

BALANCING SAFETY AND ACCESS:

MAPS Canada's
Response to Alberta's
Psychedelic Drug
Treatment Services
Regulation and
Service Standards

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I. INTRODUCTION

Psychedelics have shown great promise in treating various mental health conditions, including treatment-resistant depression, end-of-life anxiety, and PTSD. MAPS Canada believes that these medicines should be accessible to those in need in a safe and appropriate manner.

The government of Alberta recently passed an amendment to add regulations for psychedelic drug treatment services within the **Mental Health Services Protection Regulation**, which falls under the province's **Mental Health Services Protection Act**. The amendment to the Regulation focuses on the treatment of psychiatric disorders with psychedelic drugs, including in the context of psychedelic assisted psychotherapy. **Psychedelic Drug Treatment Services Standards**, pursuant to the Regulation, have also been published. The Standards provide opportunities for more responsive amendments related to the requirements in the provision of psychedelic drug treatment services. The Regulation came into effect on January 16th, 2023, and the Service Standards were published on January 17, 2023.

This legislation is the first of its kind in Canada and represents the starting point for Alberta's regulation of psychedelic drugs, and a reference point for other provinces actively working on similar frameworks. While MAPS Canada is encouraged that the Alberta government is moving forward with regulating psychedelics for therapeutic purposes, we believe safety and accessibility are not mutually exclusive and are concerned that some of the components may negatively impact access to people who could potentially benefit from these therapies.

In this document we address some of the priority areas for our community to provide clarity on the regulatory requirements, and to consider its impacts and gaps. We also provide recommendations to ameliorate access while ensuring safety and quality concerns are addressed.

II. AIM AND SCOPE OF REGULATION AND STANDARDS

The aim of Alberta's Psychedelic Drug Treatment Services Regulation and Service Standards is to provide government oversight and key protections for patients receiving psychedelic drug treatment services in Alberta. It is not intended to increase access to those who could benefit.

The Regulation provides administrative and licensing requirements for the provision of services and defines which health care professionals are eligible to prescribe, administer and monitor psychedelic drugs, including when psychedelic drugs are provided in the context of psychedelic assisted psychotherapy and for psychedelic and non-psychedelic doses. The Regulation and Standards also establish training, monitoring, safety, reporting, and other measures that must be in place.



III. PRIORITY AREAS: ISSUES AND CONSIDERATIONS

The following analysis and recommendations reflect the main issues we heard from various stakeholders, and are organized based on the essential considerations for the safe use of psychedelics: Drug; set and setting; preparation and integration.

1. DRUG

A. PSYCHEDELIC DRUGS

The psychedelic drugs included in the Regulation (i.e., designated psychedelic drugs) are psilocybin, psilocin, MDMA, LSD, mescaline, DMT, 5 methoxy DMT, and ketamine.

Under federal law in Canada, all psychedelic drugs, except ketamine, are illegal and require special permission from Health Canada either through an exemption under section 56 of the **Controlled Drugs and Substances Act (CDSA)** or via the **Special Access Program (SAP)** before they can be legally accessed and used.

Ketamine is a legal substance and can be used by eligible health care providers to treat their patients without special permission from Health Canada. By including ketamine in the Regulation, Alberta is effectively changing the current practices for the use of ketamine for a psychiatric disorder in the context of psychedelic assisted psychotherapy. This change will impose new requirements on health care providers that have been providing these services which may impact clients currently receiving these services.

RECOMMENDATION:

Given the legal use of ketamine for the treatment of psychiatric disorders prior to the Regulation, the rationale for including ketamine in this Regulation is not apparent. The rationale for its inclusion should be provided and an assessment of the impact on continuity of care for patients receiving ketamine assisted psychotherapy.

B. PRESCRIBERS

Several licensed medical practitioners (i.e., physicians, psychiatrists, and nurse practitioners) can seek access from Health Canada for psychedelic drugs (except ketamine) through a Section 56 exemption or the SAP in order to provide illegal psychedelic drugs to their patients. The Regulation assumes that the service provider has the necessary authorization from Health Canada to use the psychedelic drug.

Under Alberta's new Regulation, Albertans who want access to psychedelic drugs, other than ketamine, for the treatment of psychiatric disorders (in psychedelic doses and in the context of psychedelic assisted psychotherapy) must obtain a prescription from a psychiatrist or another physician in consultation with a psychiatrist. This means that health care practitioners other than physicians, even if they have been authorized by Health Canada, will no longer be able to prescribe a designated psychedelic drug.

Considering there are only ~460 psychiatrists in the entire province of Alberta (a ratio of approximately 1 psychiatrist for every 10,000 residents), the requirement for a psychiatrist's involvement in prescriptions for psychedelics may significantly impede access to these treatments.

Ketamine, used outside of psychedelic assisted psychotherapy, and other psychedelic drugs in non-psychedelic doses and utilized outside the context of psychedelic assisted psychotherapy, can be prescribed by other authorized regulated members (i.e., health professionals registered with the relevant college that are authorized to prescribe in Alberta).

The Regulation states that a prescriber (psychiatrist or other physician), must have the qualifications, training, and experience as per the Standards, which in turn state that training for personnel is determined by the medical director.

RECOMMENDATION:

Given the low number of psychiatrists in Alberta, to improve access and create consistency with the current SAP practices, the Regulation should allow physicians, NP's, and other regulated health care professionals with authority from their regulatory college, and with appropriate training and experience, to prescribe psychedelic drugs.

RECOMMENDATION:

To address the supply of psychiatrists in Alberta more generally, we recommend that the AB government advocate to the Royal College of Physicians and Surgeons to allow cross-jurisdictional licensing for psychiatrists.

C. DOSE

The Regulation differentiates between psychedelic and non-psychedelic doses, where “non-psychedelic dose” is defined as a dose that is not likely to result in an altered state of consciousness for the patient for whom it is prescribed, as determined by the prescriber.

Non-psychedelic doses can be self-administered, without monitoring, outside the context of psychedelic assisted psychotherapy. Doses that are deemed psychedelic must be administered at approved facilities, except at end of life, and patients must be treated and cared for while in an altered state of consciousness (and any additional time determined by prescriber) by an authorized regulated member, or an individual approved by the medical director and supervised as per standards. (note: An authorized regulated member is authorized under the **Health Professional Act** and registered with the relevant college in Alberta).

Allowing the psychedelic dose or non-psychedelic dose to be determined by the prescriber accommodates individual differences in patients. Neither the Regulation nor Standards stipulate the necessary experience and training for the prescriber; the necessary training and experience is left up to the medical director, however there is no requirement for the medical directors to have psychedelic training. This leaves a knowledge gap, and it is unclear how the prescriber will make such a determination.

RECOMMENDATION:

See ‘training’ below.



2. SET AND SETTING

A. SERVICE PROVIDER AND MEDICAL DIRECTOR

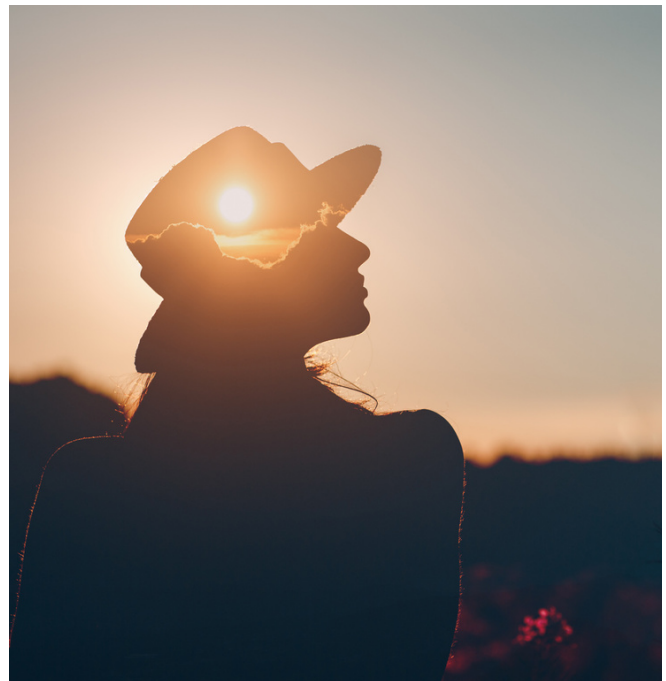
The Regulation stipulates that a “service provider” (i.e., clinics, programs, etc.) must attain a license for the provision of psychedelic drug treatment services (**Psychedelic drug treatment service provider licensing | Alberta.ca**). Service providers are exempt from the requirement to obtain a license if they are providing psychedelic drug treatment services in the context of an approved clinical research trial. The requirement for a license also does not apply to service providers who are providing ketamine outside of the context of psychedelic assisted psychotherapy; service providers that were previously providing ketamine in the context of psychedelic assisted psychotherapy will now have to apply for a license under this Regulation.

The licensed service provider must appoint a “medical director” to oversee all clinically related aspects of psychedelic drug treatment services, including supervising the administration and monitoring of the services, and ensuring all personnel have the necessary qualifications and training as laid out in the Regulation and Standards. The medical director is not required to be onsite or present during treatment.

The medical director must be a psychiatrist authorized by their college to provide psychedelic drug treatment services, and meet any qualifications, training and experience as required in the Standards. This requirement, as with the requirement for the involvement of a psychiatrist in the prescribing of psychedelics, creates a shortage in the supply of providers who can fulfill this role and provide these services.

RECOMMENDATION:

Given that role of medical director could be performed responsibly by health care practitioners other than psychiatrists, the list of regulated professionals who are able to fill the role of medical director should be broadened to include physicians and other regulated health professionals, with appropriate training and experience in the provision of psychedelic drug treatment services including psychedelic assisted psychotherapy.



B. ADMINISTRATION, TREATMENT AND MONITORING

In the context of psychedelic assisted psychotherapy, the patient must be under the care of an “authorized regulated member” for the entire duration of the therapeutic experience. The administration of psychedelic drugs (in psychedelic doses and for parenteral ketamine) must be done by, or be directly supervised by, an authorized regulated member.

Psychotherapy in the context of psychedelic assisted psychotherapy, must be provided by a person authorized to provide **restricted psychosocial interventions** under the **Government Organization Act** and who is a regulated member of one of the colleges under the Health Professions Act that regulates the following health care practitioners: Physicians, occupational therapists, psychologists, registered nurses, registered psychiatric nurses, and social workers. The Regulation thus sets a more conservative bar for psychedelic assisted psychotherapy, where the same requirement for restricted psychosocial interventions applies regardless of whether the condition being treated is considered to be a substantial disorder.

Other mental health practitioners that meet the requirements for training and experience, but are not authorized regulated members (e.g., clinical counselors), are not permitted to deliver psychotherapy in the context of psychedelic assisted psychotherapy. Here the Regulation also sets a higher bar than that laid out in the Government Organization Act, which allows authorized physicians, psychologists, occupational therapists, and social workers who can perform this restricted activity to permit unregulated practitioners to perform restricted psychosocial interventions under their supervision.

Patients who are administered psychedelic doses must be monitored, treated, and cared for while in an altered state (and any additional time as determined by the prescriber) by an authorized regulated member or other individuals approved by the medical director and supervised as per Standards. It is possible that individuals with training and experience in psychedelic assisted psychotherapy, who are not permitted to provide psychotherapy under the Regulation, may be able to support the monitoring, treatment and care if approved by the medical directors and supervised as per the Standards. The Standards stipulate that the medical director will ensure appropriate supervision of monitoring, treatment, and care.

RECOMMENDATION:

Health care professionals who are not authorized regulated members, but who demonstrate appropriate qualifications, training, and experience to provide psychedelic assisted psychotherapy under the supervision of authorized regulated members should be permitted to provide psychedelic assisted psychotherapy. This aligns with the current regulations related to restricted psychosocial interventions, and significantly increases the availability of the workforce while maintaining oversight for quality of care.

C. TRAINING

The Regulation states that licensed service providers must ensure that all employees are qualified to provide psychedelic drug treatment services and are adequately trained in all matters necessary to provide these services. The Standards, in turn, state that qualification, training, experience required of all personnel is at the discretion of the medical director.

Further, the Regulation stipulates the roles of medical director and prescriber must both be filled by a psychiatrist authorized to provide psychedelic drug treatment services and must have the qualifications, training and experience as required in the Standards. However, neither the Regulation nor Standards specify the necessary experience and training for the medical director or prescriber.

For the provision of psychotherapy in the context of psychedelic assisted psychotherapy, authorized regulated members besides psychiatrists and clinical psychologists, must have a related masters or doctoral degree, or in the assessment of the medical director have a minimum 5 years of experience treating PTSD, mood disorders, or related disorders with evidence-based psychotherapy.

All persons providing psychotherapy in the context of psychedelic assisted psychotherapy must also have training and experience respecting psychedelic assisted psychotherapy or psychological counseling as required by the medical director as set out in Standards. The Standards state that qualification, training, experience required of all personnel is up to the medical director, and at this time does not specify any training requirements.

RECOMMENDATION:

To ensure adequately informed oversight, the Regulation or Standards should stipulate the training and experience required for both the medical director and prescribers.

RECOMMENDATION:

Given the vulnerability of individuals who are in altered states of consciousness, the Standards should stipulate that experience and training with psychedelic drugs is required for all authorized regulated members that provide psychedelic drug treatment services. Additionally, the Standards should require that psychedelic assisted psychotherapy training and experience is required for the provision of psychedelic assisted psychotherapy for all providers, including psychiatrists and clinical psychologists.



D. THERAPEUTIC ENVIRONMENT

In the context of psychedelic assisted psychotherapy, and for doses that are deemed psychedelic (and parenteral ketamine), psychedelic drug treatment services must be administered at an approved hospital, accredited medical facility accredited for administering the drug, or facility or other location of a service provider licensed as per the Regulation. An exception is made for end-of-life use, at the discretion of the prescriber.

It is encouraging that the licensed service provider will be able to offer psychedelic drug treatment services in a variety of settings, including their facility or other licensed location, for both individuals and groups, including those participating in psychedelic assisted psychotherapy.

While a clinical setting may be appropriate for some patients, it may not be appropriate in certain circumstances or for certain populations, such as Indigenous peoples. It is important that the licensing process does allow for such settings.

RECOMMENDATION:

Ensure the licensing requirements for locations for psychedelic drug treatment services allow for settings appropriate for Indigenous communities and other populations.

3. PREPARATION & INTEGRATION

A. CONSULTATION

In developing the Regulation and Standards, Alberta Health convened a 13-member multidisciplinary expert panel, including clinicians, researchers, academics, and industry representatives. In addition, there was representation from the colleges, including College of Physicians and Surgeons of Alberta (CPSA) and the Alberta College of Pharmacy (ACP).

The expert panel did not include patients with lived experience or non-physician providers of psychedelic assisted psychotherapy. Importantly, First Nations, Metis or Inuit communities' perspectives were not represented.

RECOMMENDATION:

Develop ongoing mechanisms of engagement as part of the evolution of the Regulation and Standards, that prioritize the inclusion of established NGOs, national associations, established psychedelic assisted psychotherapy education and training programs, Indigenous communities, and patients with lived experience.



IV. CONCLUSION AND RECOMMENDATIONS

We acknowledge that regulations for psychedelic drug treatment services require a focus on safety, however they should also meet the goal of providing access to those in need, and not create barriers in terms of time or cost in the context of an already overburdened healthcare system. Our recommendations, stemming from the issues and considerations related to the priority areas above, propose to balance the need for safety with the need for accessibility.

In our role as a national nonprofit organization focused on education, research, and advocacy related to psychedelics, we regularly consult with various relevant stakeholders and have reflected the thoughts and concerns they have shared with us in these recommendations. Our aim is to create awareness and engagement during a time of active policy development in the area of psychedelics, including psychedelic assisted psychotherapy.

We are hopeful these recommendations support decision makers and opinion leaders to reflect on and respond to the challenges and opportunities that have been identified in relation to this Regulation and related Service Standards.



OUR RECOMMENDATIONS ARE AS FOLLOWS:

PSYCHEDELIC DRUGS, PRESCRIBERS AND DOSE

1. Given the legal use of ketamine for the treatment of psychiatric disorders prior to the Regulation, the rationale for including ketamine in this Regulation is not apparent. The rationale for its inclusion should be provided and an assessment of the impact on continuity of care for patients receiving ketamine assisted therapy.
2. Given the low number of psychiatrists in Alberta, to improve access and create consistency with the current SAP practices, the Regulation should allow physicians, NP's, and other regulated health care professionals with authority from their regulatory college, and with appropriate training and experience, to prescribe psychedelic drugs.
3. To address the supply of psychiatrists in Alberta more generally, we recommend that the AB government advocate to the Royal College of Physicians and Surgeons to allow cross-jurisdictional licensing for psychiatrists.

SET AND SETTING

4. Given that role of medical director can be performed responsibly by health care practitioners other than psychiatrists, the list of regulated professionals who are able to fill the role of medical director should be broadened to include physicians and other regulated health professionals, with appropriate training and experience in the provision of psychedelic drug treatment services including psychedelic assisted psychotherapy.
5. Health care professionals who are not authorized regulated members, but who demonstrate appropriate qualifications, training, and experience to provide psychedelic assisted psychotherapy under the supervision of authorized regulated members should be permitted to provide psychedelic assisted psychotherapy. This aligns with the current regulations related to restricted psychosocial interventions, and significantly increases the availability of the workforce while maintaining oversight for quality of care.
6. To ensure adequately informed oversight, the Regulation or Standards should stipulate the training and experience required for both the medical director and prescribers.

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7. Given the vulnerability of individuals who are in altered states of consciousness, the Standards should stipulate that experience and training with psychedelic drugs is required for all authorized regulated members that provide psychedelic drug treatment services. Additionally, the Standards should require that psychedelic assisted psychotherapy training and experience is required for the provision of psychedelic assisted psychotherapy for all providers, including psychiatrists and clinical psychologists.
8. Ensure the licensing requirements for locations for psychedelic drug treatment services allow for settings appropriate for Indigenous communities and other populations.

PREPARATION AND INTEGRATION

9. Develop ongoing mechanisms of engagement as part of the evolution of the Regulation and Standards, that prioritize the inclusion of established NGOs, national associations, established psychedelic assisted psychotherapy education and training programs, Indigenous communities, and patients with lived experience.

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WORKING WITH PARTNERS IN GOVERNMENT, BUSINESS, AND THE COMMUNITY, MAPS CANADA IS COMMITTED TO ADVANCING PSYCHEDELIC MEDICINE BY SUPPORTING SCIENTIFIC, MULTIDISCIPLINARY RESEARCH; ADVOCATING FOR DRUG POLICY REFORM; OFFERING PUBLIC EDUCATION; AND SUPPORTING EQUITABLE ACCESS TO LEGAL AND REGULATED PSYCHEDELIC MEDICINE IN CANADA.