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# 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.

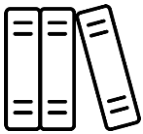
Emerging evidence shows that psychedelic assisted therapy can lead to improvements for people with certain psychiatric disorders, including PTSD and treatment-resistant depression.

**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.

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## 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.
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### 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.
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### 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.
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### 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.