

# Psychedelic Therapy in Colorado: Rules for a Safe and Accessible Program

In November 2022, Colorado voters approved Proposition 122, which allows regulated access for adults to natural psychedelic medicines that show promise in treating a variety of health conditions. The Colorado Department of Regulatory Agencies (DORA) and the Colorado Department of Revenue (DOR) developed rules to implement a statewide regulated psilocybin therapy program while gathering input from experts, stakeholders, and the public. The program allows adults to access psychedelic therapy under the supervision of trained facilitators at authorized locations, including licensed healing centers and healthcare facilities. Below is a summary of key program rules and regulations.

### **Facilitator Rules**

**Facilitator Licenses:** Multiple license types for psychedelic facilitators allows integration of psychedelic therapy into our existing mental health system and care tailored to participant needs.

- Clinical Facilitator License: Allows licensed medical and mental health providers to offer psychedelic therapy within their existing practice after completion of approved training
- Facilitator License: Allows those without a clinical license to provide psychedelic care after completion of approved training
- Distinguished Educator License: Allows
  experienced natural medicine practitioners to
  serve as practicum supervisors who are permitted
  to facilitate in the context of training programs
- Training License: Requires students to practice under supervision for a period of time prior to obtaining a full facilitator license

**Training Requirements:** Training for facilitators is focused on experiential learning and providing trainees with the skills needed to manage challenges and deliver a high standard of care.

- 150 hours of classroom-style training covering everything from ethics to screening and drug interactions
- 40 practicum hours of supervised practice training where students will experience, facilitate, and observe altered states of consciousness
- 50 consultation hours across at least 6 months in which students provide psychedelic care in consultation with an experienced facilitator, including evaluation of core competencies

Facilitator candidates may be permitted to complete accelerated training or be exempted from certain requirements if they provide proof of equivalent training or experience.

**Safety Screening:** Facilitators are required to administer a safety screen designed to identify potential risks. The safety screen determines whether participants require clearance, consultation, or referral from a medical or behavioral health provider to access psychedelic therapy.

**Standards of Practice:** These rules comprise the code of conduct facilitators must abide by, including:

- Administration session duration, based on dosage
- Responsibilities with regards to preparation, administration, and integration sessions
- Informed consent processes and disclosures
- Confidentiality and storage of client records
- The following are prohibited: discrimination, exploitation, and sexual, romantic, financial, or otherwise conflicting relationships with participants and their family members

# General Rules for Natural Medicine Businesses

- Natural medicine businesses must store psychedelic medicines in a secure, locked place that is monitored by video.
- Businesses must submit documentation to DOR of floor plans, security systems, waste logs, emergency plans, inventory tracking and more to obtain and maintain licensure.
- Cultivation, manufacture, and healing centers can share the same location. Testing laboratories, however, cannot share a location with any other natural medicine business type.

# **Healing Center Rules**

- Healing centers must designate an "administration area" where psychedelic therapy sessions will take place and take all reasonable steps to provide a risk-free environment.
- No person under 21 may be present in the administration area during a psychedelic therapy session.
- Healing centers can be located at healthcare facilities and locations that provide services other than psychedelic therapy, including counseling and wellness. This will allow the integration of psychedelic care into our existing mental health system.

 There is a two-tiered approach to Healing Center licenses. A Micro-Healing Center license allows storage of up to 750 mg of total Psilocin (about 15-30 doses) on site. Standard Healing Centers storing more than 750 mg Total Psilocin require additional security measures.

### **Cultivation Rules**

- Cultivation is initially limited to one species of mushroom, Psilocybe cubensis, and cultivators must comply with rules to ensure sanitary conditions in cultivation facilities.
- The rules create two cultivation tiers: a Micro-Cultivation tier for those storing small amounts of natural medicine (up to 750 grams of dried mushrooms) and a Standard Cultivation tier for those storing up to 5 kg. Standard Cultivation licenses require additional security measures and may petition to store more than 5 kg based on demand.

# Manufacturing, Labeling, and Testing Rules

- A manufacturing license is required to distribute mushroom capsules and tea bags for use in psychedelic therapy. Additional certification and safety requirements are required for extractions and a limited list of additional psilocybin product types, which must not be designed to appeal to children.
- Natural medicine must be clearly labeled to indicate dosage (Total Psilocin content), harvest date and strain type. Labels must not be attractive to individuals under the age of 21.
- Natural medicines must be lab tested for quality control.

<u>Click here</u> and <u>here</u> for DORA's complete rules. Click here for DOR's complete rules