
Psychedelic assisted therapy

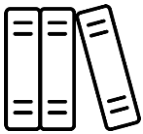
In October 2022, Alberta's government introduced new requirements for psychedelic assisted therapy through an amendment to the *Mental Health Services Protection Regulation*. These requirements come into effect on January 16, 2023.

Emerging evidence shows that psychedelic assisted therapy can lead to improvements for people with certain psychiatric disorders, including PTSD and treatment-resistant depression.

Psychedelic drugs include psilocybin, psilocin, MDMA, LSD, mescaline (peyote), DMT, 5 methoxy DMT and ketamine.

As psychedelic drugs carry health and safety risks, proper safeguards and expert medical oversight are required to ensure patient safety.

Why regulate psychedelic assisted therapy?



Emerging field

- Research on the use of psychedelics to treat certain mental health disorders is still emerging. Further study of the long-term impacts is required.
- Protecting the safety of Albertans undergoing psychedelic assisted therapy is necessary as the field continues to evolve.



Heightened vulnerability

- The mind-altering properties of psychedelics result in an increased risk of mental and physical harm.
- This can lead to dangerous situations like violence, accidents, abuse and suicide.



Side effects

- Physical side effects include high blood pressure, seizures, numbness and tremors.
- Psychiatric side effects include intense hallucinations, anxiety and panic attacks.
- Severe side effects can lead to comas, multi-organ failure and death.



Expert oversight

- Improper dose management can have serious long-term impacts.
- Expert medical supervision is required to ensure psychedelics are only administered in controlled clinical environments with proper dosing and after existing evidence-based care options have been considered.

What are the requirements?

With certain exceptions, the following requirements must be met to offer psychedelic assisted therapy for psychiatric disorders.

Administrative requirements

For all licensed providers

A licence is not required if:

Treatment is part of an approved clinical research trial, or

Offering ketamine outside of psychedelic assisted therapy, or

Only dispensing or selling psychedelic drugs for use through a licensed service provider.

- Apply for and hold a licence under the *Mental Health Services Protection Act*.
- Appoint a psychiatrist as medical director
- Develop and maintain written policies, procedures and records
- Report on service utilization and complaints
- Ensure critical incident reporting and response
- Ensure staff meet qualifications and training requirements

Service requirements

If it includes psychedelic assisted psychotherapy, or

is a psychedelic dose of a drug other than ketamine

- Prescription by a psychiatrist or physician in consult is required
- Administration must take place at medical facilities/clinic only, except for end-of-life care
- No self-administration and no direct dispensation/sale to a patient
- Rules about monitoring/care when in an altered state apply
- Qualifications to provide psychotherapy are required
- The provider must comply with the other rules in the Standards

Service requirements

If it does not include a psychedelic dose and does not include psychedelic assisted psychotherapy

- Prescription by a psychiatrist or physician in consult is required
- No restrictions on where drug administration can take place
- Direct dispensation/sale and self-administration are allowed
- The rules on monitoring and care do not apply
- The provider must comply with other rules in the Standards

Service requirements

If the drug is ketamine and is not provided as part of psychedelic assisted psychotherapy

- No additional limitations on who can prescribe
- No additional service requirements when using oral, sublingual or intranasal formulation
- For other formulations:
 - administration must take place at medical facilities/clinic only, except for end-of-life care
 - No self-administration and no direct dispensation/sale
 - Rules about monitoring/care when in an altered state apply

Changes for regulated health professionals (as of January 16, 2023)

Only a *psychiatrist* or a *physician in consultation with a psychiatrist* can prescribe a psychedelic drug for the purposes of treating a psychiatric disorder, unless the drug is ketamine provided outside of psychedelic assisted psychotherapy.

- **Prescribers** must ensure all prescriptions provide the following information:
 - direction respecting the quantity of the drug that may be dispensed or sold at any one time and the intervals of time required between each dispensation or sale
 - information about the dosage and whether the drug is to be used in the context of psychedelic assisted psychotherapy
- *Except* in cases where no psychedelic assisted psychotherapy is being provided and either the drug is ketamine in a non-parenteral formulation, or a drug other than ketamine in a non-psychedelic dose:
 - A psychedelic drug cannot be dispensed or sold directly to a patient.
 - Only an authorized regulated health professional can administer a psychedelic drug and it must take place at the facility listed on the licence of a licensed service provider, a hospital, or an accredited medical facility. An exception to the location of administration exists for end-of-life patients.
 - Authorized regulated health professionals or other approved individuals must monitor, treat and care for the patient while in an altered state of consciousness.
- **Providers of psychedelic assisted psychotherapy** must either be psychiatrists, clinical psychologists or regulated health professionals authorized to perform the restricted activity of psychosocial intervention who meet a standard of qualifications or experience and are members of one of the following regulatory colleges:
 - Alberta College of Occupational Therapists
 - College of Physicians and Surgeons of Alberta
 - College of Alberta Psychologists
 - College of Registered Nurses of Alberta
 - College of Registered Psychiatric Nurses of Alberta
 - Alberta College of Social Workers
- A **medical director** who is a psychiatrist must be appointed by the licensed service provider to oversee all clinically related aspects of the licensed services.

The Regulation *only applies* to psychedelic assisted therapy used to treat a psychiatric disorder. The requirements above *do not apply* to clinical research trials or psychedelic assisted therapy used for pain, palliative care or other illnesses.