DEPARTMENT OF REVENUE

Natural Medicine Division

COLORADO REGULATED NATURAL MEDICINE RULES

1 CCR 213-1

[Editor's Notes follow the text of the rules at the end of this CCR Document.]

Part 1 – General Applicability

Basis and Purpose – 1005

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(d), 44-50-203(2)(a), 44-50-203(2)(l), and 44-50-203(2)(r), C.R.S. This rule establishes the requirement that all Natural Medicine Licensees comply with the Natural Medicine Code and these Rules, as well as any applicable public health orders and executive orders, and that any reference to days in these Rules means calendar days, unless otherwise specified in statute or these Rules.

1005 – Applicability

A. All businesses, for the purposes of the cultivation, manufacturing, testing, storage, distribution, transport, transfer, and dispensation of Regulated Natural Medicine or Regulated Natural Medicine Product, as defined in the Natural Medicine Code at article 50 of title 44, are subject to the terms and conditions of the Natural Medicine Code and these Rules.

B. Public Health Orders and Executive Orders.

1. All Licensees, their agents, and their employees shall comply with any applicable public health orders issued by any agency of the State of Colorado including, but not limited to, the Colorado Department of Public Health and Environment.

2. All Licensees, their agents, and their employees, shall comply with any and all executive orders issued by the Governor pursuant to the Governor's disaster emergency powers under section 24-33.5-704, C.R.S.

3. A violation of this Rule by a Licensee, or by any of the agents or employees of a Licensee may result in disciplinary action up to and including license revocation and summary suspension pursuant to section 44-50-701, C.R.S., and these Rules.

C. Computation of Time. The word "days" as used in these Rules means calendar days, as provided by section 2-4-108, C.R.S.

Basis and Purpose – 1010

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(2)(l), 44-50-203(2)(r), and 44-50-904, C.R.S. The purpose of this rule is to clarify that each rule is independent of the others, and if one is found to be invalid, the remaining Rules will stay in effect. This will give the regulated community confidence in the Rules even if one is challenged.

1010 – Severability

If any portion of these Rules is found to be invalid, the remaining portion of the Rules shall remain in full force and effect.

Basis and Purpose – 1015

The statutory authority for this rule includes but is not limited to sections 24-4-105(11), 44-50-202(1)(b), 44-50-202(8), 44-50-203(2)(n), and 44-50-203(2)(r), C.R.S. The purpose of this rule is to establish a system by which a person may request the Division to issue a formal statement of position and, subsequently, petition the State Licensing Authority for a declaratory order. Typically, a position statement or declaratory order addresses matters that are likely to be applicable to other persons or licensees. The approach is similar to that utilized by other divisions within the Department of Revenue.

1015 – Statements of Position and Declaratory Orders

A. Statements of Position.

1. Requests. Any person defined in section 24-4-102(12), C.R.S., may request the Division issue a statement of position concerning the applicability to the petitioner of any provision of the Natural Medicine Code, or any regulation of the State Licensing Authority.

2. Division Response. The Division will determine, in its discretion, whether to respond to a request with a written statement of position. Following receipt of a written request in the manner determined by the Division, the Division will respond by issuing either a written statement of position or a notice declining to issue such a statement.

B. Declaratory Orders.

1. Petition for Declaratory Order. Any person who has properly requested a statement of position, and who is dissatisfied with the Division's response, may petition the State Licensing Authority for a declaratory order pursuant to section 24-4-105(11), C.R.S. The petition shall be filed within 30 days of the Division's response, or may be filed at any time before the Division's response if the Division has not responded within 60 days of receiving a proper request for a statement of position, and shall set forth the following:

a. The name and address of the petitioner.

b. Whether the petitioner is licensed pursuant to the Natural Medicine Code, and if so, the type of license and address of the Licensed Premises.

c. Whether the petitioner is involved in any pending administrative hearings before the State Licensing Authority or relevant local jurisdiction.

d. The statute, rule, or order to which the petition relates.

e. A concise statement of all of the facts necessary to show the nature of the controversy or the uncertainty as to the applicability to the petitioner of the statute, rule, or order to which the petition relates.

f. A concise statement of the legal authorities, if any, and such other reasons upon which petitioner relates.

g. A concise statement of the declaratory order the petitioner seeks.

2. State Licensing Authority Retains Discretion Whether to Entertain Petition. The State Licensing Authority will determine, in its discretion, whether to entertain any petition. If the State Licensing Authority decides it will not entertain a petition, it shall notify the petitioner in writing of its decision and the reasons for that decision. Any of the following grounds may be sufficient reason to refuse to entertain a petition:

    a. The petitioner failed to properly request a statement of position from the Division, or the petition for declaratory order was filed with the State Licensing Authority more than 30 days after the Division's response to the request for a statement of position.

    b. A ruling on the petition will not terminate the controversy nor remove uncertainties concerning the applicability to petitioner of the statute, rule, or order in question.

    c. The petition involves a subject, question, or issue that is relevant to a pending hearing before the State Licensing Authority or any Local Jurisdiction, an on-going investigation conducted by the Division, or a written complaint previously filed with the State Licensing Authority.

    d. The petition seeks a ruling on a moot or hypothetical question.

    e. The petitioner has some other adequate legal remedy, other than an action for declaratory relief pursuant to Colo. R. Civ. P. 57, which will terminate the controversy or remove any uncertainty concerning applicability of the statute, rule, or order.

3. State Licensing Authority May Adopt Division Position Statement. The State Licensing Authority may adopt the Division's statement of position as a Final Agency Order subject to judicial review pursuant to section 24-4-106, C.R.S.

4. If the State Licensing Authority Entertains a Petition for Declaratory Order. If the State Licensing Authority determines that it will entertain the petition for declaratory order, it shall so notify the petitioner within 30 days, and any of the following procedures may apply:

    a. The State Licensing Authority may expedite the matter by ruling on the basis of the facts and legal authority presented in the petition, or by requesting the petitioner or the Division submit additional evidence and legal argument in writing.

    b. In the event the State Licensing Authority determines that an evidentiary hearing is necessary to a ruling on the petition, a hearing shall be conducted in accordance with Rules 9025 – Administrative Hearings and 9030 – Administrative Hearing Appeals. The petitioner will be identified as Respondent.

    c. The parties to any proceeding pursuant to this Rule shall be the Respondent and the Division. Any other interested person may seek leave of the State Licensing Authority to intervene in the proceeding and such leave may be granted if the State Licensing Authority determines that such intervention will avoid unnecessary duplication of proceedings of a separate petition for declaratory order by the proposed intervenor.

    d. The declaratory order shall constitute a Final Agency Order subject to judicial review pursuant to section 24-4-106, C.R.S.

5. Public Inspection. Files of all requests, petitions, statements of position, and declaratory orders will be maintained by the Division. Except with respect to any material required by law to be kept confidential, such files shall be available for public inspection.

6. Posted on Division Website. The Division shall post a copy of all statements of position and all declaratory orders on the Division's website.

Basis and Purpose – 1020

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-202(3), 44-50-203(1)(b), 44-50-203(1)(k), 44-50-203(2)(o), and 44-50-203(2)(r), and 44-50-901(1)(e), C.R.S. The purpose of this rule is to clarify that law enforcement's authority to investigate and take any necessary action with regard to Natural Medicine Licensees remains unaffected by the Natural Medicine Code or these Rules.

1020 – Law Enforcement Authority Not Impaired by Natural Medicine Rules

Nothing in the Natural Medicine Code or any rules promulgated pursuant to it shall be construed to limit the ability of local police departments, sheriffs, or other state or local law enforcement agencies to investigate unlawful activity in relation to a Natural Medicine Business Licensee, Owner Licensee, or Natural Medicine Handler Licensee, and such agencies shall have the ability to run a Colorado Crime Information Center criminal history check of an Applicant or Licensee during an investigation of unlawful activity related to Regulated Natural Medicine, Regulated Natural Medicine Product, or a Natural Medicine Business.

Basis and Purpose – 1025

The statutory authority for this rule includes but is not limited to sections 44-50-103, 44-50-202(1)(b), 44-50-203(1)(d), 44-50-203(1)(n), 44-50-203(2)(a), 44-50-203(2)(g), and 44-50-203(2)(r), C.R.S. The purpose of this rule is to provide necessary definitions of terms used throughout the Rules. Defined terms are capitalized where they appear in the Rules to let the reader know to refer back to these definitions. When a term is used in a conventional sense, and is not intended to be a defined term, it is not capitalized.

1025 – Definitions

"Administration Area" means a designated and secured area within the Licensed Premises of a Healing Center where Regulated Natural Medicine and Regulated Natural Medicine Product may be stored and transferred to a Participant, where a Participant may consume Regulated Natural Medicine and Regulated Natural Medicine Product, and where Administration Sessions may take place. The Administration Area may not be part of the Restricted Area.

"Administration Session" means a session conducted at a Healing Center or another location as allowed by article 170 or article 50 of title 44 during which a participant consumes and experiences the effects of Regulated Natural Medicine or Regulated Natural Medicine Product under the supervision of a Facilitator.

“Adverse Health Event” means any untoward and unexpected health condition or medical occurrence associated with the use of natural medicine or natural medicine product. An adverse event or suspected adverse reaction is considered "life-threatening" if its occurrence places the participant at immediate risk of death. It does not include an adverse event or suspected adverse reaction that, had it occurred in a more severe form, might have caused death. An adverse event or suspected adverse reaction is considered "serious" if it results in any of the following outcomes: Death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

“Applicant” means an individual or entity that submitted an application under these rules and the Natural Medicine Code that was accepted by the Division for review but has not been approved or denied by the State Licensing Authority.

“Child Resistant” means special packaging that is:

i. Designed or constructed to be significantly difficult for children under five years of age to open and not difficult for normal adults to use properly as defined by 16 C.F.R. 1700.15 (1995) and 16 C.F.R. 1700.20 (1995). Note that this Rule does not include any later amendments or editions to the Code of Federal Regulations. The Division has maintained a copy of the applicable federal regulations, which is available to the public;

ii. Opaque so that the packaging does not allow the product to be seen without opening the packaging material; and

iii. Resealable for more than 5 grams of dried Fruiting Bodies if Regulated Natural Medicine or containing more than 10 milligrams of Total Psilocin if Regulated Natural Medicine Product.

This Rule definition does not include any later amendments or editions to the Code of Federal Regulations. The Division maintains copies of 16 C.F.R. 1700.15 (1995) and 16 C.F.R. 1700.20 (1995), at 1697 Cole Boulevard, Suite 200, Lakewood, Colorado, 80401, which are available to the public for inspection during the Division’s regular business hours.

“Code” means the Natural Medicine Code at sections 44-50-101, *et seq.*, C.R.S.

“Division” means the Department of Revenue Natural Medicine Division.

“Facilitator” means a natural person who is 21 years of age or older, has the necessary qualifications, training, experience, and knowledge to perform and supervise natural medicine services for a participant, and is licensed by the director of the division of professions and occupations to engage in the practice of facilitation.

“Final Agency Order” means an order of the State Licensing Authority issued in accordance with the Natural Medicine Code and the state Administrative Procedure Act. The State Licensing Authority will issue a Final Agency Order following review of the Initial Decision and any exceptions filed or at the conclusion of the declaratory order process. A Final Agency Order is subject to judicial review under section 24-4-106, C.R.S.

“Financial Interest” means entitlement or agreement to receive a portion of revenue, proceeds or profits from a Natural Medicine Business or a Natural Medicine Business Applicant; or a membership interest, partnership interest or other ownership interest, including but not limited to a share of stock, in a Natural Medicine Business or Natural Medicine Business Applicant.

“Fruiting Body(ies)” means the spore producing organs of the fungi *Psilocybe cubensis*.

“Harvest Lot” means a specifically identified quantity of Fruiting Bodies that is cultivated from the same Inoculation and dried under the same conditions and harvested in the same area within the Licensed Premises, that may be partially harvested, and may use the substrate material for multiple harvests. A Harvest Lot must not contain more than 1.000 kilogram by dry weight.

“Healing Center” means a facility where an entity is licensed by the State Licensing Authority pursuant to article 50 of title 44 that permits a Facilitator to provide and supervise Natural Medicine Services for a Participant.

"Inoculation" means the process by which spores or mycelium is introduced to a substrate for cultivation of fungus. Any Fruiting Bodies that are produced from the resulting colonized substrate will be considered the same Harvest Lot.

“License” means a license, permit, or registration pursuant to the Natural Medicine Code.

“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 Regulated Natural Medicine or Regulated Natural Medicine product in accordance with the Natural Medicine Code.

“Licensee” means a person licensed, registered, or permitted pursuant to the Natural Medicine Code or rules promulgated pursuant to article 50.

“Local Jurisdiction” means a county, municipality, or city and county.

“Mycelium” means the fungal threads or hyphae of *Psilocybe cubensis*.

“Natural Medicine” has the same meaning as in section 44-50-103(13), C.R.S.

“Natural Medicine Business” means any of the following entities licensed pursuant to the Natural Medicine Code:

i. A Healing Center;

ii. A Natural Medicine Cultivation Facility;

iii. A Natural Medicine Products Manufacturer;

iv. A Natural Medicine Testing Facility.

“Natural Medicine Cultivation Facility” means a location where Regulated Natural Medicine is grown, harvested, and prepared in order to be transferred and distributed to either a Healing Center, Facilitator, a Natural Medicine Products Manufacturer, or to another Natural Medicine Cultivation Facility.

"Natural Medicine Handler License" means a license issued by the State Licensing Authority pursuant to the Natural Medicine Code, to a natural person who is not an Owner. Any natural person who is not an Owner, who has unrestricted access to Regulated Natural Medicine or Regulated Natural Medicine Product or handles Regulated Natural Medicine or Regulated Natural Medicine Product must hold a Natural Medicine Handler License. For purposes of these Rules, handling Regulated Natural Medicine or Regulated Natural Medicine Product means the cultivation, manufacturing, testing, storage, distribution, transport, transfer, or dispensation of Regulated Natural Medicine and Regulated Natural Medicine Product.

"Natural Medicine Product" has the same meaning as in section 44-50-103(15), C.R.S.

"Natural Medicine Products Manufacturer" means a person who manufactures Regulated Natural Medicine Products for transfer to a Healing Center, Facilitator, or to another Natural Medicine Products Manufacturer.

"Natural Medicine Services" means a preparation session, administration session, and integration session as provided pursuant to article 170 of title 12.

"Natural Medicine Testing Facility" means a public or private laboratory licensed, or approved by the Division, to perform testing and research on Regulated Natural Medicine and Regulated Natural Medicine Product.

"Nonconformance" means a non-fulfillment of a requirement or departure from written procedures, work instructions, or quality system, as defined by the Licensee's written corrective action and preventive action (CAPA) procedures.

"Owner" means an individual or an entity that owns, possesses, or is entitled to any Financial Interest in a Natural Medicine Business or a Natural Medicine Business Applicant; an individual or an entity that owns a share of stock in a corporation, a membership in a nonprofit corporation, a membership interest in a limited liability company, the interest of a member in a cooperative or in a limited cooperative association, a partnership interest in a limited partnership, a partnership interest in a partnership, or the interest of a member in a limited partnership association that holds any interest in a Natural Medicine Business.

"Participant" means a person who is 21 years of age or older and who receives Natural Medicine Services performed by or under the supervision of a Facilitator.

"Production Lot" means psilocybin pressed tablets, tea bags, chocolate, gelatin- or agar- based gummies, or powdered capsules of the same type that were manufactured under the same conditions at the same time using the same manufacturing method, ingredients, and standard operating procedures.

"Regulated Natural Medicine" means Natural Medicine that is cultivated, manufactured, tested, stored, distributed, transported, transferred, or dispensed pursuant to the Natural Medicine Code. Regulated Natural Medicine includes:

i. Psilocybin; or

ii. Psilocin.

"Regulated Natural Medicine Product" means Natural Medicine product that is cultivated, manufactured, tested, stored, distributed, transported, transferred, or dispensed pursuant to the Natural Medicine Code.

"Regulated Natural Medicine Waste" means waste material that is:

i. A byproduct of cultivating Regulated Natural Medicine or manufacturing Regulated Natural Medicine Product that contains any Fruiting Bodies or mycelium from the cultivation or production process of psilocybin or psilocin;

ii. Partially consumed Regulated Natural Medicine Product, excluding client packaging;

iii. Psilocybin or psilocin product that a Natural Medicine Products Manufacturer, Healing Center or Testing Facility disposes; or

iv. Any psilocybin or psilocin product that is required to be designated as waste by these Rules.

"Restricted Area" means areas of Natural Medicine Cultivation Facilities, Natural Medicine Products Manufacturers, and Natural Medicine Testing Facilities where Regulated Natural Medicine or Regulated Natural Medicine Product is cultivated, manufactured, tested, or stored. Only Natural Medicine Handler Licensees and Owner Licensees may access Restricted Areas without supervision or documenting access on a visitor log. A Healing Center must have a Restricted Area, but a micro-Healing Center is not required to have a Restricted Area.

"Rules" mean these Colorado Regulated Natural Medicine Rules at 1 CCR 213-1.

"Sample" means a composite of Sample Increments collected from the same Harvest Lot or Production Lot and submitted for testing pursuant to Part 4 of these Rules.

"Sample Increment" means a portion of Regulated Natural Medicine that is removed from a Harvest Lot or Regulated Natural Medicine Product that is removed from a Production Lot and combined into a Sample for required testing under Part 4 of these Rules.

"State Licensing Authority" means the authority created for the purpose of regulating and controlling the licensing of the cultivation, manufacturing, testing, storage, distribution, transportation, transfer, and dispensation of Regulated Natural Medicine and Regulated Natural Medicine Product in Colorado pursuant to section 44-50-201, C.R.S.

"Total Psilocin" means psilocybin multiplied by 0.719 plus psilocin. Total Psilocin shall be expressed as a weight (i.e. mg Total Psilocin = (mg psilocybin x 0.719) + mg psilocin) or weight percent (i.e. % Total Psilocin = (% psilocybin x 0.719) + % psilocin).

"Unit" means a serving of no more than 10 milligrams of Total Psilocin.

Part 2 – Fees & Applications

Basis and Purpose – 2005

The statutory authority for this Rule includes but is not limited to sections 44-50-104(2), 44-50-202(1)(b), 44-50-203(1)(a), 44-50-203(1)(c), 44-50-203(2)(a), 44-50-601(2)-(3), and 44-50-602, C.R.S. The purpose of this Rule is to establish the schedule of fees required for applications, licenses, renewals, permits, or other fees associated with Natural Medicine License applications and submissions to the Division.

2005 – Fees

A. Initial Application and License Compliance Fees.

1. The following fees are effective until December 31, 2025.

License Type	Application Fee *Due at time of Application*	Compliance Fee *Due prior to License issuance*
Owner License	$250.00	$500.00
Natural Medicine Handler License	$100.00	$250.00
Facilitator-Owner	$0.00	$500.00
Facilitator-Handler	$0.00	$250.00
Micro Healing Center	$1,000.00	$2,000.00
Standard Healing Center	$1,000.00	$5,000.00
Natural Medicine Cultivation Facility *Micro-Cultivation*	$1,000.00	$2,000.00
Natural Medicine Cultivation Facility *Standard Cultivation*	$1,000.00	$4,000.00
Natural Medicine Products Manufacturer	$1,000.00	$3,000.00
Natural Medicine Products Manufacturer *Extraction Endorsement*	$1,000.00	$2,500.00
Natural Medicine Testing Facility	$1,000.00	$3,000.00

2. The following initial application and License compliance fees are effective beginning December 31, 2025.

License Type	Application Fee *Due at time of Application*	Compliance Fee *Due prior to License issuance*
Owner License	$500.00	$750.00
Natural Medicine Handler License	$100.00	$350.00
Facilitator-Owner	$0.00	$750.00
Facilitator-Handler	$0.00	$350.00
Micro Healing Center	$1,000.00	$3,000.00
Standard Healing Center	$1,000.00	$5,000.00
Natural Medicine Cultivation Facility *Micro-Cultivation*	$1,000.00	$5,000.00
Natural Medicine Cultivation	$1,000.00	$7,000.00

License Type	Application Fee *Due at time of Application*	Compliance Fee *Due prior to License issuance*
Facility *Standard Cultivation*		
Natural Medicine Products Manufacturer	$1,000.00	$7,000.00
Natural Medicine Products Manufacturer *Extraction Endorsement*	$1,000.00	$3,500.00
Natural Medicine Testing Facility	$1,000.00	$5,000.00

B. License Renewal Application and Annual License Compliance Fees.

1. The following license renewal application and annual License compliance fees are effective until December 31, 2026.

License Type	*Application Fee*	*Compliance Fee*	Total Due at Application
Owner License	$500.00	$750.00	$1,250.00
Natural Medicine Handler License	$100.00	$400.00	$500.00
Facilitator-Owner	$0.00	$750.00	$750.00
Facilitator-Handler	$0.00	$400.00	$400.00
Micro Healing Center	$1,000.00	$5,000.00	$6,000.00
Standard Healing Center	$1,000.00	$7,000.00	$8,000.00
Natural Medicine Cultivation Facility *Micro-Cultivation*	$1,000.00	$6,000.00	$7,000.00
Natural Medicine Cultivation Facility *Standard Cultivation*	$1,000.00	$7,000.00	$8,000.00
Natural Medicine Products Manufacturer	$1,000.00	$7,000.00	$8,000.00
Natural Medicine Products Manufacturer *Extraction Endorsement*	$0.00	$5,000.00	$5,000.00
Natural Medicine Testing Facility	$1,000.00	$5,000.00	$6,000.00

2. The following license renewal application and annual License compliance fees are effective December 31, 2026.

License Type	*Application Fee*	*Compliance Fee*	Total Due at Application
Owner License	$500.00	$1,000.00	$1,500.00
Natural Medicine Handler License	$100.00	$400.00	$500.00
Facilitator-Owner	$0.00	$1,000.00	$1,000.00
Facilitator-Handler	$0.00	$400.00	$400.00
Micro Healing Center	$2,000.00	$6,500.00	$8,500.00
Standard Healing Center	$2,000.00	$8,500.00	$10,500.00
Natural Medicine Cultivation Facility *Micro-Cultivation*	$2,000.00	$6,500.00	$8,500.00
Natural Medicine Cultivation Facility *Standard Cultivation*	$2,000.00	$9,000.00	$11,000.00
Natural Medicine Products Manufacturer	$2,000.00	$9,000.00	$11,000.00
Natural Medicine Products Manufacturer *Extraction Endorsement*	$0.00	$5,000.00	$5,000.00
Natural Medicine Testing Facility	$2,000.00	$7,000.00	$9,000.00

C. Other Fees.

Application Type	Total Due at Application
Changes in Ownership	$3,000.00
Duplicate Business License	$60.00
Duplicate Owner / Natural Medicine Handler License	$30.00
Reinstatement Fee	$370.00
Change of Location	$700.00

D. Cultivation Tier Changes - Application & License Compliance Fees.

1. The following fees apply to any applications to change the Natural Medicine Cultivation Facility's authorized cultivation tier.

Application Type	*Application Fee*	*Compliance Fee*	**Total Due at Application**
Natural Medicine Cultivation Facility - *Tier Increase*	$300.00	$1,500.00	$1,800.00
Natural Medicine Cultivation Facility - *Micro Tier Conversion*	$250.00	$1,500.00	$1,750.00

2. If an application to increase the Natural Medicine Cultivation Facility's cultivation tier is denied, the Licensee may request a refund of the Compliance Fee only.

E. When Fees Are Due. All fees in this Rule are due at the time the application or request is submitted to the Division or State Licensing Authority, except for Natural Medicine Business License compliance fees in subparagraphs (A) and (B), which are due upon conditional approval of the License.

F. Annual Fee Review. Pursuant to section 44-50-601, C.R.S., these fees will be reviewed at least annually, which may result in no change to the fees, increased fees, or decreased fees.

Basis and Purpose – 2105

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(b), 44-50-203(1)(d), 44-50-203(2)(a), 44-50-203(2)(l), and 44-50-203(2)(r), C.R.S. The purpose of this rule is to clarify the duties that Applicants and Licensees have when reporting to the State Licensing Authority information that is necessary for the issuance of a state license. These duties include but are not limited to reporting and keeping a current mailing and electronic address, cooperating with the State Licensing Authority and his or her employees, and notifying the State licensing Authority of any changes in the Licensee's registered agent in the State of Colorado. This rule further provides that all communications or notifications that the State Licensing Authority or Division send an Applicant or Licensee will be sent to the last known address. The Applicant or Licensee's failure to notify the Division of a change of address does not relieve the Applicant or Licensee from responding to any correspondence or notification.

2105 – Duties of All Applicants and Licensees

A. Duty to Keep Mailing Address Current: All Applicants and Licensees.

1. Timing of Notification. An Applicant or Licensee must provide a physical mailing address and an electronic mailing address to the Division. A Licensee must inform the Division in writing of any change to its physical mailing address and/or electronic mailing address within 28 days of the change. The Division will not change a Licensee's information without written notice from the Licensee or its authorized agent.

2. State Licensing Authority and Division Communications. The State Licensing Authority and Division will send any formal notifications or determinations regarding any application or an administrative action to the last physical mailing address and to the last electronic mailing address furnished to the Division by the Applicant or Licensee.

3. Failure to Change Address Does Not Relieve Applicant's or Licensee's Obligations. An Applicant's or Licensee's failure to notify the Division of a change of physical or electronic mailing address does not relieve the Applicant or Licensee from the obligation of responding to a Division communication or a State Licensing Authority communication.

B. Duty to Cooperate. Applicants and Licensees must cooperate in any investigation conducted by the Division. Failure to cooperate with a Division investigation may be grounds for denial of an application or for administrative action against a Licensee.

C. Duty to Report Change of Registered Agent. A Licensee must disclose any change of its registered agent in the State of Colorado within seven days of the change.

Basis and Purpose – 2110

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(a), 44-50-203(1)(c), and 44-50-301(1), C.R.S. The purpose of this rule is to establish requirements and processes for all applications for Natural Medicine Licenses.

2110 – General Application Requirements

A. Applicability. This Rule 2110 applies to all applications submitted to the Division for a license, permit, or registration provided by the Natural Medicine Code or these Rules.

B. Division Forms Required. All applications for licenses, registrations, or permits authorized by the Natural Medicine Code, must be made on current Division forms.

C. Application and License Fees Required.

1. Applications must be accompanied by full remittance of the required application fee, and license fee for Owner Licensees and Natural Medicine Handler Licensees. *See* Rule 2005.

2. Upon conditional approval of an application for a Natural Medicine Business, the Applicant must submit full remittance of the required license fee before the License will be issued and valid. A Licensee shall not operate prior to receiving the License certificate.

D. Complete, Accurate, and Truthful Applications Required. Applications must be complete, accurate, and truthful, and include all attachments and supplemental information. Incomplete applications may not be accepted by the Division.

E. Local Jurisdiction. An application for a Natural Medicine Business License must comply with Local Jurisdiction requirements.

F. Additional Information and Documents May Be Required.

1. Upon the Division's request, an Applicant must provide additional information or documents required to process and investigate the application. The additional information or documents must be provided within seven days of the request, however, this deadline may be extended for a period of time commensurate with the scope of the request.

2. An Applicant's failure to provide requested information or documents by the deadline may be grounds for denial of the application.

G. Application Forms Accessible. All application forms provided by the Division and filed by an Applicant for a license, registration, or permit, including attachments and any other documents associated with the investigation, may be used for a purpose authorized by the Natural Medicine Code, for investigation or enforcement of any international, federal, state, or local law, or regulation, for any other state or local law enforcement purpose, or as otherwise required by law.

Basis and Purpose – 2115

The statutory authority for this rule includes but is not limited to sections 44-50-104(2), 44-50-202(1)(b), 44-50-203(1)(a), 44-50-203(1)(d), 44-50-203(1)(n), 44-50-203(2)(r), and 44-50-301(2)(b), C.R.S. The purpose of this rule is to provide requirements and processes to obtain a Natural Medicine Handler License, which is required for any individual who has unrestricted access to or handles Regulated Natural Medicine or Regulated Natural Medicine Product.

2115 – Natural Medicine Handler Licenses: Initial Application Requirements

A. Natural Medicine Handler License Required. An individual who has unrestricted access to Regulated Natural Medicine or Regulated Natural Medicine Product or handles Regulated Natural Medicine or Regulated Natural Medicine Product must have a valid Natural Medicine Handler License issued by the Division under these Rules.

B. Application Requirements.

1. All Applicants for a Natural Medicine Handler License must meet the following criteria before receiving a License:

a. The Applicant must pay any application fees and license fees pursuant to Rule 2005;

b. The Applicant's name-based criminal history background check does not identify disqualifying events pursuant to Rule 2135;

c. The Applicant is at least 21 years of age;

d. The Division has not received notice that the Applicant has failed to comply with a court or administrative order for current child support, child support debt, retroactive child support, or child support arrearages. If the Division receives notice of the Applicant's noncompliance pursuant to sections 24-35-116 and 26-13-126, C.R.S., the application may be denied or delayed until the Applicant has established compliance with the order to the satisfaction of the state child support enforcement agency.

e. The Applicant establishes that he, she, or they are not an officer or employee of a Natural Medicine licensing authority in the state of Colorado; and

f. The Applicant establishes that he, she, or they were not a State Licensing Authority employee with regulatory oversight responsibilities for individuals or Natural Medicine Businesses licensed by the State Licensing Authority in the six months immediately preceding the date of the Applicant's application.

2. Facilitators. A Facilitator may obtain a Natural Medicine Handler License if he, she, or they intend to work in a Natural Medicine Business subject to the following requirements:

a. The Facilitator submits, on a form prescribed by the Division, information sufficient to demonstrate he, she, or they are currently licensed pursuant to article 170 of title 12; and

b. The Facilitator has passed a name-based criminal history background check.

C. Name-Based Criminal History Background Check. Applicants for a Natural Medicine Handler License must provide information establishing the Applicant is qualified to hold a Natural Medicine Handler License pursuant to Rule 2135, including but not limited to, a name-based criminal history background check.

D. A Natural Medicine Handler Licensee must be able to provide their License certificate and photo ID upon request.

Basis and Purpose – 2120

The statutory authority for this rule includes but is not limited to sections 44-50-104(2), 44-50-202(1)(b), 44-50-203(1)(a), 44-50-203(1)(d), 44-50-203(1)(n), 44-50-203(2)(r), and 44-50-301(2)(b), C.R.S. The purpose of this rule is to provide requirements and processes to obtain a Natural Medicine Owner License, which is required to own a Natural Medicine Business License. An Owner Licensee may exercise all the privileges of a Natural Medicine Handler License.

2120 – Owner Licenses: Initial Application Requirements

A. Owner License Required. All proposed Owners of a Natural Medicine Business must apply for and obtain an Owner License. An Owner Licensee may exercise all the privileges of a Natural Medicine Handler Licensee.

B. Application Requirements.

1. All Applicants for an Owner License must meet the following criteria before receiving a License:

a. The Applicant must pay any application fees and license fees pursuant to Rule 2005;

b. The Applicant's name-based criminal history background check does not identify disqualifying convictions pursuant to Rule 2135;

c. The Applicant is at least 21 years of age;

d. The Applicant has timely filed tax returns, timely paid all taxes, and timely cures any tax deficiencies related to a Natural Medicine Business;

e. The Division has not received notice that the Applicant has failed to comply with a court or administrative order for current child support, child support debt, retroactive child support, or child support arrearages. If the Division receives notice of the Applicant's noncompliance pursuant to sections 24-35-116 and 26-13-126, C.R.S., the application may be denied or delayed until the Applicant has established compliance with the order to the satisfaction of the state child support enforcement agency.

f. The Applicant establishes that he, she, or they are not an officer or employee of a Natural Medicine licensing authority in the state of Colorado; and

g. The Applicant establishes that he, she, or they were not a State Licensing Authority employee with regulatory oversight responsibilities for individuals or Natural Medicine Businesses licensed by the State Licensing Authority in the six months immediately preceding the date of the Applicant's application.

2. Facilitators. A Facilitator may obtain an Owner License if he, she, or they intend to own a Natural Medicine Business License subject to the following requirements:

    a. The Facilitator submits, on a form prescribed by the Division, information sufficient to demonstrate he, she, or they are currently licensed pursuant to article 170 of title 12; and

    b. The Facilitator has passed a name-based criminal history background check.

C. Name-Based Criminal History Background Check. Applicants for an Owner License must provide information establishing the Applicant is qualified to hold an Owner License pursuant to Rule 2135, including but not limited to, a name-based criminal history background check.

D. An Owner Licensee must be able to provide their License certificate and photo ID upon request.

Basis and Purpose – 2125

The statutory authority for this rule includes but is not limited to sections 44-50-104(2), 44-50-202(1)(b), 44-50-202(5), 44-50-203(1)(a), 44-50-203(1)(d), 44-50-203(1)(n), 44-50-203(2)(a), 44-50-203(2)(r), 44-50-301(2)(a), 44-50-302(1)-(2), 44-50-401, 44-50-402, 44-50-403, and 44-50-404, C.R.S. The purpose of this rule is to establish general requirements and processes for submitting initial applications for Natural Medicine Business Licenses to the Division and State Licensing Authority.

2125 – Natural Medicine Businesses: Initial Application Requirements

A. Natural Medicine Business Licenses. Initial applications for a Natural Medicine Business License must include the following:

1. Ownership Information. The application must include information about each proposed Owner including:

    a. The names and any required residency information for all proposed Owners of the Natural Medicine Business.

    b. If the Applicant or any of the proposed Owners is an entity:

        i. A certificate of good standing from the jurisdiction in which the entity was formed;

        ii. The identity and physical address of its registered agent in the state of Colorado;

        iii. Organizational documents, including but not limited to, articles of incorporation, by-laws, operating agreements, or partnership agreements.

    c. Identification of every Owner and each entity that holds a Financial Interest in the proposed Natural Medicine Business License and a statement that no proposed Owner holds or would hold more than five Natural Medicine Business Licenses.

2. Premises Information. The application must include information about the proposed Licensed Premises including:

a. Documents establishing the Applicant is, or will be, entitled to possession of the proposed Licensed Premises under a deed of trust, lease, rental agreement, or other arrangement for possession of the premises by virtue of ownership of the premises.

b. Documentation demonstrating that the address for the proposed Licensed Premises is permitted under the Local Jurisdiction's applicable zoning laws for the cultivation, manufacturing, testing, storage, distribution, transfer, or dispensation of Regulated Natural Medicine and Regulated Natural Medicine Product.

c. A diagram or map of the physical location for the proposed Licensed Premises demonstrating the proposed address for a Healing Center license is at least 1000 feet from a licensed child care center, preschool, elementary, middle, junior, or high school, or a residential child care facility, unless the location otherwise complies with section 44-50-302(1)(d)(I), C.R.S. This must be computed by direct measurement from the nearest property line of the land used for a school or facility to the nearest portion of the building in which the Healing Center is located, using a route of direct pedestrian access.

d. Secure facility information as required in Rule 3010, including the security/surveillance of the Licensed Premises the Licensee is or will be entitled to possess, and secure storage of Regulated Natural Medicine and Regulated Natural Medicine Product as required by Rules 3110 and 3115.

i. The security information must be provided in a portable document format (.pdf).

ii. A Healing Center must submit a security plan prior to operating and offering natural medicine services. *See* Rule 3110.

e. Confirmation that the proposed Licensed Premises for the Natural Medicine Business License is not the same licensed premises as a license or permit issued pursuant to articles 3, 4, 5, or 10 of title 44; except for Natural Medicine Testing Facility Licenses may be issued to the same licensed premises as a regulated marijuana testing facility licensed under article 10 of title 44.

f. If the proposed Licensed Premises will share a Licensed Premises with another Natural Medicine Business, the Applicant must demonstrate compliance with Rule 3105.

3. Tax Documents. While duplicate tax documentation is not required to be provided with the application, the Applicant shall cooperate with the Division to establish proof of timely compliant return filing, timely payment of taxes, and timely curing of any tax deficiencies related to a Natural Medicine Business.

4. Environmental, Social, and Governance (ESG) Criteria. Applicants must demonstrate minimum environmental and social impact criteria related to, from, or on an Applicant's proposed operations, as well as any governance policies, if applicable, related to it in accordance with this Rule. An Applicant's plan must include at least one of the categories listed below.

a. Environmental Impact Criteria. Applicants must propose a strategic, measurable, achievable, real, and time bound plan to incorporate principles of environmental resiliency or sustainability, including energy efficiency. The following are some, but by no means all, options:

i. Sustainable agricultural practices;

ii. Sourcing energy from renewable energy sources, and having all-electric appliances;

iii. Contributing to anti-pollution efforts, which could include but is not limited to the use of carbon off-sets or biodiversity credits;

iv. Using sustainable packaging;

v. Reducing plastic intake and engaging in recycling plans;

vi. Engaging in community trash clean-up efforts or sponsoring local environmental charities; or

vii. Other environmental practices that reflect resilience, sustainability, or are otherwise commonly accepted as positive environmental practices by a corporation.

b. Social Impact Criteria. Applicants must demonstrate a strategic, measurable, achievable, real and time bound plan to promote beneficial outcomes for Colorado and the Regulated Natural Medicine Program. The following are some, but by no means all, options:

i. Inclusive hiring and contracting plans;

ii. A plan for providing a livable wage;

iii. Adopting and supporting incubator or accelerator programs that seek to assist businesses that are indigenous owned, or owned by a member of a Federally Recognized American Tribe including providing:

A. grants or access to capital, including stewarding connections with funders or philanthropists;

B. workforce re-entry training or programming;

C. cultivation, manufacturing, or retail space;

D. management training or other forms of industry-specific technical training; or

E. mentorship from experts.

iv. Providing discounted or free services to historically underserved community members;

v. Providing indigenous benefit sharing and reciprocity, which is culturally understood within indigenous communities as “benefit honoring,” through a benefit honoring plan with indigenous or federally Recognized American Tribal communities that have historically worked with natural medicines, who have been keepers of traditional knowledge related to natural medicines or ceremonial healing; or who are local to Colorado;

vi. Recruiting, hiring, and implementing a development ladder for indigenous people, people from Federally Recognized American Tribes, or people from traditional communities that have connections to natural medicine;

vii. Recruiting, hiring, and implementing a development ladder for people from communities who have been disproportionately harmed by the war on drugs;

viii. Contributing to efforts seeking to repair harms from the war on drugs, harm reduction efforts, or similar programs;

ix. Hosting quarterly workforce education events led by indigenous cultural leaders; or

x. Other commonly accepted corporate social responsibility or social impact business practices.

c. Governance Criteria. If applicable, Applicants must demonstrate plans addressing corporate governance. The following are some, but by no means all, options:

i. The board of directors of the Natural Medicine Business has gender equality, and is composed of members of diverse backgrounds, including people from communities disproportionately harmed by high rates of arrest for controlled substances, persons who have traditional tribal, or indigenous history with natural medicine, or veterans;

ii. The board of directors of the Natural Medicine Business has transparent decision-making processes, by hosting regular company-wide meetings or otherwise having policies that promote transparency to its employees, and avoids board related conflicts of interest;

iii. The board of directors discloses their political contributions and lobbying to avoid the appearance of bribery or corruption;

iv. Registering as a non-profit or benefits corporation that benefits members of historically underserved or indigenous communities;

v. The Applicant has an indigenous-led trust that receives some profits of the Applicant wherein three of the five directors are from federally recognized American tribes, or people from traditional communities that have connections to natural medicine;

vi. Other commonly accepted good governance practices.

d. All ESG plans that are included in the application shall be made publicly available by the Licensee by publication on their website, or otherwise posting it in a location where it can be seen by the public.

5. Healing Center License Applications. An application for a Healing Center License must also include the following information:

a. Information demonstrating the Applicant will employ or contract with at least one Facilitator licensed pursuant to article 170 of title 12.

b. For Healing Centers whose proposed Licensed Premises includes outdoor administration areas, a detailed description of the outdoor administration areas, including identification of access points, and verification that the area is free from hazards as required in the security/surveillance plan in Rule 3110 and Part 8 of these Rules (Rules 8005 - 8030).

6. Natural Medicine Cultivation Facility License Applications.

a. Cultivation Tier Selection. An Applicant for a Natural Medicine Cultivation Facility License must indicate on the application if they are applying for the:

i. Micro-cultivation tier; or

ii. Standard cultivation tier

7. Natural Medicine Product Manufacturer License Applications.

a. Extraction Endorsement. An Applicant for a Natural Medicine Products Manufacturer License seeking to obtain an extraction endorsement must also include in the application:

i. The extraction endorsement fee;

ii. Documentation demonstrating the Applicant has or will take necessary steps to comply with the requirements in Part 6 of these Rules.

8. Natural Medicine Testing Facility License Applications. An Owner of a Natural Medicine Testing Facility may not hold any Financial Interest in a Healing Center, a Natural Medicine Cultivation Facility, or a Natural Medicine Products Manufacturer.

B. Application review.

1. Once the Division has determined that an application is complete, it must review the application to determine compliance with the Natural Medicine Code and these Rules.

2. The Division may require an inspection of the premises proposed to be licensed prior to issuing a license. There is no fee for inspections performed under this section.

C. Priority Review. In addition to the priority provided by section 44-50-104(2), C.R.S., the Division may prioritize Natural Medicine Business License applications that:

1. Identify one or more proposed Owners with at least 51% ownership in the License who have a traditional, tribal, or indigenous history with Natural Medicine, verified by at least three community references;

2. Identify one or more Owners who are veterans; or

3. Indicate the Natural Medicine Business will be located in a county other than Adams, Arapahoe, Boulder, Denver, Douglas, El Paso, Jefferson, Larimer, Pueblo, or Weld.

D. Any other forms, documents, and information required by the Division to evaluate the License application.

Basis and Purpose – 2130

The statutory authority for this rule includes but is not limited to sections 44-50-104(2), 44-50-202(1)(b), 44-50-203(1)(a), 44-50-203(1)(b), 44-50-203(1)(c), 44-50-203(1)(d), 44-50-203(2)(a), and 44-50-302(1)-(2), C.R.S. The purpose of this rule is to establish license renewal application requirements for a Licensee to renew their license with the Division and State Licensing Authority, including the circumstances under which an expired license may be reinstated.

2130 – License Renewal Application Requirements

A. License Periods.

1. All Natural Medicine Business Licenses are valid for one year from the date of issuance.

2. All Owner Licenses are valid for one year from the date of issuance.

3. All Natural Medicine Handler Licenses are valid for one year from the date of issuance.

B. Division Notice Prior to Expiration.

1. The Division will send a notice of License renewal 90 days prior to the expiration of an existing License to the electronic mail address on file, unless the Licensee requests first class mail to the physical address of record.

2. Failure to receive the Division notification does not relieve the Licensee of the obligation to timely renew a license.

C. Renewal Deadline.

1. A Licensee must apply for the renewal of an existing License prior to the License's expiration date.

2. A renewal application submitted to the Division prior to the License's expiration date shall be deemed timely pursuant to section 24-4-104(7), C.R.S., and the Licensee may continue to operate until Final Agency Order on the renewal application.

D. If License Not Renewed Before Expiration. A License is immediately invalid upon expiration if the Licensee has not filed a renewal application and remitted all of the required application and license fees prior to the license expiration date. Natural Medicine Handler Licensees and Owner Licensees whose License expires must reapply for a new License. A Natural Medicine Business that fails to file a renewal application and remit all required application and license fees prior to the License expiration date must not operate until the State Licensing Authority issues a new License pursuant to Rule 2115.

1. Reinstatement of Expired Natural Medicine Business License. A Natural Medicine Business that fails to file a renewal application and remit all required application and license fees prior to the License expiration date may request that the State Licensing Authority reinstate an expired License only in accordance with the following:

    a. The Natural Medicine Business License expired within the previous 30 days;

    b. The Natural Medicine Business License has submitted an initial application pursuant to Rule 2110. The initial application must be submitted prior to, or concurrently with, the request for reinstatement; and

    c. The Natural Medicine Business has paid the reinstatement fee in Rule 2005.

2. Reinstatement Not Available. The Division will not accept a request for reinstatement for:

    a. A Natural Medicine Business License that was surrendered or revoked;

    b. An Owner License, regardless of whether expired, surrendered, or revoked; or

    c. A Natural Medicine Handler License, regardless of whether expired, surrendered, or revoked.

3. Denial of Request for Reinstatement or Administrative Action. If the Licensee requesting reinstatement of a Natural Medicine Business License operated during a period that the License was expired, the request may be subject to denial and the Licensee may be subject to administrative action as authorized by the Natural Medicine Code or these Rules.

4. Approval of Request for Reinstatement. Upon approval of any request for reinstatement of an expired Natural Medicine Business License, the Licensee may resume operations until the agency action on the Licensee's initial application for a Natural Medicine Business License.

    a. Approval of a request for reinstatement of an expired Natural Medicine Business License does not guarantee approval of the Natural Medicine Business Licensee's initial application; and

    b. Approval of a request for reinstatement of an expired License does not waive the State Licensing Authority's authority to pursue administrative action on the expired License or initial application for a Natural Medicine Business License.

5. Final Agency Order on Initial Application for Natural Medicine Business License.

    a. If the initial application for a Natural Medicine Business License submitted pursuant to this Rule is approved, the new Natural Medicine Business License will replace the reinstated License.

    b. If the initial application for a Natural Medicine Business License submitted pursuant to this Rule is denied, the Licensee must immediately cease all operations including but not limited, transfer of Regulated Natural Medicine and Regulated Natural Medicine Product.

E. Voluntarily Surrendered or Revoked Licenses Not Eligible for Renewal. Any License that was voluntarily surrendered or that was revoked by a Final Agency Order is not eligible for renewal. Any Licensee who voluntarily surrendered its License or has had its License revoked by a Final Agency Order may submit an initial application for a new License in accordance with these Rules and any terms of the Final Agency Order. The State Licensing Authority will consider the voluntary surrender or the Final Agency Order and all related facts and circumstances in determining approval of any subsequent initial application.

F. Licenses Subject to Ongoing Administrative Action. Licenses subject to an administrative action are subject to the requirements of this Rule. Licenses that are not timely renewed expire and cannot be renewed.

G. Natural Medicine Handler License & Owner License Renewal Process.

1. Upon submission of a Natural Medicine Handler License renewal application or an Owner License renewal application, the Applicant must demonstrate:

    a. The Applicant has not failed to comply with a court or administrative order for current child support, child support debt, retroactive child support, or child support arrearages. If the Division receives notice of the Applicant's noncompliance pursuant to sections 24-35-116 and 26-13-126, C.R.S., the application may be denied or delayed until the Applicant has established compliance with the order to the satisfaction of the state child support enforcement agency.

    b. The Applicant is qualified to hold a License in accordance with Rule 2140.

2. An Owner Licensee must also demonstrate they he, she, or they have timely filed tax returns, timely paid all taxes, and timely cures any tax deficiencies related to a Natural Medicine Business

H. Natural Medicine Business - Documents Required at Renewal. A Natural Medicine Business must provide the following documents with every renewal application:

1. Any document required by Rules 2125 and 2140 that has changed since the document was last submitted to the Division;

2. A copy of complete and accurate floor plans, if they changed since initial submission required in Rules 5005, 6005, 7005, and 8005.

3. Confirmation that the Applicant is complying with all Local Jurisdiction requirements;

4. A list of any sanctions, penalties, assessments, or cease and desist orders imposed by any regulatory agency or Local Jurisdiction;

5. Any document required by Rule 5005 or 5015 regarding a Natural Medicine Cultivation Facility's cultivation tier.

6. A Healing Center Licensee must submit Administration Session logs required in Rule 8035(C) at each renewal.

7. A Natural Medicine Business operating under a single entity name with more than one License may submit the following documents only once each calendar year on the first License renewal in lieu of submission with every License renewal in the same calendar year:

a. Tax documents and financial statements required by Rule 2125;

b. Documentation of all financial interests that are required to be disclosed by Rule 2140.

8. A Natural Medicine Business shall, as a component of a renewal application, submit a status update to their ESG criteria, documenting any ESG accomplishments, initiatives, or metrics. In addition, licensees should detail any changes in their plans and strategic, measurable, achievable, realistic and time bound (SMART) goals concerning the Licensee's ESG criteria for the forthcoming renewal period. Failure to submit a status update to an ESG criteria could result in license recission or renewal denial.

Basis and Purpose – 2135

The statutory authority for this rule includes but is not limited to sections 44-50-104(2), 44-50-202(1)(b), 44-50-203(1)(b), 44-50-203(1)(d), 44-50-203(1)(e), 44-50-203(1)(n), 44-50-203(2)(a), and 44-50-203(2)(l), C.R.S. The purpose of this rule is to provide clarity on disqualifying factors that may result in the denial of an Applicant's Natural Medicine Handler or Owner License application.

2135 – Licensure Qualifications

A. A License provided by this article shall not be issued to or held by:

1. A person until the fee therefore has been paid;

2. An individual whose criminal history, as described in subparagraph B of this Rule, indicates that he, she, or they should not hold a license;

3. An entity other than an individual if the criminal history of any of its Owners, as described in subparagraph B of this Rule, indicates that an Owner should not hold a license;

4. A person under 21 years of age;

5. A person licensed pursuant to the Natural Medicine Code who, during a period of licensure, or who, at the time of application, has failed to:

a. Timely file any tax return with a taxing agency related to a Natural Medicine Business;

b. Timely pay any taxes, interest, or penalties due as determined by final agency action related to a Natural Medicine Business; or

c. Timely cure any tax deficiencies related to a Natural Medicine Business.

6. A person who fails to meet qualifications for licensure that directly and demonstrably relate to the operation of a Natural Medicine Business;

7. A publicly traded company;

8. A person the State Licensing Authority has determined the Applicant willfully disregarded regulatory warnings or actions related to unlawful marketing, manufacturing, or sale of Natural Medicine or has been ordered by a Court to discontinue unlawful marketing, manufacturing, or sale of Natural Medicine;

9. A person against whom there is evidence of commercial sale or advertising the commercial sale of Natural Medicine or Natural Medicine Product; or

10. A person who previously held a license from either the Department of Revenue or the Division of Professions and Occupations that has been denied or revoked in the previous three years.

B. Criminal History. A License may not be issued to or held by an individual who has been convicted of a felony in the preceding 3 years, or is subject to a sentence for a felony conviction, or is subject to a deferred judgment or sentence for a felony conviction, for any of the following charges:

1. A criminal sexual act;

2. Criminal fraud or embezzlement;

3. Aggravated assault;

4. Aggravated abuse, neglect, or endangerment of a child or an at-risk person;

5. Aggravated robbery;

6. Arson;

7. Manslaughter, homicide, or murder;

8. A violation of the Racketeer Influenced and Corrupt Organizations Act (RICO) or Colorado Organized Crime Control Act (COCCA); or

9. A conviction for the unlawful manufacturing with an inherently dangerous substance or commercial sale of any Natural Medicine related conduct after 2023.

Basis and Purpose – 2140

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(a), 44-50-203(1)(b), 44-50-203(1)(d), 44-50-203(1)(e), 44-50-203(1)(n), 44-50-203(2)(a), 44-50-203(2)(l), 44-50-203(2)(q), and 44-50-203(2)(r), C.R.S. The purpose of this rule is to comply with the statutory prohibition on a person having a financial interest in more than five Natural Medicine Business Licenses. This rule identifies disclosures that are required by Natural Medicine Businesses to determine compliance with the statutory limitation on the number of licenses that an individual can have a financial interest in.

2140 – Disclosure of Financial Interests and Owners of Natural Medicine Business License

A. An Applicant for a Natural Medicine Business License must disclose all Owners with any Financial Interest in each initial, renewal, and change of ownership application. Failure to accurately disclose all Owners of a Natural Medicine Business may result in denial of an application or administrative action against the License.

B. An Applicant for a Natural Medicine Business License must also disclose the following agreements to the Division with each initial application. The Natural Medicine Business shall also disclose each of the following to the Division with each renewal application if the agreement has not previously been disclosed or has changed since the last application. The following agreements do not necessarily constitute a Financial Interest for purposes of the number of Natural Medicine Businesses a person holds:

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.

C. A combination of the agreements identified in subparagraph B above may result in a person having a Financial Interest in a Natural Medicine Business if the agreements shift the financial benefit or risk from the Owner to the person or persons with the agreements with the Natural Medicine Business.

D. A Natural Medicine Business must maintain documents identifying the source of all funds invested into a Natural Medicine Business. Natural Medicines Businesses shall not accept nor utilize any funds that are from activity that is not lawful under the Natural Medicine Code.

E. An Owner shall not have a Financial Interest in more than five Natural Medicine Business Licenses. An application may be denied or a License may be subject to administrative discipline where an Owner possesses or would possess a Financial Interest in more than five Natural Medicine Business Licenses.

Basis and Purpose – 2145

The statutory authority for this rule includes but is not limited to sections 44-50-104(2), 44-50-202(1)(b), 44-50-203(1)(a), 44-50-203(1)(b), 44-50-203(1)(d), 44-50-203(2)(a), and 44-50-302(1)-(2), C.R.S. The purpose of this rule is to establish the application process and conditions an Applicant or Licensee must meet for a change in ownership of a Natural Medicine Business.

2145 – Change of Ownership Applications

A. General Requirements.

1. A Natural Medicine Business shall provide a notice with its next renewal application that identifies any transfer of interests between existing Owner Licensees of that Natural Medicine Business. A Natural Medicine Business shall also provide notice with its next renewal application that identifies any Owner Licensee of less than 100% of the Natural Medicine Business that has been removed from the Natural Medicine Business. The addition of, or the transfer of any of the interests to, an Owner Licensee who is not an existing Owner Licensee of the Natural Medicine Business requires Division approval prior to transferring any interest in a Natural Medicine Business.

2. A proposed Owner cannot operate the Natural Medicine Business for which it intends to become an Owner until it receives all approvals and/or License(s) pursuant to any change of owner application required by this Rule. An Owner that already holds an Owner License and has been approved in connection with the Natural Medicine Business may continue to operate the Natural Medicine Business while the change of owner application is pending. A violation of this requirement is grounds for denial of the change of owner application and may result in disciplinary action against existing License(s).

B. Documents Required. Any change of owner application(s) regarding an Owner of a Natural Medicine Business must include the following documents:

1. Asset purchase agreement, merger, sales contract, agreement, or any other document necessary to effectuate the change of owner;

2. Application for an Owner License for each proposed Owner that does not already hold an Owner License;

3. Operating agreement, by-laws, partnership agreement, or other governing document(s) as will apply to the Natural Medicine Business if the change of owner application is approved;

4. Request for voluntary surrender form of the Owner License of any Owner that will not remain an Owner of at least one Natural Medicine Business if the change of owner application is approved; and

5. An affirmation and consent signed by any Owner whose Owner's interest is decreasing as a result of the change of owner application.

C. Natural Medicine Business Subject to Administrative Action. If a Natural Medicine Business or any of its Owner(s) apply for a change of owner and is involved in an administrative action, the following may apply:

1. The change of owner application may be delayed or denied until the administrative action is resolved; or

2. If the change of owner application is approved by the Division, the transferor, the transferee, or both may be responsible for the actions of the Natural Medicine Business and its prior Owner(s), and subject to discipline based upon the same.

Basis and Purpose – 2150

The statutory authority for this rule includes but is not limited to sections 44-50-104(2), 44-50-202(1)(b), 44-50-203(1)(a), 44-50-203(1)(b), 44-50-203(1)(c), 44-50-203(1)(g), 44-50-203(2)(a), 44-50-203(2)(l), and 44-50-302(1)-(2), C.R.S. The purpose of this rule is to establish the application process for changing location of a Licensed Premises and to ensure that a Licensee is not operating in multiple locations under one Natural Medicine Business License.

2150 – Change of Location of Regulated Natural Medicine Business License

A. Application Required Before Changing Location of Licensed Premises. A Natural Medicine Business must apply for and receive Division approval before changing the location of its Licensed Premises.

B. Application Requirements. A change of location application must include the following:

1. At least one signature of an Owner Licensee and representation that the signing Owner Licensee(s) is/are authorized to submit the application on behalf of the Natural Medicine Business.

2. Documentation showing compliance with the Local Jurisdiction's time, place, and manner requirements, as applicable.

3. The deed, lease, sublease, rental agreement, contract, or any other document(s) establishing the Licensee is, or will be, entitled to possession of the premises for which the application is made.

4. Legible and accurate diagram for the proposed Licensed Premises that complies with the requirements of Rules 2125(A)(2)(c), 3110, and 3115. The diagram must include a plan for the proposed Licensed Premises and a separate plan for the security and surveillance plan including camera placements, number and direction of coverage. If the diagram is larger than 8.5 inches by 11 inches, the Applicant must also provide the diagram in a portable document format (.pdf).

C. Change of Location Permit Required.

1. A Natural Medicine Business cannot change the location of its Licensed Premises until it receives a change of location permit from the Division.

2. The permit is effective for 120 days from the date of issuance, and the Licensee must change the location of its Natural Medicine Business to the place specified in the change of location permit and at the same time cease to operate at the former location. The Division may extend the 120-day deadline for a period up to an additional 120 days.

3. If the Licensee fails to change its Licensed Premises location prior to expiration of the change of location permit, the Natural Medicine Business must submit a new application, pay the change of location fee, and receive a new change of location permit prior to changing the location of its Licensed Premises.

4. A Natural Medicine Business cannot operate or exercise any of the privileges of its License(s) in both locations.

Basis and Purpose – 2155

The statutory authority for this rule includes but is not limited to sections 44-50-104(2), 44-50-202(1)(b), 44-50-203(1)(a), 44-50-203(1)(b), 44-50-203(1)(d), 44-50-203(1)(n), 44-50-203(2)(a), 44-50-203(2)(c), 44-50-203(2)(l), and 44-50-302(1)-(2), C.R.S. The purpose of this rule is to clarify the procedures and factors governing the denial process and the effect of voluntary withdrawal or surrender for all Licenses issued by the State Licensing Authority.

2155 – Application Denial, Voluntary Withdrawal, and Effect of a License Surrender

A. **Applicant Burden to Meet Licensure Requirements**. An Applicant for an Owner License, Natural Medicine Handler License, or Natural Medicine Business License must establish it is qualified to hold the License. All Licenses issued under the Natural Medicine Code are a revocable privilege.

B. **Applicants Must Provide Full and Accurate Information to the Division**. An application may be denied if it includes misstatements, omissions, misrepresentations, or untruths regarding the Applicant's eligibility to hold the License. Misstatements, omissions, misrepresentations, or untruths included in an application, documents submitted with the application or additional documents requested by the Division may be the basis for administrative action including but not limited to revocation of the license pursuant to section 44-50-701, C.R.S.

C. **Grounds for Denial**.

1. The State Licensing Authority will deny an application from an Applicant that is disqualified from holding a License by the Natural Medicine Code or these Rules.

2. The State Licensing Authority will deny an application if the Applicant fails to provide all required information or documents, fails to submit all required application fees, fails to provide accurate, complete, or truthful information or documents, or fails to cooperate with the Division.

D. Voluntary Withdrawal of Application.

1. The Division and Applicant may mutually agree to voluntary withdrawal of an application in lieu of a denial proceeding.

2. Applicants must first submit a form to the Division requesting the voluntary withdrawal of the application. Applicants will submit the form with the understanding that they were not obligated to request the voluntary withdrawal and that any right to a hearing in the manner is waived once the voluntary withdrawal is accepted.

3. The Division will notify the Applicant when it accepts the voluntary withdrawal.

4. The Division may refund the application fee where the application was voluntarily withdrawn prior to initiation of the application investigation.

E. Appeal of Denied Application. An Applicant may appeal a denial pursuant to the Administrative Procedure Act at sections 24-4-104 and 24-4-105, C.R.S.

F. Effect of License Surrender or Revocation on Related Applications. If an application is withdrawn or a License is voluntarily surrendered or revoked, and there are related applications that are seeking some change to the License (including, but not limited to, renewal, change of owner, or change of location) pending Final Agency Order, the related applications become moot and those moot applications will be closed by the Division without further action or notification to the Applicant.

Basis and Purpose – 2160

The statutory authority for this rule includes but is not limited to sections 44-50-104(2), 44-50-202(1)(b), 44-50-203(1)(a), 44-50-203(1)(b), 44-50-203(1)(d),44-50-203(1)(e), 44-50-203(1)(n), 44-50-203(2)(a), 44-50-203(2)(c), 44-50-203(2)(l), and 44-50-302(1)-(2), C.R.S. The purpose of this rule is to establish that each Natural Medicine Business must have at least one Owner Licensee, and each Healing Center must employ or contract with at least one Facilitator in order to operate. The rule further clarifies that a Licensee cannot subvert responsibility for violations of the Natural Medicine Code or these Rules if the violations were performed by a third-party acting on behalf of or at the direction of the Licensee.

2160 – Revoked or Suspended Owners; At Least One Owner Licensee and One Facilitator Required; Prohibited Third-Party Acts

A. Revoked Owners.

1. Less than 100% of all Owners – Divestiture. If less than 100% of a Natural Medicine Business' Owner Licenses are revoked by a Final Agency Order, the Natural Medicine Business must divest all of the interest of the revoked Owner Licensee.

a. Unless extended for good cause, within 90 days of an Owner having his, her, or their Owner License revoked, the Natural Medicine Business must either:

i. Submit a change of owner application, where required, and any document(s) necessary to transfer all of the interests that Owner owns to one or more persons that are not prohibited from holding a license. Any required change of owner application is subject to approval by the Division; or

ii. Where a change of owner application is not required, transfer all of the interest of that Owner to one or more Persons that are not a Person prohibited from holding a license.

b. In determining whether good cause for an extension exists, the Division will consider whether there is any buy-back provision with the Owner. If a mediation, arbitration, or legal proceeding has been initiated regarding the required divestiture, the 90-day deadline is extended until 90 days following execution of a settlement agreement, arbitration order, or final judgment concluding the mediation, arbitration, or legal proceeding.

c. A Natural Medicine Business that fails to divest an Owner as required by this Rule may be subject to denial, fine, suspension, or revocation of its License(s). The State Licensing Authority may consider aggravating and mitigating factors surrounding measures taken to divest a revoked Owner when determining the imposition of a penalty.

2. All Owners are Revoked. A Natural Medicine Business's License may be revoked if 100% of its Owners have his or her or their Owner's License revoked.

B. Suspension of Owners.

1. Suspension of Less than 100% of the Owner(s) of a Natural Medicine Business. In the event of the suspension of the Owner License of an Owner, either (i) the Natural Medicine Business must comply with all requirements of Rule 9020 – Disciplinary Process: Summary Suspensions, or (ii) the non-suspended Owner Licensee(s) must control the Natural Medicine Business without participation from the suspended Owner(s).

2. Suspension of 100% of the Owners of a Natural Medicine Business. A Natural Medicine Business cannot operate if all Owners are suspended.

C. At Least One Owner Holding a Valid Owner License Required. No Natural Medicine Business may operate or be licensed unless it has at least one Owner Licensee who holds a valid Owner License.

D. At Least One Facilitator License Required for Each Healing Center License. A Healing Center may only operate if it has employed or contracted with at least one licensed Facilitator who also holds a Natural Medicine Handler License or Owner License.

E. Loss Of Owner License As An Owner Of Multiple Businesses. If an Owner License is suspended or revoked as to one Natural Medicine Business, that Owner License is automatically suspended or revoked as to any other Natural Medicine Business in which that person is an Owner.

F. Prohibited Third-Party Acts. No Licensee may employ, contract with, hire, or otherwise retain any person, including but not limited to an employee, agent, or independent contractor, to perform any act or conduct on the Licensee's behalf or for the Licensee's benefit if the Licensee is prohibited by law or these Rules from engaging in such conduct itself.

1. A Licensee may be held responsible for all actions and omissions of any person the Licensee employs, contracts with, hires, or otherwise retains, including but not limited to an employee, agent, or independent contractor, to perform any act or conduct on the Licensee's behalf or for the Licensee's benefit.

2. A Licensee may be subject to license denial or administrative action, including but not limited to fine, suspension, or revocation of its license(s), based on the act and/or omissions of any person the Licensee employs, contracts with, hires, or otherwise retains, including but not limited to an employee, agent, or independent contractor, to perform any act or conduct on the Licensee's behalf or for the Licensee's benefit.

Part 3 – General Privileges & Limitations

Basis and Purpose – 3005

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(b), 44-50-203(1)(g), 44-50-203(1)(k), and 44-50-301(4), C.R.S. The purpose of this Rule is to define prohibited acts and conduct on a Natural Medicine Business's Licensed Premises.

3005 – General Restrictions

A. Consumption of Natural Medicine.

1. Licensees are prohibited from consuming Regulated Natural Medicine or Regulated Natural Medicine Product on the Licensed Premises unless the Licensee is a Participant in an Administration Session, separate from their employment.

2. Licensees are prohibited from consuming Regulated Natural Medicine or Regulated Natural Medicine Product in transport vehicles.

B. Alcohol Beverage and Regulated Marijuana License Restrictions. A person may not operate a license issued pursuant to the Natural Medicine Code and these Rules at the same location as a license or permit issued pursuant to articles 3, 4, 5, or 10 of title 44. For purposes of this Rule, location means the Licensed Premises.

C. Sales of Natural Medicine and Natural Medicine Product to Individuals Prohibited. Licensees are prohibited from selling Regulated Natural Medicine or Regulated Natural Medicine Product to individuals outside of Natural Medicine Services. Licensees are also prohibited from disguising sales through free Regulated Natural Medicine or Regulated Natural Medicine Product transfers to individuals outside of Natural Medicine Services. Licensees may transfer Regulated Natural Medicine and Regulated Natural Medicine Product to other Licensees and to Facilitators.

D. Only Licensed Employees Can Handle Regulated Natural Medicine. A Natural Medicine Business must verify that an individual has a valid Natural Medicine Handler License issued under Rule 2115 before allowing the individual to perform any work described in Rule 2115(A) at the Natural Medicine Business's Licensed Premises.

E. Restrictions on Administration Area Only When Regulated Natural Medicine is Present. Nothing herein requires an Administration Area to only be used for Natural Medicine Services. The rules related to an Administration Area shall only apply to the Administration Area while Regulated Natural Medicine or Regulated Natural Medicine Product are present in the Administration Area.

F. No Synthetic Natural Medicine Allowed. Natural Medicine Cultivation Facilities, Natural Medicine Products Manufacturers, and Healing Centers shall not manufacture, store, distribute, transport, transfer, or dispense any Natural Medicine and Natural Medicine Product that contains synthetic or synthetic analogs of Natural Medicine, including a derivative of a naturally occurring compound of Natural Medicine that is produced using chemical synthesis, chemical modification, or chemical conversion.

G. Patient Confidentiality Required. Licensees must maintain the confidentiality of any records containing personally identifying information or medical data of Participants maintained or stored at a Natural Medicine Business's Licensed Premises, unless disclosure is otherwise required by any local, state, or federal law.

Basis and Purpose – 3010

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(b), 44-50-203(1)(j), 44-50-203(2)(f), 44-50-203(2)(i), and 44-50-203(2)(p), C.R.S. The purpose of this rule is to identify the documents Natural Medicine Businesses are required to maintain and the protocols for retention and production of these records.

3010 – Business Records Required

A. General Requirements.

1. A Natural Medicine Business must maintain the information required in this Rule in a format that is readily understandable and may be stored electronically.

2. Storage of Required Records.

a. On premises records: The Natural Medicine Business's books and records for the preceding six months (or complete copies of such records) must be available at the Licensed Premises at all times. Electronic records that are accessible from, but not physically located at, a Licensee's Licensed Premises also satisfy the requirements of this Rule 3015.

b. On- or off-premises records: Books and records associated with older periods may be archived on or off of the Licensed Premises.

3. A Natural Medicine Business must maintain books and records necessary to fully and accurately account for the Licensee's transactions related to Regulated Natural Medicine, Natural Medicine Services, or Regulated Natural Medicine Products for the current and two preceding calendar years and shall be made available to the State Licensing Authority or Division upon request.

4. Division Access to Records. A Natural Medicine Business must provide on-demand access to on-premises records following a request from the Division during normal business hours or hours of apparent operation, and must provide access to off-premises records within three business days following a request from the Division.

B. A Natural Medicine Business must maintain the following books and records for the current calendar year and the preceding two calendar years:

1. Secure Facility Information –

a. Current security plans, required by Rules 2125 and 3110;

b. The business contact information for vendors that maintain video surveillance systems and Security Alarm Systems for its Licensed Premises;

c. Security Alarm System documents required by Rule 3110; and

d. Surveillance logs that identify all authorized employees and service personnel who have access to the surveillance system and maintenance and activity log as required by Rule 3110.

2. Marketing Records – All records related to advertising and marketing, including but not limited to, audience composition data as required by Rule 3505.

3. Diagram of the Licensed Premises – At a minimum, the diagram must reflect the following:

a. All approved Restricted Areas and Administration Areas; and

b. Identification of camera placements with associated camera numbers, the direction of coverage, and the locations of the surveillance equipment maintenance, user authorization list, and operating instructions.

4. Visitor Log – A record of all people other than Natural Medicine Handlers and Natural Medicine Owners that enter the Restricted Area.

5. Regulated Natural Medicine Waste Log – Comprehensive records regarding all waste material that accounts for, reconciles, and evidences all waste related to the disposal of Regulated Natural Medicine or Regulated Natural Medicine Product.

6. License Application Records – All records provided by the Licensee to the State Licensing Authority in connection with an application for licensure pursuant to the Natural Medicine Code and these Rules, including any required tax records and records demonstrating sources of funding. This requirement includes applications for permits, registrations, and any other applications pursuant to these Rules.

7. Records related to Adverse Health Events as required by Rule 3015.

8. Current Owner and Employee List – Natural Medicine Businesses must maintain a list with the full name and License number of all Owner Licensees and every Natural Medicine Handler Licensee who the Licensee employs. The list shall include all employees, including employees who are not required to hold a Natural Medicine Handler License, who work for the Natural Medicine Business, whether or not they report to the Licensed Premises as part of their employment.

9. Administration Session documents required by Rule 8035.

10. Emergency plan per Rule 8035.

11. Safety data sheets (SDS) related to the use of any solvents, chemicals, or pesticides at a Natural Medicine Cultivation or a Natural Medicine Products Manufacturer.

12. A map of all pest control devices, if the Natural Medicine Business is a Natural Medicine Cultivation or Natural Medicine Product Manufacturer.

13. Standard Operating Procedures per Rules 5020, 6015 or 8035.

14. Recall plan documentation as required by Rule 3205.

15. Records related to spore sources confirming they are *Psilocybe cubensis*.

16. Records regarding expiration date determinations, along with any data used to establish the expiration date, such as test results pursuant to Rule 5020(H)(3) and 6015(I)(3)(d).

17. Inventory tracking documentation as required by Rules 5025, 6020, 7035, or 8040.

18. Transport Manifests as required by Rule 3405.

19. All other records required by these Rules.

C. Loss of Records or Data. Any loss of electronically-maintained records shall not be considered a mitigating factor for violations of this Rule. Licensees are required to exercise due diligence in preserving and maintaining all required records.

Basis and Purpose – 3015

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-202(6), 44-50-202(7), 44-50-203(1)(g), 44-50-203(1)(j), and 44-50-203(2)(g), C.R.S. The purpose of this Rule is to identify notice and reporting requirements for Adverse Health Events by Natural Medicine Businesses and Healing Centers, specifically.

3015 – Natural Medicine Business Reporting Requirements

A. Adverse Health Event Reporting. If a Natural Medicine Business is notified of any possible Adverse Health Event, as defined in Rule 1025, associated with Regulated Natural Medicine, Regulated Natural Medicine Product, or Natural Medicine Services it must report the Adverse Health Event to the Division no later than within two business days from being notified.

1. To the extent known after reasonable diligence to discover relevant information, the report must contain the name and contact information of the complainant, the date the complaint was received, the nature of the complaint, identifying information found on the label of the Regulated Natural Medicine or Regulated Natural Medicine Product, and any other information that may be requested by the Division for purposes of investigation.

2. Natural Medicine Businesses must maintain records of Adverse Health Event reports in accordance with Rule 3010.

B. Healing Center Requirements. In addition to the requirements in paragraph A of this Rule, a Healing Center must report Adverse Health Events to the Division no later than within two business days from being notified including:

1. Any Participant reaction requiring medical attention; and

2. Any incident requiring emergency response.

C. Crimes on the Licensed Premises or Otherwise Related to the Natural Medicine Business. Natural Medicine Businesses and all Licensees employed by a Natural Medicine Business shall report to the Division any discovered plan or other action of any individual to commit theft, burglary, sales of Regulated Natural Medicine and Regulated Natural Medicine Product, diversion of Regulated Natural Medicine and Regulated Natural Medicine Product, or other crime related to the operation of the Natural Medicine Business. A report shall be made as soon as possible after the discovery of the action or conduct, but not later than 14 days. Nothing in this paragraph C alters or eliminates the obligation a Natural Medicine Business or Licensee may have to report criminal activity to a local law enforcement agency.

Basis and Purpose – 3105

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(a), 44-50-202(1)(b), 44-50-203(1)(a), 44-50-203(1)(b), 44-50-203(1)(d), 44-50-203(1)(f)(I)(D), 44-50-203(1)(g), and 44-50-203(2)(a), 44-50-203(2)(b), 44-50-203(2)(c), and 44-50-203(2)(r), C.R.S. The purpose of this rule is to establish minimum standards and requirements for a Natural Medicine Business that is co-located with another Natural Medicine Business or health-care facility.

3105 – Co-Located Natural Medicine Business Licenses

A. Co-Location Authorized. Natural Medicine Businesses that have identical Owner Licensees may share a location for the Natural Medicine Businesses' Licensed Premises.

1. Healing Centers. A Healing Center Licensed Premises may be at the same Licensed Premises as a Natural Medicine Cultivation Facility, Natural Medicine Products Manufacturer, another Healing Center, or a health-care facility.

2. Natural Medicine Cultivation Facility. A Natural Medicine Cultivation Facility Licensed Premises may be at the same Licensed Premises as a Healing Center or a Natural Medicine Products Manufacturer.

3. Natural Medicine Products Manufacturer. A Natural Medicine Products Manufacturer Licensed Premises may be at the same Licensed Premises as a Healing Center, Natural Medicine Cultivation Facility, or another Natural Medicine Products Manufacturer.

B. Co-Location Requirements.

1. All Licensees that share a location for their Licensed Premises must clearly designate on the Licensed Premises diagram: common areas, such as lobbies, hallways, and bathrooms; Restricted Areas; and Administration Areas.

2. A Healing Center that is co-located with another Natural Medicine Business or health-care facility must be clearly identified on the Licensed Premises diagram.

3. If any Natural Medicine Business is co-located with a Healing Center, the Restricted Areas shall not overlap with Administration Areas and must not be easily accessible to Participants.

4. If a Healing Center and Natural Medicine Cultivation Facility are co-located, separate inventory limits apply to the separate licensed operations.

C. Co-Location Restrictions.

1. Natural Medicine Testing Facilities are not permitted to be at the same Licensed Premises as another Natural Medicine Business.

2. A Natural Medicine Product Manufacturer that manufactures Regulated Natural Medicine Product using hazardous substances or dangerous chemicals is not permitted to be at the same Licensed Premises as a Healing Center.

Basis and Purpose – 3110

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(b), 44-50-203(1)(g), 44-50-203(1)(h), 44-50-203(1)(j), 44-50-203(1)(k), and 44-50-203(2)(f),44-50-203(2)(g), and 44-50-204(1), C.R.S. The purpose of this rule is to describe the security requirements that apply to all Natural Medicine Businesses.

3110 – Security Standards

A. The requirements of these Rules apply to Healing Centers pursuant to Rule 8025(A)(2), Natural Medicine Cultivation Facilities pursuant to Rule 5015(B)(2), Natural Medicine Products Manufacturers, and Natural Medicine Testing Facility Licensed Premises regardless of whether the Licensed Premises is located within a building that contains separate unlicensed areas or located at an address that contains separate unlicensed structures.

B. Natural Medicine Businesses are responsible for the security of all Regulated Natural Medicine and Regulated Natural Medicine Product on the Licensed Premises or in transit between Licensed Premises, including providing adequate safeguards to protect against theft or diversion of Regulated Natural Medicine and Regulated Natural Medicine Product.

C. Healing Centers, Natural Medicine Cultivation Facilities, Natural Medicine Products Manufacturers, and Natural Medicine Testing Facilities must take adequate measures to:

1. Prevent unauthorized access to the Restricted Areas including, but not limited to, locking or monitoring exterior doors to the Licensed Premises during business hours;

2. Prevent unauthorized access to business records; and

3. Ensure that all Restricted Areas of a Licensed Premises are accessible only to Owner Licensees, Natural Medicine Handler Licensees, and other personnel authorized to be present under these Rules.

D. When the Licensee is not operating as a Natural Medicine Business, the Licensee must ensure that all Regulated Natural Medicine and Regulated Natural Medicine Product is appropriately secured. Licensees must take measures to prevent unauthorized access to Regulated Natural Medicine and Regulated Natural Medicine Product.

E. Alarm System. Healing Centers, pursuant to Rule 8025(A)(2), Natural Medicine Cultivation Facilities pursuant to 5015(B)(2), Natural Medicine Products Manufacturers, and Natural Medicine Testing Facilities must have a fully operational security alarm system on the Licensed Premises, activated at all times when the Licensed Premises is closed for business.

1. The security alarm system for the Licensed Premises must:

a. Be able to detect unauthorized entry into interior areas of the Licensed Premises and unauthorized activity within interior areas of the Licensed Premises.

b. Notify the Licensee or authorized personnel in the event of an unauthorized entry.

2. Upon request, Licensees shall make all information related to security alarm systems, monitoring, and alarm activity available to the Division.

F. All Natural Medicine Handler Licensees and Owner Licensees with unrestricted access to Restricted Areas must be able to provide their License certificate and photo ID upon Division investigator request.

G. Security Plan. All Natural Medicine Businesses Licensees must establish and maintain a security plan for each Licensed Premises, including at a minimum:

1. Protocols for the end-of-day handling and storage of Regulated Natural Medicine and Regulated Natural Medicine Product;

2. Protocols for:

a. Reporting theft or burglaries when they are discovered to state or local law enforcement and the Division; and

b. Reconciling inventory after a theft or burglary has been discovered;

3. Identification of exterior lighting of the Licensed Premises and any exterior camera angles, and protocols for maintenance of the lighting and cameras;

4. Identification of ingress and egress routes for the property and identification of any access control measures taken outside of the Licensed Premises; and

5. Identification of the points of contact for security alarm systems and video surveillance notifications required by this Rule and Rule 3115.

Basis and Purpose – 3115

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(b), 44-50-203(1)(j), 44-50-203(1)(k), 44-50-203(2)(a), 44-50-203(2)(f), 44-50-203(2)(k), 44-50-203(2)(p), and 44-50-204(1)(a), C.R.S. The purpose of this rule is to define video surveillance requirements for all Natural Medicine Businesses.

3115 – Video Surveillance

A. Minimum Requirements. The following video surveillance requirements shall apply to Healing Centers as required by Rule 8025, and all Natural Medicine Cultivation Facilities, Natural Medicine Products Manufacturers, and Natural Medicine Testing Facilities, unless stated otherwise in these Rules.

1. Prior to exercising the privileges of a Healing Center, Natural Medicine Cultivation Facility, Natural Medicine Products Manufacturer Facility, or Natural Medicine Testing Facility License, an Applicant must install a fully operational video surveillance and camera recording system. The recording system must record in digital format and meet the requirements outlined in this Rule.

2. All video surveillance records and recordings must be stored in a Restricted Area, if applicable. If the Licensee does not have a Restricted Area, surveillance records of recordings must be securely stored in a location that is identified on the diagram of the Licensed Premises, or stored virtually and accessible electronically.

3. Video surveillance records and recordings must be made available upon request to the Division or for any other state or local law enforcement purpose.

B. Video Surveillance Equipment.

1. Video surveillance equipment shall, at a minimum, consist of digital or network video recorders, cameras capable of meeting the recording requirements described in this Rule, and a minimum of one on-premises video monitor, which may be a computer, tablet, or phone.

2. Licensees are responsible for ensuring that all surveillance equipment is properly functioning, maintained, and equipped with a failure notification system that provides prompt notification to the Licensee of any prolonged surveillance interruption and/or the complete failure of the surveillance system.

3. All video surveillance equipment shall have sufficient battery backup or other uninterrupted power supply to support a minimum of one hour of recording in the event of a power outage. Licensees must notify the Division of any loss of video surveillance capabilities that extend beyond two hours.

C. Placement of Cameras and Required Camera Coverage.

1. Camera coverage is required for all areas identified as Restricted Areas including entrances and exits to Restricted Areas and any area storing video surveillance equipment or recordings.

2. Cameras shall be placed to provide a clear unobstructed view of areas where Regulated Natural Medicine is grown, sampled, weighed, packaged, tagged, tested, stored, manufactured, and prepared for transport or disposal, whether in a Restricted Area or Administration Area.

3. Cameras must be placed and angled to allow clear and certain identification of any individual and activities in the Restricted Areas.

D. Location and Maintenance of Surveillance Equipment.

1. Surveillance recording equipment must be accessible only to authorized employees, service personnel or contractors, agents of the Division, or for any other state or local law enforcement purpose.

2. Licensees must keep a current list of all authorized employees and service personnel who have access to the surveillance system. Licensees must keep a surveillance equipment maintenance activity log on the Licensed Premises to record all service activity including the identity of the individual(s) performing the service, the service date and time, and the reason for service to the surveillance system.

3. Off-site Monitoring and video recording storage of the areas identified in this Rule 3115 by the Licensee or an independent third-party is authorized as long as standards exercised at the remote location meet or exceed all standards for on-site monitoring.

4. Natural Medicine Business Licensees co-located in accordance with Rule 3105 may have a separate surveillance area or a shared surveillance area within the Licensed Premises.

a. Natural Medicine Businesses with identical Owner Licensees may have one central surveillance room or area located at one of the Licensed Premises that simultaneously serves all of the Natural Medicine Businesses' Licensed Premises.

b. Licensed Premises that do not house the surveillance recording equipment are required to have an area where surveillance may be reviewed. Nothing in this Rule is intended to prohibit a Licensee from using a computer or mobile device for surveillance review.

5. Licensed Premises where both a Natural Medicine Cultivation Facility Licensee and Natural Medicine Products Manufacturer Licensee are co-located may have one central surveillance room located at the shared Licensed Premises. *See* Rule 3105 – Co-Located Natural Medicine Business Licenses.

E. Video Recording and Retention Requirements.

1. All camera views of all Restricted Areas must be able to record 24 hours a day. The use of motion detection is authorized if a Licensee confirms that monitored activities are adequately recorded.

2. All surveillance recordings must be kept for a minimum of 30 days and be in a format that can be easily accessed for viewing. Absence of video surveillance may result in a negative inference at an administrative hearing.

3. The date and time must be embedded on all surveillance recordings without significantly obscuring the picture.

4. Time is to be measured in accordance with the official United States time established by the National Institute of Standards and Technology and the U.S. Naval Observatory at: http://www.time.gov.

5. Surveillance video recordings may not be destroyed if the Licensee knows or should have known of a pending criminal, civil, or administrative investigation, or any other proceeding for which the recording may contain relevant information. Destruction of video surveillance may result in a negative inference at an administrative hearing.

Basis and Purpose – 3120

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(b), 44-50-203(1)(j), 44-50-203(1)(k), 44-50-203(2)(i), 44-50-203(2)(j), and 44-50-203(2)(k), C.R.S. The purpose of this rule is to define the requirements to dispose of Regulated Natural Medicine Waste.

3120 – Waste Disposal

A. All Applicable Laws Apply. Regulated Natural Medicine Waste must be stored, secured, locked, and managed in accordance with all applicable federal, state, and local statutes, regulations, ordinances, or other requirements, including but not limited to the "Regulations Pertaining to Solid Waste Sites and Facilities" (6 CCR 1007-2, Part 1) established by the Colorado Department of Public Health and Environment pursuant to the "Solid Wastes Disposal Sites and Facilities Act", Title 30, Article 20, Part 1, C.R.S. and "Regulation No. 100 – Water and Wastewater Facility Operations Certification Requirements" (5 CCR 1003-2) established by the Colorado Department of Public Health and Environment pursuant to the Title 25, Article 9, Part 1, C.R.S.

B. Liquid Waste. Liquid waste from Regulated Natural Medicine Businesses shall be disposed of in compliance with all applicable federal, state, and local laws, regulations, rules, and other requirements as well as local wastewater treatment plant effluent requirements and limitations.

C. Chemical, Dangerous, and Hazardous Waste. Disposal of chemical, dangerous, and hazardous waste must be conducted in a manner consistent with federal, state, and local laws, statutes, regulations, rules, and other requirements.

D. Regulated Natural Medicine Waste consisting of psilocybin products that are fit for human consumption must be securely stored and disposed of on the Licensed Premises or transferred to another Licensee for disposal. Licensees must store Regulated Natural Medicine Waste in either a Restricted Area or a locked waste receptacle located on the Licensed Premises until it is disposed of.

E. Regulated Natural Medicine Waste consisting of psilocin or psilocybin that are unfit for human consumption may be stored prior to final disposal in a locked dumpster or other locked receptacle outside of the Licensed Premises or may be stored pursuant to section (D) of this Rule.

F. A Natural Medicine Cultivation Facility may dispose of Regulated Natural Medicine Waste that is a byproduct of cultivation or processing by rendering it unusable by autoclaving the substrate at 212° Fahrenheit (100° Celsius) for 20 minutes to ensure thorough spore destruction.

G. If a Natural Medicine Cultivation Facility or Natural Medicine Products Manufacturer generates waste while harvesting, processing, or producing finished product, or if the Regulated Natural Medicine Waste was previously designated as a finished product, the Licensee must document:

    1. A reason for the Regulated Natural Medicine Waste in the inventory tracking system.

    2. The exact time and method of destruction in the inventory tracking system.

H. All Regulated Natural Medicine Waste containing psilocybin or psilocin must be disposed of in a manner that effectively prevents spontaneous growth of Fruiting Bodies or mycelium containing psilocybin. Regulated Natural Medicine Waste may be rendered unusable by autoclaving the substrate to 212° Fahrenheit (100° Celsius) for at least 20 minutes.

I. Material that has been designated as Regulated Natural Medicine Waste must be disposed of pursuant to this rule and may not be used in the production of Regulated Natural Medicine Product.

J. All Regulated Natural Medicine Waste must be tracked in the waste log and must detail the disposal process by tracking the time and temperature or other methods that stop the Regulated Natural Medicine from producing spores.

K. Administration Sessions at Authorized Locations Other than Healing Centers. Following an Administration Session at an authorized location other than a Healing Center, any Regulated Natural Medicine Waste must be transferred in accordance with Rule 3405 to a Natural Medicine Business for proper disposal. The Natural Medicine Business must weigh the Regulated Natural Medicine Waste upon receipt and enter the date, weight, Facilitator name, and Facilitator license number in its waste log, required in Rule 3010.

L. A Licensee may dispose of Regulated Natural Medicine or Regulated Natural Medicine Product at any time in accordance with these Rules, as long as it is properly disposed of and tracked according to applicable inventory tracking Rules.

Basis and Purpose – 3125

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(g), 44-50-203(2)(g), 44-50-203(2)(h), and 44-50-203(2)(i), and 44-50-203(2)(p), C.R.S. The purpose of this rule is to establish minimum health and sanitary requirements for a Natural Medicine Business's Licensed Premises.

3125 – General Sanitary Requirements

A. Reasonable Measures and Precautions. Licensees shall take all reasonable measures and precautions to ensure:

1. Any individual who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with Regulated Natural Medicine and Regulated Natural Medicine Product shall be excluded from any operations which may be expected to result in contamination until the condition is corrected;

2. All individuals working in direct contact with Regulated Natural Medicine or Regulated Natural Medicine Product shall conform with hygienic practices while on duty, including but not limited to:

    a. Maintaining adequate personal cleanliness;

    b. Washing hands thoroughly in an adequate hand-washing area(s) before starting work, prior to engaging in the cultivation or production of Regulated Natural Medicine and Regulated Natural Medicine Product, and at any other time when the hands may have become soiled or contaminated; and

    c. Refraining from having direct contact with Regulated Natural Medicine or Regulated Natural Medicine Product if the person has or may have an illness, open lesion, including boils, sores, or infected wounds or any other abnormal source of microbial contamination, until such condition is addressed and corrected.

3. Litter and waste are removed, and waste disposal systems are maintained in a manner so that they do not constitute a source of contamination in areas where Regulated Natural Medicine or Regulated Natural Medicine Product is handled;

4. Floors, walls, and ceilings are constructed in such a manner that they may be adequately cleaned, and each is kept clean and in good repair;

5. There is adequate lighting in all areas where Regulated Natural Medicine and Regulated Natural Medicine Product is handled, including but not limited to, processing, manufacturing, sampling, testing, storing, packaging, and labeling, and where equipment or utensils are cleaned;

6. Licensees provide adequate screening or other protection against the entry of pests. Litter shall be disposed of so as to minimize the development of odor and minimize the potential for waste attracting pests, creating shelter for pests, or where pests breed;

7. Any buildings, fixtures, and other facilities are maintained in a sanitary condition, including but not limited to the prevention of microorganism growth;

8. Toxic cleaning compounds, sanitizing agents, and other chemicals shall be identified, held, stored, and disposed of in a manner that protects against contamination of Regulated Natural Medicine and Regulated Natural Medicine Product, and in accordance with any applicable local, state, or federal law, rule, regulation, or ordinance. All Safety Data Sheets from the compounds must be kept on file in accordance with Rule 3010;

9. All operations in the receiving, inspecting, transporting, preparing, manufacturing, packaging, and storing Regulated Natural Medicine and Regulated Natural Medicine Product shall be conducted in accordance with adequate sanitation principles; and

10. Cultivation or manufacturing materials, ingredients, and Regulated Natural Medicine and Regulated Natural Medicine Product that can support the rapid growth of undesirable microorganisms are stored in a manner that prevents the growth of these microorganisms.

B. Hand Washing & Facilities. All Natural Medicine Businesses must have at least one toilet facility and hand-washing facility.

1. Hand washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Hand-washing facilities shall be located in the Licensed Premises and where good sanitary practices require employees to wash or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices. A sign must be posted to remind employees to wash their hands before returning to work;

2. Each Natural Medicine Business provides its employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair by cleaning and sanitizing the facilities on a scheduled basis; and

3. Healing Centers must have both toilet and hand-washing facilities easily accessible to Participants. These facilities may be shared with non-licensed entities, as long as the Facilitator follows the procedures outlined in the Administration Session Preparedness Plan in Rule 8035(D)(1)(a)(i).

4. Potable drinking water facilities must be available for employees and Participants.

Basis and Purpose – 3130

The statutory authority for this rule includes but is not limited to sections 44-50-104(5)(a)-(d), 44-50-202(1)(b), 44-50-203(1)(b), 44-50-203(1)(g), 44-50-203(2)(g), 44-50-203(2)(p), 44-50-203(2)(r), and 44-50-301(4), C.R.S. The purpose of this rule is to establish the conditions under which a Natural Medicine Business may be subject to an inspection of its Licensed Premises by local authorities, including but not limited to a zoning inspection, a fire safety inspection, or a building inspection.

3130 – Local Safety Inspections

A. A Natural Medicine Business is subject to inspection of its Licensed Premises by the local fire department, building inspector, or code enforcement officer to inspect for compliance with state law, local ordinances or rules, these governing regulations, and all other applicable state health and safety regulations.

B. The inspection could result in additional specific standards to meet Local Jurisdiction requirements related to the operation of businesses within the Local Jurisdiction. A fire safety inspection may result in the required installation of fire suppression devices, or other means necessary for adequate fire safety. A Local Jurisdiction may also use an inspection to confirm compliance with ordinances or regulations governing the time, place, and manner of Licensee's operations.

C. Natural Medicine Businesses must comply with Local Jurisdiction ordinances and regulations related to fire safety.

Basis and Purpose – 3205

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(j), 44-50-203(1)(b), 44-50-203(2)(g), 44-50-203(2)(i), 44-50-203(2)(k), and 44-50-203(2)(p), C.R.S. The purpose of this rule is to establish minimum requirements for a recall plan and the process by which the Division or a Natural Medicine Business initiates, performs, and terminates a recall.

3205 – Recall of Regulated Natural Medicine or Regulated Natural Medicine Product

A. Applicability. This Rule 3205 applies to all Natural Medicine Business Licensees. Owner Licensees are responsible for the recall plan and the necessary steps for a recall in accordance with this Rule. The recall plan may designate additional Natural Medicine Handler Licensees as points of contact in the event of a recall.

B. Initiating a Recall. A Natural Medicine Business may initiate a recall at any time, or a recall may be initiated at the Division's request. Natural Medicine Businesses must comply with the requirements of this Rule 3205.

1. Division Request for Recall.

a. If the Division requests a Natural Medicine Business initiate a recall pursuant to this Rule, the Division's correspondence, which may be electronic, must include the reasons for the recall request and any other information necessary for the Natural Medicine Business to initiate the recall.

b. A Division request for recall does not require the Natural Medicine Business to initiate a recall. However, if the Division has reasonable grounds to believe a Licensee's Regulated Natural Medicine or Regulated Natural Medicine Product is contaminated or otherwise presents a risk to public safety, the Division may require a Natural Medicine Business to quarantine or embargo the affected inventory.

2. Voluntary Recall.

a. A Natural Medicine Business may voluntarily initiate a recall.

b. If a Natural Medicine Business elects to initiate a recall, the Licensee must notify the Division at least 24 hours prior to notifying other Licensees, Facilitators, Participants, or other interested or affected persons in order to facilitate coordination between the Licensee and the Division.

C. Recall Plan Required. Natural Medicine Cultivation Facilities and Natural Medicine Products Manufacturers must have a written recall plan. A recall plan shall include, but is not limited to, the following:

1. Evaluation of a Complaint or Condition. Natural Medicine Businesses must maintain a record of all complaints it receives regarding the quality of Regulated Natural Medicine and Regulated Natural Medicine Product that has any potential negative impact to health or an adverse reaction in accordance with Rule 3015. If an initial assessment indicates a recall may be necessary, the Natural Medicine Business shall:

a. Determine the hazard and evaluate the safety concerns with the product;

b. Undertake necessary product quarantine measures for any affected Regulated Natural Medicine and Regulated Natural Medicine Product; and

c. Determine the appropriate product removal strategy considering the potential adverse reactions and amount of product transferred to other Licensees and Participants.

2. Identification of Affected Regulated Natural Medicine and Regulated Natural Medicine Product. A recall plan must establish a process for identifying affected Regulated Natural Medicine and/or Regulated Natural Medicine Product, which shall include the following:

a. Distribution List. When identifying Regulated Natural Medicine and/or Regulated Natural Medicine Product subject to a recall, the Licensee shall create a distribution list that includes the following information:

i. The name, license number, and address of the Natural Medicine Business(es) that received the Regulated Natural Medicine and/or Regulated Natural Medicine Product subject to the recall;

ii. Ship or transfer date(s) for the Regulated Natural Medicine and/or Regulated Natural Medicine Product subject to the recall; and

iii. Business contact information for each Natural Medicine Business that received Regulated Natural Medicine and Regulated Natural Medicine Product subject to the recall, including names and telephone numbers.

b. Product Information. When identifying Regulated Natural Medicine and/or Regulated Natural Medicine Product subject to a recall, the Licensee shall document the following product information:

i. Product description;

ii. Net contents;

iii. Harvest Lot and/or Production Lot number;

iv. The license number(s) for the Natural Medicine Business(es) that cultivated or manufactured the Regulated Natural Medicine and/or Regulated Natural Medicine Product subject to the recall; and

v. To the extent known after reasonable diligence to collect information, the recall plan must also include the following additional product information: the amount of affected Regulated Natural Medicine and Regulated Natural Medicine Product returned to the Natural Medicine Cultivation or Natural Medicine Product Manufacturer in response to the recall.

3. Notifications.

a. A Licensee initiating a recall pursuant to this Rule shall issue a recall notice to all Natural Medicine Businesses identified on the Licensee's distribution list.

b. No later than 48 hours after issuing a recall notice to all Natural Medicine Businesses on the Licensee's distribution list, the Licensee shall also:

i. Notify the Division and the Department of Public Health & Environment that the recall has been initiated; and

ii. Post an alert on the Licensee's website, social media, or other method of notifying Participants and Facilitators.

c. Recall Notice. A recall notice issued by a Natural Medicine Business pursuant to this Rule shall include at least the following information:

i. The reason for recall and related hazards, if any. If the Regulated Natural Medicine and/or Regulated Natural Medicine Product is being removed for quality rather than health reasons, the notice may state that the Regulated Natural Medicine and Regulated Natural Medicine Product does not meet internal company specifications and is being removed from distribution;

ii. Natural Medicine Businesses that received the Regulated Natural Medicine and/or Regulated Natural Medicine Product;

iii. The License number(s) and name(s), including trade names or "doing business as" names, of the Natural Medicine Business(es) that cultivated or manufactured the Regulated Natural Medicine and/or Regulated Natural Medicine Product subject to the recall;

iv. Product description(s) for Regulated Natural Medicine and/or Regulated Natural Medicine Product subject to the recall;

v. Expiration date(s) for the Regulated Natural Medicine and/or Regulated Natural Medicine Product subject to the recall, if applicable;

vi. Ship or transfer date(s) for the Regulated Natural Medicine and/or Regulated Natural Medicine Product subject to the recall; and

vii. Instructions regarding the disposition of Regulated Natural Medicine and/or Regulated Natural Medicine Product subject to the recall.

4. Removal of Affected Regulated Natural Medicine and Regulated Natural Medicine Product.

   a. Removal. A Natural Medicine Business shall make all reasonable efforts to remove the affected Regulated Natural Medicine and/or Regulated Natural Medicine Product from licensed Facilities. Affected Regulated Natural Medicine and Regulated Natural Medicine Product that is either still in control of the originating Licensee or located at another Licensed Premises shall be secured, segregated, clearly labeled "Not for Distribution," and separated from any other Regulated Natural Medicine and Regulated Natural Medicine Product.

   b. Disposal. Regulated Natural Medicine and Regulated Natural Medicine Product subject to a recall under this Rule shall be disposed of in accordance with Rule 3120.

   c. Recall Effectiveness. A Natural Medicine Business initiating a recall pursuant to this Rule is responsible for determining whether the recall is effective. The Licensee shall complete recall effectiveness checks to verify that all receiving Licensees have been notified and have taken the appropriate action.

      i. Effectiveness checks shall determine:

         A. If the receiving Licensee(s) received the recall notification;

         B. If the recalled Regulated Natural Medicine and Regulated Natural Medicine Product was handled as instructed in the recall notification; and

         C. If the Regulated Natural Medicine and Regulated Natural Medicine Product was further dispensed by the receiving Licensee before receipt of the recall notification, and if so, were additional Licensees, Participants, and Facilitators notified.

      ii. If the Licensee accounts for 100 percent of the affected Regulated Natural Medicine and Regulated Natural Medicine Product, then no effectiveness checks are required.

5. Annual Audit of Recall Plan. The Natural Medicine Business must annually audit their recall plan to determine if any changes in the operation of their business would require an update to the plan.

D. Termination of Recall.

1. A Natural Medicine Business initiating a recall pursuant to this Rule may terminate a recall when the Licensee determines that reasonable efforts have been made to remove or correct the affected Regulated Natural Medicine and/or Regulated Natural Medicine Product in accordance with the recall plan, and when it is reasonable to assume that the Regulated Natural Medicine and/or Regulated Natural Medicine Product subject to the recall has been removed and properly disposed of, or correction has been made commensurate with the degree of the hazard of the recalled Regulated Natural Medicine and/or Regulated Natural Medicine Product.

2. Upon termination of the recall, the Natural Medicine Business shall provide notice to the Division with a recall status report and a description of the disposition of the recalled Regulated Natural Medicine and/or Regulated Natural Medicine Product. The recall status report shall contain the following information:

    a. Number of receiving Licensees notified of the recall, the date, and method of notification;

    b. Number of receiving Licensees who responded to the recall notice and both the quantity of affected Regulated Natural Medicine and/or Regulated Natural Medicine Product in the possession of the Licensee at the time of the response, and quantity of affected product returned or corrected;

    c. Number and results of the effectiveness checks that were made; and

    d. Approximate time that was required to complete the recall.

Basis and Purpose – 3210

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(b), 44-50-203(1)(j), 44-50-203(2)(g), 44-50-203(2)(i), 44-50-203(2)(k), and 44-50-203(2)(p), C.R.S. The purpose of this rule is to establish the reasons the Division may embargo Regulated Natural Medicine and Regulated Natural Medicine Product and the process for an embargo.

3210 – Embargo of Regulated Natural Medicine and Regulated Natural Medicine Product

A. The Division may embargo Regulated Natural Medicine and Regulated Natural Medicine Product when there are objective and reasonable grounds to believe the Regulated Natural Medicine and Regulated Natural Medicine Product poses a risk to health, safety, or welfare of Participants that imperatively requires emergency action.

B. Notice of Embargo. A Division investigator will issue a Notice of Embargo to only the Licensee from which the Regulated Natural Medicine or Regulated Natural Medicine Product originated, including a description of the Regulated Natural Medicine or Regulated Natural Medicine Product, and identifying any permitted activities regarding the inventory subject to the embargo.

    1. Following the issuance of a notice of embargo, the Licensee shall issue a recall using the recall plan required in Rule 3205. A recall for purposes of embargo may only be terminated with approval of the Division.

    2. With Division approval, a Licensee subject to a notice of embargo may instruct other Licensees to dispose of Regulated Natural Medicine and/or Regulated Natural Medicine Product as part of the recall response.

    3. The Division may also notify Licensees that received Regulated Natural Medicine and Regulated Natural Medicine Product subject to the embargo to physically segregate and secure the embargoed Regulated Natural Medicine and Regulated Natural Medicine Product.

    4. The Director, or their designee, shall promptly approve and issue a concise statement regarding the reasons for issuing the embargo.

C. Effect of Embargo.

1. The Licensee shall completely physically segregate and secure Regulated Natural Medicine and Regulated Natural Medicine Product subject to the embargo in the Restricted Area of the Licensed Premises.

2. While the embargo is in effect, the Licensee is prohibited from transferring or transporting the embargoed Regulated Natural Medicine and Regulated Natural Medicine Product, unless otherwise authorized by these Rules or Division approval. The Licensee may choose to dispose of the embargoed Regulated Natural Medicine and Regulated Natural Medicine Product in accordance with Rule 3120 after Division approval in writing.

3. While the embargo is in effect, the Licensee must secure the embargoed Regulated Natural Medicine and Regulated Natural Medicine Product, maintain the Licensed Premises in reasonable condition according to health, safety, and sanitary standards, and must comply with all security requirements in Rules 3110 and 3115.

D. The Division or State Licensing Authority may lift, revise, or extend an embargo by agreement with the Licensee at any time after the notice of embargo was served.

E. If the State Licensing Authority has not issued a written statement articulating the objective and reasonable grounds that the health, safety, or welfare of the public requires destruction of embargoed Regulated Natural Medicine and Regulated Natural Medicine Product within 120 days of the notice of embargo, the Licensee that received the notice of embargo may submit a written request for a hearing before a Department of Revenue Hearing Officer in accordance with Rule 9040(B)(4). Any hearing will be conducted by a Department of Revenue Hearing Officer pursuant to section 24-4-105, C.R.S. and in accordance with the process described in Rule 9040.

Basis and Purpose – 3305

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(k), 44-50-203(2)(d), 44-50-203(2)(e), 44-50-203(2)(g), 44-50-203(2)(j), and 44-50-203(2)(k), C.R.S. The purpose of this rule is to define the requirements for packaging and labeling Regulated Natural Medicine and Regulated Natural Medicine Products between Natural Medicine Businesses or Facilitators. The following Rule, in conjunction with Rule 3505 - Licensee Marketing, seeks to implement measures to prevent diversion to individuals under 21 years of age, prevent accidental ingestion, and avoid the excessive commercialization of natural medicine and natural medicine services. Initially, this Rule seeks to minimize opportunities for packaging and labeling to misappropriate or exploit federally recognized American tribes, indigenous people, communities, and cultures by limiting the use of color and images on packages and labels. This rule does not limit the use of color or images in a Licensee's marketing materials, which could include branding - *see* Rule 3505 for additional information, requirements, and limitations on Licensee marketing.

3305 – Packaging & Labeling Requirements

A. Any transfer of Regulated Natural Medicine and Regulated Natural Medicine Product must be in a container and packaged and labeled in accordance with this Rule.

1. Servings of Regulated Natural Medicine and Regulated Natural Medicine Product.

a. A single Unit of Regulated Natural Medicine Product may contain no more than 10 milligrams of Total Psilocin.

b. A package of Regulated Natural Medicine Product may contain no more than 50 milligrams of Total Psilocin.

c. A package of Regulated Natural Medicine may contain no more than 5 grams of dried Fruiting Bodies.

2. Tincture Product Packaging. A Natural Medicine Products Manufacturer producing tincture products allowed under Rule 6005(C)(2)(a) must package the tincture product:

a. In a manner consistent with the requirements in subparagraph (1)(b) of this Rule; and

b. Affixing the package of tincture product with a measuring device that permits the Facilitator or Natural Medicine Handler Licensee to measure each serving.

3. A container or package may be reused as long as it is effectively sanitized and complies with the requirements of these Rules.

4. All labels must comply with the following:

a. The font on the label must be legible and at least 8-point font.

b. The date the Regulated Natural Medicine was harvested or the date the Regulated Natural Medicine Product was manufactured.

c. Natural Medicine Business name, License number, and Harvest Lot and/or Production Lot number.

d. *Psilocybe cubensis* strain type and net contents in either dried weight of the Fruiting Bodies or Total Psilocin of a manufactured product.

B. Prior to Transfer to a Natural Medicine Products Manufacturer.

1. Packaging. Prior to transfer to a Natural Medicine Products Manufacturer, Regulated Natural Medicine must have completed all required processing steps in accordance with the Licensee's standard operating procedures, including passing any required testing pursuant to Rule 4010.

2. Labeling Requirements. Prior to transfer to a Natural Medicine Products Manufacturer, the Natural Medicine Cultivation Facility must affix a label that complies with paragraph (A)(4) of this Rule.

C. Prior to Transfer to a Natural Medicine Testing Facility.

1. Prior to transfer to a Natural Medicine Testing Facility, a Sample of Regulated Natural Medicine or Regulated Natural Medicine Product must be in its final form and have completed all required processing or manufacturing steps in accordance with the Licensee's standard operating procedures.

2. Packaging. Samples of Regulated Natural Medicine and Regulated Natural Medicine Product must be placed into a transparent container that permits the Sample to be photographed by the Natural Medicine Testing Facility. The container must have at least 20% empty space.

3. Labeling Requirements. Prior to transfer to a Natural Medicine Testing Facility, the Natural Medicine Cultivation Facility or Natural Medicine Products Manufacturer must affix a label that:

a. Complies with paragraph (A)(4) of this Rule; and

b. If applicable, a list of all ingredients used to manufacture the Regulated Natural Medicine Product including identification of major allergens including milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans.

D. Prior to Transfer to a Healing Center or Facilitator.

1. Prior to transfer to a Healing Center or Facilitator, all Regulated Natural Medicine or Regulated Natural Medicine Product must be in its final form and have completed all required processing or manufacturing steps in accordance with the Licensee's standard operating procedures and have passed all required testing in accordance with Part 4 of these Rules.

2. Packaging.

a. Prior to transfer to a Licensed Facilitator. Regulated Natural Medicine and Regulated Natural Medicine Product transferred to a Facilitator for an Administration Session at an authorized location other than a Healing Center must be in a Child-Resistant container.

3. Labeling Requirements. Prior to transfer to a Healing Center or Facilitator, the container must be affixed with a label that:

a. Complies with paragraph (A)(4) of this Rule;

b. Includes the Total Psilocin content in milligrams, and the date the tryptamine content analysis test was performed; and

c. If applicable, a list of all ingredients used to manufacture the Regulated Natural Medicine Product including identification of major allergens including milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans.

4. The label may include, but is not required to include, the Natural Medicine Business's logo.

5. Supplemental Information. Prior to transfer to a Healing Center or Facilitator, the Natural Medicine Cultivation or Natural Medicine Product Manufacturer must provide the following information. This supplemental information may be included on the label, provided electronically, or provided in hard-copy documentation accompanying the package to the Healing Center:

a. If the Regulated Natural Medicine or Regulated Natural Medicine Product has been subject to shelf stability testing in accordance with Rules 5020(H)(3) or 6015(I)(3), the expiration date; or

b. If the Regulated Natural Medicine or Regulated Natural Medicine Product has not been subject to shelf stability testing to support an expiration date, the label must include the following statement:

"Tryptamine content must be retested every 9 months. Whoever is in possession of this product must submit it for tryptamine content analysis testing 9 months from the harvest or production date."; and

c. Include ideal storage conditions for the Regulated Natural Medicine or Regulated Natural Medicine Product; and

d. Drug Interaction Warning Statement: The label must include the following statement:

"Drug Interaction Warning: This product may interact with other prescription drugs, recreational drugs, alcohol, or other substances. Special care should be taken by anyone consuming natural medicine and other prescription or recreational drugs."

6. Labeling Restrictions.

a. A label on Regulated Natural Medicine or Regulated Natural Medicine Product shall not make any claims regarding health or physical benefits.

b. Labels must not be attractive to individuals under the age of 21. Colors, pictures, and cartoon images are not permitted on labels.

c. Labels must not use the word "candy" or "candies."

d. A Regulated Natural Medicine Product cannot be labeled or packaged in a manner that would cause confusion as to whether the product was a trademarked food product.

e. Regulated Natural Medicine and Regulated Natural Medicine Product shall not be labeled in a way that misappropriates or exploits the identity or cultural history of Federally Recognized American Tribes, as defined in section 12-170-104(7), C.R.S., and indigenous people, their community, cultures, or religions.

Basis and Purpose – 3405

The statutory authority for this rule includes but is not limited to sections 44-50-104(5)(c), 44-50-202(1)(b), 44-50-203(1)(b), 44-50-203(1)(h)(I)-(V), 44-50-203(1)(k), 44-50-203(1)(l), and 44-50-203(2)(j), and 44-50-203(2)(k), C.R.S. The purpose of this rule is to establish requirements for transportation of Regulated Natural Medicine and Regulated Natural Medicine Product between Natural Medicine Businesses.

3405 – Transport and Storage

A. Persons Authorized to Transport. Only an individual who holds a valid Natural Medicine Handler License or Owner License may handle the transport of Regulated Natural Medicine, Regulated Natural Medicine Product, or Regulated Natural Medicine Waste in a vehicle on behalf of a Natural Medicine Business or between Natural Medicine Businesses. Any other passengers in the vehicle must be at least twenty-one years of age or older.

B. Transport Between Licensed Premises.

1. Licensees shall only transport Regulated Natural Medicine and Regulated Natural Medicine Product between Licensed Premises or transfer directly to a Facilitator licensed by the Department of Regulatory Agencies.

2. Licensees may only transfer Regulated Natural Medicine Waste between Licensed Premises or receive Regulated Natural Medicine Waste directly from a Facilitator licensed by the Department of Regulatory Agencies.

C. Securing Regulated Natural Medicine During Transport. Licensees transporting Regulated Natural Medicine, Regulated Natural Medicine Product, or Regulated Natural Medicine Waste must ensure that the Regulated Natural Medicine, Regulated Natural Medicine Product, or Regulated Natural Medicine Waste is stored within a locked, secured area, shielded from view from the exterior of the vehicle at all times during transport.

D. Transport Manifest Required. A Licensee may only transport Regulated Natural Medicine, Regulated Natural Medicine Product, or Regulated Natural Medicine Waste if he, she, or they have a Division-approved transport manifest.

1. The manifest may be either a hard copy or digital/electronic version. Licensees are required to ensure all information is preserved with valid and verified signatures on any manifest. Valid and verified signatures must be dated and can be electronic.

2. The transport manifest must include the following information:

    a. Originating Natural Medicine Business name, License number, and address;

    b. Receiving Natural Medicine Business or Facilitator name, License number, and address;

    c. Name, contact information, and Natural Medicine Handler License number or Owner License number for any individual in the vehicle transporting the Regulated Natural Medicine, Regulated Natural Medicine Product, or Regulated Natural Medicine Waste;

    d. Driver's valid state-issued driver license number:

    e. Vehicle make, model, and license plate number;

    f. Planned route for transportation;

    g. Date and estimated time of departure;

    h. Date and estimated time of arrival or completion of transport;

    i. Address and duration of any overnight stop; and

    j. Information about the product being transported.

3. A Licensee shall provide a copy of the transport manifest to each Natural Medicine Business or Facilitator receiving Regulated Natural Medicine and Regulated Natural Medicine Product described in the transport manifest. To maintain transaction confidentiality, the originating Licensee may prepare a separate transport manifest for each recipient Natural Medicine Business or Facilitator.

E. Motor Vehicle Required. A Licensee must use a motor vehicle to transport Regulated Natural Medicine and Regulated Natural Medicine Product.

1. The motor vehicle must be properly registered in the state of Colorado pursuant to motor vehicle laws but need not be registered in the name of the Licensee.

2. The motor vehicle must be equipped with an alarm system.

3. The motor vehicle must be insured at or above legal requirements.

4. The motor vehicle must have appropriate temperature control for transporting Regulated Natural Medicine and Regulated Natural Medicine Product.

F. Use of Colorado Roadways. Licensees must comply with all state and local laws when transporting Regulated Natural Medicine and Regulated Natural Medicine Product on public roads in the state of Colorado.

G. Preparation of Regulated Natural Medicine and Regulated Natural Medicine Product for Transport.

1. Licensees must weigh Regulated Natural Medicine, Regulated Natural Medicine Product, and Regulated Natural Medicine Waste prior to packaging for transport. The scale used to weigh Regulated Natural Medicine and Regulated Natural Medicine Product shall be tested and approved in accordance with measurements and standards established in section 35-14-127, C.R.S.

2. Licensees may only weigh, package, label, and prepare for transport Regulated Natural Medicine, Regulated Natural Medicine Product, and Regulated Natural Medicine Waste in the Restricted Area.

H. Licensee Responsibilities to Ensure Consistent Transport Information.

1. Responsibilities of Originating Licensee. Prior to departure, the originating Licensee shall adjust its records to reflect the removal of Regulated Natural Medicine and Regulated Natural Medicine Product from the Licensed Premises. The Licensee shall maintain a copy of the transport manifest pre-transport and post-receipt of Regulated Natural Medicine and Regulated Natural Medicine Product by receiving Licensee. The Licensee shall reconcile inventory based on product name and quantity with the applicable transport manifest.

2. Responsibilities of Recipient Licensee. Upon receipt, the receiving Licensee shall ensure that the Regulated Natural Medicine and Regulated Natural Medicine Product are as described in the transport manifest and shall immediately adjust its records to reflect the receipt of inventory. The receiving Licensee shall weigh the inventory received on a scale that is tested and approved in accordance with measurement standards in section 35-14-127, C.R.S. The Licensee shall reconcile inventory based on product name and quantity with the applicable transport manifest.

3. Discrepancies. The receiving Licensee shall document any differences between the quantity specified in the transport manifest and the quantities of Regulated Natural Medicine or Regulated Natural Medicine Product received. Licensees must maintain a record of the discrepancy, which may be included in the final, signed transport manifest.

I. Regulated Natural Medicine and Regulated Natural Medicine Products must be transported and stored in sanitary environments and kept away from conditions that could contaminate or degrade the Regulated Natural Medicine and Regulated Natural Medicine Product.

J. Transport of Contaminated Regulated Natural Medicine and Regulated Natural Medicine Product. In the event Regulated Natural Medicine and Regulated Natural Medicine Product has failed required testing, has been contaminated, or otherwise presents a risk of cross-contamination to other Regulated Natural Medicine and Regulated Natural Medicine Product, such Regulated Natural Medicine and Regulated Natural Medicine Product may only be transported if it is physically segregated and contained in a sealed package that prevents cross contamination.

K. Inventory tracking procedures must be followed.

1. For each tracking event required to be tracked, the following information must be documented.

    a. The date the Regulated Natural Medicine, Regulated Natural Medicine Product, or Regulated Natural Medicine Waste was received.

    b. The quantity of Regulated Natural Medicine, Regulated Natural Medicine Product, or Regulated Natural Medicine Waste that was received.

    c. The Natural Medicine Business License number, name, and phone number from which the transfer originated.

    d. The Natural Medicine Business License number, name, and phone number where the Regulated Natural Medicine or Regulated Natural Medicine Waste originated.

    e. If applicable, the Natural Medicine Business License number, name, and phone number for the Natural Medicine Product Manufacturer where the Regulated Natural Medicine Product was produced.

2. Licensees must report on a monthly basis all inventory tracking events from the previous calendar month in a manner prescribed by the Division, using any forms provided by the Division.

Basis and Purpose – 3505

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(j), 44-50-203(1)(k), 44-50-203(1)(m), 44-50-203(2)(a), and 44-50-203(2)(q), C.R.S. The purpose of this rule is to define the requirements and limitations on Natural Medicine Businesses in public communications promoting the Licensee, Regulated Natural Medicine, Regulated Natural Medicine Product, or Natural Medicine Services. The following rule, in conjunction with Rule 3305 - Licensee Marketing, seeks to implement measures preventing diversion to individuals under 21 years of age, prevent accidental ingestion, and avoid the excessive commercialization of natural medicine and natural medicine services. Initially, this rule seeks to minimize opportunities to misappropriate or exploit federally recognized American tribes, indigenous people, communities, and cultures by limiting the use of color and images on packages and labels. This rule does not limit the use of color or images in a Licensee's marketing materials, which could include branding - see Rule 3305 for additional information, requirements, and limitations on packaging and labeling.

3505 – Licensee Marketing

A. Applicability. This Rule applies to any communication that markets a Licensee, the Licensee's Regulated Natural Medicine or Regulated Natural Medicine Product, or Natural Medicine Services regardless of how that communication is identified. Marketing includes, but is not limited to, advertising, public relations, branding, and other promotional effects.

B. No Deceptive, False, or Misleading Statements. A Natural Medicine Business shall not engage in marketing communication that is deceptive, false, or misleading. A Natural Medicine Business shall not make any deceptive, false, or misleading assertions or statements on any product, any sign, or any document provided to a Participant.

C. No Misappropriation of Federally Recognized American Tribes or Indigenous People or Culture. Natural Medicine Businesses, Regulated Natural Medicine, Regulated Natural Medicine Product and Natural Medicine Services shall not be marketed in a way that misappropriates or exploits the identity or cultural history of Federally Recognized American Tribes as defined in section 12-170-104(7), C.R.S., or indigenous people, their community, culture or religions.

D. No Safety Claims Because Tested. A Natural Medicine Business shall not claim that Regulated Natural Medicine or Regulated Natural Medicine Product are safe because they were tested by a Natural Medicine Testing Facility.

E. Promotions Shall Not Appeal to Individuals Under 21 Years of Age. Natural Medicine Businesses shall not market in a way that appeals to individuals under 21 years old, including but not limited to images of minors, cartoons, toys, or similar images and items typically marketed towards minors, or reference to products that are commonly associated with minors or marketed to minors.

F. Audience Composition Data Required. Licensees are required to maintain audience composition data demonstrating that any communication marketing the Licensee, Regulated Natural Medicine, Regulated Natural Medicine Product, or Natural Medicine Services has an audience where at least 73.6% of the audience is reasonably expected to be at least 21 years of age or older.

G. A Natural Medicine Business may only market the Licensee's services to individuals who are legally allowed to obtain Natural Medicine Services. Licensees shall not market transfer of Regulated Natural Medicine or Regulated Natural Medicine Product for remuneration.

H. Outdoor Marketing. Prior to engaging in outdoor marketing or advertising, the Licensee shall provide the Division with audience composition data demonstrating compliance with subpart (F) of this Rule above and documentation demonstrating compliance with local outdoor marketing or advertising restrictions. The restrictions in this Rule 3505(H) do not prohibit a sign or signs on the building where the Licensed Premises is located.

Part 4 – Regulated Natural Medicine Testing Program

Basis and Purpose – 4005

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(f), 44-50-203(2)(a), 44-50-203(2)(r) and 44-50-404(2), C.R.S. The purpose of this rule is to establish the requirement that Natural Medicine Businesses pay for required testing of Regulated Natural Medicine or Regulated Natural Medicine Product.

4005 – Costs

The cost for all sampling and tests conducted pursuant to these Rules is the responsibility of the Regulated Natural Medicine Business that is required to submit the Sample for testing. A Natural Medicine Testing Facility may require prepayment or decline to provide test results until a Regulated Natural Medicine Business remits payment for the test(s).

Basis and Purpose – 4010

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(b), 44-50-203(1)(f), 44-50-203(1)(n), 44-50-203(2)(d), 44-50-203(2)(g), and 44-50-404(2), C.R.S. The purpose of this rule is to establish the required testing and sampling procedures for Regulated Natural Medicine that a Natural Medicine Cultivation Facility must complete prior to transferring Regulated Natural Medicine.

These testing rules reflect initial rules that attempt to balance the costs to Natural Medicine Businesses and protect public health and safety. These rules are based on limited available data and prior experience with other similar programs due to the nascent nature of the Regulated Natural Medicine program. The State Licensing Authority will monitor testing data and Participant experiences and may revise testing requirements to require more or less frequent testing, testing for additional or different contaminants, additional testing requirements if additional routes of administration are permitted and other testing updates. Further, if additional Natural Medicines are permitted in the Regulated Natural Medicine program, those may also require additional testing requirements.

4010 – Natural Medicine Cultivation Facility - Required Regulated Natural Medicine Testing

A. Regulated Natural Medicine must pass all required testing conducted by a Natural Medicine Testing Facility prior to transfer to a Natural Medicine Products Manufacturer, Healing Center, or Facilitator.

B. Sampling Procedures.

1. Harvest Lot Sampling. Whole fungi must be fully dried to be submitted to a Natural Medicine Testing Facility. The Sample must be a mixture of parts of the Fruiting Bodies, including caps and stems of different Fruiting Bodies.

a. Samples collected from a Harvest Lot shall be a minimum of 2.5 grams and contain a minimum of 5 Sample Increments.

b. Sample Increments collected from a Harvest Lot shall be a minimum of 0.5 grams.

2. Sampling Procedure Training. A Natural Medicine Cultivation Facility must provide standard operating procedures and training to any Natural Medicine Handler Licensee or Owner Licensee who will collect Samples for required testing.

a. The standard operating procedures and training must include at least the following topics:

i. These Part 4 Rules - Regulated Natural Medicine Testing Program;

ii. Sampling procedures or guidance established by the Division, as available;

iii. Cross contamination as it relates to Sample collection;

iv. Sample collection documentation and record keeping requirements; and

v. Use of and disinfection of Sample collection equipment.

C. Required Testing - Harvest Lot Testing. Prior to transferring any Regulated Natural Medicine to a Natural Medicine Product Manufacturer, Healing Center, or Facilitator, a Natural Medicine Cultivation Facility must comply with required testing and that testing must be completed with a Sample submitted that is representative of the Harvest Lot it came from.

1. Tryptamine Content Analysis Testing.

a. Each Harvest Lot of Regulated Natural Medicine must be submitted for tryptamine content analysis. The results of the tryptamine content analysis required in this Rule must be accurately documented in the Licensee's inventory tracking records and on the label prior to transfer to a Facilitator, Natural Medicine Products Manufacturer, or Healing Center. The tryptamine content analysis shall test for:

i. Psilocybin;

ii. Psilocin;

iii. Baeocystin;

iv. Aeruginascin; and

v. Norbaeocystin.

b. Each Sample of Regulated Natural Medicine must also be tested for the presence of 4-acetoxy-N,N-Dimethyltryptamine (4-AcO DMT). The presence of any amount of 4-AcO-DMT is considered a failing test.

c. Failed Testing. The detection of a synthetic tryptamine or synthetic analog of a tryptamine, including a derivative of naturally occurring compounds of psilocybin or psilocin that is produced using chemical synthesis, chemical modification, or chemical conversion shall constitute a failed tryptamine content analysis test.

d. Tryptamine content analysis shall be conducted every nine months from the date of the original test or most recent retest. When retesting indicates a significant deviation of Total Psilocin, more than 15% higher or lower than the previous Total Psilocin, the Regulated Natural Medicine must be relabeled with the new tryptamine content.

2. Contaminant Testing - Microbial Panel. A Natural Medicine Cultivation Facility shall subject at least one Harvest Lot to the following microbial contaminant testing once every 30-day period following the Sample submission of the last Sample. If during any 30-day period the Natural Medicine Cultivation Facility does not possess a Harvest Lot that is ready for testing, the Natural Medicine Cultivation Facility must subject its first Harvest Lot that is ready for testing to the required contaminant testing prior to transfer to a Facilitator, Healing Center, or Natural Medicine Products Manufacturer.

a. Each Sample of Regulated Natural Medicine must be submitted for the following microbial contaminant tests:

i. *Salmonella*. *Salmonella* must be absent from the Sample.

ii. Shiga toxin producing *Escherichia coli* (STEC). STEC must be absent from the Sample.

Basis and Purpose – 4015

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(b), 44-50-203(1)(f), 44-50-203(1)(n), 44-50-203(2)(d), 44-50-203(2)(g), and 44-50-404(2), C.R.S. The purpose of this rule is to establish the required testing and sampling procedures for Regulated Natural Medicine Product that a Natural Medicine Products Manufacturer must complete prior to transferring Regulated Natural Medicine Product.

These testing rules reflect initial rules that attempt to balance the costs to Natural Medicine Businesses and protecting public health and safety. These rules are based on limited available data and prior experience with other similar programs due to the nascent nature of the Regulated Natural Medicine program. The State Licensing Authority will monitor testing data and Participant experiences and may revise testing requirements to require more or less frequent testing, testing for additional or different contaminants, additional testing requirements if additional routes of administration are permitted and other testing updates. Further, if additional Natural Medicines are permitted in the Regulated Natural Medicine program, those may also require additional testing requirements.

4015 – Natural Medicine Products Manufacturer - Required Regulated Natural Medicine Product Testing.

A. Regulated Natural Medicine Product must pass all required testing conducted by a Natural Medicine Testing Facility prior to transfer to another Natural Medicine Products Manufacturer, Healing Center, or Facilitator.

B. Sampling Procedures.

1. Production Lots of Regulated Natural Medicine.

a. A Sample shall contain at least the number of Sample Increments required by the Division for a given Production Lot size, as described in the table below.

b. A Sample Increment shall contain at least one discrete unit that comprises the Production Lot (e.g. one capsule, one chocolate bar).

c. If the Production Lot will be transferred in packages that contain more than one Unit, a Sample shall contain at least two packages.

d. A Sample shall contain at least the minimum amount of Regulated Natural Medicine Product required by the Natural Medicine Testing Facility to perform all of the tests requested by the submitting Natural Medicine Business.

e. Required Natural Medicine Product Sampling. See the table below. Minimum Sample Increment = 1 Unit.

Number of Units within the Production Lot	Minimum Number Sample Increments per Sample
0-99	5
100-999	8
1000-4999	15
5000-9999	22
10000-49999	33
50000 or more	43

2. Sampling Procedure Training. A Natural Medicine Products Manufacturer must provide standard operating procedures and training to any Natural Medicine Handler Licensee or Owner Licensee who will collect Samples for required testing.

    a. The standard operating procedures and training must include at least the following topics:

        i. These Part 4 Rules - Regulated Natural Medicine Testing Program;

        ii. Sampling procedures or guidance established by the Division, as available;

        iii. Cross contamination as it relates to Sample collection;

        iv. Sample collection documentation and record keeping requirements; and

        v. Use and disinfection procedures of Sample collection equipment.

C. Required Testing - Production Lot Testing. Prior to transferring any Regulated Natural Medicine Product, a Natural Medicine Products Manufacturer must comply with required testing and that testing must be completed with a Sample submitted that is representative of the Production Lot it came from. The Sample must be of sufficient size and increments to determine the homogeneity of the product.

1. Tryptamine Content Analysis Testing.

    a. Each Production Lot of Regulated Natural Medicine Product must be submitted for tryptamine content analysis. The results of the tryptamine content analysis required in this Rule must be accurately documented in the Licensee's inventory tracking records and on the label prior to transfer to a Facilitator, Natural Medicine Products Manufacturer, or Healing Center.

        i. Psilocybin;

        ii. Psilocin;

        iii. Baeocystin;

        iv. Aeruginascin; and

        v. Norbaeocystin.

    b. Each Sample of Regulated Natural Medicine Product must also be tested for the presence of 4-acetoxy-N,N-Dimethyltryptamine (4-AcO DMT). The presence of any amount of 4-AcO-DMT is considered a failing test.

    c. Failed Testing. The detection of a synthetic tryptamine or synthetic analog of a tryptamine, including a derivative of naturally occurring compounds of psilocybin or psilocin that is produced using chemical synthesis, chemical modification, or chemical conversion shall constitute a failed tryptamine content analysis test.

d. Tryptamine content analysis shall be conducted every nine months from the date of the original test or most recent retest. When retesting indicates a significant deviation of Total Psilocin, more than 15% higher or lower than the previous Total Psilocin, the Regulated Natural Medicine Product must be relabeled with the new tryptamine content.

2. Homogeneity. Each Production Lot must be tested to ensure homogeneous distribution of tryptamines throughout the Production Lot. For homogeneity testing, a Natural Medicine Products Manufacturer must submit a minimum of four servings from a minimum of two separate items (e.g. four capsules of dried, powdered mushrooms or two complete chocolate bars if each bar contains more than one serving). A Production Lot is considered to have a homogeneous distribution of tryptamines if each serving of no more than 10 milligrams Total Psilocin that is submitted for homogeneity testing is within 15.0% of the labeled value and the relative standard deviation of the four servings is less than 15.0%.

3. Contaminant Testing - Microbial Panel. A Natural Medicine Products Manufacturer shall subject at least one Production Lot to the following microbial contaminant testing once every 30-day period following the Sample submission of the last Sample. If during any 30-day period the Natural Medicine Products Manufacturer does not possess a Production Lot that is ready for testing, the Natural Medicine Products Manufacturer must subject its first Production Lot that is ready for testing to the required contaminant testing prior to transfer to a Facilitator or Healing Center.

a. Each Sample of Regulated Natural Medicine Product must be submitted for the following microbial contaminant tests:

i. *Salmonella*. *Salmonella* must be absent from the Sample.

ii. Shiga toxin producing *Escherichia coli* (STEC). STEC must be absent from the Sample.

Basis and Purpose – 4020

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(b), 44-50-203(1)(f), 44-50-203(1)(j), 44-50-203(2)(d), 44-50-203(2)(g), 44-50-203(2)(r), and 44-50-404(2), C.R.S. The purpose of this rule is to establish the Natural Medicine Division's authority to request testing at any time and to require the Licensee to submit Samples for any required tests to a Natural Medicine Testing Facility.

These testing rules reflect initial rules that attempt to balance the costs to Natural Medicine Businesses and protect public health and safety. These rules are based on limited available data and prior experience with other similar programs due to the nascent nature of the Regulated Natural Medicine program. The State Licensing Authority will monitor testing data and Participant experiences and may revise testing requirements to require more or less frequent testing, testing for additional or different contaminants, additional testing requirements if additional routes of administration are permitted and other testing updates. Further, if additional Natural Medicines are permitted in the Regulated Natural Medicine program, those may also require additional testing requirements.

4020 – Division Directed Testing

A. Upon direction by the Division or the State Licensing Authority, a Natural Medicine Business must submit one or more Samples of Regulated Natural Medicine or Regulated Natural Medicine Product for any tests required under this Rule and other tests as may be necessary for investigation. If the Division directs a test, the results will be shared with the Natural Medicine Business.

B. Samples collected pursuant to this Rule may be tested for tryptamine content, Total Psilocin, or contaminants which may include, but is not limited to, pesticides, microbial contaminants, mycotoxins, elemental impurities, residual solvents, or other chemical contaminants.

C. A Licensee must submit a Sample(s) to a Natural Medicine Testing Facility within 48 hours of receiving a Division directive for additional testing, unless otherwise noted in the directive.

D. The Division may elect, at its sole direction, to assign Division representatives to collect Samples.

E. The Division may issue a Notice of Embargo or Notice of Destruction pursuant to Rule 3210 based on test results that pose a risk to public health, safety, or welfare.

Basis and Purpose – 4025

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(b), 44-50-203(1)(f), 44-50-203(1)(l), 44-50-203(2)(d), 44-50-203(2)(g), 44-50-203(2)(i), 44-50-203(2)(k), and 44-50-203(2)(r), and 44-50-404(2), C.R.S. The purpose of this rule is to establish the procedures and requirements when a Natural Medicine Business is notified that Regulated Natural Medicine or Regulated Natural Medicine Product fails testing.

These testing rules reflect initial rules that attempt to balance the costs to Natural Medicine Businesses and protect public health and safety. These rules are based on limited available data and prior experience with other similar programs due to the nascent nature of the Regulated Natural Medicine program. The State Licensing Authority will monitor testing data and Participant experiences and may revise testing requirements to require more or less frequent testing, testing for additional or different contaminants, additional testing requirements if additional routes of administration are permitted and other testing updates. Further, if additional Natural Medicines are permitted in the Regulated Natural Medicine program, those may also require additional testing requirements.

4025 – Failed Test Procedures

A. Failed Contaminant Tests. If a Regulated Natural Medicine Business is notified by a Natural Medicine Testing Facility or the Division of a failed contaminant test, then for each Sample the Natural Medicine Business must destroy and document the destruction of the Harvest Lot or Production Lot in the inventory tracking system, according to the waste Rule 3120.

B. If a Licensee's Sample fails contaminant testing, the Licensee shall submit Samples from the next five Harvest Lots or Production Lots for the failed test type(s) by a Natural Medicine Testing Facility regardless of amount of time between each Harvest Lot or Production Lot.

    1. If the results of any of the next five tests fail a contaminant test, the Natural Medicine Business must complete a required CAPA plan under Rule 5020(E)(3) or 6015(E)(3) and submit the results and any revisions to the Division. The Division will review the revised plan and may conduct an inspection to confirm compliance with the plan.

2. If any lot has failed contaminant testing, it cannot be further transferred until the Natural Medicine Business fulfills the CAPA plan and the Division confirms through inspection that the Nonconformances were addressed.

Part 5 – Regulated Natural Medicine Cultivation License Requirements

Basis and Purpose – 5005

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(d), 44-50-203(1)(i), 44-50-203(1)(l), 44-50-203(1)(n), 44-50-203(2)(a), and 44-50-402, C.R.S. The purpose of this rule is to establish licensing tiers and transfer authority for Natural Medicine Cultivation Facilities. The Division intends to revisit this rule and the cultivation tiers outlined in this Part 5 during a future rulemaking proceeding once baseline information and data is available from the Regulated Natural Medicine Program in order to determine if additional revisions to cultivation tiers are appropriate. Additional revisions may include a reduction or increase in the amount of Regulated Natural Medicine a Natural Medicine Cultivation Facility may cultivate and store on the Licensed Premises.

5005 – License Privileges

A. A Natural Medicine Cultivation Facility Licensee may only exercise the License privileges granted by the State Licensing Authority and these Rules.

1. No later than thirty days after beginning operations, the Natural Medicine Cultivation Facility Licensee must submit complete floor plans or diagrams of the Licensed Premises to the Division in a manner prescribed by the Division. Floor plans or diagrams must clearly show any areas designated as Administration Areas, if co-located with a Healing Center, any areas designated as Restricted Areas, and security camera placement required by these Rules.

2. Micro-Cultivation Tier. A Natural Medicine Cultivation Facility Licensee who has obtained a micro-cultivation tier License may store Regulated Natural Medicine up to 750 grams of dried Fruiting Bodies.

3. Standard Cultivation Tier. All new Natural Medicine Cultivation Facility Licensees are standard cultivation tier Licenses, unless the Licensee applied for and received a micro-cultivation tier License.

    a. A standard cultivation tier License may store up to 5.000 kilograms of dried Fruiting Bodies of Regulated Natural Medicine at any one time.

    b. In accordance with Rule 5015, a standard cultivation tier Licensee who can demonstrate demand in a manner and on a form prescribed by the Division may apply for approval to cultivate, process, and store more than 5.000 kilograms of dried Fruiting Bodies.

B. Authorized Regulated Natural Medicine Sources.

1. A Natural Medicine Cultivation Facility may only use *Psilocybe cubensis* spores and mycelium from the Licensee's previous inoculations to cultivate Regulated Natural Medicine. The Natural Medicine Cultivation Facility must maintain complete and accurate records of spore sources, including certificates of analysis or other documentation demonstrating the spore species, if available.

2. A Natural Medicine Cultivation Facility may accept transfers of Regulated Natural Medicine Waste from another Natural Medicine Cultivation Facility, a Natural Medicine Products Manufacturer, a Healing Center, or a Facilitator licensed by the Department of Regulatory Agencies to dispose of the Regulated Natural Medicine Waste. The Regulated Natural Medicine Waste must be tracked in the waste log and must be handled in accordance with the transfer requirements in Rule 3405.

C. Authorized Transfers.

1. A Natural Medicine Cultivation Facility may transfer Regulated Natural Medicine to a Natural Medicine Manufacturing Facility, a Natural Medicine Testing Facility, and a Healing Center in accordance with this subparagraph (C)(1).

   a. Prior to transfer to a Natural Medicine Testing Facility, the Regulated Natural Medicine must comply with packaging requirements in Rule 3305(C).

   b. Prior to transfer to a Healing Center, the Regulated Natural Medicine must pass all required testing in Rules 4005 - 4015.

   c. Prior to transfer to a Healing Center or Facilitator, the Regulated Natural Medicine must be packaged and labeled pursuant to Rule 3305(D).

   d. Prior to transfer to a Natural Medicine Products Manufacturer, the Regulated Natural Medicine must be packaged and labeled pursuant to Rule 3305(B).

2. A Natural Medicine Cultivation Facility may transfer up to 750 milligrams of Total Psilocin at one time of Regulated Natural Medicine that has passed all required testing and is packaged and labeled pursuant to Rule 3305(D) to a Facilitator for Administrations Sessions at authorized locations other than Healing Centers in accordance with this Rule.

   a. Facilitator Request Requirements. A Natural Medicine Cultivation Facility may only transfer Regulated Natural Medicine to a Facilitator after receiving and verifying the Facilitator's request. All requests for Facilitator transfers must including the following information:

      i. The Facilitator's Department of Regulatory Agencies issued license number;

      ii. The requested amount of Regulated Natural Medicine;

      iii. The number of Administration Sessions the Facilitator is requesting Regulated Natural Medicine for;

      iv. The number of Participants that will be consuming the requested Regulated Natural Medicine; and

      v. The requested date for pick-up.

   b. Request Verification. A Natural Medicine Cultivation Facility must verify the Facilitator's Department of Regulatory Agencies issued license number in order to complete the transfer.

3. All transfers of Regulated Natural Medicine must comply with transport and inventory tracking requirements in Rules 3405 and 5025.

D. Cultivation & Processing Privileges. A Natural Medicine Cultivation Facility Licensee may cultivate, process, package, and label Regulated Natural Medicine, including inoculation, harvesting, and processing.

1. A Natural Medicine Cultivation Facility Licensee may process harvested Regulated Natural Medicine into whole dried Fruiting Bodies.

2. A Natural Medicine Cultivation Facility Licensee shall not produce Regulated Natural Medicine Product, which requires a Natural Medicine Products Manufacturer License.

E. Research and Development Testing. A Natural Medicine Cultivation Facility may conduct or submit Samples to a Natural Medicine Testing Facility for research and development testing on Regulated Natural Medicine.

1. A Natural Medicine Cultivation Facility may not conduct or submit Samples to a Natural Medicine Testing Facility for any research and development testing on any Regulated Natural Medicine obtained from a source other than the Natural Medicine Cultivation Facility.

2. Results of research and development testing conducted under this subparagraph E shall not count towards the fulfillment of any required testing mandated by these Rules.

3. The Natural Medicine Cultivation Facility Licensee must maintain full and accurate records regarding research and development test procedures, results, and other standard operating procedures consistent with these Rules.

Basis and Purpose – 5010

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(g), 44-50-203(1)(l), 44-50-203(2)(a), 44-50-203(2)(c), 44-50-203(2)(g), and 44-50-402(1), C.R.S. The purpose of this rule is to identify prohibited actions by Natural Medicine Cultivation Facilities.

5010 – Prohibited Acts

A. A Natural Medicine Cultivation Facility shall not use pesticides and fungicides in the cultivation of Regulated Natural Medicine. If the Division has reason to believe that pesticides or fungicides were used in the cultivation of Regulated Natural Medicine, a pesticide test will be requested per Rule 4020. The State Licensing Authority shall initiate an administrative action if test results indicate the presence of pesticides or fungicides, may embargo any contaminated Regulated Natural Medicine, and may require the Licensee to initiate a recall per Rule 3205.

B. Transfer to unlicensed persons prohibited. A Natural Medicine Cultivation Facility shall not transfer any Regulated Natural Medicine to a person who does not hold a Natural Medicine Business License, or a Facilitator licensed by the Department of Regulatory Agencies under article 170 of title 12 in accordance with Rule 5005. Only a Natural Medicine Handler Licensee or Owner Licensee may receive Regulated Natural Medicine on behalf of a Natural Medicine Business.

C. One Natural Medicine Cultivation Facility per Licensed Premises. A Licensed Premises shall only have one Natural Medicine Cultivation Facility License.

Basis and Purpose – 5015

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(b), 44-50-203(1)(g), 44-50-203(1)(i), 44-50-203(1)(n), 44-50-203(2)(a), 44-50-203(2)(f), and 44-50-203(2)(k), C.R.S. The purpose of this rule is to identify the permissible inventory and inventory management requirements for Natural Medicine Cultivation Facilities. The Division intends to revisit this rule and the cultivation tiers outlined in this Part 5 during a future rulemaking proceeding once baseline information and data is available from the Regulated Natural Medicine Program in order to determine if additional revisions to cultivation tiers are appropriate. Additional revisions may include a reduction or increase in the amount of Regulated Natural Medicine a Natural Medicine Cultivation Facility may cultivate and store on the Licensed Premises.

5015 – Production and Inventory Management

A. A Natural Medicine Cultivation Facility Licensee may only possess up to the maximum amount of Natural Medicine permitted by the Licensee's cultivation tier and in accordance with these Rules.

B. Security Measures.

1. A Natural Medicine Cultivation Facility Licensee who has obtained a micro-cultivation tier must store all Regulated Natural Medicine in a secured, locked place that is:

a. Accessible only to the Owner Licensee(s) and/or Natural Medicine Handler Licensee(s); and

b. Monitored by video surveillance while Regulated Natural Medicine is possessed or stored on the Licensed Premises.

2. All other Natural Medicine Cultivation Facility Licensees must comply with all security and surveillance requirements in Rules 3110 and 3115.

C. Cultivation Tiers. Each Natural Medicine Cultivation Facility shall be designated as either a micro-cultivation tier or a standard cultivation tier for purposes of production and inventory management.

1. Requests to Cultivate, Possess, and Store More than 5.000 Kilograms of Dried Fruiting Bodies. A Natural Medicine Cultivation Facility Licensee in the standard cultivation tier may apply in a manner prescribed by the Division for approval to cultivate, possess, and store more than 5.000 kilograms of dried Fruiting Bodies. The Division may consider the following in determining whether to approve the request:

a. The Natural Medicine Cultivation Facility making the request has consistently transferred Regulated Natural Medicine to other Natural Medicine Businesses or Facilitators in the preceding 180 days;

b. The Natural Medicine Cultivation Facility making the request has entered into a written agreement(s) or contract(s) with a Healing Center or Facilitator to provide Regulated Natural Medicine for Administration Sessions that demonstrate the basis for the request;

c. The Natural Medicine Cultivation Facility making the request has either entered into written agreement(s) or contract(s) with a Natural Medicine Products Manufacturer and the additional request is necessary to make Natural Medicine Product;

d. The Natural Medicine Cultivation Facility making the request has an established history of responsible cultivation, and transfers of Regulated Natural Medicine;

e. The Natural Medicine Cultivation Facility and its Owner Licensees have not been subject to an administrative action issued by the State Licensing Authority in the preceding 180 days;

f. The Natural Medicine Cultivation Facility making the request will be conducting research and development; and

g. Any other information requested to aid the Division in its evaluation of the request.

2. Notification of Reduction in Cultivation Tier from Standard Tier to Micro-Cultivation Tier. A Natural Medicine Cultivation Facility Licensee in the standard cultivation tier may choose to change its designation to a micro-cultivation tier by notifying the Division in a manner prescribed by the Division. Upon written confirmation that the Division received the notification, the Natural Medicine Cultivation Facility License will be considered a micro-cultivation tier license.

Basis and Purpose – 5020

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(b), 44-50-203(1)(g), 44-50-203(1)(j), 44-50-203(2)(e), 44-50-203(2)(g), 44-50-203(2)(h), 44-50-203(2)(i), 44-50-203(2)(j), 44-50-203(2)(k), 44-50-203(2)(p), C.R.S. The purpose of this rule is to establish health and sanitation requirements for Natural Medicine Cultivation Facilities and the equipment used at Natural Medicine Cultivation Facilities, record requirements, waste and destruction requirements for contaminated Natural Medicine, and storage, packaging and labeling requirements.

5020 – Cultivation Procedures

A. Regulated Natural Medicine must be produced in a sanitary environment, where all surfaces are maintained and kept in a clean manner.

1. Filters for air conditioning, ventilation, and air filtration systems must be cleaned and replaced regularly. Overhead light fixtures must be reasonably free of dust and insects.

2. Water must be potable. If well water is used, wells must be maintained to protect them from contamination. Floors must drain adequately, and there shall not be standing water on the floor of the Licensed Premises.

B. Cultivation Activities - Premises and Safety Requirements.

1. Toxic cleaning compounds, sanitizing agents, and other chemicals shall be identified, held, stored, and disposed of in a manner that protects against contamination of Regulated Natural Medicine, and in accordance with any applicable local, state, or federal law, rule, regulation, or ordinance. The use of any of the above compounds must be tracked in the safety data sheet, which must be kept in accordance with Rule 3010.

2. Ambient oxygen and CO2 monitors with alarms for elevated CO2 levels (>1000 ppm) must be used in any fruiting rooms. CO2 monitors should be placed at eye level.

3. All individuals working in direct contact with Regulated Natural Medicine in open-air cultivation rooms must have access to appropriate respiratory protection equipment to prevent mushroom worker’s lung.

4. The movement of employees between growing areas and substrate production areas must be controlled to prevent contamination.

5. Any receiving areas for raw materials or substrate must be located away from areas where harvest containers, packaging materials, spores, and other sanitary supplies are received. This includes where Regulated Natural Medicine is located.

C. Equipment. Equipment must be maintained to prevent contamination.

1. Equipment must be maintained to ensure it is in proper working order and does not contribute to contamination. All lubricants used on machinery with direct or indirect food contact and all processing aids must be food grade.

2. Suppliers of baskets, lugs, trays, tills and boxes must provide documentation that the material purchased is approved by the FDA for food contact surfaces.

a. Harvest baskets, lugs, and trays must be cleaned and sanitized before use or stored, and maintained to prevent splinters or shards. Containers with Regulated Natural Medicine must be clearly marked for this purpose and not be used for any other purpose

3. Temperature probes and supporting hardware to monitor growing conditions must be monitored and calibrated on a regular basis. Only non-mercury thermometers are allowed.

4. Cultivation Equipment. All harvesting equipment must be cleaned and sanitized prior to harvesting, and on a scheduled basis.

a. Baskets, lugs, trays and boxes used for harvesting must not contact the floor. Any filled harvest containers must be moved from growing rooms to staging areas in order to not contact the floor. If any Regulated Natural Medicine comes in contact with the floor, it must be discarded.

b. Once Regulated Natural Medicine is harvested, it must be placed in a container that is protected from materials that could fall into it.

D. Cultivation materials.

1. Cultivation materials, ingredients, and Regulated Natural Medicine that can support the rapid growth of undesirable microorganisms must be stored in a manner that prevents the growth of these microorganisms.

2. Substrate Preparation. Any unpasteurized substrate and storage areas must be adequately separated from areas where pasteurized substrate is stored to prevent cross-contamination.

a. Appropriate measures must be in place to prevent any seepage or runoff from the unpasteurized substrate preparation area by collecting or diverting it from the pasteurized substrate area.

E. Records. All records must be kept on file in accordance with Rule 3010.

1. If a Natural Medicine Cultivation Facility uses raw materials in the production of Regulated Natural Medicine, the Licensee must obtain and maintain documentation of the substrate, compost or other cultivation materials purchased, including the date of purchase.

2. Standard Operating Procedures (SOP). A Natural Medicine Cultivation Facility must have standard operating procedures for each method of cultivation on file, and available upon request for inspection by the Division. The SOP must include:

    a. A documented Regulated Natural Medicine safety plan, including worker training on proper Regulated Natural Medicine handling, hand washing, hair restraint, and use of gloves.

    b. Handling of Chemicals. Written procedures must document how workers are trained on the proper use of chemicals, and containers used to store chemical solutions are clearly marked with the common name of the chemical, and instructions for proper use, and non-food containers are used to prepare and hold all chemical solutions.

    c. Pest Control. Written procedures must document pest control strategies. All pest control devices must be located away from products so as to avoid contamination. At least one pest control device should be within 10 feet of each side of an outside entrance. If used, poison bait stations are used exclusively on the outside of the building. If used, all live traps are placed a maximum of 30 feet apart and at entrances. If pest lights are used, they must be placed so as to not attract pests into the building. All pest control devices are located on a map.

    d. Cultivation Materials and Procedures. Written documentation of materials used to cultivate Regulated Natural Medicine, including any equipment, ingredients, substrate, raw materials, spore type, and any additives.

    e. Instructions for Cultivation and Sampling. Specific instructions detailing each step in the cultivation process, including the expected yield of the cultivation. Written sampling procedures including Sample collection and test submission steps.

3. Corrective Action Preventative Action. A Natural Medicine Cultivation Facility shall establish and maintain written procedures for implementing corrective action and preventive action (CAPA). The written procedures shall include the requirements listed below as determined by the Licensee. All activities required under this Rule, and their results, shall be documented and kept as business records. The written procedures shall include requirements, as appropriate, for:

    a. What constitutes a Nonconformance in the Licensee's business operation;

    b. Analyzing processes, work operations, reports, records, service records, complaints, returned product, and/or other sources of data to identify existing and potential root causes of Nonconformances or other quality problems;

    c. Investigating the root cause of Nonconformances relating to product, processes, and the quality system;

    d. Identifying the action(s) needed to correct and prevent recurrence of Nonconformance and other quality problems;

e. Verifying the CAPA to ensure that such action is effective and does not adversely affect finished products;

f. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

g. Ensuring the information related to quality problems or Nonconformances is disseminated to those directly responsible for assuring the quality of products or the prevention of such problems; and

h. Submitting relevant information on identified quality problems and CAPA documentation, and confirming the result of the evaluation, for management review.

4. Any Adverse Health Events required to be reported in Rule 3015.

5. Certificates of Analysis. All certificates of analysis provided to the Natural Medicine Cultivation Facility by a Natural Medicine Testing Facility for any Samples submitted for testing shall be maintained on the Licensed Premises in accordance with Rule 3010.

F. Contaminated Regulated Natural Medicine.

1. If a Sample that was submitted for testing is contaminated or adulterated, the Harvest Lot must be disposed of according to Rule 3120.

2. If any Regulated Natural Medicine is exposed to blood or bodily fluids or is found to contain filth or foreign matter, it must be disposed of according to Rule 3120.

G. Directed Testing. A Natural Medicine Cultivation Facility Licensee shall, upon the Division's direction, submit a sufficient quantity of Regulated Natural Medicine to a Natural Medicine Testing Facility for laboratory or chemical analysis in accordance with Rule 4020. The Division will notify the Licensee of the results of the analysis.

H. Storage, Packaging, and Labeling.

1. Storage. After cultivation, Regulated Natural Medicine should follow best practices for storage prior to packaging. Current 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.

2. Packaging. All Regulated Natural Medicine must be packaged in accordance with Rule 3305.

3. Labeling. All Regulated Natural Medicine must be labeled in accordance with Rule 3305.

a. A Natural Medicine Cultivation Facility may establish an expiration date upon which the Regulated Natural Medicine's Total Psilocin will differ by an amount greater than +/- fifteen percent from the original test results.

b. The Licensee shall determine the expiration date by conducting the required testing pursuant to Rule 4010 on the Regulated Natural Medicine to ensure the Regulated Natural Medicine can pass tryptamine content and contaminant testing through the established expiration date.

c. When determining the expiration date pursuant to this Rule, the Licensee shall also consider the ideal storage conditions for the Regulated Natural Medicine.

d. Expiration date determinations, along with any data used to establish the expiration date, such as test results, shall be documented and maintained in the Licensee's records pursuant to these Part 5 Rules and Rule 3010.

I. Internal Audit. Natural Medicine Cultivation Facilities must conduct an annual internal audit to assess that they are in substantial compliance with the requirements of this Rule 5020. A copy of the internal audit shall be retained as business records for one year.

Basis and Purpose - 5025

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(b), 44-50-203(1)(h), 44-50-203(1)(j), 44-50-203(1)(k), 44-50-203(2)(i), 44-50-203(2)(k), 44-50-203(2)(r), C.R.S. The purpose of this rule is to establish requirements for Natural Medicine Cultivation Facilities to record and track Regulated Natural Medicine transferred to and from Natural Medicine Cultivation Facilities.

5025 – Minimum Inventory Tracking Requirements

A. All Natural Medicine Cultivation Facilities must have at least one designated Natural Medicine Handler Licensee or Owner Licensee to maintain inventory records.

1. For each tracking event required to be tracked, information must be documented in accordance with subparagraph (A)(3) of this Rule and Rule 3405.

2. Licensees must report on a monthly basis all inventory tracking events from the previous calendar month in a manner prescribed by the Division, using any forms provided by the Division.

3. Tracking Events. For purposes of required inventory tracking, tracking events include events when Regulated Natural Medicine progresses through the cultivation process and moves from the Natural Medicine Cultivation Facility to another Natural Medicine Business or Facilitator. Tracking events include at least the following:

a. Harvest Lot activities required by these Rules;

b. Transfers of Regulated Natural Medicine permitted by these Rules.

B. Natural Medicine Cultivation Tracking Requirements.

1. The following tracking information must be kept on the inventory tracking document and kept as a Business Record according to Rule 3010.

a. The Harvest Lot number. The following naming conventions must be used to assign a Harvest Lot number by a Natural Medicine Cultivation: Two-digit year, two-digit month, two-digit day. For example, January 1, 2024 would be 240101.

b. The wet weight of the harvest.

c. The dried weight of the harvest.

d. *Psilocybe cubensis* strain type.

e. The date of the initial packaging.

f. Bill of Materials (BOM) detailing the weight, measure or count of each component or ingredient needed to process the Harvest Lot;

2. The following tracking information must be kept on the inventory tracking document for transfer to a Natural Medicine Testing Facility:

a. Harvest Lot number;

b. Sample weight;

c. Date of transfer;

d. The Natural Medicine Testing Facility's License number, name, and phone number.

3. The following tracking information must be kept on the inventory tracking document for transfer to a Natural Medicine Product Manufacturer:

a. Harvest Lot number;

b. Weight (in grams) of the Regulated Natural Medicine;

c. Date of the transfer; and

d. The Natural Medicine Product Manufacturer's License number, name, and phone number.

4. The following tracking information must be kept on the inventory tracking document for transfer to a Facilitator.

a. Harvest Lot number;

b. Weight of the Regulated Natural Medicine;

c. Date of the transfer;

d. If applicable, the Facilitator's Natural Medicine Handler License number, name, and phone number; and

e. The information required by Rule 5005(C)(2)(a).

5. The following tracking information must be kept on the inventory tracking document for transfer to a Healing Center.

a. Harvest Lot number;

b. Weight of the Regulated Natural Medicine;

c. Date of the transfer; and

d. The Healing Center's License number, name, and phone number.

6. If a Natural Medicine Cultivation Facility generates waste while harvesting, processing, or producing Regulated Natural Medicine, or if the Regulated Natural Medicine Waste was previously designated as a finished product, the Licensee must document:

    a. A reason for the Regulated Natural Medicine Waste in the inventory tracking document.

    b. The exact time and method of destruction in the inventory tracking document.

Part 6 – Regulated Natural Medicine Product Manufacturing License Requirements

Basis and Purpose – 6005

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(i), 44-50-203(1)(k), 44-50-203(1)(l), 44-50-203(2)(a), 44-50-203(2)(d), 44-50-203(2)(g), 44-50-203(2)(k), and 44-50-403(1), C.R.S. The purpose of this rule is to establish the privileges and permitted acts for Natural Medicine Product Manufacturers.

6005 – License Privileges

A. A Natural Medicine Products Manufacturer Licensee may only exercise the License privileges established under the Natural Medicine Code and granted by the State Licensing Authority pursuant to these Rules.

    1. No later than thirty days after beginning operations, the Natural Medicine Products Manufacturer Licensee must submit complete floor plans or diagrams of the Licensed Premises to the Division in a manner prescribed by the Division. Floor plans or diagrams must clearly show any areas designated as Administration Areas, if co-located with a Healing Center, any areas designated as Restricted Areas, and security camera placement required by these Rules.

B. A Natural Medicine Product Manufacturer may only manufacture, distribute, and transfer Regulated Natural Medicine Product intended for oral ingestion, and limited to the following product types intended for oral ingestion, unless the Licensee has an extraction endorsement pursuant to subparagraph (C) of this Rule:

    1. Intended for Oral Ingestion

        a. Capsules; and

        b. Tea bags.

    2. No other Regulated Natural Medicine Product type is allowed to be produced or transferred unless in accordance with subparagraph (C) of this Rule.

C. Extraction Endorsement. A Natural Medicine Products Manufacturer with an extraction endorsement may manufacture, distribute, and transfer the following product types in addition to the product types in subparagraph (B) of this Rule:

    1. Intended for Oral Ingestion.

        a. Chocolate;

        b. Gelatin- or agar-based gummies in basic geometric shapes; and

c. Pressed tablets.

2. Intended for Sublingual Administration.

a. Tinctures

3. No other Regulated Natural Medicine Product type is allowed to be produced or transferred.

4. A Natural Medicine Products Manufacturer shall not manufacture or package a Regulated Natural Medicine Product in a manner that reasonably appears to represent a commercially manufactured food product or reasonably appears to target individuals under the age of 21.

a. Commercially manufactured food products may be used as ingredients in a Regulated Natural Medicine Product when: (1) they are used in a way that renders them unrecognizable as the commercial food product in the final Regulated Natural Medicine Product, and (2) the Natural Medicine Products Manufacturer does not represent that the final Regulated Natural Medicine Product contains the commercially manufactured food product.

5. Only Natural Medicine Products Manufacturers with an extraction endorsement may produce Regulated Natural Medicine Product using an extraction process. A Natural Medicine Products Manufacturer without the extraction endorsement may not use any extractive process. The following solvents are allowed to be used for extraction processes:

a. Water;

b. Food grade, non-denatured ethanol; and

c. Natural food-grade oils, such as coconut oil.

6. A Natural Medicine Products Manufacturer with an extraction endorsement shall not transfer a Natural Medicine Product to a Healing Center or Facilitator until the following actions are completed:

a. At least one week prior to transfer, the Natural Medicine Products Manufacturer completes a product registration form in a manner prescribed by the Division. The registration requirement in this Rule applies to each type of product the Licensee manufactures and must include the following:

i. A copy of the product manufacturing standard operating procedure; and

ii. To the extent any of the following is not included in the standard operating procedure:

A. A list of ingredients and processing aids;

B. Any pertinent information about the safety of the product and constituent ingredients; and

C. A picture of the label.

b. The Licensee receives confirmation of submission from the Division for the Natural Medicine Product intended for transfer.

D. Authorized Sources of Regulated Natural Medicine.

1. Regulated Natural Medicine Product may only be manufactured using Regulated Natural Medicine from a Licensed Natural Medicine Cultivation Facility.

2. A Natural Medicine Product Manufacturer may accept transfers of Regulated Natural Medicine Waste from a Natural Medicine Cultivation Facility, another Natural Medicine Products Manufacturer, a Healing Center, or a Facilitator licensed by the Department of Regulatory Agencies to dispose of the Regulated Natural Medicine Waste. The Regulated Natural Medicine Waste must be tracked in the waste log, and must be handled in accordance with the transfer requirements in Rule 3405.

E. Authorized Transfers.

1. A Natural Medicine Products Manufacturer may transfer Regulated Natural Medicine Product to another Natural Medicine Products Manufacturer, a Natural Medicine Testing Facility, and a Healing Center in accordance with this subparagraph (E)(1).

a. Prior to transfer to a Natural Medicine Testing Facility, the Regulated Natural Medicine Product must be in its final form and must comply with packaging requirements in Rule 3305(C).

b. Prior to transfer to a Healing Center, the Regulated Natural Medicine Product must pass all required testing in Rules 4005 - 4015.

c. Prior to transfer to a Healing Center or Facilitator, all Regulated Natural Medicine Product must be packaged and labeled pursuant to Rule 3305.

d. Prior to transfer to a Natural Medicine Products Manufacturer, the Regulated Natural Medicine must be packaged and labeled pursuant to Rule 3305(B).

2. A Natural Medicine Products Manufacturer may transfer up to 750 milligrams of Total Psilocin of Regulated Natural Medicine Product that has passed all required testing and is packaged and labeled pursuant to Rule 3305 to a Facilitator for Administration Sessions at authorized locations other than Healing Centers in accordance with this Rule.

a. Facilitator Request Requirements. A Natural Medicine Products Manufacturer may only transfer Regulated Natural Medicine Products to a Facilitator after receiving and verifying the Facilitator's request. All requests for Facilitator transfers must including the following information:

i. The Facilitator's Department of Regulatory Agencies issued license number;

ii. The requested amount of Regulated Natural Medicine Product;

iii. The number of Administration Sessions the Facilitator is requesting Regulated Natural Medicine Product(s) for;

iv. The number of Participants that will be consuming the requested Regulated Natural Medicine Product(s); and

v. The requested date for pick-up.

b. Request Verification. A Natural Medicine Products Manufacturer must verify the Facilitator's Department of Regulatory Agencies issued license number in order to complete the transfer.

3. All transfers of Regulated Natural Medicine Product must comply with transport and inventory tracking requirements in Rules 3405 and 6020.

F. Research and Development Testing. A Natural Medicine Products Manufacturer may conduct or submit Samples to a Natural Medicine Testing Facility for research and development testing on Regulated Natural Medicine Product the Licensee manufactured in the same Licensed Premises.

1. A Natural Medicine Products Manufacturer may not conduct or submit Samples to a Natural Medicine Testing Facility for any research and development testing on any Regulated Natural Medicine Products obtained from a source other than the Natural Medicine Products Manufacturer Facility.

2. Results of research and development testing conducted under this subparagraph (F) shall not be relied upon for any required testing as mandated by these Rules.

3. The Natural Medicine Products Manufacturer Licensee must maintain full and accurate records regarding research and development test procedures, results, and other standard operating procedures consistent with these Rules.

Basis and Purpose – 6010

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(g), 44-50-203(1)(k), 44-50-203(1)(l), 44-50-203(2)(a), 44-50-203(2)(d), 44-50-203(2)(g), and 44-50-403(1)(c), C.R.S. The purpose of this rule is to define prohibited activities of Natural Medicine Products Manufacturers.

6010 – Prohibited Acts

A. A Natural Medicine Products Manufacturer shall not transfer any Regulated Natural Medicine Product that is intended to be consumed through a route of administration other than oral ingestion, unless it is a tincture intended for sublingual administration.

B. Transfer to unlicensed persons prohibited. A Natural Medicine Products Manufacturer shall not transfer any Regulated Natural Medicine Product to a person who does not hold a Natural Medicine Business License, or a Facilitator licensed by the Department of Regulatory Agencies under article 170 of title 12 in accordance with Rule 6005. Only a Natural Medicine Handler Licensee or Owner Licensee may receive Regulated Natural Medicine Product on behalf of a Natural Medicine Business.

C. One Natural Medicine Products Manufacturer per Licensed Premises. A Licensed Premises shall only have one Natural Medicine Products Manufacturer License.

D. Natural Medicine Products Manufacturers are prohibited from:

1. Performing ethanol extractions while applying heat;

2. Performing extractions at pressures above or below atmospheric pressure;

3. Performing solvent removal, concentration of extracts, or distillations; and

4. Adulterating or otherwise including any substances that are not specifically allowed under these Rules. This includes mushrooms that are not safe for human consumption or that have an intoxicating effect, including without limitation amanita muscaria.

5. Manufacturing or transferring a Regulated Natural Medicine Product:

    a. For which the Natural Medicine Products Manufacturer has not submitted the required product registration in accordance with Rule 6005(C)(6) or that deviates from the submitted product registration.

    b. That appeals to children. In evaluating whether a Regulated Natural Medicine Product appeals to children, the State Licensing Authority may evaluate the following non-exhaustive factors:

        i. Design, brand, or name that resembles a product that does not contain Regulated Natural Medicine that are primarily consumed by, and marketed to, children; or

        ii. Products in the shape of an animal, fruit, person, or cartoon.

Basis and Purpose – 6015

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(b), 44-50-203(1)(g), 44-50-203(1)(j), 44-50-203(1)(k), 44-50-203(2)(a), 44-50-203(2)(e), 44-50-203(2)(g), 44-50-203(2)(h), 44-50-203(2)(i), 44-50-203(2)(j), 44-50-203(2)(k), and 44-50-403(1), C.R.S. The purpose of this rule is to define the health and sanitation requirements for Natural Medicine Products Manufacturers and the storage, packaging and labeling, record-keeping, and disposal requirements for Natural Medicine Product Manufacturers.

6015 – Manufacturing Procedures

A. Regulated Natural Medicine Product must be produced in a sanitary environment, where all food surfaces are maintained and kept in a clean manner.

    1. Filters for air conditioning, ventilation, and air filtration systems are cleaned and replaced regularly.

    2. Water must be potable. If well water is used, wells must be maintained to protect them from contamination. Floors must drain adequately, and there shall not be standing water on the floor of the Licensed Premises.

B. Manufacturing Activities - Premises and Safety Requirements.

    1. Toxic cleaning compounds, sanitizing agents, and other chemicals shall be identified, held, stored, and disposed of in a manner that protects against contamination of Regulated Natural Medicine, and in accordance with any applicable local, state, or federal law, rule, regulation, or ordinance.

        a. The use of any of the above compounds must be tracked in the safety data sheet, which must be kept in accordance with Rule 3010.

        b. If chemicals or fertilizers are used, back-flow prevention devices must be installed on water lines that are used for the application.

C. Equipment. Equipment must be maintained to prevent contamination.

1. Equipment must be maintained to ensure it is in proper working order and does not contribute to contamination. All lubricants used on machinery with direct or indirect food contact must be food grade.

2. Manufacturing Equipment. All manufacturing equipment must be cleaned and sanitized prior to manufacturing, processing, or extraction, and on a scheduled basis.

D. Ingredients. A Natural Medicine Products Manufacturer may use conventional food ingredients in the manufacturing of Regulated Natural Medicine Product.

1. A Licensee manufacturing Regulated Natural Medicine Product may only utilize:

a. Federal Food and Drug Administration (FDA) approved ingredients listed on the Substances Added to Food Inventory; and

b. FDA approved inactive ingredients listed for the intended route of administration of oral ingestion, including for filler and binding agents in pressed tablets. The inactive ingredient shall not exceed the amount allowed by the inactive ingredient database.

E. Records. All records must be kept in accordance with Rule 3010.

1. If a Natural Medicine Products Manufacturer uses raw materials in the manufacture of a Regulated Natural Medicine Product, the Licensee must obtain and maintain documentation of the material purchased, including the date of purchase.

2. Standard Operating Procedures (SOP). A Natural Medicine Products Manufacturer must have standard operating procedures for each Regulated Natural Medicine Product it manufactures on file, and available upon request for inspection by the Division. The SOP must include:

a. A documented food safety program and food safety plan. The plan must include worker training on proper food handling, hand washing, hair restraint, and use of gloves.

b. Handling of Chemicals. Workers are trained on the proper use of chemicals, and containers used to store chemical solutions are clearly marked with the common name of the chemical, and instructions for proper use, and non-food containers are used to prepare and hold all chemical solutions.

c. Pest Control. All pest control devices must be located away from products so as to avoid contamination. At least one pest control device must be within 10 feet of each side of an outside entrance. If used, poison bait stations shall be used exclusively on the outside of the building. If used, all live traps shall be placed a maximum of 30 feet apart and at entrances. The location of all pest control devices must be indicated on a facility map.

d. Manufacturing Materials and Procedures. Written documentation of materials used to create Regulated Natural Medicine Product, including any equipment, ingredients, raw materials, strain of Fruiting Bodies, and any additives.

e. Instructions for Manufacturing and Sampling. Specific instructions detailing each step in the product manufacturing process, including the expected yield of the manufacturing process measured in 10 milligrams of Total Psilocin. Written sampling procedures including Sample collection and test submission steps.

3. Corrective Action Preventative Action (CAPA). A Natural Medicine Product Manufacturer shall establish and maintain written procedures for implementing corrective action and preventive action. The written procedures shall include the requirements listed below as determined by the Licensee. All activities required under this Rule, and their results, shall be documented and kept as business records. The written procedures shall include requirements, as appropriate, for:

    a. What constitutes a Nonconformance in the Licensee's business operation;

    b. Analyzing processes, work operations, reports, records, service records, complaints, returned product, and/or other sources of data to identify existing and potential root causes of Nonconformances or other quality problems;

    c. Investigating the root cause of Nonconformances relating to product, processes, and the quality system;

    d. Identifying the action(s) needed to correct and prevent recurrence of Nonconformance and other quality problems;

    e. Verifying the CAPA to ensure that such action is effective and does not adversely affect finished products;

    f. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

    g. Ensuring the information related to quality problems or Nonconformances is disseminated to those directly responsible for assuring the quality of products or the prevention of such problems; and

    h. Submitting relevant information on identified quality problems and CAPA documentation, and confirming the result of the evaluation, for management review.

4. Adverse Health Event Reporting. All Natural Medicine Product Manufacturers shall follow the process in Rule 3015(A) to report any Adverse Health Events that they learn of.

5. Certificates of Analysis. All certificates of analysis provided to the Natural Medicine Products Manufacturer by a Natural Medicine Testing Facility for any Samples submitted for testing shall be maintained on the Licensed Premises in accordance with Rule 3010.

F. Homogeneity of Regulated Natural Medicine Products. A Natural Medicine Products Manufacturer must ensure that its manufacturing processes are designed so that the psilocybin and psilocin content of any oral ingestion Regulated Natural Medicine Product is homogenous. All Regulated Natural Medicine Product must be submitted for homogeneity testing pursuant to Part 4 of these Rules.

G. Contaminated Product.

1. If a Sample that was submitted for testing is contaminated or is found to contain pesticides, the Production Lot may not be remediated and must be destroyed according to Rule 3120.

2. If any Regulated Natural Medicine Product is exposed to blood or bodily fluids or is found to contain filth or foreign matter, it must be disposed of according to Rule 3120.

H. Requested Testing. A Natural Medicine Products Manufacturer Licensee shall, upon the Division's request, submit a sufficient quantity of Regulated Natural Medicine Product to a Natural Medicine Testing Facility for laboratory or chemical analysis in accordance with Rule 4020. The Division will notify the Licensee of the results of the analysis.

I. Storage, Packaging, and Labeling.

1. Storage. After manufacturing, Regulated Natural Medicine Products Manufacturers should follow best practices for storage prior to packaging.

2. Packaging. All Regulated Natural Medicine Product must be packaged in accordance with Rule 3305.

3. Labeling. All Regulated Natural Medicine Product must be labeled in accordance with Rule 3305.

a. A Natural Medicine Products Manufacturer may establish an expiration date upon which the Regulated Natural Medicine Product's Total Psilocin will change +/- fifteen percent from the original test date.

b. The Licensee shall determine the expiration date by conducting the required testing pursuant to Rule 4015 on the final Regulated Natural Medicine Product prior to transfer to ensure the Regulated Natural Medicine Product can pass tryptamine content and contaminant testing prior to the established expiration date.

c. When determining the expiration date pursuant to this Rule, the Licensee shall also consider:

i. Any expiration date of ingredients used to produce the Regulated Natural Medicine Product; and

ii. The ideal storage conditions for the Regulated Natural Medicine Product.

d. Expiration date determinations, along with any data used to establish the expiration date, such as test results, shall be documented and maintained in the Licensee's records pursuant to these Part 6 Rules and Rule 3010.

J. Internal Audit. Natural Medicine Products Manufacturers must conduct an annual internal audit to assess that they are in substantial compliance with the requirements of this Rule 6015. A copy of the internal audit shall be retained as business records for one year.

Basis and Purpose - 6020

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(b), 44-50-203(1)(g), 44-50-203(1)(j), 44-50-203(1)(k), 44-50-203(2)(a), 44-50-203(2)(k), and 44-50-203(2)(r), C.R.S. The purpose of this rule is to establish requirements for Natural Medicine Products Manufacturers to record and track Regulated Natural Medicine and Regulated Natural Medicine Product transferred to and from Natural Medicine Product Manufacturers.

6020 - Minimum Inventory Tracking Requirements

A. Natural Medicine Products Manufacturers must have at least one designated Natural Medicine Handler Licensee or Owner Licensee to maintain inventory records.

1. For each tracking event required to be tracked, information must be documented in accordance with subparagraph 3 of this Rule and Rule 3405.

2. Licensees must report on a monthly basis all inventory tracking events from the previous calendar month in a manner prescribed by the Division, using any forms provided by the Division.

3. Tracking Events. For purposes of required inventory tracking, tracking events include events when Regulated Natural Medicine Product progresses through the manufacturing process and is transferred from the Natural Medicine Products Manufacturer to another Natural Medicine Business or Facilitator. Tracking events include at least the following:

    a. Production Lot activities required by these Rules; and

    b. Transfers of Regulated Natural Medicine Product permitted by these Rules.

B. Natural Medicine Products Manufacturer Tracking Requirements.

1. The following information must be kept on the inventory tracking document and kept as a business record according to Rule 3010.

    a. The Production Lot number, the type of Regulated Natural Medicine Product manufactured, and Regulated Natural Medicine strain;

    b. The amount (in grams) of Regulated Natural Medicine received from a Natural Medicine Cultivation;

    c. The name and phone number of the Natural Medicine Cultivation that the Regulated Natural Medicine was received from.

    d. Bill of Materials (BOM) detailing the weight, measure or count of each component or ingredient needed to process the Production Lot;

2. Following the production of a Regulated Natural Medicine Product, a Natural Medicine Products Manufacturer shall assign a Production Lot number. The following naming conventions must be used to assign a Production Lot number by a Natural Medicine Products Manufacturer: Two-digit year, two-digit month, two-digit day. For example, January 1, 2024 would be 240101.

3. The following tracking information must be kept on the inventory tracking document for transfer to a Natural Medicine Testing Facility:

    a. Production Lot number;

    b. Sample units and type of product;

    c. Date of transfer;

    d. The Natural Medicine Testing Facility’s License number, name, and phone number

4. The following tracking information must be kept on the inventory tracking document for transfer to a Facilitator.

    a. Production Lot number;

b. Units and type of the Regulated Natural Medicine Product;

c. Date of the transfer;

d. If applicable, the Facilitator's Natural Medicine Handler License number, name, and phone number; and

e. The information required by Rule 6005(2)(a).

5. The following tracking information must be kept on the inventory tracking document for transfer to a Healing Center.

a. Production Lot number;

b. Units and type of the Regulated Natural Medicine Product;

c. Date of the transfer; and

d. The Healing Center's License number, name, and phone number.

6. If a Natural Medicine Products Manufacturer generates waste while processing, or producing Regulated Natural Medicine Product, or if the Regulated Natural Medicine Waste was previously designated as a finished product, the Licensee must document:

a. A reason for the Regulated Natural Medicine Waste in the inventory tracking document.

b. The exact time and method of destruction in the inventory tracking document.

Part 7 – Regulated Natural Medicine Testing Facility License Requirements

Basis and Purpose – 7005

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(f), 44-50-203(1)(g), 44-50-203(1)(j), 44-50-203(1)(l), 44-50-203(2)(a), 44-50-203(2)(g), 44-50-203(2)(i), and 44-50-404(1)-(2), C.R.S. The purpose of this rule is to establish the privileges of a Natural Medicine Testing Facility license including the privilege of co-locating a Natural Medicine Testing Facility with a Licensed Marijuana Testing Facility or Certified Hemp Laboratory. This co-location privilege with different license types is exclusive to Natural Medicine Testing Facilities.

7005 – License Privileges

A. A Natural Medicine Testing Facility Licensee may only exercise the License privileges granted by the State Licensing Authority and these Rules, including conducting required and voluntary tests on Regulated Natural Medicine and Regulated Natural Medicine Product as requested by other Natural Medicine Business Licensees, the Division, the State Licensing Authority, and the Colorado Department of Public Health and Environment.

1. No later than thirty days after beginning operations, the Natural Medicine Testing Facility Licensee must submit complete floor plans or diagrams of the Licensed Premises to the Division in a manner prescribed by the Division. Floor plans must clearly show any areas designated as Restricted Areas and security camera placement required by these Rules.

B. A Natural Medicine Testing Facility may be co-located with a Licensed Marijuana Testing Facility or a Certified Hemp Laboratory.

1. If a Natural Medicine Testing Facility is co-located with any of the above testing facilities, there must be separate storage areas for Samples of Regulated Natural Medicine or Regulated Natural Medicine Product, hemp test samples, and marijuana test samples.

2. Any shared equipment for different types of testing must be properly cleaned and sanitized between testing of Regulated Natural Medicine or Regulated Natural Medicine Product, hemp, and marijuana.

C. Testing of Regulated Natural Medicine or Regulated Natural Medicine Product Authorized. A Natural Medicine Testing Facility may accept and test Samples of Regulated Natural Medicine or Regulated Natural Medicine Product properly submitted by a Natural Medicine Business.

D. A Natural Medicine Testing Facility may transfer Samples to another Natural Medicine Testing Facility for testing.

E. A Natural Medicine Testing Facility must properly dispose of all Samples it receives, that are not transferred to another Natural Medicine Testing Facility, after all requested tests have been completed and any sample retention period has elapsed, in accordance with Rule 3120.

F. A Natural Medicine Testing Facility must reject any Sample where the condition of the Sample indicates that the Sample may have been tampered with.

G. A Licensee may only exercise the License privileges of a Natural Medicine Testing Facility License if the Licensee meets all requirements for certification pursuant to Rule 7015 and any other rules required by the Department of Public Health and Environment to obtain and maintain certification.

H. Testing Services - Non-required Test Types. A Natural Medicine Testing Facility may conduct non-required testing in accordance with these Rules on Regulated Natural Medicine or Regulated Natural Medicine Product upon a Natural Medicine Business's request in accordance with this subparagraph H.

1. Non-required Regulated Natural Medicine Testing Services. Non-required Regulated Natural Medicine testing services may include, but are not limited to offering:

a. Voluntary testing for heavy metals, pesticides, solvents, or mycotoxins;

b. Shelf-stability testing; and

c. Research and development testing of alkaloid, tryptamine, and other component testing.

2. Required Disclosures. Prior to performing non-required testing on Regulated Natural Medicine or Regulated Natural Medicine Product, the Natural Medicine Testing Facility must notify the requesting Natural Medicine Business that the Natural Medicine Testing Facility Licensee is not certified to perform non-required tests and that such test results have not been certified or subject to state regulator oversight.

Basis and Purpose – 7010

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(d), 44-50-203(1)(e), 44-50-203(1)(f), 44-50-203(1)(n), 44-50-203(2)(a), and 44-50-404(3), C.R.S. The purpose of this rule is to establish conduct that is prohibited by Natural Medicine Testing Facilities which includes conflicts of interest between a Natural Medicine Testing Facility and other Natural Medicine Businesses and transfers to any unlicensed person.

7010 – Prohibited Acts

A. A person who is an Owner Licensee of a Natural Medicine Testing Facility License may not have a Financial Interest in a Healing Center License, Natural Medicine Cultivation Facility License, or Natural Medicine Products Manufacturer License granted by the State Licensing Authority.

B. Conflicts of Interest. The Natural Medicine Testing Facility shall establish policies to prevent the existence of or appearance of undue commercial, financial, or other influences that may diminish the competency, impartiality, and integrity of the Natural Medicine Testing Facility's testing processes or results, or that may diminish public confidence in the competency, impartiality, and integrity of the Natural Medicine Testing Facility's testing processes or results. At a minimum, employees, owners or agents of a Natural Medicine Testing Facility who participate in any aspect of the analysis and results of a Sample are prohibited from improperly influencing the testing process, improperly manipulating data, or improperly benefiting from any on-going financial, employment, personal or business relationship with the Natural Medicine Business that provided the Sample.

C. Transfer to unlicensed persons prohibited. A Natural Medicine Testing Facility shall not transfer any Regulated Natural Medicine or Regulated Natural Medicine Product to a person who does not hold a Natural Medicine Testing Facility License, or a Facilitator licensed by the Department of Regulatory Agencies under article 170 of title 12 in accordance with Rule 5005. Only a Natural Medicine Handler Licensee or Owner Licensee may receive Regulated Natural Medicine and Regulated Natural Medicine Product on behalf of a Natural Medicine Business.

D. A violation of any test Rule in this series of rules may be a Level I violation which is the highest severity violation under the penalty Rules. *See* Rule 9050.

Basis and Purpose – 7015

The statutory authority for this rule includes but is not limited to sections 25-2.5-120, 44-50-202(1)(b), 44-50-203(1)(a), 44-50-203(1)(d), 44-50-203(1)(f), 44-50-203(1)(n), 44-50-203(2)(a), and 44-50-404(2), C.R.S. The purpose of this rule is to establish that a Natural Medicine Testing Facility is required to have both a License issued by the State Licensing Authority and a certification from the Colorado Department of Public Health and Environment before performing any tests on Regulated Natural Medicine or Regulated Natural Medicine Product. This rule further provides the requirements for a Natural Medicine Testing Facility if its certification is suspended or reissued.

7015 – Certification Required

A. All Natural Medicine Testing Facilities licensed by the State Licensing Authority must be certified by the Colorado Department of Public Health and Environment in each of the testing categories required by these Rules. *See* Part 4, Regulated Natural Medicine Testing Program. Natural Medicine Testing Facilities must be accredited to ISO/IEC 17025:2017 and have each test type the Natural Medicine Testing Facility performs included on that Facility's scope of accreditation. Accreditation must be performed by an accreditation body that conforms to ISO/IEC 17011:2017 and is a signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (ILAC MRA) for testing.

1. This Rule incorporates the ISO/IEC 17025:2017 standard effective as of August 9, 2024, and does not include any later amendments or editions to this ISO/IEC accreditation. The Division maintains a copy of ISO/IEC 17025:2017 at 1697 Cole Boulevard, Suite 200, Lakewood, Colorado, 80401, which is available to the public for inspection during the Division's regular business hours.

2. A Natural Medicine Testing Facility offering non-required testing services, for example, pesticide testing, in accordance with Rule 7005, must disclose to the requestor which test types the Licensee is certified to perform. The Licensee must notify each requestor any requested tests for which the Licensee is not certified to perform and that such test results have not been accredited, validated, or otherwise subject to regulatory oversight and disclose this on the certificate of analysis.

B. A Natural Medicine Testing Facility shall hold both a Natural Medicine Testing Facility License issued by the State Licensing Authority and a certification issued by the Colorado Department of Public Health and Environment for each required test type that it provides for any Natural Medicine Business. Failure to obtain or suspension or revocation of either the required Natural Medicine Testing Facility License or the certification prohibits the Natural Medicine Testing Facility from providing required testing services to any Natural Medicine Business.

C. Certification Suspension. If the Colorado Department of Public Health and Environment suspends a Natural Medicine Testing Facility's certification to conduct required Regulated Natural Medicine test(s), the Licensee must immediately notify the Division and cease conducting any tests for which the Licensee has lost certification.

1. Upon notification that a Natural Medicine Testing Facility has lost certification to conduct required test(s) or that the public health, safety, or welfare imperatively require emergency action, the State Licensing Authority may immediately suspend the Natural Medicine Testing Facility's License in accordance with Part 9 of these Rules.

D. Re-certification. A Natural Medicine Testing Facility must comply with Colorado Department of Public Health and Environment requirements to re-certify to conduct required testing. Upon re-certification, the Natural Medicine Testing Facility must notify the Division with written confirmation from the Department of Public Health and Environment that the Licensee is permitted to conduct required test(s) again.

Basis and Purpose – 7020

The statutory authority for this rule includes but is not limited to sections 25-2.5-120, 44-50-202(1)(b), 44-50-203(1)(b), 44-50-203(1)(f), 44-50-203(1)(g), 44-50-203(1)(j), 44-50-203(2)(a), 44-50-203(2)(p), and 44-50-404(2), C.R.S. The purpose of this rule is to establish minimum requirements for standard operating procedures that a Natural Medicine Testing Facility must develop and maintain.

7020 – Standard Operating Procedures

A. A Natural Medicine Testing Facility must have Standard Operating Procedures. A Standard operating procedure manual must include, but is not limited to, procedures for:

1. Sample receiving;

2. Sample accessioning;

3. Sample storage;

4. Identifying, rejecting, and reporting unacceptable Samples;

5. Recording and reporting discrepancies during Sample receiving and accessioning;

6. Security of Samples, aliquots and extracts and records;

7. Validating a new or revised method prior to testing of Samples to include: accuracy, precision, analytical sensitivity, analytical specificity (interferences), LOD, LOQ, and verification of the reportable range;

8. Sample preparation, including but not limited to, sub-sampling for testing, homogenization, and aliquoting Samples to avoid contamination and carry-over;

9. Sample archive retention to assure stability, as follows:

    a. For Samples submitted for testing, Sample archive retention for 14 days;

10. Disposal of Samples;

11. The theory and principles behind each assay;

12. Preparation and identification of reagents, standards, calibrators and controls and ensure all standards are traceable to National Institute of Standards of Technology ("NIST");

13. Special requirements and safety precautions involved in performing assays;

14. Frequency and number of control and calibration materials;

15. Recording and reporting assay results;

16. Protocol and criteria for accepting or rejecting analytical procedure to verify the accuracy of the final report;

17. Pertinent literature references for each method;

18. Current step-by-step instructions with sufficient detail to perform the assay to include equipment operation and any abbreviated versions used by a testing analyst;

19. Acceptability criteria for the results of calibration standards and controls as well as between two aliquots or columns;

20. A documented system for reviewing the results of testing calibrators, controls, standards, and Sample results, as well as reviewing for clerical errors, analytical errors and any unusual analytical results and are corrective actions implemented and documented, and does the laboratory contact the requesting entity;

21. Policies and procedures to follow when Samples are requested for referral and testing by another certified Natural Medicine Testing Facility or an approved local state agency's laboratory;

22. Investigating and documenting existing or potential Nonconformances and implementing corrective actions and/or preventive actions;

23. Contacting the requesting entity about existing Nonconformances; and

24. Retesting or additional analyses of Samples, including but not be limited to, when it is appropriate to retest or perform an additional analysis of the Sample, when it is appropriate for the requesting entity to request retesting (e.g., after failing microbial contaminant testing on Regulated Natural Medicine).

Basis and Purpose – 7025

The statutory authority for this Rule includes but is not limited to sections 25-2.5-120, 44-50-202(1)(b), 44-50-203(1)(b), 44-50-203(1)(f), 44-50-203(1)(j), 44-50-203(2)(g), 44-50-203(2)(k), and 44-50-404(2), C.R.S. The purpose of this Rule is to establish chain of custody requirements for a Natural Medicine Testing Facility to track and document the Samples received from Licensees.

7025 – Chain of Custody

A. General Requirements. A Natural Medicine Testing Facility must establish an adequate chain of custody for handling Samples. Instructions must include, but are not limited to:

1. Issue instructions for the minimum Sample requirements and storage requirements;

2. Document the condition of the external package and integrity seals utilized to prevent contamination of, or tampering with, the Sample;

3. Document the condition and amount of Sample provided at the time of receipt;

4. Document all persons handling the original Sample, aliquots, and extracts;

5. Document all transfers of Samples, aliquots, and extracts referred to another certified Natural Medicine Testing Facility Licensee for additional testing or whenever requested by a client;

6. Maintain a current list of authorized personnel and restrict entry to the laboratory to only those authorized;

7. Secure the Licensed Premises during non-working hours;

8. Secure short and long-term storage areas when not in use;

9. Utilize a secured area to log-in and aliquot Samples;

10. Ensure Samples are stored appropriately;

11. Document the disposal of Samples, aliquots, and extracts; and

12. Document the License number, inventory tracking number, photograph(s), and the reason for rejection of Samples that were rejected and notify the Division within 7 days of Sample submission.

Basis and Purpose – 7030

The statutory authority for this rule includes but is not limited to sections 25-2.5-120, 44-50-202(1)(b), 44-50-203(1)(f), 44-50-203(1)(g),44-50-203(2)(g), 44-50-203(2)(k), and 44-50-404(2), C.R.S. The purpose of this rule is to establish the notification requirements for a Natural Medicine Testing Facility in the event of a failed test or detection of contaminants.

7030 – Notification

A. If Regulated Natural Medicine or Regulated Natural Medicine Product fails a contaminant test, then the Natural Medicine Testing Facility must immediately:

1. Notify the Natural Medicine Business that submitted the Sample for testing; and

2. Report the failure to the Division and track the failure in accordance with Rule 7035.

B. Other Contaminants. If any Sample is found to contain levels of any microorganism, chemical, elemental impurity, or pesticides that could be toxic if consumed or present, then the Natural Medicine Testing Facility must notify the Natural Medicine Business and the Division. The Natural Medicine Business that was notified must initiate their CAPA plan in accordance with Rule 5020(E)(3) or 6015(E)(3).

Basis and Purpose – 7035

The statutory authority for this rule includes but is not limited to sections 25-2.5-120, 44-50-202(1)(b), 44-50-203(1)(f), 44-50-203(1)(j), 44-50-203(1)(k), 44-50-203(2)(a), 44-50-203(2)(g), 44-50-203(2)(i), 44-50-203(2)(k), 44-50-203(2)(p), and 44-50-404(2), C.R.S. The purpose of this rule is to establish requirements for a Natural Medicine Testing Facility to record and track Regulated Natural Medicine and Regulated Natural Medicine Product transferred to and from the Licensed Premises.

7035 – Minimum Inventory Tracking Requirements

A. Regulated Natural Medicine Testing Facilities must have at least one designated Natural Medicine Handler Licensee or Owner Licensee to maintain inventory records.

1. For each tracking event required to be tracked, information must be documented in accordance with subparagraph (3) of this Rule and Rule 3405.

2. Licensees must report on a monthly basis all inventory tracking events from the previous calendar month in a manner prescribed by the Division or using any forms provided by the Division.

3. Tracking Events. For purposes of required inventory tracking, tracking events include events prior to and during the Sample testing process. Tracking events include at least the following:

a. Sample receiving, rejection, storage, accessioning, testing, retention, and disposal; and

b. Transfers of Regulated Natural Medicine and Regulated Natural Medicine Product.

B. Natural Medicine Testing Facility Tracking Requirements

1. The following tracking information must be kept on the inventory tracking document at a Natural Medicine Testing Facility to reflect all incoming transfers of Samples of Regulated Natural Medicine or Samples of Regulated Natural Medicine Product:

a. Harvest Lot or Production Lot number;

b. Weight (in grams) of the Regulated Natural Medicine received;

c. Weight of the Regulated Natural Medicine Product received;

d. Date of the transfer; and

e. The transferor’s Natural Medicine Business License number, name, and phone number.

2. The Natural Medicine Testing Facility must also maintain inventory tracking records that fully and accurately reflect all test results.

3. If a Natural Medicine Testing Facility works with another Natural Medicine Business to dispose of any Regulated Natural Medicine Waste, the Licensee must document:

   a. A reason for the Regulated Natural Medicine Waste in the inventory tracking document.

   b. The exact time and method of destruction in the inventory tracking document.

Part 8 – Healing Center License

Basis and Purpose – 8005

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(a), 44-50-203(1)(d), 44-50-203(1)(g), 44-50-203(1)(l), 44-50-203(2)(a), and 44-50-401, C.R.S. The purpose of this rule is to establish the privileges and permitted acts for Healing Centers.

8005 – License Privileges

A. A Healing Center Licensee may only exercise the License privileges granted by the State Licensing Authority and these Rules.

   1. No later than thirty days after beginning operations, the Healing Center Licensee must submit complete floor plans or diagrams of the Licensed Premises to the Division in a manner prescribed by the Division. Floor plans must clearly show any areas designated as Administration Areas, any areas designated as Restricted Areas, and security camera placement required by these Rules.

   2. Micro-Healing Center. A micro-Healing Center is a Healing Center license tier that does not store more than 750 milligrams of Total Psilocin on site. A micro-Healing Center must comply with security requirements in Rule 8025(A).

B. Co-Location Authorized. A Healing Center may be co-located with another Natural Medicine Business License in accordance with Rule 3105.

C. A Healing Center must comply with the provisions related to persons with disabilities in section 44-50-401(1)(b), C.R.S.

D. Authorized Sources and Transfers of Regulated Natural Medicine and Regulated Natural Medicine Product.

   1. A Healing Center may only obtain Regulated Natural Medicine and Regulated Natural Medicine Product from a Natural Medicine Cultivation Facility, Natural Medicine Products Manufacturer, or another Healing Center.

   2. A Natural Medicine Handler Licensee employed by the Healing Center may transfer Regulated Natural Medicine or Regulated Natural Medicine Product to a Participant under the supervision of a Facilitator.

3. A Healing Center may transfer up to 750 milligrams of Total Psilocin at one time of Regulated Natural Medicine or Regulated Natural Medicine Product that has passed all required testing and is packaged and labeled pursuant to Rule 3305 to a Facilitator for Administration Sessions at authorized locations other than Healing Centers in accordance with this Rule.

    a. Facilitator Request Requirements. A Healing Center may only transfer Regulated Natural Medicine to a Facilitator after receiving and verifying the Facilitator's request. All requests for Facilitator transfers must including the following information:

        i. The Facilitator's Department of Regulatory Agencies issued license number;

        ii. The requested amount of Regulated Natural Medicine;

        iii. The number of Administration Sessions the Facilitator is requesting Regulated Natural Medicine for;

        iv. The number of Participants that will be consuming the requested Regulated Natural Medicine; and

        v. The requested date for pick-up.

    b. Request Verification. A Healing Center must verify the Facilitator's Department of Regulatory Agencies issued license number in order to complete the transfer.

    c. To the extent required to comply with Rule 3405, the Healing Center may place packaged and labeled Regulated Natural Medicine and Regulated Natural Medicine Product in a Child-Resistant container; however, the Healing Center shall not re-package Regulated Natural Medicine or Regulated Natural Medicine Product.

4. All transfers of Regulated Natural Medicine and Regulated Natural Medicine Product must comply with transport and inventory tracking requirements in Rules 3405 and 5025.

E. Food and Beverages.

1. Healing Centers may provide water and pre-packaged, unopened food or beverage items to Participants during an Administration Session. This allowance includes fresh fruit and vegetables.

2. Nothing in these Rules prohibits a Healing Center from obtaining a retail food establishment license pursuant to the Food Protection Act at sections 25-4-1600, *et seq.*, C.R.S. The Healing Center's Administration Area and any Restricted Areas must not overlap with the retail food establishment licensed premises.

Basis and Purpose – 8010

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(g), 44-50-203(1)(k), 44-50-203(2)(a), and 44-50-401, C.R.S. The purpose of this rule is to describe acts which are prohibited at Healing Centers and by persons on the Licensed Premises of Healing Centers during an Administration Session.

8010 – Prohibited Acts

A. A Healing Center Licensee shall not:

1. Transfer Regulated Natural Medicine or Regulated Natural Medicine Product to an individual unless the individual is a Participant in an Administration Session.

2. Allow a Participant to take any Regulated Natural Medicine or Regulated Natural Medicine Product from the Healing Center.

3. Permit consumption of alcohol or marijuana by any person on the Licensed Premises of the Healing Center at any time.

4. Change the form or further process Regulated Natural Medicine or Regulated Natural Medicine Product once it has been transferred to the Healing Center, except an Owner Licensee or a Natural Medicine Handler Licensee may mix Regulated Natural Medicine and Regulated Natural Medicine Product with water, fruit juice, or a pre-packaged, unopened food or beverage for the Participant's consumption.

B. A Healing Center and its Owner Licensees are responsible for all conduct on the Licensed Premises by licensed and unlicensed persons.

Basis and Purpose – 8015

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(g), 44-50-203(1)(k), 44-50-203(2)(p), 44-50-203(2)(r), and 44-50-401(2), C.R.S. The purpose of this rule is to establish the acceptable forms of identification for a Healing Center to verify the lawful age of a Participant for participation in Natural Medicine Services.

8015 – Acceptable Forms of Identification for a Participant to Receive Natural Medicine Services

A. A Healing Center must confirm that a Participant is 21 years of age or older by verifying their identification. The following forms of identification in physical or digital form can be used:

1. An operator's, chauffeur's, or similar type driver's license, including a temporary license issued by any state within the United States, District of Columbia, or any U.S. territory;

2. An identification card, including a temporary identification card, issued by any state within the United States, District of Columbia, or any U.S. territory, for the purpose of proof of age using requirements similar to those in sections 42-2-302 and 42-2-303, C.R.S.;

3. A United States military identification card or any other identification card issued by the United States government including but not limited to a permanent resident card, alien registration card, or consular card;

4. A passport or passport identification card; or

5. An enrollment card issued by the governing authority of a federally recognized Indian tribe, if the enrollment card incorporates proof of age requirements similar to sections 42-2-302 and 42-2-303, C.R.S.

B. Identification must be valid. A Licensee shall refuse to provide Natural Medicine Services to a potential Participant who provides identification that is expired or invalid.

Basis and Purpose – 8020

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(a), 44-50-203(1)(d), 44-50-203(1)(g), and 44-50-401(1), C.R.S. The purpose of this rule is to provide that no Healing Center shall operate unless the Healing Center employs or contracts with a Facilitator. This rule further provides the circumstances under which a Healing Center may offer group facilitation services.

8020 – Facilitator Required

A. A Healing Center must employ or contract with at least one Facilitator holding either a Natural Medicine Handler License or an Owner License prior to operating.

B. A Facilitator that holds a Natural Medicine Handler License is an agent or employee of the Healing Center(s) where the Facilitator provides Natural Medicine Services.

C. Group Facilitation. A Healing Center may offer group facilitation Natural Medicine Services if there are an appropriate number of Facilitators to facilitate for the number of Participants in accordance with the Department of Regulatory Agencies' rules at 4 CCR 755-1.

Basis and Purpose – 8025

The statutory authority for this Rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(b), 44-50-203(1)(g), 44-50-203(1)(k), 44-50-203(2)(f), and 44-50-203(2)(g), C.R.S. The purpose of this Rule is to establish security requirements based on the amount of Regulated Natural Medicine and Regulated Natural Medicine Product stored on the Licensed Premises and to provide other requirements for the Licensed Premises of a Healing Center.

8025 – Licensed Premises Requirements

A. Security Measures and Inventory Management.

1. A micro-Healing Center must store all Regulated Natural Medicine and Regulated Natural Medicine Product in a secured, locked place that is:

    a. Accessible only to the Healing Center Owner Licensee(s) and/or Natural Medicine Handler Licensee(s); and

    b. Monitored by video surveillance while Regulated Natural Medicine and Regulated Natural Medicine Product is stored.

2. A Healing Center must:

    a. Store all Regulated Natural Medicine and Regulated Natural Medicine Product in a secured, locked place that is:

        i. Accessible only to the Healing Center Owner Licensee(s) and/or Natural Medicine Handler Licensees;

        ii. Monitored by video surveillance while Regulated Natural Medicine and Regulated Natural Medicine Product is stored.

    b. Maintain a fully operational security alarm system on the Licensed Premises, activated at all times when the Licensed Premises is closed for business. The security alarm system must meet the requirements in Rule 3110(E).

c. Maintain a fully operational video surveillance and recording system that satisfies the requirements in Rule 3115.

3. Notification of Change in Inventory Management. If a Healing Center seeks to change the amount of Regulated Natural Medicine and Regulated Natural Medicine Product it possesses and stores, the Licensee must notify the Division, in writing, on a form prescribed by the Division.

4. Participant Information Protected. Healing Center Licensees must take measures to prevent unauthorized access to business records and any Participant or Administration Session records.

5. When the Licensee is not operating as a Healing Center, the Licensee must ensure that all Regulated Natural Medicine and Regulated Natural Medicine Product is appropriately secured. Licensees must take measures to prevent unauthorized access to Regulated Natural Medicine and Regulated Natural Medicine Product.

B. Administration Areas. No one under the age of 21 years old is permitted in the Administration Area when an Administration Session is taking place, including when Regulated Natural Medicine and Regulated Natural Medicine Product are taken out of the secured storage place.

1. Licensees must take all reasonable steps and precautions to provide an environment free of risks to ensure safety of Participants.

2. Administration Areas must be easy to exit, as needed, and the area may not be locked from the outside or otherwise prevent a Participant from exiting the area if necessary.

3. Indoor Administration Area. Indoor Administration Areas must be adequately lit to allow safe exit if necessary.

4. Outdoor Administration Areas. If the Healing Center contains outdoor areas, the boundaries must be clearly marked with visible signage or barriers. The Licensee must also take reasonable measures to mitigate risks to Participants in any outdoor area that Participants are permitted to access during an Administration Session.

C. A Healing Center shall display:

1. A sign identifying any Administration Area or Restricted Area that contains Regulated Natural Medicine or Regulated Natural Medicine Product, as “Authorized Personnel Only.”

2. A copy of the Healing Center’s License issued by the State Licensing Authority.

3. Information regarding safe transportation after an Administration Session.

D. A Healing Center must make instructions or other guidance available related to:

1. How to file a complaint with the Department of Regulatory Agencies;

2. How to file a complaint with the Department of Revenue; and

3. How to report an Adverse Health Event to the Division.

Basis and Purpose – 8030

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(b), 44-50-203(1)(g), 44-50-203(1)(k), 44-50-203(2)(g), 44-50-203(2)(r), and 44-50-401(5), C.R.S. The purpose of this rule is to establish the parameters for the administration of Regulated Natural Medicine and Regulated Natural Medicine Product and consumption of food and beverages during an Administration Session at a Healing Center.

8030 – Administration Sessions

A. Only Participants, Facilitators, Owner Licensees, and Natural Medicine Handler Licensees may access the Administration Area during an Administration Session, unless each Facilitator and Participant receiving Regulated Natural Medicine and Regulated Natural Medicine Product in the Administration Area provided prior written consent for other individuals to be present.

B. Licensees must take reasonable steps to prevent access to Administration Areas by unauthorized individuals while Administration Sessions are taking place.

C. Servings of Regulated Natural Medicine and Regulated Natural Medicine Product.

1. A serving of Regulated Natural Medicine Product may contain no more than 10 milligrams of Total Psilocin.

2. A container of Regulated Natural Medicine or Regulated Natural Medicine Product may contain no more than 50 milligrams of Total Psilocin.

3. The Participant and Facilitator can agree to any number of servings or partial servings of Regulated Natural Medicine or Regulated Natural Medicine Product to be administered during an Administration Session.

D. A Natural Medicine Handler Licensee may only transfer Regulated Natural Medicine or Regulated Natural Medicine Product to a Participant within the Administration Area.

1. The Facilitator must observe a Participant consume any Regulated Natural Medicine or Regulated Natural Medicine Product transferred to that Participant. A Facilitator or Natural Medicine Handler Licensee must dispose of packaging waste appropriately.

2. Regulated Natural Medicine or Regulated Natural Medicine Product may be mixed with water, fruit juice, or pre-packaged food or beverages prior to consumption, as long as the pre-packaged food or beverages was not opened prior to mixing.

3. Any Regulated Natural Medicine or Regulated Natural Medicine Product that is not consumed by a Participant must be disposed of in accordance with Rule 3120 or returned to a secured, locked place per Rule 8020 at the end of an Administration Session.

E. A Participant may bring their own water or pre-packaged food or beverages to consume during the Administration Session. This allowance includes fresh fruit and vegetables.

F. A Healing Center that complies with the requirements in Rule 8005(E)(2), and all state and local requirements related to food handling and preparation, may provide prepared or manufactured foods to Participants after an Administration Session.

Basis and Purpose – 8035

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(b), 44-50-203(1)(g), 44-50-203(1)(j), 44-50-203(2)(i), 44-50-203(2)(k), and 44-50-203(2)(p), C.R.S. The purpose of this rule is to establish specific records a Healing Center must maintain on the Licensed Premises and the requirement for a Healing Center to maintain the confidentiality of personally identifying information and medical data in records.

8035 – Healing Center Record Requirements

A. A Healing Center must maintain records required by this Rule and Rule 3010.

B. A Healing Center must maintain copies of:

1. All Facilitator licenses, issued by the Department of Regulatory Agencies, for Facilitators providing Natural Medicine Services at the Healing Center.

2. All Natural Medicine Handler License(s) or Owner License(s), issued by the State Licensing Authority for Facilitators providing Natural Medicine Services at the Healing Center.

3. Any Adverse Health Events required to be reported in Rule 3015.

C. A Healing Center must maintain a log of Administration Sessions. The Healing Center must submit all prior year Administration Session logs required in this Rule in accordance with Rule 2130. Administration Session logs must include at least the following information:

1. The date and duration of each Administration Session;

2. The number of Participants in each Administration Session;

3. The License numbers for Facilitators participating in each Administration Session;

4. The package number, dose, and type of Regulated Natural Medicine or Regulated Natural Medicine Product the Participant(s) consumed;

5. Deidentified information regarding the intention or desired outcome for the Administration Session, including whether the Administration Session is intended to treat physical or behavioral conditions, or is for wellness services;

6. Any other food or beverages that were consumed during the Administration Session; and

7. Any amount of Regulated Natural Medicine that is disposed of as Regulated Natural Medicine Waste following each Administration Session.

D. Standard Operating Procedures. A Healing Center must maintain the following standard operating procedures on the Licensed Premises and provide copies of these standard operating procedures to all employees, Natural Medicine Handler Licensees, and Owner Licensees. The standard operating procedures required by this Rule may be contained in a single document maintained by the Healing Center.

1. Administration Session Preparedness Plan. The Administration Session preparedness plan must address how Healing Center employees, Natural Medicine Handler Licensees, and Owner Licensees will monitor a Participant's access to the Licensed Premises after consuming Regulated Natural Medicine or Regulated Natural Medicine Product when the Participant needs to temporarily leave the Administration Area.

    a. The plan should include procedures for:

        i. Escorting or monitoring a Participant who needs to use a restroom during the Administration Session;

        ii. Ensuring the Licensed Premises is maintained to prevent safety hazards;

        iii. Monitoring and limiting Participant interaction with vendors, contractors, other Participants, or other persons who may be present at the Healing Center; and

        iv. Emergency response when a Participant experiences a medical or other emergency during an Administration Session, including but not limited to, instructions for using an on-site medical kit.

    b. A Healing Center may defer implementing the Administration Session preparedness plan if the Facilitator and Participant have agreed, through written informed consent, to other procedures for the Administration Session if the Healing Center maintains a copy of the informed consent on the Licensed Premises.

2. Emergency Plan. A Healing Center must have an emergency plan that includes the following:

    a. Documented procedures for evacuating and relocating Participants to a safe and confidential location when the Administration Areas become unsafe due to unforeseen circumstances, including but not limited to fire or a power outage. Licensees should take all reasonable steps to maintain Participant confidentiality should evacuation and relocation become necessary.

3. Certificates of Analysis. All certificates of analysis provided to the Healing Center by a Natural Medicine Testing Facility of any Samples submitted for testing shall be maintained on the Licensed Premises in accordance with Rule 3010.

E. Confidentiality of Patient Records. A Healing Center must maintain the confidentiality of any personally identifying information disclosed in Participant records possessed or stored at the Healing Center's Licensed Premises.

Basis and Purpose – 8040

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-203(1)(b), 44-50-203(1)(g), 44-50-203(1)(j), 44-50-203(1)(k), and 44-50-203(2)(k), C.R.S. The purpose of this rule is to establish requirements for a Healing Center to record and track Regulated Natural Medicine and Regulated Natural Medicine Product transferred to and from its Licensed Premises.

8040 – Minimum Inventory Tracking Requirements

A. All Healing Centers must have at least one designated Natural Medicine Handler Licensee or Owner Licensee to maintain inventory records.

1. For each tracking event required to be tracked, information must be documented in accordance with subparagraph (A)(3) of this Rule and Rule 3405.

2. Licensees must report on a monthly basis all inventory tracking events from the previous calendar month in a manner prescribed by the Division, using any forms provided by the Division.

3. Tracking Events. For purposes of required inventory tracking, tracking events include any Transfers of Regulated Natural Medicine and Regulated Natural Medicine Product permitted by these Rules.

B. Healing Center Tracking Requirements.

1. The following tracking information must be kept on the inventory tracking document at a Healing Center to reflect all incoming transfers of Regulated Natural Medicine or Regulated Natural Medicine Product:

   a. Harvest Lot or Production Lot number;

   b. Weight of the Regulated Natural Medicine;

   c. Weight of the Regulated Natural Medicine Product;

   d. Date of the transfer; and

   e. The originating Natural Medicine Business License number, name, and phone number.

2. If the Healing Center works with another Natural Medicine Business to dispose of any Regulated Natural Medicine Waste, then the following information must be kept on the inventory tracking document:

   a. Weight of the Regulated Natural Medicine Waste;

   b. Date of the transfer; and

   c. The receiving Natural Medicine Business License number, name, and phone number.

3. The following tracking information must be kept on the inventory tracking document for transfer to a Facilitator.

   a. Harvest Lot or Production Lot number;

   b. Weight of the Regulated Natural Medicine or Regulated Natural Medicine Product;

   c. Date of the transfer;

   d. If applicable, the Facilitator's Natural Medicine Handler License number, name, and phone number; and

   e. The information required by Rule 5005(C)(2)(a).

Part 9 – Enforcement and Discipline

Basis and Purpose – 9005

The statutory authority for this rule includes but is not limited to sections, 44-50-202(1)(a), 44-50-202(1)(b), 44-50-202(1)(c), 44-50-203(1)(a),44-50-202(1)(b), 44-50-203(1)(j), 44-50-203(2)(l), 44-50-203(2)(p), 44-50-203(2)(q), and 44-50-203(2)(r), C.R.S. This rule explains that Licensees must cooperate with Division employees when they are acting within the normal scope of their duties and that failure to do so may result in sanctions. It also explains the process for voluntary surrender of Regulated Natural Medicine.

9005 – Requirements for Inspections and Investigations and Voluntary Surrenders

A. Applicants and Licensees Shall Cooperate with Division Employees.

1. Applicants and Licensees must cooperate with employees of the Division who are conducting inspections or investigations relevant to the enforcement of laws and regulations related to the Natural Medicine Code.

2. No Applicant or Licensee shall by any means interfere with, obstruct, or impede the State Licensing Authority or any employee of the Division from exercising their duties pursuant to the provisions of the Natural Medicine Code and these Rules. This would include, but is not limited to:

a. Threatening force or violence against an employee or investigator of the Division, or otherwise endeavoring to intimidate, obstruct, or impede employees or investigators of the Division, their supervisors, or any peace officers from exercising their duties. The term “threatening force” includes the threat of bodily harm to such individual or to a member of his or her family;

b. Denying investigators of the Division access to premises where the Licensee’s Regulated Natural Medicine or Regulated Natural Medicine Product are grown, stored, cultivated, manufactured, tested, distributed, or transferred during business hours or times of apparent activity;

c. Providing false or misleading statements;

d. Providing false or misleading documents and records;

e. Failing to timely produce requested books and records required to be maintained by the Licensee; or

f. Failing to timely respond to any other request for information made by a Division employee or investigator in connection with an investigation of the qualifications, conduct or compliance of an Applicant or Licensee.

B. Voluntary Surrender of Regulated Natural Medicine or Regulated Natural Medicine Product.

1. A Licensee, prior to a Final Agency Order and upon mutual agreement with the Division, may elect to voluntarily surrender any Regulated Natural Medicine or Regulated Natural Medicine Product to the Division.

a. Such voluntary surrender may require destruction of any Regulated Natural Medicine or Regulated Natural Medicine Product in the presence of a Division investigator and at the Licensee’s expense.

b. The individual signing the Division's voluntary surrender form on behalf of the surrendering Licensee must certify that the individual has authority to represent and bind the Licensee to such voluntary surrender.

2. The voluntary surrender form may be utilized in connection with a stipulated agency order through which the Licensee waives the right to hearing and any associated rights.

3. The voluntary surrender form may be utilized even if the Licensee does not waive the right to hearing and any associated rights, with the understanding that the outcome of the hearing does not impact the validity of the voluntary surrender.

4. A Licensee, after a Final Agency Order and upon mutual agreement with the Division, may elect to voluntarily surrender any Regulated Natural Medicine or Regulated Natural Medicine Product to the Division.

a. The Licensee must complete and return the Division's voluntary surrender form within 15 calendar days of the date of the Final Agency Order.

b. Such voluntary surrender may require destruction of any Regulated Natural Medicine or Regulated Natural Medicine Product in the presence of a Division investigator and at the Licensee's expense.

c. The individual signing the Division's voluntary surrender form on behalf of the surrendering Licensee must certify that the individual has authority to represent and bind the Licensee to such voluntary surrender.

Basis and Purpose – 9010

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(a), 44-50-202(1)(b), 44-50-202(1)(c), 44-50-203(1)(a), 44-50-203(2)(l), 44-50-203(2)(m), 44-50-203(2)(r), and 44-50-701, C.R.S. The purpose of this rule is to provide a procedure for written warnings and assurances of voluntary compliance for non-compliance with the Natural Medicine Code or these Rules.

9010 – Written Warnings and Assurances of Voluntary Compliance

A. Written Warnings. If a Division investigator identifies a violation(s) of the Natural Medicine Code or these Rules that is eligible for a written warning pursuant to subpart (D) of this Rule, the Division investigator may issue a written warning in lieu of recommending administrative action.

1. The written warning shall identify the alleged violation(s).

2. The written warning shall not constitute an admission of a violation(s) for any purpose or finding of a violation(s) by the State Licensing Authority, and shall not be evidence that the Licensee violated the Natural Medicine Code, or these Rules.

3. A written warning shall constitute evidence in any subsequent administrative proceeding, if relevant, that the Licensee was previously warned of the violation(s).

4. The Division may in its discretion initiate a subsequent administrative action and prove the violation(s) that was the subject of the written warning.

B. Assurances of Voluntary Compliance. The Director of the Division may accept an assurance of voluntary compliance regarding any act or practice alleged to violate the Natural Medicine Code or these Rules that is eligible for an assurance of voluntary compliance pursuant to subpart (D) of this Rule.

1. The assurance must be in writing and may include a stipulation for the voluntary payment of the cost commensurate with the acts or practices and an amount necessary to restore money or property which may have been acquired by the alleged violator because of the acts or practices.

2. An assurance of voluntary compliance may not be considered an admission of a violation(s) for any purpose or a finding of a violation(s) by the State Licensing Authority; however, the assurance of voluntary compliance shall constitute evidence in any subsequent administrative proceeding that Licensee entered into an agreement to comply with the Natural Medicine Code, and/or these Rules.

3. The State Licensing Authority may review an assurance of voluntary compliance.

C. Not an Administrative Action. Neither a written warning nor an assurance of voluntary compliance constitutes an administrative action.

D. Not Eligible for Written Warning or Assurance of Voluntary Compliance. If a Division investigator identifies a violation(s) of the Natural Medicine Code or these Rules, the following conduct is not eligible for a Written Warning or Assurance of Voluntary Compliance:

1. Knowingly adulterating or altering a Sample, Production Lot, or Harvest Lot;

2. A violation by a Natural Medicine Testing Facility including a deliberate or willful violation of a testing rule, a violation or deviation from a rule or a standard operating procedure that results in the potential to harm public health of safety, or any acts by a Natural Medicine Testing Facility that produce a test result favorable to a Licensee (over reporting tryptamine content, under reporting contaminants, other inaccurate test results).

3. Any sale or transfer of Regulated Natural Medicine or Regulated Natural Medicine Product in violation of the Natural Medicine Code or these Rules;

4. Transferring Regulated Natural Medicine or Regulated Natural Medicine Product to an individual under the age of 21 years;

5. Any unlawful act by a Person licensed pursuant to article 50 in violation of section 44-50-501, C.R.S.; and

6. Inversion of unregulated Natural Medicine or Natural Medicine Product to a Natural Medicine Business from a source other than another Natural Medicine Business.

Basis and Purpose – 9015

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-202(1)(d), and 44-50-203(2)(r), C.R.S. The purpose of this rule is to establish the criteria and process by which the Division petitions a district court for an investigative subpoena for a person who is not licensed pursuant to the Natural Medicine Code.

9015 – Investigative Subpoenas

A. Criteria. The State Licensing Authority may petition a district court for an investigative subpoena applicable to a person who is not licensed pursuant to the Natural Medicine Code to obtain documents or information necessary to enforce the Natural Medicine Code and these Rules after the Division has taken reasonable efforts to obtain requested documents or information.

B. Reasonable Efforts. For purposes of this Rule 9015, "reasonable efforts" may include but shall not be limited to obtaining the documents or information through a request to the unlicensed person and such unlicensed person has either declined to provide the documents or information, or failed to respond to the Division within the applicable time frame.

C. Affidavit. When seeking an investigative subpoena, the Division will supply the district court with a sworn affidavit explaining the bases for seeking the subpoena

Basis and Purpose – 9020

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-202(1)(c), 44-50-203(1)(b), 44-50-203(2)(l), and 44-50-203(2)(p), C.R.S. The purpose of this rule is to establish the circumstances in which the Division may seek an administrative search warrant for a Natural Medicine Licensee.

9020 – Administrative Warrants

A. Criteria. The Division may seek from a district court an administrative search warrant authorizing search and seizure in circumstances in which the Division makes a proper showing that:

1. A Licensee has refused entry of Division investigators during business hours or times of apparent activity;

2. A Licensee subject to an embargo or summary suspension has failed to comply with applicable rules; or

3. A Licensee otherwise has acted in a manner demonstrating willful or deliberate disregard for the Natural Medicine Code or these Rules or that threatens the public health, safety, and welfare.

B. Affidavit. When seeking an administrative search warrant, the Division will supply the district court with a sworn affidavit explaining the bases for seeking the warrant.

C. Seized Property. Neither the Division nor the State Licensing Authority shall cultivate or care for any seized Regulated Natural Medicine. The Division may seize and destroy Regulated Natural Medicine and Regulated Natural Medicine Product pursuant to agreement with the Licensee or may seek from the State Licensing Authority or a district court an order to destroy any seized Regulated Natural Medicine and Regulated Natural Medicine Product.

Basis and Purpose – 9025

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-202(1)(c), 44-50-203(1)(a), 44-50-203(1)(b), 44-50-203(2)(l), 44-50-203(2)(m), 24-4-105, and 44-50-701, C.R.S. The purpose of this rule is to describe the process for disciplinary actions that do not involve summary suspension of a Natural Medicine License.

9025 – Non-Summary Suspensions

A. How a Disciplinary Action is Initiated.

1. If the State Licensing Authority, on its own initiative or based on a complaint, has reasonable cause to believe that a Licensee has violated the Natural Medicine Code, any of these Rules, or any of its orders, the State Licensing Authority may issue and serve upon the Licensee an Order to Show Cause (administrative action) as to why its license should not be suspended, revoked, restricted, fined, or subject to other disciplinary sanction.

2. The Order to Show Cause shall identify the statute, rule, regulation, or order allegedly violated, and the facts alleged to constitute the violation. The order shall also provide an advisement that the license could be suspended, revoked, restricted, fined, or subject to other disciplinary sanction should the charges contained in the notice be sustained upon final hearing.

B. Disciplinary Hearings. Disciplinary hearings will be conducted in accordance with Rule 9040 Administrative Hearings.

C. Renewal. The issuance of an Order to Show Cause does not relieve the Licensee of the obligation to timely comply with all license renewal requirements. The Division's approval of any renewal application filed by a Licensee does not constitute a Final Agency Order or an agreement to settlement of any administrative action. The License shall continue to comply with the requirements of this Rule pending a Final Agency Order resolving any Order to Show Cause.

Basis and Purpose – 9030

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-202(1)(c), 44-50-203(1)(a), 44-50-203(1)(b), 44-50-203(2)(l), 44-50-203(2)(m), 24-4-104(4)(a), 24-4-105, and 44-50-701, C.R.S. The purpose of this rule is to describe the conditions and process for disciplinary actions that involve summary suspension of a Natural Medicine License.

9030 – Summary Suspensions

A. How a Summary Suspension is Initiated.

1. When the State Licensing Authority has reasonable grounds to believe and finds that a Licensee has been guilty of a deliberate and willful violation of any applicable law or regulation or that the public health, safety, or welfare imperatively requires emergency action it shall serve upon the Licensee a Summary Suspension Order that temporarily or summarily suspends the license.

2. The Summary Suspension Order shall identify the nature of the State Licensing Authority's basis for the summary suspension. The Summary Suspension Order shall also provide an advisement that the License may be subject to further discipline or revocation following a hearing on an Order to Show Cause.

3. Proceedings for suspension or revocation shall be promptly instituted and determined after the Summary Suspension Order is issued according to the following Procedure:

a. Either contemporaneously with, or promptly after the Summary Suspension Order is issued, the State Licensing Authority will issue and serve upon the Licensee an Order to Show Cause (administrative citation) as to why the Licensee's license should not be suspended, revoked, restricted, fined, or subject to other disciplinary sanction.

b. The Order to Show Cause will identify the statute, rule, regulation, or order allegedly violated, and the facts alleged to constitute the violation. The Order to Show Cause will also provide an advisement that the license could be suspended, revoked, restricted, fined or subject to disciplinary sanction should the charges contained in the Order to Show Cause be sustained upon final Hearing.

c. The Order to Show Cause shall be filed with the Department's Hearings Division. The hearing on the allegations set forth in the Order to Show Cause shall be expedited to the extent practicable and will be conducted in accordance with Rule 9040– Administrative Hearings.

B. Duration of Summary Suspension. Unless lifted by the State Licensing Authority, the Summary Suspension Order will remain in effect until issuance of a Final Agency Order.

Basis and Purpose – 9035

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-202(1)(c), 44-50-202(1)(e), 44-50-203(1)(a), 44-50-203(1)(b), 44-50-203(2)(l), 44-50-203(2)(n), and 44-50-203(2)(r), 24-4-104, 24-4-105, and 44-50-701, C.R.S. The State Licensing Authority recognizes that if Licensees are not able to care for their products during a period of active suspension, then their cultivated Regulated Natural Medicine could die, their products could deteriorate, and their on-hand inventory may not be properly maintained. Accordingly, this rule was written to clarify that Licensees whose licenses are summarily suspended may care for on-hand inventory, and manufactured products during the suspension (unless the State Licensing Authority does not allow such activity), provided the Licensed Premises and all Regulated Natural Medicine and Regulated Natural Medicine Product is adequately secured. In addition, the rule clarifies what activity is always prohibited during such suspension.

9035 – Suspension Process: Regular and Summary Suspensions

A. Signs Required During Suspension. Every Licensee whose license has been suspended, whether summarily or after an administrative hearing, shall post two notices in conspicuous places, one on the exterior and one on the interior of its Licensed Premises, for the duration of the suspension. The notices shall be at least 17 inches in length and 11 inches in width containing lettering not less than 1/2'' in height.

1. For suspension following issuance of a Final Agency Order, the sign shall be in the following form:

   NOTICE OF SUSPENSION REGULATED NATURAL MEDICINE LICENSES ISSUED FOR THESE PREMISES HAVE BEEN SUSPENDED BY ORDER OF THE STATE LICENSING AUTHORITY FOR VIOLATION OF THE COLORADO NATURAL MEDICINE CODE.

2. For a summary suspension pending issuance of a Final Agency Order, the sign shall be in the following form:

   NOTICE OF SUSPENSION REGULATED NATURAL MEDICINE LICENSES ISSUED FOR THESE PREMISES HAVE BEEN SUSPENDED BY ORDER OF THE STATE LICENSING AUTHORITY FOR ALLEGED VIOLATION OF THE COLORADO NATURAL MEDICINE CODE.

   Any advertisement or posted signs that indicate that the premises have been closed or business suspended for any reason other than by the manner described in this Rule shall be deemed a violation of these Rules.

B. Prohibited Activity During Active Suspension.

1. Unless otherwise ordered by the State Licensing Authority, during any period of active license suspension the Licensee shall not permit the serving, giving away, distribution, manufacture, acquisition, purchase, testing, transfer, or transport of Regulated Natural Medicine or Regulated Natural Medicine Product at the Licensed Premises, nor allow Participants to enter the Licensed Premises.

2. Unless otherwise ordered by the State Licensing Authority, during any period of suspension the Licensee may continue to possess, maintain, cultivate, or harvest Regulated Natural Medicine and Regulated Natural Medicine Product on the Licensed Premises. The Licensee must fully account for all such Regulated Natural Medicine and Regulated Natural Medicine Product during any period of suspension. The Licensee must safeguard any Regulated Natural Medicine or Regulated Natural Medicine Product in its possession or control. The Licensee must possess and maintain the Licensed Premises in reasonable condition according to health, safety, and sanitary standards, and must fully comply with all security requirements including but not limited to surveillance, lock and alarm requirements set forth in the Natural Medicine Code and these Rules.

C. Removal and Destruction of Regulated Natural Medicine and Regulated Natural Medicine Product. Regulated Natural Medicine and Regulated Natural Medicine Product shall not be removed from the Licensed Premises or destroyed unless:

1. The State Licensing Authority orders forfeiture and destruction;

2. The Licensee has voluntarily surrendered the Regulated Natural Medicine or Regulated Natural Medicine Product in accordance with Rule 9005 – Voluntary Surrender; or

3. The State Licensing Authority has seized the Regulated Natural Medicine or Regulated Natural Medicine Product pursuant to an Administrative Warrant. See Rule 9020 – Administrative Warrant.

D. Renewal. The issuance of an Order to Show Cause or an Order of Summary Suspension does not relieve the Licensee of the obligation to timely comply with all license renewal requirements. The Division's approval of any renewal application filed by a Licensee while subject to an Order to Show Cause or an Order of Summary Suspension shall not constitute a Final Agency Order or an agreement to a settlement of the administrative action. The Licensee shall continue to comply with the requirements of this Rule pending a Final Agency Order resolving the Order of Summary Suspension and any related Order to Show Cause.

Basis and Purpose – 9040

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-202(1)(c), 44-50-202(1)(e), 44-50-203(1)(a), 44-50-203(1)(b), 44-50-203(2)(l), 44-50-203(2)(n), and 44-50-203(2)(r), 24-4-104, 24-4-105, and 44-50-701, C.R.S. The purpose of this rule is to describe the requirements and procedures for administrative hearings, including prehearing practices.

9040 – Administrative Hearings

A. General Procedures.

1. Hearing Location. Hearings will generally be conducted by the Department's Hearings Division. Hearings will be held virtually unless otherwise ordered by the hearing officer for good cause. "Good cause" for an in-person hearing means that there are unusual circumstances where justice, judicial economy, and convenience of the parties would be served by holding a hearing in person. The Division, Respondent or Denied Applicant may request a hearing officer order an in-person hearing upon a showing of good cause. If the hearing officer orders an in-person hearing, the hearing will be conducted at a location in the greater Denver metropolitan area to be determined by the hearing officer.

2. Scope of Hearing Rules. This Rule shall be construed to promote the just and efficient determination of all matters presented.

3. Right to Legal Counsel. Any Denied Applicant or Respondent has a right to legal counsel throughout all processes described in rules associated with the denial of an application and disciplinary action. Such counsel shall be provided solely at the Denied Applicant's or Respondent's expense. Unless a Denied Applicant or Respondent that is an entity satisfies the exception in section 13-1-127(2), C.R.S., the Denied Applicant or Respondent must be represented by an attorney admitted to practice law in the state of Colorado.

4. Service. An Order to Show Cause, a Notice of Destruction, or a Notice of Denial must be served on a Respondent or Denied Applicant personally or by first-class mail. Service of pleadings or other papers on a Denied Applicant, Respondent, or any attorney representing a party, may be made by hand delivery, by mail to the party's last known address, or by electronic mail. Service of pleadings or other papers on the Division in an administrative hearing may be made to the attorney(s) of record, as identified on the Certificate of Service to the Order to Show Cause, Order of Summary Suspension, Notice of Embargo, or Notice of Denial, by electronic mail or first-class mail.

B. Requesting a Hearing.

1. A Denied Applicant that has been served with a Notice of Denial may request a hearing within 60 days of service of the Notice of Denial by making a written request for a hearing to the Division. The request must be submitted by United States mail or by hand delivery. Email or fax requests will not be considered. The request must be sent to the mailing address of the Division's headquarters, as listed on the Division's website. Include "Attn: Hearing Request" in the mailing address. The written request for a hearing must be received by the Division within the time stated in the Notice of Denial. An untimely request for hearing will not be considered.

2. A Denied Applicant that timely requests a hearing following issuance of a Notice of Denial shall be served with a Notice of Grounds for Denial, and shall be entitled to a hearing regarding the matters addressed therein.

3. A Respondent that has been served with an Order to Show Cause shall be entitled to a hearing regarding the matters addressed therein.

4. A Licensee that has been served with a Notice of Destruction may request a hearing within 60 days of service of the Notice of Destruction by making a written request for a hearing to the Division.

a. The request must be submitted by United States mail or by hand delivery. Email or fax requests will not be considered. The request must be sent to the mailing address of the Division's headquarters, as listed on the Division's website. Include "Attn: Hearing Request" in the mailing address. The written request for a hearing must be received by the Division within the time stated in the Notice of Destruction. An untimely request for hearing will not be considered.

b. If a Notice of Destruction is served concerning embargoed Regulated Natural Medicine or Regulated Natural Medicine Product that is also subject of an administrative action, and a hearing is timely requested by the Respondent, a single hearing shall be held for the efficiency of the Hearings Division and the parties.

C. When a Responsive Pleading is Required.

1. A Respondent shall file a written answer with the Hearings Division and the Division within 30 days after the date of mailing of any Order to Show Cause. The written answer shall comply with the requirements of Rule 8 of the Colorado Rules of Civil Procedure. If a Respondent fails to file a required answer, the hearing officer, upon motion, may enter a default against that person pursuant to section 24-4-105(2)(b), C.R.S. For good cause, as described in this Rule, shown, the hearing officer may set aside the entry of default within ten days after the date of such entry.

2. A Denied Applicant shall file a written answer with the Hearings Division and the Division within 30 days after the date of mailing of any Notice of Grounds for Denial. The written answer shall comply with the requirements of Rule 8 of the Colorado Rules of Civil Procedure. If a Denied Applicant fails to file a required answer, the hearing officer, upon motion, may enter a default against that person pursuant to section 24-4-105(2)(b), C.R.S. For good cause, as described in this Rule, shown, the hearing officer may set aside the entry of default within ten days after the date of such entry.

D. Hearing Notices.

1. Notice to Set. The Division shall send a notice to set a hearing to the Denied Applicant or Respondent in writing by electronic mail or by first-class mail to the last mailing address of record if an electronic mail address is unknown.

2. Notice of Hearing. The Hearings Division shall notify the Division and Denied Applicant or Respondent of the date, place, time, and nature of the hearing regarding denial of the license application, order of destruction, or whether discipline should be imposed against the Respondent's license at least 30 days prior to the date of such hearing, unless otherwise agreed to by both parties. This notice shall be sent to the Denied Applicant or Respondent in writing by first-class mail to the last mailing address of record. Hearings shall be scheduled and held as soon as is practicable.

a. If an Order of Summary Suspension has been issued, the hearing on the Order to Show Cause will be scheduled and held promptly.

b. Continuances may be granted for good cause, as described in this Rule, shown. A motion for a continuance must be timely.

c. "Good cause" for a continuance may include but is not limited to: death or incapacitation of a party or an attorney for a party; a court order staying proceedings or otherwise necessitating a continuance; entry or substitution of an attorney for a party a reasonable time prior to the hearing, if the entry or substitution reasonably requires a postponement of the hearing; a change in the parties or pleadings sufficiently significant to require a postponement; a showing that more time is clearly necessary to complete authorized discovery or other mandatory preparation for the hearing; or agreement of the parties to a settlement of the case which has been or will likely be approved by the final decision maker. Good cause normally will not include the following: unavailability of counsel because of engagement in another judicial or administrative proceeding, unless the other proceeding was involuntarily set subsequent to the setting in the present case; unavailability of a necessary witness, if the witness' testimony can be taken by telephone or by deposition; or failure of an attorney or a party timely to prepare for the hearing.

E. Prehearing Matters Generally.

1. Prehearing Conferences Once a Hearing is Set. Prehearing conferences may be held at the discretion of the hearing officer upon request of any party, or upon the hearing officer's own motion. If a prehearing conference is held and a prehearing order is issued by the hearing officer, the prehearing order will control the course of the proceedings.

2. Depositions. Depositions are generally not allowed; however, a hearing officer has discretion to allow a deposition if a party files a written motion and can show why such deposition is necessary to prove its case. When a hearing officer grants a motion for a deposition, C.R.C.P. 30 controls. Hearings will not be continued because a deposition is allowed unless (a) both parties stipulate to a continuance and the hearing officer grants the continuance, or (b) the hearing officer grants a continuance over the objection of any party in accordance with subsections (D)(2)(b) and (c) of this Rule.

3. Prehearing Statements. Once a Hearing is Set. Prehearing Statements are required and unless otherwise ordered by the hearing officer, each party shall file with the hearing officer and serve on each party a prehearing statement no later than seven calendar days prior to the hearing. Parties shall also exchange exhibits at that time. Parties shall also file exhibits with the hearing officer. Parties shall exchange exhibits by the date on which prehearing statements are to be filed. Prehearing statements shall include the following Information:

a. Witnesses. The name, mailing address, and telephone number of any witness whom the party may call at hearing, together with a detailed statement of the expected testimony.

b. Experts. The name, mailing address, and a brief summary of the qualifications of any expert witness a party may call at hearing, together with a statement that details the opinions to which each expert is expected to testify. These requirements may be satisfied by the incorporation of an expert's resume or report containing the required information.

c. Exhibits. A description of any physical or documentary evidence to be offered into evidence at the hearing. Exhibits should be identified as follows: Division using numbers and Denied Applicant or Respondent using letters.

d. Stipulations. A list of all stipulations of fact or law reached, as well as a list of any additional stipulations requested or offered to facilitate disposition of the case.

4. Prehearing Statements Binding. The information provided in a party's prehearing statement is binding on that party throughout the course of the hearing unless modified to prevent manifest injustice. New witnesses or exhibits may be added only if: (1) the need to do so was not reasonably foreseeable at the time of filing of the prehearing statement; (2) it would not prejudice other parties; and (3) it would not necessitate a delay of the hearing.

5. Consequence of Not Filing a Prehearing Statement Once a Hearing is Set. If a party does not timely file a prehearing statement, the hearing officer may impose appropriate sanctions including, but not limited to, striking proposed witnesses and exhibits.

F. Conduct of Hearings.

1. The hearing officer shall cause all hearings to be electronically recorded.

2. The hearing officer may allow a hearing, or any portion of the hearing, to be conducted in real time by telephone or other electronic means. If a party is appearing by telephone, the party must provide actual copies of the exhibits to be offered into evidence at the hearing to the hearing officer when the prehearing statement is filed. Electronic filings will be accepted at: dor_regulatoryhearings@state.co.us.

3. The hearing officer shall administer oaths or affirmations to all witnesses at hearing. The hearing officer may question any witness.

4. The hearing, including testimony and exhibits, shall be open to the public unless otherwise ordered by the hearing officer in accordance with a specific provision of law.

   a. Reports and other information that would otherwise be confidential pursuant to subsection 44-50-204(1)(a), C.R.S., may be introduced as exhibits at hearing.

   b. Any party may move the hearing officer to seal an exhibit or order other appropriate relief if necessary to safeguard the confidentiality of evidence.

5. Court Rules.

   a. To the extent practicable, the Colorado Rules of Evidence apply. Unless the context requires otherwise, whenever the word "court," "judge," or "jury" appears in the Colorado Rules of Evidence, such word shall be construed to mean a hearing officer. A hearing officer has discretion to consider evidence not admissible under such rules, including but not limited to hearsay evidence, pursuant to section 24-4-105(7), C.R.S.

   b. To the extent practicable, the Colorado Rules of Civil Procedure apply. However, Colorado Rules of Civil Procedure 16 and 26-37 do not apply, although parties are encouraged to voluntarily work together to resolve the case, simplify issues, and exchange information relevant to the case prior to a hearing. Unless the context otherwise requires, whenever the word "court" appears in a rule of civil procedure, that word shall be construed to mean a hearing officer.

6. Exhibits.

   a. All documentary exhibits must be paginated by the party offering the exhibit into Evidence.

   b. The Division shall use numbers to mark its exhibits.

c. The Denied Applicant or Respondent shall use letters to mark its exhibits.

7. The hearing officer may proceed with the hearing or enter default judgment if any party fails to appear at hearing after proper notice.

G. Post Hearing. After considering all the evidence, the hearing officer shall determine whether the proponent of the order has proven its case by a preponderance of the evidence, and shall make written findings of evidentiary fact, ultimate conclusions of fact, conclusions of law, and a recommendation. These written findings shall constitute an Initial Decision subject to review by the State Licensing Authority pursuant to the Colorado Administrative Procedure Act and as set forth in Rule 9030 – Administrative Hearing Appeals process: Exceptions to Initial Decision.

H. No Ex Parte Communication. Ex parte communication shall not be allowed at any point following the formal initiation of the hearing process. A party or counsel for a party shall not initiate any communication with a hearing officer or the State Licensing Authority, or with conflicts counsel representing the hearing officer or State Licensing Authority, pertaining to any pending matter unless all other parties participate in the communication or unless prior consent of all other parties (and any pro se parties) has been obtained. Parties shall provide all other parties with copies of any pleading or other paper submitted to the hearing officer or the State Licensing Authority in connection with a hearing or with the exceptions process.

I. Natural Medicine Division Representation. The Division will be represented by the Colorado Department of Law.

Basis and Purpose – 9045

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(b), 44-50-202(1)(c), 44-50-202(1)(e), 44-50-203(1)(a), 44-50-203(1)(b), 44-50-203(2)(l), 44-50-203(2)(m), and 44-50-203(2)(r), C.R.S. The purpose of this rule is to describe the exceptions process by which a Denied Applicant or Respondent may appeal an Initial Decision issued by a hearing officer pursuant to the Administrative Procedure Act.

9045 – Administrative Hearing Appeal Process: Exceptions to Initial Decision

A. Exception(s) Process. Any party may appeal an Initial Decision to the State Licensing Authority pursuant to the Colorado Administrative Procedure Act by filing written exception(s) within 30 days after the date of mailing of the Initial Decision to the Denied Applicant or Respondent and the Division. The written exception(s) shall include a statement giving the basis and grounds for the exception(s). Any party who fails to properly file written exception(s) within the time provided in these rules shall be deemed to have waived the right to an appeal. A copy of the exception(s) shall be served on all parties. The address of the State Licensing Authority is: State Licensing Authority, 1707 Cole Boulevard, Suite 350, Lakewood, CO 80401.

B. Designation of Record. Any party that seeks to reverse or modify the Initial Decision of the hearing officer shall file with the State Licensing Authority, within 20 days from the mailing of the Initial Decision, a designation of the relevant parts of the record and of the parts of the hearing transcript which shall be prepared, and advance the costs therefore. A copy of this designation shall be served on all parties. Within ten days thereafter, any other party may also file a designation of additional parts of the transcript of the proceedings which is to be included and advance the cost therefore. No transcript is required if the review is limited to a pure question of law. A copy of this designation of record shall be served on all parties.

C. Deadline Modifications. The State Licensing Authority may modify deadlines and procedures related to the filing of exceptions to the Initial Decision upon motion by either party for good cause shown.

D. No Oral Argument Allowed. Requests for oral argument will not be considered.

Basis and Purpose – 9050

The statutory authority for this rule includes but is not limited to sections 44-50-202(1)(a), 44-50-202(1)(b), 44-50-203(1)(a), 44-50-203(1)(b), 44-50-203(2)(l), 44-50-203(2)(m), 44-50-203(2)(r), and 44-50-701, C.R.S. The purpose of this rule is to establish guidelines for enforcement and penalties that will be imposed by the State Licensing Authority for non-compliance with the Natural Medicine Code or these Rules.

9050 – Penalties

A. This penalty structure is a framework providing guidance as to the range of violations, suspension description, fines, and mitigating and aggravating factors. The circumstances surrounding any penalty imposed will be determined by the State Licensing Authority on a case-by-case basis.

B. Penalty Schedule. The State Licensing Authority will make determinations regarding the type of penalty to impose based on the severity of the violation(s) in the following categories:

1. Level I Violation(s). This category of violation is the most severe and generally has an immediate or potential negative effect on public health, safety, or welfare.

a. The range of available penalties for Level I violations include one or more of the following: license suspension, a fine of up to $25,000.00 per individual violation, and/or license revocation. Sanctions may also include restrictions on the license.

b. Level I Violation(s). This category of violations includes the most severe and may include willful or deliberate violations or violations that result in harm or the potential to harm public safety, health or welfare. Level I violations include, but are not limited to:

i. Inversion of unregulated Natural Medicine or Regulated Natural Medicine Product to a Natural Medicine Business from a source other than another Natural Medicine Business;

ii. Diversion of Regulated Natural Medicine or Regulated Natural Medicine Product to a person other than a Natural Medicine Business or a Facilitator;

iii. Any transfer of Regulated Natural Medicine or Regulated Natural Medicine Product to an individual under the age of 21 years;

iv. Knowingly adulterating or altering a Sample, Production Lot, or Harvest Lot;

v. Conduct by a Natural Medicine Testing Facility that demonstrates a deliberate or willful violation of a testing rule, a deviation from a rule or a standard operating procedure that results in the potential to harm public health of safety, or any acts by a Natural Medicine Testing Facility that produce a test result favorable to a Licensee (over reporting tryptamine content, under reporting contaminants, other inaccurate test results);

vi. The manufacture or transfer of Regulated Natural Medicine or Regulated Natural Medicine Product in violation of the Natural Medicine Code or these Rules, including but not limited to the manufacture or transfer of synthetic Natural Medicine;

vii. Violations related to the sharing of Licensed Premises between Natural Medicine Businesses;

viii. Advertising violations including misleading, deceptive, or false advertising or advertising targeting individuals under the age of 21;

ix. Packaging or labeling violations that have an immediate or potential negative impact on public health and safety; or

x. Releasing personally identifying information or medical data maintained or stored at a Natural Medicine Business's Licensed Premises other than as permitted by the Code, these Rules, or any other local, state or federal law.

2. All other Violation(s). This category of violation generally does not have an immediate or potential negative impact on the public health, safety, and welfare.

a. The range of available penalties for all other violations include one or more of the following: license suspension, a fine of up to $10,000.00 per individual violation, and/or license revocation. Sanctions may also include restrictions on the license.

C. Mitigating and aggravating factors. The State Licensing Authority may consider mitigating and aggravating factors when considering the imposition of a penalty. Mitigating and aggravating factors may impact the severity of the penalty imposed for the violation(s).

1. Mitigating factors include:

a. No prior written warning(s), assurance(s) of voluntary compliance, or disciplinary action against Licensee in the preceding 24 months;

b. Corrective action(s) taken by the Licensee related to the violation(s);

c. The Licensee initiated a voluntary recall of the Natural Medicine or Regulated Natural Medicine Product;

d. Good faith efforts taken by the Licensee to comply with the rules;

e. Good faith measures by the Licensee to prevent the violation(s) prior to the Division's investigation, including standard operating procedures which comply with the rules and directly address the conduct leading to the violation, proper supervision, and regularly provided and documented employee training;

f. Licensee self-reported the violation(s); and

g. Any other relevant circumstances which mitigate the violation(s).

2. Aggravating factors include:

a. Licensee transferred unsafe or potentially unsafe Regulated Natural Medicine or Regulated Natural Medicine Product;

b. Conduct or violation(s) resulted in a recall pursuant to Rule 3215, an embargo pursuant to Rule 3220, or a health and safety advisory;

c. Willful or deliberate nature of actions by Licensee;

d. Duration of conduct and violations(s) by Licensee;

e. The quantity of Regulated Natural Medicine or Regulated Natural Medicine Product involved in the conduct or violation(s) by Licensee;

f. Licensee received verbal or written warning(s) or signed assurance(s) of voluntary compliance pursuant to Rule 9035 for the same conduct or violation(s) in the previous 24 months;

g. Prior disciplinary action against Licensee in the previous 24 months for the same conduct or violation(s);

h. Licensee subject to a summary suspension for any conduct or violation(s) in the previous 24 months;

i. Owner or manager involvement in the conduct or violation(s);

j. Involvement by a person unlicensed to work for a Natural Medicine Business;

k. Substantial risk for diversion of Regulated Natural Medicine or Regulated Natural Medicine Product as a result of the Licensee's conduct or violation(s); and

l. Any other relevant circumstances which aggravate the violation(s).

Editor's Notes

History

New rule eff. 10/01/2024.

Rule 2005 eff. 12/15/2024.