Natural Medicine Advisory Bulletin 13.5: The Birth of a Regulated Psychedelics Program

As of August 9th, 2024, Colorado regulators have completed the first round of rulemaking for the state's regulated Natural Medicine program, laying the foundation for the program's launch on January 1st, 2025. While some rules are still awaiting approval by the Attorney General, these final rules provide the full picture of Colorado's regulated Natural Medicine program. Thank you to the staff at DORA, DOR, the Attorney General's office, Natural Medicine Advisory Board members and participants, and each member of the public that contributed to the creation of this new program for state access to natural psychedelic medicines. In this article, we'll take a holistic view of the program, outlining the contours and summarizing the key components.

For any new readers, welcome, and a quick primer on Colorado's regulatory framework. First, the program requires regulation of the profession of facilitation, which includes training and licensing facilitators, as well as overseeing training programs. Second, regulators must license the operations of businesses necessary to support the profession of facilitation, such as businesses that will administer, cultivate, manufacture, and test the natural medicine used in the program. It is also important to note that, while Colorado's program may include additional natural medicines in the future, Natural Medicine currently means only psilocin and psilocybin, naturally occurring in psilocybin-containing mushrooms, which is reflected in the first round of rules.

Administratively, these duties are divided between two regulatory agencies. The Office of Natural Medicine ("Office"), part of Department of Regulatory Agencies' ("DORA") Division of Professions and Occupations, oversees the profession of facilitation. Rules promulgated by the Office set standards for education, training programs, professional conduct, and disciplinary procedures. The Division of Natural Medicine ("Division") within the Department of Revenue ("DOR") is tasked with overseeing Natural Medicine Businesses, which enable the profession of facilitation. Natural Medicine Businesses are those that cultivate, manufacture, and test natural medicine, as well as Healing Centers where facilitators will provide Natural Medicine Services.

To sum it up, DORA regulates the conduct of facilitators in all instances, while DOR regulates any activity occurring within a Natural Medicine Business.

The Practice of Facilitation

DORA's Office of Natural Medicine oversees the professional facilitators that will provide Natural Medicine Services. The Office's authority includes establishing and enforcing rules related to qualifications, training, licensing, scope of practice, and ethics.

License Fees

License fees for training programs have been set at $10,000 for the first year. Fees for other licenses have not been set. Stay tuned.

License Types

The Office will issue two full-scope licenses and two ancillary licenses. Full-scope licenses, which may provide Natural Medicine Services independently, are “Facilitator” and “Clinical Facilitator.” The Facilitator license is available to any individual that completes the education and experiential requirements. The Clinical Facilitator License is available to applicants that complete the same training requirements as a facilitator and possess a secondary license with “authority to diagnose and treat” physical or behavioral health conditions.

Two ancillary licenses are also defined. A “Distinguished Educator” license, available to individuals with significant experience providing Natural Medicine Services, allows a licensee to provide Natural Medicine Services within the context of a training program. Under the current rules, a Training license is available to individuals who complete the required 150 hours of didactic education and permits a licensee to charge for Natural Medicine Services provided during a supervised consultation period. Neither a Distinguished Educator or Training license is considered full-scope, meaning licensees may not provide Natural Medicine Services independently.[1]

Scope of Practice

Scope of Practice rules define the circumstances under which a Facilitator or Clinical Facilitator may provide Natural Medicine Services to a given Participant. Prior to an Administration Session, all facilitators are required to conduct a safety screen[2] with each Participant. If the safety screen identifies risk factors associated with the use of Natural Medicine for that participant, the facilitator’s scope of practice will dictate whether they may provide Natural Medicine Services to the Participant by default, or if additional steps are necessary. Risk factors may be physical health conditions, mental health conditions, or medication interactions. If treatment of the risk factor is outside the facilitator’s scope of practice, they may still provide Natural Medicine Services if the participant receives an opinion of a third-party that is licensed to treat the risk factor. Third-party opinions may be in the form of a direct referral, medical clearance, or consultation and risk review. So long as the participant understands and consents to any risks, a facilitator may provide Natural Medicine Services if the above steps were followed.

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[1] During the July meeting of the Natural Medicine Advisory Board, board members approved a recommendation permitting a limited training license to be issued prior to completion of all 150 didactic hours. This recommendation will need to be drafted as a rule and undergo the full rulemaking process before it is changed.

[2] Rules require that the safety screen reflects “generally accepted standards of practice.” DORA is expected to provide a model safety screen that satisfies this requirement.

In practice, this means that a participant with risk factors will need a third-party opinion to receive Natural Medicine Services from a single-licensed Facilitator. Whether a participant can receive Natural Medicine Services from a Clinical Facilitator without a third-party opinion will depend on the specific risk factor and the Clinical Facilitator's secondary license.

Standards of Practice

Standards of Practice rules are, in essence, the ethical code of conduct facilitators must abide by. They include:

- Required documentation and disclosures
- Confidentiality and storage of participant records
- Informed consent processes and disclosures
- Permitted and prohibited use of physical touch
- Prohibitions on discrimination and exploitation
- Prohibitions on sexual, romantic, financial, or otherwise conflicting relationships with participants and participants' immediate family
- Prohibitions on accepting fees for referrals
- Requirements around a Facilitators state of mind, including a prohibition on consuming Natural Medicine while providing Natural Medicine Services
- Maintaining competency as a facilitator
- Administration session duration, based on dosage

Rules also establish a facilitator's responsibilities with regards to preparation, administration, and integration sessions, including group administration and integration. Notably, these rules permit administration outside of Healing Centers, as well as group administration.

Residential Facilitation

Final rules permit Natural Medicine Services to be provided in the private residences of participants, as well as "other authorized locations," so long as at least one participant is legally entitled to occupy the residence. Participants must consent to either a second facilitator or video recording during an Administration Session outside of a Healing Center. Prior to administration at a private residence, facilitators must take appropriate measures to ensure the environment is suitable for Natural Medicine Services, such as being free of hazards, weapons, and uncontrolled animals. Additionally, minors may not be present. Facilitators are not permitted to use unregulated natural medicine in any Administration Session, including in a private residence. Facilitators may receive up to 750mg of *total psilocin*[3] in *regulated* natural medicine from a Natural Medicine Products Manufacturing Facility, Natural Medicine Cultivation Facility, or Healing Center. Facilitators are responsible for maintaining custody of Regulated Natural Medicine before and after any Administration Session that occurs outside of a Healing Center.

[3] "Total Psilocin" means psilocybin multiplied by 0.719 plus psilocin. 750mg of total psilocin is roughly equivalent to 75 grams of dried mushrooms of average potency.

Facilitator Education and Experience

As a baseline, all Facilitators and Clinical Facilitators must complete 150 hours of didactic education, 40 hours of supervised practice (practicum), and 50 hours of consultation. A training license is required for the consultation period. The 150 hour curriculum is broken into 14 required courses, with required topics prescribed by rule. Rules also set requirements for supervised practice hours, such as mandatory and permissible types of supervised practice, supervisor qualifications, distribution of hours, procedures for practicum sites, and the extent to which virtual and alternative training is permissible.

Educational Equivalence Pathways

Facilitators licensed in another jurisdiction, such as Oregon, for at least one year, may apply for licensure via an Occupational Credential Portability Program. Unlicensed applicants with experience providing Natural Medicine may also apply for accelerated licensure by petition, which grants exemptions from licensure requirements based on prior education and experience. Approved training programs can certify equivalent experience in any of the accelerated tracks.

Facilitator Training Programs

Training programs must receive approval from the Office of Natural Medicine to ensure graduating students are eligible for licensure. Rules establish standards for the approval of programs, such as requirements for organization and administration of the program, as well as program responsibilities and recordkeeping requirements. Rules also establish the privileges of “approved” status, set minimum education standards, documentation requirements, enrollment limits, and faculty composition. Finally, rules establish procedures for application, denial, revocation, maintenance, reinstatement of “Approved” status, pre-approval of programs, and for student transfer between programs.

Unlicensed Practice of Facilitation and Facilitator Discipline

Rules define grounds for disciplinary action against a licensed facilitator, including certain felonies and misdemeanors, abuse of alcohol or controlled substances, violations of laws or regulations related to Natural Medicine, misrepresentation and deception, unprofessional or dishonest conduct, unlicensed practice of Facilitation, aiding or abetting the unlicensed practice of facilitation, and failure to report certain required events. Licensees are required to report criminal convictions and any instance of unprofessional or dishonest conduct. “Unprofessional or dishonest conduct” encompasses crimes involving dishonesty or willful misrepresentation, crimes related to the practice of facilitation, and disciplinary actions taken against a facilitator by another jurisdiction or licensing board.

Natural Medicine Businesses

Final rules from DOR's Natural Medicine Division governing Natural Medicine Businesses come in at just over 100 pages. For the purposes of this article, we've focused on key aspects that form the overall shape of the program. We've omitted some rules, such as procedures for applications, product recalls and embargoes, declaratory orders, recordkeeping, disciplinary actions and appeals, inspections, and general rules like sanitation and security requirements.

License Fees

License fees for Natural Medicine Businesses will be established during a second round of rulemaking, anticipated in late summer 2024.

License Types

The Division will issue four primary types of facility license: Regulated Natural Medicine Cultivation, Regulated Natural Medicine Product Manufacturing, Regulated Natural Medicine Testing Facility, and Healing Center. Additionally, the Division will issue, and require, individual licenses for all owners of Natural Medicine Business and employees or contractors that directly handle natural medicine.

Owner & Natural Medicine Handler Licenses

Owners of Natural Medicine Businesses that are natural persons must be over twenty-one and may not have been convicted of certain violent crimes or crimes related to Natural Medicine in Colorado. Additionally, publicly-traded companies are prohibited from owning Natural Medicine Business Licenses. Owners must disclose certain financial interests, and may not hold a financial interest in more than five Natural Medicine Business licenses.

Individuals that directly handle natural medicine, or that have unrestricted access to natural medicine, are required to obtain a Natural Medicine Handler License. Notably, this includes any Facilitator that may handle natural medicine at a Healing Center. Rules establish qualifications and requirements for Owner and Natural Medicine Handler licenses.

Healing Centers

Natural Medicine Services may be provided in Healing Centers, facilities specifically licensed by the Department of Revenue for the provision of Natural Medicine Services. Final rules provide for two categories of Healing Center, based on the amount of Natural Medicine the Healing Center keeps on-hand. This bifurcation anticipates two distinct models of Healing Centers. One model mirrors Oregon's Psilocybin Service Centers. Providing Natural Medicine Services will be the primary focus of these businesses, which will likely serve multiple participants daily and maintain multiple facilitators on staff.

The second model is unique to Colorado, made possible by the Natural Medicine Health Act expressly permitting Natural Medicine Services for the treatment of mental health conditions. In this model, a mental or behavioral health professional may offer Natural Medicine Services as a part of their existing therapy or wellness practice (or any other type of business, with a few exceptions). These micro-Healing Centers, defined as those storing less than 750mg total psilocin, are subject to significantly reduced security and surveillance requirements. All Healing Centers must employ, or contract with, a DORA-licensed facilitator at all times.

Food and Beverages

During an Administration Session, Healing Centers may mix natural medicine with water, fruit juice, or pre-packaged items for the purpose of consumption. Participants may consume pre-packaged food and beverages, including fresh fruits and vegetables, during Administration Sessions. A Healing Center that is separately licensed under state and local food establishment requirements may provide prepared food before or after Administration Sessions.

Co-Location and Multi-Use Spaces

Healing Centers are expressly permitted to be co-located with health-care facilities, and are not prohibited from being co-located with other types of businesses. Additionally, flexible rules allow a Healing Center to be utilized for purposes other than Natural Medicine Services. Rules expressly permit Administration Areas to be used for other purposes when Regulated Natural Medicine is not present, and simply require that Regulated Natural Medicine be appropriately stored when a Natural Medicine Business is not operating. Additionally, a Natural Medicine Business may operate on the same parcel as a marijuana or alcohol license, so long the licensed premises of each license do not overlap. Rules permit co-location of Healing Centers with cultivation facilities, as well as manufacturing facilities that do not utilize hazardous or flammable substances.

Cultivation

Cultivation licensing reflects the same tiered approach in business models, offering multiple tiers for different business models. The standard cultivation tier may store up to 5 kilograms of dried, whole mushrooms at a time. Micro-cultivators may store up to 750 grams of dried whole mushrooms, sufficient for a small therapy practice or solo facilitator to cultivate their own Regulated Natural Medicine. Cultivators may petition for a ceiling higher than 5 kilograms upon a showing of a commercial need.

Manufacturing

A Natural Medicine Product Manufacturing license is required to produce any Regulated Natural Medicine Product, which includes anything other than whole, dried mushrooms. By default, a manufacturer may produce capsules and tea bags. Natural Medicine Product Manufacturers may receive an Extraction Endorsement, which permits production of chocolate, gummies, pressed tablets for oral consumption, as well as tinctures for sublingual administration.

Natural Medicine Testing Facilities

Natural Medicine Testing Facilities are expressly permitted to be co-located with marijuana testing facilities, allowing a laboratory to serve both the Natural Medicine and marijuana markets. Unfortunately, licensed Natural Medicine Testing Facilities are currently prohibited from testing unregulated Natural Medicine, however the Division has indicated it intends to address personal use testing at a later date. Natural Medicine Testing Facilities must be certified by the Colorado Department of Health and Environment as well as accredited in each test type the facility performs.

Required Testing

Potency Testing

Each Harvest Lot of cultivated Natural Medicine, or Production Batch of manufactured products, must be submitted for Tryptamine Content Analysis (colloquially, “potency testing”). Tryptamine Content Analysis must measure the levels of Psilocybin; Psilocin; Baeocystin; Aeruginascin; and Norbaeocystin. Each Harvest Lot or Production Batch must also be free of 4-AcO-DMT, a synthetic tryptamine often found in counterfeit or adulterated mushroom products.

Contaminant Testing

Testing for the biological contaminants salmonella and Shiga toxin producing *Escherichia coli* (STEC) must be conducted every 30 days. Testing for pesticides, heavy metals, or mycotoxins may be required by the Division on request.

Optional Testing

Natural Medicine Businesses may voluntarily conduct testing for heavy metals, pesticides, solvents, or mycotoxins. Natural Medicine Businesses may also conduct testing for the purposes of establishing shelf-stability, as well as for research and development.

Packaging and Labeling

Packaging and labeling restrictions are intended to prevent consumption by minors in the event of diversion, as well as misappropriation or commercialization of Indigenous culture. Colors, pictures, and cartoon images are prohibited from labels, as well as the words “candy” or “candies.” Regulated Natural Medicine and Regulated Natural Medicine Product intended for participant consumption must be packaged in child-resistant containers. Labels must include the following information:

- *Psilocybe cubensis* strain type;
- Net contents in dried weight of whole fruiting bodies, or total psilocin for manufactured products;
- Total Psilocin content in milligrams;
- Date tryptamine content analysis was performed;

- Harvest or production date;
- A statement that tryptamine content must be re-tested every nine months, unless an expiration date had been established;
- For Regulated Natural Medicine Product, any ingredients including allergens;
- Natural Medicine Business name and License number
- Harvest Lot and/or Production Lot number;
- A Drug Interaction Warning.

Marketing

As with packaging and labeling rules, marketing rules prohibit advertisements that appeal to minors or that appropriate Indigenous culture. Additionally, advertisements may not be false, misleading, or deceptive, and may not claim Natural Medicine is safe because it has been tested. Natural Medicine Businesses must maintain audience composition data to ensure advertisements do not target audiences under 21.

Transportation and Inventory Tracking

Natural Medicine Businesses are required to report all cultivation, production, destruction, and transfer of Regulated Natural Medicine, Regulated Natural Product, and Regulated Natural Medicine Waste each month. Only licensed individuals may transfer or transport natural medicine.

Enforcement and Penalties

Division rules establish procedures for investigation and enforcement of violations. Penalties include sanctions against the licensee, including suspension, revocation, restrictions, and monetary fines. Level I violations, the most severe, are those that have “an immediate or potential negative effect on public health, safety, or welfare.” Level I violations include adulteration of natural medicine, diversion, transfer to minors, mislabeling, and improperly releasing personally identifiable information of participants.

While these rules establish the pillars of Colorado’s program, the process remains ongoing. The Natural Medicine Division will hold a stakeholder engagement meeting related to proposed fees for Natural Medicine Businesses on August 28th, with a final hearing on September 16th. Already, the NMAB and regulators have identified areas where rules may need to be added or changed, as well as statutes that may need amending. As the Board continues to meet and make recommendations, stay tuned to this blog for updates, as well as future opportunities to help refine and improve the regulated program in Colorado.

Upcoming Public Engagement Opportunities

Subject	Regulating Agency	Meeting Type	Date	Public Opportunity
Application and Licensing Fees - Natural Medicine Businesses	DOR	Stakeholder Engagement	August 28th, 2024 3:00 p.m. - 5:00 p.m. MT	In-Person & Virtual
Application and Licensing Fees - Natural Medicine Businesses	DOR	Final Hearing	September 16th, 2024	In-Person & Virtual