

Natural Medicine Advisory Bulletin 10.5A

Summary of Natural Medicine Business Rules (No Comments)

Writer's note: This post covers the following happenings since Bulletin 10:

- Summary of draft rules released 03.13.2024 (Licensing & Financial Interests)
- Summary of draft rules released 04.04.2024 (General/Operational Rules)

License Types, Procedures, Qualifications, and Financial Interests

The Department of Revenue's ("DOR") Natural Medicine Division ("NMD") [first set of draft rules](#) focuses on the overall licensing framework for Natural Medicine Businesses. These rules establish qualification standards for licenses, as well as procedures for renewal, revocation, and appeal. They include several broad rules that apply to all four types of Natural Medicine Business, as well as rules related to permissible financial interests. Per Colorado statute, a person may not hold a financial interest in more than five natural medicine business licenses.¹ However, the statute leaves regulators to decide what qualifies as a financial interest falling within the restriction. Many sections, such as specific rules for the different types of Natural Medicine Businesses, are intentionally incomplete. The Division intends to flesh these sections out over the course of its upcoming work groups, where the Division will hear from stakeholders.

Even in their current form, these rules provide some insight into how the Division is approaching its rulemaking duties under the Natural Medicine Code ("NMC")², primarily in the overall licensing framework the Division is contemplating. Under the proposed structure, owners and employees (which includes facilitators) of Natural Medicine Businesses will require individual licenses, separate from the business license itself. Division officials have justified this additional license requirement as necessary to extend Division jurisdiction over the employees of the businesses it regulates.

A public hearing on these rules took place on March 20th, 2024, the Division's first *official* rulemaking hearing. Over the past several months, the NMD has held eleven informal "listening sessions," where interested members of the public could share any information and considerations for the Division to consider when drafting rules, before the drafting process began.

Having moved into formal rulemaking proceedings, the Division's latest round of hearings focus on discussing draft rules. Division officials requested that the public share what they like or dislike about a given rule, and welcomed suggested language changes. These hearings, also called "Work Groups", are more structured than the previous "Listening

¹ See C.R.S. § 44-50-203(1)(e) Directing the State Licensing Authority to define permissible and prohibited financial interests and prohibiting a person from holding a financial interest in more than five licenses.

² "Natural Medicine Code" refers to Article 50 of Colorado's Revised Statutes, which governs the regulated natural medicine program. See C.R.S. § 44-50-101.

Sessions.” Division officials begin with a brief presentation on a subset of draft rules, sharing high-level takeaways, sources upon which the Division drew when drafting the rules, and the intent behind the rules. The public is then invited to share feedback or ask questions, with each speaker allotted three minutes.

Thus far, the public has largely urged the Division to avoid overly broad and rigid rules, and to allow for a wide range of business arrangements, facility uses, and methods of natural medicine administration. Thankfully, Division staff have been receptive to feedback and continue to encourage public participation in the rulemaking process. Hopefully this process will lead to final rules that are flexible enough to ensure public safety while honoring the spirit of the Natural Medicine Health Act to provide Coloradans equitable access to the healing benefits of Natural Medicine.

License Types & Qualifications

Draft rules propose three types of licenses to be issued by the Division: Natural Medicine Business; Owner; and Employee. A Natural Medicine Business license is tied to a specific location, and will be issued to Healing Centers, testing facilities, product manufacturers, and cultivation facilities. All owners of a Natural Medicine Business will be required to obtain an “Owner license”, while any person who handles natural medicine or has unrestricted access to natural medicine in a Natural Medicine Business will be required to obtain an “Employee license.” This includes Facilitators, who will need to obtain a license from the NMD to work in, or own, a Healing Center.

Natural Medicine Businesses: General Qualifications for Application

All applicants for Natural Medicine Business licenses must be 21 or older, pay an application fee, be current on any taxes related to the Natural Medicine Business, and submit to a criminal background check. Applicants will be required to disclose the name and address of all owners who are natural persons. If an owner is an entity, the application must also include a certificate of good standing, information of the entity’s registered agent in Colorado, and organizational documents such as Articles of Incorporation, bylaws, operating agreements, or partnership agreements.

Colorado statute mandates that applicants undergo a criminal history background check, but leaves to regulators the discretion to determine which prior convictions would disqualify a person from licensure. Under current draft rules, the Division will not issue a license if a background check reveals previous history of violent, sexual, or fraud crimes; or of violating rules related to natural medicine after 2023.³

Disclosure of Owners and Financial Interests

All owners holding a financial interest in more than one Natural Medicine Business license must be disclosed, along with a statement that no owner holds, or will hold, an interest in more than five Natural Medicine Business licenses. Applicants must cooperate with the Division in providing tax documentation, upon request.

Facilities Requirements: All Licensed Natural Medicine Businesses

³ Disqualifying criminal history events are: A criminal sexual act; Criminal fraud or embezzlement; Aggravated assault; Aggravated abuse, neglect, or endangerment of a child or an at-risk person; Aggravated robbery; Arson; Manslaughter, homicide, or murder; A conviction for the unlawful possession, use, distribution, manufacturing, dispensing, or sale of any natural medicine related crimes after 2023.

All applications for a Natural Medicine Business License must provide documentation of the following:

- Possession, or entitlement to future possession, of the premises to be licensed;
- A security plan for the security/surveillance of the Licensed Premises;
- Compliance with local zoning laws;
- If a Healing Center, the location is not within 1000 feet of a child care center or school;
- The proposed location is not shared with an alcohol or marijuana license;

Note: Specific security requirements for licensed premises were released on April 4th, 2024, discussed in Part I.B., below.

Facilities Requirements: Healing Centers

Applicants for Healing Center licenses must additionally demonstrate:

- The applicant will employ, or contract with, at least one licensed facilitator.
- If the Healing Center will offer outdoor administration, a detailed description of outdoor administration areas, including their location and verification that the area is free from hazards as required in the security/surveillance plan, is also required.

Additional rules specific to healing centers are expected. The Division will host a work group focused on healing center-specific rules on May 1st, 2024.

Facilities Requirements: Cultivation and Product Manufacturer Licenses

This set of draft rules does not include specific facilities regulations for Cultivation and Product Manufacturing licenses. The Division will address Cultivation and Product Manufacturer Licenses in a specific rulemaking hearing on June 12, 2024.

Facilities Requirements: Testing Facility Licenses

Owners of Testing Facility Licenses may not hold a financial interest in **any** other Natural Medicine Business license type. The Division may require an inspection of testing facility premises, at no cost to the applicant. The Division will address additional questions related to testing facility licenses in a specific rulemaking hearing on June 24, 2024.

Employee and Owner Licenses

Separate from the licensing of the Natural Medicine Business itself, any owner or employee of a Natural Medicine Business must be individually licensed. Applicants for both Employee and Owner licenses must be older than twenty-one, submit to a fingerprint-based criminal background check, and pay licensing and application fees. Applicants may not currently be, nor have been in the previous six months, employed by a regulatory body overseeing the natural medicine industry in Colorado. Applicants must also be in compliance with any child support debts or payments, as required by state law⁴

Facilitators who will be working in any Natural Medicine Business, including Healing Centers, must obtain an Employee license, or Owner license if applicable.

⁴ See C.R.S. § 24-35-116(2) Requiring the Department of Revenue to revoke licenses for noncompliance with the Child Support Enforcement Act. See *also* C.R.S. § 26-13-126.

Owner License

Proposed owners of a Natural Medicine Business must obtain an Owner license from the Division. In addition to the above, applicants for an Owner license must be in compliance with any taxes related to a Natural Medicine Business.

Employee License

Individuals with “unrestricted access to the Licensed Premises of a Natural Medicine Business,” or who “handle Regulated Natural Medicine or Regulated Natural Medicine Product” will be required to obtain an Employee License from the Division of Natural Medicine.

Financial Interests

The Natural Medicine Code prohibits a person [including entities] from owning a “financial interest” in more than five Natural Medicine Business Licenses, but leaves to regulatory discretion what qualifies as a “financial interest” contributing to the five-license limitation..

Draft rules require applicants for Natural Medicine Business Licenses to disclose all “Owners” with “any financial interest” in the license, along with the following documents.

1. A real or personal property lease;
2. Secured or unsecured promissory notes;
3. Agreements with a Natural Medicine Business regarding intellectual property;
4. Management agreement(s) with the Natural Medicine Business; and
5. Insurance policy(ies) issued to the Natural Medicine Business.

The rules make clear that a single item on this list **does not, on its own**, constitute a financial interest for the purposes of restriction. However, if a combination of agreements “shift[s] the financial benefit or risk from the Owner to the person or persons with the agreements with the Natural Medicine Business,” the Department may find a restricting financial interest. Licensed businesses must maintain documentation of all funding sources and may not utilize funds generated by illegal activity.

Priority Review & Community Impact Plans

Regulators are required by statute to prioritize applications for Natural Medicine Business Licenses from applicants with established Colorado residency.⁵ Additionally, regulators must establish standards for environmental, social, and governance criteria.⁶ In addition to prioritizing applications from Colorado residents, current rules also allow prioritization of applications with one or more owners who have a traditional, tribal, or indigenous history with Natural Medicine; or are veterans. Priority review will also be granted to applicants with a Community Impact Plan showing the business will be located in or serving rural areas; offering discounted or free natural medicine services; or has in place substantial measures to minimize environmental impacts related to the natural medicine market.

⁵ C.R.S. § 44-50-102(2).

⁶ C.R.S. § 44-50-203(1)(n).

General Requirements: Operations and Facilities

On April 4th, 2024, the Division released a [second batch of draft rules](#), this time laying out a framework to govern the operations of Licensed Natural Medicine Businesses. Most of these rules are generally applicable to all Natural Medicine Businesses. They cover recordkeeping and reporting, co-location of licenses, security and video surveillance requirements, waste disposal and sanitation, transportation and storage, and zoning compliance. The rules also outline recall and embargo procedures for unsafe products.

Integral to this set of rules are definitions of “Licensed Premises,”⁷ “Restricted Area”⁸, and “Administration Area.”⁹ In short, “Licensed Premises” refers to an entire facility. A “Restricted Area” is any part of a Licensed Premises where natural medicine “is cultivated, manufactured, tested, or stored.” An “Administration Area” is an area of a Healing Center where participants will consume natural medicine and receive facilitation services.

General Restrictions

The draft rules contain four broad restrictions that apply to all Licensees. First, Licensees may not consume natural medicine on the licensed premises.¹⁰ Second, Natural Medicine Businesses **may not** be co-located with a licensed alcohol or marijuana business.¹¹ Third, licensees may not sell or give natural medicine to individuals. Finally, individuals under the age of twenty-one are completely prohibited from entering Licensed Premises and Administration Areas.

Business Records

Licensed Natural Medicine Businesses are required to maintain business records for the current and preceding calendar year. Licensees are not required to proactively provide business records to the NMD, however the most recent six month’s of records must be available on-demand, either physically on-premises or accessible electronically. Required records include information related to security and alarm systems, diagrams of the Licensed Premises including Restricted and Administration Areas, security plans, advertising, and license application records. Additionally, Licensees must maintain logs recording access to Restricted Areas,

⁷ “Licensed Premises” means the premises specified in an application for a license pursuant to this article 50 that the Licensee owns or is in possession of and within which the Licensee is authorized to cultivate, manufacture, test, store, distribute, transport, transfer, or dispense natural medicine or natural medicine product in accordance with the Natural Medicine Code.

⁸ “Restricted Area” means areas of a Licensed Premises where Regulated Natural Medicine is cultivated, manufactured, tested, or stored. Only Employee Licensees and Owner Licensees may access Restricted Areas without supervision or documenting access on a visitor log.

⁹ “Administration Area” means a designated and secured area within the Licensed Premises of a Healing Center where Regulated Natural Medicine and Regulated Natural Medicine Products may be transferred to a Participant, where a Participant may consume Regulated Natural Medicine and Regulated Natural Medicine Products, and where administration sessions may take place. No one under the age of twenty-one years old is permitted in an Administration Area and the Administration Area may not be part of the Restricted Area.

¹⁰ An exception is made if the Licensee is a participant in an Administration Session.

¹¹ The Colorado General Assembly is currently [considering a bill](#) that would permit co-location of Natural Medicine and Marijuana Testing Facilities, however current statutory language does not allow co-location of any Natural Medicine Business with a marijuana business. See C.R.S. § 44-50-301(4)(a).

waste disposal, and access to surveillance systems. Licensees will also be required to maintain “Participant and Administration Documents,” which have yet to be finalized.

Required Reporting

All Natural Medicine Businesses that learn of “Adverse Health Events” related to regulated natural medicine or natural medicine products are required to investigate and report the event to the Division within 48 hours. Licensees must also report crimes occurring on the Licensed Premises and any indication of diversion within 14 days.

Additional Required Reporting for Healing Centers

Healing Centers are subject to additional reporting requirements. Healing Centers must report Adverse Health Events within 24 hours. Healing Centers must additionally report incidents requiring emergency response, participants requiring medical attention, and any participant death that occurs within 30 days of receiving natural medicine services.

Co-Location of Natural Medicine Businesses

Draft rules permit multiple Natural Medicine Businesses with **identical owners** to share a location, subject to some restrictions. Testing facilities **may not** be co-located with any other license type. Healing Centers, but no other type of Natural Medicine Business, **may** be co-located with healthcare facilities.

Security Standards & Video Surveillance

This set of draft rules includes significant requirements which are intended to prevent theft or diversion of regulated natural medicine. The rules prescribe construction standards of Licensed Premises, alarm systems, and use of restricted storage areas for natural medicine. They also include extensive video surveillance rules, such as camera placements, equipment standards, recording storage and access, and maintenance.

These rules regarding security and video surveillance appear to draw heavily from MED rules. As written, rules apply to all Natural Medicine Businesses, and do not make allowances for Natural Medicine Businesses which may be located within larger structures that contain other businesses unrelated to natural medicine.

Waste & Disposal Of Natural Medicine

Waste products include cultivation and manufacturing byproducts, as well as unused natural medicine and natural medicine products. Cultivation and manufacturing byproducts, such as used substrates, must be disposed of in a manner that prevents spontaneous growth of mycelium or fruiting bodies after disposal. Other waste types, such as liquid and hazardous materials, must be disposed of in accordance with other applicable laws and regulations.

General Sanitary Requirements & Local Safety Inspections

Standard regulatory language requires Natural Medicine Businesses to take “Reasonable Measures and Precautions” regarding sanitation. Division rules require hand-washing and toilet facilities for employees in all Natural Medicine Businesses, and to participants in Healing Centers. Natural Medicine Businesses must also comply with local jurisdiction inspection and zoning requirements related to fire and safety.

Recall and Embargo Procedures

Cultivation and Manufacturing facilities must maintain written recall procedures. Recalls may be initiated voluntarily by licensees as well as at the request of the NMD. When there are “objective and reasonable” grounds for the NMD to believe there is an “imperative risk to public health or Participant well-being”, the NMD may issue an embargo and require immediate recall.

Transport and Storage Between Natural Medicine Businesses

Only licensed Employees or Owners may transport Natural Medicine and Natural Medicine Products. Natural medicine must be transported via a motor vehicle and secured in a locked enclosure that cannot be seen from outside the vehicle. The rules also require an extensive list of information that must be included on a transport manifest. Manifest information must be verified and logged as inventory upon receipt. Specifically, recipient businesses are charged with recording any discrepancies in the quantity of natural medicine received.

The public may continue to submit written comments on draft rules related to Natural Medicine Businesses by filling out the Division’s form [here](#).

As formal rulemaking approaches, there will be increasing opportunities for public engagement. Stay tuned to our Natural Medicine Advisory Bulletin for the latest news on Colorado’s natural medicine program, as well as upcoming opportunities to get involved. Also be sure to check DOR’s [rulemaking schedule](#) and DORA’s [public notice](#) pages for the most up-to-date information.

Upcoming Public Engagement Opportunities

Subject	Regulating Agency	Meeting Type	Date (Times in MST)	Public Opportunity
Facilitator Licensing & Training Programs	DORA	NA	Ongoing through May 3rd, 2024.	Submit written comments to dora_dpo_rulemaking@state.co.us .
Facilitator Standards of Practice & Advertising	DORA	Stakeholder Engagement	April 26, 2024 2:00 p.m.	Virtual Only Register Here .
Healing Center Requirements	DOR	Rulemaking Working Group	May 1, 2024 9:00 a.m. - 12:00 p.m.	Hybrid In-Person & Virtual

Facilitator Licensing & Training Programs	DORA	Final Rulemaking Hearing	May 3rd, 2024 9:30 a.m	Virtual Only Register Here.
Advertising, Packaging & Labeling, Recordkeeping Requirements	DOR	Rulemaking Working Group	May 22, 2024 1:00 p.m. - 4:00 p.m.	Hybrid In-Person & Virtual
Cultivation & Manufacturing Requirements	DOR	Rulemaking Working Group	June 12, 2024 9:00 a.m. - 5:00 p.m.	Virtual Only
Testing Requirements & Testing Facilities	DOR	Rulemaking Working Group	June 25, 2024 9:00 a.m. - 5:00 p.m.	Virtual Only
Fees, Enforcement, Discipline	DOR	Rulemaking Working Group	July 1, 2024 1:00 p.m. - 4:00 p.m.	Hybrid In-Person & Virtual
“Catch-All”	DOR	Rulemaking Working Group	July 9, 2024 9:00 a.m. - 5:00 p.m.	Virtual Only
All Natural Medicine Business Licenses	DOR	Final Rulemaking Hearing	July 25, 2024 9:00 a.m. - 5:00 p.m.	Hybrid In-Person & Virtual