PsyCan

White Paper 2023

Beyond the Special Access Program:

Regulatory Analysis and Recommendations on Psychedelic Medicine and Therapy in Canada

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About PsyCan

Incorporated as the Psychedelics Businesses Association, ***PsyCan*** is the not-for-profit trade association of legally operating psychedelic medicine and therapy companies in Canada. PsyCan is dedicated to working collaboratively to advance government regulation, scientific research, and the specific needs of the growing sector. Its member companies represent research, development, manufacturing, and clinic operations. At the time of incorporation, PsyCan was the first national-level trade association for the legal psychedelic medicine and therapy sector anywhere in the world.

Learn more at PsyCan.org or contact admin@psychedelicscanada.org

Executive Summary

This White Paper is intended for Canadian and international policy makers and the public. It includes an overview of the current state of regulations in Canada governing the use of psychedelic medicine and therapy, and an environmental scan of relevant regulatory proposals, acts, and academic publications from comparable jurisdictions. Each approach is assessed for its potential implications for Canadian psychedelic regulatory reform. This, in addition to survey research, is the framework of this report's quantitative and qualitative findings. **All documentation related to the regulatory analysis and review is included in Annex 1, which begins on page 30.** The White Paper concludes with evidence-based recommendations for regulatory reform that look beyond current criminal justice approaches and the limited access provided by clinical trials and Health Canada's Special Access Program.

Key Takeaways

- As research on the safety and efficacy of psychedelic therapies continues to expand, recent years have seen changes in the global regulatory landscape. Further changes are expected, prompting a potential for consideration of how to broaden accessibility to these treatments while ensuring reasonable safeguards to both reduce potential harms and maximize the benefits of psychedelics on public health.

- Canadian patient access to psychedelic medicine and therapy is presently largely based on a centralized case-by-case federal approval system: the Special Access Program (SAP).

- Evidence suggests that the SAP has provided legal access for some patients that could benefit from the use of psychedelic-assisted therapies. However, timelines for review have been inconsistent, and denials and approvals have proven unpredictable, unnecessarily increasing the stress on critically and chronically ill Canadians seeking out these treatment options, many of whom are particularly vulnerable due to their health conditions.

- A centralized, highly bureaucratic federal program involving a lengthy and complex application process with no guarantees of access is inadequate to meet the growing public and clinical interest in psychedelic-assisted psychotherapies. The extremely narrow access to psychedelics afforded by the SAP is inconsistent with the current academic understanding of the potential harms and benefits of psychedelics, particularly for those in end-of-life circumstances.

- There are many existing and theoretical regulatory models of psychedelic access for the Government of Canada and other stakeholders to review and consider. PsyCan suggests that the following principles underpin the development of any such regulations: **harm reduction, benefit maximization, cognitive liberty, personal rights and freedoms, and patient autonomy in personal medical care.**

- PsyCan is only one of many voices that bear consideration in the development of an appropriate and effective psychedelic-assisted therapy access program, Other important voices include those of patients, health care providers, Indigenous communities, and the current consumers of psychedelic substances.

- Beyond the potential benefits in alleviating patients' suffering, psychedelic medicine and therapy also presents a unique opportunity to relieve the economic strain on health care systems, as well as those in Canada's federal and provincial public service sectors.

- To make space for other stakeholders to share their thoughts and expertise, the authors have opted not to be overly prescriptive in advocating for a particular regulatory model. However, PsyCan recommends the following short, medium, and long-term steps as pragmatic responses that could help resolve current psychedelic access issues:

    1. **Immediate improvements to service standards for the Special Access Program** to maximize transparency and predictability and lessen the overall burden and response time for applicants.
    2. **Development of a medical psychedelic access program outside of the SAP**, with the goal of taking patients off the front lines of the drug war as soon as possible.
    3. **Striking of a *Federal Task Force on Psychedelic Access*** modelled on the *Federal Task Force on Cannabis Legalization*. The mandate of this consultative body would be to coordinate large, regional, and multistakeholder meetings to consider alternative access models to psychedelics for both medical and non-medical purposes.

Background

The Psychedelic Renaissance

Humanity is in the midst of a 'psychedelic renaissance' in both a scientific and cultural sense.[1] Building on thousands of years of Indigenous use, research in the mid-20th century pointed to the therapeutic potential of psychedelics, but also to possible pitfalls from misuse. As psychedelics moved out of clinical settings and into popular culture, a moral panic — 'the psychedelics scare' — ensued, leading to cultural attitudes that suppressed legitimate scientific inquiry and to laws outlawing personal possession, thereby forcing both therapeutic and recreational use underground. This historical context explains in part why psychedelics remain so tightly regulated today.

Defining Psychedelic Drugs

At present there is no universal consensus on the definition of psychedelic drugs.[2] The word 'psychedelic' (lit., 'mind manifesting') was initially coined in 1957 to describe a specific set of drugs that did not fit into existing categories (e.g., depressant, stimulant, etc.). Broadly speaking, psychedelic drugs cause changes in perception, mood, and cognition.[3] They modulate excitatory-inhibitory balance in brain circuits and can promote neuroplasticity within brain structures critical for the integration of information relevant to sensation, cognition, emotions, and the narrative of self.[4]

Psychedelics are also posited to alter the activity and connectivity of the Default Mode Network (DMN) —a grouping of interconnected brain regions that are involved in self-referencing, mind wandering, and autobiographical memories.[5] The DMN is considered to be at the top of the brain's predictive hierarchy and the seat of one's sense of self.[6] By disrupting the DMN, psychedelics may induce a state of increased entropy and flexibility in the brain, allowing for novel connections and insights to emerge.[7]

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[1] (Richert, 2019) (Hadar, et al., 2023) (The Psychedelic Renaissance, 2023)
[2] (Girn)
[3] (al. J. S., 2020)
[4] (Classic Psychedelic Drugs: Update on Biological Mechanisms, 2022)
[5] (al. G. e., 2023)
[6] (Carhart-Harris RL, 2014)
[7] (al. G. e., 2023)

“

Many researchers define psychedelics strictly as 5-HT2A agonist compounds with particular subjective effects, while others support a broader definition that includes additional pharmacologically-distinct drugs that have similar subjective effects.”

Manesh Girn, PhD
University of California San Francisco

Psychedelics are often divided into two main groups: classic and non-classic. Classic psychedelics are agonists or partial agonists of 5-HT2A serotonin receptors, their primary pharmacological target in the brain, as well as 5-HT1A and 5-HT2C receptors.

Non-classic psychedelics do not have a direct effect on 5-HT receptors but result in similar altered states, and in some cases, similar therapeutic applications, and outcomes.[8] Classic psychedelics include lysergic acid diethylamide (LSD), psilocybin, dimethyltryptamine (DMT) and mescaline, all of which are currently being studied for therapeutic potential in the treatment of intractable mental health conditions. Ketamine and 3,4-methylenedioxymethamphetamine (MDMA) are examples of non-classical psychedelics that are also under clinical investigation as treatments for depression and Post-Traumatic Stress Disorder (PTSD).[9]

Table 1: Psychedelic Drugs, Scheduling, and Restrictions

Drug	Also Known As	Schedule	Restricted
Classical Psychedelics			
Lysergic Acid Diethylamide	LSD, Acid	III	Yes
Dimethyltryptamine	DMT	III	Yes
Psilocybin	Magic Mushrooms	III	Yes
Mescaline	Peyote, San Pedro	III	Yes
Other			
Ketamine	K	I	No
3,4-Methylenedioxy-methamphetamine	MDMA, Ecstasy, Molly	I	Yes

[8] (al. F. R., 2022)
[9] (Nichols, 2004),

Scientific Research Investigating Psychedelic Medicine and Therapy

Numerous landmark scientific articles now demonstrate the safety and efficacy of psychedelic drugs in clinical trials for mental health conditions such as Anxiety, Major Depressive Disorder (MDD), Treatment Resistant Depression (TRD), Alcohol Use Disorder (AUD), Tobacco Use Disorder (TUD), Post-Traumatic Stress Disorder (PTSD), and Opioid Use Disorder (OUD), chronic pain, and other conditions. Most trials show that psychedelic-assisted psychotherapy (PAP) may be faster and more effective than current treatments for many of these conditions.[10]

Health Policy and Pharmacoeconomic Implications

While psychedelic substances show tremendous therapeutic potential, economic analysis attempting to quantify the health benefit of psychedelic-assisted therapy in monetary terms (e.g., cost savings to the healthcare system and increases in productivity) has been limited. PsyCan has found that the treatment of PTSD through MDMA-assisted psychotherapy alone could represent potential savings of $3.8 billion in healthcare costs per year, though this analysis addressed only the potential of one psychedelic substance (MDMA) to assist in one condition (PTSD).[11]

The annual economic cost of mental illness in Canada is estimated at over $50 billion (CDN) per year.[12] In the context of potential Canadian policy reform, a compelling pharmacoeconomic argument could be made for broadening access to psychedelics as medicines for mental health treatment. The benefits of psychedelic-assisted therapies go beyond offering relief to patients; they also have the potential to alleviate economic burden on Canada's health care system and address various secondary societal challenges related to mental health problems.

Mental health problems also pose significant public service costs, including increased rates of crime, homelessness, and substance abuse. By providing a novel and potentially cost-effective treatment option, psychedelic-assisted therapies could play a role in reducing these societal issues, leading to a positive impact on public services such as law enforcement, social welfare, and emergency care. The approval and integration of psychedelics into mental health treatment could, therefore, contribute to overall cost savings within the health care system by addressing these downstream consequences of untreated mental illnesses.

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[10] (Schenberg, 2018).
[11] (Psychedelics Canada, 2022, p. 21),
[12] (CAMH, 2023)

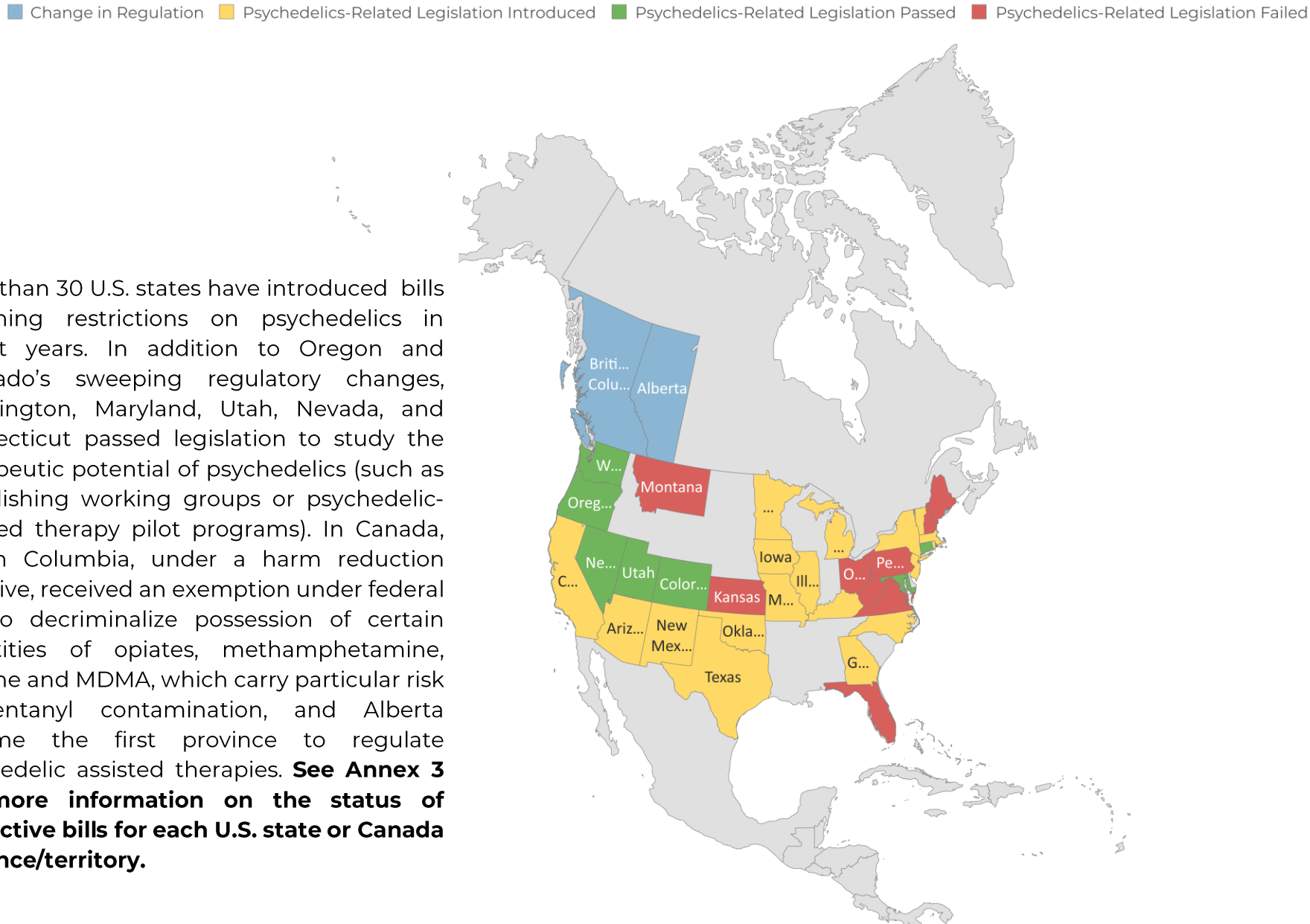
Furthermore, policy reform would undoubtedly stimulate further research and development in the field of mental health. As novel therapies, psychedelics open new avenues of investigation and innovation, potentially leading to advancements in treatment approaches and the understanding of mental health disorders globally. This, in turn, can benefit the broader health care system by promoting a culture of research and evidence-based practices on the world's stage.

82%

The percentage of Canadians who approve the use of psilocybin-assisted therapy for people with end-of-life distress. (Nanos research survey; Canadian Psychedelic Association, 2021).

North American and International Regulatory Developments

Figure 1: Recent Psychedelic Legislative and Regulatory Developments by North American Jurisdiction (~2021-2023)



More than 30 U.S. states have introduced bills loosening restrictions on psychedelics in recent years. In addition to Oregon and Colorado's sweeping regulatory changes, Washington, Maryland, Utah, Nevada, and Connecticut passed legislation to study the therapeutic potential of psychedelics (such as establishing working groups or psychedelic-assisted therapy pilot programs). In Canada, British Columbia, under a harm reduction initiative, received an exemption under federal law to decriminalize possession of certain quantities of opiates, methamphetamine, cocaine and MDMA, which carry particular risk of fentanyl contamination, and Alberta became the first province to regulate psychedelic assisted therapies. **See Annex 3 for more information on the status of respective bills for each U.S. state or Canada province/territory.**

The United States

As illustrated in the figure above, numerous efforts to reform psychedelic drug policy have taken place at the state and local levels. Last year, 2022, also saw notable shifts at the federal level, with reform efforts including:

Establishment of a Federal Task Force: In May 2022, the Assistant Secretary of Health and Human Services for Mental Health and Substance Use wrote in a letter that the Substance Abuse and Mental Health Services Administration (SAMHSA) is "exploring the prospect of establishing a Federal Task Force to monitor and address numerous complex issues associated with emerging substances," with reference to psilocybin and MDMA."[13]

Amendments to the National Defense Authorization Act (NDAA): Representatives Dan Crenshaw and Alexandria Ocasio-Cortez, representing a bipartisan collaboration, proposed amendments to the NDAA for 2023 to reduce federal restrictions on specific psychedelic research. The House of Representatives adopted these amendments.

Formation of the Congressional Psychedelics Advancing Clinical Treatments (PACT) Caucus: This congressional caucus involves a wide range of groups and aims to raise awareness of psychedelic-assisted therapies (PATs) among members of Congress and their staff, support increased federal funding for psychedelic science, and examine regulatory obstacles to psychedelic research. However, the Caucus will not make recommendations on the decriminalization, legalization, or rescheduling/de-scheduling of psychedelics.[14]

Introduction of the Breakthrough Therapies Act: Another bipartisan effort to reduce barriers to psychedelic research and access, which is discussed further in the regulatory review and analysis section below.

Bill H.R.3684: On May 25, 2023, Bill H.R.3684 was introduced in Congress to direct the Secretary of Defense to establish a $75 million grant program to fund research on the use of psychedelics in treating mental health conditions among active military personnel (U.S. Congress, 2023).

[13] (Psychedelic Alpha, 2022).
[14] Ibid.

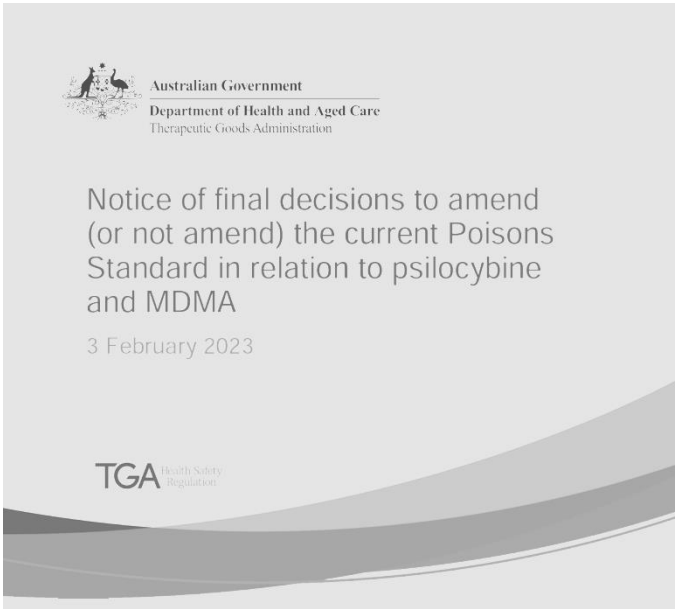
Australia

Until recently, both MDMA and psilocybin were classified by Australia's Therapeutic Goods Administration (TGA) as prohibited substances under Schedule 9—meaning that they had no established therapeutic use and were only available for teaching and other limited educational purposes, subject to state approval.[15]

In response to feedback from health care providers and patients, the TGA recently authorized the prescribing of psilocybin and MDMA by psychiatrists to treat certain mental health disorders, making Australia one of the first countries to recognize these agents as medicine.[16]

This program launched in July 2023. Under the changes, MDMA can only be prescribed to treat PTSD, and psilocybin can only be prescribed for Treatment Resistant Depression (TRD). Only certain psychiatrists, registered under Australian law, will be able to prescribe them. These individuals will be required to supervise the patients when they take the medicine and will require permission from both the TGA and from a human research ethics committee to administer them.[17]

Figure 2: Notice of Final Decisions, Poisons Standard, Psilocybin and MDMA—Australian Therapeutic Goods Administration



[15] (Kisely, 2023)
[16] Ibid.
[17](Australian Government, Department of Health and Aged Care, Therapeutic Goods Administration, 2023)

The European Union (EU)

In May of 2023, the *Members of European Parliament (MEP) Action Group for the Medical Use of Psychedelics* was launched, which aims to promote the development of EU policies and regulations for psychedelic-assisted treatments in the European Union.[18]

Latin America

In 2019, the Colombian Constitutional Court ruled that the government must respect the rights of Indigenous peoples to use ayahuasca and other traditional plants for spiritual and healing purposes, and that any regulation of these practices must be done in consultation with Indigenous authorities.[19]

In 2020, the Brazilian Supreme Court granted a *habeas corpus* to a religious group that uses ayahuasca as a sacrament, allowing them to import and use the brew without fear of prosecution. The court recognized that ayahuasca is part of the cultural and religious identity of many Indigenous and non-Indigenous peoples in Brazil.[20]

In 2021, the Mexican Supreme Court declared that the prohibition of psilocybin mushrooms is unconstitutional and violates the right to free development of personality. The court ordered the health ministry to issue guidelines for the medical and scientific use of psilocybin, as well as for its personal and recreational use by adults.[21]

As will be further detailed below, while Health Canada has stated that psychedelic drugs must progress through the normal clinical trials process prior to approval, domestic legal and international regulatory developments may necessitate a proactive, rather than reactive, regulatory response.

[18] (Peseckyte, 2023)
[19] (Mongabay, 2021)
[20] (Video: Honoring the Indigenous Roots of the Psychedelic Movement, 2021)
[21] (Chase Thompson, 2023)

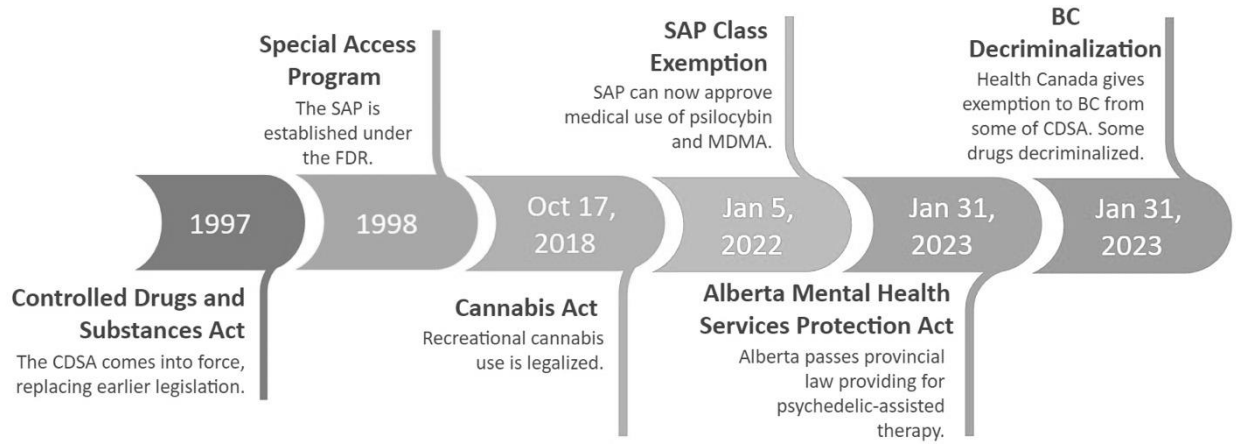
Current Canadian Regulations Governing Access to Psychedelic Medicine

UN Conventions

Canada is party to three United Nations ("**UN**") drug control conventions (collectively or in the alternative the "**UN Conventions**").[22] Canada's obligations pursuant to the UN Conventions require that criminal law in Canada impose penalties that include deprivation of liberty for production, manufacture, export, import, distribution of, trade in, use and possession of drugs outside of a medical or scientific context.[23]

The *Controlled Drugs and Substances Act* (the "**CDSA**")[24] and regulations under the CDSA provide the backbone for compliance with Canada's obligations under the UN Conventions. Figure 3 shows key dates in development of Canadian controlled substance law and policy.

Figure 3: Timeline of Canadian Psychedelic Regulatory Milestones



[22] *Single Convention on Narcotic Drugs of 1961* as amended by the 1972 Protocol, 30 March 1961 (as amended by the 1972 Protocol), 976 UNTS 14152 (entered into force 13 December 1964) (the "**Single Convention**"), *Convention on Psychotropic Substances*, 21 February 1971, 1019 UNTS 14956 (entered into force 8 August 1975) (the "**1971 Convention**") *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances*, 20 December 1988, 1582 UNTS 27627 (entered into force 11 November 1990) (the "**Vienna Convention**").

[23] Single Convention, *ibid* at Articles 4(c) and 36(1)(a); Vienna Convention, *ibid* at Articles 3(1), 3(2) and 3(4).

[24] SC 1996, c 19

CDSA Schedules and Regulations

Controlled substances are defined in the CDSA as "a substance included in Schedule I, II, III, IV or V".[25] Schedules I to IV include a variety of controlled substances. Schedule V is for temporary scheduling until a substance is added permanently to a different schedule. Schedule VI is for precursors.

Schedule I to the CDSA generally includes opiates, stimulants, depressants and arylclohexamines. Schedule III to the CDSA includes LSD, psilocybin, DMT, mescaline and other compounds generally considered to be "psychedelics". Exceptions are ring-substituted amphetamine drugs (including MDMA) and arylcyclohexamines drugs, both of which are included in Schedule I.

Separate from the numbered schedules in the CDSA, there are four categories of controlled substances, each of which is regulated under different federal regulations enacted pursuant to the CDSA. The respective regulations applicable to narcotics, controlled drugs and targeted substances are the *Narcotic Control Regulations*[26] (the "**NCR**"), Part G of the *Food and Drug Regulations*[27] (the "**FDR**"), and the *Benzodiazepines and Other Targeted Substances Regulations* (the "**BOTSR**"), respectively.

Each of the NCR, Part G of the FDR and the BOTSR provide for commercial sale as drug products to physicians or other prescribing HCPs, hospitals and pharmacies. In contrast, restricted drugs are regulated by Part J of the FDR, which does not include provision for commercial sale as drug products to physicians or other prescribing HCPs, hospitals, and pharmacies.

"Restricted Drugs" are the class of controlled substance in Canada that have no approved medical use and are essentially the Canadian equivalent of Schedule I controlled substances in the United States. However, the CDSA numbered schedules I through IV do not have the same meaning as the schedules listed to the United States' *Controlled Substances Act*. Most psychedelics that are controlled substances fall within Schedule I, Schedule III or Schedule IV of the CDSA, and most psychedelics are restricted drugs.

[25] CDSA, *ibid*. at s-s 2(1).
[26] CRC c 1041
[27] CRC c 870

Authorizations to Work with Controlled Substances

Authorizations to work with controlled substances are provided by Health Canada directly under the CDSA. Authorizations to work with restricted drugs specifically are also provided by Health Canada pursuant to Part J of the FDR.

One authorization to possess a controlled substance is a subsection 56(1) exemption, which the OCS may issue directly under the CDSA.[28] Typically, a subsection 56(1) exemption authorizes possession for the purposes of academic research, a clinical trial or other work with controlled substances that is related to research. CDSA exemptions often specify a single source or specific list of sources from which controlled substances may be sourced and strict conditions on possession and disposal of the controlled substances.

While subsection 56(1) exemptions are typically issued for research, a few subsection 56(1) exemptions issued — beginning August 4, 2020 and most recently in early 2022 — are for the therapeutic use of psychedelics, each allowing a particular individual to possess psilocybin for use to mitigate end-of-life depression.[29] Based on publicly available materials, the subsection 56(1) exemptions issued to patients for use to mitigate end-of-life depression did not define an authorized source of psilocybin. The lack of a well-defined source of psilocybin in these examples illustrates potential shortcomings of permitting ad hoc medical access under subsection 56(1).

Subsection 56(1) exemptions are appropriate for research or other limited work with controlled substances. Production and other commercial work are generally undertaken through a dealer's licence (DL). Each DL lists the narcotics, controlled drugs, targeted substances, or restricted drugs that the DL authorizes dealing with, and the amount of each that may be produced annually. For each controlled substance, the DL will list whether the dealing authorized by the DL applies to active pharmaceutical ingredient ("**API**"), drug products or both.

[28] CDSA, *supra* note 24 at s-s 56(1).
[29] (Carpenter, 2020), (CNN, 2020)

Special Access Program

Health Canada has the power to provide access to new drugs for use in emergency treatment via the Special Access Program (SAP).[30] Psychedelic Drug Products or other drugs that are not yet approved for sale under Part C of the FDR may be accessed through the SAP. To receive access through the SAP, a physician (the "**Applicant Physician**") must file an application under the SAP (an "**SAP Application**") for access to the Psychedelic Drug Products, and any manufacturer who intends to supply a drug product to the SAP must complete other administrative requirements to supply the SAP. The manufacturer is prohibited by the *Food and Drugs Act* from advertising any Psychedelic Drug Products, and in some cases also prohibited by regulations under the CDSA. As a result, the Applicant Physician may have to contact the manufacturer directly for information.

A class exemption is a subsection 56(1) exemption that applies to a defined group of individuals, corporations or other persons. A subsection 56(1) exemption has been issued authorizing the entire class of healthcare practitioners, agents, pharmacists, persons in charge of a hospital, hospital employees and licensed dealers to conduct certain activities with psilocybin and MDMA in the context of access through the SAP (the "**SAP Class Exemption**"). Suppliers of the SAP must hold a dealer's licence or collaborate with a licensed dealer to deal with controlled substances, such as MDMA or psilocybin.

The SAP Class Exemption (**a**) does not apply to Psychedelic Drug Products other than psilocybin or MDMA accessed through the SAP at this time, and (**b**) expressly excludes provision of rights to patients to possess psilocybin or MDMA.

Provincial Legislation and Exemptions

Effective in January of 2023, regulated psychedelic drug treatment services became specifically regulated in Alberta through amendment of the *Mental Health Services Protection Regulation* (the "**MHSPR**").[31]. The MHSPR require that a psychiatrist medical director for any licensed clinic providing psychedelic drug treatment services. The MHSPR and its guidelines define additional requirements that physicians and other HCPs must meet in order to provide psychedelic drug treatment services.

The additional requirements of the MHSPR currently apply primarily to use of ketamine for psychedelic assisted psychotherapy. When MDMA, psilocybin and other psychedelics become regulated drug products approved under Part C of the FDR, use

[30] FDR, *supra* note at ss C.08.010 to C.08.011.3

[31] AR 114/2021

of any such drug products in Alberta would also be regulated by the MHSPR, including medical use in the absence of psychedelic assisted psychotherapy.

Effective January 31, 2023, a subsection 56(1) class exemption (the "**BC Exemption**") exempts all adults in British Columbia from application of section 4 of the CDSA for possession of up to 2.5 grams total of cocaine, methamphetamine, opioids and MDMA. Exceptions to the BC Exemption maintain prohibition in some circumstances, such as those involving minors, impaired driving, by members of the Canadian Armed Forces or other reasonable exceptions.

The BC Exemption exempts only the offence of possession and does not allow for any commercial activity, therapeutic use, trafficking (including without payment), or any regulated source of cocaine, methamphetamine, opioids or MDMA. Rather, the BC Exemption is directed to reducing the harms that result from interaction of persons suffering from addiction with law enforcement, and to lower barriers to contacting emergency response personnel when an individual is suffering from an overdose, including when taking MDMA or other drugs contaminated with fentanyl or other substances.

Conclusion: Beyond the SAP

As our research and our review of existing and proposed regulatory models (available in Annex 1) demonstrates, **psychedelic substances are not only promising new medical treatments; they are themselves incredibly important to the lives of many Canadians, for various reasons, and across many different cultures.**

The primary finding of this detailed review is that there are many well-considered actual and theoretical options for the regulation of psychedelic substances for both medical and non-medical uses. Nonetheless, PsyCan does not feel that our role is to be overly prescriptive of the approaches Health Canada and the Government of Canada might take, particularly since many other voices would have to take part in this discussion, including those of Indigenous communities, patients, healthcare providers and psychedelic consumers themselves. The primary expertise on the safe use of psychedelics currently resides with consumers, and they should be considered the key informants in the development of any regulations addressing both the medical and non-medical use of psychedelics.

PsyCan suggests that the following principles should inform all the decisions made by government regarding psychedelic access:

- **Harm reduction/benefit maximization**
- **Personal rights and freedoms**
- **Cognitive liberty**
- **Patient autonomy in personal medical care**

Additionally, we suggest that **the government's first priority should be to address the needs of critically and chronically ill Canadians**. As it stands, patients remain on the front lines of the war on drugs, Psilocybin, MDMA, LSD, mescaline, DMT and all other psychedelics remain controlled substances with no predictable way to access these drugs in Canada, placing patients using these substances for therapeutic purposes at significant legal risk. De facto temporary decriminalization of certain controlled substances in British Columbia affords no access to MDMA for therapeutic purposes, and does not authorize possession of any other psychedelic drugs.

Therefore, to conclude this policy review, **PsyCan proposes the following short, medium, and longer-term regulatory solutions to the current challenges faced by patients and other consumers of psychedelic substances.** These evidence-based recommendations are intended to be pragmatic responses to very real obstacles in the way of safe, legal access to psychedelics.

Short-Term: Improving Patient Access and Quality of Life Under the SAP

During meetings with PsyCan, Health Canada has stated that the SAP is not the ideal vehicle for accessing psychedelics and was never intended for these purposes. However, since it provides a more consistent path to access for patients than clinical trials or subsection 56(1) exemptions, it has become the most frequently used means of access for Canadian patients at this time. However, it is apparent that steps could be taken to improve this regulatory pathway in the short term, and so **PsyCan would like to make the following patient-centered recommendations to improve the SAP:**

- **Improved service standards, so that HCPs, manufacturers and patients can rely on timely responses and approvals, particularly for common conditions such as TRD and PTSD, and particularly where the same substances has previously been approved for the same condition.**
- **Increased transparency about how the approval process is adjudicated, and reasons underpinning both approvals and rejections,**
- **Additional case managers and improved communication with applicants.**

Additionally, technological improvements could streamline the intake process, reduce staff workloads, and increase the efficiency of reviews in preparation for an expected rise in demand. The use of encrypted email as an alternative to faxing would also improve and modernize communication with practitioners.

We suggest immediate consideration and implementation of these potential improvements as an interim measure while a more comprehensive psychedelic access strategy is developed.

Medium Term: Legislative Options for Safe Access to Psychedelics

As this review has highlighted, many jurisdictions have taken steps to remove criminal prohibition of psychedelics, focusing instead on either decriminalization or regulation to provide a safe, legal supply for both medical and non-medical use of psychedelics. In fact, while making the final edits to this policy review, the California Senate passed Bill 58, which would allow people aged 21 or older to own or prepare “certain hallucinogenic substances,” including psilocybin, psilocin, DMT, ibogaine, and mescaline. Additionally, it is expected that sometime in 2024, MDMA-assisted psychotherapy for the treatment of PTSD will become a legal medical treatment in

Canada, adding another therapeutic option to ketamine-assisted psychotherapy for patients that might benefit from psychedelic medicines.

The pace of regulatory change specific to psychedelics is increasingly fast and difficult to follow. However, what is becoming apparent is that Canada's SAP-focused access strategy, which may have seemed quite progressive just a few months ago, is unfortunately proving inadequate at meeting the needs of Canadian patients and practitioners.

Despite the federal government's best intentions, rather than increasing safe access to psychedelics, the complexity and lack of transparency of the SAP program is unfortunately leading many patients who might benefit from psychedelic-assisted therapies to buy their supply from illicit and unregulated online dispensaries lacking standards around quality control and potency labelling, and to seek treatment via underground practitioners with little or no oversight on therapeutic practices or ethical standards of care. This greatly increases the potential risk of harms to this already vulnerable patient population, and it is antithetic to the improvement of public health in Canada that in many circumstances MAiD may be easier to access for critically and chronically ill patients than psychedelic-assisted therapies.

In light of these findings, PsyCan strongly recommends that the Government of Canada promptly engage with patients, practitioners, and other key stakeholders to develop and implement alternative legislative options to improve safe, legal access to psychedelics for therapeutic purposes beyond the SAP.

Long-Term: Models for Expanded Access

Finally, there is significant and growing public support in Canada, the US and other jurisdictions to legalize adult use of psychedelics, and this report corroborates global trends in favor of depenalization, decriminalization, and legalization efforts. These indicators suggest that the Government of Canada would do well to consider policy options for the regulation and legalization of the adult use of psilocybin and other psychedelics, enabling this policy and legal change to take place in the near future in the event that broader social trends demonstrate popular support for a regulatory approach other than prohibition.

Academic research has long disproved the utility of drug prohibition, finding that in nearly all cases criminal justice approaches to substance use result in more dangerous patterns of use and increase negative public health and safety outcomes.[32] With that in mind and considering the low potential for harm associated with most

[32] (Tyndall and Dodd, 2020)

psychedelics, we foresee a not-too-distant future where Canadian adult consumers can personally access or experience psychedelics via "Psychedelic Centers" for personal growth, spiritual development or to increase overall well-being, including couples' counseling and retreats.

While PsyCan is not aware of any formal analysis of the impacts of legalization measures for psilocybin in US states like Colorado and Oregon, an analysis conducted by Frederick Research and reported in Reason Magazine[33] examining public health and safety impacts of psychedelic legalization in Colorado came the following conclusions:

- Less than 3% of drug-related crimes have involved psychedelics for the past few years in Colorado. Since Denver's Ordinance 301, there has been no noticeable increase in drug-related crimes involving psychedelics.
- Psychedelics represent less than 1% of hospital incidences (like ER visits).
- Police and hospital representatives corroborate the available Colorado data.

The conclusions of this initial investigation were that the public health impacts of psychedelic legalization, if any, were minimal and negligible. While PsyCan certainly agrees there are potential risks associated with the use of psychedelics, most could be significantly reduced by legalizing and regulating access by adults, and none are as significant as the proven prohibition-related harms on medical and non-medical psychedelic consumers.

Much as was the case with cannabis legalization, necessary changes in Canada's current psychedelic policy would include a reconsideration of the current CDSA scheduling of psychedelic substances; the development of regulatory regimes promoting harm reduction, benefit maximization and safe, legal access; and education on safe use for health care providers, consumers, and law enforcement.

Many different strategies could achieve positive public health outcomes, including the potential for mandatory, low-barrier certified online consumer-focused education that might include a certificate of completion, onsite supervised use access and use models, and age-guarded access that might ultimately result in declines in youth use of psychedelics.

While all of this may seem like a distant potential future, we suggest that the federal government would do well to promptly begin consideration and public discussion of potential regulatory models for safe, legal access to psychedelics. In the event that public opinion in Canada presses further toward an updated approach to

[33] (Reason, 2023)

psychedelics, this preparation would position the Government of Canada well for a response. Further, upcoming court-decisions could force a new regulatory system upon the Government of Canada sooner than later, as was the case with medical cannabis.

Considering the current evidence and regulatory trends, PsyCan strongly supports the prompt initiation of a broad government-led national task force involving academics, public health experts, health care providers, patients and other psychedelic consumers modelled on the Federal Task Force on Cannabis Legalization and Regulation to discuss and explore potential regulatory models for safe, legal access to psychedelics for both medical and non-medical purposes.

PsyCan hopes that this publication can help inform current and future decision-making regarding safe access to psychedelics in Canada, and we look forward to working with all levels of government to ensure that our nation's psychedelic policies lead to positive and sustainable public health and safety outcomes.

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Annex 1: Regulatory Models: Review and Analysis

The following section is a review of current and proposed models and regulations regarding legal access to psychedelics. Sources are summarized in the table below. Ten sources have been analysed and organized into the following categories: academic, federal/national, U.S. state-level, and Canadian regulatory models and proposals. Each of the first nine sources include an overview of the proposed model/regulation or current legislation, its advantages and limitations, and relevant quotes. For a deeper dive into each model or legislation, further information/context can be found in Annex 3.

The last subsection – Canadian Industry and the Special Access Program (SAP) – provides an overview of Canada's Special Access Program and industry members' experiences with the application process. The critical analysis highlights the limitations in Canada's approach to medical and therapeutic access to psychedelics, despite existing research revealing the effectiveness of psychedelic-assisted therapy.

Methodology

The analysis consists of a review of relevant regulatory models of access to psychedelic substances. It is predicated on a qualitative, empirical analysis of those models, using a framework that accounts for medical and bioethical considerations, legal precedent, pharmacoeconomics, and public interest. The promises and pitfalls offered by each approach are assessed in terms of applicability to, and feasibility for, Canada. A group of reviewers with relevant backgrounds and expertise in the nascent legal psychedelic industry in Canada conducted an initial review of the models noted herein, providing feedback that was ultimately incorporated into the final report.

Source content is organized into tables, which are aggregated into a master table—the Table of Sources—providing the reader with a snapshot of data sources and regulatory relevance at a glance, facilitating comparisons between potential and existing access models. Final recommendations are evidence-based, pragmatic recommendations for regulatory reform informed by the principles of harm reduction/benefit maximization, cognitive liberty, personal rights and freedoms, and patient autonomy in personal medical care.

Table 2: Regulatory Review Sources

Table of Sources					
Source	Medical	Adult Use	Commercial Production/Sale	Personal Production	Comments
ACADEMIC REGULATORY MODELS					
Public Health Vision for the Management and Regulation of Psychedelics	X	X	X		-Recreational use must be supervised by 'Psychedelic Supervisors' Production controlled by 'PSC' -Sale only to 'Psychedelic Supervisors' -Does not discuss personal production
FEDERAL/NATIONAL REGULATORY MODELS					
Breakthrough Therapies Act	X				Reduces barriers for drug research and medical use of schedule 1 substances
Australia Poisons Standard Amendment	X				Psychiatrists are authorized to prescribe psilocybin or MDMA for specific mental illnesses
U.S. STATE-LEVEL REGULATORY MODELS					
Oregon Psilocybin Services Act	X	X	X		Regulated access to *Psilocybe cubensis*
Colorado Natural Medicine Health Act	X	X	X	X	Natural medicine includes psilocybin and psilocyn until June 2026 (other substances may be added later)
Washington Psilocybin Services Act	X				Establishes a psilocybin therapy pilot program and task force
Connecticut Act	X				Establishes a Psychedelic-Assisted Therapy Pilot Program as part of an FDA-approved expanded access program
CANADIAN REGULATORY MODELS & PROPOSALS					
TheraPsil's Access to Psilocybin for Medical Purposes	X		X	X	Sets the stage for "Psilocybin Act" as the ACMPR did for Cannabis.
KATA Practice Standards for Ketamine	X		X		Pharmacy compounding discussed
Special Access Program	X		X		

Academic Regulatory Models

Public-Health-Based Model for Management & Regulation of Psychedelics

Name of Act/Proposal/Publication:
Public Health Vision for the Management and Regulation of Psychedelics – Journal of Psychoactive Drugs.[34]

Source:
https://www.tandfonline.com/doi/abs/10.1080/02791072.2016.1202459?journalCode=ujpd20

Jurisdiction:
Canada

Substances Addressed:
LSD, psilocybin, MDMA, DMT, ayahuasca, peyote, mescaline, and other psychoactive substances based on the tryptamine or phenethylamine classes of compounds.

Primary Characteristics:

	Yes	No	N/A	Comments
Medical	X			
Adult Use	X			Recreational use must be supervised by 'Psychedelic Supervisors'
Commercial Production/Sales	X			Production controlled by 'PSC'. Sale only to 'Psychedelic Supervisors'. Proposes a ban on promoting sales such as advertising, branding and corporate sponsorship, as well as on fear-based campaigns.
Personal Production	X			Does not discuss personal production

Overview/Background

[34] (Haden, Emerson, & Tupper, 2016)

- Mark Haden, Brian Emerson, and Kenneth Tupper had their article published in the Journal of Psychoactive Drugs in 2016.

- “The purpose of this article is to explore the management and regulation of psychedelics using the lens of public health.”

- Calls for the development of a Psychoactive Substance Commission (PSC) which would have government-delegated authority to regulate various substances, including psychedelics.

- Proposes a college of psychedelic supervisors would be created with their authority delegated by the PSC.

- The college would be responsible for creating regulations, performance standards, guidelines, accreditation criteria to structure ‘appropriate environments’ to ensure safe delivery of psychedelic experiences.

- Psychedelic supervisors to be either ‘certified’ or ‘licensed’ by college. Certification = basic training, no oversight by college; Licensed = professional designation. Supply is of pharmaceutical quality; production and sale are controlled by PSC.

Advantages

- The proposed regulatory model addresses both medical and non-medical psychedelic use from a public health lens.
- Psychedelic would be available for wellness, personal growth, and recreation, in addition to medical uses.
- Strong likelihood of positive outcomes due to the rigor and control of the PSC.
- The PSC would work with religious or cultural groups to oversee cultivation or importation of plant-based preparations (e.g., peyote, ayahuasca) used in spiritual or sacramental traditions.
- The framework has been used in the post-prohibition regulatory models for cannabis.

Limitations

- Highly complex regulatory structure with multiple levels of bureaucracy would be costly and challenging to implement.
- Little commercial incentive as the model is highly critical of for-profit interests.
- Does not contemplate regulating personal production.

Relevant Excerpts/Quotes

"This framework has been used in the articulation of drug-specific, post-prohibition regulatory models for cannabis (Haden and Emerson 2014) and smokeable and injectable stimulants." (p. 243)

"All formulations would be generic, and no commercial branding of the different psychedelics would be allowed."

"The following model is drawn from the lessons learned from the regulation of alcohol and tobacco, which were used to develop a vision for public-health-based cannabis regulation (Haden and Emerson 2014). It articulates one model for regulating the production, distribution, and use of psychedelic substances, although other models are possible and deserve consideration. For example, the União do Vegetal church, whose members drink ayahuasca, and the Native American Church, whose members use peyote, have significant experiential history in the development of protective ritual safeguards.

...We propose establishing a Psychoactive Substance Commission (PSC), which would have government-delegated authority to regulate psychedelics and other currently illegal drugs (e.g., cannabis, opioids, cocaine), and potentially also alcohol and tobacco. The PSC would work with religious or cultural groups to cooperatively oversee the cultivation or importation of plant-based preparations (e.g., peyote, ayahuasca) used in specific spiritual/ sacramental traditions, and would oversee production and distribution of substances used for medical or other non-religious purposes. The PSC would regulate the production, wholesale and retail trade of psychedelics and administer any taxation schemes established for commercial trade in these substances. The PSC statutory mandate would be explicitly guided by public health principles, goals, and objectives. Revenue generation would not be a primary function. The PSC would be given responsibility for administering the financial policies for wholesale and retail sales of psychoactive drugs and subsequent revenue streams. The net revenue generated from the sales, fees, and taxation would support the regulatory structure, scientific research on psychoactive substances, and public-health-related programs and other health and social initiatives." (p. 246)

College of Psychedelic Supervisors
... "The circumstances of psychedelic supervision could vary widely, including psychotherapy, Indigenous healing circles, dance events, music festivals, palliative care wards, or natural environments. Supervisors would be expected to offer prior orientation and ongoing monitoring and oversight during the experience. From both traditional Indigenous knowledge and current scientific research, it can be expected

that the supervisors' primary function would be to provide appropriate safeguards or set and setting controls for all participants for 8–10 hours after ingestion of a psychedelic." (p. 248)

Summary/Conclusions

The article is thoughtful and provides an excellent starting place for a discussion on a public health-centered model to regulate psychedelic use. However, due to its complexity, the implementation of proposed regulations could be costly and challenging. Additionally, personal production is not contemplated and/or regulated, which is not in keeping with recent decriminalization/legalization initiatives in other jurisdictions.

Federal/National Regulatory Models

Breakthrough Therapies Act

Name of Act/Proposal/Publication:
S.5123 - Breakthrough Therapies Act (U.S. Congress, 2022)

Source:
https://www.congress.gov/bill/117th-congress/senate-bill/5123?s=1&r=3

Jurisdiction:
United States – Federal/National

Substances Addressed:
Schedule 1 Controlled Substances (e.g., ecstasy, heroin, LSD, marijuana, methaqualone, peyote, psilocybin, etc.)

Primary Characteristics:

	Yes	No	N/A	Comments
Medical	X			
Adult Use		X		
Commercial Production/Sales			X	
Personal Production		X		

Overview/Background

Bill S.5123/Breakthrough Therapies Act was introduced to Senate on November 17, 2022, "to amend the Controlled Substances Act to modify the registration requirements relating to research, and for other purposes." The bill permits the Secretary to designate an investigational new drug as a breakthrough therapy or authorize a Schedule I drug for expanded access under the Federal Food, Drug and Cosmetic Act. The therapeutic protocol for expanded use of Schedule I substances is to treat patients with serious or life-threatening diseases who don't have comparable or satisfactory therapies available. Some of the modified registration requirements for research on Schedule 1 substances include:

- Easier processes for registration.

- Research for the investigation of a new drug may be subject to expedited procedure.
- Continuation of research on substances newly added to Schedule I.
- Treatment of certain manufacturing activities as coincident to research:
    - A person researching a controlled substance should not be required to obtain a manufacturing registration under certain conditions.
    - Activities permitted include processing the substance to create extracts, tinctures, oils, solutions, derivatives, or other forms of the substance, as well as dosage form development studies (does not include growing marijuana).
- Increased transparency on the Drug Enforcement Administration website regarding special procedures to access specific psychedelic and other controlled substances for research and therapeutic purposes.

Advantages

- The Bill aims to reduce barriers to access controlled substances that can be used for research and/or therapeutic purposes.[35]
- This legislation would enable the Drug Enforcement Agency (DEA) to "make the findings necessary to transfer breakthrough therapies involving Schedule I substances such as MDMA and psilocybin from Schedule I to Schedule II, which could help facilitate a phased roll-out of these potentially lifesaving therapies via FDA-approved Expanded Access pilot programs" (Booker, 2022).
- Ease of federal laws on controlled substances may shift public perception and benefit states that have legalized psilocybin services (for further research and medical use).
- The bill is strongly supported by veterans to ensure they have access to life-changing treatments.

Limitations

- There is a potential for bifurcated rescheduling between substances and approved drug products.
- Researchers working with approved drug products could benefit, but it could increase relative costs for other formulations of the drug that are not fully approved.
- Falls well short of legalizing and regulating the medical/non-medical use of psychedelics.

[35] There is currently no accepted medical use for Schedule I drugs, substances, and chemicals in the US (examples of Schedule I drugs include heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), 3,4-methylenedioxymethamphetamine (ecstasy), methaqualone, peyote and psilocybin). (DEA, 2018)

Relevant Excerpts/Quotes

SEC. 2. REGISTRATION REQUIREMENTS RELATED TO RESEARCH.
"(j) Treatment of Certain Manufacturing Activities as Coincident To Research. —
"(2) ACTIVITIES INCLUDED. —Activities permitted under paragraph (1) include—
"(A) processing the substance to create extracts, tinctures, oils, solutions, derivatives, or other forms of the substance consistent the information provided as part of a notification submitted to the Attorney General under section 303(l) (21 U.S.C. 823(l)) or a research protocol filed with the application for registration approval; and
"(B) dosage form development studies performed for the purpose of satisfying FDA regulatory requirements for submitting an investigational new drug application.

SEC. 3. CURRENTLY ACCEPTED MEDICAL USE WITH SEVERE RESTRICTIONS.
(a) Definitions.—Section 102 of the Controlled Substances Act (*21 U.S.C. 802*) is amended by inserting after paragraph (7) the following:
"(7) (A) Subject to subparagraph (B), the term 'currently accepted medical use with severe restrictions', with respect to a drug or other substance, includes a drug or other substance that is an active moiety or active ingredient (whether in natural or synthetic form) of an investigational new drug for which a waiver is in effect under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) or section 351(a)(3) of the Public Health Service Act (42 U.S.C. 262(a)(3)) and that the Secretary—
"(i) designates as a breakthrough therapy under section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(a)); or
"(ii) authorizes for expanded access under subsection (b) or (c) of section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb), either alone or as part of a therapeutic protocol, to treat patients with serious or life-threatening diseases for which no comparable or satisfactory therapies are available.

Summary/Conclusions

The Breakthrough Therapies Act seeks to reduce barriers to accessing and furthering research on Schedule I substances (such as ecstasy, heroin, LSD, marijuana, methaqualone, peyote, psilocybin, etc.) for medical purposes through the official designation of an investigational new drug as a breakthrough therapy. MDMA and psilocybin-assisted therapy were designated as breakthrough therapies by the FDA and this bill seeks to reduce bureaucratic hurdles in studying and accessing other Schedule I substances that could lead to breakthrough therapies and medicines, as well as transferring Schedule I substances such as MDMA and psilocybin to Schedule II (Booker, 2022). The bill was introduced in the U.S. Senate on November 22, 2022, and there has not been any further action yet.

Name of Act/Proposal/Publication:
Notice of final decisions to amend (or not amend) the current Poisons Standard in relation to psilocybine and MDMA (Therapeutic Goods Administration, 2023)

Source:
https://www.tga.gov.au/sites/default/files/2023-02/notice-of-final-decision-to-amend-or-not-amend-the-current-poisons-standard-june-2022-acms-38-psilocybine-and-mdma.pdf

Jurisdiction:
Australia – Federal/National

Substances Addressed:
MDMA and psilocybin

Primary Characteristics:

	Yes	No	N/A	Comments
Medical	X			
Adult Use		X		
Commercial Production/Sales			X	
Personal Production		X		

Overview/Background

Starting July 1, 2023, authorised psychiatrists can prescribe products containing MDMA or psilocybin for specific mental health conditions. Prescribing psychiatrists are required to provide evidence and justification that a robust treatment protocol has been developed. Although such protocols do not yet exist, the Therapeutic Goods Administration (TGA) recognizes the rapidly evolving landscape of evidence and places the onus on prospective prescribers to devise suitable treatment protocol.

Authorised prescribers under the Authorized Prescriber Scheme (AP Scheme) can prescribe:

- MDMA for post-traumatic stress disorder (PTSD)
- psilocybin for treatment-resistant depression (TRD) (Therapeutic Goods Administration, 2023)

Psilocybin and MDMA can also be used in approved clinical trials. They will be listed as Schedule 8 (Controlled Drugs) medicines in the Poison Standards for these specific purposes. All other uses for these substances will remain in Schedule 9 (Prohibited Substances).[36]

Review and approval to proceed with these therapies must be granted by a Human Research Ethics Committee (HREC) and a senior medical officer at the TGA in their capacity as a delegate of the Secretary of the Department of Health and Aged Care. Psychiatrists are expected to have considered all clinically appropriate treatment options before applying for access to these substances under the AP scheme, as well as submit regular reports on numbers of patients treated and any associated adverse events.

Advantages

- The decision in support of amending the Poisons Standard was guided by evidence-based research, international regulatory status and access pathways, and a high number of public submissions, reflecting the scope and gravity of these issues for individuals and public health in Australia.
- The policy change is intended to increase access to these substances in response to the need for alternative mental health treatments.

Limitations

- Specialist psychiatrists authorized to prescribe these therapies may be inaccessible to most people due to high costs and long wait times for referrals.
- This program, while certainly groundbreaking in its recognition of the therapeutic potential of MDMA and psilocybin, actually results in many of the same restrictions and/or barriers to access patients currently face in Canada via the SAP – there is a complex application process (but for the psychiatrist), the need for review/approval from many different governing bodies and experts, and "the justification for treatment with Substances is strongest for those resistant to existing treatments and thereby already under the management of a specialist" (p. 8).
- Psilocybin can only be used for treatment resistant depression; MDMA can only be used for PTSD.
- Stakeholders are concerned about regulatory obligations related to using these substances, such as use in conjunction with psychotherapy in medically

[36] (Therapeutic Goods Administration, 2023).

controlled environments, the requirement of two independent psychiatrists to review each patient's diagnosis and treatment plan, as well as specific training for prescribers. While these additional restrictions are designed to mitigate potential risks and harms, the TGA acknowledges the potential difficulties in implementing and overseeing this unique program.

- "There are currently no approved products containing psilocybin or MDMA that the TGA has evaluated for quality, safety and efficacy. However, this amendment will allow authorised psychiatrists to access and legally supply a specified 'unapproved' medicine containing these substances to patients under their care for these specific uses." (Therapeutic Goods Administration, 2023)

Relevant Excerpts/Quotes

"The AP scheme allows authorised medical practitioners to supply therapeutic goods that are not included in the Australian Register of Therapeutic Goods (ARTG) to specified patients under their immediate care with a particular medical condition subject to certain conditions. In particular, approval must be granted by both a Human Research Ethics Committee (HREC) that is registered with the National Health and Medical Research Council (NHMRC) and, only once that approval has been granted, a senior medical officer at the TGA in their capacity as a delegate of the Secretary of the Department of Health and Aged Care. The TGA delegate will also expect that psychiatrists will have considered all clinically appropriate treatment options that are included in the ARTG before applying to access a psilocybine- or MDMA-containing product for their patient under the AP scheme. (p. 8)

The new Schedule 8 entries limit the therapeutic use of the Substances to TRD for psilocybine, and PTSD for MDMA. This provides for narrower access than originally proposed by the applicant, but in view of paragraphs 52E(1)(a) and (b) of the Act, is aligned with the current body of clinical evidence supporting the therapeutic use of the Substances that pertains primarily to these mental health conditions.

The use of psilocybine and MDMA to treat all indications other than TRD and PTSD, respectively, will remain captured by the existing Schedule 9 entries for the Substances, limiting their use to medical and scientific research, including clinical trials. I consider that the body of evidence demonstrating the efficacy of the Substances for the treatment of other indications is insufficient at this time to justify increased access for therapeutic use. (p. 9)"

Summary/Conclusions

In an historic move, Australia's Therapeutic Goods Administration amended the

Poisons Standard to allow authorized specialist psychiatrists to prescribe, under certain circumstances, MDMA for PTSD or psilocybin for treatment-resistant depression. Additionally, these controlled substances can also be used for approved clinical trials.

Unfortunately, this regulatory approach has similar limitations as those in Canada's SAP, and Alberta's new Psychedelic Drug Treatment Services Standards. The application process is complex and time-consuming, the application process is centralized, and approval is required from multiple governing bodies, and patients who might benefit from these therapies are expected to have tried (and failed) many other types of treatment prior. Additionally, limiting the ability to prescribe and oversee these therapies to psychiatrists could result in significant bottlenecks. Taken together, these obstacles to access may ultimately limit the practical application and viability of this federal access program.

U.S. State-Level Regulatory Models

Oregon Psilocybin Services Act

Name of Act/Proposal/Publication:
The Oregon Psilocybin Services Section (ORS 475A) (State of Oregon, 2023)

Administrative Rules: OAR 333-333-1010 (Oregon Health Authority, 2022)

Sources:

- https://www.oregon.gov/oha/ph/preventionwellness/pages/oregon-psilocybin-services.aspx#:~:text=The%20Oregon%20Psilocybin%20Services%20Section,and%20the%20provision%20of%20psilocybin
- https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=7102

Jurisdiction:
Oregon, United States

Substances Addressed:
Psilocybe cubensis, which must be grown in Oregon – the law does not allow synthetic psilocybin or other mushroom species.

Primary Characteristics:

	Yes	No	N/A	Comments
Medical	X			
Adult Use	X			
Commercial Production/Sales	X			
Personal Production			X	

Overview/Background

In 2020, the residents of Oregon passed Ballot Measure 109, tasking the state to create a pathway for regulated access to psilocybin. This measure has now been codified into ORS 475A, leading to the creation of the Oregon Psilocybin Services (OPS), a new section housed within the Oregon Health Authority Public Health Division's Center for Health Protection, that is the governing body that will license and regulate the manufacturing, transportation, delivery, sale, and purchase of psilocybin products and the provision of psilocybin services. These new regulations stipulate that licensed cultivators exclusively located in Oregon provide laboratory-tested and specifically labelled packages of psilocybin to licensed service centers. The law quite specifically allows for the production and distribution of *Psilocybe cubensis* cultivated in Oregon and does not allow for alternative mushroom species or synthetic psilocybin to be legally produced or consumed.

Additionally, the law requires any manufacturers or service providers to be more than 50% owned by Oregon residents of at least two years, and Facilitators must be residents for at least 2 years prior to licensure. In order to ensure these services are only marketed and available to adults, all applicants, Facilitators and their clients must be 21 or older, and restrictions on advertising and packaging limit marketing of these products and services to adults 21 and over. Vendor facilities cannot be co-located with a healthcare, cannabis, liquor or restaurant facility, and a manufacturer may only possess 200 grams of psilocybin (PC) and sell a maximum of 25 mgs PC/client package.

Finally, there are several important regulations for service centers to ensure clients are adequately supported during dosing, including regulations on client preparation, facility amenities, facilitator-to-client ratios, dosing, bodily autonomy and privacy. Facilitators must undergo OHA-approved training for a minimum of 150 hours, but must not practice psychiatry or psychotherapy during facilitation, which raises concerns about utility, client safety and industry growth.

Advantages:

- The proposed regulation provides a very comprehensive regulatory regime to ensure that psilocybin mushrooms are monitored from beginning to end.
- Clients are provided with a bill of rights and other protections aimed to protect their safety, including a provision requiring labelling of the amount of active psilocybin by weight, as confirmed via laboratory testing.

Limitations:

- Limited to *Psilocybe cubensis,* leaving other psychedelics unregulated and therefore controlled by the black market, and consumers of psychedelics other than *Psilocybe cubensis* vulnerable to arrest and prosecution, even if their use is medical.
- The proposed regulation expressly prohibits facilitators, even those licensed to practice medicine, to do so during facilitation. Specifically, the facilitator cannot practice medicine on a client during a session while being a facilitator, even if an adverse event arises. Rather, the proposed regulation requires the facilitator and/or center to contact emergency services. The express prohibition of using an outside licensure might create a personal liability risk to those with emergency training (such as an EMT) or dissuade such persons from offering emergency care if needed.
- The service centers will be charging $3500 for a session with 4 grams, $2800 for a session with 2.5 grams, and $500-800 for a microdose session, which may prove inaccessible for people with lower incomes.

Relevant Excerpts/Quotes

333-333-5130
Facilitator Scope of Practice
(1) A facilitator shall not engage in any conduct that requires additional professional licensure while providing psilocybin services to clients, including but not limited to diagnosing and treating physical or mental health conditions.
(2) A facilitator is prohibited from transferring, selling or otherwise handling any psilocybin product while they are facilitating a preparation, administration or integration session, regardless of whether the facilitator is also a licence representative of a service center.
(3) If a facilitator holds a professional licence in another field, the facilitator shall not exercise the privileges of that licence while providing psilocybin services to clients.

Conclusions

The Oregon Psilocybin Services is a new section (Ballot Measure 109 passed in 2020) housed in the Oregon Health Authority Public Health Division's Center for Health Protection. The OPS directs the OHA in all aspects of psilocybin manufacturing, delivery, sale, purchase and provision of these products and services.

The framework for these regulations has undergone a 2-year development phase with direction from the Oregon Psilocybin Advisory Board and various subcommittees to establish rules, created a facilitator training program approval system, and education, training and website information for the regulatory community and public.

This regulation is very comprehensive, providing state-level government oversight for the production and sale of psilocybin, and regulating service delivery of psilocybin-based experiences via licensed service centers and specially trained facilitators. Despite being limited to the regulation of *Psilocybe cubensis,* this is nonetheless one of the most comprehensive regulatory systems for psychedelics thus far, covering both therapeutic and non-therapeutic applications for adults. While it is too early to assess the outcomes of this state-level program, it merits ongoing scrutiny and observation by other jurisdictions interested in non-criminal justice approaches to psychedelic substances.

Colorado Natural Medicine Health Act of 2022

Name of Act/Proposal/Publication:
Article 170 – Natural Medicine Health Act Of 2022 (State of Colorado, 2022)

Sources:
- https://www.sos.state.co.us/pubs/elections/Initiatives/titleBoard/filings/2021-2022/58Final.pdf
- https://dpo.colorado.gov/dpo-home/natural-medicine-health-act-home

Jurisdiction:
Colorado, United States

Substances Addressed:
Until June 1, 2026, the term "natural medicine" only includes PSILOCYBIN and PSILOCYN.

After June 1, 2026, the Natural Medicine Advisory Board may recommend addition of one or more of the following to the term "natural medicine": DIMETHYLTRYPTAMINE;

IBOGAINE; MESCALINE (EXCLUDING LOPHOPHORA WILLIAMSII ("PEYOTE")) [12-170-104(4)(a-b)]

Primary Characteristics:

	Yes	No	N/A	Comments
Medical	X			Provide education and training to first responders
Adult Use	X			Decriminalization and regulated access for adults to natural medicines that show promise in improving well-being, life satisfaction and health
Commercial Production/Sales	X			
Personal Production	X			Decriminalized. Growing, cultivating, or processing plants or fungi must be kept on the grounds of a private residence and secured away from persons under 21.

Overview/Background

In May of 2019 the City and County of Denver, the largest municipality in Colorado, enacted Ordinance 301, which makes enforcement of personal possession and use of psilocybin the lowest priority of City and County law enforcement and additionally prohibited the use of City and County funds to enforce penalties related to personal use or possession of psilocybin. In February 2022, just under two years after Denver Ordinance 301, Colorado enacted Title 12, Article 170, "The Natural Medicine Health Act of 2022."

The legislative declaration provides the purpose of establishing a "new, compassionate and effective approach to natural medicines". [12-170-102(j)] This includes providing greater access to the enumerated substances for adults 21 and older by reducing the state's focus on criminal punishments and providing a regulated pathway for access. The Act decriminalizes non-commercial "personal use" of psilocybin for persons 21 and over and also requires the Colorado Department of Regulatory Agencies to "adopt rules necessary to implement the regulated natural medicine access program" to provide a regulated process for commercial access to psilocybin [12-170-104(3)]. For example, the establishment of healing centers and other licensed entities, as well as the development and promotion of public education and

training for first responders related to the use of natural medicines and harm reduction.

The Act continues to keep criminal and civil statutes related to psilocybin in force, but rather provides a safe harbor within them. Although the Act provides broad protections to persons 21 or over for growing, transporting, using, and gifting psilocybin to others in the state for personal use, the Act draws a clear line between personal and commercial use. This includes any *de minimis* renumeration, but rather must be strictly personal use or provision of psilocybin as a gift to another person over 21 years old. The Act's protections also exclude uses while operating a vehicle, possession in a public building, school, or detention center, or ingestion in a public place and does not require a private employer to permit or accommodate use or possession of psilocybin in the workplace. Further, the Act's protections for possession and cultivation only apply where the person is 21 years of age or older and where the "plants and fungi are secured from access by persons under twenty-one years of age." [12-170-109, 110, 111]

- The legislation provides a nice framework that is easy to understand. The cultivation, possession, use, and distribution of psilocybin are still civilly and criminally illegal under Colorado law, except where the Act's protections apply, and the Act's protections are fairly straightforward.
- Quality control measures are in place for the commercial provision of natural medicines, including "independent testing of natural medicine for concentration and contaminants".
- Many safeguards for youth, including marketing and advertising restrictions. Additionally, the penalties for production, possession and use under the age of 21 focus on small fines, and/or education and counseling rather than more severe/deleterious criminal justice approaches.
- Licensed healing centres can also cultivate and manufacture psilocybin.
- Healing centers can co-locate with other healthcare and healing services like hospitals, hospices, and community health centers (unlike Oregon).

Limitations:

- The Act's protections are limited where the Act would conflict with Federal law, which in some cases might create a state cause of action against a person who is otherwise compliant.
- Secondly, the Act is vague on exactly how much effort is required to secure psilocybin from access by persons under 21 years of age to fall within the protections of the Act. (12-170-110(3) provides that the person failing to secure such access is subject to an up to $250 fine, "in addition to any other applicable penalties." In addition to elements of the Act's protections requiring such

limitation on access, the express statement including applicable penalties would indicate that the existing criminal enforcement for cultivation and distribution may apply. The penalty for possession and use by those under 21 are capped at 4 hours of free drug education or counseling.

Relevant Excerpts/Quotes

"12-170-104.
(a) Establish the requirements governing the safe provision of natural medicine services to participants that include:
(i) holding and verifying completion of a preparation session, an administration session, and an integration session.
(ii) health and safety warnings that must be provided to participants before natural medicine services begin.
(iii) educational materials that must be provided to participants before natural medicine services begin.
(iv) the form that each facilitator, participant, and authorized representative of a healing center must sign before providing or receiving natural medicine services verifying that the participant was provided accurate and complete health information and informed of identified risk factors and contraindications.
(v) proper supervision during the administration session and safe transportation for the participant when the session is complete.
(vi) provisions for group administration sessions where one or more facilitators provide natural medicine services to more than one participant as part of the same administration session.
(vii) provisions to allow a facilitator or a healing center to refuse to provide natural medicine services to a participant.
(viii) the requirements and standards for independent testing of natural medicine for concentration and contaminants, to the extent available technology reasonably permits.
(ix) the licensure of entities permitted to engage in the testing of natural medicine for use in natural medicine services or otherwise.
(x) the standards for advertising and marketing natural medicine and natural medicine services.
(xi) the standards for qualification as a permitted organization addressing, without limitation, environmental, social, and governance criteria directed to the findings and declarations set forth in Section 12-170-102.

12-170-110. Personal use penalties. (1) Unless otherwise provided by subsection (2) of this section, a person who is under twenty-one years of age is subject to a drug petty offense, and upon conviction thereof, shall be subject only to a penalty of no more

than four (4) hours of drug education or counselling provided at no cost to the person, if the person:

(a) Possesses, uses, ingests, inhales, or transports natural medicine for personal use;
(b) Gives away without remuneration natural medicine for personal use; or 15
(c) Possesses, uses, or gives away without remuneration natural medicine paraphernalia.
(2) To the extent subsection (1) establishes a penalty for conduct not otherwise prohibited by law or establishes a penalty that is greater than exists elsewhere in law for the conduct set forth in subsection (1), the penalties in subsection (1) shall not apply.
(3) A person who cultivates natural (3) a person who cultivates natural medicines that are not secure from access by a person under twenty-one years of age in violation of 12-170-109(1)(b) is subject to a civil fine not exceeding two-hundred and fifty dollars, in addition to any other applicable penalties.

Summary/Conclusions

The Act creates a bright line test to proscribe the scope of activities necessary to comport with the protections of the Act. Specifically, criminal enforcement is abrogated for anyone in the state possessing, using, ingesting, inhaling, transporting, or cultivating psilocybin or related paraphernalia in Colorado, so long as those persons do not receive renumeration, do not provide psilocybin to those under 21, or do not violate one of the Act's limitations. Despite the bright line, the Act further ensures that penalties for being within the penumbra of the Act are de minimis civil penalties.

Despite the bright line test, the limitations create significant ambiguity. Notably, US Federalism provides that Colorado cannot abrogate US Federal Law prohibiting the possession of psilocybin, which is listed as a schedule I compound under 21 USCS § 812. Article VI, Clause 2 of the US Constitution provides that federal laws are the "supreme law of the land." At 12-170-111(k), to avoid this conflict the Act provides that, "This Article 170 shall not be construed (k) To exempt a person from federal law or obstruct the enforcement of federal law." However, as the Act is a protection from prosecution by the state, 170(k) ostensibly also acts as a safe harbor for state and local law enforcement to enforce the same acts under federal law.

Name of Act/Proposal/Publication:
Original Bill:
Senate Bill 5660 – 2021-22: Washington Psilocybin Services Wellness and Opportunity Act (Washington State Legislature, 2022)

2nd Substitute Bill (Passed Legislation):
Senate Bill 5263 – 2023-24: Washington Psilocybin Services Act (Washington State Legislature, 2023)

Sources:
Original bill:
https://app.leg.wa.gov/billsummary?BillNumber=5660&Year=2021&Initiative=false#documentSection

Passed legislation: https://app.leg.wa.gov/billsummary?BillNumber=5263&Year=2023

Jurisdiction:
State of Washington, U.S.

Substances Addressed:
Psilocybin

Primary Characteristics:

	Yes	No	N/A	Comments
Medical	X			
Adult Use		X		The original bill proposed service centers for wellness, but the passed legislation removed this and focuses on studying medical use.
Commercial Production/Sales		X		The original bill included details on regulating commercial production, licensing, packaging and selling, but this remains prohibited in the passed legislation.
Personal Production			X	

Overview/Background

This section analyzes both the original bill proposed in January 2022 and the final bill, which was signed into law May 2023, effective date July 23, 2023. They differ significantly from one another in that the original mirrors many portions of Oregon's and Colorado's legislation. The substitute bill reduced it down to studying and preparing for clinical psilocybin use and future legislation and regulations, such as establishing an advisory board, working groups and a Psilocybin Therapy Services Pilot Program.

The original Senate Bill 5660, the Washington Psilocybin Services Wellness and Opportunity Act, was read on January 10, 2022. The act concerns access to psilocybin services by individuals 21 years of age and older, and:

- "Directs the Department of Health (DOH) to administer a regulatory system for supported adult use of psilocybin, beginning January 1, 2024.
- Directs DOH to create standards for manufacturing, testing, packaging, and labeling psilocybin products with the assistance of a Psilocybin Advisory Board and other government agencies.
- Allows a person aged 21 and older to purchase psilocybin products in a psilocybin service center and undergo a preparation session, administration session, and integration session under the supervision of a trained facilitator.
- Restricts employment in the psilocybin industry to licensed or permitted individuals aged 21 and older." (Washington State Legislature, 2022, p. 1).

The 68-page original bill was amended, and a 2nd substitute bill passed legislature on April 18, 2023. This 9-page bill differs significantly from the original bill in that it seeks to establish a Psilocybin Advisory Board, an Interagency Work Group, a Psilocybin Task Force, and the Psilocybin Therapy Services Pilot Program administered by the University of Washington Department of Psychiatry and Behavioral Sciences. It does not mention anything about service centers (or healing centers), or regulations on manufacturing, packaging and selling psilocybin products. However, the Psilocybin Work Group is tasked with studying and reviewing "Oregon's psilocybin rules to assess the adaptation of similar laws and rules."[37]

Update: The governor signed the 2nd substitute bill on May 9, 2023, but vetoed Sections 1, 2, 3, 4, 5, 7, 10, 11, and 13. The governor's letter and reasoning for partially vetoing Bill 5263 can be read here.

[37] (Washington State Legislature, 2023).

Before establishing a psilocybin advisory board, the task force must complete its work and submit a report by December 1, 2023. Without an advisory board, an interagency work group and other sections of the bill would have no use.

Advantages (Original Bill):

- The bill is incredibly detailed and focuses on protecting and improving peoples' well-being and taking a compassionate approach to public health. There is a senate bill report that includes public testimonies of positive results from psilocybin therapy.
- It seeks to establish healing centers, similar to Oregon's approach, that support the adult use of psilocybin "under the supervision of a trained and licensed psilocybin service facilitator" [Sec 2(1)].
- Establishes the criteria for a Washington Psilocybin Advisory Board, an 18-month program development period and standards for testing psilocybin products. The department is also required to publish and distribute available research study results regarding psilocybin and health & safety to the public.
- Clients who are medically unable to travel to a psilocybin service center can get an exemption and receive administration sessions at their home (under the supervision of a trained facilitator which can be remotely).
- There is a section that recommends establishing social opportunity programs for the industry to "help remedy the harms resulting from historical injustice and the disproportionate and targeted enforcement of drug-related laws on poor and marginalized communities" [Sec 115(1)].

Limitations (Original Bill):

- Clients do not have to have a diagnosis or medical condition to access psilocybin services, which has both pros and cons. This approach makes psilocybin significantly more accessible to the general public without all the red tape around medical access, while still establishing safeguards like regulated provision, service centers and trained facilitators. However, this can also lead to greater potential risks of adverse events if any adult can walk in without a detailed understanding of their health conditions, and while only facilitators are responsible for their care as opposed to doctors and health care professionals.

Relevant Excerpts/Quotes (Original Bill)

SENATE BILL 5263
NEW SECTION. Sec. 1. The legislature finds that:
(4) It is the intent of Washington to facilitate the establishment of safe, legal, and affordable psilocybin service centers to provide citizens of Washington who are at

least 21 years of age with opportunities for supported psilocybin experiences for wellness and personal growth;
(6) During an 18-month program development period, the department must adopt rules for the implementation of a comprehensive regulatory framework that allows individuals 21 years of age and older in this state to be provided psilocybin services; and
(7) An advisory board must be established within the department to provide advice and recommendations to the department.
NEW SECTION. Sec. 57. A client may purchase, possess, and consume a psilocybin product:
(1) Only at a psilocybin service center unless an exception is made under rules established by the department under section 26 of this act to accommodate a client who is medically unable to travel to a psilocybin service center; and
(2) Only under the supervision of a psilocybin service facilitator.
NEW SECTION. Sec. 115. (1) The legislature finds that in the interest of establishing a legal psilocybin industry that is equitable and accessible to all, it is appropriate to establish a social opportunity program for the psilocybin industry to help remedy the harms resulting from historical injustice and the disproportionate and targeted enforcement of drug-related laws on poor and marginalized communities.

Advantages (2nd Substitute Bill):

- The substitute bill prioritizes studying and preparing for a long-term strategic plan regarding safe, accessible and affordable psilocybin access before implementing another Oregon approach.
- The outreach and engagement strategy for the pilot program is inclusive to historically marginalized populations that don't normally get included in research and clinical trials. The pilot program is for adults (21 and over) who are experiencing PTSD, mood disorders or substance use disorders.
- Indigenous and cultural practices with psilocybin will be considered and studied in addition to clinical trials and medical evidence.
- The psilocybin therapy services are through pathways approved by the FDA and can be facilitated by licensed advanced social workers, independent clinical social workers, mental health counselors, physicians, and psychiatric advanced registered nurse practitioners.
- Meetings of the task force must be open to members of the public.
- The task force will review regulatory structures for clinical use of psilocybin in other jurisdictions.

Limitations (2nd Substitute Bill):

- The passed legislation stripped most of the proposed regulations included in the original bill such as service centers, facilitators, production, sales, ordinances, etc. However, this also provides the state more time to gather research and review the impact of similar policy changes in other jurisdictions prior to implementing sweeping legislative and regulatory changes in Washington State.
- The Governor vetoed over half the bill after it passed both House and Senate. The task force established last year has not finished their work and so a psilocybin advisory board will not be established until then. Without an advisory board, the interagency work group would have no role.

Relevant Excerpts/Quotes (2nd Substitute Bill)

SECOND SUBSTITUTE SENATE BILL 5263

Passed Legislature - 2023 Regular Session

NEW SECTION. Sec. 6. (1) The health care authority must establish a psilocybin task force to provide a report on psilocybin services. The director of the health care authority or the director's 10 designee must be a member of the task force and serve as chair.

NEW SECTION. Sec. 8. (1) Subject to amounts appropriated for this purpose, the psilocybin therapy services pilot program is established within, and administered by, the University of Washington department of psychiatry and behavioral sciences. No later than January 1, 2025, the University of Washington department of psychiatry and behavioral sciences must implement this section.

(2) The pilot program must:

(a) Offer psilocybin therapy services through pathways approved by the federal food and drug administration, to populations including first responders and veterans who are:

(i) 21 years of age or older; and

(ii) Experiencing posttraumatic stress disorder, mood disorders, or substance use disorders;

(b) Offer psilocybin therapy services facilitated by:

(i) An advanced social worker, independent clinical social worker, or mental health counselor licensed under chapter 18.225 RCW;

(ii) A physician licensed under chapter 18.71 RCW; or

(iii) A psychiatric advanced registered nurse practitioner licensed under chapter 18.79 RCW as defined in RCW 71.05.020;

(c) Ensure psilocybin therapy services are safe, accessible, and affordable;

(d) Require an initial assessment to understand participant goals and expectations, and assess the participant's history for any concerns that require further intervention or information before receiving psilocybin therapy services, and an integration session after receiving psilocybin therapy services; and

(e) Use outreach and engagement strategies to include participants from communities or demographic groups that are more likely to be historically marginalized and less likely to be included in research and clinical trials represented by race, sex, sexual orientation, socioeconomic status, age, or geographic location.

NEW SECTION. Sec. 9. Medical professionals licensed by the state of Washington shall not be subject to adverse licensing action for recommending psilocybin therapy services.

Summary/Conclusions

Like recent regulatory changes in Oregon and Colorado, Washington State proposed SB 5660 last year to administer a regulatory framework for accessing psilocybin services for health, wellness and personal growth. Psilocybin service centers would provide regulated psilocybin products to adults aged 21 and older in addition to preparation sessions, administration sessions, and integration sessions under the supervision of a trained facilitator. Clients would not have to have medical diagnoses or conditions to access these services but must be under the supervision of a facilitator at a service center or remotely if exempted.

The bill was amended and substituted in 2023 with SB 5263, called the Washington Psilocybin Services Act, which passed House and Senate in April 2023. The Governor vetoed 9 out of 14 sections before enacting it as law, effective in July 2023. The 2nd substitute bill will not set up a psilocybin advisory board and interagency work group until the task force finishes their work and publishes a report, but it will establish a psilocybin therapy pilot program no later than January 1, 2025.

Name of Act/Proposal/Publication:
An Act Increasing Access to Mental Health Medication (HB-5396) (Connecticut General Assembly, 2022)

An Act Adjusting the State Budget for the Biennium Ending June 30, 2023, Concerning Provisions Related to Revenue, School Construction and Other Items to Implement the State Budget and Authorizing and Adjusting Bonds of the State (HB-5506) (Connecticut General Assembly, 2022)

Sources:
- https://www.cga.ct.gov/asp/cgabillstatus/cgabillstatus.asp?selBillType=Bill&bill_num=HB05396&which_year=2022
- https://www.cga.ct.gov/asp/cgabillstatus/cgabillstatus.asp?selBillType=Bill&bill_num=HB05506&which_year=2022

Jurisdiction:
Connecticut, U.S.

Substances Addressed:
MDMA and psilocybin

Primary Characteristics:

	Yes	No	N/A	Comments
Medical	X			
Adult Use		X		
Commercial Production/Sales			X	
Personal Production		X		

Overview/Background

The enacted budget measure (HB-5506) includes aspects of the standalone bill HB-5396 but with some sections repealed and more limits on treatment eligibility. The act establishes a Psychedelic-Assisted Therapy Pilot Program at the Connecticut Mental Health Center (CMHC) to provide funding to qualified patients for MDMA- and psilocybin-assisted therapy as part of an FDA-approved expanded access program. The pilot program will end when "the U.S. Drug Enforcement Administration (DEA)

approves MDMA and psilocybin for medical use" (Office of Legislative Research, 2022, p. 84).

"Qualified patients" include Connecticut residents who are veterans, retired first responders, or direct health care workers (the previous standalone bill had also included people from historically underserved communities and patients who have serious or life-threatening mental or behavioral health disorders and lack access to effective mental or behavioral health medication).

The Act also establishes an 11-member Connecticut Psychedelic Treatment Advisory Board. The advisory board will help the DMHAS design and develop regulations and infrastructure for psychedelic-assisted therapy if MDMA, psilocybin, or any other psychedelic compounds are legalized (Office of Legislative Research, 2022, pp. 83-86).

Advantages:

- The Act is preparing for future legalization/reclassification of psychedelic compounds by establishing an advisory board to develop regulations, and a pilot program that will last until the U.S. DEA approves the substances for medical use.
- The PAT fund will allow qualified patients to access grants for psychedelic-assisted therapy, "and the center may accept contributions from any source, public or private, for deposit in said fund." [Public Act No. 22-118, p. 293 of 739] [Sec 200(d)]

Limitations:

- The adjusted budget removed certain groups from the list of "qualified patients" from the original bill, including people from historically underserved communities and patients who have serious or life-threatening mental or behavioral health disorders, limiting access to only veterans, retired first responders and direct health care workers.
- Access to psychedelic-assisted therapy will be incredibly limited for this pilot program.

Relevant Excerpts/Quotes

Summary for Public Act (Adjusting the State Budget) (Office of Legislative Research, 2022)
Section on Psychedelic-Assisted Therapy (pp. 83-86)

Establishes (1) a Psychedelic-Assisted Therapy Pilot Program at the Connecticut Mental Health Center, (2) a fund to administer program grants, and (3) an 11-member advisory board within DMHAS to advise the department on various issues related to this therapy; makes related changes to the potential rescheduling of certain psychedelic substances (PA 22-46, § 28 repeals these sections)

The act establishes a Psychedelic-Assisted Therapy Pilot Program at the Connecticut Mental Health Center (CMHC), within available appropriations, to provide qualified patients with funding needed to receive MDMA-assisted or psilocybin-assisted therapy (hereinafter "psychedelic-assisted therapy") as part of a U.S. Food and Drug Administration (FDA)-approved expanded access program. The pilot program ends when the U.S. Drug Enforcement Administration (DEA) approves MDMA and psilocybin for medical use. (MDMA (i.e., "Molly" or "ecstasy") is a synthetic psychoactive drug and psilocybin occurs naturally in some mushrooms. Both act as serotonin receptor agonists and MDMA also acts as a reuptake inhibitor of serotonin and dopamine.)

Under the act, "qualified patients" include Connecticut residents who are veterans, retired first responders, or direct health care workers.

Additionally, the Act:

1. Establishes, within available appropriations, a Qualified Patients for Approved Treatment Sites Fund (PAT Fund) administered by CMHC to give grants to certain qualified providers to provide psychedelic-assisted therapy under the pilot program;
2. Establishes an 11-member Connecticut Psychedelic Treatment Advisory Board within DMHAS to advise the department on various issues related to psychedelic-assisted therapy;
3. Requires DCP to adopt DEA's controlled substances schedule for MDMA and psilocybin if DEA approves them for medical use and either reclassifies or unschedules them; and
4. Requires DCP to consider adopting nonbinding federal guidelines on psychedelic-assisted therapy and allow for written comments from the advisory board and the public.

The act also makes technical and conforming changes.
(PA 22-146, §§ 20 & 28, repeals this act's provisions and instead requires DMHAS, by January 1, 2023, to establish a psychedelic-assisted therapy pilot program, within available appropriations, administered by a Connecticut medical school.)
EFFECTIVE DATE: July 1, 2022

Summary/Conclusions

Effective on July 1, 2022, an Act adjusting and implementing the state budget was signed which included a section on psychedelic-assisted therapy, mirroring many aspects of Bill HB-5396 (An Act Increasing Access to Mental Health Medication). The act establishes a Psychedelic-Assisted Therapy Pilot Program (for psilocybin and MDMA) and a PAT fund to provide grants for qualified patients. Qualified patients include veterans, retired first responders or direct health care workers.

The Act also establishes an 11-member treatment advisory board which will consist of members who have “experience or expertise in psychedelic research, psychedelic-assisted therapy, public health, access to mental and behavioral health care in underserved communities, veterans’ mental and behavioral health care, harm reduction, and sacramental use of psychedelics.” The board will prepare for and advise upon the legalization of psychedelic compounds for medical use, and the development of regulations and infrastructure for psychedelic-assisted therapy. The Commissioner of Consumer Protection will also reschedule and adopt federal regulations and guidelines under the Controlled Substances Act.

Canadian Regulatory Models and Proposals

TheraPsil's Proposed Regulations – APMPR

Name of Act/Proposal/Publication:
Access to Psilocybin for Medical Purposes Regulations (APMPR) (TheraPsil, 2021)

Source:
https://therapsil.ca/apmpr-first-draft-proposed-access-to-psilocybin-for-medical-purposes-regulations/

Jurisdiction:
Canada – Federal/National

Substances Addressed:
Psilocin, Psilocybin

Primary Characteristics:

	Yes	No	N/A	Comments
Medical	X			
Adult Use		X		Sets the stage for "Psilocybin Act" as the ACMPR did for Cannabis.
Commercial Production/Sales	X			
Personal Production	X			

Overview/Background

TheraPsil, a non-profit organization that provides legal access to psychedelic-assisted therapies and associated training and advocacy, developed the *APMPR* in response to access issues using subsection 56(1) exemptions. The document is a set of proposed regulations that Health Canada could consider for the purpose of legalizing and regulating access to medical psilocybin.

The Access to Psilocybin for Medical Purposes Regulations (the "**APMPR**") would govern legal access to psilocybin for medical purposes under the Controlled Drugs and Substances Act (the "**CDSA**"). The Psilocybin and Psilocin Exemption (Food and Drugs Act) Regulations (the "**PER**") are proposed regulations under the CDSA and the Food and Drugs Act (the "**FDA**"). Since these regulations are based on the previous

ACMPR that governed access to medical cannabis prior to the Cannabis Act, no amendments to any act of parliament are necessary for these proposed regulations.

The APMPR, the PER and associated amendments to the FDR would create a system that can predictably provide quality-controlled products to Canadians for therapeutic purposes based on a medical document executed by a physician, nurse practitioner or other prescribing healthcare practitioner ("**HCP**"). The basis upon which HCPs can write medical documents would be regulated at the provincial level by colleges and other healthcare regulators.

Health Canada has experience regulating access to medical cannabis from 2001 to 2018 under the CDSA, and since 2018 under the *Cannabis Act*. Similarities between the structure of the APMPR and the structure of the Cannabis Regulations (the "**CR**") allow for efficiencies from Health Canada's experience regulating cannabis licensing, the production of cannabis products, and access to cannabis for medical purposes.

Advantages:

- Legislatively straightforward, with no amendment of the CDSA or the FDA required.
- politically defensible in that they are entirely consistent with, and promote the goals of, the UN Drug Control Conventions.
- Administratively simple for the regulator because Health Canada already has the experience and infrastructure to regulate cannabis products, and to regulate medical access to cannabis.
- Administratively simple for producers of psilocybin products by following accepted standards for licensed dealers and for license holders under the CR.
- Supported by industry in Canada that is ready to provide the products.
- Supported by healthcare practitioners in Canada who are comfortable with using psilocybin in their practices.
- Assuming reasonable and appropriate oversight by Provincial medical colleges and perhaps even legislation (Alberta), these regulations are unlikely to provide a meaningful avenue to improperly access psilocybin.
- No amendment to Controlled Drugs and Substances Act (CDSA) or Food and Drug Act (FDA) necessary – legislatively simple and compliant with existing legislation.
- Considers both synthetic products and natural products.

Limitations:

- Only addresses psilocybin, leaving out other promising psychedelic substances and associated therapies.

Summary/Conclusions

The benefits of the proposed APMPR regulations are that since they are based on the previous ACMPR, they are fully formed, easy for regulators and industry to understand, and do not require an amendment to the CDSA or FDA. Additionally, the goals are consistent with and promote the interests of the UN Drug Control Conventions.

However, there are some shortcomings to these regulations as well. Namely, they do not consider the application of medicine in great detail, but rather assume reasonable oversight by Provincial medical colleges. Moreover, in only addressing access to psilocybin, the regulations would do little to improve access to other psychedelics, or to reduce the potential negative impacts of continued criminal justice approaches to these substances on patients, health care providers and non-medical consumers.

Practice Standards for Outpatient Use of Ketamine

Name of Act/Proposal/Publication:
Outpatient Use of Ketamine for Mental Health Conditions: Practice Standards Recommendations (Hanon, Barale, Mitchell, Dhiman, & Ka, 2022)

Source:
https://katacanada.org/practice-standards/

Jurisdiction:
BC, Canada - Federal/National

Substances Addressed:
Ketamine, with a focus on non-IV administration.

Primary Characteristics:

	Yes	No	N/A	Comments
Medical	X			
Adult Use		X		
Commercial Production/Sales	X			Pharmacy compounding discussed
Personal Production			X	

Overview/Background

The Ketamine Assisted Therapy Association of Canada (KATA) is an interdisciplinary, not-for-profit organization that advances ketamine clinical practice by providing high level practice standards through the development of resources, education and policy recommendations. KATA's Outpatient *Use of Ketamine for Mental Health Conditions Practice Standards Recommendations* were developed as a guide to regulators as well as to professionals prescribing and delivering non-intravenous routes of ketamine in community settings.

Drafted in 2021 and submitted to the BC College of Physicians and Surgeons in support of their published Interim Guidance, the Standards contain specific and practical evidence-based recommendations to provide a set standard of safe care for physicians and patients, and to support regulators in the creation of appropriate policies that don't impede access to this treatment.

These recommendations were written collaboratively by an interdisciplinary team after a literature review of 53 key articles, hospital protocols, existing practice guidelines and additional data from outpatient practices and was reviewed by a panel of peers. The practice recommendations will continue to evolve as new research and clinical data emerges and as feedback is received from the ketamine practice community.

Advantages:

- Practical, user-friendly, and well referenced using recent studies and publications.
- Pragmatic and focused on safe, legal patient access.

Limitations:

- More recommended standards of care than actual regulatory standards.
- BC-based rather than national. This doc largely reflects and adds to the BC College Interim Guidance for non-IV administration of ketamine, although it does reflect federal laws/policies re. controlled substances and natural health products.
- Lacks some regulatory context re. how other countries/jurisdictions are regulating KAP.

Relevant Excerpts/Quotes

These practice standards recommendations intend to support safety, quality, and consistency of patient care; they are not meant to replace the professional clinical judgment of physicians, prescribers and other health-care professionals, but rather incorporate current evidence, consensus-based, and appropriate off-label clinical information into a safe, reasonable, and acceptable framework for patient care that promotes the best possible outcomes. (p. 3)

It is important that proper patient screening be conducted to ensure the benefits of prescribing ketamine outweigh the risks, both medically and psychologically. The prescribing physician shall evaluate and assess patients for suitability. Additionally, a psychological/psychiatric assessment is recommended to ensure that ketamine therapy is appropriate for the patient. If the prescriber does not have a longitudinal relationship with the patient, we recommend that patients are screened and assessed by several medical professionals (e.g., general practitioner, psychiatrist, psychologist, specialist, registered nurse, registered therapeutic counsellor, registered clinical counsellor) and that old records are requested and examined. Finally, all patients must have a level of comprehension and capacity to understand the benefits and risks of ketamine as a part of the detailed informed consent process for receiving off-label medications. (p.5)

In the doctor-patient therapeutic relationship, the patient has the right to make decisions about their healthcare including choosing complementary or alternative therapies instead of, or as an adjunct to, conventional medicine. With regards to patient autonomy, our opinion is that adequately informed patients are not required to have failed standard therapies prior to receiving ketamine for mental health conditions. (p.7)

By following these guidelines, prescribers can actively reduce negative outcomes, which will enhance the opportunity for optimal therapeutic results and lasting therapeutic benefits. (p.13)

It is our recommendation that community settings requiring non-commercial preparations of ketamine such as lozenges, rapid-dissolving tablets, nasal spray or others, work with a compounding pharmacy with experience processing ketamine formulations. Compounding pharmacies can use standardised protocols to ensure more consistency and objectivity in the medication preparation process. (p.13)

Summary/Conclusions

While this document is more of a recommended "standards of care" than actual regulations, it was developed by a multitude of practitioners that ultimately recommend a multidisciplinary approach to KAP, which is in keeping with the current evidence to improve patient safety and treatment outcomes. The Standards are fairly comprehensive and informed by the principles of patient autonomy in healthcare decision-making. They feature inclusion/exclusion criteria for treatments, detailed recommendations re. cardiovascular and psychological monitoring during treatments, and side effect and adverse event monitoring and emergency management.

Additionally, pharmacy compounding for non-IV preparations considered and suggested, and the recommendation in the Standards are supported by extensive appendices. However, the Standards would benefit from consideration of how other jurisdictions – particularly U.S. states - are currently regulating KAP, are largely BC-focused, and do not extend to the use or provision of other psychedelic-based therapies.

Notes

"With regards to patient autonomy, our opinion is that adequately informed patients are not required to have failed standard therapies prior to receiving ketamine for mental health conditions." (p.7)

"Includes inclusion/exclusion criteria for treatment consideration." – How clear is the criteria in comparison to SAP criteria? Could it be used to improve SAP considerations?

- From the SAP section – "Applications by practitioners on behalf of patients diagnosed with TRD are subject to multiple requirements which are not initially disclosed in specific detail. For example, for SAP applications for psilocybin, (1) the application must detail the planned drug and concomitant psychotherapy protocols and show that they at least meet the standards established in existing clinical research, (2) must show that the patient has trialed at least multiple antidepressants over several years, (3) must show how CANMAT guidelines are met. These and several other requirements are not stated in any guidance documentation."

Physicians and practitioners provided a guide to regulators with practical evidence-based recommendations. Like the article "Public Health Vision for the Management and Regulation of Psychedelics" (Haden, Emerson, & Tupper, 2016). Both raise the question: how much of SAP is shaped or guided by doctors and researchers?

Name of Act/Proposal/Publication:
Regulations Amending Certain Regulations Relating to Restricted Drugs (Special Access Program): SOR/2021-271 (Government of Canada, 2021)

Sections C.08.010 and C.08.011 of the *Food and Drugs Regulations* (Food and Drugs Act) (Government of Canada, 2022)

Sources:
- https://www.gazette.gc.ca/rp-pr/p2/2022/2022-01-05/html/sor-dors271-eng.html
- https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access.html

Jurisdiction: Canada – Federal/National

Substances Addressed:
Drugs that have not been authorized for sale in Canada.

Primary Characteristics:

	Yes	No	N/A	Comments
Medical	X			
Recreational/ Wellness		X		
Commercial Production/Sales	X			
Personal Production		X		

Background

The Special Access Program (SAP) is a mechanism whereby medical practitioners may request access to drugs not available for sale in Canada for emergency or compassionate use. SAP is intended for use by healthcare professionals who are treating patients with serious or life-threatening conditions, where conventional therapies have failed or are not suitable. The SAP office assesses each application on a case-by-case basis, taking into account the safety and effectiveness of the product, as well as the patient's medical condition and the potential benefits and risks of the treatment (Health Canada, 15 February 2023). Various facets of this application process have been criticized, as is explored here.

In addition to approving restricted or unscheduled drugs, the SAP program can (as of January 5th, 2022) also approve psychedelics such as psilocybin and MDMA. As of March 2023, "the SAP office has received 97 requests for psilocybin to provide access to 113 patients and has authorized 68 requests for 83 patients. Of the remaining requests, 23 are currently under review, and 7 have been either withdrawn or cancelled" (Benson, 2023).

PsyCan, in concert with EntheoTech BioScience, conducted numerous key informant interviews (KII) and surveys with physicians, clinics, manufacturers and other Canadian industry members to determine the Canadian industry's experience with the SAP program, and we draw from that data in our assessment.

Outstanding Issues with the Special Access Program

While the federal government deserves much credit for creating a progressive regulatory environment enabling Canada to take the Global lead in the production and sale of psychedelic substances for research purposes, unfortunately access by Canadian patients-in-need remains inconsistent and unpredictable. While moving patient access requests from subsection 56(1) exemption applications to the SAP has provided some critically and chronically ill Canadians with a means to legally access psychedelic-assisted therapies, far too many patients that could benefit from these treatments still find themselves without legal access, forcing them to suffer unnecessarily, or to seek illicit sources and underground practitioners to address their medical conditions.

As Health Canada readily admits, the SAP system was never designed with access to psychedelics in mind. As a result, Health Canada has discouraged psychedelic advocacy groups and companies in the psychedelic space from promoting this program, despite being the only legal pathway to psychedelic therapies in Canada outside of clinical trials. As our analysis will illustrate, there are many ongoing issues complicating access to psychedelics via SAP, and therefore out of concern and consideration for patients who might benefit from these treatments for end-of-life care and other intractable health conditions, we urge the federal government to look beyond the SAP and towards a more effective, transparent, and predictable access strategy for critically and chronically ill Canadians.

Application Process

According to industry reports, the approval process for the first SAP application for a practitioner typically takes from 3 weeks to 3 months.[38] The duration of the process rests mostly on the ability of the practitioner to promptly respond to faxes sent by the SAP office requesting further information. The first application to the SAP office by the practitioner or manufacturer appears to be an evaluative period, and this initial application seems to be subject to higher scrutiny than subsequent applications and, occasionally, subject to more demanding requirements. However, subsequent applications tend to be much smoother (faster and with less back-and-forth communication required), which we presume is the result of previous vetting of applicants by Health Canada.[5-6] Additionally, the applicant now has experience and better understands how to submit successful applications, what information is required, etc.

End-of-life distress

The industry experience of SAP applications for patients experiencing end-of-life distress has been generally prompt, with most applicants seeing approved requests in less than three business days.[39]

Treatment Resistant Depression (TRD) Requirements

Applications by practitioners on behalf of patients diagnosed with TRD are subject to multiple requirements which are not initially disclosed in specific detail.[6] For example, for SAP applications for psilocybin, the application must (1) detail the planned drug and concomitant psychotherapy protocols and show that they at least meet the standards established in existing clinical research, (2) indicate and detail that the patient has trialed and found inadequate therapeutic benefit from numerous antidepressants, and (3) show how CANMAT guidelines are met. These and several other requirements are not stated in official guidance documentation (Health Canada, 2022).[6]

Post-Diagnosis Validation, Access, and Fairness

SAP applicants have mentioned specific examples of deliberation or judgment by the SAP office which questioned the validity of the accompanying physician diagnoses.[5] For example, by convention, treatment-resistant depression (TRD) typically refers to inadequate response to a reasonable trial of antidepressant, adjunctive pharmaceuticals or psychotherapy. However, physicians which have applied to SAP

[38] EntheoTech BioScience. "Clinics' and Manufacturers' Experience with the Canadian SAP Program: Conducted Interviews." Conducted on December 28, 2022.

[39] PsyCan "Psychedelics Canada Government Relations Questionnaire." Survey of 10 clinics and manufacturers, conducted on February 27, 2023.

on behalf of patients diagnosed with TRD have been required by the SAP office to show that the patient has actually trialed and failed (in some cases, as many as six) antidepressants, despite intolerable side effects.[6] Moreover, patients seem to be unable to exercise reasonable autonomy in deciding what medical treatment they chose to pursue. For example, here is a requirement by the SAP office that patients must have tried Electroconvulsive Therapy and Transcranial Magnetic Stimulation to qualify, despite individual patient and practitioner treatment preferences, potentially prohibitive expenses, and a lack of accessibility to some of these therapies in certain jurisdictions.[7] There seems to be an inconsistent understanding of evidence-based medicine and common clinical practice by adjudicators in the SAP office, raising concerns from applicants (both physicians and patients) about the qualifications of the persons making these important medical decisions.[5-7]

Continuity

Some SAP applicants have reported inconsistencies in who they have been assigned as an SAP contact during the application process, leading to conflicting understandings of required information and instructions.[5] It has been suggested that applicants simply be paired with a single designated case worker.

Manufacturer vs. Clinic Application

Some clinics have reported less clarity in the SAP application process than manufacturers. For example, manufacturers have reported being typically equipped with a set of 36 questions to submit as part of their SAP application, while clinic-based practitioners have reported needing to communicate on many occasions over multiple weeks to ascertain the information required from them for a successful application, often only via fax[6]. Encrypted email has been suggested as an alternative or accompanying communication method to assist practitioners in responding to inquiries by the SAP office for additional information, as faxing communication is administratively demanding for medical clinics which routinely receive hundreds of faxes a week.

Clinical Trials

SAP applicants, particularly concerning applications for patients diagnosed with treatment-resistant depression, are strongly encouraged by SAP to consider referring the patient to a clinical trial instead of continuing with the SAP application process, despite the scarcity of recruiting clinical trials, and often very specific

inclusion/exclusion criteria.[40] As such, it appears there may be a significantly different understandings between patients, physicians and industry members and the SAP office regarding the availability of clinical trials examining psychedelic-assisted therapies in Canada. According to reports, the SAP office holds that there are more available clinical trials, whereas clinics indicate that only a limited number of those trials are actually accessible to patients, and then only in very specific geographic areas, and for very limited indications.

Additionally, clinical trials are not an especially feasible alternative for access. There is an economic limit to private funding of clinical trials, which can cost more than $20,000 per participant, and unfortunately public funding for Canadian clinical trials is underwhelming and has not resulted in a significant increase in human studies.

Current Legal Challenges to Section 56 and SAP

TheraPsil, a non-profit offering training for health-care practitioners and aiding patients in obtaining psilocybin has claimed that it was receiving approvals each time they submitted under subsection 56(1) under former Health Minister Patty Hajdu, but that they have received pushback since Jean-Yves Duclos took over the health portfolio, stating there are clients waiting 300 to 400 days for access and that the SAP is even more restrictive.[41] In July 2022, TheraPsil filed a judicial review on behalf of more than 100 psychiatrists, psychologists, doctors, therapists, and other professionals across Canada who had been denied Section 56 exemptions—including 18 who had been approved the year before—to use psilocybin mushrooms while participating in a training program organized by TheraPsil.

In an internal Health Canada email dated Nov. 3, 2020, detailing consultations with experts regarding the original 18 exemption requests, those experts “strongly indicated that personal experience with psilocybin is required in order to safely guide patients through treatment sessions.”[42] Alongside the judicial reviews, TheraPsil is also supporting a Charter challenge filed by seven patients and one health-care practitioner that argues current modes of accessing psilocybin are insufficient and a violation of Section 7 of the Canadian Charter of Rights and Freedoms, which guarantees the right to life, liberty, and security of the person. A similar challenge was argued in R. v. Parker, the landmark court case that led to Canada’s first medical cannabis laws.

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[40] PsyCan. "Meeting with Health Canada SAP Program Representatives." Zoom meeting conducted on November 22, 2023. Attended by PsyCan board members.

[41] (Benson, 2023)

[42] (Benson, 2023)

Summary/Conclusions

Via subsection 56(1) exemptions and the subsequent SAP, the Government of Canada has provided several paths to legally access psychedelic assisted therapies over the last few years. Unfortunately, evidence suggests that the challenges of administering a centralized federal access program that only considers applications on a case-by-case basis have resulted in unnecessary disappointments and delays for applicants, and uneven, unpredictable outcomes for critically and chronically ill Canadians. Considering the numerous legal challenges launched by patients and their providers, and in response to strong public support to regulate safe access to psychedelic-assisted therapies, we strongly suggest that it's time for Health Canada to look beyond SAP, and to consider other evidence-based policy alternatives that could better serve the needs of Canadian patients, while also safeguarding the general public.

Annex 2: Published Scientific Articles of Psychedelic Research

Argento, Elena, Rielle Capler, Gerald Thomas, Philippe Lucas, & Kenneth W. Tupper. (2019). Exploring ayahuasca-assisted therapy for addiction: A qualitative analysis of preliminary findings among an Indigenous community in Canada. *Drug and Alcohol Review*, *38*(7), 781–789. https://doi.org/10.1111/dar.12985

Bogenschutz, M. P., Forcehimes, A. A., Pommy, J. A., Wilcox, C. E., Barbosa, P. C., & Strassman, R. J. (2015). Psilocybin-assisted treatment for alcohol dependence: a proof-of-concept study. *Journal of Psychopharmacology, 29*(3), 289-299.

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Carhart-Harris, R. L., Bolstridge, M., Rucker, J., Day, C. M. J., Erritzoe, D., Kaelen, M., ... & Nutt, D. J. (2018). Psilocybin with psychological support for treatment-resistant depression: Six-month follow-up. *Psychopharmacology, 235*(2), 399-408.

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Hadar, A., David, J., Shalit, N., Roseman, L., Gross, R., Sessa, B., & Lev-Ran, S. (2023). The Psychedelic Renaissance in Clinical Research: A Bibliometric Analysis of Three Decades of Human Studies with Psychedelics. *Journal of Psychoactive Drugs, 55(1)*, 1–10.

Holze, F., Schmidt, A. F., Groth, N., & Riedel, O. (2022). Lysergic acid diethylamide-assisted therapy in patients with anxiety with and without a life-threatening illness: A randomized, double-blind, placebo-controlled phase II study. *Biological Psychiatry, 91(6)*, 503-511.

Johnson, M. W., Garcia-Romeu, A., Cosimano, M. P., & Griffiths, R. R. (2017). Long-term follow-up of psilocybin-facilitated smoking cessation. The American Journal of *Drug and Alcohol Abuse, 43*(1), 55-60. https://doi.org/10.3109/00952990.2016.1170135

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Migraine-Suppressing Effects of Psilocybin. *Neurotherapeutics: The Journal of the American Society for Experimental NeuroTherapeutics*, *18*(1), 534–543. https://doi.org/10.1007/s13311-020-00962-y

Vorobyeva, N., & Kozlova, A. A. (2022). Three Naturally-Occurring Psychedelics and Their Significance in the Treatment of Mental Health Disorders. *Frontiers in Pharmacology*, *13*, 927984. https://doi.org/10.3389/fphar.2022.927984

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Annex 3: Legislative and Regulatory Developments in Canadian Provinces and U.S. States

State/ Province	Bill/ Regulation	Notes
Alberta	Change in Regulation	Patients in Alberta will now be able to legally consider adding psychedelic-assisted therapy to the list of treatment options available for mental illnesses.[43]
Arizona	Legislation Introduced	House Bill 2486 would appropriate $30 million from the state's budget for psilocybin research grants and establish a psilocybin research advisory council.[44] [45]
British Columbia	Change in Regulation	Exemption trial – decriminalization of certain illegal drugs including MDMA. Not specific to psychedelics.[46]
California	Legislation Introduced	SB-58 passed Senate on March 21 and amended in Assembly on June 20. It would legalize the "possession, preparation, obtaining, transfer, as specified, or transportation of" specific amounts of psilocybin, psilocyn, DMT, ibogaine and mescaline for personal or facilitated use. A second, separate bill was introduced in February to legalize psychedelics-assisted therapy specifically for military veterans.[47] [48]
Colorado	Legislation Passed	In a historic vote, Colorado passed Proposition 122, becoming the second state in the U.S. to legalize psychedelics and treatment centers.[49]
Connecticut	Legislation Passed	The budget measure now signed by the governor requires the state Department of Mental Health and Addiction Services to launch a "psychedelic-assisted therapy pilot program to provide qualified patients with

[43] https://news.usask.ca/articles/research/2023/research-albertas-new-policy-on-psychedelic-drug-treatment-for-mental-illness-will-canada-lead-the-psychedelic-renaissance.php
[44] https://www.azleg.gov/legtext/56leg/1R/bills/HB2486P.htm
[45] https://psychedelicalpha.com/data/psychedelic-laws
[46] https://www2.gov.bc.ca/gov/content/overdose/decriminalization
[47] https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=202320240SB58
[48] https://psychedelicspotlight.com/california-takes-major-step-towards-passing-psychedelics-legalization-bill/
[49] https://www.sos.state.co.us/pubs/elections/Initiatives/titleBoard/filings/2021-2022/58Final.pdf

State/ Province	Bill/ Regulation	Notes
		the funding" to receive MDMA or psilocybin therapy as part of FDA's expanded access program.[50] [51]
Florida	Legislation Failed	"The Florida Psilocybin Mental Health Care Act" (HB549) aimed to legalize and regulate the use of psilocybin for mental health treatment. That bill died on April 30, 2021.[52]
Georgia	Legislation Introduced	A bipartisan coalition of Georgia lawmakers filed a resolution that calls for the formation of a House Study Committee to investigate alternative treatments and resources for Veterans with PTSD and for other purposes (such as psychedelics).[53] [54]
Hawaii	Legislation Introduced	The Hawaii Senate has approved a bill to legalize marijuana, and two psychedelics research measures, ahead of a key legislative deadline. The House also separately passed a companion to one of those psychedelics proposals.[55]
Illinois	Legislation Introduced	Creates the Compassionate Use and Research of Entheogens (CURE) Act. Establishes the Illinois Psilocybin Advisory Board within the Department of Public Health for the purpose of advising and making recommendations to the Department regarding the provision of psilocybin and psilocybin services. Provides that the Department shall begin receiving applications for the licensing of persons to manufacture or test psilocybin products, operate service centers, or facilitate psilocybin services.[56]

[50] https://www.cga.ct.gov/asp/cgabillstatus/cgabillstatus.asp?selBillType=Bill&bill_num=HB05396&which_year=2022

[51] https://www.marijuanamoment.net/connecticut-governor-signs-bill-creating-psychedelic-treatment-program/

[52] https://www.flsenate.gov/Session/Bill/2021/549

[53] https://www.legis.ga.gov/legislation/62532

[54] https://www.marijuanamoment.net/georgia-lawmakers-talk-next-steps-for-psychedelics-research-for-military-veterans-at-committee-hearing/

[55] https://www.marijuanamoment.net/hawaii-senate-approves-marijuana-legalization-and-psychedelic-research-bills/

[56] https://www.ilga.gov/legislation/BillStatus.asp?DocNum=1&GAID=17&DocTypeID=HB&SessionID=112&GA=103

State/ Province	Bill/ Regulation	Notes
Iowa	Legislation Introduced	This bill removes psilocybin and psilocyn from the list of substances classified as schedule I controlled substances under Iowa's uniform controlled substances Act.[57]
Kansas	Legislation Failed	On January 10, 2022, HB 2465 was introduced which aimed at reducing the penalty for individuals cultivating or possessing small quantities of certain controlled substances.[58]
Kentucky	Legislation Introduced	"A Kentucky administrative commission announced... that it is preparing to potentially distribute at least $42 million in funding for research into the potential of the psychedelic ibogaine for the treatment of opioid addiction."[59]
Maine	Legislation Failed	The Maine Senate approved a bill to create a medical psilocybin program in the state, but the House of Representatives refused to go along.[60]
Maryland	Legislation Passed	Establishing the Post-Traumatic Stress Disorder and Traumatic Brain Injury Alternative Therapies Fund to support the study of the effectiveness of and improving access to alternative therapies for PTSD and traumatic brain injuries in veterans. The department would need to first submit a report to the governor and legislation with "initial findings and recommendations" by December 1, 2022. Two years later, there would be another deadline for findings and recommendations that are based on studies that were specifically funded through the PTSD fund. The recommendations would focus on "budgetary, legislative, or regulatory changes to expand access to alternative therapies for veterans with post–traumatic stress disorder and traumatic brain injuries."[61]

[57] https://www.legis.iowa.gov/legislation/BillBook?ga=90&ba=HF240

[58] http://www.kslegislature.org/li_2022/b2021_22/measures/hb2465/

[59]https://www.marijuanamoment.net/gop-kentucky-attorney-general-launches-psychedelics-research-effort-supported-by-42-million-in-opioid-settlement-funds/

[60] https://legislature.maine.gov/legis/bills/display_ps.asp?LD=1582&snum=130

[61] https://mgaleg.maryland.gov/mgawebsite/Legislation/Details/SB0709?ys=2022rs

State/ Province	Bill/ Regulation	Notes
Massachusetts	Legislation Introduced	Eight bills have been filed in Mass. related to psychedelic legislation. Two corresponding bills filed in the State House recently — SD.949 in the Senate and HD.1450 in the House — seek to end arrests for adults who possess, consume, grow, give away, or transport less than 2 grams of certain entheogenic plants and fungi. The statewide push comes after some Massachusetts communities, including Cambridge, Somerville, and Northampton, passed resolutions decriminalizing the plants. Additionally, a public hearing was held on June 13, 2023 to consider testimonies related to 3 pieces of psychedelic-related bills.[62] [63] [64]
Michigan	Legislation Introduced	Personal use and possession of entheogenic plants has been made the lowest law enforcement priority in the city of Ann Arbor, Detroit, Hazel Park and in Washtenaw County. Legislation has also been introduced to decriminalize Schedule 1 and 2 substances and legalize "Natural Plants and Mushrooms" statewide.[65]
Minnesota	Legislation Introduced	Introduced legislation to establish a task force to study and advise on the potential legalization of substances like psilocybin, MDMA and ibogaine.[66]
Missouri	Legislation Introduced	Missouri lawmakers approved a GOP-led bill in committee to promote research into the therapeutic potential of certain psychedelics such as psilocybin, MDMA and ketamine.[67]
Montana	Legislation Failed	Montana lawmakers have defeated a bill that would have legalized psilocybin therapy for adults with certain medical conditions. However, there's talk about moving

[62] https://psychedelicspotlight.com/hearing-scheduled-in-massachusetts-for-bills-to-legalize-certain-psychedelic-plant-medicines/
[63] https://psychedelicspotlight.com/massachusetts-files-a-record-eight-bills-on-psychedelic-legalization/
[64] https://www.boston.com/news/politics/2023/01/26/massachusetts-psilocybin-mushrooms-psychedelics-decriminalize-legislation/
[65] https://psychedelicalpha.com/data/psychedelic-laws
[66] https://www.revisor.mn.gov/bills/bill.php?b=Senate&f=SF1954&ssn=0&y=2023
[67] https://www.house.mo.gov/Bill.aspx?bill=HB1154&year=2023&code=R

State/ Province	Bill/ Regulation	Notes
		a more limited measure to study possible psychedelics reforms.[68] [69]
Nevada	Legislation Passed	This bill was approved by the Governor on June 12, 2023 as Chapter 377 and "requires the Department of Health and Human Services to establish the Psychedelic Medicines Working Group to study certain issues relating to the therapeutic use of entheogens during the 2023-2024 interim."[70]
New Hampshire	Legislation Failed	A Republican New Hampshire lawmaker filed a bill to legalize the possession and use of psychedelics like psilocybin and LSD by adults 21 and older.[71] [72]
New Jersey	Legislation Introduced	A bill passed in February 2021 reducing the penalty for possession of psilocybin for personal use. On June 23, 2022, Bill S2934 was introduced (the "Psilocybin Behavioral Health Access and Services Act") which would authorize production and use of psilocybin to promote health and wellness; decriminalizes, and expunges past offenses involving, psilocybin production, possession, use, and distribution.[73]
New Mexico	Legislation Introduced	New Mexico lawmakers advanced legislation to create a state body that would study the possibility of launching a psilocybin therapy program for patients with certain mental health conditions. The House Health and Human Services approved the bill in a unanimous vote. The measure now heads to the House Appropriations & Finance Committee.[74]

[68] https://laws.leg.mt.gov/legprd/LAW0210W$BSIV.ActionQuery?P_BILL_NO1=955&P_BLTP_BILL_TYP_CD=HB&Z_ACTION=Find&P_SESS=20231

[69] https://psychedelicspotlight.com/the-biggest-psychedelic-legislation-news-stories-this-week-april-7/

[70] https://www.leg.state.nv.us/App/NELIS/REL/82nd2023/Bill/10067/Overview

[71] https://www.forbes.com/sites/ajherrington/2023/01/17/new-hampshire-lawmaker-files-psychedelics-legalization-bill/?sh=26b0613636fe

[72] https://gencourt.state.nh.us/bill_status/legacy/bs2016/bill_status.aspx?lsr=238&sy=2023&sortoption=&txtsessionyear=2023&txtbillnumber=HB328

[73] https://www.njleg.state.nj.us/bill-search/2022/S2934

[74] https://www.nmlegis.gov/Legislation/Legislation?chamber=H&legtype=B&legno=393&year=23

State/ Province	Bill/ Regulation	Notes
New York	Legislation Introduced	Legalizes adult possession and use of certain natural plant or fungus-based hallucinogens; grants certain protections for individuals lawfully using such hallucinogens; removes such hallucinogens from the list of Schedule I controlled substances; makes related provisions.[75] [76]
Ohio	Legislation Failed	SB 3 would have reformed drug sentencing laws by reducing penalties from felonies to misdemeanors for certain drug possession convictions and by diverting certain offenders to treatment instead of prison. The bill was never brought up for a final floor vote.[77]
Oklahoma	Legislation Introduced	The Oklahoma House of Representatives approved a bill to promote research into the therapeutic potential of psilocybin while providing legal protections against prosecution for people with eligible conditions who possess the psychedelic. It was referred to the Health and Human Services Committee on March 29, 2023, before heading to the Appropriations Committee.[78]
Oregon	Legislation Passed	The Oregon Psilocybin Services Section implements Ballot Measure 109 (now codified as ORS 475A), which was passed in November 2020 and directs the Oregon Health Authority to license and regulate the manufacturing, transportation, delivery, sale, and purchase of psilocybin products and the provision of psilocybin services.[79] [80]
Pennsylvania	Legislation Failed	An Act providing for research and clinical studies of psilocybin and psilocybin-assisted therapy.[81]

[75] https://assembly.state.ny.us/leg/?default_fld=&leg_video=&bn=A00114&term=2023&Summary=Y&Actions=Y&Memo=Y&Text=Y

[76] https://www.marijuanamoment.net/new-york-lawmakers-file-psychedelics-legalization-bill-for-2023/

[77] https://www.legislature.ohio.gov/legislation/legislation-summary?id=GA133-SB-3

[78] http://www.oklegislature.gov/BillInfo.aspx?Bill=hb2107&Session=2300

[79] https://www.oregonlegislature.gov/bills_laws/ors/ors475A.html

[80] https://www.oregon.gov/oha/ph/preventionwellness/pages/oregon-psilocybin-services.aspx

[81] https://www.legis.state.pa.us/cfdocs/billinfo/BillInfo.cfm?syear=2021&sind=0&body=H&type=B&bn=2421

State/ Province	Bill/ Regulation	Notes
Rhode Island	Legislation Introduced	Two Rhode Island lawmakers are pushing to decriminalize the use of "magic mushrooms" statewide. The bill hinges upon whether the Federal Drug Administration (FDA) approves psilocybin as a treatment for chronic mental health disorders.[82]
Texas	Legislation Introduced	Texas legislators introduced three new bills to advance psychedelic policy reform. All 3 were referred to Public Health on March 21 after the first reading.[83]
Utah	Legislation Passed	The governor of Utah signed a bill (March 2022) to create a task force to study and make recommendations on the therapeutic potential of psychedelic drugs and possible regulations for their lawful use. On February 10, 2023, SB 200 was introduced to Senate which would allow for the medical production and use of psilocybin.[84]
Vermont	Legislation Introduced	Four major drug reform bills have been introduced in the Vermont State Legislature to decriminalize simple possession of all drugs, expand harm reduction services, remove criminal penalties for using and selling psilocybin and decriminalize certain psychedelic plants and fungi.[85]
Virginia	Legislation Failed	Establishes the Virginia Psilocybin Advisory Board to develop a long-term strategic plan for establishing therapeutic access to psilocybin services and monitor and study federal laws, regulations, and policies regarding psilocybin. The bill reclassifies psilocybin under the Drug Control Act from a Schedule I to a Schedule III controlled substance.[86]
Washington State	Legislation Passed	2nd substitute bill passed both House and Senate on April 14, 2023. Nine out of fourteen sections were vetoed by the governor and the remaining approved bill will be

[82] https://www.wpri.com/news/politics/ri-lawmakers-seek-to-legalize-magic-mushrooms/
[83] https://psychedelicspotlight.com/texas-shows-commitment-to-psychedelic-policy-reform-as-lawmakers-file-3-new-bills/
[84] https://le.utah.gov/~2023/bills/static/SB0200.html
[85] https://psychedelicspotlight.com/vermont-legislators-file-4-bills-that-would-legalize-psychedelics-and-decriminalize-all-drugs/
[86] https://lis.virginia.gov/cgi-bin/legp604.exe?231+sum+SB932

State/ Province	Bill/ Regulation	Notes
		enacted July 2023, which will implement a psilocybin therapy pilot program.[87]
West Virginia	Legislation Failed	On March 12, 2021, HB 3113 proposed removing certain substances from schedule I of the Uniform Controlled Substances Act, including psilocybin. The bill made it as far as Health and Human Resources before the Legislature adjourned without assigning a future date for a meeting or hearing.[88]

[87] https://app.leg.wa.gov/billsummary?BillNumber=5263&Year=2023
[88] https://psychedelicalpha.com/data/psychedelic-laws

Annex 4: Source Review: Additional Context

Australia's Amendment to the Poisons Standard

Relevant Excerpts/Quotes

Notice of final decisions to amend (or not amend) the current Poisons Standard in relation to psilocybine and MDMA (Therapeutic Goods Administration, 2023)

Materials considered (p. 6)

In making these final decisions, the Delegate considered the following material: In relation to psilocybine

- The application to amend the current Poisons Standard with respect to psilocybine (the psilocybine application);
- The 6,650 public submissions on the current psilocybine proposal, including 2,332 with a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice concerning the Psilocybine Application received from the 38th meeting of the Advisory Committee on Medicines Scheduling (the Committee);
- The Delegate's final decision to not amend the Poisons Standard in relation to psilocybine on 15 December 2021 and the materials considered in making that decision;
- The Delegate's interim decision to not amend the Poisons Standard in relation to the psilocybine application on 21 October 2022 and the materials considered in making that decision;
- The 3,442 public submissions on the current psilocybine proposal, including 1,758 with a written component, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations (the psilocybine interim submissions); and
- The published study titled Single-Dose Psilocybin for a Treatment-Resistant Episode of Major Depression, published in the New England Journal of Medicine on 3 November 2022.

In relation to MDMA (p. 7)

- The application to amend the current Poisons Standard with respect to MDMA (the MDMA application);
- The 6,505 public submissions on the current MDMA proposal, including 2,068 with a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;

- The advice concerning the MDMA Application received from the 38th meeting of the Committee;
- The Delegate's final decision to not amend the Poisons Standard in relation to MDMA on 15 December 2021 and the materials considered in making those decisions;
- The Delegate's interim decision to not amend the Poisons Standard in relation to the MDMA application on 21 October 2022 and the materials considered in making that decision; and
- The 3,403 public submissions on the current MDMA proposal, including 1,658 with a written component, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations (the MDMA interim submissions).

In relation to both Substances

- The Independent expert panel report titled "An evaluation of the therapeutic value, benefits and risks of methylenedioxymethamphetamine (MDMA) and psilocybin for the treatment of mental, behavioural or developmental disorders" (the Expert Report);
- The Royal Australian and New Zealand College of Psychiatrists' (RANZCP) clinical memorandum on the therapeutic use of psychedelic substances published in July 2022;
- A presentation to the Therapeutic Goods Administration (TGA) by Professor David Nutt on 21 November 2022;
- The international regulatory status of the Substances and access pathways;
- Subsection 52E(1) of the Therapeutic Goods Act 1989 (Cth) (the Act), in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; and (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health.

Reasons for the final decisions

The AP scheme allows authorised medical practitioners to supply therapeutic goods that are not included in the Australian Register of Therapeutic Goods (ARTG) to specified patients under their immediate care with a particular medical condition subject to certain conditions. In particular, approval must be granted by both a Human Research Ethics Committee (HREC) that is registered with the National Health and Medical Research Council (NHMRC) and, only once that approval has been granted, a senior medical officer at the TGA in their capacity as a delegate of the Secretary of the Department of Health and Aged Care. The TGA delegate will also expect that psychiatrists will have considered all clinically appropriate treatment

options that are included in the ARTG before applying to access a psilocybine- or MDMA-containing product for their patient under the AP scheme. (p. 8)

The AP scheme is an established, proven and robust pathway for permitting therapeutic use of unapproved medicines, with sufficient oversight and monitoring, to ensure safe use of the Substances and address many of the concerns articulated in the interim decisions. While the Special Access Scheme (SAS) permits access to the Substances on a patient-by-patient basis, the standard pathway of approval for the AP scheme entails a rigorous application process for a qualified medical professional through both the TGA and an HREC. Under the AP approval process, I am confident that the TGA decision maker and HREC will ensure they are satisfied of matters including the applicant prescriber's clinical justification for their treatment regimen, governance over the treatment process, and the use of suitable measures to protect patients, such as records of informed consent. Consistent with the terms of the AP scheme, authorised prescribers will be required to submit regular reports on the numbers of patients treated and any associated adverse events. (p. 8)

The new Schedule 8 entries limit the therapeutic use of the Substances to TRD for psilocybine, and PTSD for MDMA. This provides for narrower access than originally proposed by the applicant, but in view of paragraphs 52E(1)(a) and (b) of the Act, is aligned with the current body of clinical evidence supporting the therapeutic use of the Substances that pertains primarily to these mental health conditions. The use of psilocybine and MDMA to treat all indications other than TRD and PTSD, respectively, will remain captured by the existing Schedule 9 entries for the Substances, limiting their use to medical and scientific research, including clinical trials. I consider that the body of evidence demonstrating the efficacy of the Substances for the treatment of other indications is insufficient at this time to justify increased access for therapeutic use. (p. 9)

I have considered the written public submissions received in response to the interim decisions on the Substances. Many of these were opposed to the interim decisions to not amend the Poisons Standard in relation to psilocybine and MDMA and followed a similar pattern to the premeeting submissions. The majority of the submissions relating to the Substances were brief, related to personal circumstances, and did not attempt to address the issues raised in the interim decisions, particularly the lack of established therapeutic value for the Substances for the treatment of mental health conditions. However, I am of the view that the number of such submissions is a reasonable indicator of the scope and gravity of the issues for individual and public health addressed in the application. In consideration of paragraph 52E(1)(a) of the Act, the submissions confirm the need for greater access to alternative treatments for patients with persistent mental health conditions where currently available treatments have not been effective. In balancing this clinical need against the current

level of evidence of safety and efficacy, I consider that it is justified to increase access to the Substances under the controls explained above. (p. 10)

Contrary to the claims made in a significant number of submissions, I note that the therapeutic use of the Substances remains largely prohibited outside of clinical trials in many countries, including Canada, New Zealand, the United Kingdom and most of the European Union. However, I recognise that the status of the Substances is under review in many of these countries, such as the USA where the Food and Drugs Administration (FDA) has designated MDMA as a "breakthrough therapy" for TRD. While it is important to note that this status is designed to expedite the development and review of particular medicines and is not an endorsement or approval for the therapeutic use of MDMA outside of a clinical trial environment, with reference to paragraph 52E(1)(f) of the Act, it is indicative of the FDA's standpoint on the potential of MDMA for the treatment of TRD. (p. 10)

I note with interest that at the time of writing this decision there are three Phase II clinical trials in Australia that are recruiting patients to investigate the use of psilocybine in the treatment of depression and/or anxiety disorders, and one mixed Phase I/II trial investigating the use of MDMA-assisted psychotherapy for the treatment of PTSD. These trials are in addition to the second MAPS-sponsored Phase III trial of MDMA-assisted therapy for PTSD, which was recently completed and is expected to have results publicly available later in 2023, and the Swinburne University trial investigating psilocybine for the treatment of TRD, which will commence in 2023. The evidence arising from current and future trials investigating the therapeutic benefits of the Substances will continue to be monitored and considered in the context of any future applications to further amend the scheduling for the Substances. (pp. 10-11)

Oregon Psilocybin Services Act

Summary

Manufacturers, laboratory testing sites, service centers and facilitator applications must include a social equity plan including objective performance measures for the implementation of diversity, equity, justice, and inclusion principles of the licensee's internal practices and policies. As well, there are strict residency requirements. Manufacturer and Service Center licences both regularly cost $10,000 USD and Facilitator licences cost $2,000.

The service center must have a lawfully proscribed number of licensed facilitators present during any sessions, based on a ratio of facilitators clients that is set based on the amount of psilocybin being ingested by the client (i.e., higher amounts of

psilocybin require a lower ratio of licensed facilitator to clients). A facilitator must complete a preparation session with every client who will participate in an administration session at least twenty-four hours but no more than 90 days prior to the commencement of the client's first administration session with the facilitator and must attempt to contact every client within 72 hours of the conclusion of the administration session to offer the client information on integration sessions and other services, including but not limited to peer support groups and community resources, in support of a client's ongoing integration needs.

A manufacturer, laboratory, or service centre cannot be co-located with a healthcare facility, cannabis outlet, liquor store, residential area, B&B or restaurant. Manufacturers that are allowed to produce "edibles" are further prohibited with respect to production at food outlets and handlers of food, or edible psilocybin products must also be licensed by the Oregon Department of Agriculture. This opens the possibility for service centres that sell microdose products with a small facilitator to client ratio, such as having 1 facilitator present for an hour in a service area with 16 clients who have all consumed a microdose product (<5 mg).

Manufacturer-specific policies

- The manufacturer may only possess max 200 grams of psilocybin analyte and may only manufacture *Psilocybe cubensis* products on the licensed premises.
- The manufacturer may sell a maximum of 25 mg of psilocybin per client package.
- The packaging must not display any misleading or untruthful content and must not be attractive to minors. Health claims about psilocybin benefits can be made if it is supported by scientific evidence.
- The manufacturer, whether as an individual or legal entity, can not have a financial interest in another manufacturer licence.

Service centre-specific policies

- An applicant of a service centre, whether an individual or legal entity, will be denied a licence if they have a financial interest in 5 or more service centres. The service centre can possess a maximum of 100 grams of psilocybin, with a request protocol to exceed that limit if needed. Microdose packages will be allowed.
- A service centre can operate between 6:00 to 11:59. Psilocybin must be administered early enough to ensure closure at 11:59 pm.
- Clients must have the ability to sit/recline in a climate-controlled and adequately lit environment. Clients may leave the client administration briefly but must be accompanied by a facilitator, with reasonable effort made to

minimize client contact with non-service centre representatives, such as other clients or vendors.

Group administration and dosing rules

The facilitator to client ratio for group administration depends on the amount of psilocybin consumed, ranging from one facilitator to sixteen clients (5mg) to one-to-one (40mg+). Group sessions must provide ample space so that clients are not in close contact. No touch is allowed even with consent, unless touch is “supportive” as defined and with prior written consent.

Clients can try up to 50 mg psilocybin. For doses of 5mg or less, an administration session must be at least 1 hour in duration and greater than 35mg must be a minimum of 6 hours.

Every client prior to consuming a psilocybin product must undergo a preparatory session one to ninety days before the dosing day. It is up to the facilitator to note any changes to the client’s application if subsequent doses are consumed in the following 12 months and no additional prep sessions are required. The client must give written consent for all personal and group services. Subsequent integration sessions are optional and “non-directive”, meaning the facilitator cannot interpret any behaviour or give therapeutic advice.

The Oregon Client Bill of Rights helps protect clients from physical, sexual, psychological, and financial abuse and ensures they are adequately informed about the benefits and risks of psilocybin use. Clients have a right to privacy and confidentiality and can request a private space with supportive facilitation.

Facilitator policies & OHA-approved curriculum

Only facilitators who have passed OHA-approved training and exams can be licensed to offer psilocybin services, such as administration of psilocybin, preparation or integration. Persons who hold a professional licence in another area, such as a medical doctor or psychotherapist, must not exercise the privileges of that licence while providing psilocybin services to a client.

An OHA-approved curriculum will be a program that provides historical and current views of plant medicines drawing on wisdom traditions, including shamanic and Indigenous traditions, along with other ethical topics such as cultural appropriation. It will focus on how psilocybin services can address the inequities and stigma suffered by those of the BIPOC communities and others due to geography or experience that have not had access to meaningful behavioural health and wellness care.

Students must be trained to assess the client application form, ensure informed consent, provide safety planning, set appropriate boundaries, as well as understand the scope of their practice and when a client should be referred to specialized treatment service.

Programming must include key areas of research on depression, TRD, substance use concerns, repressed, somatic and intergenerational trauma, palliative and existential distress, anxiety, well-being, pro-sociality, creativity, eco-mindedness, openness, and spirituality. Facilitators must be prepared for how (somatic) trauma can present itself in a psychedelic trip and what to do when this happens to minimize risk of re-traumatization and support trauma resolution. Students will be trained to serve as an empathic presence using a non-directive facilitation approach.

In addition, programming must involve study of the theories of the mechanisms of actions of psilocybin including neuroscience and relevant fields in pharmacology. Facilitators must be competent in different dosing strategies, as well as experiential/physiological differences related to different doses, delivery mechanisms, and the use of secondary doses.

Colorado Natural Medicine Health Act

Relevant Excerpts/Quotes

Article 170 – Natural Medicine Health Act of 2022 (State of Colorado, 2022)

"*12-170-104. Regulated natural medicine access program.* (1) The regulated natural medicine access program is established and the department shall regulate the manufacture, cultivation, testing, storage, transfer, transport, delivery, sale, and purchase of natural medicines by and between healing centers and other permitted entities and the provision of natural medicine services to participants.

(2) Not later than January 1, 2024, the department shall adopt rules to establish the qualifications, education, and training requirements that facilitators must meet prior to providing natural medicine services, and to approve any required training programs.

(3) Not later than September 30, 2024, the department shall adopt rules necessary to implement the regulated natural medicine access program and shall begin accepting applications for licensure by that date with decisions made on all licensing applications within 60 days of receiving the application.

(6) The rules adopted by the department shall include, but are not limited to, rules to:
(a) Establish the requirements governing the safe provision of natural medicine services to participants that include:
(i) holding and verifying completion of a preparation session, an administration session, and an integration session.
(ii) health and safety warnings that must be provided to participants before natural medicine services begin.
(iii) educational materials that must be provided to participants before natural medicine services begin.
(iv) the form that each facilitator, participant, and authorized representative of a healing center must sign before providing or receiving natural medicine services verifying that the participant was provided accurate and complete health information and informed of identified risk factors and contraindications.
(v) proper supervision during the administration session and safe transportation for the participant when the session is complete.
(vi) provisions for group administration sessions where one or more facilitators provide natural medicine services to more than one participant as part of the same administration session.
(vii) provisions to allow a facilitator or a healing center to refuse to provide natural medicine services to a participant.
(viii) the requirements and standards for independent testing of natural medicine for concentration and contaminants, to the extent available technology reasonably permits.
(ix) the licensure of entities permitted to engage in the testing of natural medicine for use in natural medicine services or otherwise.
(x) the standards for advertising and marketing natural medicine and natural medicine services.
(xi) the standards for qualification as a permitted organization addressing, without limitation, environmental, social, and governance criteria directed to the findings and declarations set forth in Section 12-170-102.

12-170-110. Personal use penalties. (1) Unless otherwise provided by subsection (2) of this section, a person who is under twenty-one years of age is subject to a drug petty offense, and upon conviction thereof, shall be subject only to a penalty of no more than four (4) hours of drug education or counseling provided at not cost to the person, if the person:
(a) Possesses, uses, ingests, inhales, or transports natural medicine for personal use;
(b) Gives away without remuneration natural medicine for personal use; or 15
(c) Possesses, uses, or gives away without remuneration natural medicine paraphernalia.
(2) To the extent subsection (1) establishes a penalty for conduct not otherwise prohibited by law or establishes a penalty that is greater than exists elsewhere in law

for the conduct set forth in subsection (1), the penalties in subsection (1) shall not apply.
(3) A person who cultivates natural (3) a person who cultivates natural medicines that are not secure from access by a person under twenty-one years of age in violation of 12-170-109(1)(b) is subject to a civil fine not exceeding two-hundred and fifty dollars, in addition to any other applicable penalties.

12-170-111. Limitations. (1) This article 170 shall not be construed:
(a) to permit a person to drive or operate a motor vehicle, boat, vessel, aircraft, or other device that is capable of moving itself, or of being moved, from place to place upon wheels or endless tracks under the influence of natural medicine;
(b) to permit a person to use or possess natural medicine in a school, detention facility, or public building;
(c) to permit a person to ingest natural medicines in a public place, other than a place licensed or otherwise permitted by the department for such use;
(d) to permit the transfer of natural medicine, with or without remuneration, to a person under twenty-one years of age or to allow a person under twenty-one years of age to use or possess natural medicine;
(e) to permit a person to engage in conduct that endangers or harms others;
(f) to require a government medical assistance program or private health insurer to reimburse a person for costs of purchasing natural medicine;
(g) to require an employer to permit or accommodate the use, consumption, possession, transfer, display, transportation, or growing of natural medicines in the workplace;
(h) to prohibit a recipient of a federal grant or an applicant for a federal grant from prohibiting the use, consumption, possession, transfer, display, transportation, or growing of natural medicines to the extent necessary to satisfy federal requirements for the grant;
(i) to prohibit a party to a federal contract or a person applying to be a party to a federal contract from prohibiting any act permitted in this article 170 to the extent necessary to comply with the terms and conditions of the contract or to satisfy federal requirements for the contract;
(j) to require a person to violate a federal law; or
(k) to exempt a person from a federal law or obstruct the enforcement of a federal law."

Washington Psilocybin Services Act

Relevant Excerpts/Quotes (original bill – 2022-23: Washington Health & Wellness Opportunity Act)

SENATE BILL 5263
NEW SECTION. Sec. 1. The legislature finds that:
(4) It is the intent of Washington to facilitate the establishment of safe, legal, and affordable psilocybin service centers to provide citizens of Washington who are at least 21 years of age with opportunities for supported psilocybin experiences for wellness and personal growth;
(5) The department of health has direct supervision over all matters relating to the preservation of life and health of the people of this state;
(6) During an 18-month program development period, the department must adopt rules for the implementation of a comprehensive regulatory framework that allows individuals 21 years of age and older in this state to be provided psilocybin services; and
(7) An advisory board must be established within the department to provide advice and recommendations to the department.
NEW SECTION. Sec. 2. The legislature declares that the purposes of this chapter are:
(1) To improve the physical, mental, and social well-being of all people in this state, and to reduce the prevalence of behavioral health disorders among adults in this state by providing for supported adult use of psilocybin under the supervision of a trained and licensed psilocybin service facilitator;
(2) To develop a long-term strategic plan for ensuring that psilocybin services become and remain a safe, accessible, and affordable option for all persons 21 years of age and older in this state for whom psilocybin may be appropriate;
(3) To protect the safety, welfare, health, and peace of the people of this state by prioritizing this state's limited law enforcement resources in the most effective, consistent, and rational way;
(4) After an 18-month program development period, to:
(a) Permit persons licensed and regulated by this state to legally manufacture psilocybin products and provide psilocybin services to persons 21 years of age and older, subject to the provisions of this chapter; and
(b) Establish a comprehensive regulatory framework concerning psilocybin products and psilocybin services under state law;
(5) To prevent the distribution of psilocybin products to other persons who are not permitted to possess psilocybin products under this chapter including but not limited to persons under 21 years of age; and
(6) To prevent the diversion of psilocybin products from this state to other states.
NEW SECTION. Sec. 57. A client may purchase, possess, and consume a psilocybin product:

(1) Only at a psilocybin service center unless an exception is made under rules established by the department under section 26 of this act to accommodate a client who is medically unable to travel to a psilocybin service center; and
(2) Only under the supervision of a psilocybin service facilitator.
NEW SECTION. Sec. 114. An employer in the state of Washington may not discriminate against an employee for receiving psilocybin services as sanctioned under this chapter absent the employee's visible impairment at work and may not test an employee for the presence of psilocybin unless they exhibit clear, observable symptoms of impairment.
NEW SECTION. Sec. 115. (1) The legislature finds that in the interest of establishing a legal psilocybin industry that is equitable and accessible to all, it is appropriate to establish a social opportunity program for the psilocybin industry to help remedy the harms resulting from historical injustice and the disproportionate and targeted enforcement of drug-related laws on poor and marginalized communities.
Relevant Excerpts/Quotes (2nd substitute bill partially vetoed before enactment)

HOUSE BILL REPORT 2SSB 5263
Brief Summary of Second Substitute Bill
https://lawfilesext.leg.wa.gov/biennium/2023-24/Pdf/Bill%20Reports/House/5263-S2%20HBR%20APP%2023.pdf?q=20230406132905
~~(Crossed out text~~ indicates text stricken from earlier version(s) of Bill).

- ~~Establishes the Psilocybin Advisory Board (Board) within the Department of Health (DOH) to provide advice and recommendations to the DOH, the Liquor and Cannabis Board (LCB), and the Washington State Department of Agriculture (WSDA).~~
- ~~Creates an Interagency Work Group of the DOH, the LCB, and the WSDA to provide advice and recommendations, in regular updates, to the Board on developing a comprehensive regulatory framework for a regulated psilocybin system, and other specified topics.~~
- ~~Requires the Health Care Authority to establish a Psilocybin Task Force, which must provide a final report to the Governor and Legislature by December 1, 2023, on specified topics including clinical information on psilocybin use and regulatory structures for clinical psilocybin use.~~
- ~~Grants the DOH certain duties, functions, and powers relating to information regarding the safety and efficacy of using psilocybin to treat mental health conditions; rulemaking authority; and other specified powers relating to psilocybin.~~
- Establishes the Psilocybin Therapy Services Pilot Program within the University of Washington Department of Psychiatry and Behavioral Sciences.

Connecticut Act

Relevant Excerpts/Quotes

Summary for Public Act (Adjusting the State Budget) (Office of Legislative Research, 2022)

§§ 200-204 — PSYCHEDELIC-ASSISTED THERAPY

PAT Fund
Starting in FY 23, the act allows (1) any federal block grant funds allocated to CMHC to be deposited in the PAT Fund and (2) CMHC to accept public or private contributions to the fund.

The act requires CMHC to use PAT funds for grants to qualified applicants to provide psychedelic-assisted therapy to qualified patients under the pilot program. Under the act, "qualified applicants" are mental or behavioral health services providers approved by the FDA as an approved treatment site with an expanded access protocol that allows the provider to access an investigational drug for treatment use, including emergency use.

Advisory Board Duties
The act establishes an 11-member Connecticut Psychedelic Treatment Advisory Board to advise DMHAS on designing and developing the regulations and infrastructure needed to safely allow therapeutic access to psychedelic-assisted therapy if MDMA, psilocybin, and any other psychedelic compounds are legalized. Specifically, the advisory board must:

5. review and consider data from the psychedelic-assisted therapy pilot program to inform the development of the regulations;
6. advise DMHAS on (a) necessary education, training, licensing, and credentialing of therapists and facilitators; (b) patient safety and harm reduction; (c) establishing equity measures in clinical and therapeutic settings; (d) cost and insurance reimbursement considerations; and (e) treatment facility standards;
7. advise DMHAS on using group therapy and other therapy options to reduce cost and maximize public health benefits from psychedelic treatments;
8. monitor updated federal regulations and guidelines for referral and consideration by the state agencies responsible for implementing them;
9. develop a long-term strategic plan to improve mental health care through psychedelic treatment;
10. recommend equity measures for clinical subject recruitment and facilitator training recruitment; and

11. help develop public awareness and education campaigns.

Advisory Board Membership
Under the act, advisory board members include:

12. two members each appointed by the Senate president pro tempore and House speaker;
13. one member each appointed by the House and Senate minority leaders;
14. two members appointed by the governor; and
15. one member each appointed by the consumer protection, mental health and addiction services, and public health commissioners.

The act requires the advisory board to include members with experience or expertise in psychedelic research, psychedelic-assisted therapy, public health, access to mental and behavioral health care in underserved communities, veterans' mental and behavioral health care, harm reduction, and sacramental use of psychedelics.

Advisory Board Leadership and Administrative Staff
The act requires the Senate president pro tempore and House speaker to select the advisory board chairpersons from among its members. The chairpersons must oversee establishing and making recommendations on the board's voting procedures.

The act allows the board to have committees and subcommittees if they are needed for its operation.

Under the act, the General Law Committee administrative staff serve as the Page 85 of 205 advisory board's administrative staff, with assistance from the Office of Legislative Research and Office of Fiscal Analysis, if needed.

Federal Guidelines on Psychedelic-Assisted Therapy
The act requires DCP to consider adopting any nonbinding U.S. Department of Health and Human Services guidelines on practicing psychedelic-assisted therapy. It permits the Connecticut Psychedelic Treatment Advisory Board and the public to submit written comments to DCP during a notice and comment period the department establishes on (1) adopting the guidelines and (2) any suggested changes to them to better meet state residents' needs.

The act requires DCP to post the procedures and deadline to submit written comments during the notice and comment period on its website."

TheraPsil's Proposed Regulations – APMPR

Features

TheraPsil's proposed regulations provide the above advantages through careful drafting choices, including:

- implementation through regulations requiring no amendment to any act of parliament:
    1. amendment of the Food and Drug Regulations (the "**FDR**") to move psilocin and psilocybin to the Schedule to Part G as a controlled drug rather than the Schedule to Part J as a restricted drug;
    2. promulgation of the APMPR under the CDSA; and
    3. promulgation of the PER under the CDSA and the FDA.

- basing the APMPR closely on the *Cannabis Regulations*, with the APMPR including the following nine parts:
    1. Licensing
    2. Security Clearances
    3. Physical Security Measures
    4. Good Production Practices
    5. Psilocybin Products
    6. Packaging and Labelling
    7. Retention of Documents and Information
    8. Reporting and Disclosure
    9. Access to Psilocybin for Medical Purposes
- licensing being generally similar to cannabis licensing, with cultivation and processing collapsed into a single production licence;
- licence holders under the APMPR being required to also hold a dealer's licence under Part G of the FDR, which facilitates reporting to the International Narcotics Control Board and other UN compliance that Canada has committed to;
- identical security clearance provisions as with the CR;
- relaxed physical security measures comparable to micro-cultivation, nursery or micro-processing licences under the CR, which stacks on top of the security measures required for a dealer's licence under Part J of the FDR;
- application of good production practices ("GPP") analogous to GPP in the CR, which is appropriate for consumer-packaged goods that (a) include an active ingredient and (b) are botanical-focused;
- allowing for cultivation of psilocybin fruiting bodies (defined to include sclerotia), and manufacturing of synthetic psilocybin or synthetic psilocin, as psilocybin materials for inputs to manufacture psilocybin products;

- defining four classes of psilocybin based on classes of cannabis, which may be used as saleable products: dried fruiting bodies, fresh fruiting bodies, psilocybin extracts and edible psilocybin;
- essentially identical packaging and labelling requirements as is the case with cannabis products;
- identical retention and reporting requirements as in the CR;
- identical medical document-based system for purchasing psilocybin products for delivery to a HCP or to a client who will use the psilocybin products as in the CR, with the expectation that most HCP will be ordering psilocybin products for provision to their patients, rather than the patients ordering directly as clients of the license holder (i.e. inverted common use cases compared with cannabis, but with the APMPR allowing for either recipient);
- essentially identical medical document and registration certificate-based system for personal cultivation by a designated person or by a person holding a medical document, to the CR; and
- identical provisions to the CR with respect to hospitals, pharmacies, HCPs (i.e. prescribing professionals) and nurses, providing safeguards against inappropriate or high-risk medical documents, and also facilitating management of this federal system by provincial governments in the event that provincial governments elect to specifically regulate use of psilocybin (perhaps along with psychedelics generally).

Practice Standards for Outpatient Use of Ketamine

Relevant Excerpts/Quotes

Outpatient Use of Ketamine for Mental Health Conditions: Practice Standards Recommendations (Hanon, Barale, Mitchell, Dhiman, & Ka, 2022)

These practice standards recommendations intend to support safety, quality, and consistency of patient care; they are not meant to replace the professional clinical judgment of physicians, prescribers and other health-care professionals, but rather incorporate current evidence, consensus-based, and appropriate off-label clinical information into a safe, reasonable, and acceptable framework for patient care that promotes the best possible outcomes. (p. 3)

Due to the unique dissociative effects of ketamine, it is our recommendation that clinicians receive appropriate training and education on how to care for patients in a way that maintains the patients' safety from a medical perspective as well as the patients' psychological safety. (p.3)

It is important that proper patient screening be conducted to ensure the benefits of prescribing ketamine outweigh the risks, both medically and psychologically. The prescribing physician shall evaluate and assess patients for suitability. Additionally, a psychological/psychiatric assessment is recommended to ensure that ketamine therapy is appropriate for the patient. If the prescriber does not have a longitudinal relationship with the patient we recommend that patients are screened and assessed by several medical professionals (e.g., general practitioner, psychiatrist, psychologist, specialist, registered nurse, registered therapeutic counsellor, registered clinical counsellor) and that old records are requested and examined. Finally, all patients must have a level of comprehension and capacity to understand the benefits and risks of ketamine as a part of the detailed informed consent process for receiving off-label medications. (p.5)

The use of ketamine for mental health issues is considered to be off-label other than the use of intranasal Spravato®. Prescribers must be aware of and comply with the College's relevant practice standards including: (1) Charging for Uninsured Services, (2) Complementary and Alternative Therapies, (3) Conflict of Interest, and (4) Sale and Dispensing of Drugs. (p.7)

In the doctor-patient therapeutic relationship, the patient has the right to make decisions about their health-care including choosing complementary or alternative therapies instead of, or as an adjunct to, conventional medicine. With regards to patient autonomy, our opinion is that adequately informed patients are not required to have failed standard therapies prior to receiving ketamine for mental health conditions. (p.7)

At sub-anesthetic doses in properly selected patients, ketamine is safe and does not require 1:1 monitoring of a critical care trained health professional or anesthesiologist. Consideration for staffing requirements should include the dose and route of administration of ketamine, other medications, comorbidities, and the patient's mental health stability. (p.10)

Based on the available data, adverse drug events in the use of non-intravenous ketamine for mental health conditions are minor, of short duration and easily managed within a non-hospital clinic or community setting. (p.11)

All prescribers must keep up to date with emerging evidence and practice within the guidelines of the CPSBC, which are expected to change over time as this new field of medicine develops. "It is an expectation of the College that registrants not only observe and monitor the patient but have the necessary equipment and competence to manage any adverse reactions" (CPSBC, Interim Guidance, 2021). (p.12)

Prescribers of ketamine for mental health conditions must anticipate and be prepared for the common and less common effects of ketamine including its unique dissociative effects which requires that the supervising health-care professional be attentive to patients' needs. With proper safeguards, screening, and planning, the main adverse effects of ketamine can be mitigated. (p.13)

By following these guidelines, prescribers can actively reduce negative outcomes, which will enhance the opportunity for optimal therapeutic results and lasting therapeutic benefits. (p.13)

It is our recommendation that community settings requiring non-commercial preparations of ketamine such as lozenges, rapid-dissolving tablets, nasal spray or others, work with a compounding pharmacy with experience processing ketamine formulations. Compounding pharmacies can use standardized protocols to ensure more consistency and objectivity in the medication preparation process. (p.13)