Natural Medicine Advisory Bulletin 8.1 Recommendation Roundup

In January of 2024, following over 75 meetings over eight months, Colorado's Natural Medicine Advisory Board adopted 123 recommendations which will form the basis of the regulated natural medicine program approved by Colorado voters in November 2022. Ranging from highly specific prescriptions, such as testing facility accreditation standards, to broad considerations for regulators when drafting rules, these recommendations and their interactions form a complex web. Many recommendations contain multiple components, some touch on multiple aspects of the program, and others overlap with competing viewpoints from different subcommittees. Even for readers who have followed the recommendation process closely, a complete picture can be hard to discern from the consolidated recommendations.

In this article we've departed from discussing recommendations in a subcommittee-by-subcommittee fashion. Instead, we've organized recommendations by subject area to place them in context. ***We've also included commentary by Vicente LLP, indicated by italics, which do not necessarily reflect the views of Psychedelic Alpha.***

First, we'll look at what facilitators can expect, from licensing and training requirements to facilitator conduct. We then turn to recommendations related to the four natural medicine business licenses. We'll look at what cultivators and producers can expect, the overall testing regime and standards for testing facilities, recommendations impacting healing centers, and recommendations for licensed facilities generally. We'll then look at general recommendations directed to the natural medicine program and state authorities broadly. They include interpretive and legislative recommendations as well as recommendations aimed at ensuring an equitable program. Finally, we'll note any gaps in the recommendations and discuss what comes next as Colorado works to build out the second legal market for psychedelics in the United States while improving on the shortcomings of Oregon's program.

The Natural Medicine Advisory Board will meet again in full on February 16th, 2024, when regulators are expected to present the first round of draft rule language, based on the Board's recommendations.

Facilitator Licensing & Training

Facilitator License Types

The Board has recommended three primary facilitator licenses. All licenses will be renewed every two years. All licensed facilitators will be required to complete the following:

1. 150 hours of instruction.
2. Basic Life Support (BLS) Certification.
3. 40 hours of supervised practicum training in the facilitation of natural medicine.
4. 6 months of consultation with a supervisor.

Wellness Natural Medicine Facilitator

The *Wellness Natural Medicine Facilitator* license will be available to **any individual that does not hold a separate behavioral health health or medical license** in Colorado. License holders are prohibited from practicing medicine or psychotherapy as defined in Colorado statute. Additionally, Wellness license holders are prohibited from independently providing natural medicine services to participants with *active* diagnosis of serious mental or medical health risk factors,[1] unless the participant is directly referred or cleared by a professional licensed to treat the condition.

Natural Medicine Behavioral Health Facilitator

The *Natural Medicine Behavioral Health Facilitator* license will be available to individuals licensed in Colorado as a psychologist, social worker, clinical social worker, marriage and family therapist, licensed professional counselor, or addiction counselor. Behavioral Health License holders may provide psychotherapy, but may not practice medicine, within the bounds of their license in conjunction with natural medicine services. Behavioral Health license holders may provide natural medicine services to participants with active diagnosis of medical risk factors only in collaboration with, when directly referred by, or when cleared by, a professional licensed to treat the condition. Students working under a licensed Natural Medicine Behavioral Health Facilitator may provide natural medicine services. Behavioral Health facilitator license holders may collaborate with other licensed facilitators to provide natural medicine services to participants with mental health risk factors.

Natural Medicine Medical Facilitator

The *Natural Medicine Medical Facilitator* license will be available to individuals licensed in Colorado as a Medical Doctor (MD), Doctor of Osteopathic Medicine (DO), Nurse Practitioner (NP), or Physician's Associate (PA). License holders are permitted to provide natural medicine services for the treatment of mental health and medical disorders. Medical facilitator license holders may collaborate with other licensed facilitators to provide natural medicine services to participants with medical and mental health risk factors.

Additionally, the Board has recommended two ancillary licenses.

[1] Risk factors include cardiovascular disease, uncontrolled hypertension, diseases of the liver, seizure disorders, severe chronic medical illness, terminal illness, severe suicidal behavior (i.e., severe current suicidal ideation, current suicidal intent, a current plan for suicide), severe (PCL-5 score above 33) current PTSD, psychosis, schizophrenia, schizoaffective disorders, or Bipolar Disorder.

Training Natural Medicine Facilitator License

Wellness, Behavioral Health, and Medical Facilitator license applicants will be eligible for a Training license upon completion of all 150 hours of didactic education, 40 hours of practicum, and BLS certification. Training license holders may provide, and charge for, natural medicine services under the supervision of a fully-licensed facilitator and must demonstrate regular meetings with the supervisor. Training license holders must apply for full licensure within two years.

Distinguished Educator License

The Distinguished Educator License will be available to individuals with significant pre-existing facilitation experience. Distinguished Educator license applicants must be affiliated with an approved training program and may provide natural medicine services for the purposes of education and training. Applicants must submit a resume, 500-word biographical statement describing their qualifications and experience, and attestation of evidence indicating the instructor's skill.[2] Distinguished Educators may not independently provide natural medicine services or independently own or operate a healing center. Licensed Distinguished Educators must renew their license annually.

Facilitator Training Programs

Facilitator training programs must provide core training that consists of at least 150 hours of instruction, 40 hours of supervised facilitation experience (practicum), and 6 months of consultation with a supervisor. Instruction and consultation may be provided virtually, however the 40 hours of supervised practicum must occur in-person. Training programs must ensure that all educators and supervisors are licensed in Colorado as facilitators or distinguished educators.

Educational Instruction

The 150 hours of instruction must contain the following courses and hours:

- Facilitator Best Practices (5 hours)
- Ethics and Colorado Natural Medicine Rules and Regulations (25 hours)
- Relational Boundaries and Introduction to Physical Touch (10 hours)
- Physical and Mental Health and State (25 hours)
- Drug Effects, Contraindications, and Interactions (5 hours)
- Introduction to Trauma Informed Care (10 hours)
- Introduction to Suicide Risk (5 hours)
- Indigenous, Social, and Cultural Considerations (10 hours)
- Screening (5 hours)
- Preparation (10 hours)
- Administration (10 hours)

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[2] Evidence may include, but is not limited to, personal narratives, client references, community references, or professional references.

- Integration (10 hours)
- Group Facilitation (10 hours)
- Facilitator Development and Self-Care (10 hours)

Supervised Practice (Practicum)

The supervised practice, or practicum, is where facilitators-in-training will apply their new knowledge. Students must complete a minimum of 40 hours of supervised practice training, including at least 30 hours of direct practice (about 5 to 6 administration sessions) in which students directly experience, co-facilitate, or observe clients or trainees receiving psilocybin services or directly participate in alternative supervised practice activity as described in section (4), and at least 10 hours of consultation relating to the student's direct practice. Practicum programs must provide an opportunity to experience, facilitate, and observe the facilitation of non-ordinary states of consciousness. A practicum *may* include in-person training where students can experience, observe, and facilitate psilocybin services under the supervision of qualified training faculty. A practicum *may* include placement at a practicum site where students can observe and facilitate psilocybin services under the supervision of a practicum site supervisor, and Licensed Healing Centers may serve as supervised practice sites.[3] A practicum site must obtain written client consent prior to allowing a client to be observed by practicum students and prior to sharing any client information with practicum students or a training program.

Where supervised practice directly with psilocybin services is not available or accessible, supervised practice training may additionally include, but is not limited to, observation of taped facilitation sessions that were recorded with participants' consent, apprenticeship in a psychedelic peer support organization, role-playing, and experience with altered states of consciousness that are not drug-induced, for example, breathwork, meditation or spiritual journeys.

All supervised practice hours are required to be conducted in-person.

Consultation

Facilitators must complete a 6-month consultation period under the supervision of a licensed facilitator. During this period the facilitator-in-training must be actively involved in the delivery of natural medicine services and may charge for those services, provided they hold a Natural Medicine Training license. Consultation may be conducted virtually and in groups of up to 10 trainees. The consultation period must include case review and at least 10 hours of ethical training focused on issues that arise during the trainee's facilitation work. Both the supervisor and applicant must maintain documentation of consultation hours. Supervisors must evaluate the applicant in use of non-directive approach, relational boundaries and use of touch, cultural competence, non-ordinary states of consciousness, self-care, and ethics.

[3] Training programs using a healing center to satisfy the supervised practice requirement must also notify the regulatory authority.

Accelerated Training

Facilitators with significant natural medicine experience may apply for accelerated training. Accelerated training applicants must demonstrate completion of training equivalent to all required training modules[4] and experience helping with, or facilitating, at least 40 natural medicine administration sessions. Applicants must provide additional materials indicating the experience and skill of the instructor.[5] Applicants must also possess an active BLS certification. Accelerated training applicants **are not** exempted from the training on "Ethics and Colorado Natural Medicine Rules and Regulations."

Facilitator Conduct

Facilitators must also complete 40 hours of continuing education related to natural medicine service delivery every two years, including at least 5 hours of ethics training. Facilitators will be required to adhere to the Natural Medicine Facilitator Ethical Code and use a screening tool to determine the appropriate type of licensed facilitator for the participant's needs and requirements.[6] Facilitators will also be required to complete documentation for each participant, though exactly what that documentation will entail remains to be seen.

Facilitators must also adhere to an ethical code. The Board adopted the code in full, but added an addendum that they will seek to improve points E.4-E.13. These points deal with relational boundaries, and currently prohibit common practices in traditional and indigenous settings, such as providing natural medicine services to family members and consuming natural medicine during facilitation. *It is heartening to see the Board express intentions to modify these aspects of the code. Overall the ethical code is thorough, but was clearly drawn in large part from western medicine, with what appears to be a lack of understanding of how psychedelic healing takes place in the real world.*

The code of ethics defines seven principles which guide facilitator conduct: Beneficence and Nonmaleficence; Fiduciary Duties of Loyalty, Care, Confidentiality, and Professionalism; Misconduct and Responsibility for the Acts of Others; Competence; Autonomy, Dignity, Equity, Justice, and Respect; Special Considerations for Non-Ordinary States of Consciousness; and Use of Physical Touch. The document also prescribes a code of conduct. The following section summarizes key requirements of facilitator conduct.

Facilitators **must:**

- Utilize an informed consent process to ensure participants are aware of the risks of natural medicine and receive written consent for the use of supportive touch.

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[4] Either through a training program approved in Colorado or through alternative training.
[5] These materials may include, but are not limited to, personal narratives, client references, community references, or professional references.
[6] The screening tool should screen for general health, behavioral health & mental health, medical health, pharmacology (with special considerations for drug interactions), special considerations, e.g. disability needs, need for a service animal to be present, and spiritual or religious accommodations should be considered.

- Take reasonable efforts to ensure participant safety.
- Inform participants of the effects and risks of natural medicine.
- Utilize a screening tool that screens participants for risk factors.
- Return unconsumed natural medicine to a healing center.
- Allow a participant to elect either an additional person be present during an administration session, or that the administration session be recorded.
- Provide referrals if the facilitator terminates treatment.
- Acquire written consent for the use of supportive touch prior to administration.
- Allow a participant to revoke consent at any time.
- Complete the following documents for each participant: Demographic information; informed consent; preferred means of communication; transportation plan; fee arrangements; physical touch contract; participant safety and support; date, start, and end time for all sessions; information regarding the products and quantities of natural medicine products consumed during administration.
- Report witnessed misconduct.
- Refrain from engaging in natural medicine services if their personal life may interfere with their abilities to provide natural medicine services effectively.

Facilitators **may:**

- Handle, sell, or transfer natural medicine or natural medicine products in the provision of natural medicine services.
- Assist a participant with the *preparation* of natural medicine for ingestion.[7]
- Utilize supportive touch during an administration session, consistent with the physical touch contract.
- Accept non-monetary forms of remuneration for natural medicine services.

Facilitators **may NOT**:

- Permit participants to mix natural medicine with any items other than prepackaged food and beverages. *This recommendation is overly restrictive and would prohibit, for example, adding natural medicine into a smoothie or peanut butter sandwich.*
- Solicit testimonials from participants.[8] *This recommendation arose out of similar ethical rules in the psychotherapy field, though the exact justification for such a prohibition is unclear.*
- Make false, misleading, or deceptive statements.
- Disclose any participant records without written consent.
- Engage in romantic or sexual relationships with participants during the provision of natural medicine services.

[7] Preparation is defined as using a finished natural medicine product that consists only of fruiting bodies or powdered fruiting bodies to make ingestible products that only contain foods or inactive ingredients as defined by the FDA's inactive ingredient database.
[8] Testimonials are permitted, the prohibition only applies to *soliciting or requesting* participant testimonials.

- Engage in romantic or sexual relationships with participants, participants' partners, or participants' immediate family members for one year following the last date natural medicine services were provided to the participants.
- Provide facilitation services to a participant with whom they already have a romantic, sexual, or personal relationship; or someone who is related to someone whom they already have a romantic, sexual, or personal relationship with.*
- Consume or be under the influence of natural medicine during integration, administration, or preparation sessions.*

**These provisions were rightfully objected to by some members of the board because they do not reflect the longstanding reality of facilitators providing natural medicine to individuals they have personal relationships, such as family members, or the traditional indigenous practice of shamans and curanderos consuming natural medicine during ceremony. This practice is ubiquitous in ayahuasca ceremonies, and the current language applies to all natural medicine, which may include DMT (and thus, ayahuasca) at a later date.*

Group Facilitation

Under the current recommendations, group facilitation is permitted, but limited to a maximum of 64 participants and a 1:4 ratio of facilitators to participants. Several board members expressed reservations about this restriction. *Given that one of the main benefits of group facilitation is that it provides a more economical option than 1:1 facilitation, requiring a 1:4 ratio leaves much of the benefit on the table.*

Production, Cultivation, and Testing

The Products, Research, and Data subcommittee, which produced the following recommendations, relied heavily on outside experts in the form of non-voting participants in the development of their recommendations. Recognizing the limitations of their knowledge, many recommendations in this area take the form of giving a general direction to state regulators, while leaving the regulators significant discretion in the specific implementation. *Conversely, where the Board did make specific prescriptions in recommendations, they were often overly restrictive and based on fear of the unknown. Recommendations which restrict participants and facilitators from combining natural medicine with other ingredients, while targeted towards unsafe combinations, are overly broad and prohibitive. Banning common methods of extraction and limiting natural medicine products to only those which can be orally consumed effectively excludes many palliative care and end-of-life participants from realizing the benefits of natural medicine. It's disappointing to see the Board base their recommendations off of fear of the unknown rather than the reality of what is happening right now in the psychedelic healing ecosystem. If the regulators adopt these recommendations, the regulated program will be at a huge disadvantage compared to the unregulated community healing model.*

Cultivation

Like Oregon, Colorado will only permit *Psilocybe cubensis* to be cultivated and sold in the regulated market. All **strains** of *P. Cubensis* will be permitted, but no other species of psilocybin-containing mushroom will be permitted. *While there are arguments for allowing other species, this recommendation strikes the right balance, as other species are less well-studied and permitting them would inflate regulatory overhead.*

Only two other specific rule recommendations were made regarding cultivation. First, that pesticides and fungicides be prohibited during cultivation, but if the regulator chooses to permit them, they should be included on product labels. *Here the Board has made a sensible recommendation. Proper indoor mushroom cultivation should not require the use of chemical agents.* Second, only additives which "do not increase harm", such as inactive ingredients from the FDA's inactive ingredient database, or additives that encourage cultivation without increasing harm, should be permitted to be added to substrates. The Board deferred any additional rules regarding the specifics of cultivation to the Department of Revenue, including rules regarding allowable substrates. *Given that cultivating mushrooms by its very nature requires a high degree of cleanliness for success, regulators will hopefully avoid overly burdensome rules and direct their efforts towards a testing program that ensures the safety of natural medicine being sold.*

Electing not to recommend specific cultivation rules, the Board instead recommended that the FDA's Mushroom Good Agricultural Practices (MGAP) be recommended to cultivators as a **best practice** guide. O*verall, this is a sound recommendation that makes sense. While the MGAP standards are targeted to non-psychoactive food mushrooms, many aspects of mushroom cultivation are substantially similar across species and the standards will encourage safe, effective mushroom cultivation. Given that some requirements are only relevant to industrial-scale production, and would impose significant burdens on small-scale cultivators, not making them required is logical and reasonable. No need to reinvent the wheel at the expense of additional regulatory burdens.*

The Board did not take a specific stance on outdoor cultivation, recommending that if regulators choose to permit cultivation outdoors, the requirements set forth by regulators should reflect the inherent difficulties and safety risks involved. *Given the arid climate in most of Colorado, it will be interesting to watch if outdoor cultivation will be commercially successful in the state. If regulators do allow outdoor cultivation, they should take measures to ensure additional regulatory overhead does not inflate the overall cost of the program.*

Regarding storage of natural medicine, the Board recommended that cultivators should follow "best practices." Currently accepted best practices for the storage of psilocybin-containing products are to store them at room temperature in darkness and away from moisture or with devices to absorb moisture to improve the stability of the active ingredients in the products. This general recommendation reflects that current knowledge regarding psilocybin degradation is incomplete, and assumes that best practices will evolve as more studies are conducted.

Production

Recommendations regarding natural medicine-containing products were some of the most disappointing in the first round of recommendations. While the Board understandably wants to protect participants from unsafe and untested products, which was seen in the cannabis industry, the nature of the regulated natural medicine program is of a different type. Again, we see unfounded fear drive the recommendations and not a knowledge of the best practices utilized in the current psychedelic healing movement. With facilitators and healing centers serving as an intermediate check on products between producers and participants, there is room for sensible, measured introduction of new products. In this area, regulators will hopefully recognize this reality and make space for alternative products to meet the needs of all Coloradans. Otherwise everyone will be driven to continue to operate in the underground so they can utilize the medicines they prefer.

Extractions using solvents are effectively banned under the Board's recommendation with only water and fruit juice being permitted solvents. While this allows for some ultrasonic extractions and the common method of consuming mushrooms with citrus juice, *the recommendation is unnecessarily restrictive and based on fear*. In a similarly restrictive vein, products available in the regulated market shall be restricted to fruiting body mushrooms and powdered fruiting body mushrooms. Production of natural medicine products using solvent-free extractions will be required to follow Colorado food safety standards. *Here again, the Board's well-intentioned eye towards safety has hamstrung innovation in the natural medicine market, especially considering that the same goals could have been achieved through proper testing protocols. If these recommendations stand, the regulated market might not be viable.*

Additives that increase harm or intoxicating effects of natural medicine are prohibited. *This recommendation, while also well-intentioned, is unhelpfully vague. Regulators, or courts, will be left to determine what exactly increases "intoxicating effects." It is additionally problematic as many ingredients commonly used in microdosing protocols, for example niacin and lion's mane, may be prohibited under this recommendation.*

Arguably the most disappointing recommendation of all limits products in the natural medicine market to only those which may be orally ingested. While the recommendation does allow for alternative methods of consumption to be introduced, it would require peer-reviewed safety research before any new products may be introduced. *In addition to stifling innovation by imposing substantial costs of peer-reviewed studies on producers, this recommendation flies in the face of the voters who approved the Natural Medicine Health Act, which lists "end-of-life distress" in the legislative declaration as one of the many conditions natural medicine may alleviate.*[9] *Given that many individuals experiencing end-of-life distress are beset by conditions which prevent them from swallowing, this recommendation is both frustrating and heartbreaking to many Coloradans, and will surely contribute to a thriving underground market.*

[9] *See* C.R.S. § 12-170-102(1)(c).

Labeling of Products

Thankfully, product labeling remains relatively uncontroversial. Products sold in the regulated market will be labeled with the following information:

- Date of harvest.
- Actual content, in mg, of psilocybin and psilocin.
- Total psychoactive compound, expressed in terms of psilocin.[10]
- Date of potency test.
- Statement that the labeled potency reflects the maximum possible and that potency may decline over time.
- Best-by date, reflective of recent research regarding potency degradation.

Testing Program Framework

When it came to testing, the Board again relied heavily on the non-voting participants including several mycologists and professionals in the testing industry. Here, the overall testing regime is sensible and avoids undue burdens. Some specifics were left to regulators, which is arguably a good thing, given that DOR and CDPHE have the benefit of years of experience in building and refining the testing regime for the marijuana market in Colorado.

Potency testing will be required on each harvest batch and will measure actual psilocybin and psilocin content. A “harvest batch” is defined as all mushrooms harvested from a single flush of a single inoculation. For every 1 kg of dried, harvested mushrooms cultivated, 2.5g of dry material will be submitted for potency testing. Samples must represent the heterogeneity of the batch, including caps, stems and different sizes of mushroom. Potency retesting should occur every nine months for unused natural medicine and natural medicine products.[11] If, upon retesting, there is a *decrease* in potency of more than 15%, the product should be relabeled with the new maximum potency. If there is an *increase* in potency, the batch should be destroyed.

Species testing will be conducted randomly once per year through regular site visits by regulatory authorities. Testing for heavy metals, pesticides, solvents, microbials, and mycotoxins will be conducted randomly once per year through regular site visits by regulatory authorities. Failure of any of these tests will result in destruction of the sample and batch. Additionally, licensed cultivators *may* be required to work with the regulatory agency to develop a remediation plan and comply with said plan before submitting any additional products for testing. The regulator may impose additional testing for the failure of any test, at its discretion. In-house testing will be permitted, but not required.

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[10] Total potency in psilocin is calculated by summing the % psilocin with the % psilocybin multiplied by 0.719 (the multiplier places % psilocybin on the same scale as % psilocin).

[11] Or at an interval based on research on the degradation of potency over time.

Recommendations for Licensed Testing Facilities

Recommendations regarding accreditation and standards for licensed testing facilities are also likely to be uncontroversial. The Board recommended that licensed testing facilities should meet International Organization for Standardization (ISO) 17025 standards for lab testing or similar newly developed standards that are particularly relevant to the testing of natural medicines. The Department of Revenue, in collaboration with CDPHE, will develop a proficiency testing program for testing licenses. Due to the nascent nature of the natural medicine market and resulting lack of true 3rd-party proficiency tests, the initial proficiency testing program may consist of round-robin testing and subsequent annual testing.

The Board also recommended that licensed testing facilities be required to participate in proficiency testing provided by ISO 17043 accredited proficiency testing providers.[12]

Healing Centers & Licensed Premises

In total 56 recommendations related to facilities safety were adopted. The majority are substantially similar to Oregon Health Authority rules for Psilocybin Service Centers, which served as the starting point for the recommendations.

Healing Centers & Other Licensed Premises

The Board, through multiple subcommittees, urged regulators to create a path for facilitation to take place in participant homes as well as Authorized Location Other than Healing Centers. *Residential facilitation, which is specifically contemplated in Colorado statute, will be critical for ensuring access to natural medicine services. In-home facilitation will decrease costs, allow for flexible facilitation practices such as group facilitation, provide access for participants with palliative care, end-of-life, hospice, and disability-related needs.*

Taking cues from Oregon, the Board's facility recommendations differentiate between facilities generally and "administration areas" where natural medicine is consumed. The recommendations also allow for authorized locations other than healing centers ("Licensed Premises"). While the Board has yet to officially adopt recommendations for "Authorized Locations Other than Healing Centers," those recommendations are expected to be forthcoming shortly.

Administration of Natural Medicine

Licensed Healing Centers are permitted to assist a participant with the ***preparation*** of natural medicine for ingestion. "Preparation" is defined as using a finished natural medicine product that consists only of fruiting bodies or powdered fruiting bodies to make ingestible products that only contain foods or inactive ingredients as defined by the FDA's inactive ingredient database. *Like the companion recommendation for facilitators, this recommendation is overly restrictive and prohibits common forms of ingesting psilocybin.*

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[12] Or similar newly developed standards that are particularly relevant to the testing of natural medicines.

Natural medicine and natural medicine products must be transferred to participants in a designated administration area by a licensed facilitator or authorized personnel of a healing center. A licensed facilitator or authorized healing center personnel must observe participants consume natural medicine.

Safety & Facilities

The Board adopted a range of recommendations related to specific requirements for licensed facilities, however many of the specifics will be left to regulators.

Animals

Service animals ***must*** be permitted on licensed premises to the extent permitted by law. Emotional support animals ***may*** be permitted at the discretion of the licensee or licensed premises. Emotional support animals are not permitted in group facilitation.

Food

Any licensed premises selling food products (other than natural medicine products) must adhere to Colorado food handling regulations.

Storage & Transportation of Natural Medicine

Natural medicine and natural medicine products will be required to be stored in such a manner that the items are only accessible to licensee representatives, until such time as administration to the participant is completed.

Security Systems, Alarms, and Video Surveillance

Licensees or licensed premises must have a security alarm system which must be activated at all times when the licensed premises is closed for business. Licensees or licensed premises must also have a video surveillance recording system, which must cover, at a minimum, entrances as well as any areas where natural medicine is stored, produced, or destroyed.

Recording of Administration Sessions

Permanent installation of video recording equipment is **not permitted** in administration areas. If a client elects to have their session recorded, the facilitator or licensee must use portable equipment. Recording of administration sessions will require written consent of all participants and facilitators who will be recorded. Recordings must be securely stored for 3-5 years, documented, and viewable by participants on request, without charge.

Unaddressed Items & Open Questions

Despite over 300 hours of scheduled meetings, some subjects were not addressed in the initial batch of recommendations. Notably absent are specific recommendations regarding "Authorized Locations other than Healing Centers" and data collection, both subjects the Board is directly charged with. The Board did, however, recommend that regulators collect data on, and as soon as possible consider rules around, administration of natural medicine outside of authorized healing centers. Similarly, the Board recommended that regulators generally consider collecting data without making specific recommendations.

Also notably - and laudably - absent are recommendations prescribing dosing limits and administration session lengths. Microdosing advocates will be encouraged to know that there is no minimum administration length, and macrodosing advocates will celebrate a lack of upper limit. Ultimately, dosing and administration session length should be left to the facilitator's discretion and participant's needs.

Interpretive Recommendations and Considerations for Regulatory Authorities

In several instances the Board identified ambiguities in statutes and have recommended specific interpretations to regulators. First, the Board recommended that regulators interpret C.R.S. §§ 44-50-401 to 404 to explicitly allow cultivators and producers to sell or transfer natural medicine and natural medicine products to facilitators. Current statutory language neither authorizes nor prohibits transfer directly to facilitators, an ability that is seen by many as crucial to facilitator autonomy. Should regulators find their statutory authority lacking, the Board recommends the General Assembly address the ambiguity.

Similarly, the board urged regulators to interpret C.R.S. § 12-170-108(4), which permits unlicensed administration of natural medicine in the context of bona fide religious, culturally traditional, or spiritual ceremonies, broadly to allow remuneration in the regulated context.[13] This provision is separate from both the personal use provisions and the regulated market. In effect, the Board is hoping to allow something in between the two, where bona fide ceremonial facilitation can receive payment, without the requirement of licensure. This may also require legislative effort, if regulators find they lack authority to interpret the statute in such a manner.

A "Natural Medicine Sales Charge" was also recommended. This recommendation is necessary to support other recommendations, such as programs to expand equity and data collection efforts. Given the cash-fund requirements of the natural medicine program,[14] a funding source other than license and application fees is necessary to undertake any initiative without increasing fees. The Board recommended the general language of "charge" in an attempt to

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[13] C.R.S. § 12-170-108(4) "Nothing in this section prohibits an individual from performing a bona fide religious, culturally traditional, or spiritual ceremony, if the individual informs an individual engaging in the ceremony that the individual is not a licensed facilitator, and that the ceremony is not associated with commercial, business, or for-profit activity."

[14] In a cash-fund program, administration of the program must be funded purely through licensing and application fees. As a consequence, any additions to the program with fiscal impacts necessarily increase licensing and application costs.

avoid triggering TABOR laws,[15] though it is far from clear that this tactic is viable. *This recommendation is in line with the spirit of the Natural Medicine Health Act, which established a fund for natural medicine access but which was not included when legislators reworked the Act in SB23-290.*

Legislative Changes

The Board identified a need for statutory change regarding natural medicine testing facility licenses. Under current statute, holding both a Natural Medicine Testing Facility and a Marijuana Testing Facility license is prohibited. The Board has recommended that C.R.S § 44-50-301(4) be revised **to permit** testing facilities to hold both licenses due to concerns that the volume of natural medicine testing alone may not be sufficient to sustain a testing business. *This recommendation is in line with the original Natural Medicine Health Act. Given that there is neither a financial conflict of interest nor safety risk created by a lab testing both cannabis and natural medicine, we hope the legislature will correct this quickly.*

Inclusion of Diverse Perspectives & the Voice of the Indigenous Community

The Board adopted recommendations that regulators require the voice of underrepresented business leaders, facilitators, and the Federally Recognized American Tribes and Indigenous Community Working Group in decision making related to the natural medicine market. Additional recommendations urge regulators to consider Indigenous guidance, regenerative agriculture practices, commercial composting, and social equity in waste disposal regulations.

In addition to recommendations encouraging Indigenous voices in decision making generally, the Board also recommended two pathways for licensing indigenous facilitators. In one pathway, Indigenous facilitators would submit documentation of their experience and ability, mirroring the accelerated facilitator training pathway. In the second, the state would be required to create an inter-tribal council which would have the authority to approve members of their communities for licensure, thereby bypassing all facilitator training requirements.

Accessibility and Equity

The Board adopted a range of recommendations intended to expand equity when it comes to both accessing natural medicine services and licensure. Many of these recommendations are contingent upon funding, either via legislative appropriation or through a natural medicine sales charge. Several are accompanied by disclaimers that they should only be undertaken if feasible, or so long as they do not increase license costs. Recommendations of this variety include social equity licenses for facilitators and natural medicine businesses, social equity grant and loan programs, business mentorship programs, and free remote education.

The Board did, however, recommend several concrete actions that regulators can take at the outset of the program. First, the Board recommended that the State establish a clear

[15] The Taxpayer's Bill of Rights (TABOR) requires voter approval of any new tax in Colorado.

pathway for facilitators providing behavioral health services in conjunction with natural medicine services to bill the state Medicaid program for services that are already covered. *This provision is key to ensuring access to natural medicine services for the treatment of mental health disorders and is statutorily required by C.R.S. § 12-179-113(1)(c).* Second, the State should include a Health Equity Assessment in the annual report required under C.R.S. § 12-170-105(1)(j).[16] Third, the State should investigate and implement, as soon as feasible, a partnership with a payment processing application or other financial enterprise that permits licensees to pay licensing fees over a period of months or years while not delaying the State's receipt of full payment at or around the time licenses are awarded.

Fourth, the Board recommended two methods of increasing equity for natural medicine licensees.

1. **Facilitator Licensing Cost Differentials**: Based on proposed facilitator license types, [the state should] establish licensing cost differentials to expand facilitator license cost equity.[17]
2. **Social Equity Licenses**: [The state should] Allocate a percentage of total projected annual licenses for "social equity" candidates in light of state cash programs impacting license costs.[18]

Finally, the board recommended that regulators permit virtual supervision of group administration of natural medicine.[19] *This recommendation would both expand access to natural medicine services as well as increase the economic viability of the program, however a careful and nuanced approach is needed to ensure participant and facilitator safety.*

What's Next?

Now that the first round of recommendations has been officially adopted, the Department of Revenue (DOR) and the Department of Regulatory Agencies (DORA) will translate the Board's recommendations into the format of regulatory rules. Draft rules will be presented to the NMAB during monthly meetings, where the Board will have the opportunity to give feedback on regulators' proposed language. Draft rules will enter the official rulemaking process when regulators post notices of proposed rulemakings in the Colorado Register. At this point, the public will have its first meaningful opportunity to participate in the creation of the regulated

[16] This report should be undertaken only to the degree feasible without increasing licensing fees, in collaboration with community organizations, and leveraging available relevant resources. The report should assess access to Natural Medicine Services and licensure to participate in the delivery of such Services by underserved and marginalized communities, including those with below-average household income, those in or frontier rural areas, those with disabilities, indigenous peoples, racial and ethnic minorities, and those who identify as LGBTQIA+.

[17] Cost differential rules should include considerations for demographic, geographic, income, and protections against maneuvering.

[18] Social Equity licenses should not offset or increase the costs of licenses to candidates/applicants that do not meet the criteria of a "social equity" candidate.

[19] One facilitator should be required to be physically present during group administration.

natural medicine program by commenting on proposed rules in public hearings and written comments. Those comments will be presented to the Board for additional feedback and revision of rule language, possibly through multiple cycles. Once the language is satisfactory, regulators will publish notices of final rulemaking. After review by the Colorado Department of Law, rules will become effective upon publication on the Colorado Secretary of State website.

The Department of Regulatory Agencies has indicated it will prioritize rules related to facilitator training programs and facilitator licensure to account for the long lead time involved in setting up training programs. The Department of Revenue will prioritize subjects falling within its mandatory rulemaking responsibilities. Mandatory subjects for DOR include eligibility and licensing requirements, permitted financial interests of licensees, testing and labeling requirements, security and transportation, record-keeping, and advertising standards.[20] The shortest possible timeline from first publication of proposed rulemaking to effective rule is roughly 120 days, however given the many stakeholders and diverse perspectives likely to weigh in on proposed rules, the reality will likely be longer.

Concurrently with this process, the NMAB will continue to develop remaining recommendations needed to round out the program, such as requirements for "Authorized Locations Other than Healing Centers", data collection and reporting, and further incorporation of indigenous voices.

Regulatory authorities plan to post the first official notices of proposed rulemaking by late March, with a goal of having effective rules in place by October 2024. Prior to publishing rulemaking notices, the Department of Revenue will host two additional Listening Sessions (See our coverage of the most recent Listening Sessions). A catch-all meeting to revisit previously-covered topics and address any residual subjects will take place on Friday, February 23rd from 9am-12pm MST. The final Listening Session will occur on Monday, March 4th, from 1-3pm MST and focus on the Department's official duties, rulemaking priorities, and the rulemaking process generally.

The Natural Medicine Advisory Board will meet in full again on February 16th at 1pm MST, where regulators are anticipated to present the first round of draft rule language.

[20] *See* C.R.S. § 44-50-203(1).