, N., Githaiga, C., Calambás, J., Añaños, K., Chindoy, M. E., ... & Sacbajá, A. (2023). Ethical principles of traditional Indigenous medicine to guide western psychedelic research and practice. The Lancet Regional Health–Americas, 18, 100410.

Chakraborty, A., Doremus, J., & Stith, S. (2021). The effects of recreational cannabis access on labor markets: Evidence from Colorado. IZA Journal of Labor Economics, 10(1).

Cheng, C., Mayer, W. J., & Mayer, Y. (2018). The effect of legalizing retail marijuana on housing values: Evidence from Colorado. Economic Inquiry, 56(3), 1585–1601

Conklin, J., Diop, M., & Li, H. (2020). Contact high: The external effects of retail marijuana establishments on house prices. Real Estate Economics, 48(1), 135–173.

Crost, B., & Guerrero, S. (2012). The effect of alcohol availability on marijuana use: Evidence from the minimum legal drinking age. *Journal of Health Economics*, 31(1), 112–121.

Davis, J., & Lampert, J. (2022, May). Expediting psychedelic-assisted therapy adoption in clinical settings (H. McCormack, L. Raines, H. Harbin, J. Glastra, & C. Gross, Eds.). BrainFutures. https://www.brainfutures.org/mental-health-treatment/expeditingpatadoption/

Deaton, A., & Cartwright, N. (2018). Understanding and misunderstanding randomized controlled trials. *Social science & medicine*, 210, 2-21.

Delling, F. N., Vittinghoff, E., Dewland, T. A., Pletcher, M. J., Olgin, J. E., Nah, G., ... & Marcus, G. M. (2019). Does cannabis legalisation change healthcare utilisation? A population-based study using the healthcare cost and utilisation project in Colorado, USA. *BMJ Open, 9*(5), e027432

Domurat, P., & DePaola, A. (2025). It's regarded as a breakthrough treatment for depression — so why are Oregon's psilocybin centers closing? *KGW8*. https://www.kgw.com/article/news/local/the-story/psilocybin-therapy-struggles-to-take-off-across-oregon/283-5d55ce11-169f-4d51-ae22-b05e874264fb

Dos Santos, R. G., Bouso, J. C., Rocha, J. M., Rossi, G. N., & Hallak, J. E. (2021). The use of classic hallucinogens/psychedelics in a therapeutic context: Healthcare policy opportunities and challenges. *Risk Management and Healthcare Policy*, 901–910.

Eddie D, Hoffman L, Vilsaint C, Abry A, Bergman B, Hoeppner B et al. Lived experience in new models of care for substance use disorder: a systematic review of peer recovery support services and recovery coaching. Front Psychol. 2019;10:1052.

Effinger, A. (2025). Oregon's psychedelic service centers are closing amid high costs and tough regulation. *Willamette Week*. https://www.wweek.com/news/2025/06/03/oregons-psychedelic-service-centers-are-closing-amid-high-costs-and-tough-regulation/

van Elk, M., & Fried, E. I. (2023). History repeating: Guidelines to address common problems in psychedelic science. *Therapeutic Advances in Psychopharmacology*, 13, 20451253231198466.

Farah, R., Kerns, A. F., Murray, A. C., & Holstege, C. P. (2024). Psilocybin exposures reported to US poison centers: National trends over a decade. Journal of Adolescent Health, 74(5), 1053–1056.

Fischer, B., Russell, C., Rehm, J., & Leece, P. (2019). Assessing the public health impact of cannabis legalization in Canada: Core outcome indicators towards an 'index' for monitoring and evaluation. Journal of Public Health, 41(2), 412–421.

Freisthler, B., Ponicki, W. R., Gaidus, A., & Gruenewald, P. J. (2016). A micro-temporal geospatial analysis of medical marijuana dispensaries and crime in Long Beach, California. Addiction, 111(6), 1027–1035.

French, M. T., Zukerberg, J., Lewandowski, T. E., Piccolo, K. B., & Mortensen, K. (2022). Societal costs and outcomes of medical and recreational marijuana policies in the United States: A systematic review. Medical Care Research and Review, 79(6), 743–771.

Frierson, R. L. (2022). Principles of Malpractice Litigation in Psychiatry. Malpractice and Liability in Psychiatry, 3-10.

Gasser, P., Holstein, D., Michel, Y., Doblin, R., Yazar-Klosinski, B., Passie, T., & Brenneisen, R. (2014). Safety and efficacy of lysergic acid diethylamide-assisted psychotherapy for anxiety associated with life-threatening diseases. Journal of Nervous and Mental Disease, 202(7), 513–520.

Ghuran, A., van der Wieken, L. R., & Nolan, J. (2001). Cardiovascular complications of recreational drugs: Are an important cause of morbidity and mortality. BMJ, 323(7311), 464–466.

Gibbons, W. J., Jr., McKinney, M. G., O'Dell, P. J., Bollinger, B. A., & Jones, J. A. (2021). Homebrewed psilocybin: Can new routes for pharmaceutical psilocybin production enable recreational use? Bioengineered, 12(1), 8863–8871.

Glynos, N. G., Aday, J. S., Kruger, D., Boehnke, K. F., Lake, S., & Lucas, P. (2024). Psychedelic substitution: Altered substance use patterns following psychedelic use in a global survey. Frontiers in Psychiatry, 15, 1349565.

González-Sala, F., Tortosa-Pérez, M., Peñaranda-Ortega, M., & Tortosa, F. (2023). Effects of cannabis legalization on road safety: A literature review. International Journal of Environmental Research and Public Health, 20(5), 4655.

Goodwin, G. M., Aaronson, S. T., Alvarez, O., Arden, P. C., Baker, A., Bennett, J. C., ... & Malievskaia, E. (2022). Single-dose psilocybin for a treatment-resistant episode of major depression. New England Journal of Medicine, 387(18), 1637–1648.

Guarnaccia, P. J., & Rodriguez, O. (1996). Concepts of culture and their role in the development of culturally competent mental health services. Hispanic journal of behavioral sciences, 18(4), 419-443.

Haden, M., Emerson, B., & Tupper, K. W. (2016). A public-health-based vision for the management and regulation of psychedelics. Journal of Psychoactive Drugs, 48(4), 243–252.

Haden, M., Paschall, S. A., & Woods, B. (2025). Beyond prohibition: A public health analysis of naturalistic psychedelic use. Journal of Psychedelic Studies.

Hall, W., & Lynskey, M. (2016). Evaluating the public health impacts of legalizing recreational cannabis use in the United States. Addiction, 111(10), 1764–1773.

Hatfield, S. P., Thornton, N. L., Greenstien, K., & Glozier, N. (2024). A taxonomy of regulatory and policy matters relevant to psychedelic-assisted therapy in Australia. Australian & New Zealand Journal of Psychiatry, 58(7), 571–590.

Hayes, C., Wahba, M., & Watson, S. (2022). Will psilocybin lose its magic in the clinical setting? Therapeutic Advances in Psychopharmacology, 12, 20451253221090822.

Hinkle, J. T., Graziosi, M., Nayak, S. M., & Yaden, D. B. (2024). Adverse events in studies of classic psychedelics: A systematic review and meta-analysis. JAMA Psychiatry, 81(7), 657–666.

Hutson, P. R. (2025). Psilocybin dispensaries and advertising—Buyer beware. JAMA Network Open, 8(4), e252858.

Jacobs, E., Earp, B. D., Appelbaum, P. S., Bruce, L., Cassidy, K., Celidwen, Y., ... & Yaden, D. B. (2024). The Hopkins-Oxford Psychedelics Ethics (HOPE) Working Group consensus statement. American Journal of Bioethics, 24(7), 6–12.

Johnson, M. W., Garcia-Romeu, A., Cosimano, M. P., & Griffiths, R. R. (2014). Pilot study of the 5-HT2AR agonist psilocybin in the treatment of tobacco addiction. Journal of Psychopharmacology, 28(11), 983–992.

Johnson, M. W., & Griffiths, R. R. (2017). Potential therapeutic effects of psilocybin. Neurotherapeutics, 14(3), 734-740.

Jones, G., Herrmann, F., & Wang, E. (2023). Associations between individual hallucinogens and hallucinogen misuse among U.S. adults who recently initiated hallucinogen use. Addictive Behaviors Reports, 18, 100513.

Kilmer, B., Priest, M., Ramchand, R., Rogers, R. C., Senator, B., & Palmer, K. (2024). Considering alternatives to psychedelic drug prohibition. RAND Corporation. https://www.rand.org/pubs/research_reports/RRA2825-1.html

Korthuis, P. T., Hoffman, K., Wilson-Poe, A. R., Luoma, J. B., Bazinet, A., Pertl, K., ... & Stauffer, C. S. (2024). Developing the Open Psychedelic Evaluation Nexus consensus measures for assessment of supervised psilocybin services: An e-Delphi study. Journal of Psychopharmacology, 38(8), 761–768.

Krebs, T. S., & Johansen, P. Ø. (2012). Lysergic acid diethylamide (LSD) for alcoholism: meta-analysis of randomized controlled trials. Journal of Psychopharmacology, 26(7), 994-1002.

Lamkin, M. (2022). Prescription psychedelics: The road from FDA approval to clinical practice. American Journal of Medicine, 135(1), 15–16.

Langlitz, N. (2025). Experiments in medicalization: Psychedelic therapy in Switzerland and Australia. BioSocieties, 20(1), 1–25.

Litman, V. (2024). Psychedelic policy, religious freedom, and public safety: An overview. Ohio State Journal of Criminal Law, 21, 293–310

Luoma, J. B., Hoffman, K., Wilson-Poe, A. R., Levander, X. A., Bazinet, A., Cook, R. R., ... & Korthuis, P. T. (2025). Oregon's emerging psilocybin services workforce: A survey of the first legal psilocybin facilitators and their training programs. Journal of Psychoactive Drugs, 57(1), 1–11.

Magar, V., Urrutia, J., & Anderson, B. T. (2023). Psychedelic research and therapeutic practices: Embracing communities, groups, and traditional knowledge. Journal of Psychoactive Drugs, 55(5), 519–522.

Marks, M. (2018). Psychedelic medicine for mental illness and substance use disorders: Overcoming social and legal obstacles. NYU Journal of Legislation and Public Policy, 21, 69..

Marseille, E., Mitchell, J. M., & Kahn, J. G. (2022). 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(2), e0263252.

McCrone, P., Fisher, H., Knight, C., Harding, R., Schlag, A. K., Nutt, D. J., & Neill, J. C. (2023). Cost-effectiveness of psilocybin-assisted therapy for severe depression: Exploratory findings from a decision analytic model. Psychological Medicine, 53(16), 7619–7626.

McGinty, E. E., Alegria, M., Beidas, R. S., Braithwaite, J., Kola, L., Leslie, D. L., ... & Eisenberg, M. D. (2024). The Lancet Psychiatry Commission: transforming mental health implementation research. The Lancet Psychiatry, 11(5), 368-396.

McGuire, A. L., Cohen, I. G., Sisti, D., Baggott, M., Celidwen, Y., Devenot, N., ... & Yaden, D. B. (2024). Developing an ethics and policy framework for psychedelic clinical care: A consensus statement. JAMA Network Open, 7(6), e2414650.

McGuire, A. L., Lynch, H. F., Grossman, L. A., & Cohen, I. G. (2023). Pressing regulatory challenges for psychedelic medicine. Science, 380(6643), 347–350.

Meehan, B., Rusko, C. J., & Stephenson, E. F. (2020). (Pot) heads in beds: The effect of marijuana legalization on hotel occupancy in Colorado and Washington. Journal of Regional Analysis and Policy, 50(1), 46–53.

van der Meer, P. B., Fuentes, J. J., Kaptein, A. A., Schoorl, M., & Garssen, J. (2023). Therapeutic effect of psilocybin in addiction: A systematic review. Frontiers in Psychiatry, 14, 1134454.

Miller, K., & Seo, B. (2021). The effect of cannabis legalization on substance demand and tax revenues. National Tax Journal, 74(1), 107–145.

Mitchell, J. M., Bogenschutz, M., Lilienstein, A., Harrison, C., Kleiman, S., Parker-Guilbert, K., ... & Doblin, R. (2021). MDMA-assisted therapy for severe PTSD: A randomized, double-blind, placebo-controlled phase 3 study. Nature Medicine, 27(6), 1025–1033.

Monte, A. A., N. S. Schow, J. C. Black, E. A. Bemis, K. M. Rockhill, and R. C. Dart (2024), "The Rise of Psychedelic Drug Use Associated with Legalization/Decriminalization: An Assessment with the Nonmedical Use of Prescription Drugs Survey," Annals of Emergency Medicine, Vol. 83, No. 3.

Moreno, F. A., Wiegand, C. B., Taitano, E. K., & Delgado, P. L. (2006). Safety, tolerability, and efficacy of psilocybin in 9 patients with obsessive-compulsive disorder. Journal of Clinical Psychiatry, 67(11), 1735–1740.

Munn, Z., Peters, M. D., Stern, C., Tufanaru, C., McArthur, A., & Aromataris, E. (2018). Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. BMC Medical Research Methodology, 18(1), 143.

National Institute of Mental Health. (2025). Mental illness. https://www.nimh.nih.gov/health/statistics/mental-illness

Nayak, S. M., Gukasyan, N., Barrett, F. S., Erowid, E., Erowid, F., & Griffiths, R. R. (2021). Classic psychedelic coadministration with lithium, but not lamotrigine, is associated with seizures: An analysis of online psychedelic experience reports. Pharmacopsychiatry, 54(5), 240–245.

National Alliance on Mental Illness. Trends in State Mental Health Policy. 2023. Available at: https://www.nami.org/wp-content/uploads/2023/10/NAMI_2022_State_Legislation_Report.pdf

Neitzke-Spruill, L., Beit, C. S., Robinson, J. O., Singh, N., Kambala, S., Ramesh, R., & McGuire, A. L. (2025). A landscape analysis of psychedelic retreat organizations advertising online. PLOS ONE, 20(5), e0321648.

Nguyen, N., Peyser, N. D., Olgin, J. E., Pletcher, M. J., Beatty, A. L., Modrow, M. F., ... & Marcus, G. M. (2023). Associations between tobacco and cannabis use and anxiety and depression among adults in the United States: Findings from the COVID-19 citizen science study. PLOS ONE, 18(9), e0289058.

Nicholas, L. H., & Maclean, J. C. (2019). The effect of medical marijuana laws on the health and labor supply of older adults: Evidence from the Health and Retirement Study. Journal of Policy Analysis and Management, 38(2), 455–480.

Nicholas, C. R., Wang, J. B., Coker, A., Mitchell, J. M., Klaire, S. S., Yazar-Klosinski, B., ... & Doblin, R. (2022). The effects of MDMA-assisted therapy on alcohol and substance use in a phase 3 trial for treatment of severe PTSD. Drug and alcohol dependence, 233, 109356.

Olson, D. E. (2020). The subjective effects of psychedelics may not be necessary for their enduring therapeutic effects. ACS Pharmacology & Translational Science, 4(2), 563-567.

Oregon Psilocybin Services. (2025). 2025 public listening session. Oregon Health Authority. https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Documents/2025-OPS-Public-Listening-Sessions-Summary.pdf?utm_medium=email&utm_source=govdelivery

Osório, F., Sanches, R., Macedo, L., dos Santos, R., Maia-de-Oliveira, J., Wichert-Ana, L., ... & Hallak, J. E. (2015). Antidepressant effects of a single dose of ayahuasca in patients with recurrent depression: A preliminary report. Revista Brasileira de Psiquiatria, 37, 13–20.

Ostrovsky, A., & Barnett, B. S. (2024). New billing codes offer opportunity to investigate psychedelic treatment. Psychedelic Medicine, 2(3), 184–186.

Otsuka. (2024). Public comment on ICER's draft evidence report on MDMA-AT for PTSD. Institute for Clinical and Economic Review. https://icer.org/wp-content/uploads/2023/11/PTSD-Public-Comment-Folio_05142024.pdf

Psychedelic Medicine Task Force. (2025). Legislative report. Minnesota Department of Health. https://www.health.state.mn.us/people/psychmed/docs/legreport.pdf

Rab, S. F., Raison, C. L., & Marseille, E. (2024). An estimate of the number of people with clinical depression eligible for psilocybin-assisted therapy in the United States. Psychedelics, 1(2), 26–30.

Raison, C. L., Sanacora, G., Woolley, J., Heinzerling, K., Dunlop, B. W., Brown, R. T., ... & Griffiths, R. R. (2023). Single-dose psilocybin treatment for major depressive disorder: A randomized clinical trial. JAMA, 330(9), 843–853.

Rajwani, K. (2023). The "third" eye: Ethics of video recording in the context of psychedelic-assisted therapy. Canadian Journal of Bioethics, 6(3), 8–15.

Rieser, N. M., Bitar, R., Halm, S., Rossgoderer, C., Gubser, L. P., Thévenaz, M., ... & Preller, K. H. (2025). Psilocybin-assisted therapy for relapse prevention in alcohol use disorder: A phase 2 randomized clinical trial. EClinicalMedicine, 82.

Rodgers, A., Bahceci, D., Davey, C. G., Chatterton, M. L., Glozier, N., Hopwood, M., & Loo, C. (2024). Ensuring the affordable becomes accessible: Lessons from ketamine, a new treatment for severe depression. Australian & New Zealand Journal of Psychiatry, 58(2), 109–116.

Ross, S., Bossis, A., Guss, J., Agin-Liebes, G., Malone, T., Cohen, B., ... & Schmidt, B. L. (2016). Rapid and sustained symptom reduction following psilocybin treatment for anxiety and depression in patients with life-threatening cancer: A randomized controlled trial. Journal of Psychopharmacology, 30(12), 1165–1180.

Ross, M. L., Iyer, R., Williams, M. L., Boughey, M., O'Callaghan, C., Hiscock, R., & Dwyer, J. (2025). Psilocybin-assisted psychotherapy for depression and anxiety associated with life-threatening illness: A phase 2b randomized controlled trial. General Hospital Psychiatry, 86, 79–88.

von Rotz, R., Schindowski, E. M., Jungwirth, J., Schuldt, A., Rieser, N. M., Zahoranszky, K., ... & Vollenweider, F. X. (2023). Single-dose psilocybin-assisted therapy in major depressive disorder: A placebo-controlled, double-blind, randomised clinical trial. EClinicalMedicine, 56.

Sabia, J. J., & Nguyen, T. T. (2018). The effect of medical marijuana laws on labor market outcomes. Journal of Law and Economics, 61(3), 361.

Sharma, R., Batchelor, R., & Sin, J. (2023). Psychedelic treatments for substance use disorder and substance misuse: A mixed methods systematic review. Journal of Psychoactive Drugs, 55(5), 612–630.

Simon, M. W., Olsen, H. A., Hoyte, C. O., Heard, K. J., Monte, A. A., & Dargan, P. I. (2024). Clinical effects of psychedelic substances reported to United States poison centers: 2012 to 2022. Annals of Emergency Medicine, 84(6), 605–618.

Smiley-McDonald, H. M., Chung, E., Wenger, L. D., Godvin, M., Good, D., Leichtling, G., ... & Kral, A. H. (2024). Criminal legal system engagement among people who use drugs in Oregon following decriminalization of drug possession. Drug and Alcohol Dependence, 264, 112449.

Smith, W. R., & Appelbaum, P. S. (2022). Novel ethical and policy issues in psychiatric uses of psychedelic substances. Neuropharmacology, 216, 109165.

Smith, W. R., Sisti, D. A., & Appelbaum, P. S. (2024). The safety of supported psilocybin use in Oregon. Nature Medicine, 30(1), 17–18.

Spencer, N. (2023). Does drug decriminalization increase unintentional drug overdose deaths? Early evidence from Oregon Measure 110. Journal of Health Economics, 91, 102798.

Stringer, G. (2024). Oregon's psilocybin industry, a year old, seeks customers. Oregon Capital Chronicle. https://oregoncapitalchronicle.com/2024/06/10/oregons-psilocybin-industry-a-year-old-seeks-customers/

Ullman, D. F. (2017). The effect of medical marijuana on sickness absence. Health Economics, 26(10), 1322–1327.

U.S. Government Accountability Office (GAO). (2024). DEA should improve its religious exemptions petition process for psilocybin (mushrooms) and other controlled substances https://www.gao.gov/assets/gao-24-106630.pdf

Veligati, S., Howdeshell, S., Beeler-Stinn, S., Lingam, D., Allen, P. C., Chen, L. S., & Grucza, R. A. (2020). Changes in alcohol and cigarette consumption in response to medical and recreational cannabis legalization: Evidence from U.S. state tax receipt data. International Journal of Drug Policy, 75, 102585.

Wolfgang, A. S., & Hoge, C. W. (2023). Psychedelic-assisted therapy in military and veterans healthcare systems: Clinical, legal, and implementation considerations. Current Psychiatry Reports, 25(10), 513–532.

Yaden, D. B., & Griffiths, R. R. (2020). The subjective effects of psychedelics are necessary for their enduring therapeutic effects. ACS Pharmacology & Translational Science, 4(2), 568-572.

Zech, J. M., Yaden, D. B., & Jones, G. M. (2025). Associations between psychedelic use and cannabis use disorder in a nationally representative sample. Drug and Alcohol Dependence, 266, 112502.