

7.35.XX Requirements and Application for Psilocybin Educational Programs

Requirements and items submitted for Psilocybin Educational Program Applications

- All items must be submitted through the electronic system designated by the department
- Organizational chart
- Proof of registration with New Mexico Secretary of State
- Proof of registration of the business with New Mexico Taxation and Revenue Department
- Any applicable New Mexico city or county business licenses
- Certificate of Occupancy for locations utilized in New Mexico
- Additional documentation as the department may reasonably request to ensure compliance with applicable laws, regulations, or ordinances
- List and contact information of the owners or members of the Board of Directors
- Primary contact information including name, address, phone, and email
- A list of all of the instructors including their CV or resume which demonstrate their collective expertise in all of the required curriculum areas.
- Copy of the curricula which will be utilized with a brief description of how it meets the requirements for curricula
- Copy of the syllabi for the courses utilized within the educational program and a web address for where the educational program will publicly provide updated syllabi for prospective students
- Plans for record retention
- Safety and emergency response plan
- Plan for transparency and disclosure of fees for students
- Plans on how the Educational Program will ensure students graduate no more than 2 years from the date they are enrolled.
- Outline of grievance procedures for students
- Consent for contact information and educational program websites to be listed publicly on the department website, if approved.
- Consent for the curriculum and syllabi submitted to the department to be listed publicly on the department website, if approved;
- Provide a third-party evaluation report of the organization and the curricula which demonstrate meeting the requirements for Medical Psilocybin Educational Programs.
- Proof of arrangements with Healing Centers or other approved locations for practicum location placements.
- There must be a minimum of two faculty with current Practitioner or Facilitator permits from the department by January 1, 2027.
- The practicum faculty must have at least experience with 40 individual patients. How would this be determined/demonstrated.

Updates required to be reported

- If an educational program updates their curriculum, they must submit the revised curriculum to the department through the electronic system designated by the department prior to implementation and may not utilize it until approved by the department.
- Any change in ownership

- Any change in locations for instructions
- Any changes in practicum agreements
- Any change in instructors, including any new instructors' CV or resumes

1. Psilocybin Educational Program Curriculum Approval Process

- An educational program applicant must submit a completed application packet through the electronic system designated by the department;
 - The department will notify an applicant through the electronic system designated by the department if their application is approved or denied.
 - If the application is approved, the approval is effective on the date of notice and will be valid for two (2) years.
 - If the department denies an application, it will provide notice of the denial
 - If the application is denied, the applicant may re-submit their application within six months; or,
 - Applicants may not re-submit their application more than twice in a six month period; and
 - Applicants may appeal a denial utilizing the process outlined in this rule.
 - The department shall deny an application if:
 - The curriculum submitted does not match the required curriculum; or,
 - Not all required items have been submitted or are not complete; or,
 - The program instructors, staff or representatives have made false or misleading statements to the department, students, or the public.
- Applicants renewing their permit for being a Psilocybin Educational program must re-submit a full applicant packet through the electronic system no more than 60-days and no less than 30-days prior to the expiration of their permit.
 - Training programs may voluntarily relinquish their permit at any time and for any reason, including cessation of student enrollment or instruction, by providing written notice to the department.

1. Evaluation for Psilocybin Educational Programs

- The department or its designee may perform remote or on-site assessments of an approved program or applicant, with or without prior notice, during normal business hours to determine compliance with the Medical Psilocybin Act and this rule. Exception: for practicum and if patients are present – notice must be provided prior to a visit.
- Assessments may include a review of the current curriculum, including observations, to determine if the curriculum is being implemented with fidelity.
- Assessments include review of the record retention plan and if it is being followed.
- Additional documentation as the department may reasonably request to ensure compliance
- The department holds authority to withdraw approval if a program no longer meets requirements.

1. Requirements for Third Party Evaluators

The third-party evaluators would need to consist of a minimum of three individuals who have:

- a. 3 or more years of experience in one of the following areas and ensuring all of the areas are covered by the evaluators:
 - i. Psilocybin therapy practice with a Masters or Doctoral degree in Counseling, Therapy, Social Work, or a related Public or Behavioral Health Field;
 - ii. Medical or research practices with a Masters or Doctoral degree in Medicine, Pharmacy, Nursing, or a related field;
 - iii. Educational curriculum development and evaluation with a Masters or Doctoral degree in Education, Educational Psychology, or a related field.
- b. The evaluators must not have any conflict of interest with the organization and curriculum being evaluated such as:
 - i. The evaluators must not have participated in designing or teaching the curriculum being evaluated
 - ii. The evaluators must not have a financial interest in the organization being evaluated.
- c. The evaluators must sign a confidentiality and impartiality agreement
- d. Provide a report sent to both the educational program and the department which includes at a minimum:
 - i. The evaluators experience in each of the required fields;
 - ii. The evaluators conflict of interest, confidentiality, and impartiality agreements;
 - iii. Evaluations of the reliability, validity, and fidelity of implementation of the curriculum
 - iv. Evaluations of the reliability, validity and fidelity of implementation of the student evaluations of competency including tests, exams, and instructor observational feedback.
 - v. Recommendations for improvement.
 - vi. Performance evaluations of all faculty
 - vii. Evaluation of any reported student grievances

Add separate path for CME/CEUs

Reciprocity

- Individuals who have completed training in a current government (this includes New Mexico Tribe, Pueblo, and Indian Nation governments) approved psilocybin educational program which has been verified and approved by the Department to meet the minimum didactic requirements to be able to provide psilocybin treatment and therapy may apply and be permitted to be either a Practitioner or a Facilitator in New Mexico if they complete the following for each New Mexico permit:
 - Provide documentation of completion of the government approved psilocybin educational program from another jurisdiction
 - Complete the New Mexico Module

- Complete the required practicum or demonstrate completion of a practicum or practice with the minimum number of patients and hours as required in New Mexico; or,
- If some of the practicum hours have been completed in another jurisdiction, and are able to be verified by the department, the remaining practicum hours required in New Mexico may be completed through a New Mexico approved educational program so long as the total hours and minimum number of patients required by the New Mexico program are met; and
- For the practitioner permit, the reciprocal applicant will need to ensure they complete the twenty (20) supervisory practicum hours in New Mexico.
- **Exception: any reciprocal applications received by the department by December 31, 2026 will not be required to complete the full practicum hours required by New Mexico, but must demonstrate completion of at least 40 hours of contact time with a minimum of 2 separate individual sessions or 2 separate group sessions for preparation, administration, and integrative therapy with psilocybin treatment.**
- Exception: The department reserves the ability to waive, temporarily suspend, or reduce any of the rules regarding the training and practicum requirements for individuals applying for a permit through the reciprocal permit process in order to facilitate the permitting of individuals trained by other governmental approved programs to build the initial infrastructure of the program.
- For another government approved psilocybin educational program to be accepted, the applicant would need to submit the following:
 - Documentation the psilocybin educational program has been approved by another governmental agency or authority; by,
 - They are included on the list of department approved reciprocal psilocybin educational programs from other jurisdictions; or
 - Provide the following documentation:
 - Proof the educational program has been approved by a government or governmental entity; and,
 - The educational program curriculum; and,
 - A curriculum equivalency for the didactic portion of the educational program when compared to the required New Mexico educational program.
- Department approval of reciprocal psilocybin educational programs from other jurisdictions is valid for two years from the date of approval.
 - Reciprocal psilocybin educational programs may request a curriculum review 30 days prior to their expiration; and,
 - After review by the department and approval of the didactic curriculum, their approval renewed for two more years.
- **Individuals applying for reciprocity and having completed another governmental approved educational program outside of New Mexico and verified by the department will be excepted from the practicum hours if they apply for reciprocity by December 31, 2026. (clarify about the 40 contact hours needing to be demonstrated).**

Testing out of the didactic portion of the required curriculum

- Approved educational programs must offer an option for a student to take the test for each module without attending the lessons or classes for the module, except the New Mexico Module;
- The cost to take the test for each module cannot be more than one-fourth ($\frac{1}{4}$) of the normal price of each of the educational modules;
- If the student receives a passing grade for a module test, they will have been considered to have completed the module;
- If a student does not receive a passing grade for a module test, they will not have completed the module;
- The educational program may allow students to re-take the test without attending the lessons or classes for the modules at their discretion;
- Students who utilize this option must still complete all other requirements for the educational program including the New Mexico Module, certifications, simulated patient, and practicum requirements to graduate from the educational program.

Application Process

- An applicant must submit a completed application packet through the electronic system designated by the department;
- The department will notify an applicant through the electronic system designated by the department if their application is approved or denied.
 - If the application is approved, the approval is effective on the date of notice and will be valid for two (2) years.
 - If the department denies an application, it will provide notice of the denial
 - If the application is denied, the applicant may re-submit their application within six months; and,
 - Applicants may not re-submit their application more than twice in a six month period; and
 - Applicants may appeal a denial utilizing the process outlined in this rule.
 - The department shall deny an application if:
 - Not all required items have been submitted or are not complete; or,
 - Insufficient or expired licensure;
 - Missing or inadequate documentation of certification, education or practice requirements;
 - The applicant has made false or misleading statements in the application or to the department or the public;
- For renewal, applicants must complete a new applicant packet through the electronic system no more than 60-days and no less than 30-days prior to the expiration of their permit.
- Permittees may voluntarily relinquish their permit at any time and for any reason, by providing written notice to the department.
- Permittees must provide and consent to having contact information with a minimum of name, phone number, and email address published publicly.

Diagnostic Clinician, Practitioner, Facilitator Application Requirements:

- The requirements an applicant must meet and submit in a completed application packet include:
- Documentation of current professional license to practice in New Mexico for the appropriate certification (e.g. PSY, LSW, LCSW for Practitioner; MD, NP for Diagnostic Clinician);
- Documentation of completion of the appropriate department-approved training program for the specific certification (as previously outlined);
- Documentation of practicum requirements for practitioners and facilitators (as previously outlined);
- Documentation of current BLS certification (not needed for the diagnostic clinician);
- Documentation of current HIPAA certification
- Attestation they are not a registered sex offender and the department will deny or revoke a permit for anyone who is a registered sex offender;
- Personal data as appropriate:
 - Date of birth
 - NM Driver's License or state ID
 - Phone/email/mailing address
 - Legal name
 - Affirmation and consent forms

Reciprocal Practitioner or Facilitator Application:

- The applicant must submit a completed application packet including:
- Documentation of completion of a psilocybin educational program from another governmental jurisdiction; and,
 - Provide documentation the psilocybin educational program has been approved by another governmental agency or authority; by,
 - Their previous inclusion on the list of department approved reciprocal psilocybin educational programs from other jurisdictions; or
 - If not previously approved by the department:
 - Provide documented approval from another governmental agency; and
 - Provide a curriculum equivalency for the didactic educational portion of the program between New Mexico and the other program.
- Documentation of active Practitioner or Facilitator or equivalent licensure or permit in another jurisdiction;
- Documentation of minimum core practicum hours and NM-required practicum hours;
- Documentation of completion of NM-specific training module;
- Verification of current BLS certification;

Patient Application and Record:

- An applicant must submit a completed application packet through the electronic system designated by the department:
- Documentation of diagnosis of qualifying condition by a permitted Diagnosing Clinician
 - Personal data:
 - Date of birth
 - Phone/email/mailing address

- Legal name
 - Affirmation and consent forms
- Diagnostic Clinicians, Practitioners, and Facilitators must utilize the electronic system designated by the department to record information including:
 - Diagnosis qualifying the patient
 - Attestations about evaluating and treating the patient
 - Date and type of service for:
 - Evaluation
 - Preparation session
 - Administration:
 - Including approved location
 - Unique Identification Number of medicine used
 - Dosage
 - Initial Integrative Therapy Session
 - Any adverse events
- Information required for the Equity and Access Fund

Application appeal process

- Denial of an application will have a similar appeal process to the production and laboratory process.
 - Administrative review within 30 calendar days
 - Final determination within 15 calendar days

Disciplinary actions

- If the department issues a notice of disciplinary action:
- Person can request a hearing within 30 calendar days
- Hearing will be held no later than 60 calendar days from the request
 - Hearing is overseen by a hearing officer
 - Continuances can be granted.
 - Hearing officer shall submit a written recommendation of action to the secretary within 30 calendar days.
- Secretary will issue a final written decision within 45 calendar days

Healing Centers Requirements

- All items must be submitted through the electronic system designated by the department
- Name of business
- Organizational chart
- Proof of registration with New Mexico Secretary of State
- Proof of registration of the business with New Mexico Taxation and Revenue Department
- Any applicable New Mexico city or county business licenses
- Certificate of Occupancy for locations utilized in New Mexico

- Additional documentation as the department may reasonably request to ensure compliance with applicable laws, regulations, or ordinances
- List and contact information of the owners or members of the Board of Directors
- Primary contact information including name, address, phone, and email
- Maintain a list of all permitted individuals who will be utilizing or who have utilized the approved location
- Plans for record retention and confidentiality
- Plans for secured storage for medication
- Plans for wastage of any unused medication
- Safety and emergency response plan
- Documented policies and procedures for possession and storage of firearms and other weapons safely on the approved location premises.
- Plans demonstrating confidentiality of patients will be maintained within the approved location
- Plan for transparency and disclosure of fees for patients
- Outline of complaint and grievance procedures for patients
- Consent for contact information and websites to be listed publicly on the department website, if approved.
- For those conducting sessions in natural environments, also include:
 - Permission to utilize the property;
 - A detailed description of the outdoor administration area, including identification of safe entrance and exits, and verification that the area is free from hazards;
 - An emergency safety and response plan;
 - At least two individuals present who are not receiving treatment and who have:
 - Wilderness First Aid certification; or,
 - Wilderness First Responder certification
- Plan for adverse health event response/reporting

Other Approved Location Requirements

- Other approved locations include a patient's residence or other temporary location utilized if it is not possible for the patient to physically go to a Healing Center for reasons of medical necessity.
- Mobile unit for rural areas
- All items must be submitted through the electronic system designated by the department
 - A list of the permitted individuals who will be utilizing the approved location
 - Plan for secure transportation and, if necessary, storage for medication
 - Plans for wastage of any unused medication
 - A safety and emergency response plan
 - Plan for storage of firearms and other weapons safety during and after treatment sessions
 - Plans demonstrating confidentiality of patients will be maintained
 - A description of why the location is appropriate for treatment sessions

Healing Center and other approved location responsibilities

- Psilocybin products may only be consumed in an approved location.
- Only patients and certified individuals may be present during a patient treatment unless each patient gives prior written consent for other individuals to be present, except in emergency response situations.
- A permittee must maintain a copy of the daily log of activities related to psilocybin in the department designated electronic reporting system.
- May not promote unregulated cultivation and processing of psilocybin products and may not sell unregulated psilocybin products.
- Provide required information to the department upon request in a form and manner designated by the department
- Healing centers must display:
 - A copy of the healing center's certification issued by the department.
 - Information regarding safe transportation after an Administration Session.

Service Center Safety and Emergency Plan

- Every approved location shall create and maintain a safety and emergency plan which:
 - Document procedures for evacuating and relocating patients to a safe location if the approved location becomes unsafe.
 - Document general procedures for emergency response when a patient experiences a medical or other emergency.
 - Document procedures for addressing disruptive conduct and patient reactions that do not rise to the level of requiring an emergency response.
 - Document procedures for patients who attempt to leave a treatment session against medical advice.
 - Document procedures ensuring there are practitioners and facilitators present at all times according to the minimum patient/provider ratio required by the department.
- Provide the emergency and safety plan to all people utilizing the location;
- If any of the emergency procedures are utilized, there will be a documented report which will include the adherence to the plan, if there were deviations or if the plan did not work as intended, what will be changed in the future to ensure safety of individuals in the event of future incidents.

Storage

- All psilocybin products stored at an approved location must be kept within a locked area; and it must be:

- An area enclosed on all sides with permanent walls and secured with at a minimum, a properly installed steel door with a steel frame, and a commercial grade, non-residential lock; or,
- A locked safe; or,
- Products that require refrigeration may be stored within a locked refrigerator or freezer.

Adverse Health Event Reporting:

- Any possible adverse health event associated with psilocybin services it must report the adverse health event to the department no later than within two (2) business days from being notified through the designated electronic reporting system. Healing centers must maintain records of adverse health event reports in accordance with these rules. Reports must include:
 - Patient record number;
 - Product ID
 - Any participant reaction requiring medical attention; and
 - Any incident requiring emergency response;
 - Other incidents which have a negative impact on a patient(s).

Complaint Reporting:

- Patients or staff may lodge a complaint with the department.
- The complaint should be in writing and include:
- Name and contact information for the complainant which will remain confidential;
- The nature of the complaint and any other individuals who may be involved; and,
- The department may request additional information for investigation purposes.

Healing centers & approved locations must take adequate measures to:

- A Healing Center must make instructions or other guidance available related to:
- How to file a complaint with the department or other relevant state entities; and

How to report an adverse health event to the department