



## STATEMENT OF ADOPTION

To: Jim Burack, Director, Marijuana Enforcement Division

From: Heidi Humphreys, Deputy Executive Director/Chief Operating Officer of the Colorado Department of Revenue, State Licensing Authority

Re: Statement of Adoption

**Repealed Medical Marijuana Rules, 1 CCR 212-1**  
**Repealed Retail Marijuana Rules, 1 CCR 212-2**  
**New Marijuana Rules, 1 CCR 212-3**

Pursuant to the Administrative Procedure Act, Title 24, Article 4, of the Colorado Revised Statutes, I, Heidi Humphreys, Deputy Executive Director/Chief Operating Officer of the Colorado Department of Revenue, State Licensing Authority, promulgate the following rules to become effective on January 1, 2020:

**Permanent Rules, Medical Marijuana, 1 CCR 212-1**

**Secretary of State Filing Tracking Number 2019-00479**

**M 100 Series – General Applicability (Repealed Effective January 1, 2020)**

**2-200 Series – Applications and Licenses (Repealed Effective January 1, 2020)**

**M 300 Series – The Licensed Premises (Repealed Effective January 1, 2020)**

**M 400 Series – Medical Marijuana Centers (Repealed Effective January 1, 2020)**

**M 500 Series – Optional Premises Cultivation Operation: License Privileges (Repealed Effective January 1, 2020)**

**M 600 Series – Medical Marijuana-Infused Products Manufacturers (Repealed Effective January 1, 2020)**

**M 700 Series – Medical Marijuana Testing Facilities (Repealed Effective January 1, 2020)**

**M 800 Series – Transport and Storage (Repealed Effective January 1, 2020)**

**M 900 Series – Business Records (Repealed Effective January 1, 2020)**

**M 1000-1 Series – Labeling, Packaging, and Product Safety (Repealed Effective January 1, 2020)**

**M 1100 Series – Signage and Advertising (Repealed Effective January 1, 2020)**

**M 1200 Series – Enforcement (Repealed Effective January 1, 2020)**

**M 1300 Series – Discipline (Repealed Effective January 1, 2020)**

**M 1400 Series – Division, Local Licensing Authority, and Law Enforcement Procedures (Repealed Effective January 1, 2020)**

**M 1500 Series – Medical Marijuana Testing Program (Repealed Effective January 1, 2020)**

**M 1600 Series – Medical Marijuana Transporters (Repealed Effective January 1, 2020)**

**M 1700 Series – Medical Marijuana Business Operators (Repealed Effective January 1, 2020)**

**M 1800 Series – Medical Marijuana Transfers to Unlicensed Medical Research Facilities and Pesticide Manufacturers (Repealed Effective January 1, 2020)**

**M 1900 Series – Licensed Research Businesses (Repealed Effective January 1, 2020)**

## **Permanent Rules, Retail Marijuana, 1 CCR 212-2**

### **Secretary of State Filing Tracking Number 2019-00479**

**R 100 Series – General Applicability (Repealed Effective January 1, 2020)**

**2-200 Series – Applications and Licenses (Repealed Effective January 1, 2020)**

**R 300 Series – The Licensed Premises (Repealed Effective January 1, 2020)**

**R 400 Series – Retail Marijuana Stores (Repealed Effective January 1, 2020)**

**R 500 Series – Retail Marijuana Cultivation Facilities (Repealed Effective January 1, 2020)**

**R 600 Series – Retail Marijuana Products Manufacturing Facilities (Repealed Effective January 1, 2020)**

**R 700 Series – Retail Marijuana Testing Facilities (Repealed Effective January 1, 2020)**

**R 800 Series – Transport and Storage (Repealed Effective January 1, 2020)**

**R 900 Series – Business Records (Repealed Effective January 1, 2020)**

**R 1000-1 Series – Labeling, Packaging, and Product Safety (Repealed Effective January 1, 2020)**

**R 1100 Series – Signage and Advertising (Repealed Effective January 1, 2020)**

**R 1200 Series – Enforcement (Repealed Effective January 1, 2020)**

**R 1300 Series – Discipline (Repealed Effective January 1, 2020)**

**R 1400 Series – Division, Local Jurisdiction, and Law Enforcement Procedures (Repealed Effective January 1, 2020)**

**R 1500 Series – Retail Marijuana Testing Program (Repealed Effective January 1, 2020)**

**R 1600 Series – Retail Marijuana Transporters (Repealed Effective January 1, 2020)**

**R 1700 Series – Retail Marijuana Establishment Operators (Repealed Effective January 1, 2020)**

**Permanent Rules, Marijuana Rules, 1 CCR 212-3 (New Rule Series)**

**Secretary of State Filing Tracking Number 2019-00479**

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**6-200 Series – Retail Marijuana Cultivation Facilities**

**6-205** – Retail Marijuana Cultivation Facility: License Privileges

**6-210** – Retail Marijuana Cultivation Facility: General Limitations and Prohibited Acts

**6-215** – Retail Marijuana Cultivation Facility: Retail Marijuana Concentrate Production

**6-220** – Retail Marijuana Cultivation Facility: Production Management



**6-225** – Sampling Unit Protocols

**6-300 Series – Retail Marijuana Products Manufacturer**

**6-305** – Retail Marijuana Products Manufacturer: License Privileges

**6-310** – Retail Marijuana Products Manufacturer: General Limitations and Prohibited Acts

**6-315** – Retail Marijuana Products Manufacturer: Retail Marijuana Concentrate Production

**6-320** – Sampling Unit Protocols

**6-325** – Retail Marijuana Products Manufacturer: Audited Product and Alternative Use Product

**6-330** – Recall of Retail Marijuana Concentrate or Retail Marijuana Product

**6-400 Series – Retail Marijuana Testing Facility**

**6-405** – Retail Marijuana Testing Facilities: License Privileges

**6-410** – Retail Marijuana Testing Facilities: General Limitations and Prohibited Acts

**6-415** – Retail Marijuana Testing Facilities: Certification Requirements

**6-420** – Retail Marijuana Testing Facilities: Personnel

**6-425** – Retail Marijuana Testing Facilities: Standard Operating Procedure Manual

**6-430** – Retail Marijuana Testing Facilities: Analytical Processes

**6-435** – Retail Marijuana Testing Facilities: Proficiency Testing

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**6-445** – Retail Marijuana Testing Facilities: Chain of Custody

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**6-455** – Retail Marijuana Testing Facilities: Notification of Retail Marijuana Business

**6-500 Series – Retail Marijuana Transporters**

**6-505** – Retail Marijuana Transporter: License Privileges

**6-510** – Retail Marijuana Transporter: General Limitations and Prohibited Acts

**6-600 Series – Retail Marijuana Business Operators**

**6-605** – Retail Marijuana Business Operator: License Privileges

**6-610** – Retail Marijuana Business Operator: General Limitations and Prohibited Acts

**6-615** – Retail Marijuana Business Operator: Employee Licenses for Personnel

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- 7-105** – Medical Marijuana Transfers to Medical Research Facilities
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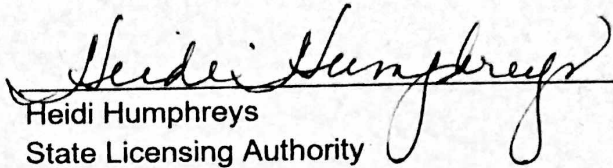
**8-100 Series – Enforcement**

- 8-105** – Duties of Employees of State Licensing Authority
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Signed this 5<sup>th</sup> day of November, 2019.

  
Heidi Humphreys  
State Licensing Authority

**DEPARTMENT OF REVENUE**

**MARIJUANA ENFORCEMENT DIVISION**

**MEDICAL MARIJUANA RULES**

**1 CCR 212-1 – Repealed Effective January 1, 2020**

**RETAIL MARIJUANA RULES**

**1 CCR 212-2 – Repealed Effective January 1, 2020**

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**COLORADO MARIJUANA RULES**

**1 CCR 212-3**

**Part 1 – General Applicability**

**Basis and Purpose – 1-105**

The statutory authority for this rule includes but is not limited to sections 44-10-102(3), 44-10-202(1)(c), and 44-10-701(2)(a), C.R.S. Unless such activity is authorized by the Colorado Constitution, article XVIII, Section 14 or Section 16, the Colorado Marijuana Code, section 25-1.5-106.5, C.R.S., or these rules, any Person who buys, Transfers, or acquires Regulated Marijuana outside the requirements of the Colorado Marijuana Code is engaging in illegal activity pursuant to Colorado law. This rule clarifies that those engaged in the business of possessing, cultivating, dispensing, Transferring, transporting, or testing Medical Marijuana or Retail Marijuana must be properly licensed to be in compliance with Colorado law. This Rule 1-105 was previously Rules M and R 101, 1 CCR 212-1 and 1 CCR 212-2.

**1-105 – Engaging in Business**

Except as authorized by the Colorado Constitution, article XVIII, sections 14 or 16, the Colorado Marijuana Code, or section 25-1.5-106.5, C.R.S., no person shall possess, cultivate, dispense, Transfer, transport, offer to sell, manufacture, or test Regulated Marijuana unless said person is duly licensed by the State Licensing Authority and approved by the relevant Local Jurisdiction(s) and/or licensed by the relevant Local Licensing Authority(-ies).

**Basis and Purpose – 1-110**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), C.R.S. The purpose of this rule is to clarify that each rule is independent of the others, so if one is found to be invalid, the remainder will stay in effect. This will give the regulated community confidence in the rules even if one is challenged. This Rule 1-110 was previously Rules M and R 102, 1 CCR 212-1 and 1 CCR 212-2.

**1-110 – Severability**

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

**Basis and Purpose – 1-115**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(j), and 44-10-103, C.R.S., and all of the Marijuana Code. 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. This Rule 1-115 was previously Rules M and R 103, 1 CCR 212-1 and 1 CCR 212-2.

## **1-115 – Definitions**

Definitions. The following definitions of terms, in addition to those set forth in section 44-10-103, C.R.S., apply to all rules promulgated pursuant to the Marijuana Code, unless the context requires otherwise:

“Acquire,” when used in connection with the acquisition of an Owner’s Interest of a Regulated Marijuana Business, means obtaining ownership, Control, power to vote, or sole power of disposition of the Owner’s Interest, directly or indirectly through one or more transactions or subsidiaries, through purchase, assignment, transfer, exchange, succession or other means.

“Acting in Concert” means knowing participation in a joint activity or interdependent conscious parallel action toward a common goal, whether or not pursuant to an express agreement.

“Advertising” means the act of providing consideration for the publication, dissemination, solicitation, or circulation, of visual, oral, or written communication, to directly induce any Person to patronize a particular Regulated Marijuana Business, or to purchase particular Regulated Marijuana. “Advertising” includes marketing, but does not include packaging and labeling, Consumer Education Materials, or Branding. “Advertising” proposes a commercial transaction or otherwise constitutes commercial speech.

“Additive” means any non-marijuana derived substance added to Regulated Marijuana to achieve a specific technical and/or functional purpose during processing, storage, or packaging. Additives may be direct or indirect. Direct additives are used to impart specific technological or functional qualities. Indirect additives are not intentionally added but may be present in trace amounts as a result of processing, packaging, shipping, or storage.

“Affiliate” of, or Person affiliated with, a specified Person, means a Person that directly or indirectly through one or more intermediaries, Controls or is Controlled by, or is under common Control with, the Person specified.

“Alarm Installation Company” means a Person engaged in the business of selling, providing, maintaining, servicing, repairing, altering, replacing, moving or installing a Security Alarm System in a Licensed Premises.

“Alternative Use Designation” means a designation approved by the State Licensing Authority, permitting a Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer to manufacture and Transfer Alternative Use Product.

“Alternative Use Product” means Regulated Marijuana that has at least one intended use that is not included in the list of intended uses in Rule 3-1015(B). Alternative Use Product may raise public health concerns that outweigh approval of the Alternative Use Product, or that require additional safeguards and oversight. Alternative Use Product cannot be Transferred except as permitted by Rule 5-325 or Rule 6-325 after obtaining an Alternative Use Designation. Rule 5-325 permits a Medical Marijuana Products Manufacturer to Transfer Alternative Use Product to a Medical Marijuana Testing Facility prior to receiving an Alternative Use Designation. Rule 6-325 permits a Retail Marijuana Products Manufacturer to Transfer Alternative Use Product to a Retail Marijuana Testing Facility prior to receiving an Alternative Use Designation. Except where the

context otherwise clearly requires, rules applying to Regulated Marijuana Concentrate or Regulated Marijuana Product apply to Alternative Use Product.

“Applicant” means a Person that has submitted an application for licensure, permit, or registration, or for renewal of licensure, permit, or registration, pursuant to these rules that was accepted by the Division for review but has not been approved or denied by the State Licensing Authority.

“Approved Training Program” means a responsible vendor program that received approval from the Division prior to being offered to a Licensee.

“Audited Product” means a Regulated Marijuana Product with an intended use of: (1) metered dose nasal spray, (2) vaginal administration, or (3) rectal administration. Audited Product types may raise public health concerns requiring additional safeguards and oversight. These product types may only be manufactured and Transferred by a Medical Marijuana Products Manufacturer in strict compliance with Rule 5-325 or Retail Marijuana Products Manufacturer in strict compliance with Rule 6-325. Prior to the first Transfer of an Audited Product to a Medical Marijuana Store, Medical Marijuana Cultivation Facility that has a Centralized Distribution Permit, Retail Marijuana Store or Retail Marijuana Cultivation Facility that has obtained a Centralized Distribution Permit, the Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer shall submit to the Division and, if applicable, to the Local Licensing Authority or Local Jurisdiction an independent third-party audit verifying compliance with Rule 5-325 or Rule 6-325. All rules regarding Regulated Marijuana Product apply to Audited Product except where Rules 5-325, 6-325, 4-115, 3-1010, and 3-1015 apply different requirements.

“Bad Actor” means a Person who:

- a. Has been convicted, within the previous ten years (or five years, in the case of issuers, their predecessors and affiliated issuers), of any felony or misdemeanor:
  - i. In connection with the purchase or sale of any Security;
  - ii. Involving the making of any false filing with the Federal Securities Exchange Commission; or
  - iii. Arising out of the conduct of the business of an underwriter, broker, dealer, municipal securities dealer, investment adviser or paid solicitor of purchasers of Securities;
- b. Is subject to any order, judgment or decree of any court of competent jurisdiction, entered within the previous five years, that restrains or enjoins such Person from engaging or continuing to engage in any conduct or practice:
  - i. In connection with the purchase or sale of any Security;
  - ii. Involving the making of any false filings with the Federal Securities Exchange Commission; or
  - iii. Arising out of conduct of the business of an underwriter, broker, dealer, municipal securities dealer, investment adviser or paid solicitor of purchasers of Securities;
- c. Is subject to a final order of a state securities commission (or an agency or officer of a state performing like functions); a state authority that supervises or examines banks, savings associations, or credit unions; a state insurance commission (or

an agency or officer of a state performing like functions); an appropriate federal banking agency; the U.S. Commodity Futures Trading Commission; or the National Credit Union Administration that:

- i. Bars the Person from:
    - A. Association with an Entity regulated by such commission, authority, agency, or officer;
    - B. Engaging in the business of Securities, insurance or banking; or
    - C. Engaging in savings association or credit union activities; or
  - ii. Constitutes a final order based on a violation of any law or regulation that prohibits fraudulent, manipulative, or deceptive conduct entered within the previous ten years;
- d. Is subject to an order of the Federal Securities Exchange Commission entered pursuant to section 15(b) or 15B(c) of the Securities Exchange Act of 1934, or section 203(e) or (f) of the Investment Advisers Act of 1940 that:
- i. Suspends or revokes such Person's registration as a broker, dealer, municipal securities dealer or investment adviser;
  - ii. Places limitations on the activities, functions or operations of such Person; or
  - iii. Bars such Person from being associated with any Entity, or from participating in the offering of any Penny Stock;
- e. Is subject to any order of the Federal Securities Exchange Commission entered within the previous five years that orders the Person to cease and desist from committing or causing a violation or future violation of:
- i. Any scienter-based anti-fraud provision of the federal securities laws, including without limitations section 17(a)(1) of the Securities Act of 1933, section 10(b) of the Securities Exchange Act of 1934 and 17 C.F.R. 240.10b-5, section 15(c)(1) of the Securities Exchange Act of 1934 and section 206(1) of the Investment Advisers Act of 1940, or any other rule or regulation thereunder; or
  - ii. Section 5 of the Securities Act of 1933.
- f. Is suspended or expelled from membership in, or suspended or barred from association with a member of, a registered national securities exchange or a registered national or affiliated securities association for any act or omission to act constituting conduct inconsistent with just and equitable principles of trade;
- g. Has filed (as a registrant or issuer), or was named as an underwriter in, any registration statement or Regulation A offering statement filed with the federal Securities Exchange Commission that, within the previous five years, was the subject of a refusal order, stop order, or order suspending the Regulation A exemption, or is the subject of an investigation or proceeding to determine whether a stop order or suspension order should be issued; or

- h. Is subject to a United States Postal Service false representation order entered with the previous five years, or is subject to a temporary restraining order or preliminary injunction with respect to conduct alleged by the United States Postal Service to constitute a scheme or device for obtaining money or property through the mail by means of false representations.

“Batch Number” means any distinct group of numbers, letters, or symbols, or any combination thereof, assigned by a Medical Marijuana Cultivation Facility or Medical Marijuana Products Manufacturer to a specific Harvest Batch or Production Batch of Medical Marijuana, or by a Retail Marijuana Cultivation Facility or Retail Marijuana Products Manufacturer to a specific Harvest Batch or Production Batch of Retail Marijuana.

“Beneficial Owner” includes the terms “beneficial ownership”, or “beneficially owns” and means:

- a. Any Person who, directly or indirectly, through any contract, arrangement, understanding, relationship, or otherwise has or shares:
  - i. Voting power which includes the power to vote, or to direct the voting of, an Owner’s Interest; and/or,
  - ii. Investment power which includes the power to dispose, or to direct the disposition of, an Owner’s Interest.
- b. Any Person who, directly or indirectly, creates or uses a trust, proxy, power of attorney, pooling arrangement or any other contract, arrangement, or device with the purpose or effect of divesting such Person of beneficial ownership of an Owner’s Interest or preventing the vesting of such beneficial ownership as part of a plan or scheme to evade the reporting requirements of section 13(d) or (g) of the Securities Act of 1933 shall be deemed for purposes of such sections to be the beneficial owner of such Owner’s Interest.
- c. All Owner’s Interests of the same class beneficially owned by a Person, regardless of the form which such beneficial ownership takes, shall be aggregated in calculating the number of shares beneficially owned by such Person.
- d. Notwithstanding the provisions of paragraphs (a) and (c) of this rule:
  - i.
    - A. A Person shall be deemed to be the beneficial owner of an Owner’s Interest, subject to the provisions of paragraph (b) of this rule, if that Person has the right to acquire beneficial ownership of such Owner’s Interest, as defined in Rule 13d-3(a) (§ 240.13d-3(a)) within sixty days, including but not limited to any right to acquire: (1) Through the exercise of any option, warrant or right; (2) through the conversion of an Owner’s Interest; (3) pursuant to the power to revoke a trust, discretionary account, or similar arrangement; or (4) pursuant to the automatic termination of a trust, discretionary account or similar arrangement; provided, however, any person who acquires an Owner’s Interest or power specified in paragraphs (d)(i)(A)(1), (2) or (3), of this section, with the purpose or effect of changing or influencing the control of the issuer, or in connection with or as a participant in any transaction having such purpose or effect, immediately upon



such acquisition shall be deemed to be the beneficial owner of the Owner's Interests which may be acquired through the exercise or conversion of such Owner's Interests or power. Any Owner's Interests not outstanding which are subject to such options, warrants, rights or conversion privileges shall be deemed to be outstanding for the purpose of computing the percentage of outstanding Owner's Interests of the class owned by such Person but shall not be deemed to be outstanding for the purpose of computing the percentage of the class by any other Person.

- B. Paragraph (d)(i)(A) of this section remains applicable for the purpose of determining the obligation to file with respect to the underlying Owner's Interests even though the option, warrant, right or convertible Owner's Interests is of a class of equity Owner's Interest, as defined in § 240.13d-1(i), and may therefore give rise to a separate obligation to file.
- ii. A member of a national securities exchange shall not be deemed to be a beneficial owner of an Owner's Interest held directly or indirectly by it on behalf of another Person solely because such member is the record holder of such Owner's Interests and, pursuant to the rules of such exchange, may direct the vote of such Owner's Interests, without instruction, on other than contested matters or matters that may affect substantially the rights or privileges of the holders of the Owner's Interests to be voted, but is otherwise precluded by the rules of such exchange from voting without instruction.
  - iii. A person who in the ordinary course of his business is a pledgee of Owner's Interests under a written pledge agreement shall not be deemed to be the beneficial owner of such pledged Owner's Interests until the pledgee has taken all formal steps necessary which are required to declare a default and determines that the power to vote or to direct the vote or to dispose or to direct the disposition of such pledged Owner's Interests will be exercised, provided, that:
    - A. The pledgee agreement is bona fide and was not entered into with the purpose nor with the effect of changing or influencing the control of the issuer, nor in connection with any transaction having such purpose or effect, including any transaction subject to Rule 13d-3(b);
    - B. The pledgee is a Person specified in Rule 13d-1(b)(ii), including Persons meeting the conditions set forth in paragraph (G) thereof; and
    - C. The pledgee agreement, prior to default, does not grant to the pledgee;
      - 1. The power to vote or to direct the vote of the pledged Owner's Interests; or
      - 2. The power to dispose or direct the disposition of the pledged Owner's Interests, other than the grant of such power(s) pursuant to a pledge agreement under which credit is extended subject to regulation T (12 CFR 220.1

to 220.8) and in which the pledgee is a broker or dealer registered under section 15 of the Securities Act of 1933.

- iv. A Person engaged in business as an underwriter of Owner's Interests who acquires Owner's Interests through his participation in good faith in a firm commitment underwriting registered under the Securities Act of 1933 shall not be deemed to be the beneficial owner of such Owner's Interests until the expiration of forty days after the date of such acquisition.

"Blank Check Company" means an Entity that:

- a. Is a development stage company that has no specific business plan or purpose or has indicated that its business plan is to engage in a merger or acquisition with an unidentified company or companies, or other Entity or Person; and
- b. Is issuing Penny Stock.

"Branding" means promotion of a Regulated Marijuana Business's brand through publicizing the Regulated Marijuana Business's name, logo, or distinct design feature of the brand.

"Cannabinoid" means any of the chemical compounds that are the active principles of marijuana.

"Centralized Distribution Permit" means a permit issued to a Medical Marijuana Cultivation Facility pursuant to section 44-10-502, C.R.S., or a Retail Marijuana Cultivation Facility pursuant to section 44-10-602, C.R.S., authorizing temporary storage of Medical Marijuana Concentrate and Medical Marijuana Product received from a Medical Marijuana Products Manufacturer or Retail Marijuana Concentrate and Retail Marijuana Product received from a Retail Marijuana Products Manufacturer for the sole purpose of Transfer to commonly owned Medical Marijuana Stores or Retail Marijuana Stores. For purposes of a Centralized Distribution Permit only, the term "commonly owned" means at least one natural person has a minimum of five percent ownership in both the Medical Marijuana Cultivation Facility possessing the Centralized Distribution Permit and the Medical Marijuana Store, or in both the Retail Marijuana Cultivation Facility possessing the Centralized Distribution Permit and the Retail Marijuana Store.

"Child-Resistant" means special packaging that is:

- a. 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;
- b. Opaque so that the packaging does not allow the product to be seen without opening the packaging material; and
- c. Resealable for any product intended for more than a single use or containing multiple servings.

"Commercially Reasonable Royalty" means a right to compensation in the form of a royalty payment for the use of intellectual property with a direct nexus to the cultivation, manufacture, Transfer or testing of Regulated Marijuana. A Commercially Reasonable Royalty must be limited to specific intellectual property the Commercially Reasonable Royalty interest owns or is otherwise authorized to license or to a product or line of products. A Commercially Reasonable

Royalty must not cause reasonable consumer confusion or violate any federal copyright, trademark or patent law or regulation will not be approved. To determine whether the Commercially Reasonable Royalty is reasonable, the Division will consider the totality of the circumstances, including but not limited to the following factors:

- a. The percentage of royalties received by the recipient for the licensing of the intellectual property.
- b. The rates paid by the Licensee for the use of other intellectual property.
- c. The nature and scope of the license, as exclusive or non-exclusive; or as restricted or non-restricted in terms of territory or with respect to whom the product may be sold.
- d. The licensor's established policy and marketing program to maintain his intellectual property monopoly by not licensing others or by granting licenses under special conditions designed to preserve that monopoly.
- e. The commercial relationship between the recipient and Licensee, such as, whether they are competitors in the same territory in the same line of business.
- f. The effect of selling the intellectual property in promoting sales of other products of the Licensee; the existing value of the intellectual property to the recipient as a generator of sales of his non-intellectual property items; and the extent of such derivative sales.
- g. The duration of the term of the license for use of the intellectual property.
- h. The established or projected profitability of the product made using the intellectual property; its commercial success; and its current popularity.
- i. The utility and advantages of the intellectual property over products or businesses without the intellectual property.
- j. The nature of the intellectual property; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the intellectual property.
- k. The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the intellectual property.
- l. The portion of the realizable profit that should be credited to the intellectual property as distinguished from non-intellectual property elements, the manufacturing process, business risks, or significant features or improvements added by the Licensee.

"Consumer Education Materials" means any informational materials that seek to educate consumers about Regulated Marijuana generally, including but not limited to education regarding the safe consumption of marijuana, Regulated Marijuana Concentrate, or Regulated Marijuana Products, provided it is not distributed or made available to individuals under twenty-one years of age.

"Consumption Area" means a designated and secured area within the Licensed Premises of a Licensed Hospitality Business where consumers can use and consume marijuana and where no

one under the age of 21 is permitted. A Consumption Area may, but is not required to, be part of a Restricted Access Area.

“Container” means the receptacle directly containing Regulated Marijuana that is labeled according to the requirements in the 3-1000 Series Rules.

“Control” means the possession, direct or indirect, of the power to direct or cause the direction of the management or policies of a Person, whether through the ownership of voting Owner’s Interests, by contract, or otherwise. This definition of Control includes Controls, Controlled, Controlling, Controlled by, and under common Control with.

“Controlling Beneficial Owner” means a Person that satisfies one or more of the following criteria:

- a. A natural person, an Entity that is organized under the laws of and for which its principal place of business is located in one of the states or territories of the United States or District of Columbia, a Publicly Traded Corporation, or a Qualified Private Fund that is not a Qualified Institutional Investor:
  - i. Acting alone or Acting In Concert, that owns or Acquires Beneficial Ownership of ten percent or more of the Owner’s Interest of a Regulated Marijuana Business;
  - ii. That is an Affiliate that Controls a Regulated Marijuana Business and includes, without limitation, any Manager; or
  - iii. That is otherwise in a position to Control the Regulated Marijuana Business except as authorized in section 44-10-506 or 44-10-606, C.R.S.; or
- b. A Qualified Institutional Investor acting alone or Acting In Concert that owns or Acquires Beneficial Ownership of more than thirty percent of the Owner’s Interest of a Regulated Marijuana Business.
- c. Unless the context otherwise requires, the defined term Controlling Beneficial Owner includes Direct Beneficial Interest Owner.

“Corrective Action” means a reactive action implemented to eliminate the root cause of a Nonconformance and to prevent recurrence.

“Court Appointee” means a Person appointed by a court as a receiver, personal representative, executor, administrator, guardian, conservator, trustee, or similarly situated Person; acting in accordance with section 44-10-401(3), C.R.S., and these rules; and authorized by court order to take possession of, operate, manage, or control a licensed Regulated Marijuana Business.

“Covered Securities” means:

- a. A Security designated as qualified for trading in the national market system pursuant to section 78k-1(a)(2) of the Securities Act of 1933 that is listed, or authorized for listing, on a national securities exchange (or tier or segment thereof); or a Security of the same issuer that is equal in seniority or that is a senior Security to a Security designated as qualified for trading in the national market system.
- b. A Security issued by an investment company that is registered, or that has filed a registration statement under the federal Investment Company Act of 1940.

- c. A Security as defined by the Federal Securities Exchange Commission by rule pursuant to 15 U.S.C. §77r(b)(3).
- d. A Security pursuant to 15 U.S.C. §77r(b)(4).

“Delivery Motor Vehicle” means any self-propelled vehicle that is designed primarily for travel on the public highways, that is generally and commonly used to transport persons and property over the public highways or a low-speed electric vehicle that is used for delivery of Regulated Marijuana to patients or consumers; except that the term does not include electric assisted bicycles, wheelchairs, or vehicles moved solely by human power.

“Denied Applicant” means any Person whose application for licensure, permit, or registration pursuant to the Marijuana Code has been denied, any Person whose application for a responsible vendor program has been denied, or any Licensee whose application for any of the following non-exhaustive list has been denied: An initial license application pursuant to Rule 2-220, a renewal application pursuant to Rule 2-225, the request for a finding of suitability pursuant to Rule 2-235, a change of owner pursuant to Rule 2-245; a change of location of the Licensed Premises pursuant to Rule 2-255; a change, alteration, or modification of the Licensed Premises pursuant to Rule 2-260; or a production management tier increase request pursuant to Rule 5-225 or 6-220.

“Department” means the Colorado Department of Revenue.

“Director” means the Director of the Marijuana Enforcement Division.

“Division” means the Marijuana Enforcement Division.

“Edible Medical Marijuana Product” means any Medical Marijuana Product for which the intended use is oral consumption, including but not limited to, any type of food, drink, or pill.

“Edible Retail Marijuana Product” means any Retail Marijuana Product for which the intended use is oral consumption, including but not limited to, any type of food, drink, or pill.

“Employee License” means a license granted by the State Licensing Authority pursuant to section 44-10-401, C.R.S., to a natural person who is not a Controlling Beneficial Owner. Any person who possesses, cultivates, manufactures, tests, dispenses, sells, serves, transports, or delivers Regulated Marijuana, who is authorized to input data into a Regulated Marijuana Business’s Inventory Tracking System or point-of-sale system, or who has unescorted access in the Restricted Access Area or Limited Access Area must hold an Employee License. Employee License includes both Key Licenses and Support Licenses.

“Entity” means a domestic or foreign corporation, cooperative, general partnership, limited liability partnership, limited liability company, limited partnership, limited liability limited partnership, limited partnership association, nonprofit association, nonprofit corporation, or any other organization or association that is formed under a statute or common law of the state of Colorado or any other jurisdiction as to which the laws of this state of Colorado or the laws of any other jurisdiction governs relations among owners and between the owners and the organization or association and that is recognized under the laws of the state of Colorado or the other jurisdiction as a separate legal entity.

“Executive Officer” means the president, any vice president in charge of a principal business unit, division or function (such as sales, administration or finance), any other officer who performs a policy making function, or any other person who performs similar policy making functions for the Regulated Marijuana Business.

“Exit Package” means an Opaque bag or other similar Opaque covering provided at the point of sale, in which Regulated Marijuana already in a Container is placed. If Regulated Marijuana flower, trim or seeds are placed into a Container that is not Child-Resistant, then the Exit Package must be Child-Resistant. The Exit Package is not required to be labeled in accordance with the 3-100 Series Rules.

“Fibrous Waste” means any roots, stalks, and stems from a Regulated Marijuana plant.

“Final Agency Order” means an Order of the State Licensing Authority issued in accordance with the Marijuana 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 thereto or at the conclusion of the declaratory order process. A Final Agency Order is subject to judicial review.

“Flammable Solvent” means a liquid that has a flash point below 100 degrees Fahrenheit.

“Flowering” means the reproductive state of the cannabis plant in which there are physical signs of flower budding out of the nodes of the stem.

“Food-Based Medical Marijuana Concentrate” means a Medical Marijuana Concentrate that was produced by extracting Cannabinoids from Medical Marijuana through the use of propylene glycol, glycerin, butter, olive oil or other typical cooking fats.

“Food-Based Retail Marijuana Concentrate” means a Retail Marijuana Concentrate that was produced by extracting Cannabinoids from Retail Marijuana through the use of propylene glycol, glycerin, butter, olive oil or other typical cooking fats.

“Foreign Private Issuer” means any foreign issuer other than a foreign government except an issuer meeting the following conditions as of the last business day of its most recently completed second fiscal quarter:

- a. More than 50 percent of the outstanding voting Securities of such issuer are directly or indirectly owned of record by residents of the United States; and
- b. Any of the following:
  - i. The majority of the executive officers or directors are United States citizens or residents;
  - ii. More than 50 percent of the assets of the issuer are located in the United States; or
  - iii. The business of the issuer is administered principally in the United States.

“Good Cause” for purposes of denial of an initial, renewal, or reinstatement of a license, registration, or permit application, means:

- a. The Licensee or Applicant has violated, does not meet, or has failed to comply with any of the terms, conditions, or provisions of the Marijuana Code, any rules promulgated pursuant to the Marijuana Code, or any supplemental relevant state or local law, rule, or regulation;

- b. The Licensee or Applicant has failed to comply with any special terms or conditions that were placed upon the license pursuant to an order of the State Licensing Authority or the relevant local jurisdiction; or
- c. The Licensee's Licensed Premises have been operated in a manner that adversely affects the public health or welfare or the safety of the immediate neighborhood in which the establishment is located.

"Good Moral Character" means having a criminal history that demonstrates honesty, fairness, and respect for the rights of others and for the law.

"Greenhouse" means a hoop house or other structure with non-rigid walls that utilizes natural light, in whole or in part, for the cultivation of Regulated Marijuana.

"Harvest Batch" means a specifically identified quantity of processed Regulated Marijuana that is uniform in strain, cultivated utilizing the same Pesticide and other agricultural chemicals and harvested at the same time.

"Harvested Marijuana" means Regulated Marijuana flower reported as a package in the Inventory Tracking System or post-harvest Regulated Marijuana not including wet whole plant, trim, concentrate, waste, or Fibrous Waste that remains on the premises of the Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility or its off-premises storage location beyond 90 days from harvest.

"Heat/Pressure-Based Medical Marijuana Concentrate" means a Medical Marijuana Concentrate that was produced by extracting Cannabinoids from Medical Marijuana through the use of heat and/or pressure. The method of extraction may be used by only a Medical Marijuana Products Manufacturer and can be used alone or on a Production Batch that also includes Water-Based Medical Marijuana Concentrate or Solvent-Based Medical Marijuana Concentrate.

"Heat/Pressure-Based Retail Marijuana Concentrate" means Retail Marijuana Concentrate that was produced by extracting Cannabinoids from Retail Marijuana through the use of heat and/or pressure. This method of extraction may be used by only a Retail Marijuana Products Manufacturer and can be used alone or on a Production Batch that also includes Water-Based Retail Marijuana Concentrate or Solvent-Based Retail Marijuana Concentrate.

"Identification Badge" means a physical badge issued to any natural person possessing an Owner License or Employee License, used to verify the identity of the natural persons on the Licensed Premises of a Regulated Marijuana Business.

"Identity Statement" means the name of the business as it is commonly known and used in any Advertising.

"Immature plant" means a nonflowering Regulated Marijuana plant that is no taller than eight inches and no wider than eight inches produced from a cutting, clipping or seedling and is in a cultivating container. Plants meeting these requirements are not attributable to a Licensee's maximum allowable plant count, but must be fully accounted for in the Inventory Tracking System.

"Indirect Financial Interest Holder" means a Person that is not an Affiliate, a Controlling Beneficial Owner, or a Passive Beneficial Owner of a Regulated Marijuana Business and that:

- a. Holds a Commercially Reasonable Royalty in exchange for a Regulated Marijuana Business's use of the Person's intellectual property;

- b. Holds a Permitted Economic Interest that was issued prior to January 1, 2020, and that has not been converted into an Owner's Interest or holds any unsecured convertible debt option, option agreement or warrant that establishes a right for a Person to obtain an interest that might convert to an ownership interest in a Regulated Marijuana Business obtained after January 1, 2020;
- c. Is a contract counterparty with a Regulated Marijuana Business, other than a customary employment agreement, that has a direct nexus to the cultivation, manufacture, sale, or testing of Regulated Marijuana, including, but not limited to, a lease of real property on which the Regulated Marijuana Business operates, a lease of equipment used in the cultivation, manufacture, or testing of Regulated Marijuana, a secured or unsecured financing agreement with the Regulated Marijuana Business, a security contract with the Regulated Marijuana Business, or a management agreement with the Regulated Marijuana Business, provided that no such contract compensates the contract counterparty with a percentage of revenue for profits of the Regulated Marijuana Business.
  - i. Any secured interest in Regulated Marijuana must expressly provide that it is subject to all required suitability and application requirements.
- d. Unless the context otherwise requires, the defined term Indirect Financial Interest Holder includes Indirect Beneficial Interest Owner.

"Industrial Fiber Products" means intermediate or finished products made from Fibrous Waste that are not intended for human or animal consumption and are not usable or recognizable as Regulated Marijuana. Industrial Fiber Products include, but are not limited to, cordage, paper, fuel, textiles, bedding, insulation, construction materials, compost materials, and industrial materials.

"Industrial Fiber Products Producer" means a Person who produces Industrial Fiber Products using Fibrous Waste.

"Industrial Hemp" means a plant of the genus Cannabis and any part of the plant, whether growing or not, containing a delta-9 tetrahydrocannabinol (THC) concentration of no more than three-tenths of one percent (0.3%) on a dry weight basis.

"Industrial Hemp Product" means a finished product containing Industrial Hemp that:

- a. Is a cosmetic, food, food additive, or herb;
- b. Is for human use or consumption;
- c. Contains any part of the hemp plant, including naturally occurring Cannabinoids, compounds, concentrates, extracts, isolates, resins, or derivatives; and
- d. Contains a delta-9 tetrahydrocannabinol concentration of no more than three-tenths of one percent.

"Industrial Hygienist" means a natural person who has obtained a baccalaureate or graduate degree in industrial hygiene, biology, chemistry, engineering, physics, or a closely related physical or biological science from an accredited college or university.

- a. The special studies and training of such persons must be sufficient in the cognate sciences to provide the ability and competency to:



- i. Anticipate and recognize the environmental factors and stresses associated with work and work operations and to understand their effects on individuals and their well-being;
  - ii. Evaluate on the basis of training and experience and with the aid of quantitative measurement techniques the magnitude of such environmental factors and stresses in terms of their ability to impair human health and well-being;
  - iii. Prescribe methods to prevent, eliminate, control, or reduce such factors and stresses and their effects.
- b. Any person who has practiced within the scope of the meaning of industrial hygiene for a period of not less than five years immediately prior to July 1, 1997, is exempt from the degree requirements set forth in the definition above.
  - c. Any person who has a two-year associate of applied science degree in environmental science from an accredited college or university and in addition not less than four years practice immediately prior to July 1, 1997, within the scope of the meaning of industrial hygiene is exempt from the degree requirements set forth in the definition above.

“Ineligible Issuer” means:

- a. Any issuer that is required to file reports pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934 that has not filed all reports and other materials required to be filed during the preceding 12 months, other than reports on Form 8-K required solely pursuant to an item specified in General Instruction I.A.3(b) of Form S-3;
- b. The issuer is, or during the past three years the issuer or any of its predecessors was:
  - i. A Blank Check Company;
  - ii. A Shell Company;
  - iii. An issuer of an offering of Penny Stock;
- c. The issuer is a limited partnership that is offering and selling its Securities other than through a firm commitment underwriting;
- d. Within the past three years, a petition under the federal bankruptcy laws or any state insolvency law was filed by or against the issuer, or a court appointed a receiver, fiscal agent or similar officer with respect to the business or property of the issuer subject to the following:
  - i. In the case of an involuntary bankruptcy in which a petition was filed against the issuer, ineligibility will occur upon the earlier to occur of:
    - A. 90 days following the date of the filing of the involuntary petition (if the case has not been earlier dismissed); or
    - B. The conversion of the case to a voluntary proceeding under federal bankruptcy or state insolvency laws; and

- ii. Ineligibility will terminate if an issuer has filed an annual report with audited financial statements subsequent to its emergence from that bankruptcy, insolvency, or receivership process;
- e. Within the past three years, the issuer or any Entity that at the time was a subsidiary of the issuer was convicted of any felony or misdemeanor described in paragraphs (i) through (iv) of section 15(b)(4)(B) of the Securities Exchange Act of 1934;
- f. Within the past three years, the issuer or any Entity that at the time was a subsidiary of the issuer was made the subject of any judicial or administrative decree or order arising out of a governmental action that:
  - i. Prohibits certain conduct or activities regarding, including future violations of, the anti-fraud provisions of the federal securities laws;
  - ii. Requires that the Person cease and desist from violating the anti-fraud provisions of the federal securities laws; or
  - iii. Determines that the Person violated the anti-fraud provisions of the federal securities laws;
- g. The issuer has filed a registration statement that is the subject of any pending proceeding or examination under section 8 of the Securities Act of 1933 or has been the subject of any refusal order or stop order under section 8 of the Securities Act of 1933 within the past three years; or
- h. The issuer is the subject of any pending proceeding under section 8A of the Securities Act of 1933 in connection with an offering.

“Ingredient” means any non-marijuana derived substance that is added to Regulated Marijuana to achieve a desired effect. The term Ingredient includes all Additives.

“Initial Decision” means a decision of a hearing officer in the Department following a licensing, disciplinary, or other administrative hearing. Either party may file exceptions to the Initial Decision. The State Licensing Authority will review the Initial Decision and any exceptions filed thereto, and will issue a Final Agency Order.

“Inventory Tracking System” means the required seed-to-sale tracking system that tracks Regulated Marijuana from either the seed or immature plant stage until the Regulated Marijuana is sold to a patient at a Medical Marijuana Store or to a consumer at a Retail Marijuana Store, Transferred to a Medical Marijuana Testing Facility or Retail Marijuana Testing Facility, Transferred to a Sampling Manager, Transferred to an Industrial Fiber Products Producer, Transferred to a Medical Research Facility, Transferred to a Pesticide Manufacturer, or destroyed by a Regulated Marijuana Business, or used in a Research Project by a Marijuana Research and Development Facility.

“Inventory Tracking System Trained Administrator” means an Owner Licensee of a Regulated Marijuana Business or an Employee Licensee employed by a Regulated Marijuana Business, each of whom has attended and successfully completed Inventory Tracking System training and has completed any additional training required by the Division.

“Inventory Tracking System User” means an Owner Licensee of a Regulated Marijuana Business or an Employee Licensee employed by a Regulated Marijuana Business, who is granted Inventory Tracking System User account access for the purposes of performing inventory tracking

functions in the Inventory Tracking System. Each Inventory Tracking System User must have been successfully trained by an Inventory Tracking System Trained Administrator in the proper and lawful use of Inventory Tracking System.

“Kief” means the resinous crystal-like trichomes that are found on Regulated Marijuana flower and that are accumulated, resulting in a higher concentration of cannabinoids.

“License” means to grant a license, permit, or registration pursuant to the Marijuana Code.

“Licensed Hospitality Business” means a Marijuana Hospitality Business or Retail Marijuana Hospitality and Sales Business.

“Licensed Premises” means the premises specified in an application for a license pursuant to the Marijuana Code that are owned or in possession of the Licensee and within which the Licensee is authorized to cultivate, manufacture, distribute, sell, store, transport, or test Medical Marijuana, or to cultivate, manufacture, distribute, sell, store, transport, test, or allow the use or consumption of Retail Marijuana, in accordance with the provisions of the Marijuana Code, and these rules. Not all areas of the Licensed Premises are Limited Access Areas or Restricted Access Areas.

“Licensee” means any Person licensed, registered, or permitted pursuant to the Marijuana Code including an Owner Licensee and an Employee Licensee.

“Limited Access Area” means a building, room, or other contiguous area upon the Licensed Premises where Regulated Marijuana and Regulated Marijuana Products are grown, cultivated, manufactured, stored, weighed, packaged, sold, possessed for sale, Transferred, or processed for Transfer, under control of the Licensee, with access limited to only those persons licensed by the State Licensing Authority and those visitors Escorted by a person licensed by the State Licensing Authority. All areas of ingress or egress to limited access areas must be clearly identified as such by a sign as designated by the State Licensing Authority.

“Limit of Detection” or “LOD” means the lowest quantity of a substance that can be distinguished from the absence of that substance (a blank value) within a stated confidence limit (generally 1%).

“Limit of Quantitation” or “LOQ” means the lowest concentration at which the analyte can not only be reliably detected but at which some predefined goals for bias and imprecision are met.

“Liquid Edible Medical Marijuana Product” means an Edible Medical Marijuana Product that is a liquid beverage or liquid food-based product for which the intended use is oral consumption, such as a soft drink or cooking sauce.

“Liquid Edible Retail Marijuana Product” means an Edible Retail Marijuana Product that is a liquid beverage or liquid food-based product for which the intended use is oral consumption, such as a soft drink or cooking sauce.

“Local Jurisdiction” means a locality as defined in section 16 (2)(e) of article XVIII of the state constitution.

“Local Licensing Authority” means an authority designated by municipal, county, or city and county charter, ordinance, or resolution, or the governing body of a municipality or city and county, or the board of county commissioners of a county if no such authority is designated.

“Manager” means:

- a. A member of a limited liability company in which management is not vested in managers rather than members;
- b. A manager of a limited liability company in which management is vested in managers rather than members;
- c. A member of a limited partnership association in which management is not vested in managers rather than members;
- d. A manager of a limited partnership association in which management is vested in managers rather than members;
- e. A general partner;
- f. An officer or director of a corporation, a nonprofit corporation, a cooperative, or a limited partnership association; or
- g. Any Person whose position with respect to an Entity, as determined under the constituent documents and organic statutes of the Entity, without regard to the Person's title, is the functional equivalent of any of the positions described in this definition.

"Marijuana-Based Workforce Development Training Program" means a program designed to train individuals to work in the Regulated Marijuana industry operated by an entity licensed under the Marijuana Code or by a school that is authorized by the Division of Private Occupational Schools.

"Marijuana Code" means the Colorado Marijuana Code found at sections 44-10-101 *et seq.*, C.R.S.

"Marijuana Consumer Waste" means any component left after the consumption of a Regulated Marijuana Product, including but not limited to Containers, packages, cartridges, pods, cups, batteries, all-in-one disposable devices, and any other waste component left after the Regulated Marijuana is consumed.

"Marijuana Hospitality Business" means an entity licensed to permit the use or consumption of marijuana within a Consumption Area.

"Marketing Layer" means packaging in addition to the Container that is the outermost layer visible to the consumer at the point of sale. The Marketing Layer is optional, but if used by a Licensee in addition to the required Container, it must be labeled according to the requirements in the 3-1000 Series Rules.

"Marijuana Research and Development Facility" means a Person that is licensed pursuant to the Marijuana Code to grow, cultivate, manufacture, and possess Medical Marijuana, and to Transfer Medical Marijuana to another Marijuana Research and Development Facility or a Medical Research and Development Facility, all for limited research purposes authorized pursuant to section 44-10-507, C.R.S.

"Material Change" means any change that would require a substantive revision to a Regulated Marijuana Business's standard operating procedures for the cultivation of Regulated Marijuana or the production of Regulated Marijuana Product.

"Medical Marijuana" means marijuana that is grown and sold pursuant to the Marijuana Code and includes seeds and Immature Plants. Unless the context otherwise requires, Medical Marijuana includes Medical Marijuana Concentrate and Medical Marijuana Products.

“Medical Marijuana Business” means a Medical Marijuana Store, a Medical Marijuana Product Manufacturer, a Medical Marijuana Cultivation Facility, a Medical Marijuana Testing Facility, a Medical Marijuana Business Operator, a Medical Marijuana Transporter, or a Marijuana Research and Development Facility.

“Medical Marijuana Business Operator” means an entity that holds a license from the State Licensing Authority to provide professional operational services to one or more Medical Marijuana Businesses, other than a Marijuana Research and Development Facility, for direct remuneration from the Medical Marijuana Business(es), which may include compensation based upon a percentage of the profits of the Medical Marijuana Business(es) being operated. A Medical Marijuana Business Operator may contract with Medical Marijuana Business(es) to provide operational services. A Medical Marijuana Business Operator’s contract with a Medical Marijuana Business does not in and of itself constitute ownership.

“Medical Marijuana Concentrate” means a specific subset of Medical Marijuana that was produced by extracting Cannabinoids from Medical Marijuana. Categories of Medical Marijuana Concentrate include Water-Based Medical Marijuana Concentrate, Food-Based Medical Marijuana Concentrate, Solvent-Based Medical Marijuana Concentrate, and Heat/Pressure-Based Medical Marijuana Concentrate. Medical Marijuana Concentrate includes Medical Marijuana Concentrate consumed using a Vaporizer Delivery Device or Pressurized Metered Dose Inhaler.

“Medical Marijuana Cultivation Facility” means a Person licensed pursuant to the Marijuana Code to operate a business as described in section 44-10-502, C.R.S.

“Medical Marijuana Product” means a product infused with Medical Marijuana and other Ingredients that is intended for use or consumption other than by smoking, including but not limited to edible product, ointments, and tinctures.

“Medical Marijuana Products Manufacturer” means a Person licensed pursuant to the Marijuana Code to operate a business as described in section 44-10-503, C.R.S.

“Medical Marijuana Store” means a Person licensed pursuant to the Marijuana Code to operate a business as described in section 44-10-501, C.R.S., and sells Medical Marijuana to registered patients or primary caregivers as defined in Article XVIII, Section 14 of the Colorado Constitution, but is not a primary caregiver.

“Medical Marijuana Testing Facility” means a public or private laboratory licensed and certified, or approved by the Division, to perform testing and research on Medical Marijuana.

“Medical Marijuana Transporter” means a Person that is licensed to transport Medical Marijuana from one Medical Marijuana Business to another Medical Marijuana Business or to a Medical Research Facility or Pesticide Manufacturer, and to temporarily store the transported Medical Marijuana at its Licensed Premises, but is not authorized to sell, give away, buy, or receive complimentary Medical Marijuana under any circumstances. A Medical Marijuana Transporter does not include a Licensee that transports its own Medical Marijuana.

“Medical Research Facility” means a Person approved and grant-funded by the State Board of Health pursuant to section 25-1.5-106.5, C.R.S., to conduct Medical Marijuana research. A Medical Research Facility is neither a Regulated Marijuana Business, nor a Licensee.

“Mobile Premises” means a Licensed Premises operated by a Marijuana Hospitality Business in a motor vehicle, which includes any self-propelled vehicle that is designed primarily for travel on the public highways and that is generally and commonly used to transport persons and property over the public highways or a low-speed electric vehicle; but does not include electrical assisted

bicycles, electric scooters, low-power scooters, wheelchairs, or vehicles moved solely by human power. A Marijuana Hospitality Business operating a Mobile Premises must comply with all requirements in Rule 6-740.

“Monitoring” means the continuous and uninterrupted attention to potential alarm signals that could be transmitted from a Security Alarm System located at a Regulated Marijuana Business Licensed Premises, for the purpose of summoning a law enforcement officer to the premises during alarm conditions.

“Monitoring Company” means a person in the business of providing security system Monitoring services for the Licensed Premises of a Regulated Marijuana Business.

“Multiple-Serving Edible Retail Marijuana Product” means an Edible Retail Marijuana Product unit for sale to consumers containing no more than 10mg of active THC and no more than 100mg of active THC. If the overall Edible Retail Marijuana Product unit for sale to the consumer consists of multiple pieces where each individual piece may contain less than 10mg active THC, yet in total all pieces combined within the unit for sale contain more than 10mg of active THC, then the Edible Retail Marijuana Product shall be considered a Multiple-Serving Edible Retail Marijuana 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 procedures.

“Non-objecting Beneficial Owner” means a Beneficial Owner who gives permission to a financial intermediary to release their name and address to the company(ies) or issuer(s) in which they have bought Securities.

“Notice of Denial” means a written statement from the State Licensing Authority, articulating the reasons or basis for denial of a license application.

“Opaque” means that the packaging does not allow the product to be seen without opening the packaging material.

“Order to Show Cause” means a document from the State Licensing Authority alleging the grounds for imposing discipline against a Licensee’s license.

“Owner’s Interest” means the shares 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, and the interest of a member in a limited partnership association.

“Owner License” means a license issued to a natural person who is a Controlling Beneficial Owner of a Regulated Marijuana Business or who is a Passive Beneficial Owner electing to be subject to licensure.

“Passive Beneficial Owner” means any Person Acquiring any Owner’s Interest in a Regulated Marijuana Business that is not otherwise a Controlling Beneficial Owner or in Control.

“Penny Stock” means any equity security other than a Security:

- a. That is an National Market System stock, provided that:

- i. The Security is registered, or approved for registration upon notice of issuance, on a national securities exchange that has been continuously registered as a national securities exchange since April 20, 1992; and the national securities exchange has maintained quantitative listing standards that are substantially similar to or stricter than those listing standards that were in place on that exchange on January 8, 2004; or
- ii. The Security is registered, or approved for registration upon notice of issuance, on a national securities exchange, or is listed, or approved for listing upon notice of issuance on, an automated quotation system sponsored by a registered national securities association, that:
  - A. Has established initial listing standards that meet or exceed the following criteria:
    - 1. The issuer shall have: (a) stockholders' equity of \$5,000,000; (b) market value of listed Securities of \$50 million for 90 consecutive days prior to applying for a listing (market value means the closing bid price multiplied by the number of Securities listed); or (c) net income of \$750,000 (excluding non-recurring items) in the most recently completed fiscal year or in two of the last three most recently completed fiscal years;
    - 2. The issuer shall have an operating history of at least one year or a market value of listed Securities of \$50 million (market value means the closing bid price multiplied by the number of Securities listed);
    - 3. The issuer's stock, common or preferred, shall have a minimum bid price of \$4 per share;
    - 4. In the case of common stock, there shall be at least 300 round lot holders of the Security (a round lot holder means a holder of a normal unit of trading);
    - 5. In the case of common stock, there shall be at least 1,000,000 publicly held shares and such shares shall have a market value of at least \$5 million (market value means the closing bid price multiplied by the number of publicly held shares, and shares held directly or indirectly by an officer or director of the issuer and by any Person who is the Beneficial Owner of more than 10 percent of the total shares outstanding are not considered to be publicly held);
    - 6. In the case of a convertible debt security, there shall be a principal amount outstanding of at least \$10 million;
    - 7. In the case of rights and warrants, there shall be at least 100,000 issued and the underlying security shall be registered on a national securities exchange or listed on an automated quotation system sponsored by a registered national securities association and shall

satisfy the requirements of paragraphs (a) or (e) of this definition;

8. In the case of put warrants (that is, instruments that grant the holder the right to sell to the issuing company a specified number of shares of the company's common stock, at a specified price until a specified period of time), there shall be at least 100,000 issued and the underlying Security shall be registered on a national securities exchange or listed on an automated quotation system sponsored by a registered national securities association and shall satisfy the requirements of paragraphs (a) or (e) of this definition;
  9. In the case of units (that is, two or more Securities traded together), all component parts shall be registered on a national securities exchange or listed on an automated quotation system sponsored by a registered national securities association and shall satisfy the requirements of paragraphs (a) or (e) of this definition; and
  10. In the case of equity Securities (other than common and preferred stock, convertible debt securities, rights and warrants, put warrants, or units), including hybrid products and derivative products, the national securities exchange or registered national securities association shall establish quantitative listing standards that are substantially similar to those found in paragraph (a)(ii) of this definition; and
- B. Has established quantitative continued listing standards that are reasonably related to the initial listing standards set forth in paragraph (a)(ii) of this definition, and that are consistent with the maintenance of fair and orderly markets;
- b. That is issued by an investment company registered under the Federal Investment Company Act of 1940;
  - c. That is a put or call option issued by the Options Clearing Corporation;
  - d. That has a price of five dollars or more;
    - i. For purposes of this paragraph (d):
      - A. A Security has a price of five dollars or more for a particular transaction if the Security is purchased or sold in that transaction at a price of five dollars or more, excluding any broker or dealer commission, commission equivalent, mark-up, or mark-down; and
      - B. Other than in connection with a particular transaction, a Security has a price of five dollars or more at a given time if the inside bid quotation is five dollars or more; provided, however, that if there is no such inside bid quotation, a Security has a price of five



dollars or more at a given time if the average of three or more interdealer bid quotations at specified prices displayed at that time in an interdealer quotation system, by three or more market makers in the Security, is five dollars or more.

- C. The term “inside bid quotation” shall mean the highest bid quotation for the Security displayed by a market maker in the Security on an automated interdealer quotation system that has the characteristics set forth in section 17B(b)(2) of the Federal Securities Exchange Act of 1934, or such other automated interdealer quotation system designated by the Federal Securities Exchange Commission for purposes of this definition, at any time in which at least two market makers are contemporaneously displaying on such system bid and offer quotation for the Security at specified prices.
  - ii. If a Security is a unit composed of one or more Securities, the unit price divided by the number of shares of the unit that are not warrants, options, rights, or similar Securities must be five dollars or more as determined in accordance with paragraph (d)(i), and any share of the unit that is a warrant, option, right, or similar security, or a convertible security, must have an exercise price or conversion price of five dollars or more;
- e. That is registered, or approved for registration upon notice of issuance, on a national securities exchange that makes transaction reports available provided that:
  - i. Price and volume of information with respect to transactions in that security is required to be reported on a current and continuing basis and is made available to vendors of market information pursuant to the rules of the national securities exchange;
  - ii. The Security is purchased or sold in a transaction that is effected on or through the facilities of the national securities exchange, or that is part of the distribution of the Security; and
  - iii. The Security satisfies the requirements of paragraphs (a)(i) or (a)(ii);
- f. That is a security futures product listed on a national securities exchange or an automated quotation system sponsored by a registered national securities association; or
- g. Whose issuer has:
  - i. Net tangible assets in excess of \$2,000,000, if the issuer has been in continuous operation for at least three years, or \$5,000,000 if the issuer has been in continuous operation for less than three years; or
  - ii. Average revenue of at least \$6,000,000 for the last three years.

“Permitted Economic Interest” means any unsecured convertible debt option, option agreement or warrant that establishes a right for a Person to obtain an interest that might convert to an ownership interest in a Regulated Marijuana Business issued prior to January 1, 2020 where the holder is a natural person who is a lawful United States resident and whose right to convert into

an ownership interest is contingent on the holder qualifying as a Controlling Beneficial Owner or Passive Beneficial Owner under the Retail Code or Medical Code. This definition is repealed effective January 1, 2020.

“Person” means a natural person, an estate, a trust, an Entity, or a state or other jurisdiction.

“Pesticide” means any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest or any substance or mixture of substances intended for use as a plant regulator, defoliant or desiccant; except that the term “pesticide” does not include any article that is a “new animal drug” as designated by the United States Food and Drug Administration.

“Pesticide Manufacturer” means a Person who (1) manufactures, prepares, compounds, propagates, or processes any Pesticide or device or active ingredient used in producing a Pesticide; (2) who possesses an establishment registration number with the U.S. Environmental Protection Agency pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136 *et seq.*; (3) who conducts research to establish safe and effective protocols, including but not limited to establishing efficacy and toxicity, for the use of Pesticides on Regulated Marijuana; (4) who has applied for and received any necessary license, registration, certifications, or permits from the Colorado Department of Agriculture, pursuant to the Pesticide Act, sections 35-9-101 *et seq.*, C.R.S. and/or the Pesticide Applicators’ Act, sections 35-10-101 *et seq.*, C.R.S.; (5) who is authorized to conduct business in the State of Colorado; and (6) who has physical possession of the location in the State of Colorado where its research activities occur. A Pesticide Manufacturer is neither a Regulated Marijuana Business, nor a Licensee.

“Pressurized Metered Dose Inhaler” means inhalable Regulated Marijuana Concentrate, which may be comprised of other Ingredients, and a pressurized propellant inside a device that administers a dose of an aerosolized composition.

“Preventive Action” means a proactive action implemented to eliminate the cause of a potential Nonconformance or other quality problem before it occurs.

“Private Residence” includes, but is not limited to, a private premises where a person lives such as a private dwelling, place of habitation, a house, a multi-dwelling unit for residential occupants, or an apartment unit. Private residence does not include any premises located at a school, on the campus of an institution of higher education, public property, or any commercial property unit such as offices or retail space.

“Production Batch” means (a) any amount of Regulated Marijuana Concentrate of the same category and produced using the same extraction methods, standard operating procedures and an identical group of Harvest Batch(es) of Medical Marijuana or Retail Marijuana; or (b) any amount of Regulated Marijuana Product of the same exact type, produced using the same Ingredients, standard operating procedures, and the same Production Batch(es) of Regulated Marijuana Concentrate.

“Professional Engineer” means a natural person who is licensed by the State of Colorado as a professional engineer pursuant to sections 12-25-101 *et seq.*, C.R.S.

“Proficiency Testing” means an assessment of the performance of a Medical Marijuana Testing Facility’s or Retail Marijuana Testing Facility’s methodology and processes. Proficiency Testing is also known as inter-laboratory comparison. The goal of Proficiency Testing is to ensure results are accurate, reproducible, and consistent.

“Propagation” means the reproduction of Regulated Marijuana plants by seeds, cuttings, or grafting.

“Public Institution,” for purposes of the 5-700 Series Rules, means any entity established or controlled by the federal government, a state government, or a local government or municipality, including but not limited to an institution of higher education or a public higher education research institution.

“Public Money,” for purposes of the 5-700 Serie Rules, means any funds or money obtained by the holder from any governmental entity, including but not limited to research grants.

“Publicly Traded Corporation” means any Person other than an individual that is organized under the laws of and for which its principal place of business is located in one of the states or territories of the United States or District of Columbia or another country that authorizes the sale of marijuana that:

- a. Has a class of Securities registered pursuant to section 12 of the Securities Exchange Act of 1934, as amended, that:
  - i. Constitutes Covered Securities; or
  - ii. Is qualified and quoted on the OTCQX or OTCQB tier of the OTC markets if:
    - A. The Person is then required to file reports and is filing reports on a current basis with the Federal Securities Exchange Commission pursuant to the Federal Securities Exchange Act of 1934, as amended, as if the Securities constituted Covered Securities; and
    - B. The Person has established and is in compliance with corporate governance measures pursuant to corporate governance obligations imposed on Securities qualified and quoted on the OTCQX tier of the OTC markets.
- b. Is an Entity that has a class of Securities listed on the Canadian Securities Exchange, Toronto Stock Exchange, TSX Venture Exchange, or NEO Exchange, if:
  - i. The Entity constitutes a Foreign Private Issuer whose Securities are exempt from registration pursuant to section 12 of the Federal Securities Exchange Act of 1934, as amended, pursuant to Rule 12g3-2(b) promulgated pursuant to the federal Securities Exchange Act of 1934, as amended; and
  - ii. The Entity has been, for the preceding three hundred sixty-five days or since the formation of the Entity, in compliance with all governance and reporting obligations imposed by the relevant exchange on such Entity; or
- c. Publicly Traded Corporation does not include:
  - i. An Ineligible Issuer, unless such Publicly Traded Corporation satisfies the definition of Ineligible Issuer solely because it is one or more of the following, and the Person is filing reports on a current basis with the Federal Securities and Exchange Commission pursuant to the Federal Securities Exchange Act of 1934, as amended, as if the Securities constituted Covered Securities, and prior to becoming a Publicly Traded

Corporation, the Person for at least two years was licensed by the State Licensing Authority as a Regulated Marijuana Business with a demonstrated history of operations in the state of Colorado, and during such time was not subject to suspension or revocation of the business license:

- A. a Blank Check Company;
  - B. an issuer in an offering of Penny Stock; or
  - C. a Shell Company.
- ii. A Person disqualified as a Bad Actor.

“Qualified Institutional Investor” means:

- a. A bank as defined in Section 3(a) (6) of the Federal Securities Exchange Act of 1934, as amended, if the bank is current in all applicable reporting and record-keeping requirements under such act and rules promulgated thereunder;
- b. A bank holding company as defined in the Federal Bank Holding Company Act of 1956, as amended, if the bank holding company is registered and current in all applicable reporting and record-keeping requirements under such act and rules promulgated thereunder;
- c. An insurance company as defined in Section 2(a) (17) of the Investment Company Act of 1940, as amended;
- d. An investment company registered under Section 8 of the Investment Company Act of 1940, as amended;
- e. An employee benefit plan or pension fund subject to the Federal Employee Retirement Income Security Act of 1974, excluding an employee benefit plan or pension fund sponsored by a licensee or an intermediary or holding company licensee which directly or indirectly owns ten percent or more of a licensee;
- f. A state or federal government pension plan; or
- g. A group comprised entirely of persons specified in (a) through (g) of this definition.

“Qualified Private Fund” means an issuer that would be an investment company, as defined in section 3 of the Federal Investment Company Act of 1940, but for the exclusions provided under sections 3(c)(1) or 3(c)(7) of that Act, and that:

- a. Is advised or managed by an investment adviser as defined and registered under sections 80b-1-21, title 15 of the Federal Investment Advisors Act of 1940, and for which the registered investment adviser is current in all applicable reporting and record-keeping requirements under such act and rules promulgated thereunder; and
- b. Satisfies one or more of the following:
  - i. Is organized under the law of a state or the United States;

- ii. Is organized, operated, or sponsored by a U.S. person, as defined under subsection 17 CFR 230.902(k), as amended; or
- iii. Sells Securities to a U.S. person, as defined under subsection 17 CFR 230.902(k), as amended.

“R&D Co-Location Permit” means a permit issued to a Marijuana Research and Development Facility authorizing it to co-locate with a commonly owned Medical Marijuana Products Manufacturer, Retail Marijuana Products Manufacturer, Medical Marijuana Cultivation Facility, or Retail Marijuana Cultivation Facility pursuant to Rule 5-705. A separate R&D Co-Location Permit is required for each location at which a Marijuana Research and Development Facility seeks to share a single Licensed Premises.

“Reasonable Cause” means just or legitimate grounds based in law and in fact to believe that the particular requested action furthers the purposes of the Marijuana Code or protects the public safety.

“Regulated Marijuana” means Medical Marijuana and Retail Marijuana. If the context requires, Regulated Marijuana includes Medical Marijuana Concentrate, Medical Marijuana Product, Retail Marijuana Concentrate, and Retail Marijuana Product.

“Regulated Marijuana Business” means Medical Marijuana Businesses and Retail Marijuana Businesses.

“Regulated Marijuana Concentrate” means Medical Marijuana Concentrate and Retail Marijuana Concentrate.

“Regulated Marijuana Product” means Medical Marijuana Product and Retail Marijuana Product.

“Remediation” means the process by which Regulated Marijuana flower and trim, which has failed microbial testing, is processed into a Solvent-Based Medical Marijuana Concentrate, or into Solvent-Based Retail Marijuana Concentrate and retested as required by these rules.

“Resealable” means that the Container maintains its Child-Resistant effectiveness for multiple openings.

“Research Project” means a discrete scientific endeavor to answer a research question or a set of research questions. A Research Project must include a description of a defined protocol, clearly articulated goal(s), defined methods and outputs, and a defined start and end date. The description must demonstrate that the Research Project will comply with all requirements in the 5-700 Series Rules – Marijuana Research and Development Facility. All research and development conducted by a Marijuana Research and Development Facility must be conducted in furtherance of an approved Research Project.

“Respondent” means a Person who has filed a petition for declaratory order that the State Licensing Authority has determined needs a hearing or legal argument, or a Licensee who is subject to an Order to Show Cause.

“Responsible Vendor Program Provider” means a Person offering an Approved Training Program, in accordance with section 44-10-1201, C.R.S., to Licensees seeking to be designated a responsible vendor.

“Restricted Access Area” means a designated and secure area within a Licensed Premises in a Medical Marijuana Store where Medical Marijuana is sold to patients, possessed for sale, and displayed for sale, and where no one without a valid patient registry card is permitted, and 2) in a

Retail Marijuana Store or a Retail Marijuana Hospitality and Sales Business where Retail Marijuana is sold to consumers, possessed for sale, and displayed for sale, and where no one under the age of 21 is permitted.

“Retail Food Establishment” means a retail operation that stores, prepares, or packages food for human consumption or serves or otherwise provides food for human consumption to consumers directly or indirectly through a delivery service, whether such food is consumed on or off the premises or whether there is a charge for such food. “Retail food establishment” does not mean:

- a. Any private home;
- b. Private boarding house;
- c. Hospital and health facility patient feeding operations licensed by the department;
- d. Child care centers and other child care facilities licensed by the department of human services;
- e. Hunting camps and other outdoor recreation locations where food is prepared in the field rather than at a fixed based of operation;
- f. Food or beverage wholesale manufacturing, processing, or packaging plants, or portions thereof, that are subject to regulatory controls under state or federal laws or regulations;
- g. Motor vehicles used only for the transport of food;
- h. Establishments preparing and serving only hot coffee, hot tea, instant hot beverages, and nonpotentially hazardous doughnuts or pastries obtained from sources complying with all laws related to food and food labeling;
- i. Establishments that handle only nonpotentially hazardous prepackaged food and operations serving only commercially prepared, prepackaged foods requiring no preparation other than the heating of the food within its original container or package;
- j. Farmers markets and roadside markets that offer only uncut fresh fruit and vegetables for sale;
- k. Automated food merchandising enterprises that supply only prepackaged nonpotentially hazardous food or drink in bottles, cans, or cartons only, and operations that dispense only chewing gum or salted nuts in their natural protective covering;
- l. The donation, preparation, sale, or service of food by a nonprofit or charitable organization in conjunction with an event or celebration if such donation, preparation, sale, or service of food:
  - i. Does not exceed the duration of the event or celebration or a maximum of fifty-two days within a calendar year; and
  - ii. Takes place in the county in which such nonprofit or charitable organization resides or is principally located.

- m. A home, commercial, private, or public kitchen in which a person produces food products sold directly to consumers pursuant to the “Colorado Cottage Foods Act,” section 25-4-1614, C.R.S.

“Retail Marijuana” means all parts of the plant of the genus cannabis whether growing or not, the seeds thereof, the resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or its resin, including but not limited to Retail Marijuana Concentrate, that is cultivated, manufactured, distributed, or sold by a licensed Retail Marijuana Business. “Retail Marijuana” does not include industrial hemp, nor does it include fiber produced from stalks, oil, or cake made from the seeds of the plant, sterilized seed of the plant which is incapable of germination, or the weight of any other Ingredient combined with marijuana to prepare topical or oral administrations, food, drink, or other product. If the context requires, Retail Marijuana includes Retail Marijuana Concentrate and Retail Marijuana Product.

“Retail Marijuana Business” means a Retail Marijuana Store, a Retail Marijuana Cultivation Facility, a Retail Marijuana Products Manufacturer, a Retail Marijuana Testing Facility, a Retail Marijuana Business Operator, a Retail Marijuana Transporter, and Licensed Hospitality Businesses.

“Retail Marijuana Business Operator” means an entity that holds a license from the State Licensing Authority to provide professional operational services to one or more Retail Marijuana Businesses for direct remuneration from the Retail Marijuana Business(es), which may include compensation based upon a percentage of the profits of the Retail Marijuana Business(es) being operated. A Retail Marijuana Business Operator contracts with Retail Marijuana Business(es) to provide operational services. A Retail Marijuana Business Operator’s contract with a Retail Marijuana Business does not in and of itself constitute ownership.

“Retail Marijuana Concentrate” means a specific subset of Retail Marijuana that was produced by extracting Cannabinoids from Retail Marijuana. Categories of Retail Marijuana Concentrate include Water-Based Retail Marijuana Concentrate, Food-Based Retail Marijuana Concentrate Solvent-Based Retail Marijuana Concentrate, and Heat/Pressure-Based Retail Marijuana Concentrate. Retail Marijuana Concentrate includes Retail Marijuana Concentrate consumed using a Vaporizer Delivery Device or Pressurized Metered Dose Inhaler.

“Retail Marijuana Cultivation Facility” means an entity licensed to cultivate, prepare, and package Retail Marijuana and Transfer Retail Marijuana to Retail Marijuana Businesses, Medical Research Facilities, and Pesticide Manufacturers, but not to consumers.

“Retail Marijuana Hospitality and Sales Business” means an entity licensed to (1) purchase Retail Marijuana from a Retail Marijuana Business, (2) Transfer Retail Marijuana to consumers, and (3) permit the use or consumption of Retail Marijuana Transferred to a consumer within the Restricted Access Area.

“Retail Marijuana Product” means a product that is comprised of Retail Marijuana and other Ingredients and is intended for use or consumption, such as, but not limited to, edible product, ointments and tinctures.

“Retail Marijuana Products Manufacturer” means an entity licensed to purchase Retail Marijuana; manufacture, prepare, and package Retail Marijuana Product; and Transfer Retail Marijuana, Retail Marijuana Concentrate, and Retail Marijuana Product only to other Retail Marijuana Products Manufacturers, Retail Marijuana Stores, Retail Marijuana Hospitality and Sales Businesses, Medical Research Facilities, and Pesticide Manufacturers.

“Retail Marijuana Store” means an entity licensed to purchase Retail Marijuana and Retail Marijuana Concentrate from a Retail Marijuana Cultivation Facility and to purchase Retail

Marijuana Product and Retail Marijuana Concentrate from a Retail Marijuana Products Manufacturer, and to Transfer Retail Marijuana to Retail Marijuana Hospitality and Sales Businesses and to consumers.

“Retail Marijuana Testing Facility” means a public or private laboratory licensed and certified, or approved by the Division, to perform testing and research on Retail Marijuana.

“Retail Marijuana Transporter” means a Person that is licensed to transport Retail Marijuana from one Retail Marijuana Business to another Retail Marijuana Business or to a Medical Research Facility or Pesticide Manufacturer, and to temporarily store the transported Retail Marijuana at its Licensed Premises, but is not authorized to sell, give away, buy, or receive complimentary Retail Marijuana under any circumstances. A Retail Marijuana Transporter does not include a Licensee that transports and distributes its own Retail Marijuana.

“RFID” means Radio Frequency Identification.

“Sample” means any item collected from a Regulated Marijuana Business that is provided to a Medical Marijuana Testing Facility or Retail Marijuana Testing Facility for testing. The following is a non-exhaustive list of types of Samples: Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana Product, Retail Marijuana, Retail Marijuana Concentrate, Retail Marijuana Product, soil, growing medium, water, solvent or swab of a counter or equipment.

“Sampling Manager” means an Owner Licensee or management personnel holding an Employee Licensee designated by a Medical Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, Retail Marijuana Cultivation Facility, or Retail Marijuana Products Manufacturer to receive Transfers of Sampling Units pursuant to Rules 5-230, 5-320, 6-225, and 6-320.

“Sampling Unit” means a unit of Regulated Marijuana Transferred to a Sampling Manager for purposes of quality control and product development pursuant to Rules 5-230 and 5-320, sections 44-10-502(4) and 44-10-503(10), C.R.S., and Rules 6-225 and 6-320, and sections 44-10-602(6) and 44-10-603(10), C.R.S.

“Security(ies)” means any note, stock, treasury stock, security future, security-based swap, bond, debenture, evidence of indebtedness, certificate of interest or participation in any profit-sharing agreement, collateral-trust certificate, preorganization certificate or subscription, transferable share, investment contract, voting-trust certificate, certificate of deposit for a security, fractional undivided interest in oil, gas, or other mineral rights, any put, call, straddle, option, or privilege on any security, certificate of deposit, or group index of securities (including any interest therein or based on the value thereof), or any put, call, straddle, option, or privilege entered into on a national securities exchange relating to foreign currency, or, in general, any interest or instrument commonly known as a “security,” or any certificate of interest or participation in, temporary or interim certificate for, receipt for, guarantee of, or warrant or right to subscribe to or purchase, any of the foregoing.

“Security Alarm System” means a device or series of devices, intended to summon law enforcement personnel during, or as a result of, an alarm condition. Devices may include hard-wired systems and systems interconnected with a radio frequency method such as cellular or private radio signals that emit or transmit a remote or local audible, visual, or electronic signal; motion detectors, pressure switches, duress alarms (a silent system signal generated by the entry of a designated code into the arming station to indicate that the user is disarming under duress); panic alarms (an audible system signal to indicate an emergency situation); and hold-up alarms (a silent system signal to indicate that a robbery is in progress).

“Shell Company” means a registrant, other than an asset-backed issuer as defined in Item 1101(b) of Regulation AB, that has:



- a. No or nominal operations; and
- b. Either:
  - i. No or nominal operations;
  - ii. Assets consisting solely of cash and cash equivalents; or
  - iii. Assets consisting of any amount of cash and cash equivalents and nominal other assets.

“Shipping Container” means a hard-sided container with a lid or other enclosure that can be secured in place. A Shipping Container is used solely for the transport of Regulated Marijuana between Regulated Marijuana Businesses, a Medical Research Facility, or a Pesticide Manufacturer.

“Single-Serving Edible Retail Marijuana Product” means an Edible Retail Marijuana Product unit for sale to consumers containing no more than 10mg of active THC.

“Solvent-Based Medical Marijuana Concentrate” means a Medical Marijuana Concentrate that was produced by extracting Cannabinoids from Medical Marijuana through the use of a solvent approved by the Division pursuant to Rule 5-315.

“Solvent-Based Retail Marijuana Concentrate” means a Retail Marijuana Concentrate that was produced by extracting Cannabinoids from Retail Marijuana through the use of a solvent approved by the Division pursuant to Rule 6-315.

“Standardized Graphic Symbol” means a graphic image or small design adopted by a Licensee to identify its business.

“Standardized Serving of Marijuana” means a standardized single serving of active THC in Retail Marijuana. The size of a Standardized Serving of Marijuana shall be no more than 10mg of active THC.

“State Licensing Authority” means the authority created for the purpose of regulating and controlling the licensing of the cultivation, manufacture, distribution, sale, and testing of Regulated Marijuana in Colorado, pursuant to section 44-10-201, C.R.S.

“Target Potency” means the potency that a Medical Marijuana Products Manufacturer intends for an individual Medical Marijuana Product, or a Retail Marijuana Products Manufacturer intends for an individual Retail Marijuana Product, prior to testing, which is also outlined in the Licensee’s standard operating procedures.

“Temporary Appointee Registration” means a registration issued to a Court Appointee pursuant to section 44-10-401(3)(a), C.R.S.

“THC” means tetrahydrocannabinol.

“THCA” means tetrahydrocannabinolic acid.

“Test Batch” means a group of Samples that are derived from a single Harvest Batch, Production Batch, or Inventory Tracking System package, and that are collectively submitted to a Medical Marijuana Testing Facility or to a Retail Marijuana Testing Facility for testing purposes.

“Total THC” means the sum of the percentage by weight of THCA multiplied by 0.877 plus the percentage by weight of THC i.e., Total THC = (%THCA x 0.877) + % THC.

“Transfer(s)(ed)(ing)” means to grant, convey, hand over, assign, sell, exchange, donate, or barter, in any manner or by any means, with or without consideration, any Regulated Marijuana from one Licensee to another Licensee, to a patient, or to a consumer. A Transfer includes the movement of Regulated Marijuana from one Licensed Premises to another, even if both premises are contiguous, and even if both premises are owned by a single entity or individual or group of individuals and also includes a virtual transfer that is reflected in the Inventory Tracking System, even if no physical movement of the Regulated Marijuana occurs.

“Universal Symbol” means the image established by the Division and made available to Licensees through the Division’s website indicating the Regulated Marijuana contains marijuana.

“Unrecognizable” means marijuana or *Cannabis* plant material rendered indistinguishable from any other plant material.

“U.S. Person” means:

- a. Any natural person resident in the United States;
- b. Any partnership or corporation organized or incorporated under the laws of the United States;
- c. Any estate of which any executor or administrator is a U.S. natural person;
- d. Any trust of which any trustee is a U.S. natural person;
- e. Any agency or branch of a foreign entity located in the United States;
- f. Any non-discretionary account or similar account (other than an estate or trust) held by a dealer or other fiduciary for the benefit or account of a U.S. natural person;
- g. Any discretionary account or similar account (other than an estate or trust) held by a dealer or other fiduciary organized, incorporated, or (if a natural person) resident in the United States; and
- h. Any partnership or corporation if:
  - i. Organized or incorporated under the laws of any foreign jurisdiction; and
  - ii. Formed by a U.S. natural person principally for the purpose of investing in Owner’s Interests not registered under the Securities Act of 1933, unless it is organized or incorporated, and owned, by accredited investors (as defined in § 230.501(a)) who are not natural persons, estates or trusts.

“Vaporizer Delivery Device” means inhalable Regulated Marijuana Concentrate, which may be comprised of other Ingredients inside a device that uses a heating element to create a vapor including, but not limited to, vaporizer cartridges and vaporizer pens.

“Vegetative” means the state of the *Cannabis* plant during which plants do not produce resin or flowers and are bulking up to a desired production size for Flowering.

“Water-Based Medical Marijuana Concentrate” means a Medical Marijuana Concentrate that was produced by extracting Cannabinoids from Medical Marijuana through the use of only water or ice.

“Water-Based Retail Marijuana Concentrate” means a Retail Marijuana Concentrate that was produced by extracting Cannabinoids from Retail Marijuana through the use of only water or ice.

## **Basis and Purpose – 104**

The statutory authority for this rule includes but is not limited to sections 24-4-105(11) and 44-10-201, C.R.S. The purpose of this rule is to establish a system by which a Licensee 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 would address matters that are likely to be applicable to other Licensees. The approach is similar to that utilized by other divisions within the Department of Revenue. This Rule 1-120 was previously Rules M and R 104, 1 CCR 212-1 and 1 CCR 212-2.

## **1-120 – Declaratory Orders Concerning the Marijuana Code**

- A. Who May Request a Statement of Position. Any person as defined in section 24-4-102(12), C.R.S., may request the Division to issue a statement of position concerning the applicability to the petitioner of any provision of the Marijuana Code, or any regulation of the State Licensing Authority.
- B. Division Response. The Division will determine, in its sound discretion, whether to respond with a written statement of position. Following receipt of a proper request, the Division will respond by issuing a written statement of position or by declining to issue such a statement.
- C. 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:
  - 1. The name and address of the petitioner.
  - 2. Whether the petitioner is licensed pursuant to the Marijuana Code, and if so, the type of license and address of the Licensed Premises.
  - 3. Whether the petitioner is involved in any pending administrative hearings with the State Licensing Authority or relevant Local Jurisdiction.
  - 4. The statute, rule, or order to which the petition relates.
  - 5. 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.
  - 6. A concise statement of the legal authorities, if any, and such other reasons upon which petitioner relies.
  - 7. A concise statement of the declaratory order sought by the petitioner.

- D. State Licensing Authority Retains Discretion Whether to Entertain Petition. The State Licensing Authority will determine, in its discretion without prior notice to the petitioner, 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:
1. 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.
  2. 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.
  3. The petition involves a subject, question or issue that is relevant to a pending hearing before the state or any Local Licensing Authority, an on-going investigation conducted by the Division, or a written complaint previously filed with the State Licensing Authority.
  4. The petition seeks a ruling on a moot or hypothetical question.
  5. Petitioner has some other adequate legal remedy, other than an action for declaratory relief pursuant to Colo. R. Civ. Pro. 57, which will terminate the controversy or remove any uncertainty concerning applicability of the statute, rule, or order.
- E. State Licensing Authority May Adopt Division Position Statement. The State Licensing Authority may adopt the Division Position Statement as a Final Agency Action subject to judicial review pursuant to section 24-4-106, C.R.S.
- F. If State Licensing Authority Entertains Petition. 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:
1. 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 to submit additional evidence and legal argument in writing.
  2. 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 8-220 – Administrative Hearings, 8-225 – Administrative Subpoenas, and 8-230 – Administrative Hearing Appeals. The petitioner will be identified as Respondent.
  3. The parties to any proceeding pursuant to this Rule shall be the petitioner/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 make unnecessary a separate petition for declaratory order by the interested person.
  4. The declaratory order shall constitute a Final Agency Order subject to judicial review pursuant to section 24-4-106, C.R.S.
- G. 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.
- H. Posted on Website. The Division shall post a copy of all statements of position and all declaratory orders on the Division's website.

### **Basis and Purpose – 1-125**

The statutory authority for this rule includes but is not limited to section 44-10-202(1)(c), C.R.S. The purpose of this rule is to clarify that any reference to days means calendar days. This Rule 1-125 was previously Rules M and R 105, 1 CCR 212-1 and 1 CCR 212-2.

### **1-125 – Computation of Time**

The word “days” as used in these rules means calendar days.

### **Basis and Purpose – 1-130**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c) and 44-10-801(4), C.R.S. The purpose of this rule is to establish the basic fees that must be paid at the time of service of any subpoena (including a subpoena for testimony and/or a subpoena duces tecum) upon the State Licensing Authority, and for production of documents pursuant to any such subpoena. This rule also establishes additional fees for meals, mileage, and each day’s testimony. The service fee is not applicable when a subpoena is served by a governmental agency. This Rule 1-130 was previously Rules M and R 106, 1 CCR 212-1 and 1 CCR 212-2.

### **1-130 – Subpoena Fees**

- A. Required Fees for Subpoenas. The following fees must be paid at the time of service of any subpoena on the Division or State Licensing Authority:
1. Subpoenas for records only (*subpoenas duces tecum*):
    - a. Responsive records - \$0.25/page. The Division and State Licensing Authority may use discretion when electronic copies are requested.
    - b. The Division or State Licensing Authority may charge \$30/hour to retrieve and review voluminous records.
  2. Subpoenas requiring any Division or State Licensing Authority employee to attend any proceeding:
    - a. \$200/day attendance;
    - b. Current state mileage reimbursement fee; and
    - c. Current state meal reimbursement fee.
- B. When Subpoena-Related Fees Are Due.
1. Subpoenas duces tecum fees must be paid before the Division or State Licensing Authority will release the records.
  2. All other subpoena-related fees are due at the time of service of the subpoena.
- C. Service Complete Only When Fees Are Paid. The Division or State Licensing Authority will not consider service to be complete unless and until all applicable fees are paid.
- D. State Employees and Private Litigation. Division and State Licensing Authority employees will not serve as expert witnesses in private litigation. In addition, the Division and State Licensing

Authority may move to quash any subpoena that seeks fact testimony from Division or State Licensing Authority employees in private litigation.

- E. Not Applicable to Government-Issued Subpoenas. This Rule does not apply to subpoenas issued by any governmental agency.

### **Basis and Purpose – 1-135**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(f), 44-10-203(1)(g), and 44-10-301, C.R.S. This rule gives general instructions regarding Regulated Marijuana Business administrative matters to local jurisdictions and clarifies for such entities what the Division and State Licensing Authority will do in certain instances. The rule also reaffirms that local law enforcement's authority to investigate and take any necessary action with regard to Regulated Marijuana Businesses remains unaffected by the Marijuana Code or any rules promulgated pursuant to it. This Rule 1-135 was previously Rules M and R 1401(A) through (D), 1 CCR 212-1 and 1 CCR 212-2.

### **1-135 – Instructions for Local Licensing Authorities and Local Jurisdictions**

A. Division Protocol for Regulated Marijuana Businesses.

1. The Division shall forward a copy of all new Regulated Marijuana Business applications to the relevant Local Licensing Authority or Local Jurisdiction.
2. The Division shall forward half of the total application fee with the copy of the Retail Marijuana Business application to the relevant Local Jurisdiction.
3. The Division shall notify the relevant Local Licensing Authority or Local Jurisdiction when an application for a Regulated Marijuana Business is either approved or denied. This includes new business applications, renewal business applications, change of location applications, change of owner applications, premises modification applications, and off-premises storage permit applications.
4. Conditioned on Local Approval. Any license issued or renewed by the Division for a Regulated Marijuana Business shall be conditioned upon relevant Local Licensing Authority or Local Jurisdiction approval of the application.

B. Local Licensing Authority/Local Jurisdiction Protocol for Regulated Marijuana Businesses.

1. As soon as practicable, a Local Licensing Authority or Local Jurisdiction that has prohibited the operation of a Regulated Marijuana Business license authorized by the Marijuana Code shall inform the Division, in writing, of such prohibition and shall include a copy of the applicable ordinance or resolution.
2. If a Local Licensing Authority or Local Jurisdiction will authorize the operation of a Regulated Marijuana Business license authorized by the Marijuana Code, it shall inform the Division of the local point-of-contact on Regulated Marijuana regulatory matters. The Local Jurisdiction shall include, at minimum, the name of the division or branch of local government, the mailing address of that entity, and telephone number.
3. Local Licensing Authorities or Local Jurisdictions may impose separate local licensing requirements related to the time, place, and manner of Regulated Marijuana Businesses, and shall otherwise determine if an application meets all those local requirements.
4. The relevant Local Licensing Authority or Local Jurisdiction shall notify the Division, in writing, of whether an application for a Regulated Marijuana Business complies with local

restrictions and requirements, and whether the application is approved or denied based on that review. If a Local Licensing Authority or Local Jurisdiction makes any written findings of fact, a copy of those written findings shall be included with the notification.

- C. Local Licensing Authority Inspections. The relevant Local Licensing Authorities or Local Jurisdiction and their investigators may inspect Regulated Marijuana Businesses during all business hours and other times of apparent activity, for the purpose of inspection or investigation.
- D. Local Licensing Authority Powers. Nothing in these rules shall be construed to limit the authority of Local Licensing Authorities or Local Jurisdictions as established by the Marijuana Code or otherwise by law.

### **Basis and Purpose – 1-140**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(f) 44-10-203(1)(g), and 44-10-301(1), C.R.S. This rule gives general instructions regarding Regulated Marijuana Business administrative matters to local jurisdictions and clarifies for such entities what the Division and State Licensing Authority will do in certain instances. The rule also reaffirms that local law enforcement's authority to investigate and take any necessary action with regard to Regulated Marijuana Businesses remains unaffected by the Marijuana Code or any rules promulgated pursuant to it. This Rule 1-140 was previously Rules M and R 1401(E), 1 CCR 212-1 and 1 CCR 212-2.

### **1-140 – Local Law Enforcement's Authority Not Impaired by Marijuana Code**

Nothing in the Marijuana 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 Regulated Marijuana Business 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 Marijuana or a Regulated Marijuana Business to ensure they are in compliance with all Local Licensing Authority regulations related to time, place, and manner.

## **Part 2 – Applications and Licenses**

### **2-200 Series – Applications and Licenses Rules**

#### **Basis and Purpose – 2-205**

The statutory basis for this rule includes but is not limited to sections 44-10-103, 44-10-202(1)(b), 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(j), 44-10-203(1)(i), 44-10-203(2)(b), 44-10-203(2)(h), 44-10-203(2)(q), 44-10-203(2)(w), 44-10-203(2)(dd)(XII), 44-10-303(2)(b), 44-10-310(7), 44-10-313, 44-10-401, 44-10-801, 44-10-802, 44-10-803, 44-10-1201, 44-10-1202, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(II). The purpose of this rule is to establish fees required for applications, renewals, licenses fees, permits, and other fees required to accompany applications and submissions to the Division. The Division anticipates evaluating all fees in connection with a fee analysis. Any recommendations from the fee analysis will be considered during subsequent rulemaking proceedings. This Rule 2-205 was previously Rules M 207, 208, 209, 210, 235, and 236, 1 CCR 212-1, and Rules R 207, 208, 209, 210, 234, and 235, 1 CCR 212-2.

#### **2-205 – Fees**

- A. Regulated Marijuana Business Initial Application and License Fees.
  - 1. Medical Marijuana Businesses.

<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
<u>Medical Marijuana Store</u>	\$5,000.00	\$2,000.00	\$7,000.00
<u>Medical Marijuana Products Manufacturer</u>	\$1,000.00	\$1,500.00	\$2,500.00
<u>Medical Marijuana Cultivation Facility</u> Class 1 (1-500 plants)	\$1,000.00	\$1,500.00	\$2,500.00
<u>Medical Marijuana Testing Facility</u>	\$1,000.00	\$1,500.00	\$2,500.00
<u>Medical Marijuana Transporter</u>	\$1,000.00	\$4,400.00	\$5,400.00
<u>Medical Marijuana Business Operator</u>	\$1,000.00	\$2,200.00	\$3,200.00
<u>Marijuana Research and Development Facility</u>	\$1,000.00	\$1,500.00	\$2,500.00

2. Retail Marijuana Businesses.

<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
<u>Retail Marijuana Store</u>	\$5,000.00	\$2,000.00	<b>Separate Checks</b> \$4,500.00 State \$2,500.00 Local
<u>Retail Marijuana Products Manufacturer</u>	\$5,000.00	\$1,500.00	<b>Separate Checks</b> \$4,000.00 State \$2,500.00 Local
<u>Retail Marijuana Cultivation Facility</u> Tier 1 (1-1,800 plants)	\$5,000.00	\$1,500.00	<b>Separate Checks</b> \$4,000.00 State \$2,500.00 Local
<u>Retail Marijuana Testing Facility</u>	\$1,000.00	\$1,500.00	<b>Separate Checks</b> \$2,000.00 State \$500.00 Local



<u>Retail Marijuana Transporter</u>	\$1,000.00	\$4,400.00	<b>Separate Checks</b> \$4,900.00 State \$500.00 Local
<u>Retail Marijuana Business Operator</u>	\$1,000.00	\$2,200.00	<b>Separate Checks</b> \$2,700.00 State \$500.00 Local
<u>Marijuana Hospitality Business (Eff. Jan. 1, 2020)</u>	\$1,000.00	\$1,000.00	<b>Separate Checks</b> \$1,500.00 State \$500.00 Local
<u>Retail Marijuana Hospitality and Sales Business (Eff. Jan. 1, 2020)</u>	\$5,000.00	\$2,000.00	<b>Separate Checks</b> \$4,500.00 State \$2,500.00 Local

B. Regulated Marijuana Business Renewal Application and License Renewal Fees.

1. Medical Marijuana Businesses.

<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
<u>Medical Marijuana Store</u>	\$300.00	\$1,500.00	\$1,800.00
<u>Medical Marijuana Products Manufacturer</u>	\$300.00	\$1,500.00	\$1,800.00
<u>Medical Marijuana Cultivation Facility</u>			
Class 1 (1-500 plants)		\$1,500.00	\$1,800.00
Class 2 (501-1,500 plants)		\$2,300.00	\$2,600.00
Class 3 (1,501-3,000 plants)	\$300.00	\$3,500.00	\$3,800.00
Expanded Production Management (for each class of 3,000 plants over Class 3)		\$3,500.00 [Plus \$800 for each additional class of 3,000 plants over	\$3,800.00 [Plus \$800 for each additional class of 3,000 plants over Class 3]

		Class 3]	
<u>Medical Marijuana Testing Facility</u>	\$300.00	\$1,500.00	\$1,800.00
<u>Medical Marijuana Transporter</u>	\$300.00	\$4,400.00	\$4,700.00
<u>Medical Marijuana Business Operator</u>	\$300.00	\$2,200.00	\$2,500.00
<u>Marijuana Research and Development Facility</u>	\$300.00	\$1,500.00	\$1,800.00

2. Retail Marijuana Businesses.

<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
<u>Retail Marijuana Store</u>	\$300.00	\$1,500.00	\$1,800.00
<u>Retail Marijuana Products Manufacturer</u>	\$300.00	\$1,500.00	\$1,800.00
<u>Retail Marijuana Cultivation Facility</u> Tier 1 (1-1,800 plants)	\$300.00	\$1,500.00	\$1,800.00
Tier 2 (1,801-3,600 plants)		\$2,300.00	\$2,600.00
Tier 3 (3,601-6,000 plants)		\$3,000.00	\$3,300.00
Tier 4 (6,001-10,200 plants)		\$4,500.00	\$4,800.00
Tier 5 (10,201-13,800 plants)		\$6,500.00	\$6,800.00
Expanded Production Management (for each additional tier of 3,600 plants over Tier 5)		\$6,500.00 [Plus \$800.00 for each additional tier of 3,600 plants over Tier 5]	\$6,800.00 [Plus \$800.00 for each additional tier of 3,600 plants over Tier 5]
<u>Retail Marijuana Testing Facility</u>	\$300.00	\$1,500.00	\$1,800.00
<u>Retail Marijuana Transporter</u>	\$300.00	\$4,400.00	\$4,700.00

<u>Retail Marijuana Business Operator</u>	\$300.00	\$2,200.00	\$2,500.00
<u>Marijuana Hospitality Business (Eff. Jan. 1, 2020)</u>	\$300.00	\$750.00	\$1,050.00
<u>Retail Marijuana Hospitality and Sales Business (Eff. Jan. 1, 2020)</u>	\$300.00	\$1,500.00	\$1,800.00

C. Owner Request for a Finding of Suitability, Owner License, and Owner Identification Badge – Initial Application and Renewal Fees.

1. Controlling Beneficial Owner Request for a Finding of Suitability Fee.
  - a. \$800.00 per Natural Person
  - b. \$800.00 for an Entity that is not a Publicly Traded Corporation, plus the fee in paragraph (C)(1)(a) and (C)(1)(b), for each associated natural person subject to suitability
  - c. \$5,000.00 for a Publicly Traded Corporation, plus the fee in paragraph (C)(1)(a) and (C)(1)(b), for each associated natural person or Entity subject to suitability.
2. Passive Beneficial Owner Request for Finding of Suitability Fee. A Passive Beneficial Owner may, but is not required to, apply for an Owner License and Identification Badge, and if the Passive Beneficial Owner chooses to do so, must submit the fees required by subparagraph (C)(1).
3. Renewal Fee for an Owner License. All Controlling Beneficial Owners and licensed Passive Beneficial Owners - \$500.00.

D. Employee License – Initial Fees and Renewal Fees.

1. Employee License Initial Application and License Fee – \$100.00
  - a. Of the total Employee License application and license fee, \$75.00 is the application fee and \$25.00 is the license fee. An individual submitting an application for an Employee License may submit the total fee of \$100.00 in one form of payment.
2. Employee License Renewal Fee – \$75.00
  - a. Of the total Employee License Renewal fee, \$50.00 is the application fee and \$25.00 is the license fee. An individual submitting an application for an Employee License renewal may submit the total fee of \$75.00 in one form of payment.
3. All Key Licenses and Support Licenses issued before January 1, 2020 will be converted to an Employee License upon the first license renewal following January 1, 2020.

E. Temporary Appointee Registration – Request for Finding of Suitability Fees.

1. Natural Person – \$225.00

2. Entity – \$800.00

F. Other Fees. The following other fees apply:

1. Permits.

- a. Off Premises Storage Permit – \$1,500.00
- b. Transporter Off Premises Storage Permit – \$2,200.00
- c. Centralized Distribution Permit Initial and Renewal Fee – \$20.00
- d. R&D Co-Location Permit Initial and Renewal Fee – \$50.00
- e. Delivery Permit:
  - i. Initial Fee Business License that will expire in 6 months or less - \$2,000.00.
  - ii. Initial Fee Business License that will expire in more than 6 months - \$4,000.00.
  - iii. All Renewals - \$2,000.00
- f. Transition Permit – \$250.00

2. Regulated Marijuana Business Changes. The following fees apply per license:

- a. Change of Controlling Beneficial Owner – \$1,600.00
- b. Changes Exempt from Change of Owner Application Requirement – \$800.00
- c. Change of Trade Name – \$50.00
- d. Change of Location – \$500.00
- e. Modification of Licensed Premises – \$100.00

3. Marijuana Research and Development Facility Research Project Proposal – \$500.00

4. Responsible Vendor Provider Applications.

- a. Responsible Vendor Program Provider Initial Application – \$850.00
- b. Responsible Vendor Program Provider Renewal Application – \$350.00

5. Duplicate License, Identification Badge, or Certificate.

- a. Duplicate Business License – \$20.00
- b. Duplicate Owner or Employee Identification Badge – \$20.00
- c. Responsible Vendor Program Provider Duplicate Certificate – \$50.00

- G. When Fees are Due. All fees in this Rule are due at the time the application or request is submitted.

### **Basis and Purpose – 2-210**

The statutory basis for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(w), 44-10-305, 44-10-901(2), and 24-4-105(2) 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 mailing address current, reporting a felony conviction or other disqualifying event, cooperating with the State Licensing Authority and his or her employees, and notifying the State Licensing Authority of any change of 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's or Licensee's failure to notify the Division of a change of address does not relieve the Applicant or Licensee from timely responding to any correspondence or notification.

### **2-210 – 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 to the Division and may provide 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 mailing address and to the last electronic mailing address, if any, 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 Report Felony Convictions, Deferred Sentences and Judgments. An Applicant or Licensee must notify the Division in writing of any felony conviction or deferred sentence or judgment regarding a felony against him or her within seven days of the conviction or deferred sentence or judgment. The notification must include disposition documents. Failure to make required notification to the Division may be grounds for administrative action.
- C. Duty to Report Any Disqualifying Event. Applicants and Licensees must notify the Division within seven days of any change of fact that would result in the Applicant or Licensee being disqualified from holding a license, permit, or registration pursuant to the Marijuana Code, or these Rules.
- D. 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.
- E. Duty to Report Change of Registered Agent. A Regulated Marijuana Business must disclose any change of its registered agent in the State of Colorado within seven days of the change.

### **Basis and Purpose – 2-215**

The statutory basis for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), 44-10-203(2)(a), 44-10-203(2)(c), 44-10-203(2)(k), 44-10-203(2)(w), 44-10-305, 44-10-307, 44-10-308, 44-10-309, 44-10-310, 44-10-311, 44-10-312, 44-10-313, 44-10-314 and 44-10-316, C.R.S. The purpose of this rule is to establish requirements for all applications including: required application fees; complete, accurate and truthful applications; notification of the applicable local licensing authority or local jurisdiction; that the Applicant or Licensee establish he, she or it is not a person prohibited from licensure; submission of additional information or documents upon request by the Division; and notification that all application material may be disclosed consistent with the Marijuana Code.

## **2-215 – All Applications Requirements**

- A. Applicability. This Rule 2-215 applies to all applications submitted to the Division for a license, permit, or registration provided by the Marijuana Code.
- B. Division Forms Required. All applications for licenses, registrations, or permits authorized by subsections 44-10-401(2) and (3), C.R.S., must be made on current Division forms.
- C. Application Fees Required. Applications must be accompanied by full remittance of the required application and license fees. See Rule 2-205.
- 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 Licensing Authority/Local Jurisdiction.
  - 1. Each application must identify the applicable Local Licensing Authority or Local Jurisdiction.
  - 2. If the Local Licensing Authority or Local Jurisdiction requires a physical copy of the application, the Applicant or Licensee must submit the original application and one identical copy to the Division. Otherwise the Applicant or Licensee must submit only the original application to the Division.
- F. Applicant Not Prohibited From Licensure. Applicants must provide information establishing the Applicant is not a Person prohibited from licensure by section 44-10-307, C.R.S. Each natural person required to obtain an Owner License or an Employee License must provide proof of lawful presence or citizenship, and Colorado residency, if required.
- G. Additional Information and Documents May Be Required.
  - 1. Upon request by the Division, 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.
- H. 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 Marijuana Code, for investigation or enforcement of any international, federal, state, or local securities law or regulation, for any other state or local law enforcement purpose, or as otherwise required by law.

## **Basis and Purpose – 2-220**

The statutory basis for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(a), 44-10-203(2)(w), 44-10-203(2)(ee), 44-10-203(7), 44-10-301, 44-10-305, 44-10-307, 44-10-308, 44-10-309, 44-10-310, 44-10-311, 44-10-312, 44-10-313, and 44-10-316, C.R.S. The purpose of this rule is to establish the general requirements and processes for submission of an initial application for a Regulated Marijuana Business to the State Licensing Authority.

### **2-220 – Initial Application Requirements for Regulated Marijuana Businesses**

- A. Documents and Information Requested. Every initial application for a Regulated Marijuana Business license must include all required documents and information including, but not limited to:
1. A copy of the local license application, if required, for a Regulated Marijuana Business.
  2. Certificate of Good Standing from the jurisdiction in which the Entity was formed, which must be one of the states of the United States, territories of the United States, District of Columbia, or another country that authorizes the sale of marijuana.
  3. If the Applicant is an Entity, the identity and physical address of its registered agent in the state of Colorado.
  4. Organizational Documents. Articles of Incorporation, by-laws, and any shareholder agreement for a corporation; articles of organization and operating agreement for a limited liability company; or partnership agreement for a partnership.
  5. Corporate Governance Documents.
    - a. A Regulated Marijuana Business that is a Publicly Traded Corporation must maintain corporate governance documents as required by the securities exchange on which its securities are listed and traded, and section 44-10-103(50), C.R.S., and must provide those corporate governance documents with each initial application.
    - b. A Regulated Marijuana Business that is not a Publicly Traded Corporation is not required to maintain any corporate governance documents. However, if the Regulated Marijuana Business that is not a Publicly Traded Corporation voluntarily maintains corporate governance documents, the Division encourages inclusion of such documents with each initial application.
  6. The deed, lease, sublease, rental agreement, contract, or any other document(s) establishing the Applicant is, or will be, entitled to possession of the premises for which the application is made.
  7. Legible and accurate diagram for the facility. The diagram must include a plan for the Licensed Premises and a separate plan for the security/surveillance plan including camera location, number and direction of coverage. If the diagram is larger than 8.5 x 11 inches, the Applicant must also provide a copy of the diagram in a portable document format (.pdf).
  8. All required findings of suitability issued by the Division.
  9. If the Applicant is a Publicly Traded Corporation:

- a. Documents establishing the Publicly Traded Corporation qualifies to hold a Regulated Marijuana Business license including but not limited to disclosure of securities exchange(s) on which its Securities are listed and traded, the stock symbol(s), the identity of all regulators with regulatory oversight over its Securities; and
  - b. Divestiture plan for any Controlling Beneficial Owner that is a Person prohibited by the Marijuana Code, has had her or his Owner License revoked, or has been found unsuitable.
10. Financial Statements. Consolidated financial statements (which may be prepared on either a calendar or fiscal year basis) that were prepared in the preceding 365 days, and which must include a balance sheet, an income statement, and a cash flow statement. If the Applicant or Regulated Marijuana Business is required to have audited financial statements by another regulator (e.g. United States Securities and Exchange Commission or the Canadian Securities Administrators) the financial statements provided to the Division must be audited and must also include all footnotes, schedules, auditors' report(s), and auditor's opinion(s). If the financial statements are publicly available on a website (e.g. EDGAR or SEDAR), the Applicant or Regulated Marijuana Business may provide notification of the website link where the financial statements can be accessed in lieu of hardcopy submission.
11. Tax Documents. Documentation establishing compliant return filing and payment of taxes related to any Regulated Marijuana Business in which the Person is, or was, required to file and pay taxes.
- B. Local Licensing/Approval Required.
- 1. Regulated Marijuana Business Local Licensing Authority Approval Required.
    - a. If the Division grants a license to a Regulated Marijuana Business before the Local Licensing Authority or Local Jurisdiction approves the application or grants a local license, the state license will be conditioned upon local approval. If the Local Licensing Authority denies the application, the state license will be revoked.
    - b. An Applicant is prohibited from operating a Regulated Marijuana Business prior to obtaining all necessary licenses, registrations, permits, or approvals from both the State Licensing Authority and the Local Licensing Authority or Local Jurisdiction.
  - 2. Retail Marijuana Business One Year to Obtain Local Jurisdiction Approval Required.
    - a. The Applicant has one year from the date of licensing by the State Licensing Authority to obtain approval or licensing from the Local Jurisdiction. If the Applicant fails to obtain Local Jurisdiction approval or licensing within one year from grant of the state license, the state license expires and may not be renewed.

### **Basis and Purpose – 2-225**

The statutory basis for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(c), 44-10-203(2)(a), 44-10-203(2)(c), 44-10-203(2)(w), 44-10-203(2)(ee), 44-10-203(7), 44-10-307, 44-10-308, 44-10-309, 44-10-313, 44-10-314, and 44-10-316 C.R.S. The purpose of this rule is to establish the requirements and procedures for the license renewal process.



## 2-225 – Renewal Application Requirements for All Licensees

### A. License Periods.

1. Regulated Marijuana Business and Owner Licenses are valid for one year from the date of issuance.
2. Medical Marijuana Transporters, Retail Marijuana Transporters, and Employee Licenses are valid for two years from the date of issuance.

### B. Division Notification Prior to Expiration.

1. The Division will send a notice of license renewal 90 days prior to the expiration of an existing license by first class mail to the Licensee's physical address of record.
2. Failure to receive the Division notification does not relieve the Licensee of the obligation to timely renew the license.

### C. Renewal Deadline.

1. A Licensee must apply for the renewal of an existing license prior to the Licensee's expiration date.
2. A renewal application submitted to the Division prior to the license's expiration date shall be deemed timely pursuant to subsection 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. A Regulated Marijuana 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 unless it first obtains a new state license and any required local license.

### 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 only submit an initial application. 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. Documents Required at Renewal. A Regulated Marijuana Business must provide the following documents with every renewal application:

1. Any document required by Rule 2-220(A)(1) through (10) that has changed since the document was last submitted to the Division. It is a license violation affecting public safety to fail to submit any document that changed since the last submission for the purpose of circumventing the requirements of the Marijuana Code, or these Rules;

2. A copy of the Local Licensing Authority or Local Jurisdiction approval, licensure, and/or documentation demonstrating timely submission of pending local license renewal application;
3. A list of any sanctions, penalties, assessments, or cease and desist orders imposed by any securities regulatory agency, including but not limited to the United States Securities and Exchange Commission or the Canadian Securities Administrators;
4. A Regulated Marijuana 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 2-220(A)(11) and (12);
  - b. If the Regulated Marijuana Business is a Publicly Traded Corporation, the most recent list of Non-Objecting Beneficial Owners possessed by the Regulated Marijuana Business;
  - c. A copy of all management agreement(s) the Regulated Marijuana Business has entered into regardless of whether the Person is licensed or unlicensed.; and
  - d. Contracts, agreements, royalty agreements, equipment leases, financing agreement, or security contract for any Indirect Financial Interest Holder that is required to be disclosed by Rule 2-230(A)(3).

H. Controlling Beneficial Owner Signature. At least one Controlling Beneficial Owner shall sign the renewal application. However, other Controlling Beneficial Owners may be required to sign authorizations and/or requests to release information.

### **Basis and Purpose – 2-230**

The statutory basis for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(c), 44-10-203(2)(t), 44-10-203(2)(u), 44-10-203(2)(w), 44-10-203(2)(ee), 44-10-203(7), 44-10-308, 44-10-309, and 44-10-316, C.R.S. Section 44-10-309, C.R.S., establishes varying disclosure requirements for Applicants and Licensees regarding disclosure of financial interests and ownership in a Regulated Marijuana Business. The purpose of this rule is to clarify information an Applicant or Licensee must disclose to the State Licensing Authority at the various levels, which include mandatory disclosure, disclosure in the State Licensing Authority's discretion, and disclosure for reasonable cause. This rule also provides factors that will be considered in determining whether a Regulated Marijuana Business exercised reasonable care and whether a Person is in control of a Regulated Marijuana Business.

### **2-230 – Disclosure of Financial Interests in a Regulated Marijuana Business**

- A. Mandatory Disclosures. Information required to be disclosed by section 44-10-309, C.R.S., must be identified in every initial, renewal, and change of owner application. Mandatory disclosures include, but are not limited to:
1. All Regulated Marijuana Businesses (including Publicly Traded Corporations and Entities that are not Publicly Traded Corporations) must disclose an organizational chart including the identity and ownership percentages of all Controlling Beneficial Owners;
  2. All Controlling Beneficial Owners.

- a. For any Controlling Beneficial Owner that is an Entity (including Publicly Traded Corporations and entities that are not Publicly Traded Corporations):
    - i. The Controlling Beneficial Owner's Executive Officers; and
    - ii. Beneficial Owners of ten percent or more of the Controlling Beneficial Owner.
  - b. Natural persons:
    - i. Name;
    - ii. Address;
    - iii. Date of birth;
    - iv. Social Security Number or other Federal Government-issued identification number.
  - c. Qualified Private Fund: Organizational chart reflecting the identity and ownership percentages of the Qualified Private Fund's Executive Officers, investment advisers, investment adviser representatives, any trustee or equivalent, and any other Person that controls the investment in, or management or operations of, a Regulated Marijuana Business.
3. Any Indirect Financial Interest Holder that:
- a. Holds two or more indirect financial interests;
  - b. Is also a Passive Beneficial Owner; or
  - c. That is contributing debt financing, secured or unsecured, that has not previously been disclosed and exceeds fifty percent of the operating capital of the Regulated Marijuana Business or if the calculation yields a negative number. Operating capital is defined as total current and fixed assets less total liabilities (as presented on the balance sheet consistent with the business's past practices), measured as of the nearest month's end prior to the date of the applicable loan document(s).

B. Discretionary Disclosure. In his or her reasonable discretion, the State Licensing Authority may require disclosure following an initial or renewal application for a Regulated Marijuana business as follows:

- 1. For a Regulated Marijuana Business or a Controlling Beneficial Owner, neither of which is a Publicly Traded Corporation, its:
  - a. Affiliates;
  - b. Beneficial Owners of a Controlling Beneficial Owner;
- 2. Qualified Private Fund's Affiliates; and
- 3. Managers of a Controlling Beneficial Owner.

- C. Reasonable Cause Disclosure. An Applicant will be notified by the State Licensing Authority of Reasonable Cause to require additional disclosure. The State Licensing Authority's notification will identify the facts and law supporting Reasonable Cause for the disclosure and the deadline for disclosure. The following may be required to be disclosed by the State Licensing Authority's notification:
1. An updated list of all Non-objecting Beneficial Owners in a Publicly Traded Corporation that is either a Regulated Marijuana Business or a Controlling Beneficial Owner reflecting ownership as of the date of request;
  2. All Passive Beneficial Owners in a Regulated Marijuana Business that is not a Publicly Traded Corporation. If the Passive Beneficial Owner is not a natural person, the members of the board of directors, general partners, managing members, or Managers or Executive Officers and Beneficial Owners of ten percent or more of the Passive Beneficial Owner;
  3. A list of all Beneficial Owners of a Qualified Private Fund;
  4. All Indirect Financial Interest Holders of a Regulated Marijuana Business, and, for any Indirect Financial Interest Holder that is an Entity, the Beneficial Owners of ten percent or more of the Indirect Financial Interest Holder.
- D. Affirmation of Reasonable Care.
1. Reasonable Care Affirmation for a Regulated Marijuana Business That is Not a Publicly Traded Corporation. A Regulated Marijuana Business that is not a Publicly Traded Corporation must affirm it exercised reasonable care to confirm its Passive Beneficial Owner(s), including any Qualified Institutional Investor(s), and Indirect Financial Interest Holder(s) are not Persons prohibited from holding a license under these Rules or the Marijuana Code. A Regulated Marijuana Business exercises reasonable care if it:
    - a. Receives documentation from each Passive Beneficial Owner, including any Qualified Institutional Investor, and each Indirect Financial Interest Holder affirming each is not a Person prohibited from holding a license by these Rules or the Marijuana Code; and
    - b. The Regulated Marijuana Business does not know or reasonably should not know facts that would contradict the Passive Beneficial Owner or Indirect Financial Interest Holder's affirmation.
  2. Reasonable Care Affirmation for a Regulated Marijuana Business That is a Publicly Traded Corporation. A Regulated Marijuana Business that is a Publicly Traded Corporation must affirm it exercised reasonable care to confirm its Passive Beneficial Owners, including any Qualified Institutional Investor(s), both of which are Non-Objecting Beneficial Owners, and Indirect Financial Interest Holder(s) are not Person prohibited from holding a license by these Rules and the Marijuana Code. A Regulated Marijuana Business that is a Publicly Traded Corporation exercises reasonable care if it:
    - a. At least annually, checks a list of its Passive Beneficial Owners, including any Qualified Institutional Investor(s), both of which are Non-Objecting Beneficial Owners, against the Specially Designated Nationals and Blocked Persons List (SDN List) on the United States Treasury Office of Foreign Assets Control (OFAC) website and the Financial Industry Regulatory Authority (FINRA) website for Persons Barred by FINRA to determine if there are any prohibited Persons;

- b. Receives documentation from its Indirect Financial Interest Holder(s) affirming each is not a Person prohibited from holding a license by these Rules or the Marijuana Code; and
  - c. The Regulated Marijuana Business does not know or reasonably should not know facts that would contradict the Indirect Financial Interest Holder's affirmation.
- E. Control. The State Licensing Authority will consider all facts and circumstances in determining whether a Person has Control of a Regulated Marijuana Business or is a Controlling Beneficial Owner by virtue of common control.
- 1. Non-Exhaustive Factors. Non-exhaustive facts and circumstances that will be considered when evaluating Control include, but are not limited to:
    - a. The Person's percentage of ownership, if any;
    - b. The Person's ability to influence the decision of the Regulated Marijuana Business;
    - c. The Person is a Manager of the Regulated Marijuana Business;
    - d. The Person has a close relationship, familial tie, or common purpose or motive with one or more Persons in Control of the Regulated Marijuana Business;
    - e. The Person has substantial business relationship(s) with the Regulated Marijuana Business;
    - f. The Person has the ability to control the proxy machinery or to win a proxy contest;
    - g. The Person is a primary creditor of the Regulated Marijuana Business; or
    - h. The Person is the original incorporator of the Regulated Marijuana Business.
  - 2. Totality of the Evidence. The State Licensing Authority may consider the totality of the evidence when determining whether a Person has Control of a Regulated Marijuana Business or is a Controlling Beneficial Owner by virtue of common control.

### **Basis and Purpose – 2-235**

The statutory basis for this rule includes but is not limited to sections 44-10-202(1)(e), 44-10-203(2)(c), 44-10-203(2)(ee), 44-10-309, 44-10-310, and 44-10-312(4), C.R.S. Section 44-10-310, C.R.S., requires that persons disclosed or who should have been disclosed to the State Licensing Authority obtain a finding of suitability from the State Licensing Authority. The purpose of this rule is to explain the conditions under which a Person is subject to either a mandatory finding of suitability or a finding of suitability for reasonable cause, to identify exemptions from an otherwise required finding of suitability and to identify the information and documents that, at a minimum, must be submitted in connection with any Person's request for a finding of suitability.

### **2-235 – Suitability**

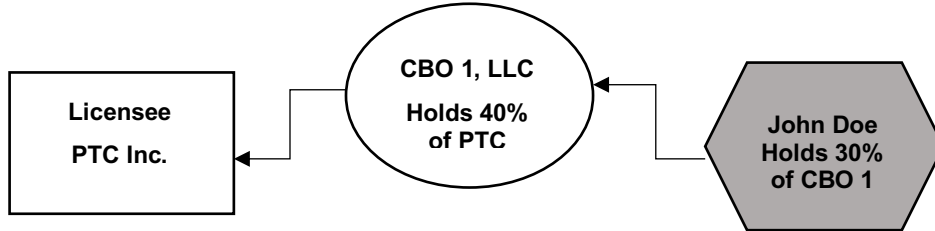
- A. Persons Subject to a Mandatory Finding of Suitability for Regulated Marijuana Businesses That Are Not Publicly Traded Corporations.

1. Except as provided in subparagraph (A)(1)(a), any Person intending to become a Controlling Beneficial Owner by submitting an initial application for any Regulated Marijuana Business that is not a Publicly Traded Corporation must first submit a request to the State Licensing Authority for a finding of suitability.
  - a. An individual who is a Controlling Beneficial Owner because he or she is a member of the board of directors or an Executive Officer of a Regulated Marijuana Business or is Controlling a Regulated Marijuana Business but who does not possess ten percent or more of the Owner's Interest in a Regulated Marijuana Business must submit a request for a finding of suitability to the State Licensing Authority within 45 days of becoming such a Controlling Beneficial Owner.
  - b. Whether an individual is an Executive Officer required to obtain a mandatory finding of suitability is based on the definition in these rules and the facts and circumstances. In determining whether an individual is an Executive Officer, the State Licensing Authority will consider the following, non-exhaustive factors:
    - i. Title is not dispositive, however, the Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, president, the General Counsel, and any individual with similar policy making authority are Executive Officers;
    - ii. The level of decision making authority the individual possess;
    - iii. The Controlling Beneficial Owner and/or Regulated Marijuana Business's organizational chart; and
    - iv. Any relevant guidance from the United States Securities and Exchange Commission or similar securities regulator, securities rules or securities case law.
2. For a Controlling Beneficial Owner that is an Entity, the Entity's request for finding of suitability must include all information necessary for the State Licensing Authority to determine whether its Executive Officers and any Person that indirectly owns ten percent or more of the Owner's Interest in the Regulated Marijuana Business are suitable.
3. Any Person that has not received a finding of suitability and who intends to become a Controlling Beneficial Owner of a Regulated Marijuana Business that is not a Publicly Traded Corporation must submit their request for a finding of suitability contemporaneously with the change of owner application, unless exempt from the change of owner application requirement under Rule 2-245(C).

**B. Persons Subject to a Mandatory Finding of Suitability for Regulated Marijuana Businesses That Are Publicly Traded Corporations.**

1. The following Persons must apply to the State Licensing Authority for a finding of suitability:
  - a. Any Person that becomes a Controlling Beneficial Owner of any Regulated Marijuana Business that is a Publicly Traded Corporation; and
  - b. Any Person that indirectly Beneficially Owns ten percent or more of the Regulated Marijuana Business that is a Publicly Traded Corporation through direct or indirect ownership of its Controlling Beneficial Owner. For example,

assuming the scenario depicted below, Licensee PTC Inc. has one-million shares of outstanding Securities and CBO 1 owns 400,000 of those securities. John Doe owns 30% of CBO 1. Therefore, John Doe indirectly owns 12% of the outstanding securities of Licensee PTC Inc., and must apply to the State Licensing Authority for a finding of suitability.



2. For a Controlling Beneficial Owner that is an Entity, the Entity’s request for finding of suitability must include all information necessary for the State Licensing Authority to determine whether its Executive Officers and any Person that indirectly owns ten percent or more of the Owner’s Interest in the Regulated Marijuana Business are suitable.
3. Timing of Request for Finding of Suitability Involving Publicly Traded Corporation.
  - a. Unless exempted under Rule 2-235(E), all Persons that will be a Controlling Beneficial Owner in a Regulated Marijuana Business that is entering into a Publicly Traded Corporation transaction described in Rule 2-245(C)(1) must first obtain a finding of suitability by the State Licensing Authority before the transaction can close or the public offering can occur.
  - b. A Person who becomes a Controlling Beneficial Owner in a Regulated Marijuana Business that is a Publicly Traded Corporation must submit a request for a finding of suitability to the State Licensing Authority within 45 days of becoming a Controlling Beneficial Owner.
  - c. An individual who is a Controlling Beneficial Owner because he or she is a member of the board of directors or an Executive Officer of a Regulated Marijuana Business or is Controlling a Regulated Marijuana Business but who does not possess ten percent or more of the Owner’s Interest in a Regulated Marijuana Business must submit a request for a finding of suitability to the State Licensing Authority within 45 days of becoming such a Controlling Beneficial Owner.
- C. Finding of Suitability for Reasonable Cause. For Reasonable Cause, any other Person that was disclosed or should have been disclosed pursuant to subsections 44-10-309(1) or (2) or that was required to be disclosed based on previous notification of Reasonable Cause must submit a request to the State Licensing Authority for a finding of suitability. Any Person required to submit a request for a finding of suitability pursuant to this Rule must submit such request within 45 days from notice of the State Licensing Authority’s determination of Reasonable Cause for the finding of suitability.
- D. Information Required in Connection with a Request for a Finding of Suitability. When determining whether a Person is suitable or unsuitable for licensure, the State Licensing Authority may consider the Person’s criminal character or record, licensing character or record, or financial character or record. To consider a Person’s criminal character or record, licensing character or

record, and financial character or record, all requests for a finding of suitability must, at a minimum, be accompanied by the following information:

1. Criminal Character or Record:

- a. A set of the natural person's fingerprints for purposes of a fingerprint-based criminal history record check.

2. Licensing Character or Record:

- a. Affirmation that the Person is not prohibited from holding a license under section 44-10-307, C.R.S.
- b. A list of all Colorado Department of Revenue-issued business licenses held in the three years prior to submission of the request for a finding of suitability;
- c. A list of all Department of Regulatory Agencies business, professional, or occupational licenses held in the three years prior to submission of the request for a finding of suitability;
- d. A list of any marijuana business or personal license(s) held in any other state or territory of the United States or District of Columbia or another country, where such license is or was at any time subject to a denial, suspension, revocation, surrender, or equivalent action by the licensing agency, commission, board, or similar authority; and
- e. Disclosure of any civil lawsuits in which the Person was named a party where pleadings included allegations involving any Regulated Marijuana Business.

3. Financial Character or Record:

- a. Disclosure of any sanctions, penalties, assessments, or cease and desist orders imposed by any securities regulatory agency other than the United States Securities Exchange Commission;
- b. If the Person's request for a finding of suitability is for purposes of acquiring ten percent or more of the Owner's Interest in the Regulated Marijuana Business, copies of the Person's financial account statements for the preceding one-hundred eighty days for any accounts serving as a source of funding used to acquire the Owner's Interest in the Regulated Marijuana Business; or, if the Person is contributing one or more asset(s) to the Regulated Marijuana Business in exchange for the Owner's Interests, documents establishing the Person has owned such asset(s) for the preceding one-hundred eighty days.

E. Exemptions from a Finding of Suitability.

1. The following Persons are exempt from an otherwise required finding of suitability:

- a. Any Person that currently possesses an approved Owner License issued by the State Licensing Authority and such Owner License has not, in the preceding 365 days, been subject to suspension or revocation.

2. Exemptions from an otherwise required finding of suitability are limited to those listed in this Rule. The State Licensing Authority will consider other factors that may inform amendments to this Rule through the Department's formal rulemaking session.



- F. Timing to Approve or Deny a Request for Finding of Suitability. Absent Reasonable Cause, the State Licensing Authority must approve or deny a request for a finding of suitability within 120 days from the date of submission of the request for such finding, where such request was accompanied by all information required under subsection (D) of this Rule.

#### **Basis and Purpose – 2-240**

The statutory basis for this rule includes but is not limited to sections 44-10-103(53), 44-10-203(2)(ee)(C), 44-10-309(3), and 44-10-310(10), C.R.S. The purpose of this rule is to clarify factors the State Licensing Authority will consider when determining whether reasonable cause exists to require disclosure, to require a finding of suitability or to extend the 120 day deadline for granting or denying a request for a finding of suitability.

#### **2-240 – Factors Considered in Determining Reasonable Cause for Disclosure, Finding of Suitability, and Extension of 120 Day Deadline for Finding of Suitability**

- A. Non-Exhaustive Factors Informing Reasonable Cause Considerations. The State Licensing Authority may consider the following non-exhaustive factors when evaluating whether Reasonable Cause exists for disclosure, requiring a reasonable cause finding of suitability or extension of time to provide a finding of suitability:
1. The Person provided materially inaccurate or incomplete documents to the Division;
  2. The Person failed to provide required documents to the Division;
  3. The request for a finding of suitability is sufficiently complex such that a determination cannot be completed within the 120-day deadline specified;
  4. Information that an undisclosed Person is controlling or has the ability to control the Regulated Marijuana Business;
  5. Information indicating one or more Persons prohibited holds an interest in the Regulated Marijuana Business;
  6. Inability to obtain documents or information expected to be available from third-parties or publicly available sources;
  7. The Person interfered with, obstructed, or impeded a Division investigation; or
  8. The Person failed to make any filing required by a securities regulator or securities exchange that has regulatory oversight over the Person.

#### **Basis and Purpose – 2-245**

The statutory basis for this rule includes but is not limited to sections 44-10-202(1)(e), 44-10-203(1)(d), 44-10-203(1)(j), 44-10-203(2)(ee)(I)(A) and (E), 44-10-203(7), 44-10-308(3)(b), 44-10-309, 44-10-310, 44-10-311, and 44-10-312, C.R.S. The purpose of this rule is define the application process and conditions an Applicant or Licensee must meet when changing Beneficial Ownership in a Regulated Marijuana Business. This rule further describes requirements in the event of a dispute between the Controlling Beneficial Owners of a Regulated Marijuana Business.

#### **2-245 – Change of Controlling Beneficial Owner Application or Notification**

- A. Application for Change of Controlling Beneficial Owner(s) – Not a Publicly Traded Corporation.

1. Unless excepted pursuant to subparagraph (C) of this Rule, a Regulated Marijuana Business that is not a Publicly Traded Corporation must obtain Division approval before it transfers the Owner's Interests of any Controlling Beneficial Owner(s).
2. All applications for change of Controlling Beneficial Owner(s) must be executed by every Controlling Beneficial Owner whose Owner's Interests are proposed to change and any Person proposed to become a Controlling Beneficial Owner(s). Controlling Beneficial Owners whose Owner's Interest will not change are not required to execute the change of owner application; however, at least one Controlling Beneficial Owner and all Persons proposed to become a Controlling Beneficial Owner must execute every change of owner application.
3. Upon completion of the investigation of a change of owner application, the State Licensing Authority will issue a contingent approval letter. However, the State Licensing Authority will not issue the state license until:
  - a. Local Approval Required. If local approval is required, the proposed Controlling Beneficial Owner(s) demonstrates to the State Licensing Authority that local approval has been obtained and notifies the State Licensing Authority of the date by which the change of owner will be completed, which must be within thirty days of the notification. The proposed Controlling Beneficial Owner's notification to the Division must be within 365 days of the issuance of the Division's contingent approval letter.
    - i. If a Local Licensing Authority or Local Jurisdiction requires a change of owner application and that application is denied, the State Licensing Authority will deny the State change of owner application;
  - b. No Local Approval Required. If local approval is not required, the proposed Controlling Beneficial Owner(s) demonstrates that such approval is not required and notifies the State Licensing Authority of the date by which the change of owner will be completed, which must be within thirty days of the notification. However, the proposed Controlling Beneficial Owner's notification to the Division must be made within 365 days of issuance of the Division's contingent approval letter.
4. Any proposed new Controlling Beneficial Owner cannot operate the Regulated Marijuana Business for which it intends to become a Controlling Beneficial Owner until it receives any required finding of suitability and is issued all approvals and/or license(s) pursuant to any change of owner application required by this Rule. Controlling Beneficial Owners that have already been approved in connection with ownership of the Regulated Marijuana Business may continue to operate the Regulated Marijuana Business. A violation of this requirement is grounds for denial of the change of owner application, may be a violation affecting public safety, and may result in disciplinary action against existing license(s).
5. If a Regulated Marijuana Business or any of its Controlling Beneficial Owner(s) apply for a change of owner and is involved in an administrative investigation or administrative action, the following may apply:
  - a. The change of owner application may be delayed or denied until the administrative action is resolved; or
  - b. 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 Regulated Marijuana

Business and its prior Controlling Beneficial Owner(s), and subject to discipline based upon the same.

6. Documents Required. Any change of owner application regarding a Controlling Beneficial Owner of a Regulated Marijuana Business that does not involve a Publicly Traded Corporation must include the following documents:
    - a. Asset purchase agreement, merger, sales contract, agreement, or any other document necessary to effectuate the change of owner;
    - b. Request for a finding of suitability for each proposed Controlling Beneficial Owner(s);
    - c. Operating agreement, by-laws, partnership agreement, or other governing document(s) as will apply to the Regulated Marijuana Business if the change of owner application is approved;
    - d. Request for voluntary surrender form of the Owner License of any Controlling Beneficial Owner that will not remain a Controlling Beneficial Owner, or Passive Beneficial Owner electing to hold an Owner License in a Regulated Marijuana Business if the change of owner application is approved.
    - e. Copy of current Medical Marijuana or Retail Marijuana State Sales Tax or Wholesale license and any other documents necessary to verify tax compliance; and
    - f. Any required finding of suitability for any proposed Controlling Beneficial Owner that does not already hold a valid Owner License.
  7. Licensee Initiates Change of Owner for Permitted Economic Interests Issued Prior to January 1, 2020. All natural persons holding a Permitted Economic Interest who seek to become a Controlling Beneficial Owner are subject to this Rule. The Regulated Marijuana Business must initiate the change of owner process for a natural person holding a Permitted Economic Interest who seeks to convert its interest and become a Controlling Beneficial Owner in a Regulated Marijuana Business. Prior to submitting a change of owner application, the Permitted Economic Interest holder must obtain a finding of suitability pursuant to Rule 2-235 including any required criminal history record check. Permitted Economic Interest holders who fail to obtain a finding of suitability to become a Controlling Beneficial Owner may remain as a Permitted Economic Interest holder.
  8. Medical Marijuana Transporters and Retail Marijuana Transporters Not Eligible for Change of Owner. Medical Marijuana Transporters and Retail Marijuana Transporters are not eligible to transfer the entire Beneficial Ownership of their Regulated Marijuana Business.
- B. Change of Owner Involving a Publicly Traded Corporation. This Rule applies to transactions involving any Publicly Traded Corporation.
1. Publicly Traded Corporation Transactions. A Regulated Marijuana Business may transact with a Publicly Traded Corporation in the following ways:
    - a. Merger with a Publicly Traded Corporation. A Regulated Marijuana Business that intends or that has a Controlling Beneficial Owner that intends to receive, directly or indirectly, an investment from, or intends to merge or consolidate with a Publicly Traded Corporation, whether by way of merger, combination, exchange,

consolidation, reorganization, sale of assets or otherwise, including but not limited to any shell company merger.

- b. Investment by a Publicly Traded Corporation. A Regulated Marijuana Business that intends or that has a Controlling Beneficial Owner that intends to transfer, directly or indirectly, ten percent or more of the Securities in the Regulated Marijuana Business to a Publicly Traded Corporation, whether by sale or other transfer of outstanding Securities, issuance of new Securities, or otherwise.
- c. Public Offering. A Regulated Marijuana Business that intends or that has a Controlling Beneficial Owner that intends to become, directly or indirectly, a Publicly Traded Corporation, whether by effecting a primary or secondary offering of its Securities, uplisting of outstanding Securities, or otherwise.

2. Required Finding(s) of Suitability.

- a. Pre-Transaction Findings of Suitability Required. Any Person intending to become a Controlling Beneficial Owner in a Regulated Marijuana Business in connection with any transaction identified in subparagraph (B)(1)(a) through (c) above, must obtain a finding of suitability prior to the Publicly Traded Corporation transaction closing or becoming effective
- b. Ongoing Suitability Requirements. Any Person who becomes a Controlling Beneficial Owner of a Publicly Traded Corporation that is a Regulated Marijuana Business must apply to the State Licensing Authority for a finding of suitability or an exemption from a finding of a suitability pursuant to Rule 2-235 within forty-five days of becoming a Controlling Beneficial Owner. A Publicly Traded Corporation that is a Regulated Marijuana Business must notify any Person that becomes a Controlling Beneficial Owner of the suitability requirements as soon as the Regulated Marijuana Business becomes aware of the ownership subjecting the Person to this requirement; however, the Controlling Beneficial Owner's obligation to timely request the required finding of suitability is independent of, and unaffected by, the Regulated Marijuana Business's failure to make the notification.

3. Change of Owner Application Required. A Licensee entering into a transaction permitted in subparagraph (B)(1)(a)-(c) above with Publicly Traded Corporation must submit any required change of owner application to the Division prior to the transaction closing. The change of owner application may be submitted simultaneously with the requests for finding(s) of suitability required by subparagraph (B)(2) or after the or after the request(s) for findings of suitability were submitted to the Division.

4. Mandatory Disclosure of Required, United States Securities and Exchange Commission, Canadian Securities Administrators and/or Securities Exchange Filings. A Regulated Marijuana Business and any Controlling Beneficial Owner that is required to file any document with the United States Securities and Exchange Commission, the Canadian Securities Administrators, any other similar securities regulator or any securities exchange regarding any change of owner in subparagraphs (C)(1)(a) through (c) above must also provide a notice to the Division at the same time as the filing with the United States Securities and Exchange Commission, the Canadian Securities Administrators or the securities exchange.

5. Ordinary Broker Transactions. Resales or transfers of Securities of a Publicly Traded Corporation that is a Regulated Marijuana Business or Controlling Beneficial Owner or Passive Beneficial Owner in ordinary broker transactions through an established trading

market do not require a change of owner application or prior approval from the State Licensing Authority.

C. Exemptions to the Change of Owner Application Requirement.

1. Entity Conversions or Change of Legal Name. A Regulated Marijuana Business or a Controlling Beneficial Owner may combine with or convert, including but not limited to under sections 7-90-201 et seq., C.R.S., for the exclusive purpose of changing its Entity jurisdiction to one of the states or territories of the United States or the District of Columbia, its Entity type or change the legal name of an Entity without filing a change of owner application. These exemptions apply only if the Controlling Beneficial Owners and their Owner's Interests will remain the same after the combination, conversion, or change of legal name, and there will not be any new Controlling Beneficial Owners (individuals or Entities). Within fourteen days of the combination, conversion, or change of legal name the Regulated Marijuana Business must submit the following to the Division:
  - a. A copy of the transaction documents;
  - b. Documents submitted to the Colorado Secretary of States;
  - c. Any document submitted to the secretary of state or similar regulator if the Entity is organized under the laws of a state of the United States other than Colorado, a territory of the United States, or the District of Columbia;
  - d. Identification of the Regulated Marijuana Business's or Controlling Beneficial Owner's registered agent;
  - e. Identification of any Passive Beneficial Owner and Indirect Financial Interest Holder for which disclosure is required by Rule 2-230; and
  - f. The fee required by Rule 2-205(F)(2)(b).
2. Reallocation of Owner's Interests Among Controlling Beneficial Owners. A Regulated Marijuana Business may reallocate Owner's Interests among existing Controlling Beneficial Owners holding valid Owner Licenses if it provides notification of the reallocation to the Division with its next application submission as long as there are no new Controlling Beneficial Owners. A reallocation under this rule is subject to the following requirements:
  - a. All Owner's Interests of a Controlling Beneficial Owner may be reallocated to other existing Controlling Beneficial Owners;
  - b. If any Controlling Beneficial Owner will not hold any Owner's Interest in a Regulated Marijuana Business following the reallocation, that Controlling Beneficial Owner shall voluntarily surrender his or her Owner's License and identification badge within 30 days of the reallocation;
  - c. All Controlling Beneficial Owners remain responsible for all actions of the Regulated Marijuana Business while they were a Controlling Beneficial Owner and are subject to administrative action based on the same regardless of the reallocation; and
  - d. Disclosure and submission of the fee required by Rule 2-205(F)(2)(b) at the next application submission which shall not be longer than 365 days.

3. Passive Beneficial Owner Licensed Prior to August 1, 2019. A Passive Beneficial Owner who was issued an Owner License prior to August 1, 2019, and who has continuously maintained that license, is not required to submit a change of owner application if he or she becomes a Controlling Beneficial Owner in the business license(s) with which the Owner License is associated but must disclose and submit the fee required by Rule 2-205(F)(2)(b) at the next application submission, which shall not be longer than 365 days.
  4. Change of Executive Officer or Member of the Board of Directors. A change of owner application is not required for a change of an Executive Officer or member of the board of directors of a Regulated Marijuana Business or an Entity Controlling Beneficial Owner of a Regulated Marijuana Business so long as the new Executive Officer or member of the board of directors does not possess ten percent or more of the Owner's Interest in the Regulated Marijuana Business or is otherwise Controlling the Regulated Marijuana Business. However, a change of Executive Officer or member of the board of directors is subject to the following requirements:
    - a. Any such Executive Officer or member of the board of directors of the Regulated Marijuana Business must submit a request for a finding of suitability as required by Rule 235-1 or, if exempt from a finding of suitability pursuant to Rule 235-1(E), the Regulated Marijuana Business subject to any such change of the Executive Officer or members of their board of directors must provide notice to the Division of the new Controlling Beneficial Owner within forty-five days.
  5. Change of Passive Beneficial Owner. Persons are not required to submit an application or obtain prior approval of their ownership if: (1) the Person will remain a Passive Beneficial Owner after the acquisition of Owner's Interests is complete, and (2) disclosure is not otherwise required by section 44-10-309, C.R.S., or Rule 2-230.
- E. Refundable and Nonrefundable Deposits Permitted. A proposed Controlling Beneficial Owner may provide a selling Controlling Beneficial Owner with a refundable or nonrefundable deposit in connection with a change of owner application.
- F. Controlling Beneficial Owner Dispute.
1. In the event of a dispute between Controlling Beneficial Owner(s) not involving divestiture under Rule 2-275 and precluding or otherwise impeding the ability to comply with these Rules, a Regulated Marijuana Business that is not a Publicly Traded Corporation must submit a change of owner application, notification pursuant to subparagraph (C) of this Rule, or initiate mediation, arbitration, or a judicial proceeding within 90 days of the dispute. The 90-day period may be extended for an additional 90 days upon a showing of good cause by the Regulated Marijuana Business.
  2. A Regulated Marijuana Business that is not a Publicly Traded Corporation must submit a change of owner application or notification pursuant to subparagraph (C) of this Rule within forty-five days of entry of a final court order, final arbitration award, or full execution of a settlement agreement altering the Controlling Beneficial Owner(s) of a Regulated Marijuana Business. Any change of owner application or notification based on a final court order, final arbitration award, or fully executed settlement agreement must include a copy of the order or settlement agreement and remains subject to approval by the Division. In this circumstance, the change of owner application or notification needs to be executed by at least one remaining Controlling Beneficial Owner.
  3. If mediation, arbitration, or a judicial proceeding is not timely initiated, or if a change of owner application or notification pursuant to subparagraph (C) of this Rule is not timely submitted following entry of a final court order, final arbitration award, or full execution of a settlement agreement altering the Controlling Beneficial Owner(s) of a Regulated

Marijuana Business that is not a Publicly Traded Corporation, the Regulated Marijuana Business and its Owner Licensee(s) may be subject to fine, suspension, or revocation of their license(s).

### **Basis and Purpose – 2-250**

The statutory basis for this rule includes but is not limited to sections 44-10-202(1)(e), 44-10-203(2)(ee)(I), 44-10-203(7), and 44-10-309(6), C.R.S. The purpose of this rule is to require notification to the State Licensing Authority of any filing with a securities regulator by an Applicant or Licensee.

### **2-250 – Regulated Marijuana Business that is a Publicly Traded Corporation – Notification of Non-Confidential Securities Filings**

- A. A Regulated Marijuana Business that is a Publicly Traded Corporation must provide notice on Division forms within two business days of any non-confidential filing with the United States Securities and Exchange Commission, the Canadian Securities Administrators, any other securities regulator, or any security exchange on which the Securities are listed or traded. The notice must identify the title of the document and include a hyperlink to the website where the document is publicly available (example EDGAR or SEDAR link for the Publicly Traded Corporation).
- B. In addition to any other administrative or investigative requests or inquiries, the Division may contact a Regulated Marijuana Business that is a Publicly Traded Corporation to obtain clarification of a securities filing.
- C. This Rule is currently limited to require notice of securities filings that are not confidential. However, this Rule may be evaluated during subsequent rulemaking proceedings and/or in connection with development of a policy regarding confidential securities filings.

### **Basis and Purpose – 2-255**

The statutory basis for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(j), 44-10-203(2)(a), 44-10-203(2)(e), 44-10-203(2)(w), 44-10-203(2)(cc), 44-10-305, 44-10-313(8), and 44-10-313(13), C.R.S. The purpose of this rule is to clarify the application process for changing location of a Licensed Premises. This rule also provides the requirements for a Medical Marijuana Cultivation Facility or a Retail Marijuana Cultivation Facility to obtain a transition permit.

### **2-255 – Change of Location of a Regulated Marijuana Business**

- A. Application Required Before Changing Location of Licensed Premises. A Regulated Marijuana 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 a Controlling Beneficial Owner and representation that the signing Controlling Beneficial Owner(s) is/are authorized to submit the application on behalf of the Regulated Marijuana Business.
  - 2. Evidence the Local Licensing Authority and/or Local Jurisdiction in which the Regulated Marijuana Business proposes to move have approved the proposed new location.
  - 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 the 3-200 Series Rules. The diagram must include a plan for the proposed Licensed Premises and a separate plan for the security/surveillance plan including camera location, number and direction of coverage. If the diagram is larger than 8.5 inches x 11 inches, the Applicant must also provide the diagram in a portable document format (.pdf).

C. Change of Location Permit Required.

1. A Regulated Marijuana 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 on the date of issuance, and the Licensee must, within 120 days, change the location of its Regulated Marijuana Business to the place specified in the change of location permit and at the same time cease to operate a Regulated Marijuana Business at the former location. For good cause shown, the 120-day deadline may be extended an additional 120 days.
3. If the Regulated Marijuana Business does not change the location of its Licensed Premises within the time period granted by the Division, including any extension, the Regulated Marijuana 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 Regulated Marijuana Business cannot operate or exercise any of the privileges of its license(s) in both locations, unless a Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility has received a transition permit.

D. Medical Marijuana Cultivation Facilities and Retail Marijuana Cultivation Facilities - Transition Permit Requirements.

1. A Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility may apply for a transition permit and a change of location at the same time.
2. A Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility that has obtained a transition permit must comply with the following requirements:
  - a. The total plants cultivated at both locations do not exceed any plant count limit imposed on the Licensee by the Marijuana Code and these rules;
  - b. The Licensed Premises of both geographical locations comply with all surveillance, security, and inventory tracking requirements imposed by the Marijuana Code and these rules at the Rule 3-200 Series and 3-800 Series;
  - c. Both geographical locations shall track all Regulated Marijuana plants in transition in the Inventory Tracking System to ensure proper tracking for taxation purposes;
  - d. Operation at both geographical locations does not exceed 180 days, unless Licensee demonstrates good cause to extend the deadline an additional 180 days; and
  - e. The Licensee obtains a transition permit pursuant to this Rule and any local permit or license, as required by the Local Licensing Authority or Local Jurisdiction.



3. Change of Location in the Same Local Jurisdiction. If the change of location is within the same local jurisdiction, the Licensee must:
    - a. First obtain a transition permit pursuant to this Rule; and
    - b. If required by the Local Licensing Authority or Local Jurisdiction, obtain a transition permit or other form of approval from the Local Licensing Authority or Local Jurisdiction.
  4. Change of Location to a Different Local Jurisdiction. If the change of location is to a different local jurisdiction, the Licensee must:
    - a. First obtain a license from the Local Licensing Authority or Local Jurisdiction where the Licensee intends to locate;
    - b. Obtain a transition permit pursuant to this Rule; and
    - c. If required by the Local Licensing Authority or Local Jurisdiction, obtain a transition permit or other form of approval from the Local Licensing Authority or Local Jurisdiction for the local jurisdiction where it intends to locate.
  5. Conduct at either location may be basis for fine, suspension, revocation, or other sanction against the License.
- E. Violation Affecting Public Safety. It is a violation affecting public safety if a Regulated Marijuana Business changes the location of its Licensed Premises without first obtaining a change of location permit from the Division, and any required approval(s) from the Local Licensing Authority and/or Local Jurisdiction.

### **Basis and Purpose – 2-260**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(e), 44-10-203(1)(j), 44-10-203(2)(a), 44-10-203(2)(h), 44-10-203(2)(w), 44-10-305, 44-10-313(8)(b), and 44-10-313(2) C.R.S. The purpose of this rule is to establish guidelines for changing, altering, modifying, or transitioning the Licensed Premises. This Rule 2-260 was previously Rules M and R 303, 1 CCR 212-1 and 1 CCR 212-2.

### **2-260 – Changing, Altering, or Modifying Licensed Premises**

- A. Application Required to Change, Alter, or Modify Licensed Premises. After obtaining a license, the Licensee shall make no physical change, alteration, or modification of the Licensed Premises that materially or substantially alters the Licensed Premises or the usage of the Licensed Premises from the plans originally approved, without the Division's prior written approval and, written approval or written acknowledgement from the relevant Local Licensing Authority or Local Jurisdiction. The Licensee whose Licensed Premises are to be materially or substantially changed is responsible for filing an application for approval on current forms provided by the Division. Changes to the Licensed Premises which do not require an application must be disclosed on a floorplan submitted with the Licensee's renewal application.
- B. What Constitutes a Material Change. This Rule does not exempt Licensees from complying with any Local Licensing Authority or Local Jurisdiction requirements regarding changes, alterations, or modifications to the Licensed Premises. Material or substantial changes, alterations, or modifications requiring Division approval include, but are not limited to, the following:
  1. Any increase or decrease in the total physical size or capacity of the Licensed Premises;

2. The sealing off, creation of or relocation of a common entryway, doorway, passage or other such means of public ingress and/or egress, when such common entryway, doorway or passage alters or changes Limited Access Areas, such as the cultivation, harvesting, manufacturing, testing, or sale of Regulated Marijuana within the Licensed Premises; or
  3. Any physical modification of the Licensed Premises which would require the installation of additional video surveillance cameras. See Rule 3-225 – Video Surveillance.
- C. Attachments to Application. The Division and relevant Local Licensing Authority or Local Jurisdiction may grant approval for the types of changes, alterations, or modifications described herein upon the filing of an application by the Licensee and payment of any applicable fee. The Licensee must submit all information requested by the Division, including but not limited to, documents that verify the following:
1. The Licensee will continue to have possession of the Licensed Premises, as changed, by ownership, lease, or rental agreement; and
  2. The proposed change conforms to any local restrictions related to the time, manner, and place of Regulated Marijuana Business regulation.

### **Basis and Purpose – 2-265**

The statutory basis for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(2)(b)-(c), 44-10-203(2)(e), 44-10-203(2)(t)-(u), 44-10-203(2)(w), 44-10-307, 44-10-308(2), 44-10-313(6), 44-10-401(2)(c), 44-10-901(1), and 24-76.5-101 et seq., C.R.S. Historically, natural persons who held an Owner's Interest in a Regulated Marijuana Business were required to hold an Associated Key License. This Rule transitions the Associated Key designation to an Owner License designation after August 1, 2019. The purpose of this rule is to clarify the requirements and procedures a Person must follow when applying for or possessing either an Owner License or an Employee License. This rule also identifies factors the State Licensing Authority will consider in determining whether a natural person is a resident and whether such person possess good moral character.

### **2-265 – Owner and Employee License: License Requirements, Applications, Qualifications, and Privileges**

- A. Associated Key Licenses. Associated Key licenses remain valid until the first renewal following August 1, 2019, after which such licenses will be renewed as an Owner License.
- B. Owner Licenses Required.
  1. Each Controlling Beneficial Owner must hold a valid Owner License.
  2. If a Controlling Beneficial Owner is an Entity, then its Executive Officer(s) and any natural person who indirectly holds ten percent or more of the Owner's Interests in the Regulated Marijuana Business must also hold a valid Owner's License.
  3. A Passive Beneficial Owner who is a natural person may elect to hold an Owner License and obtain an Owner Identification Badge provided that such Person agrees to be disclosed as holding an Owner's Interest in the Regulated Marijuana Business.
  4. Only Controlling Beneficial Owners and Passive Beneficial Owners can obtain an Owner License.

- C. Owner License and Identification Badge or Employee License and Identification Badge Required. The following natural persons must possess a valid Owner License and Identification Badge or an Employee License and Identification Badge:
1. Any natural person who possesses, cultivates, manufactures, tests, dispenses, sells, serves, transports, or delivers Regulated Marijuana or Regulated Marijuana Products as permitted by privileges of a Regulated Marijuana Business license;
  2. Any natural person who has access to the Inventory Tracking System or a Regulated Marijuana Business point-of-sale system; and
  3. Any natural person with unescorted access in the Limited Access Area.
- D. Escort or Monitoring Required.
1. Any natural person in a Limited Access Area that does not have a valid Owner License and Identification Badge or an Employee License and Identification Badge is a visitor and must be escorted at all times by a person who holds a valid Owner License and Identification Badge or Employee License and Identification Badge. Failure by a Regulated Marijuana Business to continuously escort an individual who does not have a valid Owner License and Identification Badge or an Employee License and Identification Badge in the Limited Access Area is a license violation affecting public safety.
  2. Patients and consumers in a Restricted Access Area and third-party vendors in a Limited Access Area do not need to be escorted at all times, but must be reasonably monitored to ensure compliance with these rules.
- E. Employee License Required to Commence or Continue Employment. Any natural person required to obtain an Employee License by these rules must obtain such license before commencing activities permitted by his or her Employee License.
- F. Owner License and Employee License Identification Badges Are Property of the State Licensing Authority. All Owner Licenses and Employee Licenses, and all Identification Badges are property of the State Licensing Authority.
- G. Owner and Employee Initial and Renewal Applications Required. Owner Licensees and Employee Licensees must submit initial license applications and renewal applications on Division forms and in accordance with this Rule and Rules 2-215, 2-220, and 2-225.
- H. Owner License Qualifications and Privileges.
1. Owner License Qualifications. Each Controlling Beneficial Owner, or Passive Beneficial Owner who elects to be subject to disclosure and licensure, must meet the following criteria before receiving an Owner License:
    - a. The Applicant is not prohibited from licensure pursuant to section 44-10-307, C.R.S.;
    - b. The Applicant has not been a State Licensing Authority employee with regulatory oversight responsibilities for Persons licensed by the State Licensing Authority in the six months immediately preceding the date of the Applicant's application;
    - c. 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.

- d. Each Controlling Beneficial Owner required to hold an Owner License, and any Passive Beneficial Owner that elects to hold an Owner License, must be fingerprinted at least once every two years, and may be fingerprinted more often at the Division's discretion.
  - e. An Owner Licensee who exercises day-to-day operational control on the Licensed Premises of a Regulated Marijuana Business must possess an Identification Badge and must establish and maintain Colorado residency. A Controlling Beneficial Owner will not be deemed to exercise day-to-day operational control by reason of holding a title defined as an Executive Officer.
2. Owner License Exercising Privileges of an Employee License. A natural person who is a Colorado resident and holds an Owner License and Identification Badge may exercise the privileges of an Employee License in any Regulated Marijuana Business.
  3. Business License Required. A natural person cannot hold an Owner License without holding a Regulated Marijuana Business license, or without at least submitting an application for a Regulated Marijuana Business license.

I. Employee License Qualifications and Privileges.

1. Employee License Qualifications and Requirements. An Employee License Applicant must meet the following criteria before receiving an Employee License:
  - a. The Applicant is not prohibited from licensure pursuant to section 44-10-307, C.R.S.;
  - b. The Applicant has not been a State Licensing Authority employee with regulatory oversight responsibilities for Persons licensed by the State Licensing Authority in the six months immediately preceding the date of the Applicant's application.
  - c. 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.
  - d. Employee Licensees working in a Regulated Marijuana Business must be Colorado Residents at the time of initial license application and must maintain residency during the period of licensure, unless they are applying for a workforce training or development residency exempt license.
2. Medical and Retail Employee Licenses. A natural person who holds a current, valid Employee License and Identification Badge issued pursuant to the Marijuana Code may work in any Regulated Marijuana Business.

3. Workforce Training or Development Residency Exempt License. An Applicant who wishes to obtain a workforce development or training exemption to the license residency requirement may apply for an Employee License and must:
  - a. Submit a complete application on Division approved forms;
  - b. Establish she or he meets the licensing criteria of this Rule 2-265(H)(1)(a)-(c);
  - c. Provide evidence of proof of lawful presence; and
  - d. Provide a complete Workforce Training or Development Affirmation form executed under penalty of perjury.
  
- J. Owner Licensees and Employee Licensees Required to Maintain Licensing Qualification. An Owner Licensee or Employee Licensee's failure to maintain qualifications for licensure may constitute grounds for discipline, including but not limited to, suspension, revocation, or fine.
  
- K. Factors Considered when Determining Residency and Citizenship. This Rule applies to natural persons who are required to have and maintain Colorado residency. In determining whether a natural person is a Colorado resident, the State Licensing Authority will consider the following factors:
  1. Primary Home Defined. The location of an Applicant's principal or primary home or place of abode ("primary home") may establish Colorado residency. An Applicant's primary home is that home or place in which a person's habitation is fixed and to which the person, whenever absent, has the present intention of returning after a departure or absence therefrom, regardless of the duration of such absence. A primary home is a permanent building or part of a building and may include, by way of example, a house, condominium, apartment, room in a house, or manufactured housing. No rental property, vacant lot, vacant house or cabin, or other premises used solely for business purposes will be considered a primary home.
  
  2. Reliable Indicators That an Applicant's Primary Home is in Colorado. The State Licensing Authority considers the following types of evidence to be generally reliable indicators that a person's primary home is in Colorado.
    - a. Evidence of business pursuits, place of employment, income sources, residence for income or other tax purposes, residence of spouse and any minor children, leaseholds, situs of personal and real property, existence of any other residences outside Colorado and the amount of time spent at each such residence, and any motor vehicle or vessel registration;
  
    - b. Duly authenticated copies of the following documents may be taken into account: A current driver's license with address, recent property tax receipts, copies of recent income tax returns where a Colorado mailing address is listed as the primary address, current voter registration cards, current motor vehicle or vessel registrations, and other public records evidencing place of abode or employment; and
  
    - c. Other types of reliable evidence.
  
  3. Totality of Evidence. The State Licensing Authority will review the totality of the evidence, and any single evidence regarding the location of a person's primary home is not necessarily determinative.

4. Other Considerations for Residency. The State Licensing Authority may consider the following circumstances:
  - a. Members of the armed services of the United States or any nation allied with the United States who are on active duty in this state under permanent orders and their spouses;
  - b. Personnel in the diplomatic service of any nation recognized by the United States who are assigned to duty in Colorado and their spouses; and
  - c. Full-time students who are enrolled in any accredited trade school, college, or university in Colorado. The temporary absence of such student from Colorado, while the student is still enrolled at any such trade school, college, or university, will not be deemed to terminate their Colorado residency. A student will be deemed "full-time" if considered full-time pursuant to the rules or policy of the educational institution he or she is attending.

L. Evaluating a Natural Person's Good Moral Character Based on Criminal History.

1. In evaluating whether a Person is prohibited from holding a license pursuant to sections subsections 44-10-307(1)(b) or (c), C.R.S., based on a determination that the person's criminal history indicates she or he is not of Good Moral Character, the Division will not consider the following:
  - a. The mere fact a person's criminal history contains an arrest(s) or charge(s) of a criminal offense that is not actively pending;
  - b. A conviction of a criminal offense in which the Applicant/Licensee received a pardon;
  - c. A conviction of a criminal offense which resulted in the sealing or expungement of the record; or
  - d. A conviction of a criminal offense in which a court issued an order of collateral relief specific to the application for state licensure.
2. In evaluating whether a Person is prohibited from holding a license pursuant to subsections 44-10-307(1)(b) or (c), C.R.S., based on a determination that the person's criminal history indicates he or she is not of Good Moral Character, the Division may consider the following history:
  - a. Any felony conviction(s);
  - b. Any conviction(s) of crimes involving moral turpitude;
  - c. Pertinent circumstances connected with the conviction(s); and
  - d. Conduct underlying arrest(s) or charge(s) or a criminal offense for which the criminal case is not actively pending.
3. When considering criminal history in subparagraph (K)(2) above, the Division will consider:

- a. Whether there is a direct relationship between the conviction(s) and the duties and responsibilities of holding a state license issued pursuant to the Marijuana Code;
- b. Any information provided to the Division regarding the person's rehabilitation, which may include but is not limited to the following non-exhaustive considerations:
  - i. Character references;
  - ii. Educational, vocational, and community achievements, especially those achievements occurring during the time between the person's most recent criminal conviction and the application for a state license;
  - iii. Successful participation in an alcohol and drug treatment program;
  - iv. That the person truthfully and fully reported the criminal conduct to the Division;
  - v. The person's employment history after conviction or release, including but not limited to whether the person was vetted and approved to hold a state or out-of-state license for the purposes of employment in a regulated industry;
  - vi. The person's successful compliance with any conditions of parole or probation imposed after conviction or release; or
  - vii. Any other facts or circumstances tending to show the Applicant has been rehabilitated and is ready to accept the responsibilities of a law-abiding and productive member of society.

### **Basis and Purpose – 2-270**

The statutory basis for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(j), 44-10-203(2)(a), 44-10-203(2)(l)-(m), 44-10-203(2)(w), 44-10-305, 44-10-306, 44-10-307, 44-10-313(8), 24-4-104, and 24-4-105, C.R.S. The purpose of this rule is to clarify the procedures and factors governing the denial process and voluntary withdrawal process for all licenses issued by the State Licensing Authority. This Rule 2-270 is similar to the previous Rules M and R 251, 1 CCR 212-1 and 1 CCR 212-2.

### **2-270 – Application Denial and Voluntary Withdrawal**

- A. Applicant Bears the Burden of Proving It Meets Licensure Requirements. A license, registration, or permit issued to a Person or a Regulated Marijuana Business is a revocable privilege. At all times during the application process, an Applicant must be capable of establishing it is qualified to hold a license.
- B. Applicants Must Provide Information to the Division in a Full, Faithful, Truthful, and Fair Manner. An application may be denied where the Applicant made misstatements, omissions, misrepresentations, or untruths in the application or in connection with the Applicant's suitability investigation. Providing misstatements, misrepresentations, omissions, or untruths to the Division may be the basis for administrative action, or the basis of criminal charges against the Applicant.
- C. Grounds for Denial.

1. The State Licensing Authority will deny an application for Good Cause.
2. The State Licensing Authority will deny an application from an Applicant that is statutorily disqualified from holding a license.
3. The State Licensing Authority will deny an application where the Applicant failed to provide all required information or documents, failed to obtain all required findings of suitability prior to submitting the application, provided inaccurate, incomplete, or untruthful information or documents, or failed to cooperate with the Division.

D. Voluntary Withdrawal of Application.

1. The Division and Applicant may mutually agree to allow the 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 matter is waived once the voluntary withdrawal is approved.
3. The Division will consider the request along with any circumstances at issue with the application in making a decision to accept the voluntary withdrawal. The Division may at its discretion grant the request with or without prejudice or deny the request.
4. The Division will notify the Applicant of its acceptance of the voluntary withdrawal and the terms thereof.
5. If the Applicant agrees to a voluntary withdrawal granted with prejudice, then the Applicant is not eligible to apply again for licensing or approval until after expiration of one year from the date of such voluntary withdrawal.

E. A Denied Applicant May Appeal a Denial. A Denied Applicant may appeal a denial pursuant to the Administrative Procedure Act.

**Basis and Purpose – 2-275**

The statutory basis for this rule includes but is not limited to sections 44-10-202(1)(b)-(c), 44-10-203(1)(j), 44-10-203(2)(q), 44-10-203(2)(t), 11-10-310, 44-10-401(3)(a)-(d), C.R.S. The purpose of this rule is to establish procedures and requirements for any Person appointed by a court as a receiver, personal representative, executor, administrator, guardian, conservator, trustee, or similarly situated Person acting in accordance with sections 44-10-401(3)(a)-(d), C.R.S., and authorized by court order to take possession of, operate, manage, or control a Regulated Marijuana Business. This Rule 2-275 was previously Rules M and R 253, 1 CCR 212-1 and 1 CCR 212-2.

**2-275 – Temporary Appointee Registrations for Court Appointees**

A. Notice and Application Requirements for All Court Appointees.

1. Notice to the State and Local Licensing Authorities. Within seven days of accepting an appointment as a Court Appointee pursuant to sections 44-10-401(3), C.R.S., such Court Appointee must file a notice to the State Licensing Authority and the applicable Local Licensing Authority on a form required by the State Licensing Authority which must include at least:
  - a. A copy of the order appointing the Court Appointee;



- b. A statement affirming the Court Appointee complied with the certification required by section 44-10-401(3)(a), C.R.S.;
  - c. If the Court Appointee is an entity, a list of all natural persons responsible for taking possession of, operating, managing, or controlling the Regulated Marijuana Business; and
  - d. A complete list of all Regulated Marijuana Businesses for which the Court Appointee was appointed and the respective dates during which the Court Appointee is currently serving, or has previously served, as a receiver, personal representative, executor, administrator, guardian, conservator, trustee, or similarly situated Person.
2. Application for Finding of Suitability. Within 14 days of accepting an appointment as a Court Appointee pursuant to section 44-10-401(3), C.R.S., each Court Appointee must file an application for a finding of suitability with the State Licensing Authority on forms required by the State Licensing Authority. Each entity and natural person for whom a notice was filed pursuant to Rule 2-275(A) must file an application for a finding of suitability. The Division may in its discretion extend the 14 day deadline to file an application for a finding of suitability upon a showing of good cause. The Division may also in its discretion rely upon a recent licensing background investigation for Court Appointees that currently hold a license or Temporary Appointee Registration issued by the State Licensing Authority, and may waive all or part of the application fee accordingly.
  3. Effective Date. The Temporary Appointee Registration will issue following the State Licensing Authority's receipt of the notice required by Rule 2-275(A)(1), and is effective as of the date of the court appointment.

B. Temporary Appointee Registration.

1. Entities. If the Court Appointee is an entity, the entity and all natural persons responsible for taking possession of, operating, managing, or controlling the Regulated Marijuana Business must receive a Temporary Appointee Registration. Every Court Appointee that is an entity must have at least one natural person with a Temporary Appointee Registration.
2. Temporary Appointee Registrations. Every Temporary Appointee Registration issued to a Person will be treated as an Owner License except where inconsistent with section 44-10-401(3), C.R.S., or this Rule.
3. Other employees. Any other person working under the direction of a Court Appointee who possesses, cultivates, manufactures, tests, dispenses, sells, serves, transports, researches, or delivers Regulated Marijuana as permitted by privileges granted under a Regulated Marijuana Business license must have a valid Employee License.
4. Licensed Premises. A Court Appointee cannot establish an independent Licensed Premises, but is authorized to exercise the privileges of the Temporary Appointee Registration in the Licensed Premises of the Regulated Marijuana Business for which it is appointed.
5. Medical Marijuana Business Operators or Retail Marijuana Business Operators. A Court Appointee may retain a Medical Marijuana Business Operator or a Retail Marijuana Business Operator. If the Medical Marijuana Business Operator or Retail Marijuana Business Operator is the Court Appointee, see subparagraph E of this Rule.

6. Marijuana Code and Rules Applicable. Court Appointees are subject to the requirements of the Marijuana Code and the rules promulgated thereto. Except where inconsistent with section 44-10-401(3), C.R.S., or this Rule, the State Licensing Authority may take any action with respect to a Temporary Appointee Registration that it could take with respect to any license issued under the Marijuana Code. In any action involving a Temporary Appointee Registration, these rules will be read to include the terms “registered”, “registration”, “registrant”, or any other similar terms in lieu of “licensed”, “licensee”, and any other similar terms as the context requires when applied to a Temporary Appointee Registration.

C. Administrative Actions.

1. Suspension, Revocation, Fine, or Other Administrative Action Regarding a Regulated Marijuana Business. In addition to any other basis for suspension, revocation, fine, or other administrative action, a Regulated Marijuana Business’s license may, pursuant to subsections 44-10-202(1)(b), 44-10-401(3)(b), and 44-10-901(1), C.R.S., be suspended, revoked, fined, or subject to other administrative action based upon its Court Appointee’s violations of the Marijuana Code, the rules promulgated pursuant to the Marijuana Code, the terms, conditions, or provisions of the Temporary Appointee Registration issued by the State Licensing Authority, or any order of the State Licensing Authority. Grounds for discipline include, but are not limited to, the Court Appointee’s failure to timely notify the Division of the appointment or failure to timely apply for and obtain a finding of suitability. Such administrative action may occur even after the Temporary Appointee Registration is expired or surrendered, if the action is based upon an act or omission that occurred while the Temporary Appointee Registration was in effect.
2. Suspension, Revocation, Fine, or Other Administrative Action Regarding a Temporary Appointee Registration. In addition to any other basis for suspension, revocation, fine, or other administrative action, a Temporary Appointee Registration may, pursuant to subsections 44-10-202(1)(b), 44-10-401(3)(b), and 44-10-901(1), C.R.S., be suspended, revoked, or subject to other administrative action based upon the Court Appointee’s violations of the Marijuana Code or the Rules promulgated pursuant to the Marijuana Code, the terms, conditions, or provisions of the Temporary Appointee Registration issued by the State Licensing Authority, or any order of the State Licensing Authority. Grounds for discipline include, but are not limited to, the Court Appointee’s failure to timely notify the Division of the appointment or failure to timely apply for and obtain a finding of suitability. Such administrative action may occur even after the Temporary Appointee Registration is expired or surrendered, if the action is based upon an act or omission that occurred while the Temporary Appointee Registration was in effect. If a Person holding a Temporary Appointee Registration also holds any other Owner License or Employee License, the Owner License, the Employee License, and the Temporary Appointee Registration may be suspended, revoked, fined, or subject to other administrative action for any violations of the Marijuana Code or the rules promulgated pursuant to the Marijuana Code, the terms, conditions, or provisions of the Temporary Appointee Registration, Owner License, and/or Employee License issued by the State Licensing Authority, or any order of the State Licensing Authority.
3. Suitability. If the State Licensing Authority denies an application for a finding of suitability because the Court Appointee failed to timely apply for a finding of suitability, failed to timely provide all information requested by the Division in connection with an application for a finding of suitability, or was found unsuitable, the State Licensing Authority may also pursue administrative action as set forth in this Rule.
4. Court Appointee’s Responsibility to Notify Appointing Court. The Court Appointee must notify the appointing court of any action taken against the Temporary Appointee Registration by the State Licensing Authority pursuant to sections 44-10-901 or 24-4-104,

C.R.S., within two business days. Such actions include, without limitation, the issuance of an Order to Show Cause, the issuance of an Administrative Hold, the issuance of an Order of Summary Suspension, the issuance of an Initial Decision by the Department's Hearings Division, or the issuance of a Final Agency Order by the State Licensing Authority. The Court Appointee must forward a copy of such notification to the Division at the same time the notification is made to the appointing court.

D. Expiration and Renewal.

1. Conclusion of Court Appointment. A Court Appointee's Temporary Appointee Registration expires upon the conclusion of a Court Appointee's court appointment. Each Court Appointee and each Regulated Marijuana Business that has a Court Appointee must notify the State Licensing Authority within two business days of the date on which a Court Appointee's court appointment ends, whether due to termination of the appointment by the court, substitution of another Court Appointee, closure of the court case, or otherwise. For a Court Appointee that is appointed in connection with multiple court cases, the notice must be filed with the State Licensing Authority with respect to each such case.
2. Annual Renewal. If it has not yet expired pursuant to Rule 2-270(D)(1), each Temporary Appointee Registration is valid for one year, after which it must be subject to annual renewal in accordance with the Marijuana Code and the rules promulgated pursuant to the Marijuana Code. If a Court Appointee is appointed in connection with multiple court cases, the Temporary Appointee Registration is subject to annual renewal unless all such appointments have ended, whether due to termination of the appointments by the courts, substitution of other Court Appointees, closure of the court cases, or otherwise.
3. Other Termination. A Temporary Appointee Registration may be valid for less than the applicable term if surrendered, revoked, suspended, or subject to similar action.

E. Medical Marijuana Business Operators and/or Retail Marijuana Business Operators as Court Appointees. By virtue of its privileges of licensure, a Medical Marijuana Business Operator, a Retail Marijuana Business Operator, and their respective Owner Licensees may serve as Court Appointees without a Temporary Appointee Registration subject to the following terms:

1. Notice to the State Licensing Authority of Appointment. The Medical Marijuana Business Operator or the Retail Marijuana Business Operator, and its Owner Licensee(s) are responsible for notifying the State Licensing Authority within seven days of any court appointment to serve as a receiver, personal representative, executor, administrator, guardian, conservator, trustee, or similarly situated Person and take possession of, operate, manage, or control a Regulated Marijuana Business. Such notice must be accompanied by a copy of the order making the appointment, and must identify each Regulated Marijuana Business regarding which the Medical Marijuana Business Operator and/or Retail Marijuana Business Operator is appointed.
2. Notice to the Appointing Court of State Licensing Authority Action. The Medical Marijuana Business Operator or the Retail Marijuana Business, and its Owner Licensee(s) are responsible for notifying the appointing court of any action taken against the Medical Marijuana Business Operator license, the Retail Marijuana Business Operator license and/or the Owner License by the State Licensing Authority pursuant to sections 44-10-901 or 24-4-104, C.R.S., within two business days. Such actions include, without limitation, the issuance of an Order to Show Cause, the issuance of an Administrative Hold, the issuance of an Order of Summary Suspension, the issuance of an Initial Decision by the Department's Hearings Division, or the issuance of a Final Agency Order by the State Licensing Authority. The Medical Marijuana Business Operator, the Retail Marijuana Business Operator and its Owner Licensee(s) must forward a copy of such

notification to the Division at the same time the notification is made to the appointing court.

### **Basis and Purpose – 2-280**

The statutory basis for this rule includes but is not limited to sections 44-10-203(2)(c), 44-10-203(2)(l), 44-10-203(2)(t), 44-10-203(2)(ee)(D), 44-10-203(7), 44-10-307, 44-10-309(4)-(5), 44-10-310(5) and (11), 44-10-313(8)(a), and 44-10-901, C.R.S. The purpose of this rule is to clarify the conditions and procedures for divestiture of any Person prohibited from holding a license under section 44-10-307, C.R.S., or who is found unsuitable by the State Licensing Authority. This rule also requires that every Regulated Marijuana Business have at least one Controlling Beneficial Owner and provides what happens in the event of suspension of a Regulated Marijuana Business's Controlling Beneficial Owner(s). Finally, this rule provides that Licensees cannot have unlicensed persons take actions on their behalf or for their benefit that the Licensees themselves are prohibited from taking under these rules or the Marijuana Code.

### **2-280 – Controlling Beneficial Owners that are Persons Prohibited, Unsuitable, Revoked, or Suspended; At Least One Controlling Beneficial Owner Holding a Valid Owner License Required; and Prohibited Third-Party Acts**

#### **A. Controlling Beneficial Owners That Are Persons Prohibited, Unsuitable, or Revoked.**

1. Less than 100% of all Controlling Beneficial Owners – Divestiture. If less than 100% of a Regulated Marijuana Business's Controlling Beneficial Owners are or become a Person prohibited from holding a license by these Rules or the Marijuana Code, have his or her Owner License revoked by a Final Agency Order, or are found unsuitable, the Regulated Marijuana Business must divest all of the Beneficial Ownership of that Controlling Beneficial Owner.
  - a. Unless extended for good cause, within 90 days of a Controlling Beneficial Owner becoming a Person prohibited from holding a license, having his or her Owner License revoked, or being found unsuitable, the Regulated Marijuana Business must either:
    - i. Submit a change of owner application, where required, and any document(s) necessary to transfer all of that Controlling Beneficial Owner's Interests to one or more Persons that are not prohibited from holding a license or unsuitable. 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 that Controlling Beneficial Owner's Interests to one or more Persons that are not a Person prohibited from holding a license or unsuitable.
  - b. In determining whether good cause for an extension exists, the Division will consider whether there is any Owner Interest buy-back provision with the Controlling Beneficial Owner. If mediation, arbitration, or a 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 Regulated Marijuana Business that is a Publicly Traded Corporation must have a divestiture plan with its Controlling Beneficial Owners which must be disclosed to the Division pursuant to Rule 2-220(A).

- d. A Regulated Marijuana Business that fails to divest a Controlling Beneficial 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 the unsuitable or Person prohibited from holding a license when determining the imposition of a penalty. However, a Regulated Marijuana Business that is unable to divest a Controlling Beneficial Owner that is a Person prohibited from holding a license or found unsuitable is prohibited from being issued or holding a license.
  2. All Controlling Beneficial Owners are Unsuitable, Revoked, or Persons Prohibited From Holding a License. A Regulated Marijuana Business's License may be revoked if 100% of its Controlling Beneficial Owners are found unsuitable, have his or her Owner's License revoked, or are Persons prohibited from holding a license by these Rules or the Marijuana Code.
- B. Suspension of Controlling Beneficial Owners.
1. Suspension of Less than 100% of the Controlling Beneficial Owner(s) of a Regulated Marijuana Business. In the event of the suspension of the Owner License of a Controlling Beneficial Owner, either (i) the Regulated Marijuana Business must comply with all requirements of rule 8-210 – Disciplinary Process: Summary Suspensions, or (ii) the non-suspended Owner Licensee(s) must control the Regulated Marijuana Business without participation from the suspended Controlling Beneficial Owner(s).
  2. Suspension of 100% of the Controlling Beneficial Owners of a Regulated Marijuana Business. A Regulated Marijuana Business cannot operate or Transfer Regulated Marijuana if all Controlling Beneficial Owners are suspended.
- C. At Least One Controlling Beneficial Owner Holding a Valid Owner License Required. No Regulated Marijuana Business may operate or be licensed unless it has at least one Controlling Beneficial Owner who holds a valid Owner License.
- D. Loss Of Owner License As A Controlling Beneficial Owner Of Multiple Businesses. If an Owner License is suspended, revoked, or found unsuitable as to one Regulated Marijuana Business, that Owner License is automatically suspended, revoked, or found unsuitable as to any other Regulated Marijuana Business in which that Person is a Controlling Beneficial Owner.
- E. 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 – Regulated Marijuana Business Operations**

### **3-100 Series – General Privileges and Limitations**

#### **Basis and Purpose – 3-105**

The statutory authority for this rule includes but is not limited to sections 44-10-102(2), 44-10-102(3), 44-10-202(1)(b), 44-10-202(1)(c), 44-10-203(1)(j), 44-10-203(2)(a), 44-10-401(2), 44-10-701(2)(a), 44-10-701(2)(c), and 44-10-701(3)(e), C.R.S. The purpose of this rule is to establish that it is unlawful for any Regulated Marijuana Business Licensee to exercise any privileges other than those granted to it by the State Licensing Authority.

#### **3-105 – Regulated Marijuana Businesses: Privileges Granted**

A Regulated Marijuana Business shall only exercise those privileges granted to it by the State Licensing Authority.

#### **Basis and Purpose – 3-110**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), 44-10-203(2)(g), 44-10-203(2)(h), 44-10-401(2), 44-10-701(1)(a), 44-10-701(3)(d), and 44-10-701(3)(f), C.R.S. The purpose of this rule is to clarify that, except for in a Licensed Hospitality Business, it is unlawful for a Regulated Marijuana Business to allow consumption on the Licensed Premises.

#### **3-110 – Regulated Marijuana Businesses: General Restrictions**

##### **A. Consumption Prohibited:**

1. Applicability. This subparagraph (A) applies to all Regulated Marijuana Businesses, except Licensed Hospitality Businesses.
2. Licensees shall not permit the consumption of marijuana or marijuana product on the Licensed Premises or in transport vehicles, including any Sampling Units Transferred to a Sampling Manager.

##### **B. Alcohol Beverage License Prohibited. A Person may not operate a license issued pursuant to the Marijuana Code and these rules at the same Licensed Premises as a license or permit issued pursuant to article 3, 4 or 5 of Title 44.**

#### **Basis and Purpose – 3-115**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), 44-10-203(2)(h), 44-10-203(2)(n), 44-10-203(3)(c), 44-10-401(2), and 44-10-701(2)(a), C.R.S. The purpose of this rule is to clarify those acts that are limited or prohibited in some way and to make clear that a Regulated Marijuana Business shall not offer or receive complimentary Regulated Marijuana from a licensed transporter.

#### **3-115 – Transporter Transfer Restriction**

A Licensee shall not sell or give away Regulated Marijuana to a Medical Marijuana Transporter or Retail Marijuana Transporter, and shall not buy, or receive, complimentary Regulated Marijuana from a Medical Marijuana Transporter or Retail Marijuana Transporter.

### **3-200 Series – Licensed Premises**

#### **Basis and Purpose – 3-205**

The statutory authority for this rule includes but is not limited to sections 44-10-103(14), 44-10-103(26), 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(j), 44-10-203(2)(h), 44-10-203(2)(p), and 44-10-203(2)(t), C.R.S. The purpose of this rule is to establish Limited Access Areas for Licensed Premises under the control of the Licensee to only individuals licensed by the State Licensing Authority. In addition, this rule clarifies that businesses and individuals cannot use the visitor system as a means to employ an individual who does not possess a valid and current Employee License. This Rule was previously Rules M and R 301, 1 CCR 212-1 and 1 CCR 212-2.

### **3-205 – Limited Access Areas**

- A. Proper Display of Identification Badge. All Persons in a Limited Access Area as provided for in section 44-10-103(26) C.R.S., shall be required to hold and properly display a current Identification Badge issued by the Division at all times. Proper display of the Identification Badge shall consist of wearing the badge in a plainly visible manner, at or above the waist, and with the photo of the Licensee visible. The Licensee shall not alter, obscure, damage, or deface the badge in any manner.
- B. Visitors in Limited Access Areas.
1. Prior to entering a Limited Access Area, all visitors, including outside vendors, contractors or others, must obtain a visitor identification badge from management personnel of the Licensee that shall remain visible while in the Limited Access Area.
  2. Visitors shall be escorted by the Regulated Marijuana Business's licensed personnel at all times. No more than five visitors may be escorted by a single employee. Except that trade craftspeople not normally engaged in the business of cultivating, processing, or selling Regulated Marijuana need not be accompanied on a full-time basis, but only reasonably monitored.
  3. A Regulated Marijuana Business and all Licensees employed by the Regulated Marijuana Business shall report to the Division any discovered plan or other action of any Person to (1) commit theft, burglary, underage sales, diversion of marijuana or marijuana product, or other crime related to the operation of the subject Regulated Marijuana Business; or (2) compromise the integrity of the Inventory Tracking System. A report shall be made as soon as possible after the discovery of the action, but not later than 14 days. Nothing in this paragraph (B) alters or eliminates any obligation a Regulated Marijuana Business or Licensee may have to report criminal activity to a local law enforcement agency.
  4. The Licensee shall maintain a log of all visitor activity, for any purpose, within the Limited Access Area and shall make such logs available for inspection by the Division and relevant Local Licensing Authority or Local Jurisdiction.
  5. All visitors admitted into a Limited Access Area must provide acceptable proof of age and must be at least 21 years of age. See Rule 3-405 – Acceptable Forms of Identification.
  6. The Licensee shall check the identification for all visitors to verify that the name on the identification matches the name in the visitor log. See Rule 3-405 – Acceptable Forms of Identification.
  7. A Licensee may not receive consideration or compensation for permitting a visitor to enter a Limited Access Area.
  8. Use of a visitor badge to circumvent the Employee License requirements of Rule 2-265 is prohibited and may constitute a license violation affecting public safety.

- C. Required Signage. All areas of ingress and egress to Limited Access Areas on the Licensed Premises shall be clearly identified by the posting of a sign which shall be not less than 12 inches wide and 12 inches long, composed of letters not less than a half inch in height, which shall state, "Do Not Enter - Limited Access Area – Access Limited to Licensed Personnel and Escorted Visitors." A Licensee may comply with this paragraph (C) when that sign is conspicuously placed immediately within an exterior entrance that is locked against public entry and only accessible to limited, licensed personnel and escorted visitors.
- D. Diagram for Licensed Premises. All Limited Access Areas shall be clearly identified to the Division and relevant Local Licensing Authority or Local Jurisdiction and described in a diagram of the Licensed Premises reflecting walls, partitions, counters and all areas of ingress and egress. The diagram shall also reflect all Propagation, cultivation, manufacturing, testing, consumption, and Restricted Access Areas. See Rule 3-905 – Business Records Required.
- E. Modification of Limited Access Area. A Licensee's proposed modification of designated Limited Access Areas must be approved by the Division, the Local Licensing Authority, and, if required, the relevant Local Jurisdiction prior to any modifications being made. See Rule 2-260 – Changing, Altering, or Modifying Licensed Premises.
- F. Law Enforcement Personnel Authorized. Notwithstanding the requirements of subsection A of this Rule, nothing shall prohibit investigators and employees of the Division, authorities from relevant Local Jurisdiction or state or local law enforcement, for a purpose authorized by the Marijuana Code or for any other state or local law enforcement purpose, from entering a Limited Access Area upon presentation of official credentials identifying them as such.

### **Basis and Purpose – 302**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-311(1)(b), and 44-10-311(2), C.R.S. The purpose of this rule is to establish and clarify the means by which the Licensee has lawful possession of the Licensed Premises. This Rule 3-210 was previously Rules M and R 302, 1 CCR 212-1 and 1 CCR 212-2.

### **3-210 – Possession of Licensed Premises**

- A. Evidence of Lawful Possession. Persons licensed pursuant to sections 44-10-501, 44-10-502, 44-10-503, 44-10-504, 44-10-507, 44-10-601, 44-10-602, 44-10-603, 44-10-604, 44-10-607, 44-10-608, 44-10-609, 44-10-610 C.R.S., or those applying for such licenses, must demonstrate proof of lawful possession of the premises to be licensed or Licensed Premises. Evidence of lawful possession consists of properly executed deeds of trust, leases, or other written documents acceptable to state and local licensing authorities.
- B. Relocation Prohibited. The Licensed Premises shall only be those geographical areas that are specifically and accurately described in executed documents verifying lawful possession. Licensees are not authorized to relocate to other areas or units within a building structure without first filing a change of location application and obtaining approval from the Division and the relevant Local Jurisdiction. Licensees shall not add additional contiguous units or areas, thereby altering the initially-approved premises, without filing an application and receiving approval to modify the Licensed Premises on current forms prepared by the Division, including any applicable processing fee. See Rule 2-260 - Changing, Altering, or Modifying Licensed Premises
- C. Subletting Not Authorized. Licensees are not authorized to sublet any portion of Licensed Premises for any purpose, unless all necessary applications to modify the existing Licensed Premises to accomplish any subletting have been approved by the Division and the relevant Local Licensing Authority or Local Jurisdiction.



### **Basis and Purpose – 3-215**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), 44-10-203(2)(d)(I)-(VI), 44-10-401, 44-10-501, 44-10-502, 44-10-503, 44-10-504, 44-10-601, 44-10-602, 44-10-603, 44-10-604, C.R.S. The purpose of this rule is to establish guidelines for the manner in which a Medical Marijuana Business may share its existing Licensed Premises with a Retail Marijuana Business, and to ensure the proper separation of Regulated Marijuana Business operation operations. This Rule 3-215 was previously Rules M and R 304.1, 1 CCR 212-1 and 1 CCR 212-2.

### **3-215 – Regulated Marijuana Businesses: Shared Licensed Premises and Operational Separation**

#### **A. Shared Licensed Premises For Medical Marijuana Stores and Retail Marijuana Stores.**

1. Medical Marijuana Store that authorizes only patients that are over the age of 21. A Medical Marijuana Store that authorizes only Medical Marijuana patients who are over the age of 21 years to be on the Licensed Premises may also hold a Retail Marijuana Store license and operate at the same location under the following circumstances:
  - a. The relevant Local Licensing Authority and Local Jurisdiction permit a dual operation at the same location;
  - b. The Medical Marijuana Store and Retail Marijuana Store are commonly owned;
  - c. The Medical Marijuana Store and Retail Marijuana Store shall maintain physical or virtual separation between (i) Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana Products, and other Medical Marijuana-related inventory and (ii) Retail Marijuana, Retail Marijuana Concentrate, Retail Marijuana Products, and other Retail Marijuana-related inventory;
  - d. The Medical Marijuana Store and Retail Marijuana Store shall maintain separate displays between (i) Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana Products, and other Medical Marijuana-related inventory and (ii) Retail Marijuana, Retail Marijuana Concentrate, Retail Marijuana Products, and other Retail Marijuana-related inventory, but the displays may be on the same sale floor;
  - e. Record-keeping, inventory tracking, packaging and labeling for the Medical Marijuana Store and Retail Marijuana Store shall enable the Division and Local Licensing Authority or Local Jurisdiction to clearly distinguish the inventories and business transactions of the Medical Marijuana Store from the inventories and business transactions of the Retail Marijuana Store; and
  - f. The Medical Marijuana Store shall post and maintain signage that clearly conveys that persons under the age of 21 years may not enter.
2. Medical Marijuana Store that authorizes patients under the age of 21. A Medical Marijuana Store that authorizes Medical Marijuana patients under the age of 21 years to be on the Licensed Premises may operate in the same location with a Retail Marijuana Store under the following conditions:
  - a. The relevant Local Licensing Authority and Local Jurisdiction permit a dual operation at the same location;
  - b. The Medical Marijuana Store and Retail Marijuana Store are commonly owned;

- c. The Medical Marijuana Store and Retail Marijuana Store maintain physical separation, including separate entrances and exits, between their respective Restricted Access Areas;
- d. No point of sale operations occur at any time outside the physically separated Restricted Access Areas;
- e. All Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana Product in a Restricted Access Area must be physically separated from all Retail Marijuana, Retail Marijuana Concentrate, and Retail Marijuana Product in a Restricted Access Area, and such physical separation must include separate entrances and exits;
- f. Any display areas shall be located in the physically separated Restricted Access Areas;
- g. In addition to the physically separated sales and display areas, the Medical Marijuana Store and Retail Marijuana Store shall maintain physical or virtual separation for storage of Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana Products, and other Medical Marijuana-related inventory from storage of Retail Marijuana, Retail Marijuana Concentrate, Retail Marijuana Products, and other Retail Marijuana-related inventory; and
- h. Record-keeping, inventory tracking, packaging and labeling for the Medical Marijuana Store and Retail Marijuana Store shall enable the Division and Local Licensing Authority or Local Jurisdiction to clearly distinguish the inventories and business transactions of the Medical Marijuana Store from the inventories and business transactions of the Retail Marijuana Store.

B. Shared Licensed Premises For Medical Marijuana Cultivation Facility and Retail Marijuana Cultivation Facility. A Medical Marijuana Cultivation Facility and a Retail Marijuana Cultivation Facility may share a single Licensed Premises and operate at the same location under the following circumstances:

- 1. The relevant Local Licensing Authority and Local Jurisdiction permit a dual operation at the same location;
- 2. The Medical Marijuana Cultivation Facility and the Retail Marijuana Cultivation Facility are commonly owned;
- 3. The Medical Marijuana Cultivation Facility and Retail Marijuana Cultivation Facility shall maintain either physical or virtual separation between (i) Medical Marijuana and Medical Marijuana Concentrate and (ii) Retail Marijuana and Retail Marijuana Concentrate; and
- 4. Record-keeping, inventory tracking, packaging and labeling for the Medical Marijuana Cultivation Facility and Retail Marijuana Cultivation Facility must enable the Division and relevant Local Licensing Authority or Local Jurisdiction to clearly distinguish the inventories and business transactions of the Medical Marijuana Cultivation Facility from the Retail Marijuana Cultivation Facility.

C. Shared Licensed Premises For Medical Marijuana Products Manufacturer and Retail Marijuana Products Manufacturer. A Medical Marijuana Products Manufacturer and a Retail Marijuana Products Manufacturer may share a single Licensed Premises and operate at the same location under the following circumstances:

1. The relevant Local Licensing Authority and Local Jurisdiction permit a dual operation at the same location;
  2. The Medical Marijuana Products Manufacturer and the Retail Marijuana Products Manufacturer are commonly owned;
  3. The Medical Marijuana Products Manufacturer and Retail Marijuana Products Manufacturer shall maintain either physical or virtual separation between (i) Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana Products, and other Medical Marijuana-related inventory and (ii) Retail Marijuana, Retail Marijuana Concentrate, Retail Marijuana Products, and other Retail Marijuana-related inventory. Nothing in this Rule prohibits a Retail Marijuana Products Manufacturer and Medical Marijuana Products Manufacturer from sharing raw Ingredients in bulk, for example flour or sugar, except Retail Marijuana and Medical Marijuana may not be shared under any circumstances; and
  4. Record-keeping, inventory tracking, packaging and labeling for the Medical Marijuana Products Manufacturer and Retail Marijuana Products Manufacturer must enable the Division and Local Licensing Authority or Local Jurisdiction to clearly distinguish the inventories and business transactions of the Medical Marijuana Products Manufacturer from the Retail Marijuana Products Manufacturer.
- D. Shared Licensed Premises For Medical Marijuana Store, Medical Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, Retail Marijuana Store, Retail Marijuana Cultivation Facility, and Retail Marijuana Products Manufacturer. A Medical Marijuana Store, Medical Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, Retail Marijuana Store, Retail Marijuana Cultivation Facility, or Retail Marijuana Products Manufacturer may share the common areas of a Licensed Premises where the cultivation, manufacture, packaging, storing, or Transfers to patients and consumers of Regulated Marijuana does not occur. For example, the shared common areas may include hallways, break rooms, bathrooms, etc. Licensees must maintain physical separation of all Regulated Marijuana inventory. Nothing in this paragraph D prohibits Licensees sharing premises in accordance with paragraphs (B) and (C) of this Rule.
- E. Shared Licensed Premises For Medical Marijuana Testing Facility and Retail Marijuana Testing Facility. A Medical Marijuana Testing Facility and a Retail Marijuana Testing Facility may share a single Licensed Premises and operate at the same location under the following circumstances:
1. The relevant Local Licensing Authority and Local Jurisdiction permit dual operation at the same location;
  2. The Medical Marijuana Testing Facility and Retail Marijuana Testing Facility are identically owned;
  3. The Medical Marijuana Testing Facility and Retail Marijuana Testing Facility shall maintain either physical or virtual separation between (i) Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana Products, and other Medical Marijuana-related inventory and (ii) Retail Marijuana, Retail Marijuana Concentrate, Retail Marijuana Products, and other Retail Marijuana-related inventory; and
  4. Record-keeping, inventory tracking, packaging and labeling for the Medical Marijuana Testing Facility and Retail Marijuana Testing Facility must enable the Division and Local Licensing Authority or Local Jurisdiction to clearly distinguish the inventories and business transactions of the Medical Marijuana Testing Facility from the Retail Marijuana Testing Facility.

- F. Shared Licensed Premises Medical Marijuana Transporter and Retail Marijuana Transporter. A Medical Marijuana Transporter and a Retail Marijuana Transporter may share a single Licensed Premises and operate dual transporting, logistics, and temporary storage business operation at the same location under the following circumstances:
1. The relevant Local Licensing Authority and Local Jurisdiction permit dual operation at the same location;
  2. The Medical Marijuana Transporter and Retail Marijuana Transporter are identically owned;
  3. The Medical Marijuana Transporter and Retail Marijuana Transporter shall maintain either physical or virtual separation between (i) Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana Products, and other Medical Marijuana-related inventory and (ii) Retail Marijuana, Retail Marijuana Concentrate, Retail Marijuana Products, and other Retail Marijuana-related inventory; and
  4. Record-keeping, inventory tracking, packaging and labeling for the Medical Marijuana Transporter and Retail Marijuana Transporter must enable the Division and Local Licensing Authority or Local Jurisdiction to clearly distinguish the inventories and business transactions of the Medical Marijuana Transporter from the Retail Marijuana Transporter.
- G. Shared Licensed Premises Marijuana Research and Development Facility. A Marijuana Research and Development Facility that has obtained an R&D Co-Location Permit pursuant to Rule 5-705(C) may share a single Licensed Premises and operate at the same location as another Regulated Marijuana Business to the extent permitted by the R&D Co-Location Permit and otherwise in compliance with all applicable rules. See 5-700 Series Rules.
- H. Violation Affecting Public Safety. Violation of this Rule may be considered a license violation affecting public safety.

### **Basis and Purpose – 3-220**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), 44-10-203(2)(e), and 29-2-114(8)(a), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(IV). The purpose of this rule is to ensure adequate control of the Licensed Premises and Regulated Marijuana contained therein. This rule establishes the minimum guidelines for security requirements for alarm systems and commercial locking mechanisms for maintaining adequate security. This rule also establishes fencing and lighting requirements for outdoor cultivations. This Rule 3-220 was previously Rules M and R 305, 1 CCR 212-1 and 1 CCR 212-2.

### **3-220 – Security Alarm Systems and Lock Standards**

- A. Security Alarm Systems – Minimum Requirements. The following Security Alarm Systems and lock standards apply to all Regulated Marijuana Businesses, unless stated otherwise by these rules.
1. Each Licensed Premises shall have a Security Alarm System, installed by an Alarm Installation Company, on all perimeter entry points and perimeter windows.
  2. Each Licensee must ensure that all of its Licensed Premises are continuously monitored. Licensees may engage the services of a Monitoring Company to fulfill this requirement.

3. A Licensee shall maintain up-to-date and current records and existing contracts on the Licensed Premises that describe the location and operation of each Security Alarm System, a schematic of security zones, the name of the Alarm Installation Company, and the name of any Monitoring Company. See Rule 3-905 – Business Records Required.
4. Upon request, Licensees shall make available to agents of the Division or relevant Local Licensing Authority or Local Jurisdiction or state or local law enforcement agency, for a purpose authorized by the Marijuana Code or for any other state or local law enforcement purpose, all information related to Security Alarm Systems, Monitoring, and alarm activity.
5. Any outdoor or Greenhouse Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility is a Limited Access Area and must meet all of the requirements for Security Alarm Systems described in this Rule. An outdoor or Greenhouse Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility must provide sufficient security measures to demonstrate that outdoor areas are not readily accessible by unauthorized individuals. It shall be the responsibility of the Licensee to maintain physical security in a manner similar to a Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility located in an indoor Limited Access Area so it can be fully secured and alarmed. The fencing requirements shall include, at a minimum, perimeter fencing designed to prevent the general public from entering the Limited Access Areas and shall meet at least the following minimum requirements:
  - a. The entire Limited Access Area shall be surrounded by a fence constructed of nine gauge or lower metal chain link fence or another similarly secure material. The fence shall measure at least eight feet from the ground to the top, or in the alternative, the fence may measure six feet from the ground to the top with a 1 foot barbed wire arm with at least three strands along the entire fence. All support posts shall be steel and securely anchored.
  - b. All gates of ingress or egress shall measure at least eight feet from the ground to the top of the entry gate, or in the alternative, the gate may measure six feet from the ground to the top with a 1 foot barbed wire arm with at least three strands, and shall be constructed of nine gauge or lower metal chain link fence or a similarly secure material.
  - c. The fence shall obscure the Limited Access Area so that it is not easily viewed from outside the fence.
  - d. All areas of ingress and egress of the fence shall be illuminated including a 20 foot radius from the point of ingress or egress. The required lights may be, but are not required to be, motion sensing. See Rule 3-225(C).
  - e. A Licensee or Applicant for initial licensure may, in writing, request that the Division waive one or more of the security requirements described in this subparagraphs (a) through (d) of this Rule, by submitting on a form prescribed by the Division a security waiver request for Division approval. The Division may, in its discretion and on a case-by-case basis, approve the security waiver if it finds that the alternative safeguard proposed by the Licensee or Applicant for initial licensure meets the goals of the above security requirements or that the security requirements are in conflict with a local ordinance of general applicability. Approved security waivers expire at the same time as the underlying License and may be renewed at the time the License renewal application is submitted. The Licensee's or Applicant for initial licensure's request for a waiver shall include:
    - i. The specific rules and subsections of a rule that is requested to be waived;

- ii. The reason for the waiver;
- iii. A description of an alternative safeguard the Licensee will implement in lieu of the requirement that is the subject of the waiver; and
- iv. An explanation of how and why the alternative safeguard accomplishes the goals of the security rules, specifically public safety, prevention of diversion, accountability, and prohibiting access to minors.

**B. Lock Standards – Minimum Requirement**

- 1. At all points of ingress and egress, the Licensee shall ensure the use of a commercial-grade, non-residential door locks.
- 2. Any outdoor or Greenhouse Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility must meet all of the requirements for the lock standards described in this Rule.

**Basis and Purpose – 3-225**

The statutory authority for this rule includes but is not limited to sections 44-10-203(2)(h), 44-10-203(1)(j), 44-10-203(2)(e), and 44-10-1001, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VI). The purpose of this rule is to ensure adequate control of the Licensed Premises and Regulated Marijuana contained therein. This rule also establishes the minimum guidelines for security requirements for video surveillance systems for maintaining adequate security. This Rule 3-225 was previously Rules M and R 306, 1 CCR 212-1 and 1 CCR 212-2.

**3-225 – Video Surveillance**

**A. Minimum Requirements. The following video surveillance requirements shall apply to all Regulated Marijuana Businesses, unless stated otherwise in these rules.**

- 1. Prior to exercising the privileges of a Regulated Marijuana Business, 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 secure area that is only accessible to a Licensee’s management staff.
- 3. Video surveillance records and recordings must be made available upon request to the Division, the relevant Local Licensing Authority or Local Jurisdiction, or any other state or local law enforcement agency for a purpose authorized by the Marijuana Code or for any other state or local law enforcement purpose.
- 4. Video surveillance records and recordings of point-of-sale areas shall be held in confidence by all employees and representatives of the Division, except that the Division may provide such records and recordings to the Local Licensing Authority or Local Jurisdiction, or any other state or local law enforcement agency for a purpose authorized by the Marijuana Code, 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, video monitors, digital archiving devices, and a color printer capable of delivering still photos.

2. All video surveillance systems must be 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. Licensees are responsible for ensuring that all surveillance equipment is properly functioning and maintained, so that the playback quality is suitable for viewing and the surveillance equipment is capturing the identity of all individuals and activities in the monitored areas.
4. All video surveillance equipment shall have sufficient battery backup to support a minimum of four hours of recording in the event of a power outage. Licensee must notify the Division of any loss of video surveillance capabilities that extend beyond four hours.

C. Placement of Cameras and Required Camera Coverage.

1. Camera coverage is required for all areas identified as Restricted Access Areas or Limited Access Areas, point-of-sale areas, security rooms, all points of ingress and egress to Limited Access Areas, all areas where Regulated Marijuana is displayed for sale, and all points of ingress and egress to the exterior of the Licensed Premises.
2. Camera placement shall be capable of identifying activity occurring within 20 feet of all points of ingress and egress and shall allow for the clear and certain identification of any individual and activities on the Licensed Premises.
3. At each point-of-sale location, camera coverage must enable recording of the patients, caregivers or consumer(s), and employee(s) facial features with sufficient clarity to determine identity.
4. All entrances and exits to the facility shall be recorded from both indoor and outdoor vantage points.
5. The system shall be capable of recording all pre-determined surveillance areas in any lighting conditions. If the Licensed Premises has a Regulated Marijuana cultivation area, a rotating schedule of lighted conditions and zero-illumination can occur as long as ingress and egress points to Flowering areas remain constantly illuminated for recording purposes.
6. Areas where Regulated Marijuana is grown, tested, cured, manufactured, researched, or stored shall have camera placement in the room facing the primary entry door at a height which will provide a clear unobstructed view of activity without sight blockage from lighting hoods, fixtures, or other equipment.
7. Cameras shall also be placed at each location where weighing, packaging, transport preparation, processing, or tagging activities occur.
8. At least one camera must be dedicated to record the access points to the secured surveillance recording area.
9. All outdoor cultivation areas must meet the same video surveillance requirements applicable to any other indoor Limited Access Areas.

D. Location and Maintenance of Surveillance Equipment.

1. The surveillance room or surveillance area shall be a Limited Access Area.
2. Surveillance recording equipment must be housed in a designated, locked, and secured room or other enclosure with access limited to authorized employees, agents of the Division, and the relevant Local Licensing Authority or Local Jurisdiction, state or local law enforcement agencies for a purpose authorized by the Marijuana Code or for any other state or local law enforcement purpose, and service personnel or contractors.
3. Licensees must keep a current list of all authorized employees and service personnel who have access to the surveillance system and/or room on the Licensed Premises. 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.
4. Off-site Monitoring and video recording storage of the areas identified in this Rule 3-225(C) 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.
5. Each Regulated Marijuana Business Licensed Premises located in a common or shared building, or commonly owned Regulated Marijuana Businesses located in the same Local Jurisdiction, must have a separate surveillance room/area that is dedicated to that specific Licensed Premises. Commonly-owned Regulated Marijuana Businesses located in the same Local Jurisdiction may have one central surveillance room located at one of the commonly owned Licensed Premises which simultaneously serves all of the commonly-owned Licensed Premises. The facility that does not house the central surveillance room is required to have a review station, printer, and map of camera placement on the premises. All minimum requirements for equipment and security standards as set forth in this section apply to the review station.
6. Licensed Premises that combine both a Medical Marijuana Business and a Retail Marijuana Business may have one central surveillance room located at the shared Licensed Premises. See Rule 3-215 – Regulated Marijuana Businesses: Shared Licensed Premises and Operational Separation.

E. Video Recording and Retention Requirements.

1. All camera views of all Limited Access Areas must be continuously recorded 24 hours a day. The use of motion detection is authorized when a Licensee can demonstrate that monitored activities are adequately recorded.
2. All surveillance recordings must be kept for a minimum of 40 days and be in a format that can be easily accessed for viewing. Video recordings must be archived in a format that ensures authentication of the recording as legitimately-captured video and guarantees that no alteration of the recorded image has taken place.
3. The Licensee's surveillance system or equipment must have the capabilities to produce a color still photograph from any camera image, live or recorded, of the areas identified in this Rule 3-225(C).
4. The date and time must be embedded on all surveillance recordings without significantly obscuring the picture. The date and time must be synchronized with any point-of-sale system.



5. 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/timezone.cgi?Mountain/d/-7/java>.
6. After the 40 day surveillance video retention schedule has lapsed, surveillance video recordings must be erased or destroyed prior to: sale or transfer of the facility or business to another Licensee; or being discarded or disposed of for any other purpose. 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.

F. Other Records.

1. All records applicable to the surveillance system shall be maintained on the Licensed Premises. At a minimum, Licensees shall maintain a map of the camera locations, direction of coverage, camera numbers, surveillance equipment maintenance activity log, user authorization list, and operating instructions for the surveillance equipment.
2. A chronological point-of-sale transaction log must be made available to be used in conjunction with recorded video of those transactions.

**Basis and Purpose – 3-230**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), and 44-10-203(2)(h), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to establish waste disposal requirements for Regulated Marijuana Businesses. This Rule 3-230 was previously Rules M and R 307, 1 CCR 212-1 and 1 CCR 212-2.

**3-230 – Waste Disposal**

- A. All Applicable Laws Apply. Regulated Marijuana waste must be stored, secured, locked, and managed in accordance with all applicable federal, state, and local statutes, regulations, ordinances, or other requirements.
- B. Liquid Waste. Liquid waste from Regulated Marijuana Businesses shall be disposed of in compliance with all applicable federal, state and local laws, regulations, rules, and other requirements.
- C. Chemical, Dangerous and Hazardous Waste. Disposal of chemical, dangerous, or hazardous waste must be conducted in a manner consistent with federal, state and local laws, regulations, rules, and other requirements. This may include, but is not limited to, the disposal of all Pesticide or other agricultural chemicals, certain solvents or other chemicals used in the production of Regulated Marijuana Concentrate or any Regulated Marijuana soaked in a Flammable Solvent for purposes of producing a Regulated Marijuana Concentrate.
- D. Waste Must Be Made Unusable and Unrecognizable. Regulated Marijuana waste, excluding Fibrous Waste disposed of in accordance with Rule 3-235 and Marijuana Consumer Waste Transferred in accordance with Rule 3-240, must be made unusable and Unrecognizable prior to leaving the Licensed Premises.
- E. Methods to Make Waste Unusable and Unrecognizable. Regulated Marijuana waste shall be rendered unusable and Unrecognizable through one of the following methods:

1. Grinding or compacting and incorporating the marijuana waste with non-consumable, solid wastes listed below such that the resulting mixture is at least 50 percent non-marijuana waste, and such that the resulting mixture cannot easily be separated and sorted:
    - a. Paper waste;
    - b. Plastic waste;
    - c. Cardboard waste;
    - d. Food waste;
    - e. Grease or other compostable oil waste;
    - f. Bokashi or other compost activators;
    - g. Soil;
    - h. Sawdust; and
    - i. Other wastes approved by the Division that will render the Regulated Marijuana waste unusable and Unrecognizable.
  2. Mobile Waste Rendering. A Licensee or a third party vendor may render marijuana waste unusable and Unrecognizable outside of the Licensed Premises for the purpose of depositing the waste at a composting or solid waste facility pursuant to paragraph F of this Rule. Use of such service must be in accordance with the following requirements:
    - a. The waste must be rendered unusable and Unrecognizable in accordance with subparagraph E of this Rule on property under the control of the Licensee that is immediately adjacent to the Licensed Premises;
    - b. The waste must be taken from the Licensed Premises by an Owner Licensee or Employee Licensee directly to the vehicle where the rendering will occur;
    - c. An Owner Licensee or Employee Licensee must monitor and observe the rendering to ensure the waste is made unusable and Unrecognizable;
    - d. Licensee shall ensure the rendering of any marijuana waste unusable and Unrecognizable by a third party is recorded on the Licensee's video surveillance system; and
    - e. Any other restrictions imposed by the Local Licensing Authority or Local Jurisdiction.
- F. After Waste is Made Unusable and Unrecognizable. Excluding Fibrous Waste disposed of in accordance with Rule 3-235 and Marijuana Consumer Waste Transferred in accordance with Rule 3-240, after the Regulated Marijuana waste is made unusable and Unrecognizable, then the rendered waste shall be disposed of as solid waste, as defined at 6 CCR 1007-2, Part 1. The solid waste shall be:
1. Disposed of at a solid waste site and disposal facility that has a Certificate of Designation from the local governing authority;

2. Deposited at a compost facility that is permitted or approved by the Colorado Department of Public Health and Environment; or
  3. Composted on-site at a facility owned by the generator of the waste and operated in compliance with the Regulations Pertaining to Solid Waste Sites and Facilities (6 CCR 1007-2, Part 1) in the Colorado Department of Public Health and Environment.
  4. These waste rules are in addition to, not in lieu of, those solid waste rules as established and enforced by the Colorado Department of Public Health and Environment at 6 CCR 1007-2, Part 1.
- G. Proper Disposal of Waste. A Licensee shall only dispose of Regulated Marijuana waste in a secured waste receptacle in possession and control of the Licensee.
- H. Inventory Tracking Requirements.
1. In addition to all other tracking requirements set forth in these rules, a Licensee shall utilize the Inventory Tracking System to ensure its post-harvest waste and Fibrous Waste materials are identified, weighed, and tracked while on the Licensed Premises until disposed of.
  2. All Regulated Marijuana waste must be weighed before leaving any Regulated Marijuana Business. A scale used to weigh Regulated Marijuana waste prior to entry into the Inventory Tracking System shall be tested and approved in accordance with section 35-14-127, C.R.S. See Rule 3-805 – Regulated Marijuana Businesses: Inventory Tracking System.
  3. A Licensee is required to maintain accurate and comprehensive records regarding waste material that accounts for, reconciles, and evidences all waste activity related to the disposal of Regulated Marijuana. See Rule 3-905 – Business Records Required.
  4. A Licensee is required to maintain accurate and comprehensive records regarding any waste material produced through the trimming or pruning of a Regulated Marijuana plant prior to harvest, which must include weighing and documenting all waste, including Fibrous Waste. Unless required by an Inventory Tracking System procedure, records of waste produced prior to harvest must be maintained on the Licensed Premises. Waste, excluding Fibrous Waste and Marijuana Consumer Waste, whether produced prior or subsequent to harvest, must be disposed of in accordance with this Rule and be made unusable and Unrecognizable. See Rule 3-235 – Transfers of Fibrous Waste and Rule 3-240 – Collection of Marijuana Consumer Waste.

### **Basis and Purpose – 3-235**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(2)(h), 44-10-203(2)(i), 44-10-203(1)(j), and 44-10-203(2)(x), C.R.S. The purpose of this rule is to establish conditions under which a Licensee is authorized to Transfer Fibrous Waste to a Person for the purpose of producing only Industrial Fiber Products. This Rule 3-235 was previously Rules M and R 307.5, 1 CCR 212-1 and 1 CCR 212-2.

### **3-235 – Transfers of Fibrous Waste**

- A. All Applicable Laws Apply. Fibrous Waste must be stored and managed in accordance with all applicable state and local statutes, regulations, ordinances, or other requirements.

- B. Medical Marijuana Cultivation Facilities, Medical Marijuana Products Manufacturers, Retail Marijuana Cultivation Facilities, and Retail Marijuana Products Manufacturers may Transfer Fibrous Waste to an Industrial Fiber Products Producer in accordance with the requirements of this Rule 3-235.
- C. Contract Requirements. Medical Marijuana Cultivation Facilities, Medical Marijuana Products Manufacturers, Retail Marijuana Cultivation Facilities, and Retail Marijuana Products Manufacturers that Transfer Fibrous Waste to an Industrial Fiber Products Producer shall enter into a written contract prior to Transferring any Fibrous Waste.
1. The written contract must be complete, and must fully incorporate all terms and conditions.
  2. The written contract shall include the following terms:
    - a. The identity of the Industrial Fiber Products Producer;
    - b. A requirement that the Industrial Fiber Products Producer shall be and shall remain in good standing with the Colorado Secretary of state during the contract term; and
    - c. A requirement that the Industrial Fiber Products Producer shall ensure the security of Fibrous waste during transport from the Licensed Premises to the point of processing by the Industrial Fiber Products Producer.
  3. The Licensee and Industrial Fiber Products Producer shall sign an affirmation that the Fibrous Waste is being Transferred only for the purpose of producing Industrial Fiber Products, which may be incorporated as part of a purchase order, invoice, or manifest.
- D. Business Records. Medical Marijuana Cultivation Facilities, Medical Marijuana Products Manufacturers, Retail Marijuana Cultivation Facilities, and Retail Marijuana Products Manufacturers that Transfer Fibrous Waste to an Industrial Fiber Products Producer shall keep all contracts, receipts, and inventory records relating to the Transfer of any Fibrous Waste in accordance with Rule 3-905, including but not limited to Rule 3-905(A)(2).
- E. Security Measures.
1. Medical Marijuana Cultivation Facilities, Medical Marijuana Products Manufacturers, Retail Marijuana Cultivation Facilities, and Retail Marijuana Products Manufacturers that Transfer Fibrous Waste to an Industrial Fiber Products Producer shall comply with all security requirements pursuant to Rules 3-220 and 3-225.
  2. Medical Marijuana Cultivation Facilities, Medical Marijuana Products Manufacturers, Retail Marijuana Cultivation Facilities, and Retail Marijuana Products Manufacturers preparing Fibrous Waste for Transfer to an Industrial Fiber Products Producer must separate Fibrous Waste from other Regulated Marijuana plant material and waste within the Limited Access Area and on video surveillance.
  3. Medical Marijuana Cultivation Facilities, Medical Marijuana Products Manufacturers, Retail Marijuana Cultivation Facilities, and Retail Marijuana Products Manufacturers shall physically segregate all Fibrous Waste from other waste and Regulated Marijuana.
  4. Medical Marijuana Cultivation Facilities, Medical Marijuana Products Manufacturers, Retail Marijuana Cultivation Facilities, and Retail Marijuana Products Manufacturers shall affix a label to all receptacles holding Fibrous Waste that has already been separated

from other Regulated Marijuana plant material and waste within the Limited Access Area prior to Transfer to an Industrial Fiber Products Producer. The label must identify the receptacle as “Contains Fibrous Waste.”

5. An Industrial Fiber Products Producer, or its employee or agent, must sign the visitor log, unless such individual has a valid Division-issued Employee License, to enter the Limited Access Area for any Transfer of Fibrous Waste.
  6. The Licensee remains responsible for all Fibrous Waste until the Industrial Fiber Products Producer takes possession and removes Fibrous Waste from the Licensed Premises.
  7. The Licensee shall ensure that only Fibrous Waste and waste that has been made unusable and Unrecognizable pursuant to Rule 3-320 is Transferred to the Industrial Fiber Products Producer.
- F. Inventory Tracking Requirements.
1. A Licensee shall utilize the Inventory Tracking System to ensure its post-harvest Fibrous Waste materials are identified, weighed, and tracked while on the Licensed Premises until Transferred.
  2. A scale used to weigh Fibrous Waste prior to entry into the Inventory Tracking System shall be tested and approved in accordance with section 35-14-127, C.R.S. See Rule 3-805 – Regulated Marijuana Business: Inventory Tracking System.
  3. A Licensee is required to maintain accurate and comprehensive records regarding waste material that accounts for, reconciles, and evidences all Fibrous Waste Transfers. See Rule 3-905 – Business Records Required.
- G. Medical Marijuana Cultivation Facilities, Medical Marijuana Products Manufacturers, Retail Marijuana Cultivation Facilities and Retail Marijuana Products Manufacturers shall not Transfer contaminated Fibrous Waste to an Industrial Fiber Products Producer and shall handle contaminated Fibrous Waste using the same reasonable protocols used to handle waste.
- H. Violation Affecting Public Safety. It may be considered a violation of public safety for a Licensee to Transfer anything to an Industrial Fiber Products Producer other than in accordance with this Rule 3-235.

### **Basis and Purpose – 3-240**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(h), and 44-10-203(2)(bb), C.R.S. The purpose of this rule is to establish conditions under which a Medical Marijuana Store, Retail Marijuana Store, and Licensed Hospitality Businesses are permitted to collect marijuana consumer waste for purposes of reuse and recycling.

### **3-240 – Collection of Marijuana Consumer Waste**

- A. All Applicable Laws Apply. Marijuana Consumer Waste must be stored and managed in accordance with all applicable state and local statutes, regulations, ordinances, or other requirements.
- B. Medical Marijuana Stores, Retail Marijuana Stores, and Licensed Hospitality Businesses may collect, reuse, and recycle Marijuana Consumer Waste in accordance with the requirements of this Rule 3-240.

C. Collection, Separation, and Processes.

1. Collection. A Licensee must comply with the following requirements when collecting Marijuana Consumer Waste pursuant to paragraph B of this Rule:
  - a. The Licensee utilizes receptacles that are sealed and designed to require specialized tools in order to open and access the contents of the receptacle;
  - b. All receptacles used for collection of Marijuana Consumer Waste shall be located within the Restricted Access Area or Consumption Area of the Licensed Premises and shall be reasonably supervised by a Licensee to ensure any Marijuana Consumer Waste collected is only removed by a Licensee;
  - c. All receptacles used for collection of Marijuana Consumer Waste shall be recorded on video surveillance; and
  - d. All receptacles used for collection of Marijuana Consumer Waste shall be labeled. The label must at least identify the receptacle as "Contains Marijuana Consumer Waste." A Licensee may choose to include additional information on the receptacle label.
2. Separation. Medical Marijuana Stores, Retail Marijuana Stores, and Licensed Hospitality Businesses must separate electronic and battery components from the Marijuana Consumer Waste.
3. Processes. Medical Marijuana Stores, Retail Marijuana Stores, and Licensed Hospitality Businesses must establish standard operating procedures that ensure at a minimum any remaining Regulated Marijuana in Marijuana Consumer Waste is removed and destroyed to the extent practicable. A Licensee may remove and destroy any remaining Regulated Marijuana within either the Restricted Access Area or the Limited Access Area of the Licensed Premises.

D. Transfers of Marijuana Consumer Waste.

1. Once any remaining Regulated Marijuana has been removed and destroyed, a Licensee may Transfer Marijuana Consumer Waste to another Regulated Marijuana Business for purposes of further processing and recycling; or
2. Medical Marijuana Stores, Retail Marijuana Stores, and Licensed Hospitality Businesses may Transfer Marijuana Consumer Waste, excluding the electronic components and battery components, to a Person for purposes of recycling. Such Person shall be registered as required by the Colorado Department of Public Health and Environment's regulations at 6 CCR 1007-2, Part 1, Section 8; or
3. Medical Marijuana Stores, Retail Marijuana Stores, and Licensed Hospitality Businesses may Transfer the electronic and battery components of Marijuana Consumer Waste to a Person for purposes of recycling in accordance with the Colorado Department of Public Health and Environment's regulations at 6 CCR 1007-3.

- E. Business Records. Medical Marijuana Stores, Retail Marijuana Stores, and Licensed Hospitality Businesses that collect and Transfer Marijuana Consumer Waste for recycling shall keep all contracts, standard operating procedures, and receipts relating to the collection and Transfer of any Marijuana Consumer Waste in accordance with Rule 3-905, including but not limited to Rule 3-905(A)(2).

- F. Violation Affecting Public Safety. It may be considered a violation affecting public safety for a Licensee to Transfer Marijuana Consumer Waste that has remaining Regulated Marijuana and in a manner other than in accordance with this Rule 3-240.

### **Basis and Purpose – 3-245**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), 44-10-203(2)(dd)(XIII), 44-10-609(1), 44-10-610(1), and 44-10-301(3)(b) C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(f). The purpose of this rule is to establish hours of operation requirements for Regulated Marijuana Businesses. The State Licensing Authority modeled this rule after the Colorado Department of Revenue's liquor rules. This Rule 3-245 was previously Rules M and R 308, 1 CCR 212-1 and 1 CCR 212-2.

### **3-245 – Selling and Serving Regulated Marijuana – Hours of Operation**

A. Hours of Operation.

1. Medical Marijuana Stores and Retail Marijuana Stores shall not sell or serve Regulated Marijuana between the hours of 12:00 a.m. and 8:00 a.m., Mountain Time, Monday through Sunday.
2. Retail Marijuana Hospitality and Sales Businesses shall not sell Retail Marijuana or permit the consumption or use of Retail Marijuana on its Licensed Premises, between the hours of 2:00 a.m. and 7:00 a.m., Mountain Time, Monday through Sunday.
3. Marijuana Hospitality Businesses shall not permit the consumption or use of marijuana on its Licensed Premises, between the hours of 2:00 a.m. and 7:00 a.m., Mountain Time, Monday through Sunday.
4. Regulated Marijuana Businesses with a valid delivery permit shall not make or complete deliveries of Regulated Marijuana at any time between the hours of 12:00 a.m. and 8:00 a.m., Mountain Time, Monday through Sunday. Regulated Marijuana Businesses with a valid delivery permit may accept orders for delivery 24 hours a day, Monday through Sunday.

- B. Local Jurisdictions May Further Restrict Hours. Nothing in this Rule shall prohibit a Local Jurisdiction from further restricting hours of operation within its jurisdiction.

### **3-300 Series – Health and Safety Regulations**

#### **Basis and Purpose – 3-305**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), 44-10-203(3)(f), and 44-10-1001(2), C.R.S. The purpose of this rule is to clarify the conditions under which a Regulated Marijuana Business may be subject to an inspection of its Licensed Premises by a county or municipal employee, specifically but not exclusively a fire safety inspection.

#### **3-305 – Local Safety Inspections**

A Regulated Marijuana Businesses may be subject to inspection of its Licensed Premises by the local fire department, building inspector, or code enforcement officer to confirm that no health or safety concerns are present. The inspection could result in additional specific standards to meet Local Jurisdiction restrictions related to Regulated Marijuana or other local businesses. An annual fire safety inspection may result in the required installation of fire suppression devices, or other means necessary for adequate fire safety

### **Basis and Purpose – 3-310**

The statutory authority for this rule includes but is not limited to sections 44-10-203(1)(j), 44-10-203(2)(g), 44-10-203(2)(h), and 44-10-203(2)(i), C.R.S. The purpose of this rule is to clarify the minimum health and sanitary conditions under which a Regulated Marijuana Business must maintain its Licensed Premises.

### **3-310 – General Sanitary Requirements**

- A. The Licensee shall take all reasonable measures and precautions to ensure the following:
1. That any person 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 Marijuana shall be excluded from any operations which may be expected to result in contamination until the condition is corrected;
  2. That 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;
  3. That all persons working in direct contact with Regulated Marijuana shall conform to 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 production of Regulated Marijuana Product, and at any other time when the hands may have become soiled or contaminated; and
    - c. Refraining from having direct contact with Regulated Marijuana 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 corrected.
  4. That litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where Regulated Marijuana are exposed;
  5. That 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;
  6. That there is adequate lighting in all areas where Regulated Marijuana is stored or sold, and where equipment or utensils are cleaned;
  7. That the Licensee provides adequate screening or other protection against the entry of pests. Rubbish shall be disposed of so as to minimize the development of odor and minimize the potential for the waste becoming an attractant, harborage, or breeding place for pests;
  8. That any buildings, fixtures, and other facilities are maintained in a sanitary condition, including but not limited to the prevention of microorganism growth;



9. That 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 Marijuana and in a manner that is in accordance with any applicable local, state or federal law, rule, regulation, or ordinance;
10. That all operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of Regulated Marijuana shall be conducted in accordance with adequate sanitation principles;
11. That each Regulated Marijuana Business provides its employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair; and
12. That Regulated Marijuana that can support the rapid growth of undesirable microorganisms are held in a manner that prevents the growth of these microorganisms.

### **Basis and Purpose – 3-315**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(1)(g), 44-10-203(2)(g), 44-10-203(2)(h), 44-10-203(2)(i), and 44-10-1001(2), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). It sets forth general standards and basic sanitary requirements for Retail Marijuana Stores. It covers the physical premises where the products are made as well as the individuals handling the products. This rule authorizes the State Licensing Authority to require an independent consultant to conduct a health and sanitary audit of a Regulated Marijuana Business. The purpose of this rule is to establish the conditions under an independent health and safety audit may be required. This rule explains when an independent health and sanitary audit may be deemed necessary and sets forth possible consequences of a Regulated Marijuana Businesses refusal to cooperate or pay for the audit. The State Licensing Authority intends for this rule to reduce any product contamination, which will benefit both the Licensees and consumers. The State Licensing Authority modeled this rule after those adopted by the Colorado Department Revenue for Medical Marijuana and those adopted by the Colorado Department of Public Health and Environment. Overall, the State Licensing Authority intends this rule to help maintain the integrity of Colorado's Retail Marijuana businesses and the safety of the public.

### **3-315 – Independent Health and Safety Audit**

#### **A. State Licensing Authority May Require A Health and Sanitary Audit.**

1. When the State Licensing Authority determines a health and sanitary audit by an independent consultant is necessary, it may require a Regulated Marijuana Business to undergo such an audit. The scope of the audit may include, but need not be limited, to whether the Regulated Marijuana Business is in compliance with the requirements set forth in this Rule and other applicable health, sanitary, or food handling laws, rules, and regulations.
2. In such instances, the Division may attempt to mutually agree upon the selection of the independent consultant with a Regulated Marijuana Business. However, the Division always retains the authority to select the independent consultant regardless of whether mutual agreement can be reached.
3. The Regulated Marijuana Business will be responsible for all costs associated with the independent health and sanitary audit.

- B. When Independent Health and Sanitary Audit Is Necessary. The State Licensing Authority has discretion to determine when an audit by an independent consultant is necessary. The following is a non-exhaustive list of examples that may justify an independent audit:
1. The Division has reasonable grounds to believe that the Regulated Marijuana Business is in violation of one or more of the requirements set forth in this Rule or other applicable public health or sanitary laws, rules, or regulations;
  2. The Division has reasonable grounds to believe that the Regulated Marijuana Business was the cause or source of contamination of Regulated Marijuana;
  3. A Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility does not provide requested records related to the use of Pesticide or other agricultural chemicals used in the cultivation process;
  4. Multiple Harvest Batches or Production Batches produced by a Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility failed contaminant testing;
  5. A Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer does not provide requested records related to the production of Regulated Marijuana Products, including but not limited to, certification of its Licensed Premises, equipment or standard operating procedures, food handling training required for Owner Licensees and Employee Licensees engaged in the production of Regulated Marijuana Products, or Production Batch specific records to the Division;
  6. Multiple Production Batches of Regulated Marijuana Products produced by the Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer failed contaminant testing.
- C. Compliance Required. A Regulated Marijuana Business must pay for and timely cooperate with the State Licensing Authority's requirement that it undergo an independent health and sanitary audit in accordance with this Rule.
- D. Suspension of Operations.
1. If the State Licensing Authority has objective and reasonable grounds to believe and finds upon reasonable ascertainment of the underlying facts that the public health, safety, or welfare imperatively requires emergency action and incorporates such findings into its order, it may order summary suspension of the Regulated Marijuana Business's license. See Rule 8-210 – Disciplinary Process: Summary Suspensions.
  2. Prior to or following the issuance of such an order, the Regulated Marijuana Business may attempt to come to a mutual agreement with the Division to suspend its operations until the completion of the independent audit and the implementation of any required remedial measures.
    - a. If an agreement cannot be reached or the State Licensing Authority, in its sole discretion, determines that such an agreement is not in the best interests of the public health, safety, or welfare, then the State Licensing Authority will promptly institute license suspension or revocation procedures. See Rule 8-210 – Disciplinary Process: Summary Suspensions.
    - b. If an agreement to suspend operations is reached, then the Regulated Marijuana Business may continue to care for its inventory and conduct any necessary internal business operations, but it may not Transfer any Regulated Marijuana or

Regulated Marijuana Product to another Regulated Marijuana Business, a patient, or a consumer during the period of time specified in the agreement

### **Basis and Purpose – 3-320**

The statutory authority for this rule includes but is not limited to sections 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(d), 44-10-203(2)(g), 44-10-203(2)(h), 44-10-203(2)(dd)(X), and 44-10-203(3)(c), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). This rule prohibits a Regulated Marijuana Business from Transferring any contaminated Regulated Marijuana or Regulated Marijuana Product to any Person or another Regulated Marijuana Business.

### **3-320 – Contaminated Product**

A Regulated Marijuana Business shall not accept or Transfer to any Person any Regulated Marijuana that has failed required testing pursuant to Rule 4-120 or Rule 4-125, unless otherwise permitted in these rules. See Rule 4-135(B)(3) and (C)(3). If, despite the prohibitions in these rules, another Regulated Marijuana Business Transfers any Regulated Marijuana that has failed or subsequently fails required testing pursuant to Rule 4-120 or Rule 4-125, the receiving Regulated Marijuana Business shall ensure that all Regulated Marijuana that failed required testing are safely disposed of in accordance with Rule 3-230.

### **Basis and Purpose – 3-325**

The statutory authority for this rule includes but is not limited to sections 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(d), 44-10-203(2)(g), 44-10-203(2)(h), 44-10-203(2)(dd)(X), and 44-10-203(3)(c), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to clarify that a Regulated Marijuana Business engaged in the cultivation of Regulated Marijuana is prohibited from using certain chemicals or pesticides that may cause harm to employees or consumers.

### **3-325 – Prohibited Chemicals**

- A. Applicability. This Rule 3-325 applies to Medical Marijuana Cultivation Facilities, Retail Marijuana Cultivation Facilities, and Marijuana Research and Development Licensees.
- B. The following chemicals are prohibited and shall not be used in Regulated Marijuana cultivation. Possession of chemicals and/or containers from these chemicals upon the Licensed Premises shall be a violation of this Rule. Additionally, possession of Regulated Marijuana or Regulated Marijuana Concentrate on which any of the following chemicals is detected shall constitute a violation of this Rule.
  1. Any Pesticide the use of which would constitute a violation of the Pesticide Act, section 35-9-101 *et seq.*, C.R.S., the Pesticide Applicators' Act, section 35-10-101 *et seq.*, C.R.S., or the rules and regulations pursuant thereto.
  2. Other chemicals (listed by chemical name and CAS Registry Number (or EDF Substance ID)):
    - ALDRIN  
309-00-2
    - ARSENIC OXIDE (3)  
1327-53-3

ASBESTOS (FRIABLE)

1332-21-4

AZODRIN

6923-22-4

1,4-BENZOQUINONE, 2,3,5,6-TETRACHLORO-

118-75-2

BINAPACRYL

485-31-4

2,3,4,5-BIS (2-BUTENYLENE) TETRAHYDROFURFURAL

126-15-8

BROMOXYNIL BUTYRATE

EDF-186

CADMIUM COMPOUNDS

CAE750

CALCIUM ARSENATE [2ASH3O4.2CA]

7778-44-1

CAMPHECHLOR

8001-35-2

CAPTAFOL

2425-06-1

CARBOFURAN

1563-66-2

CARBON TETRACHLORIDE

56-23-5

CHLORDANE

57-74-9

CHLORDECONE (KEPONE)

143-50-0

CHLORDIMEFORM

6164-98-3

CHLOROBENZILATE

510-15-6

CHLOROMETHOXYPROPYLMERCURIC ACETATE [CPMA] EDF-

183

COPPER ARSENATE

10103-61-4

2,4-D, ISOOCTYL ESTER

25168-26-7

DAMINOZIDE

1596-84-5

DDD

72-54-8

DDT

50-29-3

DI(PHENYLMERCURY)DODECENYLSUCCINATE [PMDS] EDF-

187

1,2-DIBROMO-3-CHLOROPROPANE (DBCP)

96-12-8

1,2-DIBROMOETHANE

106-93-4

1,2-DICHLOROETHANE

107-06-2

DIELDRIN

60-57-1

4,6-DINITRO-O-CRESOL

534-52-1

DINITROBUTYL PHENOL

88-85-7

ENDRIN

72-20-8

EPN

2104-64-5

ETHYLENE OXIDE

75-21-8

FLUOROACETAMIDE

640-19-7

GAMMA-LINDANE

58-89-9

HEPTACHLOR

76-44-8

HEXACHLOROBENZENE

118-74-1

1,2,3,4,5,6-HEXACHLOROCYCLOHEXANE (MIXTURE OF ISOMERS)

608-73-1

1,3-HEXANEDIOL, 2-ETHYL-

94-96-2

LEAD ARSENATE

7784-40-9

LEPTOPHOS

21609-90-5

MERCURY

7439-97-6

METHAMIDOPHOS

10265-92-6

METHYL PARATHION

298-00-0

MEVINPHOS

7786-34-7

MIREX

2385-85-5

NITROFEN

1836-75-5

OCTAMETHYLDIPHOSPHORAMIDE

152-16-9

PARATHION

56-38-2

PENTACHLOROPHENOL

87-86-5

PHENYLMERCURIC OLEATE [PMO]

EDF-185

PHOSPHAMIDON

13171-21-6

PYRIMINIL

53558-25-1

SAFROLE

94-59-7

SODIUM ARSENATE

13464-38-5

SODIUM ARSENITE

7784-46-5

2,4,5-T

93-76-5

TERPENE POLYCHLORINATES (STROBANE6)

8001-50-1

THALLIUM(I) SULFATE

7446-18-6

2,4,5-TP ACID (SILVEX)

93-72-1

TRIBUTYLTIN COMPOUNDS

EDF-184

2,4,5-TRICHLOROPHENOL

95-95-4

VINYL CHLORIDE

75-01-4

- C. DMSO. The use of Dimethylsulfoxide (DMSO) in the production of Regulated Marijuana shall be prohibited and the possession of DMSO upon the Licensed Premises is prohibited.

**Basis and Purpose – 3-330**

The statutory authority for this rule includes but is not limited to sections 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(d), 44-10-203(2)(g), 44-10-203(2)(h), 44-10-203(2)(i), 44-10-203(3)(c), 44-10-203(3)(e), and 44-10-1001, C.R.S. The purpose of this rule is to clarify the minimum health and safety requirements imposed on a Medical or Retail Marijuana Cultivation Facility. The State Licensing Authority has determined the cultivation of Medical or Retail Marijuana requires the application of processes and procedures, and the use of materials, chemicals, and pesticides which, if improperly used, may be potentially harmful to employees and consumers. Therefore, the cultivation of Medical or Retail Marijuana must be performed in a manner that reduces the likelihood of exposure to such materials, chemicals and pesticides, or other microbials or molds. The State Licensing Authority intends for this rule to reduce any product contamination, which will benefit both the Licensees and consumers. The State Licensing Authority modeled this rule after those adopted by the Colorado Department Revenue for Medical Marijuana and those adopted by the Colorado Department of Public Health and Environment. Overall, the State Licensing Authority intends this rule to help maintain the integrity of Colorado's Retail Marijuana businesses and the safety of the public.

**3-330 – Cultivation of Regulated Marijuana: Specific Health and Safety Requirements**

- A. Additional Sanitary Requirements. In addition to the general sanitary requirements in Rule 3-310, a Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility shall take all reasonable measure and precautions to ensure the following:
1. That all contact surfaces, including utensils and equipment used for the preparation of Regulated Marijuana, Water-Based Medical Marijuana Concentrate, or Water-Based Retail Marijuana Concentrate shall be cleaned and sanitized as frequently as necessary to protect against contamination. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable and shall be properly



maintained. Only sanitizers and disinfectants registered with the Environmental Protection Agency shall be used in a Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility;

2. That the water supply shall be sufficient for the operations intended and shall be derived from a source that is a regulated water system. Private water supplies shall be derived from a water source that is capable of providing a safe, potable, and adequate supply of water to meet the Licensed Premises' needs. Reclaimed water may also be used only for the cultivation of Regulated Marijuana to the extent authorized under the Reclaimed Water Control Regulations (5 CCR 1002-84), and subject to approval of the Water Quality Control Division of the Colorado Department of Public Health and Environment and the local water provider;
  3. That plumbing shall be of adequate size and design and adequately installed and maintained to carry sufficient quantities of water to required locations throughout the plant and that shall properly convey sewage and liquid disposable waste from the Licensed Premises. There shall be no cross-connections between the potable water, reclaimed water, and waste water lines; and
  4. That any room used for the cultivation of Regulated Marijuana has measures to prevent the accumulation of dangerous levels of CO<sub>2</sub>.
- B. Pesticide Application. A Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility may only use Pesticide in accordance with the "Pesticide Act" sections 35-9-101 et seq., C.R.S., the "Pesticides Applicators' Act," sections 35-10-101 et seq., C.R.S., and all other applicable federal, state, and local laws, statutes, rules and regulations. This includes, but shall not be limited to, the prohibition on detaching, altering, defacing or destroying, in whole or in part, any label on any Pesticide. The Colorado Department of Agriculture's determination that the Licensee used any quantity of a Pesticide that would constitute a violation of the Pesticide Act or the Pesticide Applicators' Act shall constitute prima facie evidence of a violation of this Rule.
- C. Application of Other Agricultural Chemicals. A Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility may only use agricultural chemicals, other than a Pesticide, in accordance with all applicable federal, state, and local laws, statutes, rules, and regulations.
- D. Required Documentation.
1. Standard Operating Procedures. A Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility must establish written standard operating procedures for the cultivation, harvesting, drying, curing, trimming, packaging, storing, and sampling for testing of Regulated Marijuana, and the processing, packaging, storing, and sampling for testing of Regulated Marijuana Concentrate. A copy of all standard operating procedures must be maintained on the Licensed Premises of the Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility.
    - a. The standard operating procedures must include when, and the manner in which, all Pesticide and other agricultural chemicals are to be applied during its cultivation process.
    - b. The standard operating procedures must also include any methods and processes related to decontamination of Harvest Batches.
  2. Material Change. If a Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility makes a Material Change to its cultivation procedures, it must

document the change and revise its standard operating procedures accordingly. Records detailing the Material Change must be maintained on the relevant Licensed Premises.

3. Safety Data Sheet. A Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility must obtain a safety data sheet for any Pesticide or other agricultural chemical used or stored on its Licensed Premises. A Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility must maintain a current copy of the safety data sheet for any Pesticide or other agricultural chemical on the Licensed Premises where the product is used or stored.
  4. Labels of Pesticide and Other Agricultural Chemicals. A Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility must have the original label or a copy thereof at its Licensed Premises for all Pesticide and other agricultural chemicals used during its cultivation process.
  5. Pesticide Application Documentation. A Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility that applies any Pesticide or other agricultural chemical to any portion of a Regulated Marijuana plant, water, or feed used during cultivation or generally within the Licensed Premises must document, and maintain a record on its Licensed Premises of, the following information:
    - a. The name, signature, and Employee License number of the individual who applied the Pesticide or other agricultural chemical;
    - b. Applicator certification number if the applicator is licensed through the Department of Agriculture in accordance with the "Pesticides Applicators' Act," sections 35-10-101 et seq., C.R.S.;
    - c. The date and time of the application;
    - d. The EPA registration number of the Pesticide or CAS number of any other agricultural chemical(s) applied;
    - e. Any of the active ingredients of the Pesticide or other agricultural chemical(s) applied;
    - f. Brand name and product name of the Pesticide or other agricultural chemical(s) applied;
    - g. The restricted entry interval from the product label of any Pesticide or other agricultural chemical(s) applied;
    - h. The RFID tag number of the Regulated Marijuana plant(s) that the Pesticide or other agricultural chemical(s) was applied to or if applied to all plants, a statement to that effect; and
    - i. The total amount of each Pesticide or other agricultural chemical applied.
- E. Adulterants. A Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility may not treat or otherwise adulterate Regulated Marijuana with any chemical or other compound whatsoever to alter its color, appearance, weight, or smell.

#### **Basis and Purpose – 3-335**

The statutory authority for this rule includes but is not limited to sections 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(2)(g), 44-10-203(2)(h), 44-10-203(2)(i), 44-10-202(2)(y), 44-10-203(3)(b), 44-10-203(3)(c), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-203(3)(g), and 44-10-1001, C.R.S. The State Licensing Authority has determined the manufacturing of Medical or Retail Marijuana Infused Products involves the application of processes and procedures, materials, chemicals, and additives, which, if improperly applied, may cause harm to employees and consumers. Therefore, the purpose of this Rule is to clarify the minimum and specific health and safety requirements imposed on a Medical or Retail Marijuana Products Manufacturing Facility. This Rule clarifies which Edible Medical or Retail Marijuana Products, due to their specific composition, are *per se* practicable to mark with the Universal Symbol but exempts certain Liquid Products from the Universal Symbol requirements. Additionally, the Rule imposes manufacturing and production requirements (e.g. prohibiting products from being shaped like fruit or humans), identifies the standard THC portion, prohibits licensees from using commercial food products to remanufacture Medical or Retail Marijuana Products, and prohibits the use of toxic additives.

### **3-335 – Production of Regulated Marijuana Concentrate and Regulated Marijuana Products: Specific Health and Safety Requirements**

#### **A. Training.**

1. Prior to engaging in the manufacture of any Edible Medical Marijuana Product or Edible Retail Marijuana Product each Owner Licensee or Employee Licensee must:
  - a. Have a currently valid ServSafe Food Handler Certificate obtained through the successful completion of an online assessment or print exam; or
  - b. Take a food safety course that includes basic food handling training and is comparable to, or is a course given by, the Colorado State University extension service or a state, county, or district public health agency, and must maintain a status of good standing in accordance with the course requirements, including attending any additional classes if necessary. Any course taken pursuant to this rule must last at least two hours and cover the following subjects:
    - i. Causes of foodborne illness, highly susceptible populations and worker illness;
    - ii. Personal hygiene and food handling practices;
    - iii. Approved sources of food;
    - iv. Potentially hazardous foods and food temperatures;
    - v. Sanitization and chemical use; and
    - vi. Emergency procedures (fire, flood, sewer backup).
2. A Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer must obtain documentation evidencing that each Owner Licensee or Employee Licensee has successfully completed the examination or course required by this Rule and is in good standing. A copy of the documentation must be kept on file at any Licensed Premises where that Owner Licensee or Employee Licensee is engaged in the manufacturing of an Edible Medical Marijuana Product or Edible Retail Marijuana Product.

- B. A Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer that manufactures Edible Medical Marijuana Products or Edible Retail Marijuana Products shall comply with all kitchen-related health and safety standards of the relevant Local Licensing Authority or Local Jurisdiction and, to the extent applicable, with all Colorado Department of Public Health and Environment health and safety regulations applicable to retail food establishments, as set forth in 6 CCR 1010-2.
- C. Additional Sanitary Requirements. A Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer shall take all reasonable measures and precautions to ensure the following:
1. That there is sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations for production of Regulated Marijuana or Regulated Marijuana Products;
  2. That all contact surfaces, including utensils and equipment used for the preparation of Regulated Marijuana or Regulated Marijuana Product, shall be cleaned and sanitized as frequently as necessary to protect against contamination. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable and shall be properly maintained. Only sanitizers and disinfectants registered with the Environmental Protection Agency shall be used by a Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer, and used in accordance with labeled instructions;
  3. That the water supply shall be sufficient for the operations intended and shall be derived from a source that is a regulated water system. Private water supplies shall be derived from a water source that is capable of providing a safe, potable, and adequate supply of water to meet the Licensed Premises needs;
  4. That plumbing shall be of adequate size and design and adequately installed and maintained to carry sufficient quantities of water to required locations throughout the plant and that shall properly convey sewage and liquid disposable waste from the Licensed Premises. There shall be no cross-connections between the potable and waste water lines; and
  5. That storage and transport of finished Regulated Marijuana Product shall be under conditions that will protect products against physical, chemical, and microbial contamination as well as against deterioration of any Container.
- D. Product Safety.
1. A Medical Marijuana Products Manufacturer that manufactures Edible Medical Marijuana Product, or a Retail Marijuana Products Manufacturer that manufactures Edible Retail Marijuana Product, shall create and maintain standard production procedures and detailed manufacturing processes for each Edible Medical Marijuana Product or Edible Retail Marijuana Product it manufactures. These procedures and processes must be documented and made available on the Licensed Premises for inspection by the Division, the Colorado Department of Public Health & Environment, and local licensing authorities.
  2. Universal Symbol Marking Requirements.
    - a. The following categories of Edible Medical Marijuana Products and Edible Retail Marijuana Products are considered to be per se practicable to mark, and shall be marked, stamped, or otherwise imprinted with the Universal Symbol directly on the Regulated Marijuana Product:

- i. Chocolate;
  - ii. Soft confections;
  - iii. Hard confections or lozenges;
  - iv. Consolidated baked goods (e.g. cookie, brownie, cupcake, granola bar);
  - v. Pressed pills and capsules.
- b. The Universal Symbol marking shall:
- i. Be marked, stamped, or otherwise imprinted on at least one side of the Edible Medical Marijuana Product or Edible Retail Marijuana Product;
  - ii. Be centered either horizontally or vertically on the Edible Medical Marijuana Product or Edible Retail Marijuana Product;
  - iii. If centered horizontally on the Edible Medical Marijuana Product or Edible Retail Marijuana Product, the height and width of the Universal Symbol shall be of a size that is at least 25% of the product's height, but not less than ¼ inch by ¼ inch.
  - iv. If centered vertically on the Edible Medical Marijuana Product or Edible Retail Marijuana Product, the height and width of the Universal Symbol shall be of a size that is at least 25% of the product's height, but not less than ¼ inch by ¼ inch.
- c. The following categories of Edible Medical Marijuana Product and Edible Retail Marijuana Product are considered to be per se impracticable to mark with the Universal Symbol marking requirements, provided that they comply with labeling and Container requirements of 3-1000 Series Rules.
- i. Loose bulk goods (e.g. granola, cereals, popcorn);
  - ii. Powders;
  - iii. Liquid Edible Medical Marijuana Products;
  - iv. Liquid Edible Retail Marijuana Products.

3. Medical Marijuana Products Manufacturer Specific Requirements.

- a. Standard Portion of THC. A Medical Marijuana Products Manufacturer may determine a standard portion of THC for each Edible Medical Marijuana Product it manufactures. If a Medical Marijuana Products Manufacturer determines a standard portion for an Edible Medical Marijuana Product, that information must be documented in the product's standard production procedure.
- b. Documentation. For each Edible Medical Marijuana Product, the total amount of active THC contained within the product must be documented in the standard production procedures.
- c. If a Medical Marijuana Products Manufacturer elects to determine standard portions for an Edible Medical Marijuana Product, then the Universal Symbol

shall be applied to each portion in accordance with the requirements of subparagraph (D)(2)(b) of this Rule 3-335. Except that the size of the Universal Symbol marking shall be determined by the size of the portion instead of the overall product size and shall not be less than ¼ inch by ¼ inch.

4. Retail Marijuana Products Manufacturer Specific Requirements.
  - a. Standardized Serving of Marijuana. The size of a Standardized Serving of Marijuana shall be no more than 10mg of active THC. A Retail Marijuana Products Manufacturer that manufactures Edible Retail Marijuana Product shall determine the total number of Standardized Servings of Marijuana for each product that it manufactures. No individual Edible Retail Marijuana Product unit packaged for Transfer to a consumer shall contain more than 100 milligrams of active THC.
  - b. Documentation. The following information must be documented in the standard production procedures for each Edible Retail Marijuana Product: the amount in milligrams of Standardized Serving of Marijuana, the total number of Standardized Servings of Marijuana, and the total amount of active THC contained within the product.
  - c. Notwithstanding the requirement of subparagraph (D)(2)(b), an Edible Retail Marijuana Product shall contain no more than 10 mg of active THC per Container and the Retail Marijuana Products Manufacturer must ensure that the product is packaged in accordance with the Rules 3-1005(C)(1) and 1010(D)(1), when:
    - i. The Edible Retail Marijuana Product is of the type that is impracticable to mark, stamp, or otherwise imprint with the Universal Symbol directly on the product in a manner to cause the Universal Symbol to be distinguishable and easily recognizable; or
    - ii. The Edible Retail Marijuana Product is of the type that is impracticable to clearly demark each Standardized Serving of Marijuana or to make each Standardized Serving of Marijuana separable.
  - d. Liquid Edible Retail Marijuana Product.
    - i. Pursuant to 44-10-603(4)(b), C.R.S., Liquid Edible Retail Marijuana Products are impracticable to mark with the Universal Symbol and are exempt from the provision in subparagraph (D)(4)(c) of this Rule 3-335 that requires Edible Retail Marijuana Products that are impracticable to mark with the Universal Symbol to contain 10mg or less active THC per Container.
    - ii. This exemption permits the manufacture and Transfer of Multi-Serving Liquid Edible Retail Marijuana Products so long as the product is packaged in accordance with Rules 3-1005(C)(1) and 3-1010(D)(1)(c)(ii).
  - e. Multiple-Serving Edible Retail Marijuana Product.
    - i. A Retail Marijuana Products Manufacturer must ensure that each single Standardized Serving of Marijuana of a Multiple-Serving Edible Retail Marijuana Product is physically demarked in a way that enables a reasonable person to intuitively determine how much of the product constitutes a single serving of active THC.

- ii. Each demarked Standardized Serving of Marijuana must be easily separable in order to allow an average person 21 years of age and over to physically separate, with minimal effort, individual servings of the product.
- iii. Each single Standardized Serving of Marijuana contained in a Multiple-Serving Edible Retail Marijuana Product shall be marked, stamped, or otherwise imprinted with the Universal Symbol directly on the product in a manner to cause the Universal Symbol to be distinguishable and easily recognizable. The Universal Symbol marking shall comply with the requirements of subparagraph (D)(2)(b) of this Rule 3-335.
- iv. A Multiple-Serving Edible Retail Marijuana Product that is a Liquid Edible Retail Marijuana Product shall comply with the requirements in subparagraph (D)(4)(d)(ii) of this Rule 3-335 and is exempt from subparagraphs (i)-(iii) of this subparagraph (D)(4)(e)(iv).

E. Remanufactured Products Prohibited. A Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer shall not utilize a commercially manufactured food product as its Edible Medical Marijuana Product or Edible Retail Marijuana Product. The following exceptions to this prohibition apply:

- 1. A food product that was commercially manufactured specifically for use by the Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer Licensee to infuse with marijuana shall be allowed. The Licensee shall have a written agreement with the commercial food product manufacturer that declares the food product's exclusive use by the Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer.
- 2. Commercially manufactured food products may be used as Ingredients in an Edible Medical Marijuana Product or Edible Retail Marijuana Product so long as: (1) they are used in a way that renders them unrecognizable as the commercial food product in the final Edible Medical Marijuana Product or Edible Retail Marijuana Product, and (2) the Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer does not state or advertise to the consumer that the final Edible Medical Marijuana Product or Edible Retail Marijuana Product contains the commercially manufactured food product.

F. Trademarked Food Products. Nothing in this Rule alters or eliminates a Medical Marijuana Products Manufacturer's or Retail Marijuana Products Manufacturer's responsibility to comply with the trademarked food product provisions required by the Marijuana Code per section 44-10-503(9)(a-c), C.R.S.

G. Edibles Prohibited that are Shaped like a Human, Animal, or Fruit.

- 1. The production, Transfer, and donation of Edible Medical Marijuana Products or Edible Retail Marijuana Products in the following shapes is prohibited:
  - i. The distinct shape of a human, animal, or fruit; or
  - ii. A shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings.

2. The prohibition on human, animal, and fruit shapes does not apply to the logo of a licensed Regulated Marijuana Business. Nothing in this subparagraph (G)(2) alters or eliminates a Licensee's obligation to comply with the requirements of the 3-1000 Series Rules – Labeling, Packaging, and Product Safety.
3. Edible Medical Marijuana Products and Edible Retail Marijuana Products that are geometric shapes and simply fruit flavored are not considered fruit and are permissible; and
4. Edible Medical Marijuana Products and Edible Retail Marijuana Products that are manufactured in the shape of a marijuana leaf are permissible.

H. Inactive Ingredients.

1. Only non-cannabis derived inactive Ingredients listed in the Federal Food and Drug Administration Inactive Ingredient Database <https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm>, or approved by another equivalent international government agency, may be used in the manufacture of Audited Product and Regulated Marijuana Concentrate intended for use through a Vaporizer Delivery Device or Pressurized Metered Dose Inhaler.
2. All non-cannabis derived inactive Ingredients contained in any Audited Product or in any Regulated Marijuana Concentrate intended for use through a Vaporizer Delivery Device or Pressurized Metered Dose Inhaler must be less than or equal to the concentration listed in the Federal Food and Drug Administration Inactive Ingredient Database, or approved by another equivalent international government agency for:
  - a. The inhalation route of administration for any Audited Product to be used in a metered dose nasal spray, or any Regulated Marijuana Concentrate to be used in a Vaporizer Delivery Device or pressurized metered dose inhaler;
  - b. The vaginal route of administration for any Audited Product to be used for vaginal administration; or
  - c. The rectal route of administration for any Audited Product to be used for rectal administration.

I. Other Permitted Ingredients. Nothing in paragraph H above prohibits a Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer from using marijuana-derived ingredients or botanically-derived terpenes and/or terpenoids.

J. Standard Operating Procedures.

1. A Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer must have written standard operating procedures for each category and type of Medical Marijuana Product or Retail Marijuana Product that it produces.
  - a. All standard operating procedures for the production of a Medical Marijuana Concentrate or Retail Marijuana Concentrate must follow the requirements in Rules 5-315 and 6-315.
  - b. A copy of all standard operating procedures must be maintained on the Licensed Premises of the Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer.



2. If a Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer makes a Material Change to its standard Medical Marijuana Product production process or Retail Marijuana Product production process, it must document the change and revise its standard operating procedures accordingly. Records detailing the Material Change must be maintained on the relevant Licensed Premises.
- K. Additives. A Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer shall not include any Additive that is toxic within a Regulated Marijuana Product; nor include any Additive for the purposes of making the product more addictive, appealing to children, or misleading to patients or consumers.
- L. Prohibited Ingredients. A Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer shall not use the following Ingredients in the production of Regulated Marijuana Concentrate and Regulated Marijuana Product for which the inhaled product is the intended use in accordance with Rule 3-1015:
1. Polyethylene glycol (PEG);
  2. Vitamin E Acetate; and
  3. Medium Chain Triglycerides (MCT Oil).
- M. DMSO. The use of Dimethylsulfoxide (DMSO) in the production of Regulated Marijuana Product shall be prohibited and possession of DMSO upon the Licensed Premises is prohibited.

### **Basis and Purpose – 3-340**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(b)-(c), 44-10-203(1)(j), 44-10-203(2)(l), 44-10-203(2)(m), and 44-10-901(1), C.R.S. The purpose of this Rule is to clarify that a Regulated Marijuana Businesses failure to comply with the requirements of 3-300 Rules Series may jeopardize the public health and safety.

### **3-340 – Violation Affecting Public Safety**

A violation of these 3-300 Rules may be considered a license violation affecting public safety.

### **3-400 Series – Acceptable Forms of Identification for Regulated Marijuana Sales**

#### **Basis and Purpose – 3-405**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), 44-10-203(2)(v), 44-10-203(2)(z), 44-10-401(2)(a)(I), 44-10-401(2)(b)(I), 44-10-501(3)(b), 44-10-501(3)(c), 44-10-501(3)(d), 44-10-501(4), 44-10-501(10)(b)(II), 44-10-601(3)(b), 44-10-701(1)(b), 44-10-701(2)(a), 44-10-701(4)(a), and 44-10-701(5)(a), C.R.S. The purpose of this rule is to establish guidelines for the acceptable forms of identification for verifying the lawful sale of Regulated Marijuana. This Rule 3-405 was previously Rule M 405, 1 CCR 212-1, and Rule R 404, 1 CCR 212-2.

#### **3-405 – Identification**

- A. Medical Marijuana Transfers.
1. Necessary Identification. Medical Marijuana Stores may only Transfer Medical Marijuana to any patient or caregiver who is permitted to deliver Medical Marijuana to homebound patients or minor patients as permitted by section 25-1.5-106(9)(e), C.R.S., if the patient or caregiver can produce:

- a. Proof of identification that complies with subparagraphs (C) and (D) of this Rule; and
  - b. Either a valid patient registry card, including any valid and verified digital registry card, or a copy of a current and complete new application for the Medical Marijuana registry that is documented by proof of submittal to the Colorado Department of Public Health and Environment within the preceding 35 days.
2. Physical Inspection Required. A Licensee must physically view and inspect the patient or caregiver's registry card, including any valid and verified digital registry card, and proof of identification to confirm the information contained on the documents and also to judge the authenticity of the documents presented.
3. Valid and Verified Registry Card. For the purposes of these rules, a valid and verified digital registry card may include:
- a. A hard copy of the patient's registry card; or
  - b. A portable document format (PDF) of the patient's registry card presented on a phone or other portable device.
    - i. If a patient is presenting his or her registry card on a phone or other portable device, the PDF of the registry card must be presented.
    - ii. A screen shot of the patient's profile, text image of a blank card, or photo of the hard copy is unacceptable.
- B. Retail Marijuana Transfers. A Retail Marijuana Store or a Retail Marijuana Hospitality and Sales Business may only Transfer Retail Marijuana to a consumer that first produces a form of identification that complies with subparagraphs (C) and (D) of this Rule establishing the consumer is 21 years of age or older.
1. Fraudulent Identification and Licensee's Burden. Pursuant to section 44-10-601(3)(b)(I), C.R.S., if a person under 21 years of age present a fraudulent proof of age to a Retail Marijuana Store, any action based upon the fraudulent proof of age shall not be grounds for the revocation or suspension of a license. To establish that the identification presented by the minor was a fraudulent proof of age, the Licensee must establish that:
- a. The minor presented fraudulent identification of the type established in subparagraph (C) below;
  - b. During the transaction in which Retail Marijuana was Transferred to the minor, the Licensee inspected the identification provided, compared the identification to the person presenting the identification, and:
    - i. Inspected an identification book issued within the past three years;
    - ii. Used an electronic scanner;
    - iii. Used an ID checking software or other device used in the inspection of identification; or
    - iv. Used other ID security features.

- C. Forms of Valid Identification. If the identification presented to a Licensee contains a picture and date of birth, including any valid and verified digital identification, the kind and type of identification deemed adequate shall be limited to the following:
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 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.
- D. Identification Must Be Valid. A Licensee shall refuse the Transfer of Regulated Marijuana if a person produces identification that is invalid or expired.

### **3-500 Series – Responsible Vendor Program**

#### **Basis and Purpose – 3-505**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-12-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(v), 44-203(2)(dd)(II), 44-10-609(3)(b), 44-10-1201, and 44-10-1202, C.R.S. The purpose of this rule is to establish the standards for a Marijuana Store, Retail Marijuana Store, Medical Marijuana Transporter, Retail Marijuana Transporter, Marijuana Hospitality Businesses, and Retail Marijuana Hospitality and Sales Businesses to obtain and maintain a “responsible vendor” designation. This rule identifies Licensees required to attend the Approved Training Program and requirements to maintain a “responsible vendor” designation after initially being designated a “responsible vendor.” This Rule 3-505 was previously Rules M 408, 1 CCR 212-1, and R 407, 1 CCR 212-2.

#### **3-505 – General Standards for a Regulated Marijuana Business Designated A Responsible Vendor**

- A. Pursuant to section 44-10-1202, C.R.S., a Medical Marijuana Store, Retail Marijuana Store, Medical Marijuana Transporter, Retail Marijuana Transporter, or Licensed Hospitality Business shall comply with the 3-500 Series Rules to be designated a “responsible vendor” of Regulated Marijuana.
- B. To be designated a “responsible vendor” all Controlling Beneficial Owners with day-to-day operational control of the Licensed Premises, management personnel, and Employee Licensees involved in the handling and Transfer of Regulated Marijuana shall attend and successfully complete an Approved Training Program.
- C. Once a Licensee is designated a “responsible vendor,” all new employees involved in the handling and Transfer of Regulated Marijuana shall successfully complete the training described in these 3-500 Series Rules within 90 days of hire.
- D. After initial successful completion of a responsible vendor program, each Controlling Beneficial Owner with day-to-day operational control of the Licensed Premises, management personnel,

and Employee Licensee of a Regulated Marijuana Business shall successfully complete the program once every two years thereafter to maintain designation as a “responsible vendor.”

### **Basis and Purpose – 3-510**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-12-203(1)(c), 44-10-203(2)(v), and 44-10-203(1)(j), 44-10-1201, 44-10-1202, C.R.S. The purpose of this rule is to establish general application and notification requirements for Responsible Vendor Program Providers. This Rule 3-510 was previously Rules M 408, 1 CCR 212-1, and R 407, 1 CCR 212-2.

### **3-510 – General Standards for Responsible Vendor Program Provider**

- A. An application for approval of a responsible vendor program pursuant to section 44-10-1201 or 44-10-1202, C.R.S., shall be made upon current forms prescribed by the Division and in accordance with the 2-200 Series Rules.
- B. Changes to an Approved Program. Within 30 days of any changes to the Marijuana Code, or these rules, a Responsible Vendor Program Provider shall update its responsible vendor program curriculum with any such changes.

### **Basis and Purpose – 3-515**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-12-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(v), 44-203(2)(dd)(II), 44-10-609(3)(b), 44-10-1201, and 44-10-1202, C.R.S. The purpose of this rule is to provide the general standards for an Approved Training Program including the minimum amount of instruction time required, that the training must be provided in a classroom setting which may be virtual or online and the testing and passing score requirements for successful completion of the Approved Training Program. This Rule 3-515 was previously Rules M 408, 1 CCR 212-1, and R 407, 1 CCR 212-2.

### **3-515 – Certification Training Program Standards**

- A. No owner or employee of a responsible vendor program may have an Owner’s Interest in a Regulated Marijuana Business.
- B. A Responsible Vendor Program Provider shall submit their responsible vendor program for approval every two years in order to maintain designation as a Responsible Vendor Program Provider . The renewal application must be submitted within 60 days of the expiration of the Approved Training Program.
- C. The responsible vendor program shall include at least two hours of instruction time.
- D. Classroom setting. The responsible vendor program shall be taught in a classroom setting where the instructor is able to verify the identification of each individual attending the responsible vendor program and certify completion of the responsible vendor program by the individual identified.
  - 1. An Approved Training Program may be delivered in an on-line or virtual based classroom setting provided the Responsible Vendor Program Provider utilizes a learning management system or other means to verify the identification of each individual attending the responsible vendor program. For purposes of this Rule, a learning management system means the platform or database used to monitor participation, attendance, and to deliver core-curriculum materials.

2. Any Approved Training Program delivered in an on-line or virtual based classroom setting must comply with the core curriculum and assessment requirements of Rule 3-520.
- E. The Responsible Vendor Program Provider shall maintain its training records in a format that is readily understood by a reasonably prudent business person during the applicable year and for the following three years. The Responsible Vendor Program Provider shall make the records available for inspection by the State Licensing Authority upon request during normal business hours.
  - F. The responsible vendor program shall provide to the Licensee written or electronic documentation of attendance and successful passage of a test on the knowledge of the required curriculum for each attendee.
    1. Successful completion of an Approved Training Program requires a minimum passage score of 70% or better. A Responsible Vendor Program Provider may provide a reasonable testing accommodation or modification to a Licensee participant, provided the results of the test are documented and meet the minimum passing score requirement.
  - G. A Responsible Vendor Program Provider shall solicit effectiveness evaluations from individuals who have completed the Approved Training Program.

### **Basis and Purpose – 3-520**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-12-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(v), 44-203(2)(dd)(II), 44-10-609(3)(b), 44-10-1201, and 44-10-1202, C.R.S. The purpose of this rule is to establish the required curriculum for an Approved Training Program. This rule also includes the required additional curriculum for Licensees engaged in delivery activity pursuant to a valid delivery permit and employees and Controlling Beneficial Owners of a Licensed Hospitality Businesses. This Rule 3-520 was previously Rules M 408, 1 CCR 212-1, and R 407, 1 CCR 212-2.

### **3-520 – Certification Training Class Core Curriculum**

When considering whether to approve a responsible vendor program, the Division, after consulting with the Colorado Department of Public Health and Environment, will consider the following criteria.

- A. Discussion concerning the health and safety concerns of marijuana use. Training shall include:
  1. Health effects of marijuana use, including but not limited to the effects in connection with pregnancy and breast-feeding;
  2. The amount of time to feel impairment based on the type of marijuana or marijuana product;
  3. Recognizing signs of impairment;
  4. The amount of time to wait before driving after marijuana use based on the type of marijuana or marijuana product;
  5. Safe storage of marijuana;
  6. Responsible use of marijuana; and
  7. Appropriate responses in the event of unintentional or over-consumption of marijuana or marijuana product, including but not limited to access to the appropriate resources provided by state and local public health authorities.

- B. Transfers to minors. Training shall cover all pertinent Colorado statutes, rules, and regulations.
- C. Quantity Limitations on Transfer to Patients and Consumers. Training shall cover all pertinent Colorado statutes, rules, and regulations.
- D. Acceptable Forms of Identification. Training shall include:
1. How to check identification;
  2. Spotting false identification;
  3. Patient Registry Cards issued by the Colorado Department of Public Health and Environment and equivalent patient verification documentation;
  4. Provisions for confiscating false identification; and
  5. Common mistakes made in verification.
- E. Other Key State Laws and Rules That Apply to Medical Marijuana Stores, Medical Marijuana Transporters, Retail Marijuana Stores, Retail Marijuana Transporters Licensed Hospitality Businesses, and their Owners, Management Personnel, and Employees. Training shall include:
1. Local and state licensing and enforcement;
  2. Compliance with all Inventory Tracking System regulations;
  3. Administrative and criminal liability;
  4. License sanctions and court sanctions;
  5. Waste handling, management, and disposal;
  6. Health and safety standards;
  7. Patrons prohibited from bringing marijuana onto licensed premises;
  8. Permitted hours of sale;
  9. Licensee security and surveillance requirements;
  10. Permitting inspections by state and local licensing and enforcement authorities;
  11. Licensee responsibility for activities occurring within licensed premises;
  12. Maintenance of records;
  13. Privacy issues;
  14. Applicable laws and regulations concerning Transfers to patients and consumers;
  15. Packaging and labeling requirements for Transfers to patients and consumers; and
  16. How to access the Medical Marijuana Patient Registry website and how to sign up for the Registry's voluntary email list.

- F. Evaluation of Program Participants. The Responsible Vendor Program Provider shall establish that it has an adequate mechanism for evaluating attendees' successful completion of the Approved Training Program.
- G. Additional Curriculum for Delivery to Patients and Consumers. In addition to the required curriculum in subparagraphs (B) through (F) above, training provided to any Licensee involved in activity pursuant to a valid delivery permit must also include all Colorado statutes and rules related to delivery of Regulated Marijuana to patients and consumers. Responsible Vendor Program Providers may provide the delivery curriculum as a separate training or as part of the core curriculum training. Licensees that do not engage in delivery activity are not required to, but may, complete the delivery training. Training provided to Licensees involved in delivery activity must include, but is not limited to:
1. Verification of identification and patient registry cards required before delivering Regulated Marijuana to a patient or consumer;
  2. Maintaining confidentiality of patients' and consumers' personally identifiable information;
  3. Methods for Licensees to identify themselves and verify the delivery permit during an interaction with law enforcement, Division employees or local regulators; and
  4. Strategies to de-escalate potentially dangerous situations which could include development of an emergency action plan.
- H. Additional Curriculum for Licensed Hospitality Businesses. In addition to the required curriculum in subparagraphs (B) through (F) above, training provided to Controlling Beneficial Owners of and any Licensee employed by a Licensed Hospitality Business must also include all Colorado statutes and rules related to Licensed Hospitality Businesses. Responsible Vendor Program Providers may provide the hospitality curriculum as a separate training or as part of the core curriculum training. Licensees that are not employed by a Licensed Hospitality Business are not required to, but may, complete the hospitality training. Training provided to Controlling Beneficial Owners of and employees of a Licensed Hospitality Business must include, but is not limited to:
1. Identifying signs of visible impairment including alcohol and drug impairment;
  2. Resources to mitigate impaired driving including safe transportation options available to consumers;
  3. Understanding customer's varying experience with Regulated Marijuana and options for lower dose Regulated Marijuana Products;
  4. Resources available from the Colorado Department of Public Health and Environment regarding responsible Regulated Marijuana use;
  5. Ceasing all consumption and other activities until law enforcement, firefighters, emergency medical service providers, or other public safety personnel have completed any investigation or services and left the Licensed Premises of the Licensed Hospitality Business;
  6. Methods for Licensees to identify themselves during an interaction with law enforcement, Division employees or local regulators;
  7. Poly-substance interactions including but not limited to interactions of Regulated Marijuana with alcohol, prescription and over-the-counter medications and other substances;

8. Risks and potential responses to adverse events such as overconsumption, altitude sickness, dehydration, poly-substance use or other similar events.
9. Strategies to de-escalate interactions with intoxicated consumers and potentially dangerous situations which could include development of an emergency action plan.

### **3-600 Series – Transport and Storage**

#### **Basis and Purpose – 3-605**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(h), 44-10-203(2)(n), 44-10-203(3)(c), 44-10-313(5)(b), 44-10-505, and 44-10-605 C.R.S. The purpose of the rule is to provide clarity as to the requirements associated with the transport and delivery of Regulated Marijuana between Licensed Premises. It also prescribes the manner in which licensed entities will track inventory in the transport process to prevent diversionary practices. This Rule 3-605 was previously Rules M and R 801, 1 CCR 212-1 and 1 CCR 212-2.

#### **3-605 – Transport: All Regulated Marijuana Businesses**

- A. Persons Authorized to Transport. Except as provided in the these 3-600 Series Rules, any individual who transports Regulated Marijuana, Regulated Marijuana Vegetative plants, Regulated Marijuana Immature plants, Regulated Marijuana, or Regulated Marijuana Product on behalf of a Regulated Marijuana Business must hold a valid Owner License or Employee License and must be an employee of the Regulated Marijuana Business. An individual who does not possess a current and valid Owner's License or Employee License from the State Licensing Authority may not transport Regulated Marijuana, Regulated Marijuana Vegetative plants, Regulated Marijuana Immature plants, Regulated Marijuana Concentrate, or Regulated Marijuana Product between Licensed Premises.
- B. Transport Between Licensed Premises.
  1. Regulated Marijuana. Regulated Marijuana shall only be transported by Licensees between Licensed Premises; between Licensed Premises and a permitted off-premises storage facility; between Licensed Premises and a Medical Research Facility; and between Licensed Premises and a Pesticide Manufacturer. Licensees transporting Regulated Marijuana are responsible for ensuring that all Regulated Marijuana are secured at all times during transport.
  2. Regulated Marijuana Vegetative Plants and Regulated Marijuana Immature Plants.
    - a. Regulated Marijuana Vegetative plants may only be transported between Licensed Premises and such transport shall only be permitted due to an approved change of location pursuant to Rule 2-255.
    - b. Regulated Marijuana Immature plants shall only be transported between Licensed Premises; between Licensed Premises and a Medical Research Facility; and between Licensed Premises and a Pesticide Manufacturer.
    - c. Licensees transporting Regulated Marijuana Vegetative plants and Regulated Marijuana Immature plants are responsible for ensuring that all Regulated Marijuana Vegetative plants and Regulated Marijuana Immature plants are secure at all times during transport. Transportation of Regulated Marijuana Vegetative plants and Regulated Marijuana Immature plants to a permitted off-premises storage facility shall not be allowed. Transport of Regulated Marijuana plants other than Vegetative Plants and Immature plants shall not be allowed.



- C. Inventory Tracking System-Generated Transport Manifest Required. A Licensee may only transport Regulated Marijuana if he or she has a copy of an Inventory Tracking System-generated transport manifest that contains all the information required by this Rule and shall be in the format prepared by the State Licensing Authority.
1. A Licensee may elect to use a hard copy or digital copy of an Inventory Tracking System-generated transport manifest. Licensees are required to ensure all information is preserved with valid and verified signatures on any digital copy of an Inventory Tracking System-generated transport manifest.
  2. Regulated Marijuana. A Licensee may transport Regulated Marijuana from an originating location to multiple destination locations so long as the transport manifest correctly reflects the specific inventory destined for specific Regulated Marijuana Businesses, Medical Research Facilities, and/or Pesticide Manufacturers.
  3. Regulated Marijuana Vegetative Plants. A Licensee shall transport Regulated Marijuana Vegetative plants only from the originating Licensed Premises to the destination Licensed Premises due to a change of location that has been approved by the Division pursuant to Rule 2-255.
  4. Manifest for Transfers to Medical Research Facilities and Pesticide Manufacturers. A Licensee may not transport or permit the transportation of Regulated Marijuana to a Medical Research Facility or Pesticide Manufacturer unless an Inventory Tracking System-generated transport manifest has been generated.
- D. Motor Vehicle Required. Transport of Regulated Marijuana shall be conducted by a motor vehicle that is properly registered in the state of Colorado pursuant to motor vehicle laws, but need not be registered in the name of the Licensee. Except that when a rental truck is required for transporting Regulated Marijuana Vegetative plants or Regulated Marijuana Immature plants, Colorado motor vehicle registration is not required.
- E. Documents Required During Transport. Transport of Regulated Marijuana shall be accompanied by a copy of the originating Regulated Marijuana Business's business license, the driver's valid Owner's License or Employee License, the driver's valid motor vehicle operator's license, and all required vehicle registration and insurance information.
- F. Use of Colorado Roadways. State law does not prohibit the transport of Regulated Marijuana on any public road within the state of Colorado as authorized in this Rule. However, nothing herein authorizes a Licensee to violate specific local ordinances or resolutions enacted by any city, town, city and county, or county related to the transport of Regulated Marijuana.
- G. Preparation of Regulated Marijuana for Transport.
1. Final Weighing and Packaging. A Regulated Marijuana Business shall comply with the specific rules associated with the final weighing and packaging of Regulated Marijuana before such items are prepared for transport pursuant to this Rule. The scale used to weigh product to be transported shall be tested and approved in accordance with measurement standards established in 35-14-127, C.R.S.
  2. Preparation in Limited Access Area. Regulated Marijuana shall be prepared for transport in a Limited Access Area, including the packaging and labeling of Containers or Shipping Containers.
  3. Shipping Containers. Licensees may Transfer multiple Containers of Regulated Marijuana in a Shipping Container. The contents of Shipping Containers shall be easily

accessible and may be inspected by the State Licensing Authority, Local Licensing Authorities, Local Jurisdictions, and state and local law enforcement agency for a purpose authorized by the Marijuana Code or for any other state or local law enforcement purpose.

- a. Licensees shall ensure that either the multiple Containers placed within a Shipping Container each have an RFID tag, or the Shipping Container itself must have an RFID tag. If the Licensee elects to place the RFID tag on the Shipping Container, the Shipping Container shall contain only one Harvest Batch, or Production Batch of Regulated Marijuana. If a Shipping Container consists of more than one Harvest Batch or Production Batch, then each group of multiple Containers shall be affixed with an RFID tag
- b. Regulated Marijuana Vegetative Plants and Regulated Marijuana Immature Plants. Each Regulated Marijuana Vegetative plant that is transported pursuant to this Rule must have a RFID tag affixed to it prior to transport. Each receptacle containing Regulated Marijuana Immature plants transported pursuant to this Rule must have an RFID tag affixed prior to transport.

#### H. Creation of Records and Inventory Tracking.

##### 1. Use of Inventory Tracking System – Generated Transport Manifest.

- a. Regulated Marijuana. Licensees who transport or permit the transportation of Regulated Marijuana shall create an Inventory Tracking System-generated transport manifest to reflect inventory that leaves the Licensed Premises destined for another Licensed Premises, Medical Research Facilities, or Pesticide Manufacturers. The transport manifest may either reflect multiple destination locations within a single trip or separate transport manifests may reflect each single destination location. In either case, no inventory shall be transported without an Inventory Tracking System-generated transport manifest.
- b. Use of a Medical Marijuana Transporter or Retail Marijuana Transporter. In addition to subparagraph (H)(1)(a), Licensees shall also follow the requirements of this subparagraph (H)(1)(b) when a Licensee utilizes the services of a Medical Marijuana Transporter or Retail Marijuana Transporter.
  - i. When a Medical Marijuana Business utilizes a Medical Marijuana Transporter for transporting its Medical Marijuana, the originating Licensee shall input the requisite information on the Inventory Tracking System-generated transport manifest for the final destination Licensee, Medical Research Facility, or Pesticide Manufacturer who will be receiving the Medical Marijuana.
  - ii. When a Retail Marijuana Business utilizes a Retail Marijuana Transporter for transporting its Retail Marijuana the originating Licensee shall input the requisite information on the Inventory Tracking System-generated transport manifest for the final destination Licensee, Medical Research Facility, or Pesticide Manufacturer who will be receiving the Retail Marijuana.
  - iii. A Medical Marijuana Transporter or Retail Marijuana Transporter is prohibited from being listed as the final destination Licensee.

- iv. A Medical Marijuana Transporter or Retail Marijuana Transporter shall not alter the information of the final destination Licensee, Medical Research Facility, or Pesticide Manufacturer after the information has been entered on the Inventory Tracking System-generated transport manifest by the Licensee.
  - v. If the Medical Marijuana Transporter or Retail Marijuana Transporter is not delivering the originating Licensee's Regulated Marijuana directly to the final destination Licensee, Medical Research Facility, or Pesticide Manufacturer, the Medical Marijuana Transporter or Retail Marijuana Transporter shall communicate to the originating Licensee which of the Medical Marijuana Transporter's or Retail Marijuana Transporter's Licensed Premises or off-premises storage facilities will receive and temporarily store the Regulated Marijuana. The originating Licensee shall input the Medical Marijuana Transporter's or Retail Marijuana Transporter's location address and license number on the Inventory Tracking System-generated transport manifest.
- c. Medical Marijuana Vegetative Plants and Retail Marijuana Vegetative Plants.
- i. Licensees who transport Medical Marijuana Vegetative or Retail Marijuana Vegetative plants shall create an Inventory Tracking System-generated transport manifest to reflect inventory that leaves the originating Licensed Premises to be transported to the destination Licensed Premises due to a change of location approved by the Division pursuant to Rule 2-255, or a one-time transfer pursuant to Rule 3-805.
  - ii. Retail Marijuana Transporters are permitted to transport Retail Marijuana Vegetative plants on behalf of other Licensees due to a change of location approved by the Division pursuant to Rule 2-255, or a one-time transfer pursuant to Rule 3-805. The Retail Marijuana Transporter shall transport the Retail Marijuana Vegetative Plants directly from the originating Licensed Premises to the final destination Licensed Premises.
  - iii. Medical Marijuana Transporters are permitted to transport Medical Marijuana Vegetative plants on behalf of other Licensees due to a change of location approved by the Division pursuant to Rule 2-255, or a one-time transfer pursuant to Rule 3-805. The Medical Marijuana Transporter shall transport the Medical Marijuana Vegetative plants directly from the originating Licensed Premises to the final destination Licensed Premises.
2. Copy of Transport Manifest to Recipient. A Licensee shall provide a copy of the transport manifest to each Regulated Marijuana Business, Medical Research Facility, or Pesticide Manufacturer receiving the inventory described in the transport manifest. In order to maintain transaction confidentiality, the originating Licensee may prepare a separate Inventory Tracking System-generated transport manifest for each recipient Regulated Marijuana Business, Medical Research Facility, or Pesticide Manufacturer.
3. The Inventory Tracking System-generated transport manifest shall include the following:
- a. Departure date and approximate time of departure;
  - b. Name, location address, and license number of the originating Regulated Marijuana Business;

- c. Name, location address, and license number of the destination Regulated Marijuana Business(es), name and location address of the Medical Research Facility, or name and location address of the destination Pesticide Manufacturer;
  - d. Name, location address, and license number of the Medical Marijuana Transporter or Retail Marijuana Transporter if applicable pursuant to Rule 3-605(H)(1)(b)(iv).
  - e. Product name and quantities (by weight and unit) of each product to be delivered to each specific destination location(s);
  - f. Arrival date and estimated time of arrival;
  - g. Transport vehicle make and model and license plate number; and
  - h. Name, Employee or Owner License number, and signature of the Licensee accompanying the transport.
- I. Inventory Tracking. In addition to all the other tracking requirements set forth in these rules, a Regulated Marijuana Business shall be responsible for all the procedures associated with the tracking of inventory that is transported between Licensed Premises. See Rule 3-905 – Business Records Required.
1. Responsibilities of Originating Licensee.
    - a. Regulated Marijuana. Prior to departure, the originating Regulated Marijuana Business shall adjust its records to reflect the removal of Regulated Marijuana. The scale used to weigh product to be transported shall be tested and approved in accordance with measurement standards established in 35-14-127, C.R.S. Entries to the records shall note the Inventory Tracking System-generated transport manifest and shall be easily reconciled, by product name and quantity, with the applicable transport manifest.
    - b. Regulated Marijuana Vegetative Plants and Regulated Marijuana Immature Plants. Prior to departure, the originating Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility shall adjust its records to reflect the removal of Medical Marijuana Vegetative plants and Medical Marijuana Immature plants, or Retail Marijuana Vegetative plants and Retail Marijuana Immature plants. Entries to the records shall note the Inventory Tracking System-generated transport manifest and shall be easily reconciled, by product name and quantity, with the applicable transport manifest.
  2. Responsibilities of Recipient Licensee.
    - a. Regulated Marijuana. Upon receipt, the receiving Licensee shall ensure that the Regulated Marijuana received are as described in the transport manifest and shall immediately adjust its records to reflect the receipt of inventory. The scale used to weigh product being received shall be tested and approved in accordance with measurement standards established in 35-14-127, C.R.S. Entries to the inventory records shall note the Inventory Tracking System-generated transport manifest and shall be easily reconciled, by product name and quantity, with the applicable transport manifest. Medical Marijuana Transporters and Retail Marijuana Transporters shall comply with all requirements of this subparagraph (I)(2)(a) except that they are not required to weigh Regulated Marijuana.

- i. When a Regulated Marijuana Business transfers Regulated Marijuana to a Medical Research Facility or Pesticide Manufacturer, the originating Licensee is responsible for confirming receipt of the Regulated Marijuana in the Inventory Tracking System.
  - b. Regulated Marijuana Vegetative Plants and Regulated Marijuana Immature Plants. Upon receipt, the recipient Licensee shall ensure that the Regulated Marijuana Vegetative plants received are as described in the transport manifest, accounting for all RFID tags and each associated plant, and shall immediately adjust its records to reflect the receipt of inventory. Upon Receipt, the recipient Licensee shall ensure that the Regulated Marijuana Immature plants received are as described in the transport manifest, accounting for all RFID tags and each receptacle containing Regulated Marijuana Immature plants, and shall immediately adjust its records to reflect the receipt of inventory.
    - i. When a Regulated Marijuana Business transfers Regulated Marijuana Immature plants to a Medical Research Facility or Pesticide Manufacturer, the originating Licensee is responsible for confirming receipt of the Retail Marijuana Immature plants in the Inventory Tracking System.
- 3. Discrepancies.
  - a. Licensees. A recipient Licensee shall separately document any differences between the quantity specified in the transport manifest and the quantities received. Such documentation shall be made in the Inventory Tracking System and in any relevant business records.
  - b. Medical Research Facilities and Pesticide Manufacturers. In the event of a discrepancy between the quantity specified in a transport manifest and the quantity received by a Medical Research Facility or Pesticide Manufacturer, the originating Licensee shall document the discrepancy in the Inventory Tracking System and in any relevant business records, and account for the discrepancy.
- J. Adequate Care of Perishable Regulated Marijuana Product. A Regulated Marijuana Business must provide adequate refrigeration for perishable Regulated Marijuana Product during transport.
- K. Failed Testing. In the event Regulated Marijuana has failed required testing, has been contaminated, or otherwise presents a risk of cross-contamination to other Regulated Marijuana, such Regulated Marijuana may only be transported if it is physically segregated and contained in a sealed package that prevents cross-contamination.

### **Basis and Purpose – 3-610**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(h), 44-10-203(2)(n), 44-10-505(2), 44-10-605(2), and 44-10-1001(2), C.R.S. The purpose of this rule is to establish that Regulated Marijuana may not be stored outside of Licensed Premises unless the Licensee obtains an off-premises storage facility permit. This Rule 3-610 was previously Rules M and R 802, 1 CCR 212-1 and 1 CCR 212-2.

### **3-610 – Off-Premises Storage of Regulated Marijuana: All Regulated Marijuana Businesses**

- A. Off-Premises Storage Permit Authorized.

1. A Medical Marijuana Store, Medical Marijuana Products Manufacturer, Medical Marijuana Cultivation Facility, Medical Marijuana Testing Facility may only store Medical Marijuana in their Limited Access Area or in their one permitted off-premises storage facility. Medical Marijuana Transporters are allowed to have more than one permitted off-premises storage facility.
  2. A Retail Marijuana Store, Retail Marijuana Products Manufacturer, a Retail Marijuana Cultivation Facility, and a Retail Marijuana Testing Facility may only store Retail Marijuana in their Limited Access Area or in their one permitted off-premises storage facility. Retail Marijuana Transporters are allowed to have more than one permitted off-premises storage facility.
- B. Permitting. To obtain a permit for an off-premises storage facility, a Regulated Marijuana Business must apply on current Division forms and pay any applicable fees.
1. A Medical Marijuana Transporter may only apply for and hold an off-premises storage permit in a local jurisdiction that permits the operation of Medical Marijuana Stores.
  2. A Retail Marijuana Transporter may only apply for and hold an off-premises storage permit in a Local Jurisdiction that permits the operation of Retail Marijuana Stores.
- C. Extension of Licensed Premises. A permitted off-premises storage facility shall constitute an extension of the Regulated Marijuana Business's Licensed Premises, subject to all applicable Regulated Marijuana regulations.
- D. Limitation on Inventory to be Stored.
1. A Medical Marijuana Store, Medical Marijuana Products Manufacturer, and a Medical Marijuana Cultivation Facility possessing a valid off-premises storage facility permit may only have upon the permitted off-premises storage facility Medical Marijuana that is part of the particular Medical Marijuana Business's finished goods inventory. The aforementioned Licensees may only share the premises with and store inventory belonging to, a Medical Marijuana Business that has identical Controlling Beneficial Owners. A Medical Marijuana Business shall not share an off-premises storage facility with a Retail Marijuana Business.
  2. A Retail Marijuana Store, Retail Marijuana Products Manufacturer, and a Retail Marijuana Cultivation Facility possessing a valid off-premises storage facility permit may only have upon the permitted off-premises storage facility Retail Marijuana that is part of the particular Retail Marijuana Business's finished goods inventory. The aforementioned Licensees may only share the premises with and store inventory belonging to a Retail Marijuana Business that has identical Controlling Beneficial Owners. A Retail Marijuana Business shall not share an off-premises storage facility with a Medical Marijuana Business.
- E. Privileges and Restrictions. The permitted off-premises storage facility may be utilized for storage only. A Regulated Marijuana Business must not Transfer, cultivate, manufacture, process, test, research, or consume any Regulated Marijuana within the premises of the permitted off-premises storage facility.
1. A Medical Marijuana Store or Retail Marijuana Store with a valid delivery permit may use its own off-premises storage facility to package, label, and fill orders for delivery of Regulated Marijuana to a patient or consumer after the Medical Marijuana Store or Retail Marijuana Store receives an order for delivery, unless otherwise restricted by the local jurisdiction.

2. A Medical Marijuana Transporter or Retail Marijuana Transporter shall not use its own off-premises storage facility to package, label, or fill orders for delivery of Regulated Marijuana to a patient or customer. A Medical Marijuana Transporter or a Retail Marijuana Transporter may use its own off-premises storage facility to store Regulated Marijuana that is packaged and labeled for delivery to a patient or consumer, unless otherwise restricted by the Local Licensing Authority or Local Jurisdiction.
- F. Display of Off-premises Storage Permit and License. The off-premises storage facility permit and a copy of the Regulated Marijuana Business's license must be displayed in a prominent place within the permitted off-premises storage facility.
- G. Local Licensing Authority or Local Jurisdiction Approval.
1. Prior to submitting an application for an off-premises storage facility permit, the Regulated Marijuana Business must obtain approval or acknowledgement from the relevant Local Licensing Authority or Local Jurisdiction.
  2. A copy of the relevant Local Licensing Authority's or Local Jurisdiction's approval or acknowledgement must be submitted by the Regulated Marijuana Business in conjunction with its application for an off-premises storage facility.
  3. No Regulated Marijuana may be stored within a permitted storage facility until the relevant Local Licensing Authority or Local Jurisdiction has been provided a copy of the off-premises storage facility permit.
  4. Any off-premises storage permit issued by the Division shall be conditioned upon the Regulated Marijuana Business's receipt of all required Local Jurisdiction approvals or acknowledgments.
- H. Security in Storage Facility. A permitted off-premises storage facility must meet all video, security and lock requirements applicable to a Licensed Premises. See Rules 3-220 – Security Alarm and Lock Standards and Rule 3-225 – Video Surveillance.
- I. Transport to and from a Permitted Off-Premises Storage Facility. A Licensee must comply with the provisions of Rule 3-605 – Transport: All Regulated Marijuana Businesses, when transporting any Regulated Marijuana to and from a permitted off-premises storage facility.
- J. Inventory Tracking. In addition to all the other tracking requirements set forth in these rules, a Regulated Marijuana Business shall utilize the Inventory Tracking System to track its inventories from the point of transfer to or from a permitted off-premises storage facility. See Rules 3-805 – All Regulated Marijuana Businesses: Inventory Tracking System and Rule 3-905 – Business Records Required.
- K. Inventory Tracking System Access and Scale. Every permitted off-premises storage facility must have an Inventory Tracking System terminal and a scale tested and approved in accordance with measurement standards established in section 35-14-127, C.R.S.
- L. Adequate Care of Perishable Regulated Marijuana Product. A Regulated Marijuana Business must provide adequate refrigeration for perishable Regulated Marijuana Product and shall utilize adequate storage facilities and transport methods.
- M. Consumption Prohibited. A Regulated Marijuana Business shall not permit the consumption of marijuana or marijuana product on the premises of its permitted off-premises storage facility.

#### **Basis and Purpose – 3-615**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(h), 44-10-203(2)(n), 44-10-203(2)(dd), C.R.S. The purpose of this rule is to provide requirements for a Medical Marijuana Store, Retail Marijuana Store, Medical Marijuana Transporter or Retail Marijuana Transporter to apply for and conduct deliveries to Private Residences pursuant to a delivery permit. This rule provides application and renewal requirements for a delivery permit. Additionally, the rule describes requirements for responsible vendor training, requirements for use of the inventory tracking system, Delivery Motor Vehicles requirements including security, requirements for delivery orders, requirements prior to completing a delivery to a patient or consumer at a Private Residence and requirements for maintaining the confidentiality of all patient and customer information.

### **3-615 – Regulated Marijuana Delivery Permits**

#### **A. Application, Qualification, and Eligibility for Delivery Permit.**

1. Beginning January 2, 2020, a Medical Marijuana Store may apply for a delivery permit. The application shall be made on Division forms and in accordance with the 2-200 Series Rules. The delivery permit application can be submitted simultaneously with a Medical Marijuana Store initial or renewal application or it can be separate from a Medical Marijuana Store application but the application must identify the Medical Marijuana Store(s) seeking to obtain the delivery permit.
2. Beginning January 2, 2021, a Retail Marijuana Store, a Medical Marijuana Transporter, and a Retail Marijuana Transporter may apply for a delivery permit. The delivery permit application can be submitted simultaneously with a Retail Marijuana Store, Medical Marijuana Transporter, or Retail Marijuana Transporter initial or renewal application or it can be separate from a Retail Marijuana Store, Medical Marijuana Transporter, or Retail Marijuana Transporter application but the application must identify the Retail Marijuana Store(s), Medical Marijuana Transporter(s), or Retail Marijuana Transporter(s) seeking to obtain the delivery permit.
3. Prior to the State Licensing Authority issuing an Applicant a delivery permit, the Applicant must establish the Local Licensing Authority and/or Local Jurisdiction where the Applicant is located:
  - a. By ordinance or resolution has permitted delivery of Regulated Marijuana in the jurisdiction, and
  - b. Is currently accepting applications for delivery permits in the jurisdiction, if required.
4. Multiple Medical Marijuana Stores, Retail Marijuana Stores, Medical Marijuana Transporters, or Retail Marijuana Transporters with identical Controlling Beneficial Owners that are in the same local jurisdiction may obtain one delivery permit that allows all Medical Marijuana Stores, all Retail Marijuana Stores, all Medical Marijuana Transporters, or all Retail Marijuana Transporters in that jurisdiction to make deliveries to patients or consumers.
5. Delivery Permit Renewal.
  - a. A delivery permit must be renewed annually with the Medical Marijuana Store, Retail Marijuana Store, Medical Marijuana Transporter, or Retail Marijuana Transporter license it accompanies. A Medical Marijuana Store or Retail Marijuana Store must disclose to the Division any online platform provider that the Licensee has utilized during the previous year at the time of renewal.



b. Length of Delivery Permit.

- i. A delivery permit issued with an initial or renewal license application is valid for one year and will expire at the same time as the license for the associated Medical Marijuana Store, Retail Marijuana Store, Medical Marijuana Transporter, or Retail Marijuana Transporter.
- ii. A delivery permit that is not issued with an initial or renewal application will be valid for less than one year to align the license expiration date of the related Medical Marijuana Store, Retail Marijuana Store, Medical Marijuana Transporter, or Retail Marijuana Transporter. In all years after the first year, such a delivery permit will be valid for one year.

c. In addition to any other basis for denial of renewal application, the State Licensing Authority may also consider the following facts and circumstances as an additional basis for denial of a delivery permit renewal application:

- i. The Medical Marijuana Store or Retail Marijuana Store failed to collect the one-dollar surcharge on every delivery or failed to timely remit the one-dollar surcharge to the municipality where the Medical Marijuana Store or Retail Marijuana Store is located, or to the county if the Medical Marijuana Store or Retail Marijuana Store is in an unincorporated area.

B. Responsible Vendor Certification Required. A Medical Marijuana Store, Retail Marijuana Store, Medical Marijuana Transporter, or Retail Marijuana Transporter must obtain a responsible vendor designation pursuant to sections 44-10-1201 or 44-10-1202, C.R.S., and the 3-500 Series Rules including the delivery curriculum prior to conducting its first delivery.

C. Inventory Tracking System Required. A Medical Marijuana Store, Retail Marijuana Store, Medical Marijuana Transporter, or Retail Marijuana Transporter must track all Regulated Marijuana until delivered to a patient or consumers as required by Rule 5-130. This includes the use of a transport manifest.

D. Delivery Motor Vehicle Requirements.

1. Any Delivery Motor Vehicle must be owned or leased by the Medical Marijuana Store, Retail Marijuana Store, Medical Marijuana Transporter, Retail Marijuana Transporter, or an Owner Licensee of the Regulated Marijuana Business that holds the delivery permit, must be registered in the State of Colorado, and must be insured.
2. Any Delivery Motor Vehicle must have a vehicle tracking system that is capable of real-time tracking and recording of the route taken by the Delivery Motor Vehicle while conducting deliveries that can be accessed remotely in real-time by the Medical Marijuana Store, Retail Marijuana Store, Medical Marijuana Transporter, or Retail Marijuana Transporter. The vehicle tracking system may be an application installed on a mobile device. The real-time location of the Delivery Motor Vehicle shall not be displayed to any patients or consumers.
3. Any Delivery Motor Vehicle must not have any external markings, words, or symbols that indicate the Delivery Motor Vehicle is used for delivery of Regulated Marijuana or is owned or leased by a Medical Marijuana Business or a Retail Marijuana Business.
4. Regulated Marijuana must not be visible from outside the Delivery Motor Vehicle.
5. Delivery Motor Vehicle security requirements include but are not limited to:

- a. A security alarm system, and
  - b. A secure, locked, opaque storage compartment that is securely affixed to the Delivery Motor Vehicle for the purpose of securing Regulated Marijuana.
6. Video Surveillance Requirements.
- a. The Delivery Motor Vehicle must be equipped with video surveillance equipment that digitally records during all deliveries. The video surveillance shall record at least the secured, locked, opaque storage compartment containing the Regulated Marijuana and the front view of the Delivery Motor Vehicle (e.g. dash camera).
  - b. Video surveillance shall be kept for a minimum of 40 days, must be capable of being embedded with the date and time, must be reproducible upon request from law enforcement, the Division, a Local Licensing Authority or a Local Jurisdiction and must be archived in a format that ensures authentication and guarantees no alteration of the video.
7. An enclosed Delivery Motor Vehicle shall not contain more than \$10,000.00 in retail value of Regulated Marijuana. A Delivery Motor Vehicle that is not enclosed shall not contain more than \$2,000.00 in retail value of Regulated Marijuana.
8. A Delivery Motor Vehicle must not leave the State of Colorado while any amount of Regulated Marijuana is in the Delivery Motor Vehicle.
9. Only persons licensed by the State Licensing Authority and identified on the transport manifest may occupy a Delivery Motor Vehicle while conducting deliveries of Regulated Marijuana.

E. Delivery Order Requirements.

1. A Medical Marijuana Store or a Retail Marijuana Store that has a valid delivery permit may accept orders for delivery of Regulated Marijuana to patients who are at least 21 years of age, parents or guardians of patient under 18 years of age, or consumers who are at least 21 years of age at a Private Residence. Delivery orders to patients ages 18 to 20 are not permitted.
2. For a Medical Marijuana Store or a Retail Marijuana Store that utilizes an online platform provider:
  - a. The online platform provider must require that the patient or consumer choose a Medical Marijuana Store or Retail Marijuana Store before displaying the price of Regulated Marijuana to the patient or consumer; and
  - b. The Medical Marijuana Store or Retail Marijuana Store must receive verification that there has not already been a delivery of Regulated Marijuana to that Private Residence through the online platform provider that same business day.
3. All delivery orders must document the following information which must be maintained pursuant to Rule 3-905 by the Medical Marijuana Store or the Retail Marijuana Store:
  - a. The name and date of birth of the patient or consumer placing the delivery order;
  - b. The address of the Private Residence where the order will be delivered;

- c. For Medical Marijuana delivery orders only, the registration number reflecting on the patient's registry identification card; and
  - d. For Medical Marijuana delivery orders only, if the patient is under 18 years of age, the parent or guardian designated as the patient's primary caregiver, and if applicable, the registration number of the primary caregiver.
4. A Medical Marijuana Store or a Retail Marijuana Store may accept payment for delivery orders using any legal method of payment, gift card pre-payments or payment on delivery, or pre-payment accounts established with a Medical Marijuana Store or Retail Marijuana Store except that any payment with an Electronic Benefits Transfer Services Card is not permitted.
- a. A Local Licensing Authority or Local Jurisdiction may further restrict legal methods of payment not expressly permitted by section 44-10-203(2)(dd)(XV), C.R.S.
5. Regulated Marijuana must be weighed, packaged, prepared, and labeled for delivery on the Licensed Premises of a Medical Marijuana Store or Retail Marijuana Store or at their off-premises storage facility after receipt of a delivery order. Regulated Marijuana cannot be placed into a Delivery Motor Vehicle until after an order has been received and the Regulated Marijuana has been packaged and labeled for delivery to the patient or consumer as required by the 3-1000 Series Rules.
6. Medical Marijuana Transporters and Retail Marijuana Transporters shall not take delivery orders but may deliver Regulated Marijuana on behalf of Medical Marijuana Stores and Retail Marijuana Stores pursuant to a contract with the Medical Marijuana Store or Retail Marijuana Store provided that the store also holds a valid delivery permit. The Medical Marijuana Store and Medical Marijuana Transporter must maintain copies of all contracts for delivery pursuant to Rule 3-905. The Retail Marijuana Store and Retail Marijuana Transporter must maintain copies of all contracts for delivery pursuant to Rule 3-905.

F. Regulated Marijuana Delivery Requirements.

- 1. A Medical Marijuana Store, Retail Marijuana Store, Medical Marijuana Transporter, or Retail Marijuana Transporter shall not deliver Regulated Marijuana to patients, parents, guardians, or consumers while also transporting Regulated Marijuana between Licensed Premises in the same Delivery Motor Vehicle.
- 2. Delivery of Medical Marijuana and Retail Marijuana.
  - a. A Medical Marijuana Store and Retail Marijuana Store, both of which hold a valid delivery permit, and which have identical Controlling Beneficial Owners, may complete deliveries of Medical Marijuana and Retail Marijuana using the same Delivery Motor Vehicle and without returning to the Medical Marijuana Store or Retail Marijuana Store between deliveries.
  - b. A Medical Marijuana Transporter and Retail Marijuana Transporter, both of which hold a valid delivery permit, and which have identical Controlling Beneficial Owners may complete deliveries of Medical Marijuana and Retail Marijuana using the same Delivery Motor Vehicle and without returning to the Medical Marijuana Store or Retail Marijuana Store between deliveries.
  - c. A Medical Marijuana Transporter holding a valid delivery permit may make deliveries for multiple Medical Marijuana Stores that also hold valid delivery

permits using the same Delivery Motor Vehicle and without returning to a Medical Marijuana Store between deliveries.

- d. A Retail Marijuana Transporter holding a valid delivery permit may make deliveries for multiple Retail Marijuana Stores that also hold valid delivery permits using the same Delivery Motor Vehicle and without returning to a Retail Marijuana Store between deliveries.
3. An Owner Licensee or Employee Licensee delivering Regulated Marijuana shall not open any Container of Regulated Marijuana in the Delivery Motor Vehicle and is prohibited from packaging or re-packaging Regulated Marijuana once the Delivery Motor Vehicle has departed from the Licensed Premises of a Medical Marijuana Store or Retail Marijuana Store.
4. A Medical Marijuana Store or Retail Marijuana Store shall not accept delivery orders for Regulated Marijuana Product that is perishable unless the Delivery Motor Vehicle that will make the delivery has the ability to secure the Regulated Marijuana Product in climate controlled storage.
5. A Medical Marijuana Store, Retail Marijuana Store, Medical Marijuana Transporter, or Retail Marijuana Transporter must maintain a transport manifest that documents the following:
  - a. The time of delivery and the name, patient's or consumer's identification number, address of the Private Residence, patient registry number, if applicable, and acknowledgement of receipt of delivery by the person receiving the delivery; and
  - b. For every Regulated Marijuana delivery that could not be completed, the reason the delivery could not be completed.
6. Proof of Patient Medical Registry and Identification.
  - a. Prior to transferring possession of the order, the Owner Licensee or Employee Licensee delivering Medical Marijuana to a patient or a patient's parent or guardian must:
    - i. Inspect the patient's or parent's or guardian's identification and registry identification card;
    - ii. Verify the possession of a valid registry identification card; iii. Verify that the information provided at the time of order match the name and age on the patient's or parent or guardian's identification; and
    - iv. Verify that the identification and registry identification card belong to the person receiving the delivery.
  - b. The Owner Licensee or Employee Licensee must refuse delivery of Medical Marijuana if the person attempting to accept the delivery order cannot establish all of the requirements of subparagraph (F)(6)(a)(i) through (iv) above.
7. Proof of Consumer Identification.
  - a. The Owner Licensee or Employee Licensee delivering Retail Marijuana to a consumer must first verify that the natural person accepting the delivery has an acceptable form of identification demonstrating the person is at least 21 years of

age and that the person is the same as the person that placed the order for delivery with the Retail Marijuana Store.

- b. The Owner Licensee or Employee Licensee must refuse delivery of Retail Marijuana if the natural person attempting to accept the delivery order cannot establish all the requirements of subparagraph (F)(5)(a) above.

8. Daily Delivery Limits.

- a. A Medical Marijuana Store or Medical Marijuana Transporter must not deliver individually or in any combination, more than two ounces of Medical Marijuana, 40 grams of Medical Marijuana Concentrate, or Medical Marijuana Products containing more than 20,000 milligrams of THC to a patient in a single business day.
- b. A Medical Marijuana Store or Medical Marijuana Transporter must not deliver to a patient, parent, or guardian or Private Residence where the Licensee knows or reasonably should know that the patient, parent or guardian, or Private Residence has already received a delivery during that same business day. This does not prohibit delivery to more than one patient at the same time and private residence.
- c. A Retail Marijuana Store or Retail Marijuana Transporter must not deliver individually or in any combination, more than one ounce of Retail Marijuana, 8 grams of Retail Marijuana Concentrate, or Retail Marijuana Products containing more than ten 80 milligram servings of THC to a customer in a single business day.
- d. A Retail Marijuana Store or Retail Marijuana Transporter must not deliver to a consumer or Private Residence where the Licensee knows or reasonably should know that the consumer or Private Residence has already received a delivery during that same business day. This does not prohibit delivery to more than one consumer at the same time and private residence.

- 9. An Owner Licensee or Employee Licensee who cannot complete a delivery order for any reason must return the Regulated Marijuana to the Medical Marijuana Store, Retail Marijuana Store, or off-premises storage facility from which the delivery order originated. If the Container is unopened and has not been tampered with, the Medical Marijuana Store, Retail Marijuana Store, or off-premises storage facility may return the Regulated Marijuana into its inventory and reconcile it with the Inventory Tracking System by the close of business that same day. Otherwise, the Regulated Marijuana must be destroyed in accordance with this Rule and Rule 3-235.

- G. Confidentiality of Patient and Consumer Personal Identifying Information. A Medical Marijuana Store, a Retail Marijuana Store, a Medical Marijuana Transporter, a Retail Marijuana Transporter, and their respective Owner Licensees and Employee Licensees must keep all personal identifying information and any health care information obtained from patients and consumers confidential and must not disclose such personally identifiable information and any health care information to any person other than those who need that information to take, process, or deliver the order or otherwise as required by the Marijuana Code, or Title 18, or Title 25 of the Colorado Revised Statutes.

**3-700 Series – Signage and Advertising**

**Basis and Purpose – 3-705**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(3)(a), and 44-10-701(3)(c), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VIII). The purpose of this rule is to clearly delineate that a Regulated Marijuana Business is not permitted to make deceptive, false, or misleading statements in Advertising materials or on any product or document provided to a patient or consumer. This Rule 3-705 was previously Rules M and R 1102, 1 CCR 212-1 and 1 CCR 212-2.

### **3-705 – Advertising General Requirement: No Deceptive, False or Misleading Statements**

A Regulated Marijuana Business shall not engage in Advertising that is deceptive, false, or misleading. A Regulated Marijuana Business shall not make any deceptive, false, or misleading assertions or statements on any product, any sign, or any document provided to a patient or consumer.

### **Basis and Purpose – 3-710**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), 44-10-203(3)(a), and 44-10-701(3)(c), C.R.S. Authority also exists throughout Article XVIII, Section 16 of the Colorado Constitution. The purpose of this rule is to clarify the definition of the term “minor” as used in the Marijuana Code and these rules. This Rule 3-710 was previously Rules M and R 1103, 1 CCR 212-1 and 1 CCR 212-2.

### **3-710 – The Term “Minor” as Used in the Marijuana Code and These Rules**

The term “minor” as used in the Marijuana Code and these rules means an individual under the age of 18 for Medical Marijuana and under the age of 21 for Retail Marijuana.

### **Basis and Purpose 3-715**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), 44-10-203(3)(a), and 44-10-103(10), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, subsections 16(5)(a)(V) and (5)(a)(VIII). The purpose of this rule is to clarify the restrictions applicable to Advertising and Branding.

### **3-715 – Use of Branding**

- A. For the purposes of these 3-700 Series Rules, the term Branding includes taglines, which may or may not be trademarked.
- B. Branding may not be used to target minors.

### **Basis and Purpose – 3-720**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), and 44-10-203(3)(a), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsections 16(5)(a)(V) and (5)(a)(VIII). The purpose of this rule is to clarify the restrictions applicable to Advertising.

The operation of Regulated Marijuana Businesses in Colorado is authorized solely within the narrow confines of the Colorado Constitution, Article XVIII, Sections 14 and 16. The Colorado Constitution prohibits the purchase, possession, and consumption of Medical Marijuana by those under the age 18, and of Retail Marijuana by those under the age of 21. *See for example* Colo. Const. art XVIII, §16(1)(a), (1)(b)(I), (1)(b)(II), 2)(b), (3), (4), (5)(a)(V), (5)(c), and 6(c). The Colorado Constitution calls for the regulation of marijuana “in a manner similar to alcohol” in certain key respects. Colo. Const. Art. XVIII, §16(1)(b). The constitutionally mandated regulatory scheme governing Regulated Marijuana Businesses must include rules establishing restrictions on the advertising and display of marijuana and marijuana

product, and must include requirements to prevent the sale or diversion of marijuana and marijuana product to minors. Colo. Const. Art. XVIII, §16(5)(a)(V) and (VIII). Through the Marijuana Code the Colorado General Assembly provided further direction regarding mandated advertising restrictions. See § 44-10-203(3)(a), C.R.S. Voluntary standards adopted by the alcohol industry direct the industry to refrain from advertising where more than 29.4 percent of the audience is reasonably expected to be under the legal age of purchase. These rules apply to Advertising as defined in Rule 1-115. This Rule 3-720 was previously Rules M and R 1104, 1105, 1106, and 1107, 1 CCR 212-1 and 1 CCR 212-2.

### **3-720 – Advertising: All Media**

- A. Medical Marijuana Businesses. A Medical Marijuana Business may Advertise in television, radio, a print publication, or via the internet only where at least 71.6 percent of the audience is reasonably expected to be at least the age of 18.
- B. Retail Marijuana Businesses. A Retail Marijuana Business may Advertise in television, radio, a print publication or via the internet only where at least 71.6 percent of the audience is reasonably expected to be at least the age of 21.

### **Basis and Purpose – 3-725**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), and 44-10-203(3)(a), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII Subsections 16(5)(a)(V) and (5)(a)(VIII). The purpose of this rule is to clarify the Advertising restrictions applicable to safety and health and benefit claims that are by nature misleading, deceptive, or false.

The operation of Regulated Marijuana Businesses in Colorado is authorized solely within the narrow confines of the Colorado Constitution, Article XVIII, Sections 14 and 16. The Colorado Constitution prohibits the purchase, possession, and consumption of Medical Marijuana by those under the age 18, and of Retail Marijuana by those under the age of 21. *See for example* Colo. Const. art XVIII, §16(1)(a), (1)(b)(I), (1)(b)(II), 2)(b), (3), (4), (5)(a)(V), (5)(c), and 6(c). The Colorado Constitution calls for the regulation of marijuana “in a manner similar to alcohol” in certain key respects. Colo. Const. Art. XVIII, §16(1)(b). The constitutionally mandated regulatory scheme governing Regulated Marijuana Businesses must include rules establishing restrictions on the advertising and display of marijuana and marijuana product, and must include requirements to prevent the sale or diversion of marijuana and marijuana product to minors. Colo. Const. Art. XVIII, §16(5)(a)(V) and (VIII). Through the Marijuana Code the Colorado General Assembly provided further direction regarding mandated advertising restrictions. See § 44-10-203(3)(a), C.R.S. Voluntary standards adopted by the alcohol industry direct the industry to refrain from advertising where more than 29.4 percent of the audience is reasonably expected to be under the legal age of purchase. These rules apply to Advertising as defined in Rule 1-115. This Rule 3-725 was previously Rules M and R 1109, 1 CCR 212-1 and 1 CCR 212-2.

### **3-725 – Signage and Advertising: No Safety Claims Because Regulated by State Licensing Authority**

No Regulated Marijuana Business may engage in Advertising or utilize signage that asserts its products are safe because they are regulated by the State Licensing Authority.

### **Basis and Purpose – 3-730**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c) and 44-10-203(3)(a), and 44-10-701(3)(c), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VIII). The purpose of this rule is to clarify the Advertising restrictions applicable to safety claims that are by nature misleading, deceptive, or false. This Rule 3-730 was previously Rules M and R 1110, 1 CCR 212-1 and 1 CCR 212-2.

### **3-730 – Signage and Advertising: No Safety Claims Because Tested**

A Regulated Marijuana Business shall not engage in Advertising or utilize signage that asserts its products are safe because they are tested by a Medical Marijuana Testing Facility or Retail Marijuana Testing Facility.

#### **Basis and Purpose – 3-735**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), and 44-10-203(3)(a), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsections 16(5)(a)(V) and (5)(a)(VIII). The purpose of this rule is to clarify the restrictions applicable to outdoor Advertising and signage.

The operation of Regulated Marijuana Businesses in Colorado is authorized solely within the narrow confines of the Colorado Constitution, Article XVIII, Sections 14 and 16. The Colorado Constitution prohibits the purchase, possession, and consumption of Medical Marijuana by those under the age 18, and of Retail Marijuana by those under the age of 21. *See for example* Colo. Const. art XVIII, §16(1)(a), (1)(b)(I), (1)(b)(II), 2)(b), (3), (4), (5)(a)(V), (5)(c), and 6(c). The Colorado Constitution calls for the regulation of marijuana “in a manner similar to alcohol” in certain key respects. Colo. Const. Art. XVIII, §16(1)(b). The constitutionally mandated regulatory scheme governing Regulated Marijuana Businesses must include rules establishing restrictions on the advertising and display of marijuana and marijuana product, and must include requirements to prevent the sale or diversion of marijuana and marijuana product to minors. Colo. Const. Art. XVIII, §16(5)(a)(V) and (VIII). Through the Marijuana Code the Colorado General Assembly provided further direction regarding mandated advertising restrictions. *See* § 44-10-203(3)(a), C.R.S. Voluntary standards adopted by the alcohol industry direct the industry to refrain from advertising where more than 29.4 percent of the audience is reasonably expected to be under the legal age of purchase. These rules apply to Advertising as defined in Rule 1-115. This Rule 3-735 was previously Rules M and R 1111, 1 CCR 212-1 and 1 CCR 212-2.

### **3-735 – Signage and Advertising: Outdoor Advertising**

- A. Local Ordinances. In addition to any requirements within these rules, a Regulated Marijuana Business shall comply with any applicable local ordinances regulating signs and Advertising.
- B. All Applicable State Laws Apply. A Regulated Marijuana Business that engages in any Advertising shall comply with all applicable state laws, including but not limited to the Outdoor Advertising Act at sections 43-1-401 through 43-1-420, C.R.S..
- C. A Regulated Marijuana Business shall not Advertise on any outdoor sign that is within 500 feet of established and conspicuously identified elementary or secondary schools, places of worship, or public playgrounds.

#### **Basis and Purpose – 3-740**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), and 44-10-203(3)(a), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsections 16(5)(a)(V) and (5)(a)(VIII). The purpose of this rule is to prohibit signage and Advertising that has a high likelihood of reaching individuals under the age of 21.

The operation of Regulated Marijuana Businesses in Colorado is authorized solely within the narrow confines of the Colorado Constitution, Article XVIII, Sections 14 and 16. The Colorado Constitution prohibits the purchase, possession, and consumption of Medical Marijuana by those under the age 18, and of Retail Marijuana by those under the age of 21. *See for example* Colo. Const. art XVIII, §16(1)(a), (1)(b)(I), (1)(b)(II), 2)(b), (3), (4), (5)(a)(V), (5)(c), and 6(c). The Colorado Constitution calls for the regulation of marijuana “in a manner similar to alcohol” in certain key respects. Colo. Const. Art. XVIII,



§16(1)(b). The constitutionally mandated regulatory scheme governing Regulated Marijuana Businesses must include rules establishing restrictions on the advertising and display of marijuana and marijuana product, and must include requirements to prevent the sale or diversion of marijuana and marijuana product to minors. Colo. Const. Art. XVIII, §16(5)(a)(V) and (VIII). Through the Marijuana Code the Colorado General Assembly provided further direction regarding mandated advertising restrictions. See § 44-10-203(3)(a), C.R.S. Voluntary standards adopted by the alcohol industry direct the industry to refrain from advertising where more than 29.4 percent of the audience is reasonably expected to be under the legal age of purchase. These rules apply to Advertising as defined in Rule 1-115. This Rule 3-740 was previously Rules M and R 1112, 1 CCR 212-1 and 1 CCR 212-2.

### **3-740 – Signage and Advertising: No Content That Targets Minors**

- A. A Medical Marijuana Business shall not include in any form of Advertising or signage any content that specifically targets individuals under the age of 18, including but not limited to cartoon characters or similar images.
- B. A Retail Marijuana Business shall not include in any form of Advertising or signage any content that specifically targets individuals under the age of 21, including but not limited to cartoon characters or similar images.

### **Basis and Purpose – 3-745**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), and 44-10-203(3)(a), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(V) and 16(5)(a)(VIII). The purpose of this rule is to clarify the Advertising restrictions applicable to marketing directed toward location-based devices.

The operation of Regulated Marijuana Businesses in Colorado is authorized solely within the narrow confines of the Colorado Constitution, Article XVIII, Sections 14 and 16. The Colorado Constitution prohibits the purchase, possession, and consumption of Medical Marijuana by those under the age 18, and of Retail Marijuana by those under the age of 21. See *for example* Colo. Const. art XVIII, §16(1)(a), (1)(b)(I), (1)(b)(II), 2)(b), (3), (4), (5)(a)(V), (5)(c), and 6(c). The Colorado Constitution calls for the regulation of marijuana “in a manner similar to alcohol” in certain key respects. Colo. Const. Art. XVIII, §16(1)(b). The constitutionally mandated regulatory scheme governing Regulated Marijuana Businesses must include rules establishing restrictions on the advertising and display of marijuana and marijuana product, and must include requirements to prevent the sale or diversion of marijuana and marijuana product to minors. Colo. Const. Art. XVIII, §16(5)(a)(V) and (VIII). Through the Marijuana Code the Colorado General Assembly provided further direction regarding mandated advertising restrictions. See § 44-10-203(3)(a), C.R.S. Voluntary standards adopted by the alcohol industry direct the industry to refrain from advertising where more than 29.4 percent of the audience is reasonably expected to be under the legal age of purchase. These rules apply to Advertising as defined in Rule 1-115. This Rule 3-745 was previously Rules M and R 1113, 1 CCR 212-1 and 1 CCR 212-2.

### **3-745 – Advertising: Advertising via Marketing Directed Toward Location-Based Devices**

A Regulated Marijuana Business shall not engage in Advertising via marketing directed towards location-based devices, including, but not limited to, cellular phones, unless the marketing is a mobile device application installed on the device by the owner of the device who is 18 years of age or older for Medical Marijuana, 21 years of age or older for Retail Marijuana, and includes a permanent and easy opt-out feature.

### **Basis and Purpose – 3-750**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), and 44-10-203(3)(a), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection

16(5)(a)(V) and (5)(a)(VIII). The purpose of this rule is to clarify the Advertising restrictions applicable to pop-up Advertising.

The operation of Regulated Marijuana Businesses in Colorado is authorized solely within the narrow confines of the Colorado Constitution, Article XVIII, Sections 14 and 16. The Colorado Constitution prohibits the purchase, possession, and consumption of Medical Marijuana by those under the age 18, and of Retail Marijuana by those under the age of 21. *See for example* Colo. Const. art XVIII, §16(1)(a), (1)(b)(I), (1)(b)(II), 2)(b), (3), (4), (5)(a)(V), (5)(c), and 6(c). The Colorado Constitution calls for the regulation of marijuana “in a manner similar to alcohol” in certain key respects. Colo. Const. Art. XVIII, §16(1)(b). The constitutionally mandated regulatory scheme governing Regulated Marijuana Businesses must include rules establishing restrictions on the advertising and display of marijuana and marijuana product, and must include requirements to prevent the sale or diversion of marijuana and marijuana product to minors. Colo. Const. Art. XVIII, §16(5)(a)(V) and (VIII). Through the Marijuana Code the Colorado General Assembly provided further direction regarding mandated advertising restrictions. *See* § 44-10-203(3)(a), C.R.S. Voluntary standards adopted by the alcohol industry direct the industry to refrain from advertising where more than 29.4 percent of the audience is reasonably expected to be under the legal age of purchase. These rules apply to Advertising as defined in Rule 1-115. This Rule 3-750 was previously Rules M and R 1114, 1 CCR 212-1 and 1 CCR 212-2.

### **3-750 – Pop-Up Advertising**

A Regulated Marijuana Business shall not utilize unsolicited pop-up Advertising on the internet.

### **Basis and Purpose – 3-755**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), and 44-10-203(3)(a), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VIII). The purpose of this rule is to clarify the Advertising restrictions applicable to event sponsorship.

The operation of Regulated Marijuana Businesses in Colorado is authorized solely within the narrow confines of the Colorado Constitution, Article XVIII, Sections 14 and 16. The Colorado Constitution prohibits the purchase, possession, and consumption of Medical Marijuana by those under the age 18, and of Retail Marijuana by those under the age of 21. *See for example* Colo. Const. art XVIII, §16(1)(a), (1)(b)(I), (1)(b)(II), 2)(b), (3), (4), (5)(a)(V), (5)(c), and 6(c). The Colorado Constitution calls for the regulation of marijuana “in a manner similar to alcohol” in certain key respects. Colo. Const. Art. XVIII, §16(1)(b). The constitutionally mandated regulatory scheme governing Regulated Marijuana Businesses must include rules establishing restrictions on the advertising and display of marijuana and marijuana product, and must include requirements to prevent the sale or diversion of marijuana and marijuana product to minors. Colo. Const. Art. XVIII, §16(5)(a)(V) and (VIII). Through the Marijuana Code the Colorado General Assembly provided further direction regarding mandated advertising restrictions. *See* § 44-10-203(3)(a), C.R.S. Voluntary standards adopted by the alcohol industry direct the industry to refrain from advertising where more than 29.4 percent of the audience is reasonably expected to be under the legal age of purchase. These rules apply to Advertising as defined in Rule 1-115. This Rule 3-755 was previously Rules M and R 1115, 1 CCR 212-1 and 1 CCR 212-2.

### **3-755 – Advertising: Event Sponsorship**

- A. A Medical Marijuana Business may sponsor a charitable, sports, or similar event, but a Medical Marijuana Business shall not engage in Advertising at, or in connection with, such an event unless the Medical Marijuana Business has reliable evidence that 71.6 percent of the audience at the event and/or viewing Advertising in connection with the event is reasonably expected to be at least the age of 18.

- B. A Retail Marijuana Business may sponsor a charitable, sports, or similar event, but a Retail Marijuana Business shall not engage in Advertising at, or in connection with, such an event unless the Retail Marijuana Business has reliable evidence that 71.6 percent of the audience at the event and/or viewing Advertising in connection with the event is reasonably expected to be at least the age of 21.

### **3-800 Series – Inventory Tracking Requirements**

#### **Basis and Purpose – 3-805**

The statutory authority for this rule includes but is not limited to sections, 44-10-201(1), 44-10-202(1)(a), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(h), 44-10-501(1)(b), 44-10-502(2), 44-10-503(1)(b), 44-10-505(3), 44-10-601(1)(d), 44-10-602(3), 44-10-603(1)(b), 44-10-605(3), and 44-10-610(3)(a), C.R.S. The purpose of this rule is to establish a system that will allow the State Licensing Authority and the industry to jointly track Regulated Marijuana from either seed or immature plant stage until the Regulated Marijuana is sold to a patient or consumer, or destroyed.

The Inventory Tracking System is a web-based tool coupled with RFID technology that allows both the Inventory Tracking System User and the State Licensing Authority the ability to identify and account for all Regulated Marijuana. Through the use of RFID technology, a Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility will tag either the seed or immature plant with an individualized number, which will follow the Regulated Marijuana through all phases of production and final sale to a patient or consumer. This will allow the State Licensing Authority and the Inventory Tracking System User the ability to monitor and track Regulated Marijuana inventory. The Inventory Tracking System will also provide a platform for the State Licensing Authority to exchange information and provide compliance notifications to the industry.

The State Licensing Authority finds it essential to regulate, monitor, and track all Regulated Marijuana to eliminate diversion, inside and outside of the state, and to ensure that all marijuana grown, processed, sold, and disposed of in the Regulated Marijuana market is transparently accounted for.

The State Licensing Authority will engage the industry and provide training opportunities and continue to evaluate the Inventory Tracking System to promote an effective means for this industry to account for and monitor its Regulated Marijuana inventory. This Rule 3-805 was previously Rules M and R 309, 1 CCR 212-1 and 1 CCR 212-2.

#### **3-805 – Regulated Marijuana Businesses: Inventory Tracking System**

- A. Inventory Tracking System Required. A Regulated Marijuana Business is required to use the Inventory Tracking System as the primary inventory tracking system of record. A Regulated Marijuana Business must have an Inventory Tracking System account activated and functional prior to operating or exercising any privileges of a license. Medical Marijuana Businesses converting to or adding a Retail Marijuana Business must follow the inventory transfer guidelines detailed in Rule 3-805(C) below. Because Marijuana Hospitality Businesses are not authorized to receive or conduct Transfers of Regulated Marijuana, this Rule does not apply to Marijuana Hospitality Businesses.
- B. Inventory Tracking System Access - Inventory Tracking System Administrator.
1. Inventory Tracking System Administrator Required. A Regulated Marijuana Business must have at least one Owner Licensee who is an Inventory Tracking System Administrator. A Regulated Marijuana Business may also designate additional Owner Licensees and Employee Licensees to obtain Inventory Tracking System Administrator accounts.

2. Training for Inventory Tracking System Administrator Account. In order to obtain an Inventory Tracking System Administrator account, a Person must attend and successfully complete all required Inventory Tracking System training. The Division may also require additional ongoing, continuing education for an individual to retain his or her Inventory Tracking System Administrator account.
  3. Inventory Tracking System Access - Inventory Tracking System User Accounts. A Regulated Marijuana Business may designate licensed Owners and employees who hold valid Employee Licenses as Inventory Tracking System Users. A Regulated Marijuana Business shall ensure that all Owner Licensees and Employee Licensees who are granted Inventory Tracking System User account access for the purposes of conducting inventory tracking functions in the system are trained by Inventory Tracking System Administrators in the proper and lawful use of Inventory Tracking System.
- C. Medical Marijuana Business License Conversions - Declaring Inventory Prior to Exercising Licensed Privileges as a Retail Marijuana Business.
1. Medical Marijuana Inventory Transfer to Retail Marijuana Business.
    - a. Except pursuant to Rules 5-205 and 6-205:
      - i. The only allowed Transfer of marijuana between a Medical Marijuana Business and Retail Marijuana Business is Medical Marijuana and Medical Marijuana Concentrate that was produced at the Medical Marijuana Cultivation Facility, from the Medical Marijuana Cultivation Facility to a Retail Marijuana Cultivation Facility.
      - ii. Each Medical Marijuana Cultivation Facility that is either converting to or adding a Retail Marijuana Cultivation Facility license must create a Retail Marijuana Inventory Tracking System account for each license it is converting or adding.
      - iii. A Medical Marijuana Cultivation Facility must Transfer all relevant Medical Marijuana and Medical Marijuana Concentrate into the Retail Marijuana Cultivation Facility's Inventory Tracking System account and affirmatively declare those items as Retail Marijuana or Retail Marijuana Concentrate as appropriate.
      - iv. The marijuana subject to the one-time Transfer is subject to the excise tax upon the first Transfer from the Retail Marijuana Cultivation Facility to another Retail Marijuana Business.
      - v. All other Transfers are prohibited, including but not limited to Transfers from a Medical Marijuana Store or Medical Marijuana Products Manufacturer to any Retail Marijuana Business.
  2. No Further Transfer Allowed. Once a Licensee has declared any portion of its Medical Marijuana inventory as Retail Marijuana, no further Transfers of inventory from Medical Marijuana to Retail Marijuana shall be allowed.
- D. RFID Tags Required.
1. Authorized Tags Required and Costs. Licensees are required to use RFID tags issued by a Division-approved vendor that is authorized to provide RFID tags for the Inventory

Tracking System. Each licensee is responsible for the cost of all RFID tags and any associated vendor fees.

2. Use of RFID Tags Required. A Licensee is responsible to ensure its inventories are properly tagged where the Inventory Tracking System requires RFID tag use. A Regulated Marijuana Business must ensure it has an adequate supply of RFID tags to properly tag Regulated Marijuana as required by the Inventory Tracking System. An RFID tag must be physically attached to every Regulated Marijuana plant being cultivated that is greater than eight inches tall or eight inches wide. Prior to a plant reaching a viable point to support the weight of the RFID tag and attachment strap, the RFID tag may be securely fastened to the stalk. An RFID tag must be assigned to all Regulated Marijuana. See Rule 3-805(D); Rule 3-1005(G) – Shipping Containers.
3. Reuse of RFID Tags Prohibited. A Licensee shall not reuse any RFID tag that has already been affixed or assigned to any Regulated Marijuana.
4. When plants reach a viable point to support the weight of the RFID tag and attachment strap, the RFID tag shall be securely fastened to a lower supporting branch.

E. General Inventory Tracking System Use.

1. Reconciliation with Inventory. All inventory tracking activities at a Regulated Marijuana Business must be tracked through use of the Inventory Tracking System. A Licensee must reconcile all on-premises and in-transit Regulated Marijuana inventories each day in the Inventory Tracking System at the close of business.
2. Common Weights and Measures.
  - a. A Regulated Marijuana Business must utilize a standard of measurement that is supported by the Inventory Tracking System to track all Regulated Marijuana.
  - b. A scale used to weigh product prior to entry into the Inventory Tracking System shall be tested and approved in accordance with section 35-14-127, C.R.S.
3. Inventory Tracking System Administrator and User Accounts – Security and Record.
  - a. A Regulated Marijuana Business shall maintain an accurate and complete list of all Inventory Tracking System Administrators and Inventory Tracking System Users for each Licensed Premises. A Regulated Marijuana Business shall update this list when a new Inventory Tracking System User is trained. A Regulated Marijuana Business must train and authorize any new Inventory Tracking System Users before those Owners or employees may access Inventory Tracking System or input, modify, or delete any information in the Inventory Tracking System.
  - b. A Regulated Marijuana Business must cancel any Inventory Tracking System Administrators and Inventory Tracking System Users from their associated Inventory Tracking System accounts once any such individuals are no longer employed by the Licensee or at the Licensed Premises.
  - c. A Regulated Marijuana Business is accountable for all actions employees take while logged into the Inventory Tracking System or otherwise conducting Regulated Marijuana inventory tracking activities.

- d. Each individual user is also accountable for all of his or her actions while logged into the Inventory Tracking System or otherwise conducting Regulated Marijuana inventory tracking activities, and shall maintain compliance with all relevant laws.

4. Secondary Software Systems Allowed.

- a. Nothing in this Rule prohibits a Regulated Marijuana Business from using separate software applications to collect information to be used by the business including secondary inventory tracking or point-of-sale systems.
- b. A Licensee must ensure that all relevant Inventory Tracking System data is accurately transferred to and from the Inventory Tracking System for the purposes of reconciliations with any secondary systems.
- c. A Regulated Marijuana Business must preserve original Inventory Tracking System data when transferred to and from a secondary application(s). Secondary software applications must use the Inventory Tracking System data as the primary source of data and must be compatible with updating to the Inventory Tracking System.

F. Conduct While Using Inventory Tracking System.

1. Misstatements or Omissions Prohibited. A Regulated Marijuana Business and its designated Inventory Tracking System Administrator(s) and Inventory Tracking System User(s) shall enter data into the Inventory Tracking System that fully and transparently accounts for all inventory tracking activities. Both the Regulated Marijuana Business and the individuals using the Inventory Tracking system are responsible for the accuracy of all information entered into the Inventory Tracking System. Any misstatements or omissions may be considered a license violation affecting public safety.
2. Use of Another User's Login Prohibited. Individuals entering data into the Inventory Tracking System shall only use that individual's Inventory Tracking System account.
3. Loss of System Access. If at any point a Regulated Marijuana Business loses access to the Inventory Tracking System for any reason, the Regulated Marijuana Business must keep and maintain comprehensive records detailing all Regulated Marijuana tracking inventory activities that were conducted during the loss of access. See Rule 3-905 – Business Records Required. Once access is restored, all Regulated Marijuana inventory tracking activities that occurred during the loss of access must be entered into the Inventory Tracking System. A Regulated Marijuana Business must document when access to the system was lost and when it was restored. A Regulated Marijuana Business shall not Transfer any Regulated Marijuana to another Regulated Marijuana Business until such time as access is restored and all information is recorded into the Inventory Tracking System.

G. System Notifications.

1. Compliance Notifications. A Regulated Marijuana Business must monitor all compliance notifications from the Inventory Tracking System. The Licensee must resolve the issues detailed in the compliance notification in a timely fashion. Compliance notifications shall not be dismissed in the Inventory Tracking System until the Regulated Marijuana Business resolves the compliance issues detailed in the notification.
2. Informational Notifications. A Regulated Marijuana Business must take appropriate action in response to informational notifications received through the Inventory Tracking

System, including but not limited to notifications related to RFID billing, enforcement alerts, and other pertinent information.

- H. Lawful Activity Required. Proper use of the Inventory Tracking System does not relieve a Licensee of its responsibility to maintain compliance with all laws, rules, and other requirements at all times.
- I. Inventory Tracking System Procedures Must Be Followed. A Regulated Marijuana Business must utilize Inventory Tracking System in conformance with these rules and Inventory Tracking System procedures, including but not limited to:
1. Properly indicating the creation of a Harvest Batch and/or Production Batch including the assigned Harvest Batch and/or Production Batch Number;
  2. Accurately identifying the cultivation rooms and location of each plant within those rooms on the Licensed Premises;
  3. Accurately identifying when inventory is no longer on the Licensed Premises;
  4. Properly indicating that a Test Batch is being used as part of achieving process validation;
  5. Accurately indicating the Inventory Tracking System category for all Regulated Marijuana; and
  6. Accurately including a note explaining the reason for any destruction of Regulated Marijuana, and reason for any adjustment of weights to Inventory Tracking System packages.
  7. Properly designating one or more Sampling Managers before Transferring any Sampling Units;
  8. Fully and accurately tracking the Transfer of any Sampling Unit from a Regulated Marijuana Business to a Sampling Manager identified by name and license number; and
  9. When entering into the Inventory Tracking System a unit of Regulated Marijuana the Inventory Tracking System Trained Administrator or Inventory Tracking System User shall also identify the net contents of each unit consistent with Rules 3-1005(B)(2)(e) and (C)(2)(a)(iv). For example, if the Inventory Tracking System User enters 1 unit of Retail Marijuana Product that contains 100 mg of Retail Marijuana Product, then the Inventory Tracking System User shall also identify that each unit contains 100 mg. Further, if the Inventory Tracking System User enters 1 unit of Medical Marijuana Product that contains 200 mg of Medical Marijuana Product, the Inventory Tracking System User shall also identify that each unit contains 200 mg.

### **Basis and Purpose – 3-810**

The statutory authority for this rule includes but is not limited to sections, 44-10-201, 44-10-202(1)(a), 44-10-202(1)(c), 44-10-203(2)(n), 44-10-501(1)(b), 44-10-502(2), 44-10-503(1)(b), 44-10-505(3), 44-10-601(1)(d), 44-10-601(4), 44-10-602(1), 44-10-602(6)(f), 44-10-603(1)(b), and 44-10-605(3), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to maintain a system that will allow the State Licensing Authority and the industry to jointly track Regulated Marijuana from either seed or immature plant stage until the Regulated Marijuana is sold to the patient or consumer or destroyed.

### **3-810 – Minimum Tracking Requirements**

- A. Requirement to Track Regulated Marijuana From Seed-to-Sale. Licensees must use the Inventory Tracking System to ensure Regulated Marijuana is identified and tracked from the point the Regulated Marijuana is Propagated from seed or cutting to the point when it is Transferred to another Regulated Marijuana Business, the Medical Marijuana Transporter or Retail Marijuana Transporter takes control of the Regulated Marijuana by removing it from the originating Licensee's Licensed Premises and placing the Regulated Marijuana in the transport vehicle, or it is Transferred to a Sampling Manager as a designated Sampling Unit, and through the delivery, point-of-sale, or the Regulated Marijuana is otherwise disposed of. See Rule 3-805 – Inventory Tracking System
- B. Ability to Reconcile Required. Licensees must have the ability to reconcile transported and on-hand Regulated Marijuana inventory with the Inventory Tracking System and the associated transaction history and transportation order receipts. See Rule 3-905 – Business Records Required.

### **Basis and Purpose – 3-815**

The statutory authority for this rule includes but is not limited to 44-10-201, 44-10-202(1)(a), 44-10-202(1)(c), 44-10-313(5)(b), 44-10-505(3), and 44-10-605(2) C.R.S. The purpose of this rule is allow the State Licensing Authority and the industry to jointly track the transfer and delivery of Regulated Marijuana and Regulated Marijuana Product between licensed Regulated Marijuana Businesses. It also prescribes the manner in which licensed entities will track inventory in the transport process to prevent diversionary practices.

### **3-815 – Transport Manifest Required**

- A. Transport of Regulated Marijuana Without Transport Manifest Prohibited. Licensees are prohibited from transporting any Regulated Marijuana without a valid transport manifest generated by the Inventory Tracking System.
- B. Accepting Regulated Marijuana Without Transport Manifest Prohibited. Licensees are prohibited from accepting any Regulated Marijuana from another Regulated Marijuana Business without receiving a valid transport manifest generated from the Inventory Tracking System.
- C. Information Must Be Accurate. All information on the Inventory Tracking System generated transport manifest must be accurate.

### **Basis and Purpose – 3-820**

The statutory authority for this rule includes but is not limited to sections 44-10-201, 44-10-202(1)(a), 44-10-202(1)(c), 44-10-502(3), 44-10-503(10), 44-10-602(6), and 44-10-603(10). The purpose of this rule is to establish inventory tracking, reporting and recordkeeping requirements for Sampling Units to ensure that any Regulated Marijuana or Regulated Marijuana Products designated as a Sampling Unit is identified and tracked from the point of such designation.

### **3-820 – Sampling Unit Tracking Requirements**

- A. Applicability. This Rule 3-820 applies to Medical Marijuana Cultivation Facilities, Retail Marijuana Cultivation Facilities, Medical Marijuana Products Manufacturers, and Retail Marijuana Products Manufacturers.
- B. Sampling Unit Tracking Requirements.



1. In addition to all other requirements set forth in these rules, a Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or Retail Marijuana Products Manufacturer shall utilize the Inventory Tracking System to ensure that any Regulated Marijuana designated as a Sampling Unit is identified and tracked from the point of such designation until the Sampling Unit is Transferred to a Sampling Manager. See Rules 5-230, 5-320, 6-225, 6-320 – Sampling Unit Protocols.
2. The Inventory Tracking System must adequately reflect all Transfers of Sampling Units. At a minimum, a Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or Retail Marijuana Products Manufacturer must ensure that the Inventory Tracking System reflects the date the Sampling Unit was Transferred, the weight of the Sampling Unit, and the name and license number of the recipient Sampling Manager.
3. A Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or Retail Marijuana Products Manufacturer must have the ability to reconcile its Sampling Manager and Sampling Unit records with the Inventory Tracking System and any associated transaction history.

### **Basis and Purpose – 3-825**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(a), 44-10-203(2)(d)(I), 44-10-504, and 44-10-604 The Purpose of this rule is to establish reporting standards for Medical Marijuana Testing Facilities and Retail Marijuana Testing Facilities.

### **3-825 – Medical Marijuana Testing Facilities and Retail Marijuana Testing Facilities Specific Tracking Requirements**

- A. Required Procedures. A Medical Marijuana Testing Facility or Retail Marijuana Testing Facility must establish procedures to ensure that results are accurate, precise, and scientifically valid prior to reporting such results.
- B. Reports. Every final report, whether submitted to the Division, to a Regulated Marijuana Business, or to any other Person authorized to receive the report, must include the following:
  1. Report quantitative results that are only above the lowest concentration of calibrator or standard used in the analytical run;
  2. Verify results that are below the lowest concentration of calibrator or standard and above the LOQ by using a blank and a standard that falls below the expected value of the analyte in the sample in duplicate prior to reporting a quantitative result;
  3. Qualitatively report results below the lowest concentration of calibrator or standard and above the LOD as either trace or using a non-specific numerical designation;
  4. Adequately document the available external chain of custody information;
  5. Ensure all final reports contain the name and location of the Medical Marijuana Testing Facility or Retail Marijuana Testing Facility that performed the test, name, and unique identifier of Sample, submitting client, Sample received date, date of report, type of Sample tested, test result, units of measure, and any other information or qualifiers needed for interpretation when applicable to the test method and results being reported, to include any identified and documented discrepancies; and

6. Provide the final report to the Division, as well as the Regulated Marijuana Business, and/or any other Person authorized to receive the report in a timely manner.
- B. Inventory Tracking System. Each Medical Marijuana Testing Facility and Retail Marijuana Testing Facility shall:
1. Report all test results to the Division as part of daily reconciliation by the close of business and in accordance with all Inventory Tracking System Procedures under Rule 3-805 – All Regulated Marijuana Businesses: Inventory Tracking System. The requirement to report all test results includes:
    - a. Both positive and negative test results;
    - b. Results from both mandatory and voluntary testing; and
    - c. For quantitative tests, a quantitative value.
  2. As part of Inventory Tracking System reporting, when results of tested Samples exceed maximum levels of allowable potency or contamination, or otherwise result in failed potency, homogeneity, or contaminant testing, the Medical Marijuana Testing Facility or Retail Marijuana Testing Facility shall, in the Inventory Tracking System, indicate failed test results for the Inventory Tracking System package associated with the failed Sample. This requirement only applies to testing of Samples that are comprised of Regulated Marijuana.
- C. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

### **3-900 Series – Business Records**

#### **Basis and Purpose – 3-905**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-301, and 44-10-1001(1), C.R.S. This rule explains what business records a Licensee must maintain and clarifies that such records must be made available to the Division on demand. This Rule 3-905 was previously Rules M and R 901, 1 CCR 212-1 and 1 CCR 212-2.

#### **3-905 – Business Records Required**

A. General Requirements

1. A Regulated Marijuana Business must maintain the information required in this Rule in a format that is readily understood by a reasonably prudent business person.
2. Each Regulated Marijuana Business shall retain all books and records necessary to fully account for the business transactions conducted under its license for the current year and three preceding calendar years.
  - a. On premises records: The Regulated Marijuana Business's books and records for the preceding six months (or complete copies of such records) must be maintained on the Licensed Premises at all times.
  - b. On- or off-premises records: Books and records associated with older periods may be archived on or off of the Licensed Premises.

3. The books and records must fully account for the transactions of the business and must include, but shall not be limited to:
  - a. Current Employee List – This list must provide the full name and Employee License number of each employee and all Owner Licensees, who work at a Regulated Marijuana Business.
    - i. Each Licensed Premises shall enter the full name and Employee License number of every employee that works on the premises into the Inventory Tracking System. The Licensed Premises shall update its list of employees in the Inventory Tracking System within 10 days of an employee commencing or ceasing employment on the premises.
  - b. Secure Facility Information – For its Licensed Premises and any associated permitted off-premises storage facility, a Regulated Marijuana Business must maintain the business contact information for vendors that maintain video surveillance systems and Security Alarm Systems.
  - c. Advertising Records – All records related to Advertising and marketing, including, but not limited to, audience composition data.
  - d. Licensed Premises – Diagram of all approved Limited Access Areas, Restricted Access Areas, and any permitted off-premises storage facilities.
  - e. Visitor Log – List of all visitors entering Limited Access Areas or Restricted Access Areas.
  - f. All records normally retained for tax purposes.
  - g. Waste Log – Comprehensive records regarding all waste and Fibrous Waste material that accounts for, reconciles, and evidences all waste and Fibrous Waste activity related to the disposal of marijuana.
  - h. Surveillance Logs – Surveillance logs as required by Rule 3-225.
  - i. Every Licensee shall maintain a record of its identity statement and Standardized Graphic Symbol which shall be available upon request by the State Licensing Authority or Division. A Licensee may elect to have its Identity Statement also serve as its Standardized Graphic Symbol for purposes of complying with this rule.
  - j. Testing Records – All testing records required by Rule 5-450.
  - k. Sampling Unit Records – All records related to designated Sampling Managers, identified Sampling Units, and Transfers of Sampling Units. See Rules 3-810, 5-230, 5-320, 6-225, 6-320. This includes, but is not limited to, standard operating procedures that explain the requirements of sections 44-10-502(5), 44-10-503(10), 44-10-602(6) and 44-10-603(10), C.R.S., the personal possession limits pursuant to section 18-18-406, C.R.S., and the requirements imposed by Rules 5-230, 5-320, 6-225, 6-320.
  - l. License Application Records – All records provided by the Licensee to both the state and local licensing authorities in connection with an application for licensure pursuant to the Marijuana Code and these Rules.

- m. Standard Operating Procedures – All standard operating procedures as required by these Rules.
  - n. Audited Product and/or Alternative Use Product Records – All records required to demonstrate compliance with Rule 5-325 and 6-325.
  - o. All records required by Rule 3-240 regarding collection and Transfers of Marijuana Consumer Waste.
  - p. Corrective Action and Preventive Action records required by Rules 5-115, 5-210, 5-310, 6-110, 6-210, 6-310.
  - q. Certificates of analysis or other records demonstrating the full composition of each Ingredient used in the manufacture of Vaporizer Delivery Devices or Pressurized Metered Dose Inhalers as required by Rule 5-310(F).
  - r. Records required to be maintained by Delivery Permit holders.
  - s. Records required to be maintained by Licensed Hospitality Businesses.
  - t. All other records required by these Rules.
- B. Loss of Records and 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.
- C. Violation Affecting Public Safety. Violation of this Rule may constitute a license violation affecting public safety.
- D. Records Related to Inventory Tracking. A Regulated Marijuana Business must maintain accurate and comprehensive inventory tracking records that account for, reconcile and evidence all inventory activity for Regulated Marijuana from either seed or Immature Plant stage until the Regulated Marijuana is destroyed or Transferred to another Regulated Marijuana Business, a consumer, a patient, a Medical Research Facility, or a Pesticide Manufacturer.
- E. Records Related to Transport. A Regulated Marijuana Business must maintain adequate records for the transport of all Regulated Marijuana. See Rule 3-605 – Transport: All Regulated Marijuana Businesses.
- F. Provision of Any Requested Record to the Division. A Licensee 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.

### **Basis and Purpose – 3-910**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), and 44-10-203(2)(j), C.R.S. A Regulated Marijuana Business must collect and remit sales tax on all retail sales made pursuant to the licensing activities. The purpose of this rule is to clarify when such taxes must be remitted to the Colorado Department of Revenue. This Rule 3-910 was previously Rules M and R 902, 1 CCR 212-1 and 1 CCR 212-2.

### **3-910 – Reporting and Transmittal of Taxes**

- A. Sales and Use Tax Returns Required. All state and state-collected sales and use tax returns must be filed, and all taxes must be remitted to the Department of Revenue, on or before the 20<sup>th</sup> day of the month following the reporting month. For example, a January return and remittance will be due to the Department of Revenue by February 20<sup>th</sup>. If the due date (20<sup>th</sup> of the month) falls on a weekend or holiday, the next business day is considered the due date for the return and remittance.
- B. Excise and Retail Marijuana Sales Tax Returns Required. A Retail Marijuana Business shall submit any applicable tax returns and remit any payments due pursuant to Article 28.8 of Title 39, C.R.S.
- C. Proof of Tax Remittance Required. All state tax payments shall require proof of remittance with the State Licensing Authority. A Retail Marijuana Cultivation Facility must maintain records evidencing the payment of all required excise taxes. Proof of retail sales taxes shall be identified in required tax records, tracking systems, and sales receipts provided to consumers.

### **Basis and Purpose – 3-915**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), and 44-10-1001(1), C.R.S. The Marijuana Code mandates that a Regulated Marijuana Business must pay for an audit when the State Licensing Authority deems an audit necessary. This rule explains when an audit may be deemed necessary and sets forth possible consequences of a Regulated Marijuana Business's refusal to cooperate or pay for the audit. This Rule 3-915 was previously Rules M and R 903, 1 CCR 212-1 and 1 CCR 212-2.

### **3-915 – Independent Audit May Be Required**

- A. State Licensing Authority May Require Independent Audit.
  - 1. When the State Licensing Authority deems it necessary, it may require a Regulated Marijuana Business to undergo an audit by an independent accountant. The scope of the audit may include, but need not be limited, to financial transactions and inventory control measures.
  - 2. In such instances, the Division may attempt to mutually agree upon the selection of the independent accountant with a Regulated Marijuana Business. However, the Division always retains the right to select the independent accountant regardless of whether mutual agreement can be reached. The independent accountant shall be a certified public accountant licensed by, and in good standing with, the Colorado State Board of Accountancy.
  - 3. The Regulated Marijuana Business will be responsible for all direct costs associated with the independent audit.
- B. When Independent Audit Is Necessary. The State Licensing Authority has discretion to determine when an audit by an independent accountant is necessary. The following is a non-exhaustive list of examples that may justify an independent audit:
  - 1. A Regulated Marijuana Business does not provide requested records to the Division;
  - 2. The Division has reason to believe that the Regulated Marijuana Business does not properly maintain its business records;
  - 3. A Regulated Marijuana Business has a prior violation related to recordkeeping or inventory control;

4. A Regulated Marijuana Business has a prior violation related to diversion.
  5. As determined by the Division, the scope of an audit conducted by the Division would be so extensive as to jeopardize the regular duties and responsibilities of the Division's audit or enforcement staff.
- C. Compliance Required. A Regulated Marijuana Business must pay for and timely cooperate with the State Licensing Authority's requirement that it undergo an audit in accordance with this Rule.
- D. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

### **Basis and Purpose – 3-920**

The statutory authority for this rule includes but is not limited to sections 44-10-201(4), 44-10-204(1)(a), 44-10-202(1)(c), 44-10-202(1)(a), 44-10-204(1)(a), 44-10-203(1)(j), 44-10-313(12), and 44-10-701(2)(a), C.R.S. The State Licensing Authority must be able to immediately access information regarding a Regulated Marijuana Business's managing individual. Accordingly, this rule reiterates the statutory mandate that Licensees provide any management change to the Division within seven days of any change, and also clarifies that a Licensee must save a copy of any management change report to the Division, and clarifies that failure to follow this rule can result in discipline.

The State Licensing Authority finds it essential to the stringent and comprehensive enforcement of the Marijuana Code to regulate, monitor, and track all Regulated Marijuana in order to prevent diversion and to ensure that all Regulated Marijuana grown, processed, sold, and disposed of in the Regulated Marijuana market is accounted for transparently in accordance with the Marijuana Code.

Requiring Licensees to report instances when the Regulated Marijuana they cultivate, manufacture, distribute, sell, test, or dispose of is stolen, unlawfully transferred, or otherwise diverted from the regulated market, or when Licensees discover plans to divert the Regulated Marijuana, emphasizes that Licensees are accountable for their Regulated Marijuana at all times and contributes to the transparency of the regulated market.

In addition to maintaining transparency in the regulated marijuana industry, the State Licensing Authority also must ensure the confidentiality of certain Licensee information and records, including information in the Inventory Tracking System. Requiring Licensees to report instances where the Inventory Tracking System was compromised or planned to be compromised through unlawful access, use for unlawful purposes, the deliberate alteration or deletion of data, or deliberately entering false data, contributes to ensuring the accuracy and transparency of the system and therefore the regulated market, and aids in maintaining the confidentiality of Licensee data.

This Rule 3-920 was previously Rules M and R 904, 1 CCR 212-1 and 1 CCR 212-2.

### **3-920 – Regulated Marijuana Business Reporting Requirements**

- A. Management Personnel Change Must Be Reported.
1. When Required. A Regulated Marijuana Business shall provide the Division a written report within seven days after any change in management personnel occurs. In addition, a Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or Retail Marijuana Products Manufacturer shall report any designation or change of Sampling Manager(s) through the Inventory Tracking System.

2. Licensee Must Maintain Record of Reported Change. A Regulated Marijuana Business must also maintain a copy of this written report with its business records.
  3. Consequence of Failure to Report. Failure to report a change in a timely manner may result in discipline.
- B. Reporting of Crime on the Licensed Premises or Otherwise Related to a Regulated Marijuana Business. A Regulated Marijuana Business and all Licensees employed by the Regulated Marijuana Business shall report to the Division any discovered plan or other action of any Person to (1) commit theft, burglary, underage sales, diversion of marijuana or marijuana product, or other crime related to the operation of the subject Regulated Marijuana Business; or (2) compromise the integrity of the Inventory Tracking System. A report shall be made as soon as possible after the discovery of the action, but not later than 14 days. Nothing in this paragraph (B) alters or eliminates any obligation a Regulated Marijuana Business or Licensee may have to report criminal activity to a local law enforcement agency.

### **Basis and Purpose – 3-925**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-204(1)(a), 44-10-203(2)(j), 44-10-203(2)(k), 44-10-203(1)(j), and 44-10-307(1)(e), C.R.S. See also articles 21, 22, 26 and 28.8 of title 39, C.R.S. The purpose of this rule is to clarify the Division's authority to provide taxation divisions within the Department copies of or access to reports or other information obtained from or regarding a Licensee, for the purpose of ensuring accurate and complete filing of tax returns and payment of sales, excise and income taxes required by Title 39 of the Colorado Revised Statutes. Such information sharing is for a purpose authorized by the Marijuana Code. This Rule 3-925 was previously Rules M and R 905, 1 CCR 212-1 and 1 CCR 212-2.

### **3-925 – Department Information Access**

- A. Department Access to Reports or Other Information. The Division may provide taxation divisions within the Department copies of or access to reports or other information obtained from or regarding a Licensee for the purpose of ensuring accurate and complete filing of tax returns and payment of sales, excise, and income taxes required by Title 39 of the Colorado Revised Statutes.
- B. Confidentiality. Reports or other information provided to or accessed by taxation divisions within the Department for the purpose of ensuring accurate and complete filing of tax returns and payment of sales, excise, and income taxes required by Title 39 of the Colorado Revised Statutes shall be considered part of the Department's investigation pursuant to subsection 39-21-113(4)(a), C.R.S., and the Division shall continue to maintain such records and information in its possession or control as confidential pursuant to subsection 44-10-204(1)(a), C.R.S.

### **3-1000 Series – Labeling, Packaging, and Product Safety**

#### **Basis and Purpose – 3-1005**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(a), 44-10-202(1)(c), 44-10-202(6), 44-10-203(2)(f), 44-10-203(1)(j), 44-10-203(3)(a)-(b), 44-10-601(2)(a), 44-10-601(5), 44-10-603(1)(d), 44-10-603(4)(a), and 44-10-603(8), C.R.S. The purpose of this rule is to define minimum packaging and labeling requirements for Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product transferred between Regulated Marijuana Businesses. The State Licensing Authority finds it essential to regulate and establish labeling requirements for Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product and that this is in the interest of the health and safety of the people of Colorado. This rule identifies information that is required on all labels to provide information necessary for the Division to regulate the cultivation, production, and sale of

Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product. This rule also seeks to minimize, to the extent practicable, the burden of labeling compliance to Licensees. The labeling requirements in this rule apply to all Containers immediately containing Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product. This Rule 3-1005 was previously Rules M and R 1001-1, 1 CCR 212-1 and 1 CCR 212-2.

### **3-1005 - Packaging and Labeling: Minimum Requirements Prior to Transfer to a Regulated Marijuana Business**

- A. Applicability. This Rule establishes minimum requirements for packaging and labeling Regulated Marijuana prior to Transfer to a Regulated Marijuana Business. The labeling requirements in this Rule apply to all Containers immediately containing Medical Marijuana, Retail Marijuana, Medical Marijuana Concentrate, Retail Marijuana Concentrate, Medical Marijuana Product, and Retail Marijuana Product.
- B. Packaging and Labeling of Regulated Marijuana Flower, Trim, Wet Whole Plant, and Regulated Marijuana Concentrate, Prior to Transfer to a Regulated Marijuana Business. A Regulated Marijuana Business shall comply with the following minimum packaging and labeling requirements prior to Transferring Medical Marijuana flower, trim, wet whole plant, or Medical Marijuana Concentrate to another Medical Marijuana Business, or Retail Marijuana flower, trim, wet whole plant, or Retail Marijuana Concentrate to another Retail Marijuana Business:
1. Packaging of Regulated Marijuana Flower and Trim, and Regulated Marijuana Concentrate.
    - a. Prior to Transfer to a Regulated Marijuana Business, Regulated Marijuana flower, trim, wet whole plant, or Regulated Marijuana Concentrate shall be placed into a Container. The Container may but is not required to be Child-Resistant.
    - b. Each Container of Regulated Marijuana flower or trim that is Transferred to a Regulated Marijuana Business shall not exceed 10 pounds of Regulated Marijuana flower or trim, but may include pre-weighed units that are within the sales limit in Rules 5-115(C), 6-110(C), and 6-725(G).
    - c. A Container of wet whole plant that is Transferred to a Regulated Marijuana Business may exceed 10 pounds, but shall not exceed 100 pounds.
    - d. Each Container of Medical Marijuana Concentrate that is Transferred to a Medical Marijuana Business, or Retail Marijuana Concentrate that is Transferred to a Retail Marijuana Business, shall not exceed 10 pounds of Medical Marijuana Concentrate or Retail Marijuana Concentrate, but may include pre-weighed units that are within the applicable sales limit in Rules 5-115(C), 6-110(C), and 6-725(G).
  2. Labeling of Regulated Marijuana Flower, Trim, Wet Whole Plant, and Regulated Marijuana Concentrate. Prior to Transfer to a Regulated Marijuana Business, every Container of Regulated Marijuana flower, trim, wet whole plant, or Regulated Marijuana Concentrate shall be affixed with a label that includes at least the following information:
    - a. The license number of the Medical Marijuana Cultivation Facility where the Medical Marijuana was grown, or the Retail Marijuana Cultivation Facility where the Retail Marijuana was grown;
    - b. The Harvest Batch Number(s) assigned to the Regulated Marijuana or the Production Batch Number(s) assigned to the Regulated Marijuana Concentrate;



- c. If applicable, the license number of the Medical Marijuana Cultivation Facility(ies) that produced the Water-Based Medical Marijuana Concentrate, or the Retail Marijuana Cultivation Facility(ies) that produced the Water-Based Retail Marijuana Concentrate;
- d. If applicable, the license number of the Medical Marijuana Products Manufacturer(s) where the Medical Marijuana Concentrate was produced, or the Retail Marijuana Products Manufacturer(s) where the Retail Marijuana Concentrate was produced;
- e. The net contents, using a standard of measure compatible with the Inventory Tracking System, of the Regulated Marijuana or Regulated Marijuana Concentrate prior to its placement in the Container; and
- f. Potency test results as required to permit the receiving Regulated Marijuana Business to label the Medical Marijuana, Retail Marijuana, Medical Marijuana Concentrate, or Retail Marijuana Concentrate as required by these rules.
- g. Vaporizer Delivery Devices and Pressurized Metered Dose Inhalers. A list of all Ingredients, including Additives, used to manufacture the Vaporizer Delivery Device or Pressurized Metered Dose Inhaler.

C. Packaging and Labeling of Regulated Marijuana Product Prior to Transfer to a Regulated Marijuana Business. A Regulated Marijuana Business shall comply with the following minimum packaging and labeling requirements prior to Transferring Medical Marijuana Product to another Medical Marijuana Business, or Transferring Retail Marijuana Product to another Retail Marijuana Business:

1. Packaging of Regulated Marijuana Product.

- a. Transfer to a Regulated Marijuana Business Other Than a Medical Marijuana Store or Retail Marijuana Store. Prior to Transfer to a Regulated Marijuana Business other than a Medical Marijuana Store or Retail Marijuana Store, Regulated Marijuana Product shall be placed into a Container. The Container may but is not required to be Child-Resistant.
- b. Transfer to a Medical Marijuana Store or Retail Marijuana Store. Prior to Transfer to a Medical Marijuana Store or Retail Marijuana Store, all Regulated Marijuana Product shall be packaged in a Child-Resistant Container that is ready for sale to the patient or consumer as required by the Rule 3-1010(D).

2. Labeling of Regulated Marijuana Product.

- a. Transfer to a Regulated Marijuana Business other than a Medical Marijuana Store or Retail Marijuana Store. Prior to Transfer to a Regulated Marijuana Business other than a Medical Marijuana Store or Retail Marijuana Store, every Container of Regulated Marijuana Product shall be affixed with a label that includes at least the following information:
  - i. The license number of the Medical Marijuana Cultivation Facility(ies) where the Medical Marijuana was grown, or Retail Marijuana Cultivation Facility(ies) where the Retail Marijuana was grown;

- ii. The license number of the Medical Marijuana Products Manufacturer that produced the Medical Marijuana Product, or the Retail Marijuana Products Manufacturer that produced the Retail Marijuana Product;
  - iii. The Production Batch Number(s) assigned to the Regulated Marijuana Product;
  - iv. The net contents, using a standard of measure compatible with the Inventory Tracking System, of the Regulated Marijuana Product prior to its placement in the Container; and
  - v. Potency test results as required to permit the receiving Regulated Marijuana Business to label the Medical Marijuana Product or Retail Marijuana Product as required by these rules.
- b. Transfer to a Medical Marijuana Store or Retail Marijuana Store. Prior to Transfer to a Medical Marijuana Store or Retail Marijuana Store, every Container of Medical Marijuana Product or Retail Marijuana Product shall be affixed with a label ready for sale to the patient or consumer including all information required by Rules 3-1010(D)(2) and 3-1015(B).

D. Packaging and Labeling of Regulated Marijuana Seeds and Immature Plants Prior to Transfer to a Regulated Marijuana Business. A Regulated Marijuana Business shall comply with the following minimum packaging and labeling requirements prior to Transferring Regulated Marijuana seeds or Immature plants to another Regulated Marijuana Business:

1. Packaging of Regulated Marijuana Seeds.

- a. Prior to Transfer to a Regulated Marijuana Business, Regulated Marijuana seeds shall be placed into a Container. The Container may but is not required to be Child-Resistant.
- b. Each Container of Regulated Marijuana seeds that is Transferred to a Regulated Marijuana Business shall not exceed 10 pounds of Regulated Marijuana seeds.

2. Packaging of Immature Plants. Prior to Transfer to a Regulated Marijuana Business, Immature plants shall be placed into a receptacle. The receptacle may but is not required to be Child-Resistant.

3. Labeling of Regulated Marijuana Seeds and Immature Plants. Prior to Transfer to a Regulated Marijuana Business, every Container of Regulated Marijuana seeds and all receptacles holding an Immature plant shall be affixed with a label that includes at least the license number of the Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility where the Regulated Marijuana that produced the seeds or the Immature plant was grown.

E. Packaging and Labeling of Sampling Units. A Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or Retail Marijuana Products Manufacturer shall comply with the following minimum packaging and labeling requirements prior to Transferring any Sampling Unit to a Sampling Manager.

- 1. Packaging of Sampling Units. Prior to Transfer to a Sampling Manager, a Sampling Unit must be placed in a Container. If the Sampling Unit is Regulated Marijuana flower, trim, Medical Marijuana Concentrate, or Retail Marijuana Concentrate, the Container may, but is not required to, be Child-Resistant; however, the Container shall be placed into a

Child-Resistant Exit Package at the point of Transfer to the Sampling Manager. If the Sampling Unit is composed of Regulated Marijuana Product, the Sampling Unit shall be packaged in a Child-Resistant Container.

2. Labeling of Sampling Units. Prior to Transfer to a Sampling Manager, every Container for a Sampling Unit shall be affixed with a label that includes at least the following information:
    - a. Required License Number. The license number for the Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer Transferring the Sampling Unit.
    - b. Batch Number(s). The relevant Harvest Batch number and/or Production Batch number from which the Sampling Unit was designated.
    - c. Universal Symbol. The Universal Symbol on the front of the Container and any Marketing Layer, no smaller than ½ of an inch by ½ of an inch, with the following statement directly below the Universal Symbol: **“Contains Marijuana. Keep away from children.”**
    - d. Required Potency Statement.
      - i. For a Sampling Unit composed of Regulated Marijuana, Medical Marijuana Concentrate, or Retail Marijuana Concentrate, the potency of the Sampling Unit’s active THC and CBD expressed as a percentage.
      - ii. For a Sampling Unit composed of Regulated Marijuana Product, the potency of the Sampling Unit’s active THC and CBD expressed in milligrams.
      - iii. The required potency statement shall be displayed either: (1) In a font that is bold, and enclosed within an outlined shape such as a circle or square; or (2) highlighted with a bright color, such as yellow.
    - e. Date of Transfer. The label shall include the date of Transfer to the Sampling Unit.
    - f. Patient Number. If the Sampling Unit contains Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana Product, the label must also include the patient registration number of the recipient Sampling Manager.
    - g. Required Warning Statements. Either the label affixed to the Container or the Marketing Layer shall include the following information:
      - i. “This product was received as a Sampling Unit and may have been produced with undisclosed allergens, solvents, or pesticides, and may pose unknown physical or mental health risks. This product is not for resale and should not be used by anyone else.”
- F. Prohibited Transfers – All Regulated Marijuana Businesses. A Regulated Marijuana Business shall not Transfer to a Medical Marijuana Store, Retail Marijuana Store, or Retail Marijuana Hospitality and Sales Business—and a Medical Marijuana Store, Retail Marijuana Store, or Retail Marijuana Hospitality and Sales Business shall not accept nor offer for sale—any Regulated Marijuana that is not packaged and labeled in conformance with the requirements of these rules

or that does not provide all information necessary to permit the Medical Marijuana Store, Retail Marijuana Store, or Retail Marijuana Hospitality and Sales Business to package and label the Regulated Marijuana prior to Transfer to a patient or consumer. However, a Medical Marijuana Store or Retail Marijuana Store is not required to open any tamper evident Marketing Layer received from a Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or a Retail Marijuana Products Manufacturer to verify the Container is Child-Resistant or labeled.

- G. Shipping Containers. Licensees may Transfer multiple Containers of Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product to a Regulated Marijuana Business in a Shipping Container.
1. RFID Tag Required. Licensees shall ensure that either the multiple Containers placed within a Shipping Container each have an RFID tag, or the Shipping Container itself must have an RFID tag. If the Licensee elects to place the RFID tag on the Shipping Container, the Shipping Container shall contain only one Harvest Batch of Regulated Marijuana, one Production Batch of Regulated Marijuana Concentrate, or one Production Batch of Regulated Marijuana Product. If a Shipping Container consists of more than one Harvest Batch or Production Batch, then each group of multiple Containers shall be affixed with an RFID tag. See Rule 3-805 – Inventory Tracking System; Rule 3-605 – Transport: All Regulated Marijuana Businesses.
  2. Labeling of Shipping Containers. Any Shipping Container that will not be displayed to the consumer is not required to be labeled according to these rules.
- H. Packaging and Labeling of Regulated Marijuana Flower and Trim Prior to Transfer to a Medical Research Facility, a Pesticide Manufacturer, or a Marijuana Research and Development Facility. The packaging and labeling requirements in these 3-1000 Series Rules also apply to any Transfer of Regulated Marijuana, Regulated Marijuana Concentrate, or Regulated Marijuana Product to a Medical Research Facility, a Pesticide Manufacturer, or a Marijuana Research and Development Facility.
- I. Marijuana Research and Development Facility Transfers to Persons as Part of an Approved Research Project. Any Marijuana Research and Development Facility conducting research as part of an approved Research Project involving human subjects shall comply with all packaging and labeling requirements that are applicable to a Medical Marijuana Store prior to Transfer to a patient, unless the Marijuana Research and Development Facility requests and receives in advance a waiver of specific packaging or labeling requirements in connection with the approved Research Project.
- J. Research Transfers Prohibited. A Medical Marijuana Store or Retail Marijuana Store shall not Transfer any Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana Product, Retail Marijuana, Retail Marijuana Concentrate, or Retail Marijuana Product to a Medical Research Facility, a Pesticide Manufacturer, or a Licensed Research Business.
- K. Violation Affecting Public Safety. A violation of any rule in these 3-1000 Series Rules may be considered a license violation affecting public safety.

### **Basis and Purpose – 3-1010**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(a), 44-10-202(1)(c), 44-10-202(6), 44-10-203(2)(f), 44-10-203(1)(j), 44-10-203(3)(a)-(b), 44-10-601(2)(a), 44-10-601(5), 44-10-603(1)(d), 44-10-603(4)(a), and 44-10-603(8), C.R.S. The purpose of this rule is to define general packaging and labeling requirements for Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product prior to Transfer to a patient or consumer. The labeling requirements in this

rule apply to all Containers immediately containing Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product. The State Licensing Authority finds it essential to regulate and establish labeling requirements for Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product and that this is in the interest of the health and safety of the people of Colorado. This rule identifies information that is required on all labels to provide necessary information to patients and consumers to make informed decisions and first responders in the event of accidental ingestion, over ingestion or allergic reaction. This rule also seeks to minimize, to the extent practicable, the burden of labeling compliance to Licensees. This Rule 3-1010 was previously Rules M and R 1002-1, 1 CCR 212-1 and 1 CCR 212-2.

### **3-1010 – Packaging and Labeling: General Requirements Prior to Transfer to a Patient or Consumer**

- A. Applicability. This Rule establishes general requirements for packaging and labeling Regulated Marijuana prior to Transfer to a patient or consumer. The labeling requirements in this Rule apply to all Containers immediately containing any Regulated Marijuana. The labeling requirements based on intended use in Rule 3-1015 are in addition to, not in lieu of, the requirements in this Rule.
1. Exemption for Transfers to Consumers by a Retail Marijuana Hospitality and Sales Business. Unless otherwise provided by these rules, a Retail Marijuana Hospitality and Sales Business Transferring Retail Marijuana to consumers in compliance with the packaging and labeling requirements of Rule 3-1020 is exempt from the requirements of this Rule.
- B. Labeling Requirements – All Regulated Marijuana.
1. Font Size. Required labeling text on the Container and any Marketing Layer must be no smaller than 1/16 of an inch.
  2. Labels Shall Not Be Designed to Appeal to Children. A Regulated Marijuana Business shall not place any content on a Container or the Marketing Layer in a manner that reasonably appears to target individuals under the age of 21, including but not limited to, cartoon characters or similar images.
  3. False or Misleading Statements. Label(s) on a Container and any Marketing Layer shall not include any false or misleading statements.
  4. Trademark Infringement Prohibited. No Container or Marketing Layer shall be intentionally or knowingly labeled so as to cause a reasonable consumer confusion as to whether the Regulated Marijuana is a trademarked product or labeled in a manner that violates any federal trademark law or regulation.
  5. Health and Benefit Claims. The label(s) on the Container and any Marketing Layer shall not make any claims regarding health or physical benefits to the patient or consumer.
  6. Use of English Language. Labeling text on the Container and any Marketing Layer must be clearly written or printed and in the English language. In addition to the required English label, Licensees may include an additional, accurate foreign language translation on the label that otherwise complies with these rules.
  7. Unobstructed and Conspicuous. Labeling text on the Container and any Marketing Layer must be unobstructed and conspicuous. A Licensee may affix multiple labels to the Container, provided that none of the information required by these rules is obstructed.

For example and not by means of limitation, labels may be accordion, expandable, extendable or layered to permit labeling of small Containers.

8. Use of the Word “Candy” and/or “Candies” Prohibited.
    - a. Licensees shall not use the word(s) “candy” and/or “candies” on the label of any Container holding Regulated Marijuana, or of any Marketing Layer.
    - b. Notwithstanding the requirements of this subparagraph, a Regulated Marijuana Business whose identity statement contains the word(s) “candy” and/or “candies” may place its Identity Statement on the label of the Container holding Regulated Marijuana, or of any Marketing Layer.
  9. Child Resistant Certificate(s). A Licensee shall maintain a copy of the certificate showing that each Child-Resistant Container into which the Licensee places Regulated Marijuana is Child-Resistant and complies with the requirements of 16 C.F.R. 1700.15 (1995) and 16 C.F.R. 1700.20 (1995) in accordance with the requirements of Rule 3-905(A).
    - a. 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 16 C.F.R. 1700.15 (1995) and 16 C.F.R. 1700.20 (1995), which is available to the public for inspection and copying during the Division’s regular business hours.
  10. Containers and Marketing Layers. The Container and any Marketing Layer shall have a label with all information required by these 3-1000 Series Rules. Any intermediary packaging between the Container and the Marketing Layer is not required to be labeled in accordance with these rules.
  11. Exit Packages.
    - a. Exit Packages Permitted for Child-Resistant Containers. A Medical Marijuana Store or Retail Marijuana Store may but is not required to place a Child-Resistant Container into an Opaque Exit Package at the point of Transfer to the patient or consumer.
    - b. Exit Packages Required for Regulated Marijuana Flower, Trim, and Seeds. Any Regulated Marijuana flower, trim, or seeds in a Container that is not Child-Resistant shall be placed into a Child-Resistant Exit Package at the point of Transfer to a patient or consumer. The Exit Package is not required to be labeled but may include the Medical Marijuana Store’s or Retail Marijuana Store’s Identity Statement and/or Standardized Graphic Symbol.
- C. Packaging and Labeling of Regulated Marijuana Flower and Trim, and Regulated Marijuana Concentrate Prior to Transfer to a Patient or Consumer. A Medical Marijuana Store or Retail Marijuana Store shall comply with the following minimum packaging and labeling requirements prior to Transferring Medical Marijuana flower and trim, Retail Marijuana flower and trim, Medical Marijuana Concentrate, or Retail Marijuana Concentrate to a patient or consumer:
1. Packaging of Regulated Marijuana Flower and Trim. Prior to Transfer to a patient or a consumer, Regulated Marijuana flower and trim shall be in a Container that does not exceed the sales limit in Rules 5-115(C) and 6-110(C). The Container may but is not required to be Child-Resistant. Any Regulated Marijuana flower and trim in a Container that is not Child-Resistant shall be placed into a Child-Resistant Exit Package at the point of Transfer to a patient or consumer.

2. Packaging of Regulated Marijuana Concentrate. Prior to Transfer to a patient or consumer, Regulated Marijuana Concentrate shall be in a Child-Resistant Container that does not exceed the sales limit in Rules 5-115(C) and 6-110(C).
  - a. A Pressurized Metered Dose Inhaler, Vaporizer Delivery Device, or syringe-type device that is within an intended use that is listed in Rule 3-1015(B) and is not an Alternative Use Product need not itself be Child-Resistant but must be placed into a Child-Resistant Container prior to Transfer to a patient or consumer.
  - b. A Pressurized Metered Dose Inhaler, Vaporizer Delivery Device, or syringe-type device with an intended use that is listed in Rule 3-1015(B) and that is not an Alternative Use Product must be labeled with at least the Universal Symbol, but is not required to include “**Contains Marijuana. Keep away from children.**”, prior to Transfer to a patient or consumer. The Universal Symbol shall be legible and no smaller than ¼ of an inch by ¼ of an inch.
  - c. A Pressurized Metered Dose Inhaler or Vaporizer Delivery Device must be affixed with a label that states “**Not approved by the FDA.**” For example and not by means of limitation, labels may be affixed using the following methods: accordion, expandable, extendable, layered, tags, or stickers.
  - d. Nothing in this Rule authorizes the use of a syringe for any type of injection involving a needle piercing the skin.
  
3. Labeling of Regulated Marijuana Flower and Trim, and Regulated Marijuana Concentrate. Prior to Transfer to a patient or consumer, every Container of Regulated Marijuana flower and trim, or Regulated Marijuana Concentrate and any Marketing Layer shall be affixed with a label that includes at least the following information:
  - a. Required License Number(s). The license number for each of the following:
    - i. The Medical Marijuana Cultivation Facility where the Medical Marijuana was grown or the Retail Marijuana Cultivation Facility where the Retail Marijuana was grown;
    - ii. If applicable, the Medical Marijuana Cultivation Facility(ies) where the Water-Based Medical Marijuana Concentrate was produced, or the Retail Marijuana Cultivation Facility(ies) where the Water-Based Retail Marijuana Concentrate was produced;
    - iii. If applicable, the Medical Marijuana Products Manufacturer where the Medical Marijuana Concentrate was produced, or the Retail Marijuana Products Manufacturer where the Retail Marijuana Concentrate was produced; and
    - iv. The Medical Marijuana Store or Retail Marijuana Store that sold the Medical Marijuana, Retail Marijuana, Medical Marijuana Concentrate, or Retail Marijuana Concentrate to the patient or consumer, except the Medical Marijuana Store or Retail Marijuana Store may affix its license number to the Container or Marketing Layer.
  - b. Batch Numbers. The Harvest Batch Number(s) assigned to the Regulated Marijuana or the Production Batch Number(s) assigned to the Regulated Marijuana Concentrate.

- c. Statement of Net Contents. The statement of net contents must identify the net weight of the Regulated Marijuana or net weight or volume of Regulated Marijuana Concentrate prior to its placement in the Container, using a standard of measure compatible with the Inventory Tracking System.
- d. Universal Symbol. The Universal Symbol on the front of the Container and any Marketing Layer, no smaller than ½ of an inch by ½ of an inch, with the following statement directly below the Universal Symbol: **“Contains Marijuana. Keep away from children.”**
- e. Required Potency Statement. The potency of Regulated Marijuana flower or trim shall be expressed as: (1) the percentage of total THC and CBD from the test results for that Harvest Batch, or (2) if the Harvest Batch is not required to be tested, either as: (i) a range of percentages of total THC and CBD that extends from the lowest percentage to the highest percentage for each cannabinoid listed, from every test conducted on that strain of Regulated Marijuana cultivated by the same Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility during the preceding six months or (ii) an average for each cannabinoid listed, from every test conducted on that strain of Regulated Marijuana cultivated by the Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility during the preceding six months. If CBD is not detected in Harvest Batch, then Total CBD potency is not required. The potency of Medical Marijuana Concentrate’s or Retail Marijuana Concentrate’s Total THC and CBD shall be expressed as a percentage. If CBD is not detected in the Production Batch, then Total CBD potency is not required. The potency of Regulated Marijuana, Medical Marijuana Concentrate, and Retail Marijuana Concentrate shall be displayed either:
  - i. In a font that is bold, and enclosed within an outlined shape such as a circle or square; or
  - ii. Highlighted with a bright color such as yellow.
- f. Date of Sale. The Medical Marijuana Store or Retail Marijuana Store shall affix the date of sale to the patient or consumer to the Container or Marketing Layer.
- g. Patient Number. The Medical Marijuana Store shall affix the patient’s registration number to the Container or Marking Layer at the time of Transfer to the patient.
- h. Solvent List. A list of any solvent(s) used to produce any Solvent-Based Medical Marijuana Concentrate or Solvent-Based Retail Marijuana Concentrate.
- i. Ingredient List Including Major Allergens. If applicable, a list of all Ingredients used to manufacture the Regulated Marijuana Concentrate including identification of any major allergens contained in the Regulated Marijuana Concentrate in accordance with the Food Allergen Labeling and Consumer Protection Act of 2004, 21 U.S.C. § 343 (2010). The Food Allergen Labeling and Consumer Protection Act of 2004, 21 U.S.C. § 343 (2010) requires disclosure of the following major food allergens: milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans.
  - i. Note that this Rule does not include any later amendments or editions to the United States Code. The Division maintains a copy of 21 U.S.C. § 343 (2010), which is available to the public for inspection and copying during the Division’s regular business hours.



- j. Required Warning Statements. Either the label affixed to the Container or the Marketing Layer shall include the following information:
  - i. **“This product was produced without regulatory oversight for health, safety, or efficacy.”**
  - ii. **“There may be long term physical or mental health risks from use of marijuana including additional risks for women who are or may become pregnant or are breastfeeding. Use of marijuana may impair your ability to drive a car or operate machinery.”**
- k. Vaporizer Delivery Devices and Pressurized Metered Dose Inhalers. A list of all Ingredients, including Additives, used to manufacture the Vaporizer Delivery Device or Pressurized Metered Dose Inhaler

D. Packaging and Labeling of Regulated Marijuana Product and Audited Product. A Medical Marijuana Products Manufacturer, Retail Marijuana Products Manufacturer, Medical Marijuana Store, and a Retail Marijuana Store shall comply with the following minimum packaging and labeling requirements prior to Transferring Regulated Marijuana Product:

- 1. Packaging of Regulated Marijuana Product. Every Regulated Marijuana Product shall be in a Child-Resistant Container at the time of Transfer to a Medical Marijuana Store or Retail Marijuana Store in accordance with the following packaging limits:
  - a. Regulated Marijuana Product Other than Edible Medical Marijuana Product or Edible Retail Marijuana Product. Medical Marijuana Product that is not Edible Medical Marijuana Product and Retail Marijuana Product that is not Edible Retail Marijuana Product shall be placed into a Child-Resistant Container that does not exceed the sales limit in Rule 5-115(C) and 6-110(C). A Pressurized Metered Dose Inhaler, Vaporizer Delivery Device, or syringe-type device that is within the intended use that is listed in Rule 3-1015(B) and is not an Alternative Use Product need not itself be Child-Resistant but must be placed into a Child-Resistant Container prior to Transfer to a patient or consumer. A Pressurized Metered Dose Inhaler, Vaporizer Delivery Device, or syringe-type device within an intended use that is listed in Rule 3-1015(B) and that is not an Alternative Use Product must be labeled with at least the Universal Symbol, but is not required to include **“Contains Marijuana. Keep away from children.”**, prior to Transfer to a patient or consumer. The Universal Symbol shall be legible and no smaller than ¼ of an inch by ¼ of an inch. Nothing in this Rule authorizes the use of a syringe for any type of injection involving a needle piercing the skin.
  - b. Edible Medical Marijuana Product. Every Edible Medical Marijuana Product including Liquid Edible Medical Marijuana Product shall be in a Child-Resistant Container. If the Edible Medical Marijuana Product contains multiple portions then it shall be placed into a Child-Resistant Container that is Resealable.
  - c. Edible Retail Marijuana Product. Edible Retail Marijuana Product shall be in a Child-Resistant Container as follows:
    - i. Single-Serving Edible Retail Marijuana Product. Every Single-Serving Edible Retail Marijuana Product must be placed into a Child-Resistant Container.
    - ii. Bundled Single-Serving Edible Retail Marijuana Product. Single-Serving Edible Retail Marijuana Products that are placed into a Child-Resistant

Container may be bundled into a larger Marketing Layer so long as the total amount of active THC per Marketing Layer does not exceed 100 milligrams.

- iii. Multiple-Serving Edible Retail Marijuana Product. Every Multiple-Serving Edible Retail Marijuana Product shall be placed into a Child-Resistant Container that is Resealable and shall not exceed 100 milligrams of active THC per Container.
  
- d. Liquid Edible Medical Marijuana Product and Liquid Edible Retail Marijuana Product. Liquid Edible Medical Marijuana Product and Liquid Edible Retail Marijuana Product shall be in a Child-Resistant Container as follows:
  - i. Single-Serving Liquid Edible Medical Marijuana Product Liquid Edible Retail Marijuana Product. Each Liquid Edible Medical Marijuana Product and Liquid Edible Retail Marijuana Product that is a Single-Serving must be packaged in a Child-Resistant Container.
  
  - ii. Multiple-Serving Liquid Edible Retail Marijuana Product. Each Liquid Edible Retail Marijuana Product that is a Multiple-Serving Edible Retail Marijuana Product shall be:
    - a. Packaged in a structure that uses a single mechanism to achieve both Child-Resistant properties and accurate pouring measurement of each liquid serving in increments equal to or less than 10 milligrams of active THC per serving, with no more than 100 milligrams of active THC total per Container; and
  
    - b. The measurement component is within the Child-Resistant cap or closure of the bottle and is not a separate component.
  
  - iii. Multiple-Serving Liquid Edible Medical Marijuana Product. Each Liquid Edible Medical Marijuana Product that is a Multiple-Serving Edible Medical Marijuana Product shall be:
    - a. Packaged in a structure that uses a single mechanism to achieve both Child-Resistant properties and accurate pouring measurement of each liquid serving; and
  
    - b. The measurement component is within the Child-Resistant cap or closure of the bottle, and is not a separate component.
  
- e. Audited Product. The Container containing Audited Product for administration by: (i) metered dose nasal spray or (ii) vaginal administration must be Child Resistant and labeled. A Container holding Audited Product for rectal administration need not be Child-Resistant but must be placed into a Child-Resistant Container prior to Transfer to a patient.
  - i. A metered dose nasal spray must be affixed with a label that states: “**Not approved by FDA.**”
  
  - ii. The Container holding Audited Product for vaginal administration and rectal administration must be affixed with a label that states: “**Not approved by FDA.**”

- iii. For example and not by means of limitation, labels may be affixed using the following methods: accordion, expandable, extendable, layered, tags, or stickers.
2. Labeling of Regulated Marijuana Product. Prior to Transfer to a Medical Marijuana Store and a patient, or Retail Marijuana Store and a consumer, every Container of Regulated Marijuana Product and any Marketing Layer shall be affixed with a label that includes at least the following information:
- a. Required License Number(s). The license number for each of the following:
    - i. The Medical Marijuana Cultivation Facility where the Medical Marijuana was grown, or the Retail Marijuana Cultivation Facility where the Retail Marijuana was grown;
    - ii. The Medical Marijuana Products Manufacturer where the Medical Marijuana Product was produced, or the Retail Marijuana Products Manufacturer where the Retail Marijuana Product was produced; and
    - iii. The Medical Marijuana Store that sold the Medical Marijuana Product to a patient, or the Retail Marijuana Store that sold the Retail Marijuana Product to the consumer, except the Medical Marijuana Store or Retail Marijuana Store may affix its license number to the Container or Marketing Layer.
  - b. Batch Numbers. The Production Batch Number(s) assigned to the Regulated Marijuana Product.
  - c. Statement of Net Contents. The statement of net contents must identify the net weight, volume, or number of Regulated Marijuana Products prior to its placement in the Container, using a standard of measure compatible with the Inventory Tracking System.
  - d. Universal Symbol. The Universal Symbol on the front of the Container and any Marketing Layer, no smaller than ½ of an inch by ½ of an inch, with the following statement directly below the Universal Symbol: **“Contains Marijuana. Keep away from children.”**
  - e. Ingredient List Including Major Allergens. A list of all Ingredients used to manufacture the Regulated Marijuana Product including identification of any major allergens contained in the Regulated Marijuana Product in accordance with the Food Allergen Labeling and Consumer Protection Act of 2004, 21 U.S.C. § 343 (2010). The Food Allergen Labeling and Consumer Protection Act of 2004, 21 U.S.C. § 343 (2010) requires disclosure of the following major food allergens: milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans.
    - i. Note that this Rule does not include any later amendments or editions to the United States Code. The Division maintains a copy of 21 U.S.C. § 343 (2010), which is available to the public for inspection and copying during the Division’s regular business hours.
  - f. Required Potency Statement. The Target Potency or potency value determined from testing by a Medical Marijuana Testing Facility or Retail Marijuana Testing Facility of the Regulated Marijuana Product’s active THC and CBD expressed in milligrams, If CBD is not detected in the Regulated Marijuana Product, then

active CBD potency is not required. The Target Potency or potency value, shall be displayed either:

- i. In a font that is bold, and enclosed within an outlined shape such as a circle or square; or
- ii. Highlighted with a bright color such as yellow.

- g. Solvent List. A list of any solvent(s) used to produce any Solvent-Based Medical Marijuana Concentrate used as a production input in any Medical Marijuana Product, or Solvent-Based Retail Marijuana Concentrate used as a production input in any Retail Marijuana Product.
- h. Date of Sale. The Medical Marijuana Store or Retail Marijuana Store shall affix the date of sale to the Container or Marketing Layer at the time of Transfer to the patient or consumer.
- i. Required Warning Statements. Either the label affixed to the Container or the Marketing Layer shall include the following information:
  - i. **“This product was produced without regulatory oversight for health, safety, or efficacy.”**
  - ii. **“There may be long term physical or mental health risks from use of marijuana including additional risks for women who are or may become pregnant or are breastfeeding. Use of marijuana may impair your ability to drive a car or operate machinery.”**

E. Packaging and Labeling of Seeds and Immature Plants Prior to Transfer to a Patient or Consumer. A Medical Marijuana Store or Retail Marijuana Store shall comply with the following minimum packaging and labeling requirements prior to Transferring seeds or Immature plants to a patient or consumer:

- 1. Packaging of Regulated Marijuana Seeds. Prior to Transfer to a patient or consumer, Regulated Marijuana seeds shall be in a Container. The Container may but is not required to be Child-Resistant. Any Regulated Marijuana seeds in a Container that is not Child-Resistant shall be placed into a Child-Resistant Exit Package at the point of Transfer to a patient or consumer.
- 2. Packaging of Immature Plants. Prior to Transfer to a patient or consumer, Immature plants shall be placed into a receptacle. The receptacle may but is not required to be Child-Resistant.
- 3. Labeling of Seeds and Immature Plants. Prior to Transfer to a patient or consumer, every Container holding Regulated Marijuana seeds and any receptacle containing an Immature plant must be affixed with a label that includes at least the following information:
  - a. Required License Number(s). The license number for each of the following:
    - i. The Medical Marijuana Cultivation Facility where the Medical Marijuana that produced the seeds or Immature plant was grown, or the Retail Marijuana Cultivation Facility where the Retail Marijuana that produced the seeds or the Immature plant was grown; and

- ii. The Medical Marijuana Store that sold the seeds or Immature plant to the patient, or the Retail Marijuana Store that sold the seeds or Immature plant to the consumer.
- b. Universal Symbol. The Universal Symbol on the front of the Container holding seeds and the receptacle containing each Immature plant, no smaller than ½ of an inch by ½ of an inch, with the following statement directly below the Universal Symbol: **“Contains Marijuana. Keep away from children.”**
- c. Statement of Net Contents for Seeds. A statement of net contents identifying the number of seeds in the Container.
- d. Date of Sale. The Medical Marijuana Store or Retail Marijuana Store shall affix the date of sale to the patient or consumer to the Container or receptacle.
- e. Patient Number. The Medical Marijuana Store shall affix the patient’s registration number to the Container or receptacle at the time of Transfer to the patient.
- f. Required Warning Statements:
  - i. **“This product was produced without regulatory oversight for health, safety, or efficacy.”**
  - ii. **“There may be long term physical or mental health risks from use of marijuana including additional risks for women who are or may become pregnant or are breastfeeding. Use of marijuana may impair your ability to drive a car or operate machinery.”**

F. Permissive Information.

- 1. Identity Statement. A label affixed to a Container of Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product or any Marketing Layer may include, but is not required to include, the Identity Statement and/or Standardized Graphic Symbol for:
  - a. The Medical Marijuana Cultivation Facility(ies) where the Medical Marijuana was grown, or the Retail Marijuana Cultivation Facility(ies) where the Retail Marijuana was grown;
  - b. The Medical Marijuana Products Manufacturer that manufactured the Medical Marijuana Product or Medical Marijuana Concentrate, or the Retail Marijuana Products Manufacturer that manufactured the Retail Marijuana Product or Retail Marijuana Concentrate; and/or
  - c. The Medical Marijuana Store that sold the Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana Product, or the Retail Marijuana Store that sold the Retail Marijuana, Retail Marijuana Concentrate, or Retail Marijuana Product.
- 2. Nutritional Fact Panel. Label(s) may include, but are not required to include, a nutritional fact panel or dietary supplement fact panel in substantial conformance with 21 CFR 101.9 (2016) or 21 C.F.R. 101.36 (2016) as follows:
  - a. For Edible Medical Marijuana Products or Edible Retail Marijuana Products other than pills, capsules, and tinctures and Food-Based Medical Marijuana

Concentrate or Food-Based Retail Marijuana Concentrate the nutritional fact panel shall be in substantial conformance with the requirements of 21 C.F.R. 101.9(C) (2016) which provides the FDA's nutritional labeling requirements for food;

b. For pills, capsules, and tinctures, the dietary supplement fact panel shall be in substantial conformance with the requirements of 21 C.F.R. 101.36 (2016) which provides the FDA's nutritional labeling requirements for dietary supplements.

i.. Note that this Rule does not include any later amendments or editions to the Code of Federal Regulations. The Division maintains copies of 21 C.F.R. 101.9(C) (2016) and 21 C.F.R. 101.36 (2016), which are available to the public for inspection and copying during the Division's regular business hours.

3. Other Permissive Information. The labeling requirements in the 3-1000 Series Rules provide only the minimum labeling requirements. Licensees may include additional information on the label(s) so long as such information is consistent with the requirements of these Rules.

### **Basis and Purpose – 3-1015**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(a), 44-10-202(1)(c), 44-10-202(6), 44-10-203(2)(d)(IV)(A)-(C), 44-10-203(2)(f), 44-10-203(2)(w), 44-10-203(1)(a), 44-10-601(2)(a), 44-10-603(4)(a), and 44-10-603(8), C.R.S. The purpose of this rule is to define additional labeling requirements for Regulated Marijuana, Regulated Marijuana Concentrate, and/or Regulated Marijuana Product (except Regulated Marijuana seeds and Immature plants) based on its intended use. These labeling requirements are in addition to, not in lieu of, the labeling requirements in Rule 3-1010. This Rule 3-1015 was previously Rules M and R 1003-1, 1 CCR 212-1 and 1 CCR 212-2.

### **3-1015 – Additional Labeling Requirements Prior to Transfer to a Patient or Consumer**

A. Applicability. This Rule establishes additional labeling requirements for Regulated Marijuana (except seeds and Immature plants), Regulated Marijuana Concentrate, and Regulated Marijuana Product prior to Transfer to a patient or consumer. The labeling requirements in this Rule apply to all Containers immediately containing Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product. These labeling requirements based on intended use are in addition to, not in lieu of, the requirements in Rule 3-1010.

1. Exemption for Transfers to Consumers by a Retail Marijuana Hospitality and Sales Business. Unless otherwise provided by these rules, a Retail Marijuana Hospitality and Sales Business Transferring Retail Marijuana to consumers in compliance with the packaging and labeling requirements of Rule 3-1020 is exempt from the requirements of this Rule.

B. Additional Information Required on Every Container (Except Seeds and Immature Plants) Prior to Transfer to a Patient or Consumer. Prior to Transfer to a patient or consumer, every Container of Regulated Marijuana (except seeds and Immature plants), Regulated Marijuana Concentrate, or Regulated Marijuana Product and any Marketing Layer must have a label that includes at least the following additional information.

1. Statement of Intended Use. The Container and any Marketing Layer shall identify one or more intended use(s) for Medical Marijuana, Retail Marijuana, Medical Marijuana Concentrate, Retail Marijuana Concentrate, Medical Marijuana Product, and Retail Marijuana Product from the following exclusive list:

- a. Inhaled Product:
  - i. Flower or Trim (including pre-rolled joint and Kief);
  - ii. Solvent-Based Medical Marijuana Concentrate;
  - iii. Solvent-Based Retail Marijuana Concentrate;
  - iv. Water-Based Medical Marijuana Concentrate;
  - v. Water-Based Retail Marijuana Concentrate;
  - vi. Heat/Pressure-Based Medical Marijuana Concentrate;
  - vii. Heat/Pressure-Based Retail Marijuana Concentrate;
  - viii. Vaporizer Delivery Device;
  - ix. Pressurized Metered Dose Inhaler.
- b. For Oral Consumption:
  - i. Food or drink infused with Regulated Marijuana;
  - ii. Regulated Marijuana Concentrate intended to be consumed orally;
  - iii. Pills and capsules;
  - iv. Tinctures.
- c. Skin and Body Products:
  - i. Topical;
  - ii. Transdermal.
- d. Audited Product:
  - i. Metered Dose Nasal Spray;
  - ii. Vaginal Administration;
  - iii. Rectal Administration.

2. Inhaled Product. The “Inhaled Product” intended use may be used only for products intended for consumption by smoking or Vaporizer Delivery Device where the product is heated or burned prior to consumption, or through use of a Pressurized Metered Dose Inhaler. The label(s) on all inhaled product intended use shall also include:

- a. The potency statement required by Rule 3-1010 for: (1) flower (including pre-rolls and Kief), (2) Solvent-Based Medical Marijuana Concentrate, (3) Solvent-Based Retail Marijuana Concentrate, (4) Water-Based Medical Marijuana Concentrate, (5) Water-Based Retail Marijuana Concentrate, (6) Heat/Pressure-Based Medical Marijuana Concentrate, (7) Heat/Pressure-Based Retail Marijuana Concentrate

shall be stated as the percentage of Total THC and CBD. If CBD is not detected, then total CBD potency is not required.

- b. The potency statement required by Rule 3-1010 for Vaporizer Delivery Devices and Pressurized Metered Dose Inhalers shall be stated as either the percentage of Total THC and CBD, or the number of milligrams of Total THC and CBD, per cartridge, pen, or inhaler. If CBD is not detected in the Vaporizer Delivery Device or Pressurized Metered Dose Inhaler, then total CBD potency is not required.
3. For Oral Consumption. The label(s) on all Edible Medical Marijuana Products and Edible Retail Marijuana Products, including but not limited to confections, liquids pills, capsules and tinctures, shall also include:
- a. Potency Statement. The potency statement required by Rule 3-1010 shall be stated as: (1) milligrams of active THC and CBD per serving and (2) milligrams of active THC and CBD per Container where the Container contains more than one serving. The Target Potency may be used to fulfill the requirement of this Rule. If CBD is not detected, then active CBD potency is not required.
  - b. Additional Warning Statement Required. The following additional warning statement shall be included on the label on the Container or Marketing Layer for all Edible Medical Marijuana Product and Edible Retail Marijuana Product: **“The intoxicating effects of this product may be delayed by up to 4 hours.”**
  - c. Expiration/Use-By Date. A product expiration date, upon which the Edible Medical Marijuana Product or Edible Retail Marijuana Product will no longer be fit for consumption, or a use-by-date, upon which the Edible Medical Marijuana Product or Edible Retail Marijuana Product will no longer be optimally fresh. Once a label with an expiration or use-by date has been affixed to a Container containing an Edible Medical Marijuana Product or Edible Retail Marijuana Product and any Marketing Layer, a Licensee shall not alter that expiration or use-by date or affix a new label with a later expiration or use-by date.
  - d. Production Date. The date on which the Edible Medical Marijuana Product or Edible Retail Marijuana Product was produced which may be included in the Batch Number required by Rule 3-1010.
  - e. Statement Regarding Refrigeration. If an Edible Medical Marijuana Product or Edible Retail Marijuana Product is perishable, a statement that the product must be refrigerated.
4. Skin and Body Products (Topical and Transdermal). The “Skin and Body Products” intended use may be used only for products intended for consumption by topical or transdermal application, and must be intended for external use only. The label(s) on all skin and body products shall also include:
- a. Topical Product Potency Statement. For topical product the potency statement required by Rule 3-1010 shall be stated as the number of milligrams of active THC and CBD per Container. The Target Potency may be used to fulfill the requirement of this Rule. If CBD is not detected, then active CBD potency is not required.
  - b. Transdermal Product Potency Statement. For transdermal product, the potency statement required by Rule 3-1010 shall be stated as the number of milligrams of active THC and CBD per transdermal product, and the total number of milligrams



of active THC and CBD per Container. The Target Potency may be used to fulfill the requirement of this Rule. If CBD is not detected, then active CBD potency is not required.

- c. Expiration/Use-By Date. A product expiration or use-by date, after which the skin and body product will no longer be fit for use. Once a label with an expiration or use-by date has been affixed to any Container holding a skin and body product and any Marketing Layer, a Licensee shall not alter that expiration or use-by date or affix a new label with a later expiration or use-by date.
  - d. Production Date. The date on which the skin and body product was produced which may be included in the Batch Number required by Rule 3-1010.
5. Audited Product. Packaging and labeling for all Audited Products: (i) metered dose nasal spray, (ii) vaginal administration, or (iii) rectal administration shall include:
- a. All packaging and labeling requirements required by this 3-1000 Series for Regulated Marijuana Products; except Rules 5-325 and 6-325 control where the context otherwise clearly requires.
  - b. Audited Product shall be packaged and labeled for Transfer to a patient or consumer prior to Transfer from a Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer.
  - c. Expiration/Use-By Date. A product expiration date that is appropriate for the Audited Product when stored at room temperature as verified by testing required by Rules 5-325 and 6-325. Once a label with an expiration date has been affixed to a Container containing and Audited Product, a Licensee shall not alter that expiration date, or affix a new label with a later expiration date.
  - d. Production Date. The date on which the Audited Product was produced, which may be included in the Batch Number required by Rule 3-1010.
- C. No Other Intended Use Permitted. No intended use other than those identified in this Rule shall be identified on any label, except as permitted by an Alternative Use Designation approved by the State Licensing Authority pursuant to Rules 5-325 and 6-325. Licensees shall accurately identify all intended use(s) from the exclusive list of intended uses in this Rule, or as required by the Alternative Use Designation, on the label.
1. Alternative Use Product. No Regulated Marijuana Business shall Transfer or accept an Alternative Use Product unless the Alternative Use Product received an Alternative Use Designation in accordance with Rules 5-325 and 6-325 and complied with all the requirements of Rules 5-325, 6-325, and 3-1005 through 3-1015, and with any additional packaging and labeling requirements identified in the Alternative Use Designation. At a minimum the label(s) on all Alternative Use Products shall include:
- a. All packaging and labeling requirements applicable to the Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer by these 3-1000 Series Rules unless inconsistent with the Alternative Use Designation in which case the Alternative Use Designation shall control.
  - b. Expiration/Use-By Date. A product expiration date that is appropriate for the Alternative Use Product when stored at room temperature as verified by a Medical Marijuana Testing Facility or Retail Marijuana Testing Facility. Once a label with an expiration date has been affixed to a Container containing

Alternative Use Product, a Licensee shall not alter that expiration date, or affix a new label with a later expiration date.

- c. Production Date. The date on which the Alternative Use Product was produced, which may be included in the Batch Number required by Rule 3-1010.
- d. All other requirements identified by the Alternative Use Designation.

- D. Multiple Intended Uses. Any Regulated Marijuana having more than one intended use shall identify every intended use on the label and shall comply with all labeling requirements for each intended use. If there is any conflict between the labeling requirements for multiple intended uses, the most restrictive labeling requirements shall be followed. Licensees shall not counsel or advise any patient or consumer to use Regulated Marijuana other than in accordance with the intended use(s) identified on the label.

### **Basis and Purpose – 3-1020**

The statutory authority for this rule includes but is not limited to 44-10-202(1)(a), 44-10-202(1)(c), 44-10-202(6), 44-10-203(2)(ff), 44-10-305(2)(b), 44-10-609, and 44-10-610, C.R.S. The purpose of this rule is to define minimum packaging and labeling requirements for Retail Marijuana Hospitality and Sales Businesses.

### **3-1020 – Packaging and Labeling: Requirements for Transfers to a Consumer at a Retail Marijuana Hospitality and Sales Business**

- A. Applicability. This Rule establishes minimum requirements for packaging and labeling Retail Marijuana Transferred to a consumer at a Retail Marijuana Hospitality and Sales Business.
- B. Packaging and Labeling Exemptions and Minimum Requirements. A Retail Marijuana Hospitality and Sales Business may Transfer Retail Marijuana to a consumer without packaging and labeling under the following conditions:
  - 1. The consumer intends to consume the Retail Marijuana on the Licensed Premises of the Retail Marijuana Hospitality and Sales Business;
  - 2. At the time of Transfer to a consumer, the Retail Marijuana Hospitality and Sales Business provides the consumer with a written statement of the potency of the Retail Marijuana's active THC and CBD, which shall be expressed as a percentage for Retail Marijuana and Retail Marijuana Concentrate, and expressed in milligrams for Retail Marijuana Product. If CBD is not detected in the Retail Marijuana, then active CBD potency is not required;
  - 3. The Retail Marijuana Hospitality and Sales Business maintains within the Restricted Access Area of the Licensed Premises—and makes available to the consumer upon request—written or electronic documentation reflecting all relevant information required in Rules 3-1010 and 3-1015; and
  - 4. For Multiple-Serving Edible Retail Marijuana Product or Multiple-Serving Liquid Edible Retail Marijuana Product, the Retail Marijuana Hospitality and Sales Business shall at the time of Transfer to the consumer provide a measurement device necessary for the consumer to achieve accurate measurements of each serving in increments equal to or less than 10 milligrams of active THC per serving.

- C. Packaging and Labeling Required Before Retail Marijuana is Removed from the Licensed Premises. Prior to a consumer removing any unconsumed Retail Marijuana from the Licensed Premises, the Retail Marijuana Hospitality and Sales Business shall:
1. Provide the consumer with written or electronic documentation reflecting all relevant information required in Rules 3-1010 and 3-1015; and
  2. Place the unconsumed Retail Marijuana into a Child-Resistant Container, or if the Container is not Child-Resistant, a Child-Resistant Exit Package. The Container must be affixed with a label that includes at least the following:
    - i. Universal Symbol. The Universal Symbol on the Container, no smaller than ½ inch by ½ inch, with the following statement directly below the Universal Symbol: **“Contains Marijuana. Keep away from children.”**; and
    - ii. Required Potency Statement. A written statement of the potency of the Retail Marijuana’s total THC and CBD expressed as a percentage. A written statement of the potency of the Retail Marijuana Product’s active THC and CBD expressed in milligrams. If CBD is not detected in the Retail Marijuana, then active CBD potency is not required.
    - iii. For Multiple-Serving Edible Retail Marijuana Product or Multiple-Serving Liquid Edible Retail Marijuana Product, the Retail Marijuana Hospitality and Sales Business shall provide a measurement device necessary for the consumer to achieve accurate measurements of each serving in increments equal to or less than 10 milligrams of active THC per serving.
- D. Additional Packaging and Labeling Requirements for Retail Marijuana Hospitality and Sales Businesses.
1. Font Size. Required labeling text on the Container must be no smaller than 1/16 of an inch.
  2. Labels Shall Not Be Designed to Appeal to Children. A Retail Marijuana Hospitality and Sales Business shall not place any content on a Container that reasonably appears to target individuals under the age of 21, including but not limited to, cartoon characters or similar images.
  3. False or Misleading Statements. Label(s) on a Container shall not include any false or misleading statements.
  4. Trademark Infringement Prohibited. No Container shall be intentionally or knowingly labeled so as to cause a reasonable consumer confusion as to whether the Retail Marijuana is a trademarked product or labeled in a manner that violates any federal trademark law or regulation.
  5. Health and Benefit Claims. The label(s) on the Container shall not make any claims regarding health or physical benefits to the consumer.
  6. Use of English Language. Labeling text on the Container must be clearly written or printed and in the English language. In addition to the required English label, Licensees may include an additional, accurate foreign language translation on the label that otherwise complies with these rules.

7. Unobstructed and Conspicuous. Labeling text on the Container must be unobstructed and conspicuous. A Licensee may affix multiple labels to the Container, provided that none of the information required by these rules is obstructed. For example and not by means of limitation, labels may be accordion, expandable, extendable or layered to permit labeling of small Containers.
8. Use of the Word “Candy” and/or “Candies” Prohibited. Licensees shall not use the word(s) “candy” and/or “candies” on the label of any Container.
9. Child Resistant Certificate(s). A Licensee shall maintain a copy of the certificate showing that each Child-Resistant Container into which the Licensee places Retail Marijuana is Child-Resistant and complies with the requirements of 16 C.F.R. 1700.15 (1995) and 16 C.F.R. 1700.20 (1995) in accordance with the requirements of Rule 3-905(A). 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 16 C.F.R. 1700.15 (1995) and 16 C.F.R. 1700.20 (1995), which is available to the public for inspection and copying during the Division’s regular business hours.

#### **Part 4 – Regulated Marijuana Testing Program**

##### **Basis and Purpose – 4-105**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(g), 44-10-203(1)(j), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b), 44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing the mandatory testing portion of the Division’s Regulated Marijuana sampling and testing program. This Rule 4-105 was previously Rules M and R 1502, 1 CCR 212-1 and 1 CCR 212-2.

##### **4-105 – Regulated Marijuana Testing Program: Mandatory Testing**

- A. Required Sample Submission. A Regulated Marijuana Business may be required by the Division to submit a Sample(s) of Regulated Marijuana it possesses to a Medical Marijuana Testing Facility or a Retail Marijuana Testing Facility at any time regardless of whether its process has been validated and without notice.
  1. Samples collected pursuant to this Rule may be tested for potency or contaminants which may include, but is not be limited to, Pesticide, microbials, mycotoxin, molds, metals, residual solvents, biological contaminants, and chemical contaminants.
  2. When a Sample(s) is required to be submitted for testing, the Regulated Marijuana Business may not Transfer or process into a Medical Marijuana Concentrate or Medical Marijuana Product any Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana Product, or Transfer or process into a Retail Marijuana Concentrate or Retail Marijuana Product any Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product, from the Inventory Tracking System package, Harvest Batch or Production Batch from which the Sample was taken, unless or until it passes all required testing.
- B. Methods for Determining Required Testing.
  1. Random Testing. The Division may require Samples to be submitted for testing through any one or more of the following processes: random process, risk-based process, or

other internally developed process, regardless of whether a Regulated Marijuana Business's process has been validated.

2. Inspection or Enforcement Tests. In addition, the Division may require a Regulated Marijuana Business to submit a Sample for testing if the Division has reasonable grounds to believe that:
    - a. Regulated Marijuana is contaminated or mislabeled;
    - b. A Regulated Marijuana Business is in violation of any product safety, health or sanitary statute, rule or regulation; or
    - c. The results of a test would further an investigation by the Division into a violation of any statute, rule, or regulation.
  3. Beta Testing. The Division may require a Regulated Marijuana Business to submit Samples from certain randomly selected Harvest Batches or Production Batches for potency or contaminant testing prior to implementing mandatory testing.
- C. Minimum Testing Standards. The testing requirements contained in this 4-100 Series are the minimum required testing standards. Regulated Marijuana Businesses are responsible for ensuring adequate testing on any Regulated Marijuana they produce or Transfer to ensure safety for human consumption.
- D. Additional Sample Types. The Division may also require a Regulated Marijuana Business to submit Samples comprised of items other than Regulated Marijuana to be tested for contaminants which may include, but may not be limited to, Pesticide, microbials, molds, metals, residual solvents, biological contaminants, and chemical contaminants. The following is a non-exhaustive list of the types of Samples that may be required to be submitted for contaminant testing:
1. Specific Regulated Marijuana plant(s) or any portion of a Regulated Marijuana plant(s);
  2. Any growing medium, water, or other substance used in the cultivation process;
  3. Any water, solvent, or other substance used in the processing of a Regulated Marijuana Concentrate;
  4. Any Ingredient or substance used in the manufacturing of a Regulated Marijuana Product; or
  5. Swab of any equipment or surface.
- E. R&D Testing.
1. R&D Tests. A Regulated Marijuana Business may submit Test Batches from a Harvest or Production Batch for R&D testing. R&D testing may be performed for any test required by these 4-100 Series Rules or any other test.
    - a. Passing R&D Test Results. If a Harvest or Production Batch passes an R&D test it shall not constitute a pass for the purposes of compliance with required contaminant or potency testing. If a Harvest or Production Batch passes an R&D test it shall not constitute a pass for purposes of obtaining or maintaining process validation. See Rules 4-120 and 4-125.

- b. Failing R&D Test Results. If a Harvest or Production Batch fails an R&D test that is a contaminant or potency test required by these rules, it does not require compliance with failed test procedures. See Rule 4-135. A Licensee cannot obtain process validation if a Harvest or Production Batch fails an R&D test that is required by contaminant and potency testing rules. See Rules 4-120 and 4-125. If a Licensee is process validated, and fails an R&D test that is required by contaminant and potency testing rules, the Licensee must comply with Rules 4-120(F)(2) and 4-125(H)(2).

F. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

### **Basis and Purpose – 4-110**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(g), 44-10-203(1)(j), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b), 44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing sampling procedures and rules for the Division's Regulated Marijuana sampling and testing program. This Rule 4-110 was previously Rules M and R 1504, 1 CCR 212-1 and 1 CCR 212-2.

### **4-110 – Regulated Marijuana Testing Program: Sampling Procedures**

#### **A. Collection of Samples.**

1. Sample Collection. All Samples submitted for testing pursuant to this Rule must be collected by Division representatives or in accordance with the Division's sampling policy reflected in the marijuana laboratory testing reference library available at the Colorado Department of Public Health and Environment's website. This reference library may be continuously updated as new materials become available in accordance with section 25-1.5-106(3.5)(d), C.R.S.
2. Sample Selection. The Division may elect, at its sole direction, to assign Division representatives to collect Samples, or may otherwise direct Sample selection, including, but not limited to, through Division designation of a Harvest Batch or Production Batch in the Inventory Tracking System from which a Regulated Marijuana Business shall select Samples for testing. A Regulated Marijuana Business, its Controlling Beneficial Owners, Passive Beneficial Owners, and employees shall not attempt to influence the Samples selected by Division representatives. If the Division does not select the Harvest Batch or Production Batch to be tested, a Regulated Marijuana Business must collect and submit Sample(s) that are representative of the Harvest Batch or Production Batch being tested.
3. Adulteration or Alteration Prohibited. A Licensee or its agent shall not adulterate or alter, or attempt to adulterate or alter, any Samples of Regulated Marijuana for the purpose of circumventing contaminant testing detection limits or potency testing requirements. The Sample(s) collected and submitted for testing must be representative of the Harvest Batch or Production Batch being tested. A violation of this sub-paragraph (A)(3) shall be considered a license violation affecting public safety.
4. Timing of Samples. A Licensee shall not collect or submit Samples for testing until the Regulated Marijuana has completed all required steps and is in its final form prior to Transfer to another Regulated Marijuana Business as outlined in the standard operating procedures of the Licensee submitting the Test Batch. This includes the addition of all

Ingredients and Additives. This Rule 4-110(A)(4) does not apply for the submission of Samples submitted for R&D testing.

- B. Minimum Number of Samples Per Test Batch Submission. These sampling rules shall apply until such time as the State Licensing Authority revises these rules to implement a statistical sampling model. Each Test Batch of Regulated Marijuana submitted for testing must be comprised of a representative selection of Samples. Unless a greater amount is required to comply with these rules, each Test Batch of Regulated Marijuana must be comprised of at least the following number of separately taken Samples, which may be submitted for testing in all required testing categories:

1. Samples for Test Batches of Regulated Marijuana.
  - a. For Harvest Batches weighing up to 10 pounds, a minimum of eight separate 0.5 gram Samples must be combined into one 4 gram Sample and submitted as one Test Batch.
  - b. For Harvest Batches weighing more than 10 pounds but less than 20 pounds, a minimum of 12 separate 0.5 gram Samples must be combined into one 6 gram Sample and submitted as one Test Batch.
  - c. For Harvest Batches weighing 20 pounds or more but less than 30 pounds, a minimum of 15 separate 0.5 gram Samples must be combined into one 7.5 gram Sample and submitted as one Test Batch.
  - d. For Harvest Batches weighing 30 pounds or more but less than 40 pounds, a minimum of 18 separate 0.5 gram Samples must be combined into one 9 gram Sample and submitted as one Test Batch.
  - e. For Harvest Batches or weighing 40 pounds or more but less than 100 pounds, a minimum of 23 separate 0.5 gram Samples must be combined into one 11.5 gram Sample and submitted as one Test Batch.
  - f. For Harvest Batches weighing 100 pounds or more, a minimum of 29 separate 0.5 gram Samples must be combined into one 14.5 gram Sample and submitted as one Test Batch.
2. Samples for Test Batches of Regulated Marijuana Concentrate. A Licensee shall submit Samples of Regulated Marijuana Concentrate that has completed all required steps and is in its final form prior to Transfer to another Regulated Marijuana Business as outlined in the standard operating procedures of the Licensee submitting the Test Batch. This includes the addition of all Ingredients and Additives.
  - a. For Production Batches weighing up to one pound, a minimum of eight separate 0.25 gram Samples must be combined into one 2 gram Sample and submitted as one Test Batch.
  - b. For Production Batches weighing more than one pound and less than two pounds, a minimum of 12 separate 0.25 gram Samples must be combined into one 3 gram Sample and submitted as one Test Batch.
  - c. For Production Batches weighing two pounds or more but less than three pounds, a minimum of 15 separate 0.25 gram Samples must be combined into one 3.75 gram Sample and submitted as one Test Batch.

- d. For Production Batches weighing three pounds or more but less than four pounds, a minimum of 18 separate 0.25 gram Samples must be combined into one 4.5 gram Sample and submitted as one Test Batch.
  - e. For Production Batches weighing four pounds or more but less than 10 pounds, a minimum of 23 separate 0.25 gram Samples must be combined into one 5.75 gram Sample and submitted as one Test Batch.
  - f. For Production Batches weighing 10 pounds or more, a minimum of 29 separate 0.25 gram Samples must be combined into one 7.25 gram Sample and submitted as one Test Batch.
3. Samples for Test Batches of Regulated Marijuana Product. A Sample of Regulated Marijuana Product must be packaged for sale, including a statement of the Target Potency, prior to Transfer to a Medical Marijuana Testing Facility or a Retail Marijuana Testing Facility. Each such package of Regulated Marijuana Product shall constitute one Sample. If a Retail Marijuana Products Manufacturer intends to Transfer Edible Retail Marijuana Product in bulk to a Retail Marijuana Hospitality and Sales Business a Sample of Edible Retail Marijuana Product shall be a unit not exceeding 100mg of THC, include a statement of the Target Potency, and need not be packaged for sale to a consumer.
- a. For Production Batches of up to 100 Samples, a minimum of two separate Samples must be submitted as one Test Batch.
  - b. For Production Batches of up to 500 Samples, a minimum of four separate Samples must be submitted as one Test Batch.
  - c. For Production Batches of up to 1000 Samples, a minimum of six separate Samples must be submitted as one Test Batch.
  - d. For Production Batches of up to 5000 Samples, a minimum of eight separate Samples must be submitted as one Test Batch.
  - e. For Production Batches of up to 10,000 Samples, a minimum of 10 Samples must be submitted as one Test Batch.
  - f. For Production Batches of more than 10,000 Samples, a minimum 12 Samples must be submitted as one Test Batch.
- C. Medical Marijuana Testing Facility and Retail Marijuana Testing Facility Selection. Unless otherwise restricted or prohibited by these rules or ordered by the State Licensing Authority, a Regulated Marijuana Business may select which Medical Marijuana Testing Facility or Retail Marijuana Testing Facility will test a Sample collected pursuant to this Rule. However, the Division may elect, at its sole discretion, to assign a Medical Marijuana Testing Facility or a Retail Marijuana Testing Facility to which a Regulated Marijuana Business must submit for testing any Sample collected pursuant to this Rule.
- D. Industrial Hemp Product Sampling Procedures. Absent sampling and testing standards established by the Colorado Department of Public Health and Environment for the sampling and testing of Industrial Hemp Product, a Person Transferring an Industrial Hemp Product to a Licensee pursuant to the Marijuana Code and these Rules shall comply with the sampling and testing standards set forth in these 4-100 Series Rules – Regulated Marijuana Testing Program and as required by these Rules.



- E. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

#### **Basis and Purpose – 4-115**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(g), 44-10-203(1)(j), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b), 44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to establish the portion of the Division's mandatory testing and sampling program that is applicable to Regulated Marijuana Businesses, and specifically Medical Marijuana Testing Facilities and Retail Marijuana Testing Facilities. While the Marijuana Code requires the State Licensing Authority to establish acceptable limits of potential contaminants, it also requires the State Licensing Authority to enact a plus or minus 15 percent potency variance, which is also included in this rule. This Rule 4-115 was previously Rules M and R 712, 1 CCR 212-1 and 1 CCR 212-2.

#### **4-115 – Regulated Marijuana Testing Program: Sampling and Testing Program**

- A. Division Authority. The Division may require that a Test Batch be submitted to a specific Medical Marijuana Testing Facility or Retail Marijuana Testing Facility for testing to verify compliance, perform investigations, compile data or address a public health and safety concern.
1. Independent Third Party Review. The Division may require Regulated Marijuana to undergo an independent third-party review to verify that the Regulated Marijuana does not pose a threat to public health and safety when the Division, in consultation with the Colorado Department of Public Health and Environment, has objective and reasonable grounds to believe and finds, upon a full investigation, one of the following:
    - a. The Regulated Marijuana contains one or more substances known to cause harm; or
    - b. The Regulated Marijuana contains one or more substances that could be toxic as consumed or applied in accordance with the intended use.
  2. The fact that Regulated Marijuana contains marijuana shall not constitute grounds to require an independent third-party review. Ingredients Generally Recognized as Safe by the U.S. Food & Drug Administration or that are regulated by the U.S. Food & Drug Administration under the Dietary Supplement Health and Education Act of 1994 that are included in Edible Medical Marijuana Product or Edible Retail Marijuana Product shall not constitute grounds to require an independent third-party review.
  3. Quarantine. In addition to any other remedies provided by law, the Division may immediately quarantine Regulated Marijuana pursuant to Rule 4-135(A) in any one of the following circumstances:
    - a. The Division has objective and reasonable grounds to believe and finds, upon a full investigation, that a Regulated Marijuana Business has been guilty of deliberate and willful violations of these rules;
    - b. The Regulated Marijuana or Alternative Use Product poses a potential threat to public health and safety;
    - c. The Division has received one or more reports of an adverse event related to Regulated Marijuana or Alternative Use Product. For purpose of this Rule,

adverse event means any untoward medical occurrence associated with the use of Regulated Marijuana or Alternative Use Product—this could include any unfavorable and unintended sign (including hospitalization, emergency department visit, doctor’s visit, abnormal laboratory finding), symptom, or disease temporally associated with the use of a Regulated Marijuana or Alternative Use Product;

- d. The Division determines the independent third-party audit submitted pursuant to Rules 5-325(B) or 6-325(B) does not meet the requirements of Rules 5-325 or 6-325; or
  - e. The Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer has violated or is not in compliance with all of the requirements in Rules 5-325 or 6-325.
- 4. Any quarantine pursuant to subparagraph (A)(3) above shall remain in effect unless and until the Regulated Marijuana undergoes an independent third-party review to verify the Regulated Marijuana does not pose a risk to public health and safety.
  - 5. For the purpose of this Rule, full investigation means a reasonable ascertainment of the underlying facts on which the agency action is based.

B. Test Batches.

- 1. Regulated Marijuana and Regulated Marijuana Concentrate. A Medical Marijuana Testing Facility must establish a standard minimum weight of Medical Marijuana and Medical Marijuana Concentrate, and a Retail Marijuana Testing Facility must establish a standard minimum weight of Retail Marijuana and Retail Marijuana Concentrate that must be included in a Test Batch for every type of test that it conducts.
- 2. Regulated Marijuana Product. Medical Marijuana Testing Facilities and Retail Marijuana Testing Facilities must establish a standard number of Samples required to be included in each Test Batch of Medical Marijuana Product or Retail Marijuana Product for every type of test that it conducts. See Rule 4-110 – Regulated Marijuana Testing Program – Sampling Procedures.

C. Rejection of Test Batches.

- 1. A Medical Marijuana Testing Facility or Retail Marijuana Testing Facility may not accept a Test Batch that is smaller than its standard minimum amount.
- 2. A Medical Marijuana Testing Facility or Retail Marijuana Testing Facility may not accept a Test Batch that it knows was not taken in accordance with these rules, unless otherwise permitted by Rule 4-105(E), and except a Medical Marijuana Testing Facility or Retail Marijuana Testing Facility may accept a Test Batch that was collected by Division representatives or that was collected by a Licensee pursuant to Division direction.

D. Permissible Levels of Contaminants. If Regulated Marijuana is found to have a contaminant in levels exceeding those established as permissible under this Rule, then it shall be considered to have failed contaminant testing. Notwithstanding the permissible levels established in this Rule, the Division reserves the right to determine, upon good cause and reasonable grounds, that a particular Test Batch presents a risk to the public health or safety and therefore shall be considered to have failed a contaminant test.

- 1. Microbials (Bacteria, Fungus)

<b>Substance</b>	<b>Acceptable Limits Per Gram</b>	<b>Product to be Tested</b>
-Shiga-toxin producing Escherichia coli (STEC)*- Bacteria	< 1 Colony Forming Unit (CFU)	Regulated Marijuana Flower and trim; Regulated Marijuana Products (other than Audited Product); Water-Based, Heat/Pressure-Based, and Food-Based Medical Marijuana Concentrate; Water-Based, Heat/Pressure-Based, and Food-Based Retail Marijuana Concentrate; Industrial Hemp Products; Pressurized Metered Dose Inhalers; Vaporizer Delivery Device
Salmonella species* – Bacteria	< 1 Colony Forming Unit (CFU)	
Total Yeast and Mold	< 10 <sup>4</sup> Colony Forming Unit (CFU)	Audited Product: administration by metered dose nasal spray or vaginal administration
	≤10 <sup>1</sup> cfu/ml or ≤10 <sup>1</sup> cfu/g	
	≤10 <sup>2</sup> cfu/ml or ≤10 <sup>2</sup> cfu/g	
Total aerobic microbial count	≤10 <sup>2</sup> cfu/ml or ≤10 <sup>2</sup> cfu/g	Audited Product: administration by metered dose nasal spray or vaginal administration
	≤10 <sup>3</sup> cfu/ml or ≤10 <sup>3</sup> cfu/g	Audited Product: rectal administration
<i>Staphylococcus Aureus</i>	Absent in 1 ml or 1 g	Audited Product: administration by metered dose nasal spray or vaginal administration
<i>Pseudomonas aeruginosa</i>	Absent in 1 ml or 1 g	Audited Product: administration by metered dose nasal spray or vaginal administration
<i>Bile tolerant gram negative bacteria</i>	Absent in 1 ml or 1 g	Audited Product: administration by metered dose nasal spray
<i>Candida albicans</i>	Absent in 1 ml or 1 g	Audited Product: vaginal administration

\*The Medical Marijuana Testing Facility or Retail Marijuana Testing Facility shall contact the Colorado Department of Public Health and Environment when STEC and Salmonella are detected beyond the acceptable limits.

## 2. Mycotoxins

<b>Substance</b>	<b>Acceptable Limits Per Gram</b>	<b>Product to be Tested</b>
Aflatoxins (B1, B2, G1, and G2)	< 20 parts per billion (PPB)	Solvent-Based Medical

	(total of B1 + B2 + G1 + G2)	Marijuana Concentrate manufactured from Medical Marijuana flower or trim that failed microbial testing; Solvent-Based Retail Marijuana Concentrate manufactured from Retail Marijuana flower or trim that failed microbial testing
Ochratoxin A	< 20 parts per billion (PPB)	

3. Residual Solvents

<u>Substance</u>	<u>Acceptable Limits Per Gram</u>	<u>Product to be Tested</u>
Acetone	< 1,000 Parts Per Million (PPM)	Solvent-Based Medical Marijuana Concentrate; Solvent-Based Retail Marijuana Concentrate; Industrial Hemp Product (if a solvent was used)
Butanes	< 1,000 Parts Per Million (PPM)	
Ethanol***	< 1,000 Parts Per Million (PPM)	
Heptanes	< 1,000 Parts Per Million (PPM)	
Isopropyl Alcohol	< 1,000 Parts Per Million (PPM)	
Propane	< 1,000 Parts Per Million (PPM)	
Benzene**	< 2 Parts Per Million (PPM)	
Toluene**	< 180 Parts Per Million (PPM)	
Pentane	< 1,000 Parts Per Million (PPM)	
Hexane**	< 60 Parts Per Million (PPM)	
Total Xylenes (m,p, o-xylenes)**	< 430 Parts Per Million (PPM)	
Methanol	< 600 Parts Per Million (PPM)	
Ethyl Acetate	< 1000 Parts Per Million (PPM)	
Any other solvent not permitted for use pursuant to Rules 5-315 and 6-315.	None Detected	

\*\* Note: These solvents are not approved for use. Due to their possible presence in the solvents approved for use per Rule R 605, limits have been listed here accordingly.

\*\*\*Note: Solvent-Based Medical Marijuana Concentrate and Solvent-Based Retail Marijuana Concentrate that exceeds the acceptable limit for ethanol may only be used in Medical Marijuana Concentrate or Medical Marijuana Product, or Retail Marijuana Concentrate or Retail Marijuana Product, which intended use is oral consumption, skin and body products, a vaporizer delivery device, pressurized metered dose inhaler, or Audited Product .

4. Metals

<u>Substance</u>	<u>Acceptable Limits Per Gram Based on Intended Use</u>	<u>Product to be Tested</u>
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Metals (Arsenic, Cadmium, Lead and Mercury)	<b>Inhaled Product or Audited Product: administration by metered dose nasal spray</b> Lead – Max Limit: < .5 ppm Arsenic – Max Limit: < 0.2 ppm Cadmium – Max Limit: < 0.2 ppm Mercury – Max Limit: < 0.1 ppm	Regulated Marijuana Flower and trim; Water-Based, Food-Based, Heat/Pressure-Based, and Solvent-Based Medical Marijuana Concentrate; Water-Based, Food-Based, Heat/Pressure-Based Retail Marijuana Concentrate; Regulated Marijuana Product; Pressurized Metered Dose Inhaler; Vaporizer delivery device; Audited Product; Industrial Hemp Product
	<b>Topical and/or Transdermal</b> Lead – Max Limit: < 10 ppm Arsenic – Max Limit: < 3 ppm Cadmium – Max Limit: < 3 ppm Mercury – Max Limit: < 1 ppm	
	<b>Oral Consumption or Audited Product: rectal or vaginal administration</b> Lead – Max Limit: < 1 ppm Arsenic – Max Limit: < 1.5 ppm Cadmium – Max Limit: < 0.5 ppm Mercury – Max Limit: < 1.5 ppm	

5. Pesticides

Substance	Detection Limits	Product to be Tested
Abamectin (Avermectins: B1a & B1b)	< 0.07 Parts Per Million (PPM)	Regulated Marijuana flower and trim
Azoxystrobin	< 0.02 Parts Per Million (PPM)	
Bifenazate	< 0.02 Parts Per Million (PPM)	
Etoxazole	< 0.01 Parts Per Million (PPM)	
Imazalil	< 0.04 Parts Per Million (PPM)	
Imidacloprid	< 0.02 Parts Per Million (PPM)	
Malathion	< 0.05 Parts Per Million (PPM)	
Myclobutanil	< 0.04 Parts Per Million (PPM)	
Permethrin (mix of isomers)	< 0.04 Parts Per Million (PPM)	
Spinosad (Mixture of A and D)	< 0.06 Parts Per Million (PPM)	
Spiromesifen	< 0.03 Parts Per Million (PPM)	
Spirotetramat	< 0.02 Parts Per Million (PPM)	
Tebuconazole	< 0.01 Parts Per Million (PPM)	

6. Other Contaminants

Pesticide	If the Test Batch is found to contain banned prohibited Pesticide not listed in paragraph (5) above, or the improper application of a permitted Pesticide, then that Test Batch shall be considered to have failed contaminant testing.
Chemicals	If the Test Batch is found to contain levels of any chemical that could be toxic if consumed or as applied, then the Division may determine that the Test Batch has failed contaminant testing.
Microbials	If the Test Batch is found to contain levels of any microbial that could be toxic if consumed or present, then the Division may determine that the Test Batch has failed contaminant testing.
Metals	If the Test Batch is found to contain levels of any metal that could be toxic if consumed or present then the Division may determine that the Test Batch has failed contaminant testing.

7. Division Notification. A Medical Marijuana Testing Facility or Retail Marijuana Testing Facility must notify the Division by timely input in the Inventory Tracking System if a Test Batch is found to contain levels of a contaminant not listed within this Rule that could be injurious to human health if consumed. See Rule 3-825.

E. Potency Testing.

1. Cannabinoids Potency Profiles. A Medical Marijuana Testing Facility or Retail Marijuana Testing Facility may test and report results for any Cannabinoid provided the test is conducted in accordance with the Division's Medical Marijuana Testing Facility's or Retail Marijuana Testing Facility's standard operating procedure.
2. Reporting of Results.
  - a. For potency tests on Regulated Marijuana and Regulated Marijuana Concentrate, results must be reported by listing a single percentage concentration for each Cannabinoid that represents an average of all Samples within the Test Batch. This includes reporting the Total THC in addition to each Cannabinoid required in Rule 4-125.
  - b. For potency tests conducted on Regulated Marijuana Product, whether conducted on each individual Production Batch or via process validation per Rule 4-125, results must be reported by listing the total number of milligrams contained within a single Regulated Marijuana Product unit for sale for each Cannabinoid and stating whether the THC content is homogenous as defined in Paragraph (4)(b) of this Rule.
3. Failed Potency Tests for Medical Marijuana Product.
  - a. If the Cannabinoid content of Medical Marijuana Product is determined not to be homogeneous, then it shall be considered to have failed potency testing. A Production Batch of Medical Marijuana Product shall be considered homogeneous if a minimum of a total of four servings from two packaged units of a Test Batch has a relative standard deviation of less than 10 percent for each Cannabinoid listed on the label. A Production Batch of Medical Marijuana Product shall be considered homogenous if a minimum of a total of four servings from four individual single serve packaged units of a Test Batch has a relative standard deviation of less than 10 percent for each Cannabinoid listed on the label.
    - i. The four servings must also test within plus or minus 15 percent of the Target Potency.

- ii. Any Cannabinoid that makes up less than 10 percent of the total amount of Cannabinoids in the Medical Marijuana Product shall not be subject to the requirements set forth in this subparagraph (F)(3).
  - b. If an individually packaged Edible Medical Marijuana Product is determined to have more than the total milligrams of THC stated on the Container, or less than the total milligrams of THC stated on the Container, then the Test Batch shall be considered to have failed potency testing. Except that the potency variance provided for in subparagraph (F)(5) of this Rule 4-115 shall apply to potency testing.
- 4. Failed Potency Tests for Retail Marijuana Product.
  - a. If the Cannabinoid content of Retail Marijuana Product is determined not to be homogeneous, then it shall be considered to have failed potency testing. A Production Batch of Retail Marijuana Product shall be considered homogeneous if a minimum of a total of four servings from two packaged units of a Test Batch has a relative standard deviation of less than 10 percent for each Cannabinoid listed on the label. A Production Batch of Retail Marijuana Product shall be considered homogenous if a minimum of a total of four servings from four individual single serve packaged units of a Test Batch has a relative standard deviation of less than 10 percent for each Cannabinoid listed on the label.
    - i. The four servings must also test within plus or minus 15 percent of the Target Potency.
    - ii. Any Cannabinoid that makes up less than 10 percent of the total amount of Cannabinoids in the Retail Marijuana Product shall not be subject to the requirements set forth in this subparagraph (F)(4).
  - b. If an individually packaged Edible Retail Marijuana Product is determined to have more than 100 milligrams of THC within it, then the Test Batch shall be considered to have failed potency testing. If an individually packaged Edible Retail Marijuana Product is determined to have more than the total milligrams of THC stated on the Container, or less than the total milligrams of THC stated on the Container, then the Test Batch shall be considered to have failed potency testing. If a single serving in an individually packaged Edible Retail Marijuana Product is determined to have more than 10 milligrams of THC, or less than 10 milligrams of THC, then the Test Batch shall be considered to have failed potency testing. Except that the potency variance provided for in subparagraph (F)(5) of this Rule 4-115 shall apply to potency testing.
- 5. Potency Variance. Regulated Marijuana Product shall differ no more than plus or minus 15 percent from the Target Potency provided to the Medical Marijuana Testing Facility or Retail Marijuana Testing Facility. If Regulated Marijuana is submitted to a Medical Marijuana Testing Facility or Retail Marijuana Testing Facility making a potency claim, the potency shall differ no more than plus or minus 15 percent.
- F. Testing Regulated Marijuana Ready for Transfer. All tests must occur at the time the Regulated Marijuana is ready for Transfer to another Regulated Marijuana Business, according to the required steps outlined in the standard operating procedures of the Licensee submitting the Test Batch.

**Basis and Purpose – 4-120**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(g), 44-10-203(1)(j), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b), 44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing the contaminant testing and related process validation portion of the Division's Regulated Marijuana sampling and testing program. This Rule 4-120 was previously Rules M and R 1501, 1 CCR 212-1 and 1 CCR 212-2.

#### **4-120 – Regulated Marijuana Testing Program: Contaminant Testing**

##### **A. Contaminant Testing Required.**

1. Unless a Medical Marijuana Cultivation Facility's or a Medical Marijuana Products Manufacturer's cultivation or production process has achieved process validation under this Rule, it shall not Transfer or process into a Medical Marijuana Concentrate or Medical Marijuana Product any Medical Marijuana unless Samples from each Harvest Batch or Production Batch from which that Medical Marijuana was derived has been tested by a Medical Marijuana Testing Facility for contaminants and passed all contaminant tests required by this Rule, except as permitted in Rule 5-205(C).
2. Unless a Retail Marijuana Cultivation Facility's or a Retail Marijuana Product Manufacturing Facility's cultivation or production process has achieved process validation under this Rule, it shall not Transfer, or process into a Retail Marijuana Concentrate or Retail Marijuana Product any Retail Marijuana unless Samples from each Harvest Batch or Production Batch from which that Retail Marijuana was derived has been tested by a Retail Marijuana Testing Facility for contaminants and passed all contaminant tests required by this Rule, except as permitted in Rule 6-205(C).

##### **B. Process Validation and Ongoing Testing – Contaminant Testing.**

1. Regulated Marijuana. A Medical Marijuana Cultivation Facility's or a Retail Marijuana Cultivation Facility's cultivation process shall be deemed validated for Contaminant testing if every Harvest Batch that it produced during at least a six-week period but no longer than a 12-week period passed all contaminant tests required by Paragraph (C) of this Rule. This must include at least six Test Batches. A Medical Marijuana Cultivation Facility or a Retail Marijuana Cultivation Facility can obtain process validation for all contaminants listed in paragraph (C) of this Rule at the same time or separately for each contaminant.
  - a. Visual Microbial Growth. If a Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility is aware that a Harvest Batch contains visual microbial contamination, the Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility shall subject the Harvest Batch to microbial contaminant testing pursuant to Rule 4-120(C)(1). If the Test Batch fails testing, then the Harvest Batch shall be subject to the requirements in Rule 4-135(C). The Licensees must also follow Rule 4-120(F)(2).
2. Regulated Marijuana Concentrate or Regulated Marijuana Product. A Medical Marijuana Cultivation Facility's, Retail Marijuana Cultivation Facility's, Medical Marijuana Products Manufacturer's, or a Retail Marijuana Products Manufacturer's production process shall be deemed validated for contaminant testing if every Production Batch that it produced during at least a four-week period but no longer than an eight-week period passed all contaminant tests required by Paragraph (C) of this Rule. This must include Test Batches from at least four Production Batches.



3. Process Validation is Effective for One Year. Once a Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or Retail Marijuana Products Manufacturer has successfully obtained process validation for each of the contaminants listed in paragraph (C) of this Rule, the process validation shall be effective for one year from the date of the last passing test required to satisfy the process validation requirements.
4. Regulated Marijuana Ongoing Contaminant Testing. After successfully obtaining process validation, once every 30 days a Medical Marijuana Cultivation Facility or a Retail Marijuana Cultivation Facility shall subject at least one Harvest Batch to all contaminant testing required by Paragraph (C) of this Rule. If during any 30-day period a Medical Marijuana Cultivation Facility or a Retail Marijuana Cultivation Facility does not possess a Harvest Batch that is ready for testing, the Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility must subject its first Harvest Batch that is ready for testing to the required contaminant testing prior to Transfer or processing of the Regulated Marijuana. If a Harvest Batch subject to ongoing contaminant testing fails contaminant testing, the Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility shall follow the procedure in Paragraph (F)(2) of this Rule. Ongoing contaminant testing pursuant to this Rule 4-120 shall be subject to the requirements in Rule 4-110. See Rule 4-110(A) – Collection of Samples.
  - a. The Division may reduce the frequency of ongoing contaminant testing required by Medical Marijuana Cultivation Facilities and Retail Marijuana Cultivation Facilities if the Division has reasonable grounds to believe Medical Marijuana Testing Facilities and Retail Marijuana Testing Facilities have reached maximum capacity to perform testing required by this Rule. The Division will provide notification of any reduction to the frequency of ongoing contaminant testing to the Licensee's last electronic mailing address provided to the Division.
  - b. If the Licensee fails to comply with paragraph (B)(4) of this Rule, the Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility is no longer process validated.
    5. Regulated Marijuana Concentrate or Regulated Marijuana Product Ongoing Contaminant Testing. After successfully obtaining process validation, once every 30 days a Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or Retail Marijuana Products Manufacturer shall subject at least one Production Batch to all contaminant testing required by Paragraph (C) of this Rule. If during any 30-day period a Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or Retail Marijuana Products Manufacturer does not possess a Production Batch that is ready for testing, the Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or Retail Marijuana Products Manufacturer must subject its first Production Batch that is ready for testing to the required contaminant testing prior to Transfer or processing of the Regulated Marijuana. If a Production Batch submitted for ongoing contaminant testing fails contaminant testing, the Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or Retail Marijuana Products Manufacturer shall follow the procedure in Paragraph (F)(2) of this Rule.
      - a. The Division may reduce the frequency of ongoing contaminant testing required by Medical Marijuana Cultivation Facilities, Retail Marijuana Cultivation Facilities, Medical Marijuana Products Manufacturers, and Retail Marijuana Products Manufacturers if the Division has reasonable grounds to believe Medical Marijuana Testing Facilities and Retail Marijuana Testing Facilities have reached maximum capacity to perform testing required by this Rule. The Division will provide notification of any reduction to the frequency of ongoing contaminant testing to the Licensee's last electronic mailing address provided to the Division.

- b. If the Licensee fails to comply with paragraph (B)(5) of this Rule, the Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility is no longer process validated

C. Required Contaminant Tests.

1. Microbial Contaminant Testing. Harvest Batches of Regulated Marijuana, Production Batches of Water, Heat/Pressure-, or Food-Based Medical Marijuana Concentrate, Production Batches of Water, Heat/Pressure-, or Food-Based Retail Marijuana Concentrate, Regulated Marijuana Product, and Audited Product must be tested for microbial contamination by a Medical Marijuana Testing Facility or a Retail Marijuana Testing Facility at the frequency established by Paragraphs (A) and (B) of this Rule. The microbial contamination test must include, but need not be limited to, testing to determine the presence of and amounts present of microbial contaminants listed in Rule 4-115(E)(1).
2. Residual Solvent Contaminant Testing. Production Batches of Solvent-Based Medical Marijuana Concentrate, Solvent-Based Retail Marijuana Concentrate, and Audited Product that contains any Solvent-Based Medical Marijuana Concentrate or Solvent-Based Retail Marijuana Concentrate produced by a Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer must be tested by a Medical Marijuana Testing Facility or a Retail Marijuana Testing Facility for residual solvent contamination at the frequency established by Paragraphs (A) and (B) of this Rule. The residual solvent contamination test must include, but need not be limited to, testing to determine the presence of, and amounts present of acetone, butane, ethanol, heptanes, isopropyl alcohol, propane, benzene\*, toluene\*, pentane, hexane\*, methanol, ethyl acetate, and total xylenes\* (m, p, o – xylenes).  
  
\* Note: These solvents are not approved for use. Testing is required for these solvents due to their possible presence in the solvents approved for use per Rule 5-315 and 6-315.
3. Mycotoxin Contaminant Testing. As part of Remediation, each Production Batch of Solvent-Based Medical Marijuana Concentrate produced by a Medical Marijuana Products Manufacturer or Solvent-Based Retail Marijuana Concentrate produced by a Retail Marijuana Products Manufacturer from Regulated Marijuana that failed microbial contaminant testing produced must be tested by a Medical Marijuana Testing Facility or a Retail Marijuana Testing Facility for mycotoxin contamination. The mycotoxin contaminant test must include, but need not be limited to, testing to determine the presence of, and amounts present of, aflatoxins (B1, B2, G1, and G2) and ochratoxin A. This is in addition to all other contaminant testing required by this Paragraph (C). This contaminant test cannot be process validated in accordance with subparagraph (B)(2) of this Rule.
4. Pesticide Contaminant Testing. Harvest Batches of Regulated Marijuana must be tested for Pesticide contamination by a Medical Marijuana Testing Facility or a Retail Marijuana Testing Facility at the frequency established by this Rule 4-120(A) and (B). The Pesticide contamination test must include, but need not be limited to, testing to determine the presence of, and amounts present of, the Pesticides listed in Rule 4-115(E)(5).
5. Metals Contaminant Testing. Each Harvest Batch and Production Batch of Regulated Marijuana must be tested for metals contamination by a Medical Marijuana Testing Facility or a Retail Marijuana Testing Facility at the frequency established in paragraphs (A) and (B) of this Rule. The metals contamination test must include, but need not be limited to, testing to determine the presence of, and amounts present of, arsenic, cadmium, lead, and mercury.

- D. Additional Required Tests. The Division may require additional tests to be conducted on a Harvest Batch or Production Batch prior to a Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or a Retail Marijuana Products Manufacturer Transferring, or processing into a Medical Marijuana Concentrate, Retail Marijuana Concentrate, Medical Marijuana Product, or Retail Marijuana Product any Regulated Marijuana from that Harvest Batch or Production Batch. Additional tests may include, but need not be limited to, screening for Pesticide, chemical contaminants, biological contaminants, or other types of microbials, molds, metals, or residual solvents.
- E. Exemptions.
1. Medical Marijuana Concentrate.
    - a. A Medical Marijuana Products Manufacturer who combines multiple Production Batches of Solvent-Based Medical Marijuana Concentrate into a Production Batch of Solvent-Based Medical Marijuana Concentrate shall be considered exempt from residual solvent testing pursuant to this Rule and the 4-100 Series Rules only if all original Production Batches passed residual solvent testing. This does not apply if a solvent, Additive, or any other Ingredient was introduced during the combination of the Production Batches.
    - b. A Production Batch of Medical Marijuana Concentrate shall be considered exempt from this Rule if the Medical Marijuana Products Manufacturer that produced it does not Transfer any portion of the Production Batch and uses the entire Production Batch to manufacture Medical Marijuana Product, except that a Solvent-Based Medical Marijuana Concentrate must still be submitted for residual solvent contaminant testing. The manufactured Medical Marijuana Product shall be subject to mandatory testing under this Rule.
  2. Retail Marijuana Concentrate.
    - a. A Retail Marijuana Products Manufacturer who combines multiple Production Batches of Solvent-Based Retail Marijuana Concentrate into a Production Batch of Solvent-Based Retail Marijuana Concentrate shall be considered exempt from residual solvent testing pursuant to this Rule and the 4-100 Series Rules only if all original Production Batches passed residual solvent testing. This does not apply if a solvent, Additive or any other Ingredient was introduced during the combination of the Production Batches.
    - b. A Production Batch of Retail Marijuana Concentrate shall be considered exempt from this Rule if the Retail Marijuana Products Manufacturer that produced it does not Transfer any portion of the Production Batch and uses the entire Production Batch to manufacture Retail Marijuana Product, except that a Solvent-Based Retail Marijuana Concentrate must still be submitted for residual solvent contaminant testing. The manufactured Retail Marijuana Product shall be subject to testing under this Rule.
- F. Required Re-Validation - Contaminants.
1. Material Change Re-Validation. If a Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or a Retail Marijuana Products Manufacturer makes a Material Change to its cultivation or production process or its standard operating procedure manual, then it must have the first five Harvest Batches or Production Batches produced using the new procedures tested for all of the contaminants required by Paragraph (C) of this Rule regardless of whether

its process has been previously validated regarding contaminants. If any of those tests fail, then the Regulated Marijuana Business's process must be re-validated.

- a. Pesticide. It is a Material Change if a Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility begins using a new or different Pesticide during its cultivation process.
  - b. Solvents. It is a Material Change if a Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer begins using a new or different solvent or combination of solvents or changes any parameters for equipment related to the solvent purging process, including but not limited to, time, temperature, or pressure.
  - c. Cultivation. It is a Material Change if a Medical Marijuana Cultivation Facility or a Retail Marijuana Cultivation Facility begins using a new or different method for any material part of the cultivation process, including, but not limited to, changing from one growing medium to another.
  - d. Notification. A Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or a Retail Marijuana Products Manufacturer must notify the Medical Marijuana Testing Facility or the Retail Marijuana Testing Facility of the Material Change.
  - e. Testing Required Prior to Transfer or Processing. When a Harvest Batch or Production Batch is required to be submitted for testing pursuant to this Rule, the Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or Retail Marijuana Products Manufacturer that produced it may not Transfer or process into a Medical Marijuana Concentrate, Retail Marijuana Concentrate, Medical Marijuana Product, or Retail Marijuana Product any of the Regulated Marijuana from that Harvest Batch or Production Batch unless and until the Harvest Batch or Production Batch passes all required testing.
2. Failed Contaminant Testing and Re-Validation. Failed contaminant testing may constitute a violation of these rules.
- a. If a Sample is required to be tested by these Rules or required to be tested by the Division pursuant to Rule 4-120(A) and fails contaminant testing, the Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or Retail Marijuana Products Manufacturer shall follow the procedures in Rule 4-135(B) for any Inventory Tracking System package, Harvest Batch, or Production Batch from which the failed Sample was taken.
  - b. The Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or Retail Marijuana Products Manufacturer shall also submit Test Batches from three new Harvest Batches or Production Batches of the Regulated Marijuana for contaminant testing by a Medical Marijuana Testing Facility or a Retail Marijuana Testing Facility within no more than 30 days. If any one of the three submitted Test Batches fails contaminant testing, the Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or Retail Marijuana Products Manufacturer shall re-validate its process for contaminants.

- G. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

#### **Basis and Purpose – 4-125**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(g), 44-10-203(1)(j), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b), 44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing the potency testing and related process validation portion of the Division's Regulated Marijuana sampling and testing program. This Rule 4-125 was previously Rules M and R 1503, 1 CCR 212-1 and 1 CCR 212-2.

#### **4-125 – Regulated Marijuana Testing Program: Potency Testing**

A. Potency Testing – General.

1. Test Batches. A Test Batch submitted for potency testing may only be comprised of Samples that are of the same strain of Medical Marijuana or Retail Marijuana or from the same Production Batch of Medical Marijuana Concentrate or Medical Marijuana Product, or from the same Production Batch of Retail Marijuana Concentrate or Retail Marijuana Product.
2. Cannabinoid Profile. A potency test conducted pursuant to this Rule must at least determine the level of concentration of THC, THCA, CBD, CBDA, and CBN.

B. Potency Testing for Regulated Marijuana.

1. Initial Potency Testing. A Medical Marijuana Cultivation Facility or a Retail Marijuana Cultivation Facility must have potency tests conducted by a Medical Marijuana Testing Facility or a Retail Marijuana Testing Facility on four Harvest Batches, created a minimum of one week apart, for each strain of Regulated Marijuana that it cultivates. See Rule 4-105(B).
  - a. The first potency test must be conducted on each strain prior to the Medical Marijuana Cultivation Facility or the Retail Marijuana Cultivation Facility Transferring or processing into a Medical Marijuana Concentrate any Medical Marijuana of that strain, or into a Retail Marijuana Concentrate any Retail Marijuana of that strain.
  - b. All four potency tests must be conducted on each strain no later than December 1, 2014 or six months after the Medical Marijuana Cultivation Facility or the Retail Marijuana Cultivation Facility begins cultivating that strain, whichever is later.
2. Ongoing Potency Testing. After the initial four potency tests, a Medical Marijuana Cultivation Facility or a Retail Marijuana Cultivation Facility shall have each strain of Regulated Marijuana that it cultivates tested for potency at least once per quarter.
  - a. If the Licensee fails to comply with paragraph (B)(2) of this Rule, the Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility is no longer process validated.

C. Potency Testing for Regulated Marijuana Concentrate.

1. A Medical Marijuana Cultivation Facility or a Medical Marijuana Products Manufacturer must have a potency test conducted by a Medical Marijuana Testing Facility on every Production Batch of Medical Marijuana Concentrate that it produces prior to Transferring or processing into a Medical Marijuana Product any of the Medical Marijuana Concentrate from that Production Batch.
  2. A Retail Marijuana Cultivation Facility or Retail Marijuana Products Manufacturer must have a potency test conducted by a Retail Marijuana Testing Facility on every Production Batch of Retail Marijuana Concentrate that it produces prior to Transferring or processing into a Retail Marijuana Product any of the Retail Marijuana Concentrate from that Production Batch.
- D. Potency Testing for Regulated Marijuana – Kief. A Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or Retail Marijuana Products Manufacturer must have a potency test conducted by a Medical Marijuana Testing Facility or a Retail Marijuana Testing Facility on every Harvest Batch of Kief that it produces prior to Transferring the Kief.
- E. Potency Testing for Regulated Marijuana Product.
1. Potency Testing Required for Regulated Marijuana Product. A Medical Marijuana Products Manufacturer or a Retail Marijuana Products Manufacturer shall have potency tests conducted by a Medical Marijuana Testing Facility or a Retail Marijuana Testing Facility on every Production Batch of each type of Regulated Marijuana Product that it produces prior to Transferring any of the Regulated Marijuana Product from that Production Batch, unless the Medical Marijuana Products Manufacturer or the Retail Marijuana Products Manufacturer has successfully completed process validation for potency and homogeneity for the particular type of Regulated Marijuana Product.
  2. Required Tests. Potency and homogeneity tests conducted on Regulated Marijuana Product must determine the level of concentration of the required Cannabinoids and whether or not THC is homogeneously distributed throughout the product.
  3. Partially Infused Regulated Marijuana Products. If only a portion of a Regulated Marijuana Product is infused with Regulated Marijuana, then the Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer must inform the Medical Marijuana Testing Facility or Retail Marijuana Testing Facility of exactly which portions of the Regulated Marijuana Product are infused and which portions are not infused.
- F. Process Validation - Potency and Homogeneity.
1. A Retail Marijuana Products Manufacturer may process validate potency and homogeneity for each type of Retail Marijuana Product it manufactures.
  2. A Medical Marijuana Products Manufacturer may process validate potency and homogeneity for each type of non-Edible Medical Marijuana Product and each type of Edible Medical Marijuana Product that it manufactures so long as the Edible Medical Marijuana Product contains 100 milligrams or less of THC.
  3. A Medical Marijuana Products Manufacturer's production process for a particular type of Medical Marijuana Product, and a Retail Marijuana Products Manufacturer's production process for a particular type of Retail Marijuana Product shall be deemed valid regarding potency and homogeneity if every Production Batch that it produces for that particular type of Regulated Marijuana Product during at least a four-week period but no longer

than an eight-week period passes all potency and homogeneity tests required by Rule 4-125(D)(2). This must include at least four Test Batches.

4. Expiration of Process Validation. A Medical Marijuana Products Manufacturer or a Retail Marijuana Products Manufacturer shall be required to re-validate its process every 12 months from the date process validation is achieved, after which point the process validation expires. If the process validation expires, the Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer shall comply with the requirements of Paragraph (D)(1) of this Rule.
5. Regulated Marijuana Product Ongoing Potency and Homogeneity Testing. After successfully obtaining process validation, once per quarter a Medical Marijuana Products Manufacturer and a Retail Marijuana Products Manufacturer shall subject at least one Production Batch of each type of Medical Marijuana Product or Retail Marijuana Product that it produces to potency and homogeneity testing required by Paragraph (D) of this Rule. If during any quarter a Medical Marijuana Products Manufacturer or a Retail Marijuana Products Manufacturer does not possess a Production Batch that is ready for testing, the Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer must subject its first Production Batch that is ready for testing to the required potency and homogeneity testing prior to Transfer or processing of the Regulated Marijuana. If a Test Batch submitted for ongoing potency and homogeneity testing fails potency and homogeneity testing, the Medical Marijuana Products Manufacturer or the Retail Marijuana Products Manufacturer shall follow the procedure in Paragraph (F)(2) of this Rule. Ongoing potency and homogeneity testing pursuant to this Rule 4-125 shall be subject to the requirements in Rule 4-110. See Rule 4-110(A) – Collection of Samples.
  - a. The Division may reduce the frequency of ongoing potency and homogeneity testing required by Medical Marijuana Products Manufacturers and Retail Marijuana Products Manufacturers if the Division has reasonable grounds to believe Medical Marijuana Testing Facilities and Retail Marijuana Testing Facilities have reached maximum capacity to perform testing required by this Rule. The Division will provide notification of any reduction to the frequency of ongoing potency and homogeneity testing to the Licensee's last electronic mailing address provided to the Division.
  - b. If the Licensee fails to comply with paragraph (F)(5) of this Rule, the Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility is no longer process validated.
- G. Exemption. Any Regulated Marijuana that will be allocated for extraction in the Inventory Tracking System shall be considered exempt from potency testing pursuant to this Rule and the 4-100 Series Rules.
- H. Required Re-Validation - Potency and Homogeneity - Regulated Marijuana Product.
  1. Material Change Re-Validation. If a Medical Marijuana Products Manufacturer or a Retail Marijuana Products Manufacturer elects to process validate any Medical Marijuana Products or Retail Marijuana Product for potency and homogeneity and it makes a Material Change to its production process for that particular type of Medical Marijuana Product or Retail Marijuana Product, then the Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer must re-validate the production process.
    - a. New Equipment. It is a Material Change if the Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer begins using new or different equipment for any material part of the production process.

- b. Notification. A Medical Marijuana Products Manufacturer or a Retail Marijuana Product Manufacturer must notify the Medical Marijuana Testing Facility or Retail Marijuana Testing Facility of a Material Change.
  - c. Testing Required Prior to Transfer. When a Production Batch is required to be submitted for testing pursuant to this Rule, the Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer that produced it may not Transfer Regulated Marijuana Product from that Production Batch unless or until it obtains a passing test.
2. Failed Potency Testing Re-Validation. Failed potency testing may constitute a violation of these rules.
- a. If a Sample is required to be tested by these Rules or required to be tested by the Division pursuant to Rule 4-120(A) and fails potency testing, the Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer shall follow the procedures in Rule 4-135(C) for any Inventory Tracking System package or Production Batch associated with the failed Sample.
  - b. The Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer shall also submit Test Batches from three new Production Batches of the Medical Marijuana Product or Retail Marijuana Product for potency testing by a Medical Marijuana Testing Facility or Retail Marijuana Testing Facility within no more than 30 days. If any one of the three submitted Test Batches fails potency testing, the Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer shall re-validate its process for potency.
- I. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

#### **Basis and Purpose – 4-130**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(g), 44-10-203(1)(j), 44-10-203(2)(d), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b), 44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing rules requiring Regulated Marijuana Businesses to cover certain costs associated with the Division's Regulated Marijuana Sampling and Testing Program. This Rule 4-130 was previously Rules M and R 1506, 1 CCR 212-1 and 1 CCR 212-2.

#### **4-130 – Regulated Marijuana Testing Program: Costs**

The cost for all sampling and tests conducted pursuant to these rules shall be the financial responsibility of the Regulated Marijuana Business that is required to submit the Sample for testing.

#### **Basis and Purpose – 4-135**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(g), 44-10-203(1)(j), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b), 44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing rules governing the quarantining of potentially contaminated product and the destruction of product that failed contaminant or potency testing for Division's Regulated



Marijuana Sampling and Testing Program. This Rule 4-135 was previously Rules M and R 1507, 1 CCR 212-1 and 1 CCR 212-2.

#### **4-135 – Regulated Marijuana Testing Program: Contaminated Product and Failed Test Results and Procedures**

##### **A. Quarantining of Product.**

1. If the Division has reasonable grounds to believe that a particular Harvest Batch, Production Batch, or Inventory Tracking System package of Regulated Marijuana is contaminated or presents a risk to public safety, then the Division may require a Regulated Marijuana Business to quarantine it until the completion of the Division's investigation, which may include, but is not limited to, the receipt of any test results.
2. If a Regulated Marijuana Business is notified by any local or state agency, or by a Medical Marijuana Testing Facility or a Retail Marijuana Testing Facility, that a Test Batch failed a contaminant or potency testing, then the Regulated Marijuana Business shall quarantine any Regulated Marijuana from any Inventory Tracking System package, Harvest Batch or Production Batch associated with that failed Test Batch and must follow the procedures established pursuant to paragraph (B)(1), (B)(2), (B)(3) and/or (C) of this Rule.
3. Except as provided by this Rule, Regulated Marijuana that has been quarantined pursuant to this Rule must be physically separated from all other inventory and the Licensee may not Transfer or further process the Regulated Marijuana.
4. In addition to any other method authorized by law, the Division may implement the quarantine through the Inventory Tracking System by (a) indicating failed test results and (b) limiting the Licensee's ability to Transfer the quarantined Regulated Marijuana unless otherwise permitted by these rules.

##### **B. Failed Contaminant Testing: All Contaminant Testing Except Microbial Testing of Regulated Marijuana Flower or Trim and Pesticide Testing.** If a Regulated Marijuana Business is notified by the Division, a Medical Marijuana Testing Facility, or a Retail Marijuana Testing Facility that a Test Batch failed contaminant testing (except microbial testing of Regulated Marijuana flower or trim and Pesticide testing), then for each Inventory Tracking System package, Harvest Batch, or Production Batch associated with that failed Test Batch the Regulated Marijuana Business must either:

1. Destroy and document the destruction of the Inventory Tracking System package, Harvest Batch or Production Batch pursuant to Rule 3-230 – Waste Disposal;
2. Decontaminate the Inventory Tracking System package, Harvest Batch, or Production Batch, if possible, and create two new Test Batches, each containing the requisite number of Samples, and have those Test Batches tested for the required contaminant test that failed. Such testing must comport with the sampling procedures under Rule 4-110.
  - a. A Licensee must either (1) submit both new Test Batches to the same Medical Marijuana Testing Facility or Retail Marijuana Testing Facility that reported the original failed test result, or (2) submit the new Test Batches to two different Medical Marijuana Testing Facilities or Retail Marijuana Testing Facilities;
  - b. If both new Test Batches pass the required contaminant testing, then the Inventory Tracking System package, Harvest Batch, or Production Batch of

Regulated Marijuana or Regulated Marijuana Product associated with each Test Batch may be Transferred or processed into a Medical Marijuana Concentrate, Retail Marijuana Concentrate, Medical Marijuana Product, or Retail Marijuana Product;

- c. If one or both of the Test Batches do not pass contaminant testing, then the Regulated Marijuana Business must destroy and document the destruction of the Inventory Tracking System package, Harvest Batch, or Production Batch included in that Test Batch pursuant to Rule 3-230 – Waste Disposal; or
  3. The Regulated Marijuana Business may Transfer the Production Batches that failed contaminant testing to another Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer for decontamination, if possible, and create two new Test Batches after decontamination has occurred, each containing the requisite number of Samples, and have those Test Batches tested for the required contaminant test that failed. Such testing must comport with the sampling procedures under Rule 4-110.
    - a. A Licensee must either (1) submit both new Test Batches to the same Medical Marijuana Testing Facility or Retail Marijuana Testing Facility that reported the original failed test result, or (2) submit the new Test Batches to two different Medical Marijuana Testing Facilities or Retail Marijuana Testing Facilities;
    - b. If both new Test Batches pass the required contaminant testing, then the Inventory Tracking System package, Harvest Batch, or Production Batch of Regulated Marijuana or Regulated Marijuana Product associated with each Test Batch may be Transferred or processed into a Medical Marijuana Concentrate, Retail Marijuana Concentrate, Medical Marijuana Product, or Retail Marijuana Product;
    - c. If one or both of the Test Batches do not pass contaminant testing, then the Regulated Marijuana Business must destroy and document the destruction of the Inventory Tracking System package, Harvest Batch, or Production Batch included in that Test Batch pursuant to Rule 3-230 – Waste Disposal.
- C. Failed Contaminant Testing: Microbial Testing of Regulated Marijuana Flower, Wet Whole Plant, or Trim. If a Regulated Marijuana Business is notified by the Division, a Medical Marijuana Testing Facility, or a Retail Marijuana Testing Facility that a Test Batch of Regulated Marijuana flower, wet whole plant, or trim failed microbial testing, then for each Inventory Tracking System package or Harvest Batch associated with that failed Test Batch the Regulated Marijuana Business must either:
1. Destroy and document the destruction of the Inventory Tracking System package or Harvest Batch pursuant to Rule 2-230 – Waste Disposal;
  2. Decontaminate the Inventory Tracking System package or Harvest Batch of Regulated Marijuana flower, wet whole plant, or trim, if possible, and create two new Test Batches, each containing the requisite number of Samples, and have those Test Batches tested for the required microbial test that failed. Such testing must comport with the sampling procedures under Rule 4-110.
    - a. A Licensee must either (1) submit both new Test Batches to the same Medical Marijuana Testing Facility or Retail Marijuana Testing Facility that reported the original failed test result, or (2) submit the new Test Batches to two different Medical Marijuana Testing Facilities or Retail Marijuana Testing Facilities

- b. If both Test Batches pass the required microbial testing, then the Inventory Tracking System package or Harvest Batch of Regulated Marijuana flower, wet whole plant, or trim associated with each Test Batch may be Transferred or processed into a Regulated Marijuana Concentrate or Regulated Marijuana Product.
  - c. If one or both of the Test Batches do not pass microbial testing, then the Regulated Marijuana Business must either: (i) destroy and document the destruction of the Inventory Tracking System package or Harvest Batch pursuant to Rule 3-230 – Waste Disposal; or (ii) Transfer the Inventory Tracking System package or Harvest Batch for Remediation pursuant to Paragraph (C)(3)(b) below.
3. In lieu of decontamination pursuant to Paragraph (C)(2) above, the Regulated Marijuana Business may transfer all Inventory Tracking System packages or Harvest Batches associated with that failed Test Batch to a Medical Marijuana Cultivation Facility or a Retail Marijuana Cultivation Facility for decontamination, or to a Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer for decontamination and/or Remediation r.
- a. Decontamination. The Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, the Medical Marijuana Products Manufacturer, or Retail Marijuana Products Manufacturer may decontaminate the Inventory Tracking System package or Harvest Batch of Regulated Marijuana flower or trim, if possible, and create two new Test Batches, each containing the requisite number of Samples, and have those Test Batches tested for the required microbial test that failed. Such testing must comport with the sampling procedures under Rule 4-110.
    - i. A Licensee must either (1) submit both new Test Batches to the same Medical Marijuana Testing Facility or Retail Marijuana Testing Facility that reported the original failed test result, or (2) submit the new Test Batches to two different Medical Marijuana Testing Facilities or Retail Marijuana Testing Facilities
    - ii. If both Test Batches pass the required microbial testing, then the Inventory Tracking System package or Harvest Batch of Regulated Marijuana flower or trim associated with each Test Batch may be Transferred or processed into a Regulated Marijuana Concentrate or Regulated Marijuana Product.
    - iii. If one or both of the Test Batches do not pass microbial testing, then the Regulated Marijuana Business must either: (i) destroy and document the destruction of the Inventory Tracking System package or Harvest Batch pursuant to Rule 3-230 – Waste Disposal; or (ii) attempt Remediation of the Inventory Tracking System package or Harvest Batch at a Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer for Remediation pursuant to Paragraph (C)(3)(b) below.
  - b. Remediation.
    - i. For Remediation, the Regulated Marijuana Business shall process the Inventory Tracking System package or Harvest Batch of Regulated Marijuana flower or trim associated with the failed Test Batch into a Solvent-Based Medical Marijuana Concentrate or Solvent-Based Retail Marijuana Concentrate. No other Regulated Marijuana shall be included

in the Solvent-Based Medical Marijuana Concentrate or Solvent-Based Retail Marijuana Concentrate.

- ii. The Solvent-Based Medical Marijuana Concentrate or Solvent-Based Retail Marijuana Concentrate that was manufactured pursuant to Paragraph (C)(3)(b) shall undergo all required contaminant testing pursuant to Rule 4-120(C) – Regulated Marijuana Testing Program – Contaminant Testing, potency testing pursuant to Rule 4-125 – Regulated Marijuana Testing Program – Potency Testing, and any other testing required or allowed by the Marijuana Code or these rules, including but not limited to mycotoxins. Such testing must comport with the sampling procedures under Rule 4-110.
  - iii. If the Solvent-Based Medical Marijuana Concentrate or Solvent-Based Retail Marijuana Concentrate that was manufactured pursuant to Paragraph (C)(3)(b) fails contaminant testing, the Regulated Marijuana Business shall destroy and document the destruction of the Inventory Tracking System package(s) or Production Batch(es) of Solvent-Based Medical Marijuana Concentrate or Solvent-Based Retail Marijuana Concentrate pursuant to Rule 3-230 – Waste Disposal.4. Nothing in this Rule removes or alters the responsibility of the Retail Marijuana Business Transferring the Retail Marijuana that failed microbial testing from complying with the requirement to pay excise tax pursuant to article 28.8 of title 39, C.R.S.
- D. Failed Contaminant Testing: Pesticide Testing. If a Regulated Marijuana Business is notified by the Division, a Medical Marijuana Testing Facility, or a Retail Marijuana Testing Facility that a Test Batch failed Pesticide testing, then for each Inventory Tracking System package, Harvest Batch, or Production Batch associated with that failed Test Batch the Regulated Marijuana Business must either:
1. Destroy and document the destruction of the Inventory Tracking System package, Harvest Batch, or Production Batch pursuant to Rule 3-230 – Waste Disposal; or
  2. Request that the Medical Marijuana Testing Facility or Retail Marijuana Testing Facility that reported the original fail conduct two additional analyses of the original Test Batch submitted in accordance with Ruel 4-110.
    - a. If both retesting analyses pass the required Pesticide testing, then the Inventory Tracking System package, Harvest Batch, or Production Batch of Regulated Marijuana or Regulated Marijuana Product may be Transferred or processed into a Regulated Marijuana Concentrate or Regulated Marijuana Product.
    - b. If one or both of the retesting analyses do not pass Pesticide testing, then the Regulated Marijuana Business must destroy and document the destruction of the Inventory Tracking System package, Harvest Batch, or Production Batch pursuant to Rule 3-230 – Waste Disposal.
- E. Failed Potency Testing. If a Regulated Marijuana Business is notified by the Division, a Medical Marijuana Testing Facility, or a Retail Marijuana Testing Facility that a Test Batch of Regulated Marijuana Product failed potency testing, then for each Inventory Tracking System package or Production Batch associated with that failed Test Batch the Regulated Marijuana Business must either:
1. Destroy and document the destruction of the Inventory Tracking System package or Production Batch pursuant to Rule 3-230 – Waste Disposal; or

2. Attempt corrective measures, if possible, and create two new Test Batches each containing the requisite number of Samples, and have those Test Batches tested for the required potency test that failed. Such testing must comport with the sampling procedures under Rule 4-110.
  - a. A Licensee must either (1) submit both new Test Batches to the same Medical Marijuana Testing Facility or Retail Marijuana Testing Facility that reported the original failed test result, or (2) submit the new Test Batches to two different Medical Marijuana Testing Facilities or Retail Marijuana Testing Facilities
  - b. If both new Test Batches pass potency testing, then the Inventory Tracking System package or Production Batch associated with each Test Batch may be Transferred.
  - c. If one or both of the Test Batches do not pass potency testing, then the Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer must destroy and document the destruction of Inventory Tracking System package or Production Batch pursuant to Rule 3-230 – Waste Disposal.

F. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

## **Part 5 – Medical Marijuana Business License Types**

### **5-100 Series – Medical Marijuana Stores**

#### **Basis and Purpose – 5-105**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), 44-10-203(2)(d)(I)-(VI), 44-10-313(7), 44-10-313(4), 44-10-401(2)(a)(I), 44-10-501, and 44-10-505, C.R.S. The purpose of this rule is to establish a Medical Marijuana Store's license privileges. This Rule 5-105 was previously Rule M 401, 1 CCR 212-1.

#### **5-105 – Medical Marijuana Store: License Privileges**

- A. Licensed Premises. To the extent authorized by Rule 3-215 – Medical Marijuana Business and Retail Marijuana Business – Shared Licensed Premises and Operational Separation, a Medical Marijuana Store may share a Licensed Premises with a commonly-owned Retail Marijuana Store. However, a separate license is required for each specific business or business entity, regardless of geographical location.
- B. Authorized Sources of Medical Marijuana. A Medical Marijuana Store may only Transfer Medical Marijuana that was obtained from a Medical Marijuana Business.
- C. Authorized Transfers. A Medical Marijuana Store may only Transfer Medical Marijuana to a patient, a primary caregiver, another Medical Marijuana Store, a Medical Marijuana Cultivation Facility, a Medical Marijuana Products Manufacturer, or a Medical Marijuana Testing Facility.
- D. Samples Provided for Testing. A Medical Marijuana Store may provide Samples of its products to a Medical Marijuana Testing Facility for testing and research purposes. The Medical Marijuana Store shall maintain the testing results as part of its business books and records. See Rule 3-905 – Business Records Required.
- E. Authorized On-Premises Storage. A Medical Marijuana Store is authorized to store inventory on the Licensed Premises. All inventory stored on the Licensed Premises must be secured in a

Limited Access Area or Restricted Access Area, and tracked consistently with the inventory tracking rules.

- F. Authorized Marijuana Transport. A Medical Marijuana Store is authorized to utilize a licensed Medical Marijuana Transporter for transportation of its Medical Marijuana so long as the place where transportation orders are taken and delivered is a licensed Medical Marijuana Business. Nothing in this Rule prevents a Medical Marijuana Store from transporting its own Medical Marijuana.
- G. Performance-Based Incentives. A Medical Marijuana Store may compensate its employees using performance-based incentives, including sales-based performance-based incentives.
- H. Authorized Transfers of Industrial Hemp Products. This rule is effective July 1, 2020. A Medical Marijuana Store may Transfer Industrial Hemp Product to a patient only after it has confirmed:
  - 1. That the Industrial Hemp Product has passed all required testing pursuant to the 4-100 Rule Series at a Medical Marijuana Testing Facility; and
  - 2. That the Person Transferring the Industrial Hemp Product to the Medical Marijuana Store is registered with the Colorado Department of Public Health and Environment pursuant to section 25-5-426, C.R.S.
- I. Medical Marijuana Store Delivery Permit. A Medical Marijuana Store with a valid delivery permit may accept delivery orders and deliver Medical Marijuana to a patient who is 21 years of age or older, or the patient's parent or guardian who is also the patient's primary caregiver pursuant to Rule 3-615. A Medical Marijuana Store that does not possess a valid delivery permit cannot deliver Medical Marijuana to a patient, parent, or guardian.
- J. A Medical Marijuana Store may use an automated machine in the Restricted Access Area of its Licensed Premises to dispense Regulated Marijuana to patients without interaction with an Owner Licensee or Employee Licensee if the automated machine is reasonably monitored and complies with all requirements of these rules including but not limited to:
  - 1. Health and safety standards,
  - 2. Testing,
  - 3. Packaging and labeling requirements,
  - 4. Inventory tracking,
  - 5. Identification requirements, and
  - 6. Transfer limits to patients.

### **Basis and Purpose – 5-110**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), 44-10-313(7), 44-10-313(4), 44-10-401(2)(a)(l), and 44-10-501, C.R.S. The purpose of this rule is to establish the requirements and processes applicable to a Medical Marijuana Store registering patients for primary center purposes. This Rule 5-110 was previously Rule M 402, 1 CCR 212-1.

### **5-110 – Registration of a Primary Medical Marijuana Store**

- A. Patient Designation Required. A Medical Marijuana Store may possess in the aggregate, only the amount of Medical Marijuana permitted by Rule 5-115 for each patient who has designated the Medical Marijuana Store as being his or her primary center. A patient's designation of a Medical Marijuana Store as his or her primary Medical Marijuana Store in accordance with these Rules establishes the Medical Marijuana Store registration requirements set forth in section 25-1.5-106(8)(f), C.R.S.
- B. Change Only Allowed Every 30 Days. A Medical Marijuana Store shall not register a patient as being the patient's primary center if the patient has designated another Medical Marijuana Store as his or her primary center in the preceding 30 days. The Medical Marijuana Store and its employees must require a patient to sign in writing that he or she has not designated another Medical Marijuana Store as his or her primary center before including that patient's Medical Marijuana in its maximum allowed on-hand Medical Marijuana inventory calculation under Rule 5-115.
- C. Notification to Former Medical Marijuana Store. A Medical Marijuana Store must maintain a copy of a written or electronic notification that it provided to a patient's former primary Medical Marijuana Store advising that the Medical Marijuana Store has been designated as the patient's new primary Medical Marijuana Store.
- D. Documents Required. The new primary Medical Marijuana Store shall maintain written authorization from the patient, any relative plant count waiver to support the number of ounces of Medical Marijuana (excluding Medical Marijuana Products and Medical Marijuana Concentrate) included in its on-hand inventory for that patient, a hard or electronic copy of the patient's registry card, and a copy of the patient's proof of identification. See *also* Rule 3-905 – Business Records Required.
- E. Violation Affecting Public Safety. Notwithstanding the provisions in Rule 5-110(B), it may be considered a violation affecting public safety for a Medical Marijuana Store and its employees to become a patient's primary center when the patient already had designated one or more other Medical Marijuana Stores as his or her primary center.

**Basis and Purpose – 5-115**

The statutory authority for this includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), 44-10-313(7), 44-10-313(4), 44-10-401(2)(a)(l), 44-10-501, and 44-10-505, 44-10-501(10) C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 14(4). The purpose of this rule is to clarify those acts that are prohibited, or limited in some fashion, by a licensed Medical Marijuana Store.

The sales limitations provision reflects the sales limitation imposed by statute. Clarifying the limitations on sales provides Medical Marijuana Stores and their employees with necessary information to avoid being complicit in a patient acquiring more Medical Marijuana than is lawful under the Colorado Constitution pursuant to Article XVIII, Subsection 14(4).

This Rule 5-115 was previously Rule M 403, 1 CCR 212-1.

**5-115 – Medical Marijuana Sales: General Limitations or Prohibited Acts**

- A. Possession Limits. A Medical Marijuana Store may only possess at its Licensed Premises the number of ounces of Medical Marijuana (excluding Medical Marijuana Products and Medical Marijuana Concentrate) that equals the greater of: 1) twice the total, aggregate ounces of Medical Marijuana all of its registered patients are allowed to possess, or 2) the total, aggregate ounces of Medical Marijuana that the Medical Marijuana Store Transferred to patients in the thirty (30) previous calendar days. Under no circumstance shall a Medical Marijuana Store possess more Medical Marijuana than permitted by this subparagraph.

B. Medical Marijuana Products Manufacturers. A Medical Marijuana Store may also contract for the manufacture of Medical Marijuana Product with Medical Marijuana Products Manufacturer Licensees utilizing a contract as provided for in Rule 5-310 – Medical Marijuana Products Manufacturer: General Limitations or Prohibited Acts (Infused Product Contracts). Medical Marijuana distributed to a Medical Marijuana Products Manufacturer by a Medical Marijuana Store pursuant to such a contract for use solely in Medical Marijuana Product(s) that are returned to the contracting Medical Marijuana Store shall not be included for purposes of determining compliance with paragraph A.

C. Sales Limitations.

1. A Medical Marijuana Store and its employees shall not sell to a patient in a single business day, individually or in any combination, more than:
  - a. Two ounces of medical marijuana flower;
  - b. 40 grams of Medical Marijuana Concentrate; or
  - c. Medical Marijuana Products containing a combined total of 20,000 mg;
2. A Medical Marijuana Store and its employees shall not sell more than:
  - a. Six Immature plants unless the patient has designated the Medical Marijuana Store as his or her primary center and supplied it with documentation from the patient's physician allowing the patient more than six plants;
  - b. Six half of the patient's extended plant count to a patient who has designated the Medical Marijuana Store as his or her primary center and supplied it with documentation from the patient's physician allowing the patient more than six plants; or
  - c. Six Medical Marijuana plant seeds unless the patient has designated the Medical Marijuana Store as his or her primary center and supplied it with documentation from the patient's physician allowing the patient more than six Medical Marijuana seeds. One Medical Marijuana plant is equivalent to one Medical Marijuana seed.
3. Exemptions to Sales Limitations.
  - a. A Medical Marijuana Store may sell Medical Marijuana or Medical Marijuana Product in an amount that exceeds the sales limitation in subparagraph (C)(1) of this Rule if:
    - i. The patient has received a physician recommendation for more than two ounces of Medical Marijuana flower and has designated the Medical Marijuana Store as his or her primary center; or ii. The patient has received a physician recommendation exempting the patient from the Medical Marijuana Concentrate or Medical Marijuana Product sales limitation and the patient has designated the Medical Marijuana Store as his or her primary center.

;



- D. For purposes of Rule 5-115(C), a single transaction to a patient includes multiple Transfers to the same patient during the same business day where the Medical Marijuana Store employee knows or reasonably should know that such Transfer would result in the patient possessing more than the quantities of Medical Marijuana set forth above. In determining the imposition of any penalty for violation of this Rule 5-115(C), the State Licensing Authority will consider any mitigating and aggravating factors set forth in Rule 8-235(C).
- E. Transfer Restriction.
1. Sampling Units. A Medical Marijuana Store may not possess or Transfer Sampling Units.
  2. Research Transfers Prohibited. A Medical Marijuana Store shall not Transfer any Medical Marijuana to a Medical Research Facility, a Pesticide Manufacturer, or a Marijuana Research and Development Facility.
- F. Licensees May Refuse Sales. Nothing in these rules prohibits a Licensee from refusing to Transfer Medical Marijuana to a patient.
- G. Delivery Outside Colorado Prohibited. A Medical Marijuana Store holding a valid delivery permit shall not deliver Medical Marijuana to an address that is outside the state of Colorado.
- H. Storage and Display Limitations. A Medical Marijuana Store shall not display Medical Marijuana outside of a designated Restricted Access Area or in a manner in which Medical Marijuana can be seen from outside the Licensed Premises. Storage of Medical Marijuana shall otherwise be maintained in Limited Access Areas or Restricted Access Area.
- I. Transfer of Expired Product Prohibited. A Medical Marijuana Store shall not Transfer any expired Medical Marijuana Product to a patient.
- J. Edibles Prohibited that are Shaped like a Human, Animal, or Fruit
1. The Transfer of Edible Medical Marijuana Product in the following shapes is prohibited:
    - a. The distinct shape of a human, animal, or fruit; or
    - b. A shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings.
  2. The prohibition on human, animal, and fruit shapes does not apply to the logo of a licensed Medical Marijuana Business. Nothing in this subparagraph (L)(2) alters or eliminates a Licensee's obligation to comply with the requirements of the 3-1000 Series Rules – Packaging, Labeling, and Product Safety.
  3. Edible Medical Marijuana Products that are geometric shapes and simply fruit flavored are not considered fruit and are permissible; and
  4. Edible Medical Marijuana Products that are manufactured in the shape of a marijuana leaf are permissible.
- K. Adverse Event Reporting. A Medical Marijuana Store that Transfers Audited Product and/or Alternative Use Product must report any adverse event related to an Audited Product and/or Alternative Use Product directly to the Medical Marijuana Products Manufacturer that Transferred the Audited Product or Alternative Use Product to the Medical Marijuana Store. The report must be submitted within forty-eight (48) hours after learning of the adverse event by the Medical

Marijuana Store. For the purpose of this Rule, adverse event means any untoward medical occurrence associated with the use of marijuana—this could include any unfavorable and unintended sign (including a hospitalization, emergency department visit, doctor’s visit, abnormal laboratory finding), symptom or disease temporally associated with the use of a marijuana product, and may include concerns or reports on the quality or possible adverse reactions to a specific Audited Product or Alternative Use Product. To the extent known after reasonable diligence to ascertain the information, the report to the Medical Marijuana Products Manufacturer must contain the name and contact information of the complainant, the date the complaint was received, the nature of the complaint, and the name and Production Batch number of the Audited Product or Alternative Use Product.

- L. Corrective and Preventive Action. This paragraph L shall be effective January 1, 2021. A Medical Marijuana Store 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. See Rule 3-905. The written procedures shall include requirements, as appropriate, for:
1. What constitutes a Nonconformance in the Licensee’s business operation;
  2. 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;
  3. Investigating the root cause of Nonconformances relating to product, processes, and the quality system;
  4. Identifying the action(s) needed to correct and prevent recurrence of Nonconformance and other quality problems;
  5. Verifying the Corrective Action or Preventive Action to ensure that such action is effective and does not adversely affect finished products;
  6. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;
  7. 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
  8. Submitting relevant information on identified quality problems and Corrective Action and Preventive Action documentation, and confirming the result of the evaluation, for management review.
- M. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

### **Basis and Purpose – 5-120**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(b), 44-10-203(1)(j), and 44-10-203(3)(h), C.R.S. The purpose of this rule is to establish that a Medical Marijuana Store must control and safeguard access to certain areas where Medical Marijuana will be sold, and to prevent diversion to non-patients. This Rule 5-120 was previously Rule M 404, 1 CCR 212-1.

### **5-120 – Point of Sale: Restricted Access Area**

- A. Identification of Restricted Access Area. All areas where Medical Marijuana is sold, possessed for sale, displayed, or dispensed for sale shall be identified as a Restricted Access Area and shall be clearly identified by the posting of a sign which shall be not less than 12 inches wide and 12 inches long, composed of letters not less than a half inch in height, which shall state, "Restricted Access Area – Only Medical Marijuana Patients Allowed."
- B. Patients in Restricted Access Area. The Restricted Access Area must be supervised by a Licensee at all times to ensure that only persons with a valid patient registry card or caregivers permitted to deliver Medical Marijuana to homebound patients as permitted by section 25-1.5-106(9)(e), C.R.S., are present in the Restricted Access Area. When allowing a patient or caregiver access to a Restricted Access Area, Employee Licensees shall make reasonable efforts to limit the number of patients in relation to the number of Employee Licensees in the Restricted Access Area at any time.
- C. Display of Medical Marijuana. The display of Medical Marijuana for sale is allowed only in Restricted Access Areas. Any product displays that are readily accessible to the patient must be supervised by the Employee Licensee at all times when patients are present.
- D. Pregnancy Warning. Medical Marijuana Stores must post, at all times and in a prominent place inside the Restricted Access Area, a warning that is at minimum three inches high and six inches wide that reads:

**WARNING:** Using marijuana, in any form, while you are pregnant or breastfeeding passes THC to your baby and may be harmful to your baby. There is no known safe amount of marijuana use during pregnancy or breastfeeding.

## **5-200 Series – Medical Marijuana Cultivation Facility: License Privileges**

### **Basis and Purpose – 5-205**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), 44-10-401(2)(a)(II), 44-10-313, 44-10-502(5), and 44-10-503, C.R.S. The purpose of this rule is to establish a Medical Marijuana Cultivation Facility's license privileges in addition to the privileges outlined in these rules. This Rule 5-205 was previously Rule M 501, 1 CCR 212-1.

### **5-205 – Medical Marijuana Cultivation Facility: License Privileges**

- A. Licensed Premises. To the extent authorized by Rule 3-215 – Regulated Marijuana Business – Shared Licensed Premises and Operational Separation, a Medical Marijuana Cultivation Facility may share a Licensed Premises with a commonly owned Retail Marijuana Cultivation Facility. However, a separate license is required for each specific business entity regardless of geographical location. In addition, a Medical Marijuana Cultivation Facility may share and operate at the same Licensed Premises as a Marijuana Research and Development Facility so long as:
  1. Each business or business entity holds a separate license;
  2. The Marijuana Research and Development Facility obtains an R&D Co-Location Permit;
  3. Both the Marijuana Research and Development Facility and the Medical Marijuana Cultivation Facility comply with all terms and conditions of the R&D Co-Location Permit; and
  4. Both the Marijuana Research and Development Facility and the Medical Marijuana Cultivation Facility comply with all applicable rules. See 5-700 Series Rules.

- B. Cultivation of Medical Marijuana Authorized. A Medical Marijuana Cultivation Facility may Propagate, cultivate, harvest, prepare, cure, package, store, and label Medical Marijuana, whether in concentrated form or otherwise.
- C. Authorized Transfers. A Medical Marijuana Cultivation Facility may Transfer Medical Marijuana and Water-Based Medical Marijuana Concentrate to another Medical Marijuana Cultivation Facility, a Medical Marijuana Store, a Medical Marijuana Products Manufacturer, a Medical Marijuana Testing Facility, a Marijuana Research and Development Facility, a Medical Research Facility, or a Pesticide Manufacturer.
1. A Medical Marijuana Cultivation Facility shall not Transfer Flowering plants or Vegetative plants to any Person except as authorized pursuant to Rule 3-605.
  2. A Medical Marijuana Cultivation Facility may Transfer Sampling Units of Medical Marijuana or Medical Marijuana Concentrate to a designated Sampling Manager in accordance with the restrictions set forth in section 44-10-502(5), C.R.S., and Rule 5-230.
  3. A Medical Marijuana Cultivation Facility may Transfer Medical Marijuana or Medical Marijuana Concentrate to another Medical Marijuana Cultivation Facility prior to testing required by these rules for the purpose of decontamination only after all other steps outlined in the Medical Marijuana Cultivation Facility's standard operating procedures have been completed, including but not limited to drying, curing, and trimming.
- D. Packaging Processed Medical Marijuana. Processed Medical Marijuana plants shall be packaged in units of ten pounds or less and labeled pursuant to the 3-1000 Series Rules – Labeling, Packaging, and Product Safety, and securely sealed in a tamper-evident manner.
- E. Authorized Marijuana Transport. A Medical Marijuana Cultivation Facility is authorized to utilize a licensed Medical Marijuana Transporter for transportation of its Medical Marijuana so long as the place where transportation orders are taken is a Medical Marijuana Business and the transportation order is delivered to a licensed Medical Marijuana Business, Medical Research Facility, or Pesticide Manufacturer. Nothing in this Rule prevents a Medical Marijuana Cultivation Facility from transporting its own Medical Marijuana.
- F. Performance-Based Incentives. A Medical Marijuana Cultivation Facility may compensate its employees using performance-based incentives, including sales-based performance-based incentives. However, a Medical Marijuana Cultivation Facility may not compensate a Sampling Manager using Sampling Units. See Rule 5-230 – Sampling Unit Protocols.
- G. Authorized Sources of Medical Marijuana Seeds and Immature Plants. A Medical Marijuana Cultivation Facility shall only obtain Medical Marijuana seeds or Immature Plants from its own Medical Marijuana, properly Transferred Retail Marijuana cultivated at a Retail Marijuana Cultivation Facility with at least one identical Controlling Beneficial Owner, or properly transferred from another Medical Marijuana Business pursuant to the inventory tracking requirements in the Rule 3-800 Series.
- H. Centralized Distribution Permit. A Medical Marijuana Cultivation Facility may apply to the State Licensing Authority for a Centralized Distribution Permit for authorization to temporarily store Medical Marijuana Concentrate and Medical Marijuana Product received from a Medical Marijuana Products Manufacturer for the sole purpose of Transfer to commonly owned Medical Marijuana Stores.
1. For purposes of a Centralized Distribution Permit only, the term “commonly owned” means at least one natural person has a minimum of five percent ownership in both the

Medical Marijuana Cultivation Facility possessing a Centralized Distribution Permit and the Medical Marijuana Store to which the Medical Marijuana Concentrate and Medical Marijuana Product will be Transferred.

2. To apply for a Centralized Distribution Permit, a Medical Marijuana Cultivation Facility may submit an addendum to its new or renewal application or a separate addendum prior to a renewal application on forms prepared by the Division to request a Centralized Distribution Permit. The Medical Marijuana Cultivation Facility shall send a copy of its Centralized Distribution Permit addendum to the Local Licensing Authority in the jurisdiction in which the Centralized Distribution Permit is proposed at the same time it submits the addendum to the State Licensing Authority.
  3. A Medical Marijuana Cultivation Facility that has been issued a Centralized Distribution Permit and has obtained all required approvals from the local licensing jurisdiction where it is located, if any, may accept Transfers of Medical Marijuana Concentrate and Medical Marijuana Product from a Medical Marijuana Products Manufacturer for the sole purpose of temporary storage and Transfer to commonly owned Medical Marijuana Stores.
    - a. A Medical Marijuana Cultivation Facility may only accept Medical Marijuana Concentrate and Medical Marijuana Product that is packaged and labeled for sale to a patient pursuant to the 3-1000 Series Rules.
    - b. A Medical Marijuana Cultivation Facility storing Medical Marijuana Concentrate and Medical Marijuana Product pursuant to a Centralized Distribution Permit shall not store such Medical Marijuana Concentrate or Medical Marijuana Product on the Medical Marijuana Cultivation Facility's Licensed Premises for more than 90 days from the date of receipt.
    - c. All Transfers of Medical Marijuana Concentrate and Medical Marijuana Product by a Medical Marijuana Cultivation Facility shall be without consideration.
  4. All security and surveillance requirements that apply to a Medical Marijuana Cultivation Facility apply to activities conducted pursuant to the privileges of a Centralized Distribution Permit.
- I. Transition Permit. A Medical Marijuana Cultivation Facility may only operate at two geographical locations pursuant to Rule 2-255(D).

### **Basis and Purpose – 5-210**

The statutory authority for this rule includes but is not limited to sections 44-10-201, 44-10-202(1)(c), 44-10-203(1)(j), 44-10-313, 44-10-401(2)(a)(II), 44-10-501, 44-10-502, 44-10-503, and 44-10-505, C.R.S. The purpose of this rule is to clarify what activity is or is not allowed at a Medical Marijuana Cultivation Facility. This Rule 5-210 was previously Rule M 502, 1 CCR 212-1.

### **5-210 – Medical Marijuana Cultivation Facility: General Limitations or Prohibited Acts**

- A. Packaging and Labeling Standards Required. A Medical Marijuana Cultivation Facility is prohibited from Transferring Medical Marijuana and Medical Marijuana Concentrate that is not packaged and labeled in accordance with these rules. See 3-1000 Series Rules – Labeling, Packaging, and Product Safety.
- B. Transfer to Patient Prohibited. A Medical Marijuana Cultivation Facility is prohibited from Transferring Medical Marijuana to a patient. This prohibition does not apply to Transfers to a Sampling Manager that comply with section 44-10-502(5), C.R.S., and Rule 5-230.

- C. Inventory Limit. A Medical Marijuana Cultivation Facility shall not possess more plants than it is permitted to possess based on its production management class. See Rule 5-225 – Medical Marijuana Cultivation Facility: Production Management.
- D. Corrective and Preventive Action. This paragraph D shall be effective January 1, 2021. A Medical Marijuana Cultivation Facility 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. See Rule 3-905. The written procedures shall include requirements, as appropriate, for:
1. What constitutes a Nonconformance in the Licensee’s business operation;
  2. 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;
  3. Investigating the root cause of Nonconformances relating to product, processes, and the quality system;
  4. Identifying the action(s) needed to correct and prevent recurrence of Nonconformance and other quality problems;
  5. Verifying the Corrective Action or Preventive Action to ensure that such action is effective and does not adversely affect finished products;
  6. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;
  7. 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
  8. Submitting relevant information on identified quality problems and Corrective Action and Preventive Action documentation, and confirming the result of the evaluation, for management review.

### **Basis and Purpose – 5-215**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), 44-10-203(2)(i), 44-10-203(2)(d)(I)-(VI), 44-10-502(3), and 44-10-401(2)(a)(II), C.R.S. The purpose of this rule is to permit laboratory testing of Medical Marijuana for Medical Marijuana Cultivation Facilities. The State Licensing Authority intends this rule to help maintain the integrity of Colorado's Medical Marijuana Businesses. This Rule 5-215 was previously Rule M 505, 1 CCR 212-1.

### **5-215 – Medical Marijuana Cultivation Facility: Testing**

- A. Samples on Demand. Medical Marijuana Cultivation Facility shall, upon request of the Division, submit a sufficient quantity of Medical Marijuana to a Medical Marijuana Testing Facility to enable laboratory or chemical analysis thereof. The Division will notify the Licensee of the results of the analysis. See Rule 3-805 – Regulated Marijuana Business: Inventory Tracking System and Rule 3-405 – Business Records Required.
- B. Samples Provided for Testing. A Medical Marijuana Cultivation Facility may provide Samples of its Medical Marijuana to a Medical Marijuana Testing Facility for testing and research purposes.

The Medical Marijuana Cultivation Facility shall maintain the testing results as part of its business books and records. See Rule 3-405 – Business Records Required.

### **Basis and Purpose – 5-220**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(d), 44-10-203(1)(j), 44-10-203(1)(c), 44-10-203(2)(d)(I)-(VI), and 44-10-401(2)(a)(II), C.R.S. The purpose of this rule is to establish the categories of Medical Marijuana Concentrate that may be produced at a Medical Marijuana Cultivation Facility and standards for the production of those concentrate. This Rule 5-220 was previously Rule M 506, 1 CCR 212-1.

### **5-220 – Medical Marijuana Cultivation Facility: Medical Marijuana Concentrate Production**

- A. Permitted Production of Certain Categories of Medical Marijuana Concentrate. A Medical Marijuana Cultivation Facility may only produce Water-Based Medical Marijuana Concentrate on its Licensed Premises and only in an area clearly designated as a Limited Access Area. See Rule 3-405- Business Records Required. No other method of production or extraction for Medical Marijuana Concentrate may be conducted within the Licensed Premises of a Medical Marijuana Cultivation Facility unless the Controlling Beneficial Owner(s) of the Medical Marijuana Cultivation Facility also has a valid Medical Marijuana Products Manufacturer license and the room in which Medical Marijuana Concentrate is to be produced is physically separated from all cultivation areas and has clear signage identifying the room.
- B. Safety and Sanitary Requirements for Concentrate Production. If a Medical Marijuana Cultivation Facility produces Water-Based Medical Marijuana Concentrate, then all areas in which those concentrates are produced and all Owner Licensees and Employees Licensees engaged in the production of those concentrate shall be subject to all of requirements imposed upon a Medical Marijuana Products Manufacturer that produces Medical Marijuana Concentrate, including general requirements. See 3-300 Series Rules – Health and Safety Regulations and Rule 5-315 Medical Marijuana Products Manufacturer: Medical Marijuana Concentrate Production.
- C. Possession of Other Categories of Medical Marijuana Concentrate.
  - 1. It shall be considered a violation of this Rule if a Medical Marijuana Cultivation Facility possesses a Medical Marijuana Concentrate other than a Water-Based Medical Marijuana Concentrate on its Licensed Premises unless: the Controlling Beneficial Owner(s) of the Medical Marijuana Cultivation Facility also has a valid Medical Marijuana Products Manufacturer license, or the Medical Marijuana Cultivation Facility has been issued a Centralized Distribution Permit and is in possession of the Medical Marijuana Concentrate in compliance with Rule 5-205(H).
  - 2. Notwithstanding subparagraph (C)(1) of this Rule 5-220, a Medical Marijuana Cultivation Facility shall be permitted to possess Solvent-Based Medical Marijuana Concentrate only when the possession is due to the Transfer of Medical Marijuana flower or trim that failed microbial testing to a Medical Marijuana Products Manufacturing Facility for processing into a Solvent-Based Medical Marijuana Concentrate, and the Medical Marijuana Products Manufacturer Transfers the resultant Solvent-Based Medical Marijuana Concentrate back to the originating Medical Marijuana Cultivation Facility.
    - a. The Medical Marijuana Cultivation Facility shall comply with all requirements in Rule 4-135(C) when having Solvent-Based Medical Marijuana Concentrate manufactured out of Medical Marijuana flower or trim that failed microbial testing.
    - b. The Medical Marijuana Cultivation Facility is responsible for submitting the Solvent-Based Medical Marijuana Concentrate for all required testing for

contaminants pursuant to Rule 4-120 – Medical Marijuana Testing Program – Contaminant Testing, for potency pursuant to Rule 4-125 – Medical Marijuana Testing Program – Potency Testing, and any other testing required or allowed by the Marijuana Rules or Marijuana Code.

- D. Production of Alternative Use Product or Audited Product Prohibited. A Medical Marijuana Cultivation Facility shall not produce an Alternative Use Product or Audited Product.
- E. Possession of Alternative Use Product or Audited Product. A Medical Marijuana Cultivation Facility is authorized to possess or Transfer Alternative Use Product and/or Audited Product only if the Medical Marijuana Cultivation Facility received the Alternative Use Product and/or Audited Product pursuant to a Centralized Distribution Permit from a Medical Marijuana Products Manufacturer that is manufacturing and Transferring the Alternative Use Product or Audited Product in accordance with Rule 5-325.

### **Basis and Purpose – 5-225**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), 44-10-203(5), 44-10-401(2)(a)(II), 44-10-502, C.R.S. The rule establishes a means by which to manage the overall production of Medical Marijuana. The intent of this rule is to encourage responsible production to meet demand for Medical Marijuana, while also avoiding overproduction or underproduction. The establishment of production management is necessary to ensure there is not significant under or over production, either of which will increase incentives to engage in diversion and facilitate the sale of illegal marijuana. This Rule 5-225 was previously Rule M 507, 1 CCR 212-1.

### **5-225 – Medical Marijuana Cultivation Facility: Production Management**

- A. One Medical Marijuana Cultivation Facility per Licensed Premises. Except as permitted by subparagraph (B)(1)(b), a Licensed Premises shall only have one Medical Marijuana Cultivation Facility license and each Licensed Premises must be located at a distinct address recognized by the local jurisdiction.
  - 1. Existing Medical Marijuana Cultivation Facilities that have Multiple Licenses at a single Licensed Premises.
    - a. Mandatory Collapse for Licenses with Identical Controlling Beneficial Owner Percentages.
      - i. Medical Marijuana Cultivation Facilities that have multiple licenses at a single Licensed Premises and that have identical Controlling Beneficial Owners holding identical ownership percentages are subject to mandatory collapse. Such Licensees shall notify the Division prior to June 30, 2019 which Medical Marijuana Cultivation Facility license they desire to survive. The Medical Marijuana Cultivation Facility license identified as the surviving license will remain active after July 1, 2019; all other Medical Marijuana Cultivation Facility licenses shall be surrendered effective July 1, 2019.
      - ii. The production management class for the surviving Medical Marijuana Cultivation Facility license will be calculated pursuant to subparagraph (B)(3) below using the aggregate average plants actually cultivated by all Medical Marijuana Cultivation Facility licenses that were located at the Licensed Premises during the period January 1, 2018 to December 31, 2018.



- b. Optional Collapse for Licenses with Non-Identical Controlling Beneficial Owner Percentages. Medical Marijuana Cultivation Facilities that have multiple licenses at a single Licensed Premises and that do not have identical Controlling Beneficial Owners holding identical ownership percentages as of July 1, 2019, may continue operating all Medical Marijuana Cultivation Facility licenses that existed at that Licensed Premises prior to July 1, 2019. The maximum plant count for each such Medical Marijuana Cultivation Facility will be calculated pursuant to subparagraph (B)(3) below based on the number of average plants actually cultivated by that Medical Marijuana Cultivation Facility during the period January 1, 2018 to December 31, 2018.
  - i. Medical Marijuana Cultivation Facilities that are permitted to continue operating multiple licenses at a single Licensed Premises after July 1, 2019, may collapse through one or more approved change of ownership applications, or one or more voluntary license surrenders, establishing identical Controlling Beneficial Owners holding identical ownership percentages for all Medical Marijuana Cultivation Facilities at the single Licensed Premises.
  - ii. For any change of ownership application or voluntary license surrender seeking collapse after July 1, 2019, the Medical Marijuana Cultivation Facility shall identify the license that will survive. The Medical Marijuana Cultivation Facility license identified as the surviving license will remain after collapse; all other Medical Marijuana Cultivation Facility licenses will be surrendered at the time of collapse.
  - iii. The class for the surviving Medical Marijuana Cultivation Facility license will be determined according to subparagraph (B)(3) below based on the aggregate average number of Medical Marijuana plants actually cultivated by all Medical Marijuana Cultivation Facility Licensees that were located at the Licensed Premises during the 180 days prior to the collapse.
- 2. Collapse after July 1, 2019. After July 1, 2019, Medical Marijuana Cultivation Facility licenses shall be permitted to collapse at a single Licensed Premises through an approved change of location application if all Medical Marijuana Cultivation Facility licenses for which collapse is sought meet the following requirements:
  - a. All Medical Marijuana Cultivation Facility licenses sought to be collapsed have been consistently operating for at least 180 days prior to the proposed collapse;
  - b. All Medical Marijuana Cultivation Facility licenses sought to be collapsed have identical Controlling Beneficial Owners holding identical ownership percentages;
  - c. There is no pending administrative action regarding any of Medical Marijuana Cultivation Facility licenses sought to be collapsed;
  - d. The class for the surviving Medical Marijuana Cultivation Facility license has not been decreased in the 180 days prior to the change of location application;
  - e. All Medical Marijuana Cultivation Facility Licensees identify the desired surviving license and agree that all other Medical Marijuana Cultivation Facility licenses will be surrendered at the time of collapse; and
  - f. Determining Class for Surviving License.

- i. Surviving License Class Will Not Decrease. The class for the surviving license will not be decreased as a result of any approved change of location application.
- ii. Surrendered License is Class 1, Class 2, or Class 3. For the surviving license to increase one class or one increment of 3,000 plants if already higher than class 3, during the 180 days prior to the change of location application, the surrendered license must have cultivated at least 50% of the maximum authorized plant count and Transferred at least 85% of the inventory it produced during that time.
- iii. Surrendered License is Higher than Class 3. For the surviving license to increase by the maximum authorized plant count of the surrendered license, during the 180 days prior to the change of location application the surrendered license must have cultivated at least 50% of the maximum authorized plant count and transferred at least 85% of the inventory it produced during that time. If during the 180 days prior to the change of location application, the surrendering license did not cultivate at least 50% of the maximum authorized plant count and transfer at least 85% of the inventory it produced, the surviving license will only increase one class or one increment of 3,000 plants if already higher than class 3.
- iv. Division Determination of Class. If a collapse results in a maximum authorized plant count in the middle of a class, the surviving license's maximum authorized plant count will be rounded up to the top of that class.

B. Production Management.

- 1. Production Management Classes.
  - a. Class 1: 1 – 500 plants
  - b. Class 2: 501 – 1,500 plants
  - c. Class 3: 1,501 – 3,000 plants
    - i. The maximum authorized plant count above 3,000 plants shall increase in one or two increments of 3,000 plants. A Medical Marijuana Cultivation Facility may be allowed to increase its maximum authorized plant count one or two increments of 3,000 plants at a time upon application and approval by the Division pursuant to the requirements of paragraph (E) of this Rule 5-225.
- 2. All initial Medical Marijuana Cultivation Facility licenses issued on or after July 1, 2019 will be Class 1 and shall not cultivate more than 500 plants at any time.
- 3. Each Medical Marijuana Cultivation Facility with a license(s) granted before July 1, 2019, at a minimum, will be placed into the production management class that includes the average number of plants it cultivated during the period January 1, 2018 to December 31, 2018.
  - a. Medical Marijuana Cultivation Facilities with less than 180 days of consistent cultivation history will be placed into the class 1 production management class.

- b. Any Medical Marijuana Cultivation Facility that artificially increases plant count or otherwise misrepresents any data in connection with its plant count will be placed into the class the Division determines it would have been placed into without the artificial increase or misrepresentation. In addition, any such artificial increase of plant count or other misrepresentation is a public safety violation that may result in administrative action.
  4. Immature Plants. For purposes of calculating the maximum number of authorized plants, Immature Plants are excluded.
  5. Ground for Denial. The Division may deny an application for additional plants pursuant to paragraph E of this Rule if the Licensee exceeded the authorized plant count during the relevant time period for production.
  6. Violation Affecting Public Safety. It may be considered a license violation affecting public safety for a Licensee to exceed the authorized plant count pursuant to these Rules.
- C. Inventory Management.
1. Inventory Management for Medical Marijuana Cultivation Facilities that Have One or Two Harvest Seasons a Year. Beginning the 721<sup>st</sup> day from the commencement of its first cultivation activities, a Medical Marijuana Cultivation Facility that has one or two harvest seasons a year may not accumulate Harvested Marijuana in excess of the total amount of Medical Marijuana flower and trim the Licensee produced that was Transferred to another Medical Marijuana Business in the previous 720 days.
  2. Inventory Management for Medical Marijuana Cultivation Facilities That Have More Than Two Harvest Seasons a Year. Beginning the 181<sup>st</sup> day from the commencement of its first cultivation activities, a Medical Marijuana Cultivation Facility that has more than two harvest seasons a year may not accumulate Harvested Marijuana in excess of the total amount of Medical Marijuana flower and trim the Licensee produced that was Transferred to another Medical Marijuana Business in the previous 180 days.
- D. Class Decrease. For any Medical Marijuana Cultivation Facility that is authorized to cultivate more than 500 plants, the Division may review the purchases, Transfers, and cultivated plant count in connection with the license renewal process or after an investigation. Based on the Division's review, it may reduce the Licensee's maximum allowed plant count to a lower production management class identified in subparagraph (B)(1) of this Rule 5-225. When determining whether to reduce the maximum authorized plant count, the Division may consider the following non-exhaustive factors including but not limited to:
1. The Licensee Transferred less than 70% of the inventory it reported as packaged in the Inventory Tracking System during any 180 day review period;
  2. On average during the previous 180 days, the Licensee actually cultivated less than 90% of the maximum number of plants authorized by the next lower production management class;
  3. Whether the plants/inventory suffered a catastrophic event during the review period;
  4. Existing inventory and inventory history;
  5. Sales contracts;
  6. Number of patients registered to any commonly owned Medical Marijuana Store; and

7. Any other factors relevant to ensuring responsible cultivation, production, and inventory management.

E. Application for Additional Plants.

1. Medical Marijuana Cultivation Facilities That Have One or Two Harvest Seasons Per Year.

- a. After one harvest season during which the Medical Marijuana Cultivation Facility Transferred and consistently cultivated, the Licensee may apply to the Division for a production management class increase to be authorized to cultivate the number of plants in the next highest production management class. The Licensee must demonstrate:
  - i. That during the previous harvest season, prior to the class increase application, it consistently cultivated an average amount of plants that is at least 85% of its maximum authorized plant count;
  - ii. That the Licensee Transferred at least 85% of the inventory it reported as a package in the Inventory Tracking System in the previous 360 days to another Medical Marijuana Business;
  - iii. The Division may consider Transfers of over 85% of the inventory it reported as a package in the Inventory Tracking System during the previous 360 days, if the Licensee cultivated between 75% and 85% of its maximum authorized plant count; and
  - iv. Any other information requested to aid the Division in its evaluation of the production management class increase application.
- b. If the Division approves the production management class increase application, the Licensee shall pay the applicable Expanded Production Management Class Fee prior to cultivating the additional authorized plants. See Rule 2-205 – Fees.
- c. For a Licensee with an authorized plant count in Classes 2 or 3 to continue producing at its expanded authorized plant count, the Licensee shall pay the requisite Medical Marijuana Cultivation Facility license fee and the applicable expanded production management class fee at license renewal. See Rule 2-205 – Fees.
- d. After one harvest season during which the Medical Marijuana Cultivation Facility Transferred and consistently cultivated the Licensee may apply to increase its authorized plant count by: (a) two production management classes, or (b) if already authorized to cultivate at a class 3, two increments of 3,000 plants (6,000 plants total), every 360 days. It is within the Division’s discretion to determine whether or not to grant the requested two classes or two increments of 3,000 plant (6,000 plants total).
  - i. The Licensee must demonstrate:
    - A. That the Licensee consistently cultivated an average amount of plants that is at least 90% of its maximum authorized plant count, and

- B. That the Licensee Transferred at least 90% of the inventory it reported as a package in the Inventory Tracking System during that time period to another Medical Marijuana Business;
  - C. If the Medical Marijuana Cultivation Facility cultivated between 80% and 90% of its maximum authorized plant count, the Division may also consider Transfers of over 90% of the inventory it reported as a package in the Inventory Tracking System during that time period and/or Transfers into the Medical Marijuana Cultivation Facility or related Medical Marijuana Store(s).
- ii. In making its determination, the Division may consider the following exclusive factors:
- A. The Medical Marijuana Cultivation Facility currently has possession of, or has entered into a written agreement or contract to possess, sufficient space to grow the requested two classes or two increments of 3,000 plants;
  - B. The Medical Marijuana Cultivation Facility cultivated on average at least 90% of its authorized plant count and during the preceding 360 days the Medical Marijuana Cultivation Facility and/or one or more commonly owned Medical Marijuana Stores Transferred in Medical Marijuana from one or more unrelated Medical Marijuana Cultivation Facility(ies);
  - C. The Medical Marijuana Cultivation Facility has entered into written agreement(s) or contract(s) for the sale of Medical Marijuana in the next 360 days supporting the requested two production management class increase or two increments of 3,000 plants; or
  - D. An established history of responsible cultivation and Transfer by the Medical Marijuana Cultivation Facility;
  - E. Any history of noncompliance with the Medical Code, Marijuana Code, and/or Rules by the Medical Marijuana Cultivation Facility, or any commonly owned Medical Marijuana Business, and/or any investigation of, or administrative action against, the Medical Marijuana Cultivation Facility or any commonly owned Medical Marijuana Business; or
  - F. Any other pertinent facts or circumstances regarding responsible production and inventory management.
2. Medical Marijuana Cultivation Facilities That Have More Than Two Harvest Seasons per Year.
- a. After a 180-day period during which the Medical Marijuana Cultivation Facility Transferred and consistently cultivated, the Licensee may apply to the Division for a production management class increase to be authorized to cultivate the number of plants in the next highest production management class. The Division may consider the following in determining whether to approve the production management class increase:

- i. That for the 180 days prior to the production management class increase application, the Licensee consistently cultivated an average amount of plants that is at least 85% of its maximum authorized plant count, and
  - ii. That the Licensee Transferred at least 85% of the inventory it reported as a package in the Inventory Tracking System during that time period to another Medical Marijuana Business.
  - iii. The Division may also consider Transfers of over 85% of the inventory it reported as a package in the Inventory Tracking System during the 180-day time period, if the Licensee cultivated between 75% and 85% of its maximum authorized plant count.
  - iv. Any other information requested to aid the Division in its evaluation of the production management class increase application.
- b. If the Division approves the production management class increase application, the Licensee shall pay the applicable Expanded Production Management class License Fee prior to cultivating the additional authorized plants. See Rule 2-205 – Fees.
  - c. For a Licensee with an authorized plant count in Class 2 or Class 3 to continue producing at its expanded authorized plant count, the Licensee shall pay the requisite Medical Marijuana Cultivation Facility license fee and the applicable expanded production management class fee at license renewal. See Rule 2-205 – Fees.
  - d. After accruing 180 days during which the Medical Marijuana Cultivation Facility Transferred and consistently cultivated the Licensee may apply to increase its authorized plant count by: (a) two production management classes, or (b) if already authorized to cultivate at a class 3, two increments of 3,000 plants (6,000 plants total) every 180 days. It is within the Division's discretion to determine whether or not to grant the requested two classes or increments of 3,000 plants (6,000 plants total).
    - i. The Licensee must demonstrate:
      - A. That the Licensee consistently cultivated an average amount of plants that is at least 90% of its maximum authorized plant count; and
      - B. That the Licensee Transferred at least 90% of the inventory it reported as a package in the Inventory Tracking System during that time period to another Medical Marijuana Business;
      - C. If the Medical Marijuana Cultivation Facility cultivated between 80% and 90% of its maximum authorized plant count, the Division may also consider Transfers of over 90% of the inventory it reported as a packing in the Inventory Tracking System during that time period and/or Transfers into the Medical Marijuana Cultivation Facility or related Medical Marijuana Store(s).
    - ii. In making its determination, the Division may consider the following exclusive factors:

- A. The Medical Marijuana Cultivation Facility currently has possession of, or has entered into a written agreement or contract to possess, sufficient space to grow the requested two classes or two increments of 3,000 plants;
  - B. The Medical Marijuana Cultivation Facility cultivated on average at least 90% of its authorized plant count and during the preceding 180 days the Medical Marijuana Cultivation Facility and/or one or more commonly owned Medical Marijuana Stores Transferred in Medical Marijuana from one or more unrelated Medical Marijuana Cultivation Facility(ies);
  - C. The Medical Marijuana Cultivation Facility has entered into a written agreement(s) or contract(s) for the sale of Medical Marijuana in the next 180 days supporting the requested two production management class increase or two increments of 3,000 plants;
  - D. An established history of responsible cultivation and Transfer by the Medical Marijuana Cultivation Facility;
  - E. Any history of noncompliance with the Medical Code, Marijuana Code, and/or Rules by the Medical Marijuana Cultivation Facility, or any commonly owned Medical Marijuana Business, and/or any investigation of, or administrative action against, the Medical Marijuana Cultivation Facility or any commonly owned Medical Marijuana Business; or
  - F. Any other pertinent facts or circumstances regarding responsible production and inventory management.
3. Application for Class Increase. Applications for a class increase shall be submitted on Division forms, and shall be complete and accurate. Applications for a class increase that include any artificial increase of plant count, manipulation of Transfer history, or other misrepresentation will be denied. In addition to denial, any artificial increase of plant count, manipulation of Transfer history, or other misrepresentation is a public safety violation that may result in administrative action.
- F. Maximum Allowed Medical Marijuana Cultivation Facility Licenses.
- 1. A Person that is a Controlling Beneficial Owner with an Interest in Three or More Medical Marijuana Cultivation Facility Licenses. For every multiple of three Medical Marijuana Cultivation Facility licenses in which a Person is a Controlling Beneficial Owner, the Person must also be a Controlling Beneficial Owner in at least one Medical Marijuana Store. For example: (1) a Person that is a Controlling Beneficial Owner in three, four, or five Medical Marijuana Cultivation Facility licenses also must be a Controlling Beneficial Owner in at least one Medical Marijuana Store; (2) a Person that is a Controlling Beneficial Owner in six, seven, or eight Medical Marijuana Cultivation Facility licenses also must be a Controlling Beneficial Owner in at least two Medical Marijuana Stores; (3) a Person that is a Controlling Beneficial Owner in nine, ten, or eleven Medical Marijuana Cultivation Facility licenses also must be a Controlling Beneficial Owner in at least three Medical Marijuana Stores; etcetera.
  - 2. A Person that is a Controlling Beneficial Owner in Less than Three Medical Marijuana Cultivation Facility Licenses. A Person that is a Controlling Beneficial Owner in less than

three Medical Marijuana Cultivation Facility licenses shall not be required to be a Controlling Beneficial Owner in a Medical Marijuana Store.

- G. The State Licensing Authority, in his or her sole discretion, may adjust any of the plant limits described in this Rule 5-225 on an industry-wide aggregate basis for all Medical Marijuana Cultivation Facilities subject to that limitation.

### **Basis and Purpose – 5-230**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-401(2)(a)(II), and 44-10-502(5), C.R.S. The purpose of this rule is to establish the circumstances under which a Medical Marijuana Cultivation Facility may provide Sampling Units to a designated Sampling Manager for quality control or product development purposes. In order to maintain the integrity of Colorado's regulated Medical Marijuana Businesses, this rule establishes limits on the amount of Sampling Units a Sampling Manager may receive in a calendar month and imposes inventory tracking, reporting and recordkeeping requirements on a Medical Marijuana Cultivation Facility that Transfer Sampling Units. This Rule 5-230 was previously Rule M 508, 1 CCR 212-1.

### **5-230 – Sampling Unit Protocols**

- A. Designation of Sampling Manager(s). In any calendar month, a Medical Marijuana Cultivation Facility may designate no more than five Sampling Managers in the Inventory Tracking System.
1. Only management personnel of the Medical Marijuana Cultivation Facility who holds an Owner License or an Employee License may be designated as a Sampling Manager.
  2. An individual designated as a Sampling Manager by a Medical Marijuana Cultivation Facility must possess a valid patient registry card.
  3. An individual may be designated as a Sampling Manager by more than one Regulated Marijuana Business.
  4. By virtue of the decision to be designated as a Sampling Manager, the Sampling Manager expressly consents to being identified in the Inventory Tracking System and makes a voluntary decision that any Sampling Units Transferred to the Sampling Manager will be identified in the Inventory Tracking System.
  5. A Medical Marijuana Cultivation Facility that wishes to provide Sampling Units to a Sampling Manager shall first establish and provide to each Sampling Manager standard operating procedures that explain the requirements of section 44-10-502(5), C.R.S., the personal possession limits pursuant to section 18-18-406, C.R.S., and the requirements of this Rule 5-230. *See also* Rule 3-905 – Business Records Required. A Medical Marijuana Cultivation Facility shall maintain and update such standard operating procedures as necessary to reflect accurately any changes in the relevant statutes and rules.
- B. Sampling Unit Limits. Only one Sampling Unit may be designated per Harvest Batch or Production Batch. A Sampling Unit shall not be designated until the Harvest Batch or Production Batch has satisfied the testing requirements in 4-100 Series Rules – Regulated Marijuana Testing Program.
1. A Sampling Unit of Medical Marijuana flower or trim shall not exceed one gram.
  2. A Sampling Unit of Medical Marijuana Concentrate shall not exceed one-quarter of one gram; except that a Sampling Unit of Medical Marijuana Concentrate which has the



intended use of being delivered in a vaporized form shall not exceed one-half of one gram.

C. Transfer Restrictions.

1. No Sampling Unit shall be Transferred unless it is packaged and labeled in accordance with the requirements in the 3-1000 Series Rules – Labeling, Packaging, and Product Safety.
2. No Sampling Unit shall be Transferred to any individual who is not currently designated in the Inventory Tracking System by the Medical Marijuana Cultivation Facility as a Sampling Manager for the calendar month in which the Transfer occurs.
3. In any calendar month, a Sampling Manager shall not receive Sampling Units totaling more than one ounce of Medical Marijuana or fifteen grams of Medical Marijuana Concentrate.
4. The monthly limit established in subparagraph (C)(3) applies to each Sampling Manager, regardless of the number of Medical Marijuana Businesses with which the Sampling Manager is associated.
5. A Sampling Manager shall not accept Sampling Units in excess of the monthly limit established in subparagraph (C)(3). Before Transferring any Sampling Units, a Medical Marijuana Cultivation Facility shall verify with the recipient Sampling Manager that the Sampling Manager will not exceed the monthly limits established in subparagraph (C)(3).
6. A Sampling Manager shall not Transfer any Sampling unit to any other Person, including but not limited to any other Person designated as a Sampling Manager.

D. Compensation Prohibited. A Medical Marijuana Cultivation Facility may not use Sampling Units to compensate a Sampling Manager.

E. On-Premises Consumption Prohibited. A Sampling Manager shall not consume any Sampling Unit on any Licensed Premises.

F. Acceptable Purposes. Sampling Units shall only be designated and Transferred for purposes of quality control and product development in accordance with section 44-10-502(5), C.R.S.

G. Recordkeeping Requirements. A Medical Marijuana Cultivation Facility shall maintain copies of any material documents created regarding the quality control and product development purpose(s) of each Sampling Unit. Such documents shall constitute business records under Rule 3-905 – Business Records Required. At a minimum, a Medical Marijuana Cultivation Facility shall maintain records that show whether a Sampling Unit Transferred to a Sampling Manager is for the purpose of either quality control or product development. A Medical Marijuana Cultivation Facility shall also maintain copies of the Medical Marijuana Cultivation Facility’s standard operating procedures provided to Sampling Managers.

H. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

**5-300 Series – Medical Marijuana Products Manufacturers**

**Basis and Purpose – 5-305**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), 44-10-203(2)(d)(I)-(VI), and 44-10-503, C.R.S. The purpose of this rule is to establish a Medical Marijuana Products Manufacturer's license privileges. This Rule 5-305 was previously Rule M 601, 1 CCR 212-1.

### **5-305 – Medical Marijuana Products Manufacturer: License Privileges**

- A. Licensed Premises. A separate license is required for each specific business or business entity and geographical location. A Retail Marijuana Products Manufacturer may share and operate at the same Licensed Premises with a commonly owned Medical Marijuana Products Manufacturer. However, a separate license is required for each specific business or business entity, regardless of geographical location. In addition, a Medical Marijuana Products Manufacturer may share, and operate at, the same Licensed Premises as a Marijuana Research and Development Facility so long as:
1. Each business or business entity holds a separate license;
  2. The Marijuana Research and Development Facility obtains an R&D Co-Location Permit;
  3. Both the Marijuana Research and Development Facility and the Medical Marijuana Products Manufacturer comply with all terms and conditions of the R&D Co-Location Permit; and
  4. Both the Marijuana Research and Development Facility and the Medical Marijuana Products Manufacturer comply with all applicable rules. See 5-700 Series Rules.
- B. Authorized Transfers. A Medical Marijuana Products Manufacturer is authorized to Transfer Medical Marijuana as follows:
1. Medical Marijuana Concentrate and Medical Marijuana Product.
    - a. A Medical Marijuana Products Manufacturer may Transfer its own Medical Marijuana Product and Medical Marijuana Concentrate to Medical Marijuana Stores, other Medical Marijuana Products Manufacturers, Medical Marijuana Testing Facility, Marijuana Research and Development Facility, Medical Research Facilities, and Pesticide Manufactures.
    - b. A Medical Marijuana Products Manufacturer may Transfer Medical Marijuana Product and Medical Marijuana Concentrate to a Medical Marijuana Cultivation Facility that has been issued a Centralized Distribution Permit.
      - i. Prior to any Transfer pursuant to this Rule 5-305(B)(1)(b), a Medical Marijuana Products Manufacturer shall verify Medical Marijuana Cultivation Facility possesses a valid Centralized Distribution Permit. See Rule 5-205 – Medical Marijuana Cultivation Facility: License Privileges.
      - ii. For any Transfer pursuant to this Rule 5-305(B)(1)(b), A Medical Marijuana Products Manufacturer shall only Transfer Medical Marijuana Product and Medical Marijuana Concentrate that is packaged and labeled for Transfer to a patient. See 3-1000 Series Rules.
  2. Medical Marijuana.
    - a. A Medical Marijuana Products Manufacturer may Transfer Medical Marijuana to another Medical Marijuana Products Manufacturer, a Medical Marijuana Store, a

Marijuana Research and Development Facility, a Medical Research Facility, or a Pesticide Manufacturer.

3. Sampling Units. A Medical Marijuana Products Manufacturer may also Transfer Sampling Units of its own Medical Marijuana Products and Medical Marijuana Concentrate to a designated Sampling Manager in accordance with the restrictions set forth in section 44-10-503(10), C.R.S., and Rule 5-320.
- C. Manufacture of Medical Marijuana Concentrate and Medical Marijuana Product Authorized. A Medical Marijuana Products Manufacturer may manufacture, prepare, package, and label Medical Marijuana Concentrate and Medical Marijuana Product, whether in concentrated form or that are comprised of Medical Marijuana and other Ingredients intended for use or consumption, such as Edible Medical Marijuana Products, ointments, or tinctures.
1. Industrial Hemp Product Authorized. This subparagraph (C)(1) is effective July 1, 2020. A Medical Marijuana Products Manufacturer that uses Industrial Hemp Product as an Ingredient in the manufacture and preparation of Medical Marijuana Product must comply with this subparagraph (C)(1) of this Rule.
    - a. Prior to accepting and taking possession of any Industrial Hemp Product for use as an Ingredient in a Medical Marijuana Product the Medical Marijuana Products Manufacturer shall verify the following:
      - i. That the Industrial Hemp Product has passed all required testing pursuant to the 4-100 Series Rules at a Medical Marijuana Testing Facility; and
      - ii. That the Person Transferring the Industrial Hemp Product to the Medical Marijuana Products Manufacturer is registered with the Colorado Department of Public Health and Environment pursuant to section 25-5-426, C.R.S.
- D. Location Prohibited. A Medical Marijuana Products Manufacturer may not manufacture, prepare, package, store, or label Medical Marijuana Product in a location that is operating as a retail food establishment.
- E. Samples Provided for Testing.
1. A Medical Marijuana Products Manufacturer may provide samples of its Medical Marijuana Concentrate or Medical Marijuana Product to a Medical Marijuana Testing Facility for testing and research purposes. The Medical Marijuana Products Manufacturer shall maintain the testing results as part of its business books and records. See Rule 3-905 – Business Records Required.
- F. Authorized Marijuana Transport. A Medical Marijuana Products Manufacturer is authorized to utilize a Medical Marijuana Transporter for transportation of its Medical Marijuana Product or Medical Marijuana Concentrate so long as the place where transportation orders are taken is a licensed Medical Marijuana Business and the transportation order is delivered to a Medical Marijuana Business, Medical Research Facility, or Pesticide Manufacturer. Nothing in this Rule prevents a Medical Marijuana Products Manufacturer from transporting its own Medical Marijuana or Medical Marijuana Concentrate.
- G. Performance-Based Incentives. A Medical Marijuana Products Manufacturer may compensate its employees using performance-based incentives, including sales-based performance-based

incentives. However, a Medical Marijuana Products Manufacturer may not compensate a Sampling Manager using Sampling Units. See Rule 5-320 – Sampling Unit Protocols.

### **Basis and Purpose – 5-310**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), 44-10-401(2)(a)(III), and 44-10-503, C.R.S. The Marijuana Code sets forth minimum requirements for written agreements between Medical Marijuana Products Manufacturers and Medical Marijuana Stores. Specifically, the written agreements must set forth the total amount of Medical Marijuana obtained from a Medical Marijuana Store to be used in the manufacturing process, and the total amount of Medical Marijuana Product to be manufactured from the Medical Marijuana obtained from the Medical Marijuana Store. This rule clarifies that the Division must approve such written agreements to ensure they meet those requirements. This rule also provides those acts that are generally limited or prohibited. This Rule 5-310 was previously Rule M 602, 1 CCR 212-1.

### **5-310 – Medical Marijuana Products Manufacturer: General Limitations or Prohibited Acts**

- A. Contract Required. Any contract required pursuant to section 44-10-503(3), C.R.S., shall contain such minimum requirements as to form and substance as required by statute. All contracts need to be current and available for inspection on the Licensed Premises by the Division when requested. See Rule 3-905 – Business Records and Reporting.
- B. Packaging and Labeling Standards Required. A Medical Marijuana Products Manufacturer is prohibited from Transferring Medical Marijuana Concentrate or Medical Marijuana Product that are not properly packaged and labeled. See 3-1000 Series Rules – Labeling, Packaging, and Product Safety
- C. Transfer to Patient Prohibited. A Medical Marijuana Products Manufacturer is prohibited from Transferring Medical Marijuana to a patient. This prohibition does not apply to Transfers to a Sampling Manager that comply with section 44-10-503(10), C.R.S., and Rule 5-320.
- D. Adequate Care of Perishable Product. A Medical Marijuana Products Manufacturer must provide adequate refrigeration for perishable Medical Marijuana Product that will be consumed and shall utilize adequate storage facilities and transport methods.
- E. Homogeneity of Edible Medical Marijuana Product. A Medical Marijuana Products Manufacturer must ensure that its manufacturing processes are designed so that the Cannabinoid content of any Edible Medical Marijuana Product is homogenous.
- F. Use of Ingredients. A Medical Marijuana Products Manufacturer must obtain and maintain certificates of analysis or other records demonstrating the full composition of each Ingredient used in the manufacture of Vaporizer Delivery Devices or Pressurized Metered Dose Inhalers.
- G. Corrective and Preventive Action. This paragraph G shall be effective January 1, 2021. A Medical Marijuana Products 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. See Rule 3-905. The written procedures shall include requirements, as appropriate, for:
  - 1. What constitutes a Nonconformance in the Licensee’s business operation;

2. 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;
3. Investigating the root cause of Nonconformances relating to product, processes, and the quality system;
4. Identifying the action(s) needed to correct and prevent recurrence of Nonconformance and other quality problems;
5. Verifying the Corrective Action or Preventive Action to ensure that such action is effective and does not adversely affect finished products;
6. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;
7. 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
8. Submitting relevant information on identified quality problems and Corrective Action and Preventive Action documentation, and confirming the result of the evaluation, for management review.

#### **Basis and Purpose – 5-315**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(i), 44-10-401(2)(a)(III), and 44-10-503, C.R.S. The purpose of this rule is to establish the categories of Medical Marijuana Concentrate that may be produced at a Medical Marijuana Products Manufacturer and establish standards for the production of those concentrate. Nothing in this rule authorizes the unlicensed practice of engineering under Article 25 of Title 12, C.R.S. This Rule 5-315 was previously Rule M 605, 1 CCR 212-1.

#### **5-315 – Medical Marijuana Products Manufacturer: Medical Marijuana Concentrate Production.**

##### **A. Permitted Categories of Medical Marijuana Concentrate Production.**

1. A Medical Marijuana Products Manufacturer may produce Water-Based Medical Marijuana Concentrate, Food-Based Medical Marijuana Concentrate, and Heat/Pressure-Based Medical Marijuana Concentrate
2. A Medical Marijuana Products Manufacturer may also produce Solvent-Based Medical Marijuana Concentrate using only the following solvents: butane, propane, CO<sub>2</sub>, ethanol, isopropanol, acetone, heptane, ethyl acetate, and pentane. The use of any other solvent is expressly prohibited unless and until it is approved by the Division.
3. A Medical Marijuana Products Manufacturer may submit a request to the Division to consider the approval of solvents not permitted for use under this Rule during the next formal rulemaking.

##### **B. General Applicability. A Medical Marijuana Products Manufacturer that engages in the production of Medical Marijuana Concentrate, regardless of the method of extraction or category of concentrate being produced, must:**

1. Ensure that the space in which any Medical Marijuana Concentrate is to be produced is a fully enclosed room and clearly designated on the current diagram of the Licensed Premises. See Rule 3-905 – Business Records Required.
2. Ensure that all applicable sanitary rules are followed. See 3-300 Series Rules.
3. Ensure that the standard operating procedure for each method used to produce a Medical Marijuana Concentrate includes, but need not be limited to, step-by-step instructions on how to safely and appropriately:
  - a. Conduct all necessary safety checks prior to commencing production;
  - b. Prepare Medical Marijuana for processing;
  - c. Extract Cannabinoids and other essential components of Medical Marijuana;
  - d. Purge any solvent or other unwanted components from a Medical Marijuana Concentrate,
  - e. Clean all equipment, counters and surfaces thoroughly; and
  - f. Dispose of any waste produced during the processing of Medical Marijuana in accordance with all applicable local, state and federal laws, rules and regulations. See Rule 3-230 – Waste Disposal.
4. Establish written and documentable quality control procedures designed to maximize safety for Owner Licensees and Employee Licensees and minimize potential product contamination.
5. Establish written emergency procedures to be followed by Owner Licensees or Employee Licensees in case of a fire, chemical spill or other emergency.
6. Have a comprehensive training manual that provides step-by-step instructions for each method used to produce a Medical Marijuana Concentrate. The training manual must include, but need not be limited to, the following topics:
  - a. All standard operating procedures for each method of concentrate production used;
  - b. The Medical Marijuana Products Manufacturer's quality control procedures;
  - c. The emergency procedures;
  - d. The appropriate use of any necessary safety or sanitary equipment;
  - e. The hazards presented by all solvents used as described in the safety data sheet for each solvent;
  - f. Clear instructions on the safe use of all equipment involved in each process and in accordance with manufacturer's instructions, where applicable; and
  - g. Any additional periodic cleaning required to comply with all applicable sanitary rules.

7. Provide adequate training to every Owner Licensee or Employee Licensee prior to that individual undertaking any step in the process of producing a Medical Marijuana Concentrate.
  - a. Adequate training must include, but need not be limited to, providing a copy of the training manual for that Licensed Premises and live, in-person instruction detailing at least all of the topics required to be included in the training manual.
  - b. The individual training an Owner Licensee or Employee Licensee must sign and date a document attesting that all required aspects of training were conducted and that he or she is confident that the Owner Licensee or Employee Licensee can safely produce a Medical Marijuana Concentrate. See Rule 3-905 – Business Records Required.
  - c. The Owner Licensee or Employee Licensee that received the training must sign and date a document attesting that he or she can safely implement all standard operating procedures, quality control procedures, and emergency procedures, operate all closed-loop extraction systems, use all safety, sanitary and other equipment and understands all hazards presented by the solvents to be used within the Licensed Premises and any additional period cleaning required to maintain compliance with all applicable sanitary rules. See Rule 3-905 – Business Records Required.
8. Maintain clear and comprehensive records of the name, signature and Owner Licensee or Employee License number of every individual who engaged in any step related to the creation of a Production Batch of Medical Marijuana Concentrate and the step that individual performed. See Rule 3-905 – Business Records Required.

C. Water-Based Medical Marijuana Concentrate, Food-Based Medical Marijuana Concentrate, and Heat/Pressure-Based Medical Marijuana Concentrate. Medical Marijuana Products Manufacturer that engages in the production of a Medical Marijuana Concentrate must:

1. Ensure that all equipment, counters, and surfaces used in the production of a Medical Marijuana Concentrate is food-grade including ensuring that all counters and surface areas were constructed in such a manner that it reduces the potential for the development of microbials, molds and fungi and can be easily cleaned.
2. Ensure that all equipment, counters, and surfaces used in the production of a Medical Marijuana Concentrate are thoroughly cleaned after the completion of each Production Batch.
3. Ensure that any room in which dry ice is stored or used in processing Medical Marijuana into a Medical Marijuana Concentrate is well ventilated to prevent against the accumulation of dangerous levels of CO<sub>2</sub>.
4. Ensure that the appropriate safety or sanitary equipment, including personal protective equipment, is provided to, and appropriately used by, each Owner Licensee or Employee Licensee engaged in the production of a Medical Marijuana Concentrate.
5. Ensure that only finished drinking water and ice made from finished drinking water is used in the production of a Water-Based Medical Marijuana Concentrate.
6. Ensure that if propylene glycol or glycerin is used in the production of a Food-Based Medical Marijuana Concentrate, then the propylene glycol or glycerin to be used is food-grade.

7. Follow all of the rules related to the production of a Solvent-Based Medical Marijuana Concentrate if a pressurized system is used in the production of a Medical Marijuana Concentrate.

D. Solvent-Based Medical Marijuana Concentrate. A Medical Marijuana Products Manufacturer that engages in the production of Solvent-Based Medical Marijuana Concentrate must:

1. Obtain a report from an Industrial Hygienist or a Professional Engineer that certifies that the equipment, Licensed Premises and standard operating procedures comply with these rules and all applicable local and state building codes, fire codes, electrical codes and other laws. If a local jurisdiction has not adopted a local building code or fire code or if local regulations do not address a specific issue, then the Industrial Hygienist or Professional Engineer shall certify compliance with the International Building Code of 2012 (<http://www.iccsafe.org>), the International Fire Code of 2012 (<http://www.iccsafe.org>) or the National Electric Code of 2014 (<http://www.nfpa.org>), as appropriate. Note that this Rule does not include any later amendments or editions to each Code. The Division has maintained a copy of each code, which are available to the public;
  - a. Flammable Solvent Determinations. If a Flammable Solvent is to be used in the processing of Medical Marijuana into a Medical Marijuana Concentrate, then the Industrial Hygienist or Professional Engineer must:
    - i. Establish a maximum amount of Flammable Solvents and other flammable materials that may be stored within that Licensed Premises in accordance with applicable laws, rules, and regulations.
    - ii. Determine what type of electrical equipment, which may include but need not be limited to outlets, lights, junction boxes, must be installed within the room in which Medical Marijuana Concentrate are to be produced or Flammable Solvents are to be stored in accordance with applicable laws, rules, and regulations.
    - iii. Determine whether a gas monitoring system must be installed within the room in which Medical Marijuana Concentrate are to be produced or Flammable Solvents are to be stored, and if required the system's specifications, in accordance with applicable laws, rules, and regulations.
    - iv. Determine whether fire suppression system must be installed within the room in which Medical Marijuana Concentrate are to be produced or Flammable Solvents are to be stored, and if required the system's specifications, in accordance with applicable laws, rules, and regulations.
  - b. CO<sub>2</sub> Solvent Determination. If CO<sub>2</sub> is used as solvent at the Licensed Premises, then the Industrial Hygienist or Professional Engineer must determine whether a CO<sub>2</sub> gas monitoring system must be installed within the room in which Medical Marijuana Concentrate are to be produced or CO<sub>2</sub> is stored, and if required the system's specifications, in accordance with applicable laws, rules, and regulations.
  - c. Exhaust System Determination. The Industrial Hygienist or Professional Engineer must determine whether a fume vent hood or exhaust system must be installed within the room in which Medical Marijuana Concentrate are to be produced, and if required the system's specifications, in accordance with applicable laws, rules, and regulations.



- d. Material Change. If a Medical Marijuana Products Manufacturer makes a Material Change to its Licensed Premises, equipment or a concentrate production procedure, in addition to all other requirements, it must obtain a report from an Industrial Hygienist or Professional Engineer re-certifying its standard operating procedures and, if changed, its Licensed Premises and equipment as well.
  - e. Manufacturer's Instructions. The Industrial Hygienist or Professional Engineer may review and consider any information provided to the Medical Marijuana Products Manufacturer by the designer or manufacturer of any equipment used in the processing of Medical Marijuana into a Medical Marijuana Concentrate.
  - f. Records Retention. A Medical Marijuana Products Manufacturer must maintain copy of all reports received from an Industrial Hygienist and Professional Engineer on its Licensed Premises. Notwithstanding any other law, rule, or regulation, compliance with this Rule is not satisfied by storing these reports outside of the Licensed Premises. Instead the reports must be maintained on the Licensed Premises until the Licensee ceases production of Medical Marijuana Concentrate.
- 2. Ensure that all equipment, counters, and surfaces used in the production of a Solvent-Based Medical Marijuana Concentrate must be food-grade and must not react adversely with any of the solvents to be used in the Licensed Premises. Additionally, all counters and surface areas must be constructed in a manner that reduces the potential development of microbials, molds, and fungi and can be easily cleaned;
  - 3. Ensure that the room in which Solvent-Based Medical Marijuana Concentrate shall be produced must contain an emergency eye-wash station;
  - 4. Ensure that a professional grade, closed-loop extraction system capable of recovering the solvent is used to produce Solvent-Based Medical Marijuana Concentrate;
    - a. UL or ETL Listing.
      - i. If the system is UL or ETL listed, then a Medical Marijuana Products Manufacturer may use the system in accordance with the manufacturer's instructions.
      - ii. If the system is UL or ETL listed but the Medical Marijuana Products Manufacturer intends to use a solvent in the system that is not listed in the manufacturer's instructions for use in the system, then, prior to using the unlisted solvent within the system, the Medical Marijuana Products Manufacturer must obtain written approval for use of the non-listed solvent in the system from either the system's manufacturer or a Professional Engineer after the Professional Engineer has conducted a peer review of the system. In reviewing the system, the Professional Engineer shall review and consider any information provided by the system's designer or manufacturer.
      - iii. If the system is not UL or ETL listed, then there must a designer of record. If the designer of record is not a Professional Engineer, then the system must be peer reviewed by a Professional Engineer. In reviewing the system, the Professional Engineer shall review and consider any information provided by the system's designer or manufacturer.

- b. Ethanol or Isopropanol. A Medical Marijuana Products Manufacturer Facility need not use a professional grade, closed-loop system extraction system capable of recovering the solvent for the production of a Solvent-Based Medical Marijuana Concentrate if ethanol or isopropanol are the only solvents being used in the production process.
- 5. Ensure that all solvents used in the extraction process are food-grade or at least 99% pure;
  - a. A Medical Marijuana Products Manufacturer must obtain a safety data sheet for each solvent used or stored on the Licensed Premises. A Medical Marijuana Products Manufacturer must maintain a current copy of the safety data sheet and a receipt of purchase for all solvents used or to be used in an extraction process. See Rule 3-905 – Business Records Required.
  - b. A Medical Marijuana Products Manufacturer is prohibited from using denatured alcohol to produce a Medical Marijuana Concentrate, unless the denaturant is an approved solvent listed in Rule 5-315(A)(2) and the alcohol and the denaturant meet all other requirements set forth in this Rule.
- 6. Ensure that all Flammable Solvents or other flammable materials, chemicals and waste are stored in accordance with all applicable laws, rules and regulations. At no time may a Medical Marijuana Products Manufacturer store more Flammable Solvent on its Licensed Premises than the maximum amount established for that Licensed Premises by the Industrial Hygienist or Professional Engineer;
- 7. Ensure that the appropriate safety and sanitary equipment, including personal protective equipment, is provided to, and appropriately used by, each Owner Licensee or Employee Licensee engaged in the production of a Solvent-Based Medical Marijuana Concentrate; and
- 8. Ensure that a trained Owner Licensee or Employee Licensee is present at all times during the production of a Solvent-Based Medical Marijuana Concentrate whenever an extraction process requires the use of pressurized equipment.
- E. Ethanol and Isopropanol. If a Medical Marijuana Products Manufacturer only produces Solvent-Based Medical Marijuana Concentrate using ethanol or isopropanol at its Licensed Premises and no other solvent, then it shall be considered exempt from the requirements in paragraph D of this Rule and instead must follow the requirements in paragraph C of this Rule. Regardless of which rule is followed, the ethanol or isopropanol must be food grade or at least 99% pure and denatured alcohol cannot be used. The Medical Marijuana Products Manufacturer shall comply with contaminant testing required in Rule 4-120(C)(3).
- F. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

**Basis and Purpose – 5-320**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-401(2)(a)(III), and 44-10-503 C.R.S. The purpose of this rule is to establish the circumstances under which a Medical Marijuana Products Manufacturer may provide Sampling Units to a designated Sampling Manager for quality control or product development purposes. In order to maintain the integrity of Colorado’s regulated Medical Marijuana Businesses, this rule establishes limits on the amount of Sampling Units a Sampling Manager may receive in a calendar month and imposes inventory tracking, reporting, and recordkeeping requirements on a Medical Marijuana

Products Manufacturer that Transfer Sampling Units. This Rule 5-320 was previously Rule M 606, 1 CCR 212-1.

### **5-320 – Sampling Unit Protocols**

- A. Designation of Sampling Manager(s). In any calendar month, a Medical Marijuana Products Manufacturer may designate no more than five Sampling Managers in the Inventory Tracking System.
1. Only management personnel of the Medical Marijuana Products Manufacturer who holds an Owner License or an Employee License may be designated as a Sampling Manager.
  2. An individual designated as a Sampling Manager by a Medical Marijuana Products Manufacturer must possess a valid patient registry card.
  3. An individual may be designated as a Sampling Manager by more than one Medical Marijuana Business.
  4. By virtue of the decision to be designated as a Sampling Manager, the Sampling Manager expressly consents to being identified in the Inventory Tracking System and makes a voluntary decision that any Sampling Units Transferred to the Sampling Manager will be identified in the Inventory Tracking System.
  5. A Medical Marijuana Products Manufacturer that wishes to provide Sampling Units to a Sampling Manager shall first establish and provide to each Sampling Manager standard operating procedures that explain the requirements of section 44-10-503(10), C.R.S., the personal possession limits pursuant to section 18-18-406, C.R.S., and the requirements of this Rule 5-320. *See also* Rule 3-905 – Business Records Required. A Medical Marijuana Products Manufacturer shall maintain and update such standard operating procedures as necessary to reflect accurately any changes in the relevant statutes and rules.
- B. Sampling Unit Limits. Only one Sampling Unit may be designated per Production Batch. A Sampling Unit shall not be designated until the Production Batch has satisfied the testing requirements in 4-100 Series Rules – Regulated Marijuana Testing Program.
1. A Sampling Unit of Edible Medical Marijuana Product shall not exceed one serving size. Before designating any Sampling Units, a Medical Marijuana Products Manufacturer shall establish the specific serving size for each Edible Medical Marijuana Product it produces and maintain a record of the serving size in its standard operating procedures provided pursuant to subparagraph (A)(5).
  2. A Sampling Unit of non-Edible Medical Marijuana Product shall not exceed the equivalent of one serving size. Before designating any Sampling Units, a Medical Marijuana Products Manufacturer shall establish the specific serving size for each non-Edible Medical Marijuana Product it produces and maintain a record of the serving size in its standard operating procedures provided pursuant to subparagraph (A)(5).
  3. A Sampling Unit of Medical Marijuana Concentrate shall not exceed one-quarter of one gram; except that a Sampling Unit of Medical Marijuana Concentrate which has the intended use of being delivered in a vaporized form shall not exceed one-half of one gram.
- C. Transfer Restrictions.

1. No Sampling Unit shall be Transferred unless it is packaged and labeled in accordance with the requirements in the 3-1000 Series Rules – Labeling, Packaging, and Product Safety.
  2. No Sampling Unit shall be Transferred to any individual who is not currently designated in the Inventory Tracking System by the Medical Marijuana Products Manufacturer as a Sampling Manager for the calendar month in which the Transfer occurs.
  3. In any calendar month, a Sampling Manager shall not receive Sampling Units totaling more than:
    - a. Fourteen servings of Medical Marijuana Products; and
    - b. Fifteen grams of Medical Marijuana Concentrate.
  4. The monthly limit established in subparagraph (C)(3) applies to each Sampling Manager, regardless of the number of Medical Marijuana Businesses with which the Sampling Manager is associated.
  5. A Sampling Manager shall not accept Sampling Units in excess of the monthly limit established in subparagraph (C)(3). Before Transferring any Sampling Units, a Medical Marijuana Products Manufacturer shall verify with the recipient Sampling Manager that the Sampling Manager will not exceed the monthly limit established in subparagraph (C)(3).
  6. A Sampling Manager shall not Transfer any Sampling Unit to any other Person, including but not limited to any Person designated as a Sampling Manager.
- D. Compensation Prohibited. A Medical Marijuana Products Manufacturer may not use Sampling Units to compensate a Sampling Manager.
- E. On-Premises Consumption Prohibited. A Sampling Manager shall not consume any Sampling Unit on any Licensed Premises.
- F. Acceptable Purposes. Sampling Units shall only be designated and Transferred for purposes of quality control and product development in accordance with section 44-10-503(10), C.R.S.
- G. Record keeping requirements. A Medical Marijuana Products Manufacturer shall maintain copies of any material documents created regarding the quality control and product development purpose(s) of each Sampling Unit. Such documents shall constitute business records under Rule 3-905 – Business Records Required. At a minimum, A Medical Marijuana Products Manufacturer shall maintain records that show whether a Sampling Unit Transferred to a Sampling Manager is for the purpose of either quality control or product development. A Medical Marijuana Products Manufacturer shall also maintain copies of the Medical Marijuana Products Manufacturer’s standard operating procedures provided to Sampling Managers.
- H. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

**Basis and Purpose – 5-325**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(i), 44-10-203(3)(b), 44-10-203(2)(d), 44-10-203(3)(a), 44-10-401(2)(a)(III), 44-10-503, and 44-10-701(3)(c), C.R.S. The purpose of this rule is to define requirements for manufacture of Audited Product for administration by: (1) metered dose nasal spray, (2) vaginal

administration, or (3) rectal administration which may raise public health concerns. This rule defines audit, insurance, minimum product requirements, minimum production process requirements, and pre-production testing requirements for Medical Marijuana Products Manufacturers that manufacture Audited Products. The purpose of this rule further recognizes that Alternative Use Product not within an intended use identified in Rule 3-1015 may raise public health concerns that outweigh its manufacturer or Transfer entirely or that require additional safeguards to protect public health and safety prior to manufacturer or Transfer. This rule identifies general requirements for Medical Marijuana Products Manufacturer to seek an Alternative Use Designation from the State Licensing Authority to manufacture any type of Medical Marijuana Product that is not within an intended use identified in Rule 3-1015. This Rule 5-325 was previously Rule M 607, 1 CCR 212-1.

### **5-325 – Medical Marijuana Products Manufacturer: Audited Product and Alternative Use Product**

- A. General Rule. A Medical Marijuana Products Manufacturer shall not Transfer Audited Product to a Medical Marijuana Store, another Medical Marijuana Products Manufacturer, or a Medical Marijuana Cultivation Facility that has obtained a Centralized Distribution Permit except in accordance with all requirements of this Rule 5-325. The requirements of this Rule 5-325 are in addition to all other Rules that apply to Medical Marijuana Products Manufacturers; except where the context otherwise clearly requires this Rule 5-325 controls.
- B. Audited Products – Mandatory Audit Prior to Transfer. Following submission of an independent third-party audit to the Division and to the Local Licensing Authority as required by this Rule, a Medical Marijuana Products Manufacturer may Transfer Audited Product with an intended use of: (1) metered dose nasal spray, (2) vaginal administration, or (4) rectal administration to another Medical Marijuana Products Manufacturer, a Medical Marijuana Cultivation Facility that has obtained a Centralized Distribution Permit, or a Medical Marijuana Store.
1. A written audit report from an independent third-party auditor that was completed within the last twenty-four (24) months shall be submitted to the Division and to the Local Licensing Authority: (i) before the first Transfer of Audited Product to any Medical Marijuana Store, (ii) prior to Transfer of any Audited Product following a Material Change to any standard operating procedure or master formulation record regarding the Audited Product, and (iii) with the Medical Marijuana Products Manufacturer's renewal application if the Medical Marijuana Products Manufacturer will Transfer Audited Product after renewal.
  2. The independent third-party audit shall be performed by either a certified quality auditor or a certified GMP auditor. The Medical Marijuana Products Manufacturer shall be responsible for all costs associated with obtaining the independent third-party audit.
  3. The independent third-party written audit report shall include the following minimum requirements:
    - a. The independent third-party auditor's qualifications and an attestation that the certified quality auditor or certified GMP auditor has no conflict of interest;
    - b. Establish that the Medical Marijuana Products Manufacturer and the Audited Product meet all requirements of this Rule 5-325, including but not limited to the specific requirements of this Rule 5-325(C), 5-325(D), 5-325(E), 5-325(G), and 5-325(H);
    - c. Verify the written standard operating procedure(s) for Audited Product include sufficient and detailed step-by-step instructions on how to produce the Audited Product in a manner that prevents contamination and protects the public health and safety;

- d. Verify, based upon a physical inspection, the manufacture of Audited Product by the Medical Marijuana Products Manufacturer adheres to all applicable standard operating procedures;
  - e. Verify, based upon a physical inspection, of any Licensed Premises that such Licensed Premises complies with the requirements of this Rule 5-325(E), including any Limited Access Area where the Audited Product is to be manufactured;
  - f. Include the independent third-party auditor's findings;
  - g. Include the plan of correction identifying any corrective actions and/or preventative actions implemented as a result of the findings of the independent third-party audit; and
  - h. Include the independent third-party auditor's assessment that the Medical Marijuana Products Manufacturer demonstrated compliance with all requirements of Rule 5-325 and with the requirements of all standard operating procedures, master formulation records, and Batch manufacturing records that apply to the Audited Product.
- C. Products Liability Insurance. Any Medical Marijuana Products Manufacturer that intends to Transfer Audited Product shall first obtain products liability insurance providing coverage for liability arising from manufacture or Transfer of Audited Product and shall provide an unredacted certificate of product liability insurance to the Division and the independent third-party auditor.
- D. Audited Product Requirements. Audited Product shall meet the following minimum product requirements:
- 1. Inactive Ingredients. Audited Product must meet the requirements outlined in Rule 3-335 – Production of Regulated Marijuana Products.
    - a. If the Audited Product contains a fungicidal or bactericidal Ingredient listed in, and with a concentration that is at or below the maximum concentration permitted in, the Federal Food and Drug Administration Inactive Ingredients Database, <https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm>, the Audited Product is not required to undergo microbial contaminant testing required by Rules 4-115 and 4-120.
  - 2. Required Product Development Testing. The Medical Marijuana Products Manufacturer must establish the Audited Product meets the following through independent third-party testing:
    - a. The Audited Product must deliver the amount of each cannabinoid identified on the label throughout the entire volume of the Audited Product using the intended delivery device and in accordance with the instructions provided by the Medical Marijuana Products Manufacturer, as demonstrated by testing at a Medical Marijuana Testing Facility.

- i. For Audited Product with an intended use of metered dose nasal spray, compliance with this requirement shall be established by test results verifying the delivered dose of each cannabinoid identified on the label using the methods described in The United States Pharmacopeia Physical Test and Determination Chapter 601, *Aerosols, Nasal Sprays, Metered-Dose Inhalers, and Dry Powder Inhalers*.
  - ii. For Audited Product with an intended use of either vaginal administration or rectal administration, compliance with this testing requirement shall be established by test results demonstrating that each cannabinoid identified on the label is within +/- 15% of the amount identified on the label.
- b. The expiration date identified on the label of the Audited Product is appropriate when the Audited Product is stored at room temperature, as demonstrated by testing from a Medical Marijuana Testing Facility.
  - c. Identification of all non-marijuana derived Ingredients and constituents in the Audited Product at concentrations of 1%, which verification is obtained from one or more of the following:
    - i. Testing by a Medical Marijuana Testing Facility;
    - ii. Testing by a laboratory that is ISO 17025 accredited but is not a Medical Marijuana Testing Facility, except that no Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana Product may be Transferred to such a laboratory; and/or
    - iii. One or more certificate(s) of analysis from the manufacturer of any Ingredient or constituent included in the Audited Product.

E. Additional Production Requirements for Audited Product. In addition to all other requirements applicable to Medical Marijuana Products Manufacturers, a Medical Marijuana Products Manufacturer that manufactures and Transfers Audited Product shall meet the following additional requirements:

1. Personnel Training. All personnel directly involved in the manufacture and handling of Audited Product must be trained, must demonstrate competency, and must undergo annual refresher training, which shall be documented and maintained at the Medical Marijuana Products Manufacturer's Licensed Premises. Personnel directly involved in the manufacture and handling of Audited Product must be trained and demonstrate proficiency in hand hygiene, cleaning and sanitizing, performing necessary calculations, measuring and mixing, and documenting the manufacturing process including master formulation records and batch manufacturing records.
2. Facility Requirements. A Medical Marijuana Products Manufacturer must have a space that is specifically designated for the manufacture of Audited Products that is designed and operated to prevent cross contamination from other areas of the Licensed Premises. The surfaces, walls, floors, fixtures, shelving, work surfaces, and cabinets in this designated area must be non-porous and cleanable.
3. Cleaning and Sanitizing. A Medical Marijuana Products Manufacturer must clean and sanitize surfaces where Audited Product is manufactured and handled on a regular basis and at a minimum, work surfaces and floors must be cleaned and sanitized daily. All other surfaces must be cleaned and sanitized at least every three months. A Medical

Marijuana Products Manufacturer must clean and sanitize all surfaces when a spill occurs and when surfaces, floors, and walls are visibly soiled.

4. Hand Hygiene. Hand hygiene is required when entering and re-entering any area where Audited Product is manufactured and handled. Hand hygiene includes washing hands and forearms up to the elbows with soap and water for at least 30 seconds followed by drying completely with disposable towels. Alcohol hand sanitizers alone are not sufficient.
  - a. Gloves are required to be worn for all mixing activities. Other garb such as shoe covers, head and facial hair covers, face masks, and gowns must be worn as appropriate to protect Employee Licensees and/or prevent contamination of the Audited Product.
5. Equipment. Mechanical, electronic, and other types of equipment used in mixing, measuring, or testing of Audited Product must be inspected prior to use and verified for accuracy at the frequency recommended by the manufacturer, and at least annually.
6. Ingredient Quality. All Ingredients used to manufacture Audited Product must be handled and stored in accordance with the manufacturer's instructions. Ingredients that lack a manufacturer's expiration date shall not be used if a reasonable manufacturer would not use the Ingredient or after 1 year from the date of receipt, whichever period is shorter.
7. Master Formulation Record. A master formulation record must be prepared and maintained for each unique Audited product a Medical Marijuana Products Manufacturer manufactures. A master formulation record must include at least the following information:
  - a. Name of the Audited Product;
  - b. Ingredient identities and amounts;
  - c. Specifications on the delivery device (if applicable);
  - d. Complete instructions for preparing the Audited Product, including equipment, supplies, and description of the manufacturing steps;
  - e. Quality control procedures; and
  - f. Any other information needed to describe the Medical Marijuana Products Manufacturer's production and ensure its repeatability.
8. Batch Manufacturing Records. A batch manufacturing record shall be created for each Production Batch of Audited Product. This record shall include at the least the following information:
  - a. Name of the Audited Product;
  - b. Master formulation record reference for the Audited Product;
  - c. Date and time of preparation of the Audited Product;
  - d. Production Batch number;
  - e. Signature or initials of individuals involved in each manufacturing step;



- f. Name, vendor, or manufacturer, Production Batch number, and expiration date of each Ingredient;
  - g. Weight or measurement of each Ingredient;
  - h. Documentation of quality control procedures;
  - i. Any deviations from the master formulation record, and any problems or errors experienced during the manufacture; and
  - j. Total quantity of the Audited Product manufactured.
- F. Audited Product Testing. For each Production Batch, the Audited Product shall undergo all required testing in the 4-100 Series Rules for Medical Marijuana Product and/or Audited Product. See *also* Rule 4-115 – Regulated Marijuana Testing Program: Sampling and Testing Program.
- G. Packaging and Labeling of Audited Product. Audited Product must be packaged and labeled in accordance with all requirements of the 3-1000 Series Rules regarding packaging and labeling for Transfer to a patient prior to any Transfer.
- H. Adverse Event Reporting. A Medical Marijuana Products Manufacturer that manufactures Audited Product must maintain a record of all complaints it receives, which may include concerns or reports on the quality or possible adverse reactions to a specific Audited Product. For purposes of this Rule, adverse event means any untoward medical occurrence associated with the use of marijuana—this could include any unfavorable and unintended sign (including a hospitalization, emergency department visit, doctor’s visit, abnormal laboratory finding), symptom or disease temporally associated with the use of a marijuana product. To the extent known after reasonable diligence to ascertain the information, the record must contain the name of the complainant, the date the complaint was received, the nature of the complaint, the steps taken to investigate the complaint, the response to the complaint, and the name and Production Batch number of the Audited Product. Adverse events must also be reported directly to the Colorado Department of Public Health and Environment and the Division within 48 hours of receipt by the Medical Marijuana Products Manufacturer.
- I. Alternative Use Designation – Any Other Method of Consumption or Administration. A Medical Marijuana Products Manufacturer shall not Transfer to a Medical Marijuana Store, to another Medical Marijuana Products Manufacturer, or a Medical Marijuana Cultivation Facility that has obtained a Centralized Distribution Permit any Medical Marijuana Concentrate or Medical Marijuana Product that is not within any intended use identified in Rule 3-1015(B) until it applies for and receives an Alternative Use Designation from the State Licensing Authority in consultation with the Colorado Department of Public Health and Environment. In the process of applying for an Alternative Use Designation, the Medical Marijuana Products Manufacturer shall work with the Division and the Colorado Department of Public Health and Environment to determine whether the proposed Alternative Use Product may be manufactured in a manner that does not pose a threat to public health and safety when particular independent review factors, safeguards, and tests are in place. The following are minimum requirements for any application for an Alternative Use Designation:
- 1. The Medical Marijuana Products Manufacturer shall identify provisions of this Rule 5-325 that apply to its Alternative Use Product, any proposed additional or alternative requirements, and how any proposed alternatives protect public health and safety. The Medical Marijuana Products Manufacturer shall also provide any additional information as may be requested by the Division, in consultation with the Colorado Department of Public Health and Environment.

2. The Medical Marijuana Products Manufacturer bears the burden of proving its proposed Alternative Use Product may be manufactured in a manner that does not pose a threat to public health and safety when the identified independent review factors, safeguards and tests are in place.
  3. A Medical Marijuana Products Manufacturer seeking an Alternative Use Designation shall cooperate with the Division. Failure to cooperate with the Division is grounds for denial of an Alternative Use Designation.
  4. The granting of an Alternative Use Designation shall rest in the discretion of the State Licensing Authority, in consultation with the Colorado Department of Public Health and Environment. The State Licensing Authority may in his or her discretion deny an Alternative Use Designation where the Medical Marijuana Products Manufacturer does not meet the burden established in this Rule 5-325.
- J. Alternative Use Designation – Packaging and Labeling Requirements. If the Division recommends, and the State Licensing Authority grants, an Alternative Use Designation, the State Licensing Authority, in consultation with the Colorado Department of Public Health and Environment shall provide the Medical Marijuana Products Manufacturer the appropriate statement of intended use label to be affixed to the Alternative Use Product, and any additional or distinct packaging and labeling requirements applicable to the Alternative Use Product. See Rules 3-1010 and 3-1015.
- K. Required Records. A Medical Marijuana Products Manufacturer manufacturing or Transferring Audited Product and/or Alternative Use Product shall maintain accurate and comprehensive records on the Licensed Premises regarding the manufacturing process, a list of all active and inactive Ingredients used in the Audited Product and/or Alternative Use Product, and such other documentation as required by this Rule 5-325. See Rule 3-905 – Business Records Required.

### **Basis and Purpose – 5-330**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), 44-10-203(2)(d)(I)-(VI), 44-10-401(2)(a)(III), and 44-10-503, C.R.S. The purpose of this rule is to provide the process by which the Division or a Medical Marijuana Products Manufacturer initiates a product recall, the requirements any recall must meet, and how such recall is terminated.

### **5-330 – Recall of Medical Marijuana Concentrate or Medical Marijuana Product**

- A. Effective Date. This Rule shall be effective January 1, 2021.
- B. A Medical Marijuana Products Manufacturer may voluntarily undertake a recall at any time, or at the request of the Division. A request by the Division is to be directed to the Medical Marijuana Products Manufacturer that Transferred the Medical Marijuana Concentrate or Medical Marijuana Product for sale and that is to be recalled.
1. If a Medical Marijuana Products Manufacturer voluntarily undertakes a recall or the Division requests a recall, the Licensee shall notify the Local Licensing Authority or Local Jurisdiction in which the Medical Marijuana Products Manufacturer is located of such recall.
- C. A Medical Marijuana Products Manufacturer 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. A Medical Marijuana Products Manufacturer must maintain a record of all complaints it receives, which may include concerns or reports in

the quality of possible adverse reactions to a specific product. To the extent known after reasonable diligence to ascertain the information, the record must contain the name of the complainant, the purchase date, the location of where the product was purchased, the date the complaint was received, the nature of the complaint, the steps taken to investigate the complaint, the response to the complaint, and the name and Production Batch number of the Medical Marijuana Concentrate or Medical Marijuana Product.

- a. If an initial assessment indicates a recall may be necessary, the Medical Marijuana Products Manufacturer shall determine the hazard and evaluate the safety concerns with the product and;
  - i. Assure adequate product quarantine steps have occurred for product still in control of the Licensee;
  - ii. Determine the product removal strategy appropriate to the threat and location in commerce; and
  - iii. Report directly to the Colorado Department of Public Health and Environment and the Division immediately after a determination to recall is made.

2. Identification of Implicated Medical Marijuana Concentrate or Medical Marijuana Product.

- a. A distribution list shall be prepared as part of the identification process. The distribution list shall, at minimum, identify the following:
  - i. Business name that received the recalled Medical Marijuana Concentrate or Medical Marijuana Product(s);
  - ii. Product ship date(s);
  - iii. Business license number;
  - iv. Business address;
  - v. Business contact name; and
  - vi. Business contact telephone numbers.
- b. Product Information shall include:
  - i. Type of the Medical Marijuana Concentrate or Medical Marijuana Product
  - ii. Product description
  - iii. Net contents
  - iv. Production Batch number, and
  - v. The Medical Marijuana Products Manufacturer license number.
- c. Additional Product Information. To the extent known after reasonable diligence to ascertain the information, the recall plan shall include:

- ii. Amount of Medical Marijuana Concentrate or Medical Marijuana Product returned;
- iii. Amount of Medical Marijuana Concentrate or Medical Marijuana Product Transferred to patients; and
- iv. Amount of Medical Marijuana Concentrate or Medical Marijuana Product still in the marketplace.

3. Notification of affected parties.

- a. In the event of a recall, the Medical Marijuana Products Manufacturer shall notify the receiving Licensee(s) of the recalled Medical Marijuana Concentrate or Medical Marijuana Product(s) by providing a recall notice in accordance with the written recall plan. The recall notice shall include:
  - i. Medical Marijuana Concentrate or Medical Marijuana Product type;
  - ii. Reason for recall and hazard involved, if any. If the product is being removed for quality rather than health reasons, the notice may state that the Medical Marijuana Concentrate or Medical Marijuana Product does not meet internal company specifications and is being removed from distribution;
  - iii. Licensed business name that manufactured the Medical Marijuana Concentrate or Medical Marijuana Product;
  - iv. License number of the business that manufactured the Medical Marijuana Concentrate or Medical Marijuana Product;
  - v. The trade name of the business that manufactured the Medical Marijuana Concentrate or Medical Marijuana Product;
  - vi. Medical Marijuana Concentrate or Medical Marijuana Product description;
  - vii. Production Batch number of the Medical Marijuana Concentrate or Medical Marijuana Product;
  - viii. Expiration date of the Medical Marijuana Concentrate or Medical Marijuana Product(s), if applicable;
  - ix. Medical Marijuana Concentrate or Medical Marijuana Product ship date(s);
  - x. Regulated Marijuana Businesses that received the Medical Marijuana Concentrate or Medical Marijuana Product; and
  - xi. Instructions regarding the disposition of the Medical Marijuana Concentrate or Medical Marijuana Product.
- b. The Medical Marijuana Products Manufacturer shall immediately notify the Division and Colorado Department of Public Health and Environment of the recalled Medical Marijuana Concentrate or Medical Marijuana Product(s) by providing a recall notice as described above.

- c. Consumers shall be notified by the most effective method available. If appropriate, a press release can be used to notify patients.
4. Removal of affected Medical Marijuana Concentrate or Medical Marijuana Product(s).
- a. Removal. The Medical Marijuana Products Manufacturer shall make all reasonable efforts to remove the affected Medical Marijuana Concentrate or Medical Marijuana Product(s) from commerce.
    - i. Medical Marijuana Concentrate or Medical Marijuana Product(s) in commerce shall be detained, segregated, and handled in a manner determined by the originating Medical Marijuana Products Manufacturer.
    - ii. Medical Marijuana Concentrate or Medical Marijuana Product(s) that are still in control of the originating Medical Marijuana Products Manufacturer shall be detained and segregated.
    - iii. All affected Medical Marijuana Concentrate or Medical Marijuana Product(s) returned shall be clearly labeled, not for sale or distribution, and clearly separated from any other Medical Marijuana Concentrate or Medical Marijuana Product(s).
  - b. Product disposition. The final disposition of the Medical Marijuana Concentrate or Medical Marijuana Product shall be determined by the Division. The Division shall notify the Medical Marijuana Products Manufacturer to either:
    - i. Destroy and document the destruction of the Medical Marijuana Concentrate or Medical Marijuana Product(s) Inventory Tracking System package or Production Batch pursuant to Rule 3-235; or
    - ii. Decontaminate the affected Inventory Tracking System package or Production Batch pursuant to Rule 4-135(B)(2).
  - c. Recall effectiveness. The Medical Marijuana Products Manufacturer shall be 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 received the recall notification;
      - B. If the recalled Medical Marijuana Concentrate or Medical Marijuana Product was handled as instructed in the recall notification; and
      - C. If the Medical Marijuana Concentrate or Medical Marijuana Product was further distributed or sold by the receiving Licensee before receipt of the recall notification, and if so, were these additional Licensees notified.
      - D. If 100 percent of the affected Medical Marijuana Concentrate or Medical Marijuana Product has been accounted for, then no effectiveness checks are required.

- d. Termination of recall. A recall shall be terminated when the Licensee, or the Division if the recall was requested by the Division, determines that all reasonable efforts have been made to remove or correct the Medical Marijuana Concentrate or Medical Marijuana Product in accordance with the recall plan, and when it is reasonable to assume that the Medical Marijuana Concentrate or Medical Marijuana Product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled Medical Marijuana Concentrate or Medical Marijuana Product. Written notification that a recall is terminated will be issued by the Division.
- i. A recalling Medical Marijuana Products Manufacturer may request termination of its recall by submitting a written request to the Division stating that the recall is effective in accordance with this Rule, and by accompanying the request with a recall status report and a description of the disposition of the recalled Medical Marijuana Concentrate or Medical Marijuana 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 communication and quantity of Medical Marijuana Concentrate or Medical Marijuana Product(s) on hand at the time it was received;
  - C. Number of receiving Licensees that did not respond;
  - D. Number of products returned or corrected by each receiving Licensee contacted and the quantity of Medical Marijuana Concentrate or Medical Marijuana Product(s) accounted for;
  - E. Number and results of the effectiveness checks that were made; and
  - F. Estimated time frame for completion of the recall.

## **5-400 Series – Medical Marijuana Testing Facilities**

### **Basis and Purpose – 5-405**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(2)(h), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(d), 44-10-203(2)(f)(II), 44-10-203(2)(f)(IV), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-313(8)(a), 44-10-401(2)(a)(IV), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1), and 44-10-504(2), C.R.S. The purpose of this rule is to establish the license privileges of a Medical Marijuana Testing Facility. This Rule 5-405 was previously Rule M 701.5, 1 CCR 212-1.

### **5-405 - Medical Marijuana Testing Facilities: License Privileges**

- A. Licensed Premises. A separate License is required for each specific Medical Marijuana Testing Facility and only those privileges granted by the Marijuana Code and any rules promulgated pursuant to it may be exercised on the Licensed Premises.

- B. Testing of Medical Marijuana Authorized. A Medical Marijuana Testing Facility may accept Samples of Medical Marijuana from Medical Marijuana Businesses for testing and research purposes only, which purposes may include the provision of testing services for Samples submitted by a Medical Marijuana Business for the purpose of product development. The Division may require a Medical Marijuana Business to submit a Sample of Medical Marijuana to a Medical Marijuana Testing Facility upon demand.
- C. Testing of Industrial Hemp Product Authorized.
1. A Medical Marijuana Testing Facility may accept and test samples of Industrial Hemp Products.
  2. Before a Medical Marijuana Testing Facility accepts a sample of Industrial Hemp Product, the Medical Marijuana Testing Facility shall verify that the Person submitting the sample is registered with the Colorado Department of Public Health and Environment pursuant to section 25-5-426, C.R.S.
  3. A Medical Marijuana Testing Facility is responsible for entering and tracking samples of Industrial Hemp Product in the inventory tracking system pursuant to the 3-800 Series Rules.
  4. A Medical Marijuana Testing Facility shall be permitted to test Industrial Hemp Product only in the category(ies) that the Medical Marijuana Testing Facility is certified to perform testing in pursuant to Rule 5-415 – Medical Marijuana Testing Facilities: Certification Requirements.
  5. A Medical Marijuana Testing Facility may provide the results of any testing performed on Industrial Hemp Product to the Person submitting the sample of Industrial Hemp Product.
  6. Nothing in these rules shall be construed to require a Medical Marijuana Testing Facility to accept and/or test samples of Industrial Hemp Product.
- D. Testing Medical Marijuana for Patients in Research Project. A Medical Marijuana Testing Facility is authorized to accept Samples of Medical Marijuana from an individual person for testing under only the following conditions:
1. The individual person is:
    - a. A currently registered patient pursuant to section 25-1.5-106, C.R.S.; and
    - b. A participant in an approved clinical or observational study conducted by a Marijuana Research and Development Facility.
  2. The Medical Marijuana Testing Facility shall require the patient to produce a valid patient registry card and a current and valid photo identification. See Rule 3-405(A) – Acceptable Forms of Identification.
  3. The Medical Marijuana Testing Facility shall require the patient to produce verification on a form approved by the Division from the Marijuana Research and Development Facility that the patient is a participant in an approved clinical or observational Research Project conducted by the Marijuana Research and Development Facility and that the testing will be in furtherance of the approved Research Project.

4. A primary caregiver may transport Medical Marijuana on behalf of a patient to the Medical Marijuana Testing Facility. A Medical Marijuana Testing Facility shall require the following documentation before accepting Medical Marijuana from a primary caregiver:
    - a. A copy of the patient registry card and valid photo identification for the patient;
    - b. A copy of the caregiver's registration with the State Department of Health pursuant to section 25-1.5-106, C.R.S. and a current and valid photo identification, see Rule 3-405 – Acceptable Forms of Identification; and
    - c. A copy of the Marijuana Research and Development Facility's verification on a form approved by the Division that the patient is participating in an approved clinical or observational Research Project being conducted by the Marijuana Research and Development Facility and that the testing will be in furtherance of the approved Research Project.
  5. The Medical Marijuana Testing Facility shall report all results of testing performed pursuant to this Paragraph (C.5) to the Marijuana Research and Development Facility identified in the verification form submitted pursuant to Paragraph (D)(3) or (4)(c), or as otherwise directed by the approved Research Project being conducted by the Marijuana Research and Development Facility. Testing result reporting shall conform with the requirements under these Rules.
- E. Product Development Authorized. A Medical Marijuana Testing Facility may develop Medical Marijuana Product, but is not authorized to engage in the manufacturing privileges described in section 44-10-503, C.R.S. and Rule 5-305 – Medical Marijuana Products Manufacturer: License Privileges.
  - F. Transferring Samples to Another Licensed and Certified Medical Marijuana Testing Facility. A Medical Marijuana Testing Facility may Transfer Samples to another Medical Marijuana Testing Facility for testing. All laboratory reports provided to or by a Medical Marijuana Business, or to a patient or primary caregiver must identify the Medical Marijuana Testing Facility that actually conducted the test.
  - G. Authorized Medical Marijuana Transport. A Medical Marijuana Testing Facility is authorized to utilize a licensed Medical Marijuana Transporter to transport Samples of Medical Marijuana for testing, in accordance with the Marijuana Code and the rules adopted pursuant thereto, between the originating Medical Marijuana Business requesting testing services and the destination Medical Marijuana Testing Facility performing testing services. Nothing in this Rule requires a Medical Marijuana Business to utilize a Medical Marijuana Transporter to transport Samples of Medical Marijuana for testing.

#### **Basis and Purpose – 5-410**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(2)(h), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(d), 44-10-203(2)(f)(II), 44-10-203(2)(f)(IV), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-313(8)(a), 44-10-401(2)(a)(IV), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1), and 44-10-504(2), 44-10-701, and 35-61-105.5, C.R.S. The purpose of this rule is to clarify those acts that are limited in some fashion, or prohibited, by a Medical Marijuana Testing Facility. This Rule 5-410 was previously Rule M 702, 1 CCR 212-1.

#### **5-410 – Medical Marijuana Testing Facilities: General Limitations or Prohibited Acts**

- A. Prohibited Financial Interest. A Person who is a Controlling Beneficial Owner or Passive Beneficial Owner of a Medical Marijuana Cultivation Facility, Medical Marijuana Products



Manufacturing Facility, Medical Marijuana Store, Retail Marijuana Cultivation Facility, Retail Marijuana Products Manufacturer, or a Retail Marijuana Store shall not be a Controlling Beneficial Owner or Passive Beneficial Owner of a Medical Marijuana Testing Facility.

- B. Conflicts of Interest. The Medical Marijuana 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 Medical Marijuana Testing Facility's testing processes or results, or that may diminish public confidence in the competency, impartiality, and integrity of the Medical Marijuana Testing Facility's testing processes or results. At a minimum, employees, owners or agents of a Medical Marijuana 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 Medical Marijuana Business that provided the Sample.
- C. Transfer of Medical Marijuana Prohibited. A Medical Marijuana Testing Facility shall not Transfer Medical Marijuana to a Medical Marijuana Business, a consumer, a patient, or primary caregiver, except that a Medical Marijuana Testing Facility may Transfer a Sample to another Medical Marijuana Testing Facility.
- D. Destruction of Received Samples. A Medical Marijuana Testing Facility shall properly dispose of all Samples it receives, that are not Transferred to another Medical Marijuana Testing Facility, after all necessary tests have been conducted and any required period of storage. See Rule 3-230 – Waste Disposal.
- E. Sample Rejection. A Medical Marijuana Testing Facility shall reject any Sample where the condition of the Sample at receipt indicates that that the Sample may have been tampered with.
- F. Medical Marijuana Business Requirements Applicable. A Medical Marijuana Testing Facility shall be considered a Licensed Premises. A Medical Marijuana Testing Facility shall be subject to all requirements applicable to Medical Marijuana Businesses.
- G. Medical Marijuana Testing Facility – Inventory Tracking System Required. A Medical Marijuana Testing Facility must use the Inventory Tracking System to ensure all Test Batches or Samples containing Medical Marijuana are identified and tracked from the point they are Transferred from a Medical Marijuana Business, a patient, or a patient's primary caregiver through the point of Transfer, destruction, or disposal. The Inventory Tracking System reporting shall include the results of any tests that are conducted on Medical Marijuana. See Rule 3-805 – Regulated Marijuana Business: Inventory Tracking System, Rule 3-825 – Reporting and Inventory Tracking System, and Rule 5-405(D)(5). The Medical Marijuana Testing Facility must have the ability to reconcile its Sample records with the Inventory Tracking System and the associated transaction history. See Rule 3-905 – Business Records Required and Rule 3-825 Reporting and Inventory Tracking
- H. Industrial Hemp Testing Prohibited. A Medical Marijuana Testing Facility shall not perform testing on Industrial Hemp.
- I. Testing of Unregistered or Untracked Industrial Hemp Products Prohibited. A Medical Marijuana Testing Facility is authorized to accept or test Industrial Hemp Product only if (1) the entity providing the Samples of Industrial Hemp Product is registered and regulated pursuant to Article 4 or Title 25, C.R.S., and (2) the Industrial Hemp Product being submitted for testing is tracked in the Inventory Tracking System.

#### **Basis and Purpose – 5-415**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(2)(h), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(d), 44-10-203(2)(f)(II), 44-10-203(2)(f)(IV), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-313(8)(a), 44-10-401(2)(a)(IV), and 44-10-504, C.R.S. The purpose of this rule is to establish a frame work for certification for Medical Marijuana Testing Facilities. This Rule 5-415 was previously Rule M 703, 1 CCR 212-1.

#### **5-415 – Medical Marijuana Testing Facilities: Certification Requirements**

- A. Certification Types. If certification in a testing category is required by the Division, then the Medical Marijuana Testing Facility must be certified in the category in order to perform that type of testing.
1. Microbials;
  2. Mycotoxins;
  3. Residual solvents;
  4. Pesticides;
  5. THC and other Cannabinoid potency; and
  6. Metals.
- B. In order to obtain certification for Pesticide testing, a Medical Marijuana Testing Facility must also obtain certification for mycotoxin testing.
- C. Certification Procedures. The Medical Marijuana Testing Facility certification program is contingent upon successful on-site inspection, successful participation in Proficiency Testing, and ongoing compliance with the applicable requirements in this Rule.
1. Certification Inspection. A Medical Marijuana Testing Facility must be inspected prior to initial certification and annually thereafter by an inspector approved by the Division.
  2. Standards for Certification. A Medical Marijuana Testing Facility must meet standards of performance, as established by these rules, in order to obtain and maintain certification. Standards of performance include but are not limited to: personnel qualifications, standard operating procedure manual, analytical processes, Proficiency Testing, quality control, quality assurance, security, chain of custody, Sample retention, space, records, and results reporting. In addition, a Medical Marijuana Testing Facility must be accredited under the International Organization for Standardization/International Electrotechnical Commission 17025:2005 Standard, or any subsequent superseding ISO/IEC 17025 standard. In order to obtain certification in a testing category from the Division, the Medical Marijuana Testing Facility's scope of accreditation must specify that particular testing category.
    - a. Subsequent to initial approval of a Medical Marijuana Testing Facility License, the Division may grant provisional certification if the Applicant has not yet obtained ISO/IEC 17025:2005 accreditation, but meets all other Division requirements. Such provisional certification shall be for a period not to exceed twelve months.
    - b. A Medical Marijuana Testing Facility which is not accredited to the ISO/IEC 17025:2005 standard, but obtained certification prior to January 1, 2019, may submit a request for a temporary exemption from the ISO/IEC 17025:2005

accreditation requirement. Such request must be made on Division-approved forms. In order to receive a temporary exemption, a Medical Marijuana Testing Facility must establish good cause, which includes, but is not limited to, circumstances in which the Medical Marijuana Testing Facility has submitted an application for accreditation prior to December 31, 2018, and the application is still pending. A temporary exemption shall not exceed twelve months.

3. Personnel Qualifications.
  - a. Laboratory Director. A Medical Marijuana Testing Facility must employ, at a minimum, a laboratory director with sufficient education and experience in a regulated laboratory environment in order to obtain and maintain certification. See Rule 5-420 – Medical Marijuana Testing Facilities: Personnel.
  - b. Employee Competency. A Medical Marijuana Testing Facility must have a written and documented system to evaluate and document the competency in performing authorized tests for employees. Prior to independently analyzing Samples, testing personnel must demonstrate acceptable performance on precision, accuracy, specificity, reportable ranges, blanks, and unknown challenge samples (proficiency samples or internally generated quality controls).
4. Standard Operating Procedure Manual. A Medical Marijuana Testing Facility must have a written standard operating procedure manual meeting the minimum standards set forth in these rules detailing the performance of all methods employed by the facility used to test the analytes it reports and made available for testing analysts to follow at all times.
  - a. The current laboratory director must approve, sign and date each procedure. If any modifications are made to those procedures, the laboratory director must approve, sign and date the revised version prior to use.
  - b. A Medical Marijuana Testing Facility must maintain a copy of all standard operating procedures to include any revised copies for a minimum of three years. See Rule 5-450 – Medical Marijuana Testing Facilities: Records Retention and Rule 3-905 – Business Records Required.
5. Analytical Processes. A Medical Marijuana Testing Facility must maintain a listing of all analytical methods used and all analytes tested and reported. The Medical Marijuana Testing Facility must provide this listing to the Division upon request.
6. Proficiency Testing. A Medical Marijuana Testing Facility must successfully participate in a Division approved Proficiency Testing program in order to obtain and maintain certification.
7. Quality Assurance and Quality Control. A Medical Marijuana Testing Facility must establish and follow a quality assurance and quality control program to ensure sufficient monitoring of laboratory processes and quality of results reported.
8. Security. A Medical Marijuana Testing Facility must be located in a secure setting as to prevent unauthorized persons from gaining access to the testing and storage areas of the laboratory.
9. Chain of Custody. A Medical Marijuana Testing Facility must establish a system to document the complete chain of custody for Samples from receipt through disposal.

10. Space. A Medical Marijuana Testing Facility must be located in a fixed structure that provides adequate infrastructure to perform analysis in a safe and compliant manner consistent with federal, state and local requirements.
  11. Records. A Medical Marijuana Testing Facility must establish a system to retain and maintain all required records. See Rule 5-450 – Medical Marijuana Testing Facilities: Records Retention and Rule 3-905 – Business Records Required.
  12. Results Reporting. A Medical Marijuana Testing Facility must establish processes to ensure results are reported in a timely and accurate manner. See Rule 3-825 – Reporting and Inventory Tracking System.
  13. Conduct While Seeking Certification. A Medical Marijuana Testing Facility, and its agents and employees, shall provide all documents and information required or requested by the Colorado Department of Public Health and Environment and its employees, and the Division and its employees in a full, faithful, truthful, and fair manner.
- D. Violation Affecting Public Safety. A violation of this Rule may be considered a license violation affecting public safety.

#### **Basis and Purpose – 5-420**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(2)(h), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(d), 44-10-203(2)(f)(II), 44-10-203(2)(f)(IV), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-313(8)(a), 44-10-401(2)(a)(IV), and 44-10-504, C.R.S. The purpose of this rule is to establish personnel standards for the operation of a Medical Marijuana Testing Facility. This Rule 5-420 was previously Rule M 704, 1 CCR 212-1.

#### **5-420 – Medical Marijuana Testing Facilities: Personnel**

- A. Laboratory Director. The laboratory director is responsible for the overall analytical operation and quality of the results reported by the Medical Marijuana Testing Facility, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurately, and proficiently and for assuring compliance with the standards set forth in this Rule.
1. The laboratory director may also serve as a supervisory analyst or testing analyst, or both, for a Medical Marijuana Testing Facility.
  2. The laboratory director for a Medical Marijuana Testing Facility must meet one of the following qualification requirements:
    - a. The laboratory director must be a Medical Doctor (M.D.) licensed to practice medicine in Colorado and have at least three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body;
    - b. The laboratory director must hold a doctoral degree in one of the natural sciences and have at least three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body;
    - c. The laboratory director must hold a master's degree in one of the natural sciences and have at least five years of full-time laboratory experience in a

regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body; or

- d. The laboratory director must hold a bachelor's degree in one of the natural sciences and have at least seven years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body.

B. What the Laboratory Director May Delegate. The laboratory director may delegate the responsibilities assigned under this Rule to a qualified supervisory analyst, provided that such delegation is made in writing and a record of the delegation is maintained. See Rule 3-905 – Business Records Required. Despite the designation of a responsibility, the laboratory director remains responsible for ensuring that all duties are properly performed.

C. Responsibilities of the Laboratory Director. The laboratory director must:

1. Ensure that the Medical Marijuana Testing Facility has adequate space, equipment, materials, and controls available to perform the tests reported;
2. Establish and adhere to a written standard operating procedure used to perform the tests reported;
3. Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;
4. Ensure that the physical location and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards;
5. Ensure that the test methodologies selected have the capability of providing the quality of results required for the level of testing the laboratory is certified to perform;
6. Ensure that validation and verification test methods used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;
7. Ensure that testing analysts perform the test methods as required for accurate and reliable results;
8. Ensure that the laboratory is enrolled in and successfully participates in a Division approved Proficiency Testing program;
9. Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;
10. Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;
11. Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and that test results are reported only when the system is functioning properly;
12. Ensure that reports of test results include pertinent information required for interpretation;

13. Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation of said results;
  14. Employ a sufficient number of laboratory personnel who meet the qualification requirements and provide appropriate consultation, properly supervise, and ensure accurate performance of tests and reporting of test results;
  15. Ensure that prior to testing any samples, all testing analysts receive the appropriate training for the type and complexity of tests performed, and have demonstrated and documented that they can perform all testing operations reliably to provide and report accurate results;
  16. Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process Samples, perform test procedures and report test results promptly and proficiently, avoid actual and apparent conflicts of interest, and whenever necessary, identify needs for remedial training or continuing education to improve skills;
  17. Ensure that an approved standard operating procedure manual is available to all personnel responsible for any aspect of the testing process; and
  18. Specify, in writing, the responsibilities and duties of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for Sample processing, test performance or results reporting, and whether consultant or laboratory director review is required prior to reporting test results.
- D. Change in Laboratory Director. In the event that the laboratory director leaves employment at the Medical Marijuana Testing Facility, the Medical Marijuana Testing Facility shall:
1. Provide written notice to the Colorado Department of Public Health and Environment and the Division within seven days of the laboratory director's departure; and
  2. Designate an interim laboratory director within seven days of the laboratory director's departure. At a minimum, the interim laboratory director must meet the qualifications of a supervisory analyst.
  3. The Medical Marijuana Testing Facility must hire a permanent laboratory director within 60 days from the date of the previous laboratory director's departure.
  4. Notwithstanding the requirement of subparagraph (D)(3), the Medical Marijuana Testing Facility may submit a waiver request to the Division Director to receive an additional 60 days to hire a permanent laboratory director provided that the Medical Marijuana Testing Facility submits a detailed oversight plan along with the waiver request.
- E. Supervisory Analyst. Supervisory analysts must meet one of the qualifications for a laboratory director or have at least a bachelor's degree in one of the natural sciences and three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body. A combination of education and experience may substitute for the three years of full-time laboratory experience.
- F. Laboratory Testing Analyst.

1. Educational Requirements. An individual designated as a testing analyst must meet one of the qualifications for a laboratory director or supervisory analyst or have at least a bachelor's degree in one of the natural sciences and one year of full-time experience in laboratory testing.
2. Responsibilities. In order to independently perform any test for a Medical Marijuana Testing Facility, an individual must at least meet the educational requirements for a testing analyst.

### **Basis and Purpose – 5-425**

The statutory authority for this rule includes but is not limited to sections 44-10-203(2)(d), 44-10-401(2)(a)(IV), and 44-10-504, C.R.S. The purpose of this rule is to establish standard operating procedures manual standards for the operation of a Medical Marijuana Testing Facility. This Rule 5-425 was previously Rule M 705, 1 CCR 212-1.

### **5-425 – Medical Marijuana Testing Facilities: Standard Operating Procedure Manual**

- A. A standard operating procedure manual must include, but need not be limited to, procedures for:
  1. Sample receiving;
  2. Sample accessioning;
  3. Sample storage;
  4. Identifying and rejecting unacceptable Samples;
  5. Recording and reporting discrepancies;
  6. Security of Samples, aliquots and extracts and records;
  7. Validating a new or revised method prior to testing Samples to include: accuracy, precision, analytical sensitivity, analytical specificity (interferences), LOD, LOQ, and verification of the reportable range;
  8. Aliquoting Samples to avoid contamination and carry-over;
  9. Sample retention to assure stability, as follows:
    - a. For Samples that comprise Test Batches submitted for testing other than Pesticide contaminant testing, Sample retention for 14 days;
    - b. For Samples that comprise Test Batches submitted for Pesticide contaminant testing, Sample retention for 90 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 subject tests results, as well as reviewing for clerical errors, analytical errors and any unusual analytical results. Are corrective actions implemented and documented, and does the laboratory contact the requesting entity; and
21. Policies and procedures to follow when Samples are requested for referral and testing by another certified Medical Marijuana Testing Facility or an approved local state agency's laboratory.

#### **Basis and Purpose – 5-430**

The statutory authority for this rule includes but is not limited to sections 44-10-203(2)(d), 44-10-401(2)(a)(IV), and 44-10-504, C.R.S. The purpose of this rule is to establish analytical processes standards for the operation of a Medical Marijuana Testing Facility. This Rule 5-430 was previously Rule M 706, 1 CCR 212-1.

#### **5-430 – Medical Marijuana Testing Facilities: Analytical Processes**

- A. Gas Chromatography (“GC”). A Medical Marijuana Testing Facility using GC must:
  1. Document the conditions of the gas chromatograph, including the detector response;
  2. Perform and document preventive maintenance as required by the manufacturer;
  3. Ensure that records are maintained and readily available to the staff operating the equipment;
  4. Document the performance of new columns before use;
  5. Use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified;
  6. Establish criteria of acceptability for variances between different aliquots and different columns; and
  7. Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system.
- B. Gas Chromatography Mass Spectrometry (“GC/MS”). A Medical Marijuana Testing Facility using GC/MS must:



1. Perform and document preventive maintenance as required by the manufacturer;
2. Document the changes of septa as specified in the standard operating procedure;
3. Document liners being cleaned or replaced as specified in the standard operating procedure;
4. Ensure that records are maintained and readily available to the staff operating the equipment;
5. Maintain records of mass spectrometric tuning;
6. Establish written criteria for an acceptable mass-spectrometric tune;
7. Document corrective actions if a mass-spectrometric tune is unacceptable;
8. Monitor analytic analyses to check for contamination and carry-over;
9. Use selected ion monitoring within each run to assure that the laboratory compare ion ratios and retention times between calibrators, controls and Samples for identification of an analyte;
10. Use an internal standard for qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;
11. Document the monitoring of the response (area or peak height) for the internal standard to ensure consistency overtime of the analytical system;
12. Define the criteria for designating qualitative results as positive;
13. When a library is used to qualitatively identify an analyte, the identity of the analyte must be confirmed before reporting results by comparing the relative retention time and mass spectrum to that of a known standard or control run on the same system; and
14. Evaluate the performance of the instrument after routine and preventive maintenance (e.g. clipping or replacing the column or cleaning the source) prior to analyzing subject Samples.

C. Immunoassays. A Medical Marijuana Testing Facility using Immunoassays must:

1. Perform and document preventive maintenance as required by the manufacturer;
2. Ensure that records are maintained and readily available to the staff operating the equipment;
3. Validate any changes or modifications to a manufacturer's approved assays or testing methods when a Sample is not included within the types of Samples approved by the manufacturer; and
4. Define acceptable separation or measurement units (absorbance intensity or counts per minute) for each assay, which must be consistent with manufacturer's instructions.

D. Thin Layer Chromatography ("TLC"). A Medical Marijuana Testing Facility using TLC must:

1. Apply unextracted standards to each thin layer chromatographic plate;
2. Include in their written procedure the preparation of mixed solvent systems, spray reagents and designation of lifetime;
3. Include in their written procedure the storage of unused thin layer chromatographic plates;
4. Evaluate, establish, and document acceptable performance for new thin layer chromatographic plates before placing them into service;
5. Verify that the spotting technique used precludes the possibility of contamination and carry-over;
6. Measure all appropriate RF values for qualitative identification purposes;
7. Use and record sequential color reactions, when applicable;
8. Maintain records of thin layer chromatographic plates; and
9. Analyze an appropriate matrix blank with each batch of Samples analyzed.

E. High Performance Liquid Chromatography ("HPLC"). A Medical Marijuana Testing Facility using HPLC must:

1. Perform and document preventive maintenance as required by the manufacturer;
2. Ensure that records are maintained and readily available to the staff operating the equipment;
3. Monitor and document the performance of the HPLC instrument each day of testing;
4. Evaluate the performance of new columns before use;
5. Create written standards for acceptability when eluting solvents are recycled;
6. Use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified when available or appropriate for the assay; and
7. Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system.

F. Liquid Chromatography Mass Spectroscopy ("LC/MS"). A Medical Marijuana Testing Facility using LC/MS must:

1. Perform and document preventive maintenance as required by the manufacturer;
2. Ensure that records are maintained and readily available to the staff operating the equipment;
3. Maintain records of mass spectrometric tuning;
4. Document corrective actions if a mass-spectrometric tune is unacceptable;

5. Use an internal standard with each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;
  6. Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system;
  7. Compare two transitions and retention times between calibrators, controls and Samples within each run;
  8. Document and maintain records when changes in source, source conditions, eluent, or column are made to the instrument; and
  9. Evaluate the performance of the instrument when changes in: source, source conditions, eluent, or column are made prior to reporting test results.
- G. Other Analytical Methodology. A Medical Marijuana Testing Facility using other methodology or new methodology must:
1. Implement a performance based measurement system for the selected methodology and validate the method following good laboratory practices prior to reporting results. Validation of other or new methodology must include when applicable, but is not limited to:
    - a. Verification of Accuracy
    - b. Verification of Precision
    - c. Verification of Analytical Sensitivity
    - d. Verification of Analytical Specificity
    - e. Verification of the LOD
    - f. Verification of the LOQ
    - g. Verification of the Reportable Range
    - h. Identification of Interfering Substances
  2. Validation of the other or new methodology must be documented.
  3. Prior to use, other or new methodology must have a standard operating procedure approved and signed by the laboratory director.
  4. Testing analysts must have documentation of competency assessment prior to testing Samples.
  5. Any changes to the approved other or new methodology must be revalidated and documented prior to testing Samples.

**Basis and Purpose – 5-435**

The statutory authority for this rule includes but is not limited to sections 44-10-203(2)(d), 44-10-401(2)(a)(IV), and 44-10-504, C.R.S. The purpose of this rule is to establish a proficiency testing program for Medical Marijuana Testing Facilities. This Rule 5-435 was previously Rule M 707, 1 CCR 212-1.

#### **5-435 – Medical Marijuana Testing Facilities: Proficiency Testing**

- A. Proficiency Testing Required. A Medical Marijuana Testing Facility must participate in a Proficiency Testing Program for each approved category in which it seeks certification under Rule 5-415 – Medical Marijuana Testing Facilities: Certification Requirements.
- B. Participation in Designated Proficiency Testing Event. If required by the Division as part of certification, the Medical Marijuana Testing Facility must have successfully participated in a proficiency test in the category for which it seeks certification, within the preceding 12 months.
- C. Continued Certification. To maintain continued certification, a Medical Marijuana Testing Facility must participate in the designated proficiency testing program with continued satisfactory performance as determined by the Division as part of certification. The Division may designate a local agency, state agency, or independent third-party to provide Proficiency Testing.
- D. Analyzing Proficiency Testing Samples. A Medical Marijuana Testing Facility must analyze Proficiency Testing Samples using the same procedures with the same number of replicate analyses, standards, testing analysts, and equipment as used in its standard operating procedures.
- E. Proficiency Testing Attestation. The laboratory director and all testing analysts that participated in a Proficiency Testing must sign corresponding attestation statements.
- F. Laboratory Director Must Review Results. The laboratory director must review and evaluate all Proficiency Testing results.
- G. Remedial Action. A Medical Marijuana Testing Facility must take and document remedial action when a score of less than 100% is achieved on any test during a Proficiency Test. Remedial action documentation must include a review of Samples tested and results reported since the last successful proficiency testing event. A requirement to take remedial action does not necessarily indicate unsatisfactory participation in a Proficiency Testing event.
- H. Unsatisfactory Participation in Proficiency Testing Event. Unless the Medical Marijuana Testing Facility positively identifies at least 80% of the target analytes tested, participation in the Proficiency Testing will be considered unsatisfactory. A positive identification must include accurate quantitative and qualitative results as applicable. Any false positive results reported will be considered an unsatisfactory score for the proficiency testing event.
- I. Consequence of Unsatisfactory Participation in Proficiency Testing Event. Unsuccessful participation in a Proficiency Testing event may result in limitation, suspension or revocation of Rule 5-415 certification.

#### **Basis and Purpose – 5-440**

The statutory authority for this rule includes but is not limited to sections 44-10-203(2)(d), 44-10-401(2)(a)(IV), and 44-10-504, C.R.S. The purpose of this rule is to establish quality assurance and quality assurance standards for a Medical Marijuana Testing Facility. This Rule 5-440 was previously Rule M 708, 1 CCR 212-1.

#### **5-440 – Medical Marijuana Testing Facilities: Quality Assurance and Quality Control**

- A. Quality Assurance Program Required. A Medical Marijuana Testing Facility must establish, monitor, and document the ongoing review of a quality assurance program that is sufficient to identify problems in the laboratory preanalytic, analytic and postanalytic systems when they occur and must include, but is not limited to:
1. Review of instrument preventive maintenance, repair, troubleshooting and corrective actions documentation must be performed by the laboratory director or designated supervisory analyst on an ongoing basis to ensure the effectiveness of actions taken over time;
  2. Review by the laboratory director or designated supervisory analyst of all ongoing quality assurance; and
  3. Review of the performance of validated methods used by the Medical Marijuana Testing Facility to include calibration standards, controls and the standard operating procedures used for analysis on an ongoing basis to ensure quality improvements are made when problems are identified or as needed.
- B. Quality Control Measures Required. A Medical Marijuana Testing Facility must establish, monitor, and document on an ongoing basis the quality control measures taken by the laboratory to ensure the proper functioning of equipment, validity of standard operating procedures and accuracy of results reported. Such quality control measures must include, but shall not be limited to:
1. Documentation of instrument preventive maintenance, repair, troubleshooting and corrective actions taken when performance does not meet established levels of quality;
  2. Review and documentation of the accuracy of automatic and adjustable pipettes and other measuring devices when placed into service and annually thereafter;
  3. Cleaning, maintaining and calibrating as needed the analytical balances and in addition, verifying the performance of the balance annually using certified weights to include three or more weights bracketing the ranges of measurement used by the laboratory;
  4. Annually verifying and documenting the accuracy of thermometers using a NIST traceable reference thermometer;
  5. Recording temperatures on all equipment when in use where temperature control is specified in the standard operating procedures manual, such as water baths, heating blocks, incubators, ovens, refrigerators, and freezers;
  6. Properly labeling reagents as to the identity, the concentration, date of preparation, storage conditions, lot number tracking, expiration date and the identity of the preparer;
  7. Avoiding mixing different lots of reagents in the same analytical run;
  8. Performing and documenting a calibration curve with each analysis using at minimum three calibrators throughout the reporting range;
  9. For qualitative analyses, analyzing, at minimum, a negative and a positive control with each batch of samples analyzed;
  10. For quantitative analyses, analyzing, at minimum, a negative and two levels of controls that challenge the linearity of the entire curve;

11. Using a control material or materials that differ in either source or, lot number, or concentration from the calibration material used with each analytical run;
12. For multi-analyte assays, performing and documenting calibration curves and controls specific to each analyte, or at minimum, one with similar chemical properties as reported in the analytical run;
13. Analyzing an appropriate matrix blank and control with each analytical run, when available;
14. Analyzing calibrators and controls in the same manner as unknowns;
15. Documenting the performance of calibration standards and controls for each analytical run to ensure the acceptability criteria as defined in the Standard Operating Procedure is met;
16. Documenting all corrective actions taken when unacceptable calibration, control, and standard or instrument performance does not meet acceptability criteria as defined in the Standard Operating Procedure;
17. Maintaining records of validation data for any new or modified methods to include; accuracy, precision, analytical specificity (interferences), LOD, LOQ, and verification of the linear range; and
18. Performing testing analysts that follow the current standard operating procedures manual for the test or tests to be performed.

#### **Basis and Purpose – 5-445**

The statutory authority for this rule includes but is not limited to sections 44-10-203(2)(d), 44-10-401(2)(a)(IV), and 44-10-504, C.R.S. The purpose of this rule is to establish chain of custody standards for a Medical Marijuana Testing Facility. In addition, it establishes the requirement that a Medical Marijuana Testing Facility follow an adequate chain of custody for Samples it maintains. This Rule 5-445 was previously Rule M 709, 1 CCR 212-1.

#### **5-445 – Medical Marijuana Testing Facilities: Chain of Custody**

- A. General Requirements. A Medical Marijuana Testing Facility must establish an adequate chain of custody and Sample requirement instructions that must include, but not be 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 Samples, aliquots, and extracts;
  5. Document all Transfers of Samples, aliquots, and extracts referred to another certified Medical Marijuana 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 Laboratory 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; and
11. Document the disposal of Samples, aliquots, and extracts.

### **Basis and Purpose – 5-450**

The statutory authority for this rule includes but is not limited to sections 44-10-203(2)(d), 44-10-401(2)(a)(IV), and 44-10-504, C.R.S. The purpose of this rule is to establish records retention standards for a Medical Marijuana Testing Facility. This Rule 5-450 was previously Rule M 710, 1 CCR 212-1.

### **5-450 – Medical Marijuana Testing Facilities: Records Retention**

- A. General Requirement. A Medical Marijuana Testing Facility must maintain all required business records. See Rule 3-905 - Business Records Required.
- B. Specific Business Records Required: Records Retention. A Medical Marijuana Testing Facility must establish processes to preserve records in accordance with Rule 3-905 that includes, but is not limited to;
  1. Test Results, including final and amended reports, and identification of analyst and date of analysis;
  2. Quality Control and Quality Assurance Records, including accession numbers, Sample type, and acceptable reference range parameters;
  3. Standard Operating Procedures;
  4. Personnel Records;
  5. Chain of Custody Records;
  6. Proficiency Testing Records; and
  7. Analytical Data to include data generated by the instrumentation, raw data calibration standards, and curves.

### **Basis and Purpose – 5-455**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(2)(h), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(d), 44-10-203(2)(f)(II), 44-10-203(2)(f)(IV), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-313(8)(a), 44-10-401(2)(a)(IV), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1), and 44-10-504(2), C.R.S. The purpose of this rule is to require Medical Marijuana Testing Facilities to provide failed test results to the Medical Marijuana Business or Person submitting the sample and to report any failed test result in the inventory tracking system. This Rule 5-455 was previously Rule M 712(D), 1 CCR 212-1.

### **5-455 – Notification of Medical Marijuana Business**

If Medical Marijuana failed a contaminant test, then the Medical Marijuana Testing Facility must immediately (1) notify the Medical Marijuana Business that submitted the Test Batch or Sample for testing and any Person as directed by an approved Research Project being conducted by a Marijuana Research and Development Facility; and (2) report the failure in accordance with the Inventory Tracking System reporting requirements in Rule 3-825(C).

## **5-500 Series – Medical Marijuana Transporters**

### **Basis and Purpose – 5-505**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(h), 44-10-203(2)(n), 44-10-203(3)(c), 44-10-401(2)(a)(V), 44-10-505, C.R.S. The purpose of this rule is to establish the license privileges of Medical Marijuana Transporter licensees. This Rule 5-505 was previously Rule M 1601, 1 CCR 212-1.

### **5-505 – Medical Marijuana Transporter: License Privileges**

- A. Licensed Premises. A separate license is required for each specific business or business entity and geographical location. A Medical Marijuana Transporter may share a location with an identically owned Retail Marijuana Transporter. However, a separate license is required for each specific business or business entity, regardless of geographical location.
- B. Transportation of Medical Marijuana and Medical Marijuana Product Authorized. A Medical Marijuana Transporter may take transportation orders, receive, transport, temporarily store, and deliver Medical Marijuana to a Medical Marijuana Business.
- C. Authorized Sources of Medical Marijuana. A Medical Marijuana Transporter may only transport and store Medical Marijuana that it received directly from the originating Medical Marijuana Business.
- D. Authorized On-Premises Storage. A Medical Marijuana Transporter is authorized to store transported Medical Marijuana on its Licensed Premises or permitted off-premises storage facility. All transported Medical Marijuana must be secured in a Limited Access Area, and tracked consistently with the inventory tracking rules.
- E. Delivery to Patients Pursuant to Delivery Permit.
  - 1. Prior to January 2, 2021, all Medical Marijuana Transporters are prohibited from delivering Regulated Marijuana to patients.
  - 2. After January 2, 2021, only Medical Marijuana Transporters that possess a valid delivery permit may deliver Medical Marijuana pursuant to contracts with Medical Marijuana Stores that also possess valid delivery permits. All deliveries of Medical Marijuana to patients must comply with all requirements of Rule 3-615.
  - 3. License Violation Affecting Public Safety. Any violation of subparagraph E of this Rule is a license violation affecting public safety.

### **Basis and Purpose – 5-510**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(h), 44-10-203(2)(n), 44-10-203(3)(c), 44-10-401(2)(a)(V), 44-10-505, C.R.S. The purpose of this rule is to clarify those acts that are limited in some fashion or prohibited by a Medical Marijuana Transporter. This Rule 5-510 was previously Rule M 1602, 1 CCR 212-1.



## 5-510 – Medical Marijuana Transporter: General Limitations or Prohibited Acts

- A. Sales, Liens, and Secured Interests Prohibited. A Medical Marijuana Transporter is prohibited from buying, selling, or giving away Medical Marijuana or from receiving complimentary Medical Marijuana. A Medical Marijuana Transporter shall not place or hold a lien or secured interest on Medical Marijuana.
- B. Licensed Premises Permitted. A Medical Marijuana Transporter shall maintain a Licensed Premises if it: (1) temporarily stores any Medical Marijuana, or (2) modifies any information in the Inventory Tracking System generated transport manifest. The Licensed Premises shall be in a local jurisdiction that authorizes the operation of Medical Marijuana Stores. If a Medical Marijuana Transporter Licensed Premises is shared with a Retail Marijuana Transporter Licensed Premises, then the combined Licensed Premises shall be in a local jurisdiction that authorizes the operation of both Medical Marijuana Stores and Retail Marijuana Stores.
- C. Off-Premises Storage Permit. A Medical Marijuana Transporter may maintain one or more permitted off-premises storage facilities. See Rule 3-610 – Off-Premises Storage of Regulated Marijuana and Regulated Marijuana Product: All Regulated Marijuana Businesses.
- D. Storage Duration. A Medical Marijuana Transporter shall not store Medical Marijuana for longer than seven days from receiving it at its Licensed Premises or off-premises storage facility. The total allowable seven day storage duration begins and applies regardless of which of the Medical Marijuana Transporter's premises receives the Medical Marijuana first, (ie. the Medical Marijuana Transporter's Licensed Premises, or any of its off-premises storage facilities). A Medical Marijuana Transporter with a valid delivery permit may store Medical Marijuana for delivery to patients pursuant to the delivery permit for no longer than seven days from receipt at its Licensed Premises or off-premises storage facility.
- E. Control of Medical Marijuana. A Medical Marijuana Transporter is responsible for the Medical Marijuana once it takes control of the Medical Marijuana and until the Medical Marijuana Transporter delivers it to the receiving Medical Marijuana Business, Medical Research Facility, Pesticide Manufacturer, or deliveries to a patient, parent, or guardian pursuant to a valid delivery permit. For purposes of this Rule, taking control of the Medical Marijuana means removing it from the originating Medical Marijuana Business's Licensed Premises and placing the Medical Marijuana in the transport vehicle or the Delivery Motor Vehicle.
- F. Location of Orders Taken and Delivered. A Medical Marijuana Transporter is permitted to take orders on the Licensed Premises of any Medical Marijuana Business to transport Medical Marijuana between Medical Marijuana Businesses. The Medical Marijuana Transporter shall deliver the Medical Marijuana to the Licensed Premises of a licensed Medical Marijuana Business, a Medical Research Facility, or Pesticide Manufacturer. A Medical Marijuana Transporter may also deliver Medical Marijuana to patients, parents, or guardians pursuant to a contract with a Medical Marijuana Store if it possesses a valid delivery permit.
- G. A Medical Marijuana Transporter shall receive Medical Marijuana from the originating Licensee packaged in the way that it is intended to be delivered to the final destination Licensee, Medical Research Facility, or Pesticide Manufacturer. The Medical Marijuana Transporter shall deliver the Medical Marijuana in the same, unaltered packaging to the final destination Licensee.
- H. A Medical Marijuana Transporter with a valid delivery permit shall receive Medical Marijuana that has been weighed, packaged, prepared, and labeled for delivery on the Licensed Premises of a Medical Marijuana Store or at the Medical Marijuana Store's off-premises storage facility after receipt of a delivery order. Medical Marijuana cannot be placed into a Delivery Motor Vehicle until after an order has been received and the Medical Marijuana has been packaged and labeled for delivery to the patient, parent, or guardian as required by the 3-1000 Series Rules.

- I. A Medical Marijuana Transporter must not deliver Medical Marijuana to patients, parents, or guardians while also transporting Regulated Marijuana between Licensed Premises in the Delivery Motor Vehicle.
- J. Opening of Sealed Packages or Containers and Re-Packaging Prohibited. A Medical Marijuana Transporter shall not open Containers of Medical Marijuana. Medical Marijuana Transporters are prohibited from re-packaging Medical Marijuana.
- K. Temperature-Controlled Transport Vehicles. A Medical Marijuana Transporter shall utilize temperature-controlled transport vehicles when necessary to prevent spoilage of the transported Medical Marijuana.
- L. Damaged, Refused, or Undeliverable Medical Marijuana. Any damaged Medical Marijuana that is undeliverable to the final destination Medical Marijuana Business, or any Medical Marijuana that is refused by the final destination Medical Marijuana Business shall be transported back to the originating Medical Marijuana Business. Any Medical Marijuana that cannot be delivered to the patient, parent, or guardian pursuant to a valid delivery permit shall be returned to the originating Medical Marijuana Store or the Medical Marijuana Store's off-premises storage facility within the same business day or pursuant to paragraph D of this Rule.
- M. Transport of Medical Marijuana Vegetative Plants Authorized. Medical Marijuana Vegetative plants may only be transported between Licensed Premises and such transport shall only be permitted due to an approved change of location pursuant to Rule 2-255 or due to a one-time transfer pursuant to Rule 3-805. Transportation of Vegetative plants to a permitted off-premises storage facility shall not be allowed. This restriction shall not apply to Immature plants.

## **5-600 Series – Medical Marijuana Business Operators**

### **Basis and Purpose – 5-605**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(o), 44-10-401(2)(a)(VI), and 44-10-506, C.R.S. The purpose of this rule is to establish the license privileges of a Medical Marijuana Business Operator license. This Rule 5-605 was previously Rule M 1701, 1 CCR 212-1.

### **5-605 – Medical Marijuana Business Operator: License Privileges**

- A. Privileges Granted. A Medical Marijuana Business Operator shall only exercise those privileges granted to it by the Marijuana Code, the rules promulgated pursuant thereto and the State Licensing Authority. A Medical Marijuana Business Operator may exercise those privileges only on behalf of the Medical Marijuana Business(es) it operates. A Medical Marijuana Business shall not contract to have more than one Medical Marijuana Business Operator providing services to the Medical Marijuana Business at any given time. A Medical Marijuana Business Operator may not provide any operational services to a Marijuana Research and Development Facility.
- B. Licensed Premises of the Medical Marijuana Business(es) Operated. A separate license is required for each specific Medical Marijuana Business Operator, and each licensed or registered Medical Marijuana Business Operator may operate one or more other Medical Marijuana Business(es). A Medical Marijuana Business Operator shall not have its own Licensed Premises, but shall maintain its own place of business, and may exercise the privileges of a Medical Marijuana Business Operator at the Licensed Premises of the Medical Marijuana Business(es) it operates.

- C. Entities Eligible to Hold Medical Marijuana Business Operator License or Registration. A Medical Marijuana Business Operator license may be held only by a business entity, including, but not limited to, a corporation, limited liability company, partnership, or sole proprietorship.
- D. Separate Place of Business. A Medical Marijuana Business Operator shall designate and maintain a place of business separate from the Licensed Premises of any Medical Marijuana Business(es) it operates. A Medical Marijuana Business Operator's separate place of business shall not be considered a Licensed Premises, and shall not be subject to the requirements applicable to the Licensed Premises of other Medical Marijuana Businesses, except as set forth in Rules 5-610 and 5-620. Possession, storage, use, cultivation, manufacture, sale, distribution, or testing of Medical Marijuana or Medical Marijuana Product is prohibited at a Medical Marijuana Business Operator's separate place of business.
- E. Agency Relationship and Discipline for Violations. A Medical Marijuana Business Operator and each of its Controlling Beneficial Owners required to hold an Owner License, as well as the agents and employees of the Medical Marijuana Business Operator, shall be agents of the Medical Marijuana Business(es) the Medical Marijuana Business Operator is contracted to operate, when engaged in activities related, directly or indirectly, to the operation of such Medical Marijuana Business(es), including for purposes of taking administrative action against the Medical Marijuana Business being operated. See § 44-10-901(1), C.R.S. Similarly, a Medical Marijuana Business Operator and its Controlling Beneficial Owners required to hold an Owner License, as well as the officers, agents and employees of the Medical Marijuana Business Operator, may be disciplined for violations committed by the Controlling Beneficial Owners, agents or employees of the Medical Marijuana Business acting under their direction or control. A Medical Marijuana Business Operator may also be disciplined for violations not directly related to a Medical Marijuana Business it is operating.
- F. Compliance with Applicable State and Local Law, Ordinances, Rules, and Regulations. A Medical Marijuana Business Operator, and each of its Controlling Beneficial Owners, agents and employees engaged, directly or indirectly, in the operation of the Medical Marijuana Business(es) it operates, shall comply with all state and local laws, ordinances, rules, and regulations applicable to the Medical Marijuana Business(es) being operated.

### **Basis and Purpose – 5-610**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(o), 44-10-401(2)(a)(VI), and 44-10-506, C.R.S. The purpose of this rule is to clarify those acts that are limited in some fashion, or prohibited, by a Medical Marijuana Business Operator. This Rule 5-610 was previously Rule M 1702, 1 CCR 212-1.

### **5-610 – Medical Marijuana Business Operators: General Limitations or Prohibited Acts**

- A. Financial Interest. A Person who holds an Owner's Interest in a Medical Marijuana Business Operator may also hold an Owner's Interest in another Medical Marijuana Business. A Medical Marijuana Business may be operated by a Medical Marijuana Business Operator where each has one or more Controlling Beneficial Owners or Passive Beneficial Owners in common. A Person may receive compensation for services provided by a Medical Marijuana Business Operator in accordance with these rules.
- B. Sale of Marijuana Prohibited. A Medical Marijuana Business Operator is prohibited from selling, distributing, or Transferring Medical Marijuana to another Medical Marijuana Business, a patient, or a consumer, except when acting as an agent of a Medical Marijuana Business(es) operated by the Medical Marijuana Business Operator.

- C. Consumption Prohibited. A Medical Marijuana Business Operator, and its Controlling Beneficial Owners, Passive Beneficial Owners, agents and employees, shall not permit the consumption of marijuana or marijuana products at its separate place of business.
- D. Inventory Tracking System. A Medical Marijuana Business Operator, and any of its Controlling Beneficial Owners, agents, or employees engaged in the operation of the Medical Marijuana Business(es) it operates, must use the Inventory Tracking System account of the Medical Marijuana Business(es) it operates, in accordance with all requirements, limitations, and prohibitions applicable to the Medical Marijuana Business(es) it operates.
- E. Compliance with Requirements and Limitations Applicable to the Medical Marijuana Business(es) Operated. In operating any other Medical Marijuana Business(es), a Medical Marijuana Business Operator, and its Controlling Beneficial Owners, agents and employees, shall comply with all requirements, limitations and prohibitions applicable to the type(s) of Medical Marijuana Business(es) being operated, under state and local laws, ordinances, rules, and regulations, and may be disciplined for violation of the same.
- F. Inventory Tracking System Access. A Medical Marijuana Business may grant access to its Inventory Tracking System account to the Controlling Beneficial Owners who are required to hold Owner Licenses, as well as the licensed agents and employees of a Medical Marijuana Business Operator having duties related to Inventory Tracking System activities of the Medical Marijuana Business(s) being operated.
1. The Controlling Beneficial Owners, agents, and employees of a Medical Marijuana Business Operator granted access to a Medical Marijuana Business's Inventory Tracking System account, shall comply with all Inventory Tracking System rules.
  2. At least one Controlling Beneficial Owner of a Medical Marijuana Business being operated by a Medical Marijuana Business Operator must be an Inventory Tracking System Trained Administrator for the Medical Marijuana Business's Inventory Tracking System account. That Inventory Tracking System Trained Administrator shall control access to its Inventory Tracking System account, and shall promptly terminate the access of the Medical Marijuana Business Operator's Controlling Beneficial Owners, agents, and employees:
    - a. When its contract with the Medical Marijuana Business Operator expires by its terms;
    - b. When its contract with the Medical Marijuana Business Operator is terminated by any party; or
    - c. When it is notified that the license of the Medical Marijuana Business Operator, or a specific Controlling Beneficial Owner, agent or employee of the Medical Marijuana Business Operator, has expired, or has been suspended or revoked.
- G. Limitations on Use of Documents and Information Obtained from Medical Marijuana Businesses. A Medical Marijuana Business Operator, and its agents and employees, shall maintain the confidentiality of documents and information obtained from the other Medical Marijuana Business(es) it operates, and shall not use or disseminate documents or information obtained from a Medical Marijuana Business it operates for any purpose not authorized by the Marijuana Code and the rules promulgated pursuant thereto, and shall not engage in data mining or other use of the information obtained from a Medical Marijuana Business to promote the interests of the Medical Marijuana Business Operator or its Controlling Beneficial Owners, Passive Beneficial Owners, Indirect Financial Interest Holders, agents or employees, or any Person other than the Medical Marijuana Business it operates.

- H. Form and Structure of Allowable Agreement(s) Between Operators and Owners. Any agreement between a Medical Marijuana Business and a Medical Marijuana Business Operator:
1. Must acknowledge that the Medical Marijuana Business Operator, and its Controlling Beneficial Owners, agents and employees who are engaged, directly or indirectly, in operating the Medical Marijuana Business, are agents of the Medical Marijuana Business being operated, and must not disclaim an agency relationship;
  2. May provide for the Medical Marijuana Business Operator to receive direct remuneration from the Medical Marijuana Business, including a portion of the profits of the Medical Marijuana Business being operated, subject to the following limitations:
    - a. The portion of the profits to be paid to the Medical Marijuana Business Operator shall be commercially reasonable, and in any event shall not exceed the portion of the net profits to be retained by the Medical Marijuana Business being operated;
    - b. The Medical Marijuana Business Operator shall not be granted, and may not accept:
      - i. A security interest in the Medical Marijuana Business being operated, or in any assets of the Medical Marijuana Business;
      - ii. An ownership or membership interest, shares, or shares of stock, or any right to obtain any direct or indirect beneficial ownership interest in the Medical Marijuana Business being operated, or a future or contingent right to the same, including but not limited to options or warrants;
    - c. The Medical Marijuana Business Operator shall not guarantee the Medical Marijuana Business's debts or production levels.
  3. Shall permit the Medical Marijuana Business being operated to terminate the contract with the Medical Marijuana Business Operator at any time, with or without cause.
- I. A Medical Marijuana Business Operator may engage in dual operation of a Medical Marijuana Business and a Retail Marijuana Business at a single location, to the extent the Medical Marijuana Business being operated is permitted to do so pursuant to subsection 44-10-501(2)(a), C.R.S., and the Medical Marijuana Business Operator shall comply with the rules promulgated pursuant to the Marijuana Code, including the requirement of obtaining a valid license as a Retail Marijuana Business Operator.
- J. Any Medical Marijuana Business Operators and the Medical Marijuana Business Operator's Owner Licensee(s) that are appointed by a court to serve as a receiver, personal representative, executor, administrator, guardian, conservator, trustee, or similarly situated Person and take possession of, operate, manage, or control a Medical Marijuana Business must comply with Rule 2-275(F).

### **Basis and Purpose – 5-615**

The statutory authority for this rule includes but is not limited to sections, 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(o), 44-10-401(2)(a)(VI), and 44-10-506, C.R.S. The purpose of this rule is to establish license requirements for the Medical Marijuana Business Operator's Controlling Beneficial Owners, agents and employees, including those directly or indirectly engaged in the operation of other Medical Marijuana Business(es). This Rule 5-615 was previously Rule M 1703, 1 CCR 212-1.

## 5-615 – Medical Marijuana Business Operators: Employee Licenses for Personnel

### A. Required Licenses.

1. Owner Licenses. All natural persons who are Controlling Beneficial Owners in a Medical Marijuana Business Operator must have a valid Owner License, associated with the Medical Marijuana Business Operator license. Such an Owner License shall satisfy all licensing requirements for work related to the business of the Medical Marijuana Business Operator and for work performed on behalf of, or at the Licensed Premises of, the Medical Marijuana Business(es) operated by the Medical Marijuana Business Operator.
2. Employee Licenses. All natural persons who are agents or employees of a Medical Marijuana Business Operator that are actively engaged, directly or indirectly, in the management, supervision, or operation of one or more other Medical Marijuana Businesses, including but not limited to all agents or employees who will come into contact with Medical Marijuana, who will have access to Limited Access Areas, or who will have access to the Inventory Tracking System account of the Medical Marijuana Business(es) being operated, must hold a valid Employee License. The Employee License shall satisfy all licensing requirements for work related to the business of the Medical Marijuana Business Operator and for work at the Licensed Premises of, or on behalf of, the Medical Marijuana Business(es) operated by the Medical Marijuana Business Operator.

B. Employee Licenses Not Required. Employee Licenses are not required for Passive Beneficial Owners of a Medical Marijuana Business Operator or for natural persons who will not come into contact with Medical Marijuana, will not have access to Limited Access Area(s) of the Medical Marijuana Business(es) being operated, and will not have access to the Inventory Tracking System account of the Medical Marijuana Business(es) being operated.

C. Designation of Management Personnel of a Medical Marijuana Business Operated by a Medical Marijuana Business Operator. If a Medical Marijuana Business Operator is contracted to manage the overall operations of a Medical Marijuana Business's Licensed Premises, the Medical Marijuana Business shall designate separate and distinct management personnel on the Licensed Premises who is an officer, agent, or employee of the Medical Marijuana Business Operator, which shall be a natural person with a valid Owner License or Employee License, as set forth in paragraph A of this Rule, and the Medical Marijuana Business shall comply with the reporting provisions of subsection 44-10-313, C.R.S.

## Basis and Purpose – 5-620

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(o), 44-10-401(2)(a)(VI), and 44-10-506, C.R.S. The purpose of this rule is to establish records retention standards for a Medical Marijuana Business Operators. This Rule 5-620 was previously Rule M 1704, 1 CCR 212-1.

## 5-620 – Medical Marijuana Business Operators: Business Records Required

A. General Requirement. A Medical Marijuana Business Operator must maintain all required business records as set forth in Rule 3-905 - Business Records Required, except that:

1. A Medical Marijuana Business Operator is not required to maintain secure facility information, diagrams of its designated place of business, or a visitor log for its separate

place of business, because a Medical Marijuana Business Operator will not come into contact with Medical Marijuana at its separate place of business; and

2. A Medical Marijuana Business Operator is not required to maintain records related to inventory tracking, or transport, because a Medical Marijuana Business Operator is prohibited from engaging in activities on its own behalf that would require inventory tracking or transport. All records relating to inventory tracking activities and records related to transport pertaining to the Medical Marijuana Business(es) operated by the Medical Marijuana Business Operator shall be maintained at the Licensed Premises of such Medical Marijuana Business(es).

- B. All records required to be maintained shall be maintained at the Medical Marijuana Business Operator's separate place of business, and not at the Licensed Premises of the Medical Marijuana Business(es) it operates.

## **5-700 Series – Marijuana Research and Development Facilities**

### **Basis and Purpose – 5-705**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(1)(i), 44-10-203(2)(s), 44-10-401(1)(a)(VII), and 44-10-507, C.R.S. The purpose of this rule is to establish and clarify the distinct license privilege granted to Marijuana Research and Development Facilities by the State Licensing Authority. This Rule 5-705 was previously Rule M 1901, 1 CCR 212-1.

### **5-705 – Marijuana Research and Development Facilities: License Privileges**

#### **A. License Privileges.**

1. Licensed Premises. A Marijuana Research and Development Facility may share a Licensed Premises with a commonly owned Medical Marijuana Testing Facility. Additionally, a Marijuana Research and Development Facility with an R&D Co-Location Permit may share a Licensed Premises with a commonly owned Medical Marijuana Products Manufacturer, Retail Marijuana Products Manufacturer, Medical Marijuana Cultivation Facility, or Retail Marijuana Cultivation Facility.
  - a. If a Marijuana Research and Development Facility shares its Licensed Premises with a commonly owned Medical Marijuana Testing Facility, the Licensees shall physically segregate all Medical Marijuana used for research purposes in order to prevent contamination or any other effect on Medical Marijuana submitted to the Medical Marijuana Testing Facility for testing.
  - b. If a Marijuana Research and Development Facility shares its Licensed Premises with a commonly owned Medical Marijuana Products Manufacturer, Retail Marijuana Products Manufacturer, Medical Marijuana Cultivation Facility, or Retail Marijuana Cultivation Facility, the Marijuana Research and Development Facility must first obtain an R&D Co Location Permit for that Licensed Premises and must comply with all terms and conditions of the R&D Co-Location Permit.
2. Authorized Sources of Medical Marijuana. A Medical Marijuana Cultivation Facility and Medical Marijuana Products Manufacturer may Transfer Medical Marijuana to a Marijuana Research and Development Facility.

3. Cultivation of Marijuana Authorized. A Marijuana Research and Development Facility may grow, cultivate, possess, and Transfer Medical Marijuana for use in research only.
  4. Production of Marijuana Concentrate. A Marijuana Research and Development Facility and a Medical Marijuana Cultivation Facility are subject to the same restrictions concerning Medical Marijuana Concentrate production. Therefore, a Marijuana Research and Development Facility may produce Medical Marijuana Concentrate only as allowed by, and in conformance with, Rule 5-220(A)-(B).
  5. Production of Marijuana Products. A Marijuana Research and Development Facility and a Medical Marijuana Products Manufacturer are subject to the same restrictions concerning Medical Marijuana Product manufacturing. Therefore, a Marijuana Research and Development Facility may manufacture Medical Marijuana Product only as allowed by, and in conformance with, Rule 5-305.
  6. Authorized Marijuana Transport. A Marijuana Research and Development Facility is authorized to utilize a licensed Medical Marijuana Transporter for transportation of Medical Marijuana to other Marijuana Research and Development Facility Licensees so long as the place where transportation orders are taken and delivered is a Marijuana Research and Development Facility. Nothing in this Rule prevents a Marijuana Research and Development Facility from transporting its own Medical Marijuana to other Marijuana Research and Development Facilities.
- B. R&D Co-Location Permit. A Marijuana Research and Development Facility may obtain an R&D Co-Location Permit to operate at the same Licensed Premises as a commonly owned Medical Marijuana Products Manufacturer, Retail Marijuana Products Manufacturer, Medical Marijuana Cultivation Facility, or Retail Marijuana Cultivation Facility under the following circumstances:
1. The Marijuana Research and Development Facility must apply on current Division forms and pay any applicable fees.
  2. A Marijuana Research and Development Facility may only apply for and hold an R&D Co-Location Permit if the Local Licensing Authority or Local Jurisdiction allow for Marijuana Research and Development Facility to operate at the same location as the specified Regulated Marijuana Business. Any R&D Co-Location Permit issued by the Division is conditioned upon the Marijuana Research and Development Facility's receipt of all required Local Licensing Authority or Local Jurisdiction approvals or acknowledgements.
  3. The Marijuana Research and Development Facility and the specified Regulated Marijuana Business shall be commonly owned.
  4. Prior to operating in the same Licensed Premises pursuant to an R&D Co-Location Permit, the Marijuana Research and Development Facility shall submit a co-location plan and standard operating procedures to the Division. The co-location plan and standard operating procedures shall demonstrate protocols to prevent cross-contamination and protect public health and safety, including but not limited to:
    - a. Standards and controls for maintaining physical separation between the Marijuana Research and Development Facility's research activities and the cultivating or manufacturing activities of the co-located Regulated Marijuana Business; and
    - b. Standards and controls for maintaining physical separation between the Marijuana Research and Development Facility's Medical Marijuana and the co-located Regulated Marijuana Business's Regulated Marijuana.



5. The Division may request the assistance of the Colorado Department of Public Health and Environment or any other state or local agency in reviewing the co-location plan and standard operating procedures, and in determining whether the co-location plan and standard operating procedures demonstrate protocols to prevent cross-contamination and protect public health and safety.
6. Modifying the co-location plan and standard operating procedures shall be considered a material change to the Licensed Premises. See Rule 2-260 – Changing, Altering, or Modifying the Licensed Premises.
7. Record keeping, inventory tracking, packaging and labeling for the Marijuana Research and Development Facility and co-located Regulated Marijuana Business must enable the Division, Local Licensing Authority, or Local Jurisdiction to clearly distinguish the inventory, transactions, and activities of the Marijuana Research and Development Facility from the inventory, transactions, and activities of the co-located Regulated Marijuana Business.

### **Basis and Purpose - 5-710**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(1)(i), 44-10-203(2)(s), 44-10-313(7), 44-10-401(1)(a)(VII), and 44-10-507, C.R.S. The purpose of this rule is to clarify those acts that are prohibited, or limited in some fashion, by a Marijuana Research and Development Facility. This Rule 5-710 was previously Rule M 1902, 1 CCR 212-1.

### **5-710 – Marijuana Research and Development Facility: General Limitations or Prohibited Acts**

#### **A. Restrictions Applicable to Any Marijuana Research and Development Facility.**

1. Packaging and Labeling Standards Required. A Marijuana Research and Development Facility is prohibited from Transferring to a Licensee or any other Person Medical Marijuana that is not packaged and labeled in accordance with these rules. See 3-1000 Rule Series – Labeling, Packaging, and Product Safety.
  - a. Unless the Medical Marijuana was subject to contaminant testing required by the Marijuana Code and these rules, a Marijuana Research and Development Facility shall disclose to any individual receiving Medical Marijuana as part of an approved Research Project that the Medical Marijuana has not been subject to mandatory contaminant testing.
2. Transfers to Individuals. A Marijuana Research and Development Facility is prohibited from Transferring Medical Marijuana to any individual, unless as part of an approved Research Project.
3. Consumption Prohibited. A Marijuana Research and Development Facility shall not permit the consumption of Medical Marijuana on its Licensed Premises, unless the consumption is part of an approved Research Project and the Marijuana Research and Development Facility does not share a Licensed Premises with a Regulated Marijuana Business.
4. Worker Health and Safety. A Marijuana Research and Development Facility shall comply with all applicable federal, state, and local laws regarding worker health and safety.

5. Performance Incentives. A Marijuana Research and Development Facility may not use performance-based incentives to compensate its employees, agents, or contractors who will conduct research, development, or testing.
6. Licensure and Research Projects. A Marijuana Research and Development Facility shall not engage in any research activities until the State Licensing Authority or its delegate approves both (1) its business license application, pursuant to Rule 2-215, and (2) one or more Research Project(s), pursuant to Rule 5-715.
  - a. A Marijuana Research and Development Facility may submit its business license application prior to or in conjunction with its Research Project proposal. Except that the Marijuana Research and Development Facility may not engage in any research activities except in conjunction with an approved Research Project.
  - b. If a Marijuana Research and Development Facility's license expires or is suspended or revoked, the Licensee shall immediately cease all activities associated with the privileges of licensure, including but not limited to research.

**B. Restrictions Applicable to Marijuana Research and Development Facilities.**

1. Transfer Restriction. A Marijuana Research and Development Facility may only Transfer Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana Product to:
  - a. A Medical Marijuana Testing Facility for testing;
  - b. A natural person as part of and in compliance with the conditions of an approved Research Project;
  - c. In the case of Medical Marijuana cultivated at the Licensed Premises of the Marijuana Research and Development Facility, to another Marijuana Research and Development Facility; or
  - d. In the case of an Immature Plant that has not been exposed to a chemical prohibited by Rule 3-325, to another Medical Marijuana Business.

**Basis and Purpose – 5-715**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(1)(i), 44-10-203(2)(s), 44-10-401(1)(a)(VII), and 44-10-507, C.R.S. The purpose of this rule is to ensure that any research or development conducted by a Marijuana Research and Development Facility shall be in furtherance of a Research Project approved by the Division. The purpose of this rule is also to establish the applicable requirements necessary for Marijuana Research and Development Facilities to seek and receive Division approval for all proposed Research Projects. This Rule 5-715 was previously Rule M 1904, 1 CCR 212-1.

**5-715 – Marijuana Research and Development Facility: Project Approval**

- A. Project Approval. Prior to engaging in any research activities, a Marijuana Research and Development Facility shall obtain approval from the Division for a Research Project by submitting a Research Project proposal. Any research or development conducted by a Marijuana Research and Development Facility shall be in furtherance of an approved Research Project.
  1. General. A Marijuana Research and Development Facility Applicant or Licensee shall seek approval of the Division by submitting its Research Project proposal.

- a. A Research Project proposal shall include a description of the Research Project's defined protocol, clearly articulated goal(s), defined methods and outputs, and a defined start and end date.
    - i. The description of the proposed Research Project proposal shall include the quantity of Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana Product reasonably required to conduct the proposed Research Project, the total quantity of which is subject to approval by the Division as part an approved Research Project.
  - b. A Marijuana Research and Development Facility may enter into contracts or agreements with a public higher education research institution or another Marijuana Research and Development Facility to conduct the proposed Research Project. A Marijuana Research and Development Facility Applicant or Licensee shall disclose all contracts or agreements with a public higher education research institution or a Marijuana Research and Development Facility.
    - i. If a Marijuana Research and Development Facility enters into a contract or agreement to conduct a Research Project with a public higher education research institution, all research activities involving possession of Medical Marijuana shall occur at the Marijuana Research and Development Facility's Licensed Premises. Employees, agents, or contractors of the public higher education research institution may not work at or conduct research activities at the Marijuana Research and Development Facility's Licensed Premises unless they hold an Employee License issued by the State Licensing Authority.
  - c. A Marijuana Research and Development Facility may submit additional Research Project proposals at any time during which its license is current and valid.
2. Private Research. Unless the proposed Research Project is being conducted in whole or in part by a Public Institution or with Public Money, the Marijuana Research and Development Facility Applicant or Licensee shall obtain a review of its proposed Research Project by one or more independent reviewers. The Division, in its discretion, may require a Marijuana Research and Development Facility Applicant or Licensee to nominate multiple independent reviewers. The Division must approve each nominated independent reviewer.
- a. Fees and Costs. The Applicant or Licensee shall be solely responsible for any fees or costs associated with all aspects and all stages of the independent reviewer's services.
  - b. Qualifications of an Independent Reviewer. Each independent reviewer nominated by a Marijuana Research and Development Facility Applicant or Licensee must be a qualified researcher within the field of study that relates to proposed Research Project.
    - i. The Division may consult with the Colorado Department of Public Health and Environment and/or the Colorado Department of Agriculture in reviewing whether a nominated independent reviewer is qualified to review the Marijuana Research and Development Facility's Research Project.

- ii. The Division, in its discretion, may require a nominated independent reviewer or the Marijuana Research and Development Facility to provide additional information or analysis that the Division deems pertinent to its review of whether to approve the Licensee's nomination of the independent reviewer.
- c. Conflicts of Interest. A Marijuana Research and Development Facility Applicant or Licensee must disclose all pre-existing financial, employment, business, or personal relationships between the Marijuana Research and Development Facility or any of its Owner Licensees and each independent reviewer. In determining whether to approve an independent reviewer, the Division may consider whether a pre-existing relationship exists that could affect the independent reviewer's independence or appearance of independence.
- d. Independent Reviewer Approval Required. If a Marijuana Research and Development Facility Applicant or Licensee nominates an independent reviewer who is not approved by the Division, the State Licensing Authority may deny a Research Project on that ground unless and until the Marijuana Research and Development Facility Applicant or Licensee nominates another independent reviewer who is approved by the Division.
- e. Independent Reviewer Report. After an independent reviewer has been approved by the Division, the Marijuana Research and Development Facility Applicant or Licensee shall submit a report by the independent reviewer to the Division as part of its Research Project proposal. The independent reviewer's report shall address the following criteria as described in the Research Project's description:
  - i. The identity of the independent reviewer and his/her employer;
  - ii. Any compensation paid by the Marijuana Research and Development Facility Applicant or Licensee for the review and report;
  - iii. A description of the review conducted by the independent reviewer, including but not limited to an identification of all documents that were reviewed;
  - iv. An analysis by the independent reviewer as to whether the proposed Research Project constitutes a type of approved research pursuant to Rule 5-720(A) and the reason(s) supporting the reviewer's analysis;
  - v. An assessment of the total quantity of Medical Marijuana reasonably required to conduct the proposed Research Project;
  - vi. An assessment of whether the proposed Research Project presents any type of danger to the public health and/or safety, and/or whether the proposed Research Project presents any health or safety risks;
  - vii. An assessment of whether the proposed Research Project has a strong scientific basis, appropriate study design, and technically sound scientific methodology;
  - viii. An assessment of whether the Marijuana Research and Development Facility Applicant or Licensee is qualified to perform the proposed Research Project, including whether Marijuana Research and

Development Facility Applicant or Licensee's employees are qualified to perform the proposed Research Project;

- ix. An assessment of whether the Marijuana Research and Development Facility Applicant or Licensee has the appropriate resources and protocols to conduct the proposed Research Project;
  - x. An assessment of whether the Marijuana Research and Development Facility Applicant or Licensee has the appropriate personnel, expertise, facilities, infrastructure, funding, and other human, animal, or other approvals in place to successfully conduct the Research Project, including but not limited to the requirements in Rule 5-720(C) and (D);
  - xi. The following certification by the independent reviewer: "I hereby certify and affirm that I do not have any financial, employment, business, or personal relationship with [INSERT MARIJUANA RESEARCH AND DEVELOPMENT FACILITY NAME] ("Licensee") that would influence or affect my review of the Licensee's proposed Research Project activity. Other than the fees disclosed herein, neither the Licensee nor any other person has given me anything of value or made any promises to me that would influence or affect my review of the Licensee's proposed research activity. I further certify and affirm that this report was drafted by me, and that the information, analysis, and conclusions herein represent solely my work and conclusions."; and
  - xii. The signature of the independent reviewer.
- f. The Marijuana Research and Development Facility shall maintain copies of all documents and correspondence sent to or from the independent reviewer. See Rule 3-905 – Business Records Required.
  - g. The Division, in its discretion, may require the independent reviewer and/or the Marijuana Research and Development Facility Applicant or Licensee to provide additional information or analysis that the Division deems pertinent to its review of the Applicant or Licensee's Research Project proposal.
  - h. The State Licensing Authority may decline to approve a Research Project proposal if an independent reviewer or the Division through further investigation concludes that:
    - i. The description of the Research Project does not meet the requirements of section 44-10-507, C.R.S., and these rules;
    - ii. The proposed Research Project presents a danger to the public health and/or safety, and/or the research to be conducted pursuant to the Research Project presents any health or safety risks;
    - iii. The proposed Research Project lacks scientific value or validity;
    - iv. The Marijuana Research and Development Facility Applicant or Licensee is not qualified to perform the proposed research;
    - v. The Marijuana Research and Development Facility Applicant or Licensee does not have the appropriate resources and/or protocols to conduct the proposed research;

- vi. The Marijuana Research and Development Facility Applicant or Licensee lacks the appropriate personnel, expertise, facilities, infrastructure, funding, or human, animal, or other approvals in place to successfully conduct the Research Project, including but not limited to the requirements in Rule 5-720(C) and (D);
  - vii. The independent reviewer(s) cannot meet the certification requirements in this Rule; or
  - viii. The Marijuana Research and Development Facility Applicant or Licensee or the proposed Research Project is otherwise not in compliance with the Marijuana Code or these rules.
3. Projects with Public Institutions or Money. If a Marijuana Research and Development Facility Applicant or Licensee's proposed Research Project will be conducted in whole or in part with a Public Institution or Public Money, the Division shall refer the Licensee's Research Project proposal to the Scientific Advisory Council established by section 25-1.5-106.5(3), C.R.S., for review.
- a. The Marijuana Research and Development Facility Applicant or Licensee shall supply the Scientific Advisory Council with any information and/or documents requested by the Scientific Advisory Council within the deadline imposed by the Scientific Advisory Council. A Marijuana Research and Development Facility Applicant or Licensee's failure to supply information and/or documents requested by the Scientific Advisory Council within the deadline set by the Scientific Advisory Council shall be grounds for denial of the Research Project proposal.
  - b. The Scientific Advisory Council shall review the proposed Research Project to ensure that the proposed Research Project meets the requirements of Rule 5-720(A).
  - c. The Scientific Advisory Council shall also assess the adequacy of the following:
    - i. The proposed Research Project's quality, study design, value, or impact;
    - ii. Whether the Marijuana Research and Development Facility Applicant or Licensee has the appropriate personnel, expertise, facilities, infrastructure, funding, and human, animal, or other approvals in place to successfully conduct the Research Project, including but not limited to the requirements in Rule 5-720(C) and (D); and
    - iii. Whether the amount of Medical Marijuana the Marijuana Research and Development Facility Applicant or Licensee proposes to grow or possess is consistent with the proposed Research Project's scope and goals.
  - d. The Scientific Advisory Council shall communicate the results of its review of the proposed Research Project to the Division. If the Scientific Advisory Council determines that the requirements of either Paragraph (b) or (c) of this Rule are not satisfied, then the proposed Research Project shall be denied.
  - e. The Marijuana Research and Development Facility shall maintain copies of all documents and correspondence sent to or from the Scientific Advisory Council. See Rule 3-905 – Business Records Required.

**Basis and Purpose – 5-720**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(1)(i), 44-10-203(2)(s), 44-10-401(1)(a)(VII), and 44-10-507, C.R.S. The purpose of this rule to establish the limited research purposes authorized for Marijuana Research and Development Facilities. The purpose of this rule is also to establish additional requirements for Research Projects involving human subjects and animal subjects, as well as restrictions on the use of Pesticides. The rule also establishes reporting requirements and explains when the State Licensing Authority may require a Marijuana Research and Development Facility to undergo an audit of its research activities. This Rule 5-720 was previously Rule M 1905, 1 CCR 212-1.

### **5-720 – Marijuana Research and Development Facility: Authorized Research Activities**

- A. Authorized Research. A Marijuana Research and Development Facility is authorized to engage in the following research at its Licensed Premises:
1. Chemical Potency and Composition Levels.
  2. Clinical Investigations of Marijuana-Derived Products.
  3. Efficacy and Safety of Administering Marijuana as Part of Medical Treatment.
  4. Genomic Research.
  5. Horticultural Research.
  6. Agricultural Research.
  7. Marijuana-Affiliated Products or Systems. A marijuana-affiliated product or system includes products or systems such as marijuana delivery systems and cultivation or processing equipment.
- B. Pesticide Research. A Marijuana Research and Development Facility shall not engage in any research activities involving Pesticides unless the Marijuana Research and Development Facility has applied for and received any necessary license, registration, certification, or permit from the Colorado Department of Agriculture pursuant to the Pesticide Act, sections 35-9-101 *et seq.*, C.R.S., and/or the Pesticide Applicators' Act, sections 35-10-101 *et seq.*, C.R.S.
1. A Marijuana Research and Development Facility engaged in research activities involving Pesticide shall at all times comply with the Pesticide Act, sections 35-9-101 *et seq.*, C.R.S., Pesticide Applicators' Act, sections 35-10-101 *et seq.*, C.R.S., and all rules promulgated pursuant thereto.
- C. Research Involving Human Subjects. A Marijuana Research and Development Facility shall not conduct any research involving human subjects unless all aspects of its proposed Research Project have been reviewed and approved by an Institutional Review Board that is registered and in good standing with Office for Human Research Protections, U.S. Department of Health and Human Services.
1. A Marijuana Research and Development Facility shall include proof of approval and ongoing oversight and review by an Institutional Review Board as part of its Research Project proposal. A Research Project may be approved conditioned upon subsequent Institutional Review Board approval. A Licensee shall not engage in any Research Project involving human subjects until it receives approval by the Institutional Review Board and its Research Project is approved. A Marijuana Research and Development Facility conducting research involving human subjects shall also comply with any ongoing monitoring required by the Institutional Review Board.

2. A Marijuana Research and Development Facility conducting research involving human subjects shall at all times comply with the U.S. Department of Health and Human Services' requirements for protection of human research subjects, including additional safeguards necessary for vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, 45 C.F.R. part 46, and all other relevant federal and/or state laws and regulations regarding research on human subjects, as well as all prevailing ethical standards and requirements for research involving human subjects.
  3. A Marijuana Research and Development Facility conducting research involving human subjects shall obtain informed consent from any individual participating in such research prior to the individual's participation in the research. A Marijuana Research and Development Facility shall comply with U.S. Food and Drug Administration requirements for informed consent and additional safeguards for children in clinical investigations, 21 C.F.R. part 50, as part of approval and ongoing oversight and review by an Institutional Review Board.
- D. Research Involving Animal Subjects. A Marijuana Research and Development Facility shall not conduct any research involving animal subjects as defined in the Animal Welfare Act, 7 U.S.C. § 2132(g) unless the Marijuana Research and Development Facility is registered with the U.S. Department of Agriculture pursuant to the Animal Welfare Act, 7 U.S.C. §§ 2131 *et seq.*
1. A Marijuana Research and Development Facility shall include proof of its current registration with the U.S. Department of Agriculture as part of its Research Project proposal. Failure to be registered with the U.S. Department of Agriculture shall be grounds for denial of Research Project proposal involving animal subjects.
  2. A Marijuana Research and Development Facility shall at all times treat animal subjects as defined in the Animal Welfare Act, 7 U.S.C. § 2132(g) involved in research humanely and consistent with all relevant federal and/or state laws and regulations, as well as all prevailing ethical standards and requirements for research on such animals.
- E. Research Involving Testing of Marijuana. A Marijuana Research and Development Facility may only engage in research regarding the testing of Medical Marijuana if the following criteria are met:
1. Testing Qualifications. A Marijuana Research and Development Facility must meet at least one of the following standards:
    - a. The Marijuana Research and Development Facility also holds a Medical Marijuana Testing Facility license and has been certified pursuant to Rule 5-415;
    - b. The Marijuana Research and Development Facility is accredited to the International Organization for Standardization/International Electrotechnical Commission 17025:2005 Standard, or any subsequent superseding ISO 17025 standard; or
    - c. The Marijuana Research and Development Facility is part of an institution of higher education whose protocols have been approved by the Colorado Department of Public Health and Environment.
  2. A Marijuana Research and Development Facility proposing to engage in research regarding the testing of Medical Marijuana shall include in its Research Project proposal documentation establishing its testing qualification pursuant to Paragraph (E)(1) of this



Rule. See Rule 5-715 – Marijuana Research and Development Facilities: Project Approval.

- F. Transfers of Marijuana Used in Research. A Marijuana Research and Development Facility shall not Transfer to any Person any Medical Marijuana unless such Transfer is authorized under Rule 5-710. Otherwise, a Marijuana Research and Development Facility shall at the conclusion of its research destroy all remaining Medical Marijuana subject to the Marijuana Research and Development Facility's approved Research Project. Unless otherwise provided, a Research Project will be deemed concluded on its defined end date as provided in the Marijuana Research and Development Facility's Research Project proposal that was submitted to and approved by the Division. The Marijuana Research and Development Facility shall ensure destruction of such remaining Medical Marijuana is destroyed in conformance with Rule 3-230.
- G. Periodic Reporting. A Marijuana Research and Development Facility shall submit to the Division a report regarding the status of approved Research Projects every six months following the Division's approval of its Research Project.
1. The periodic reports shall address the Marijuana Research and Development Facility's compliance and progress with its approved Research Project.
  2. The periodic reports shall include any protocol changes or reported protocol deviations, as well as enrollment numbers and adverse events for studies involving human subjects.
  3. If the Marijuana Research and Development Facility is conducting its Research Project in whole or in part with a Public Institution or Public Money, the Division shall submit the Marijuana Research and Development Facility's periodic reports to the Scientific Advisory Council for review.
  4. If an adverse event occurs, the Marijuana Research and Development Facility shall immediately notify the Division of the adverse event on the form prepared by the Division.
- H. Suspension or Revocation of Project Approval. Research Project approval is subject to revocation or suspension if the Marijuana Research and Development Facility's research has materially diverged from the Marijuana Research and Development Facility's approved Research Project, violates the Marijuana Code or the rules promulgated thereto, or presents a risk to public health and safety. See 8-200 Series Rules – Discipline.
- I. Reporting of Research Results. A Marijuana Research and Development Facility shall supply the Division with copies of all final reports, findings, or documentation regarding the outcomes of approved Research Projects.
- J. Independent Research Audit. The State Licensing Authority in its discretion may at any time require that a Marijuana Research and Development Facility undergo an audit of its research activities.
1. Circumstances Justifying Independent Research Audit. The following is a non-exhaustive list of examples that may justify an independent research audit:
    - a. The Division has reasonable grounds to believe that the Marijuana Research and Development Facility is in violation of one or more of the requirements set forth in these rules or other applicable statutes or regulations;
    - b. The Division has reasonable grounds to believe that the Marijuana Research and Development Facility's research activities present a danger to the public health and/or safety; or

- c. The Division has reasonable grounds to believe that the Marijuana Research and Development Facility has been or is engaged in research activities that have not received prior Division approval.
  - 2. Selection of An Independent Consultant. The Division and the Marijuana Research and Development Facility may attempt to mutually agree upon the selection of an independent consultant to perform a research audit. However, the Division always retains the authority to select the independent consultant regardless of whether mutual agreement can be reached.
  - 3. Costs. The Marijuana Research and Development Facility subject to an independent research audit will be responsible for all costs associated with the independent research audit, including but not limited to the auditor's fees.
  - 4. Compliance Required. A Marijuana Research and Development Facility must pay for and timely cooperate with the State Licensing Authority's requirement that it undergo an independent research audit in conformance with this Rule.
- K. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

#### **Basis and Purpose – 5-725**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(1)(i), 44-10-203(2)(s), 44-10-401(1)(a)(VII), and 44-10-507, C.R.S. The purpose of this rule is to permit laboratory testing of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana Products used by Marijuana Research and Development Facilities. The State Licensing Authority intends this rule to help maintain the integrity of Colorado's Marijuana Research and Development Facilities. This Rule 5-725 was previously Rule M 1907, 1 CCR 212-1.

#### **5-725 – Marijuana Research and Development Facility: Testing**

- A. Samples on Demand. Upon request of the Division, a Marijuana Research and Development Facility shall submit a sufficient quantity of Medical Marijuana to a Medical Marijuana Testing Facility for testing. The Division will notify the Marijuana Research and Development Facility of the results of the analysis. See Rule 3-805 – Medical Marijuana Business: Inventory Tracking System; Rule 3-905 – Business Records Required.
- B. Samples Provided for Testing. A Marijuana Research and Development Facility may provide Samples of its Medical Marijuana to a Medical Marijuana Testing Facility for testing purposes. The Marijuana Research and Development Facility shall maintain the testing results as part of its business books and records. See Rule 3-905 – Business Records Required.

#### **Basis and Purpose – 5-730**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(1)(i), 44-10-203(2)(s), 44-10-401(1)(a)(VII), and 44-10-507, C.R.S. The purpose of this rule is to establish a Marijuana Research and Development Facility may only possess an amount of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana Product Medical Marijuana approved in conjunction with the Licensee's approved Research Projects. The purpose of this rule is also to establish additional Inventory Tracking and separation requirements for Medical Marijuana cultivated for Transfer by a Marijuana Research and Development Cultivation. This Rule 5-730 was previously Rule M 1908, 1 CCR 212-1.

## **5-730 – Marijuana Research and Development Facility: Production Management and Possession Limits**

- A. Marijuana Authorized for Transfer. A Marijuana Research and Development Facility that is authorized to cultivate Medical Marijuana for Transfer to other Marijuana Research and Development Facilities may not have more than 500 Medical Marijuana plants and 20 pounds of Medical Marijuana in its Limited Access Area at any given time, unless expressly approved by the Division as part of an approved Research Project.
1. A Marijuana Research and Development Facility shall indicate in the Inventory Tracking System whether Medical Marijuana is going to be used by the Licensee in an approved Research Project or Transferred to another Marijuana Research and Development Facility. A Marijuana Research and Development Facility may cultivate Medical Marijuana prior to approval of a Research Project, except the Marijuana Research and Development Facility may only designate such Medical Marijuana as Medical Marijuana to be Transferred to other Marijuana Research and Development Facilities unless or until the Marijuana Research and Development Facility has an approved Research Project. Upon approval of a Research Project, a Marijuana Research and Development Facility shall indicate in the Inventory Tracking System whether any such Medical Marijuana authorized for Transfer will be subject to the Marijuana Research and Development Facility's research pursuant to the approved Research Project.
- B. Marijuana for Research. A Marijuana Research and Development Facility shall only possess for research the amount of Medical Marijuana approved by the Division pursuant to each of the Licensee's approved Research Projects.
- C. Separation of Marijuana Used in Research. A Marijuana Research and Development Facility shall physically separate all Medical Marijuana used in the Licensee's own approved Research Project(s) from Medical Marijuana to be Transferred to other Marijuana Research and Development Facilities for approved Research Projects.

## **Part 6 – Retail Marijuana Business License Types**

### **6-100 Series – Retail Marijuana Stores**

#### **Basis and Purpose – 6-105**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), 44-10-203(2)(dd), 44-10-401(2)(b)(l), 44-10-601, and 44-10-605, C.R.S. The purpose of this rule is to the license privileges of a Retail Marijuana Store licensee. This Rule 6-105 was previously Rule R 401.

#### **6-105 – Retail Marijuana Store: License Privileges**

- A. Licensed Premises. To the extent authorized by Rule 3-215 – Regulated Marijuana Business– Shared Licensed Premises and Operational Separation, a Retail Marijuana Store may share, and operate at, the same Licensed Premises with a commonly-owned Medical Marijuana Store. However, a separate license is required for each specific business or business entity, regardless of geographical location.
- B. Authorized Sources of Retail Marijuana. A Retail Marijuana Store may only Transfer Retail Marijuana that was obtained from another Retail Marijuana Business.
- C. Samples Provided for Testing. A Retail Marijuana Store may provide Samples of its products for testing and research purposes to a Retail Marijuana Testing Facility. The Retail Marijuana Store

shall maintain the testing results as part of its business books and records. See Rule 3-905 – Business Records Required.

- D. Authorized On-Premises Storage. A Retail Marijuana Store is authorized to store inventory on the Licensed Premises. All inventory stored on the Licensed Premises must be secured in a Limited Access Area or Restricted Access Area, and tracked consistently with the inventory tracking rules.
- E. Authorized Marijuana Transport. A Retail Marijuana Store is authorized to utilize a licensed Retail Marijuana Transporter for transportation of its Retail Marijuana so long as the place where transportation orders are taken and delivered is a licensed Retail Marijuana Business. Nothing in this Rule prevents a Retail Marijuana Store from transporting its own Retail Marijuana.
- F. Performance-Based Incentives. A Retail Marijuana Store may compensate its employees using performance-based incentives, including sales-based performance-based incentives.
- G. Authorized Transfers of Industrial Hemp Products. This rule is effective July 1, 2020. A Retail Marijuana Store may Transfer Industrial Hemp Product to a consumer only after it has confirmed:
  - 1. That the Industrial Hemp Product has passed all required testing pursuant to the 4-100 Series Rules at a Retail Marijuana Testing Facility; and
  - 2. That the Person Transferring the Industrial Hemp Product to the Retail Marijuana Store is registered with the Colorado Department of Public Health and Environment pursuant to section 25-5-426, C.R.S.
- H. Retail Marijuana Store Delivery Permit.
  - 1. Prior to January 2, 2021, all Retail Marijuana Stores are prohibited from delivering Regulated Marijuana to consumers.
  - 2. After January 2, 2021, a Retail Marijuana Store with a valid delivery permit may accept delivery orders deliver Retail Marijuana to consumers pursuant to Rule 3-615.
  - 3. A Retail Marijuana Store that does not possess a valid delivery permit cannot deliver Retail Marijuana.
- I. A Retail Marijuana Store may use an automated machine in the Restricted Access Area of its Licensed Premises to dispense Regulated Marijuana to consumers without interaction with an Owner Licensee or Employee Licensee if the automated machine is reasonably monitored and complies with all requirements of these rules including but not limited to:
  - 1. Health and safety standards,
  - 2. Testing,
  - 3. Packaging and labeling requirements,
  - 4. Inventory tracking,
  - 5. Identification requirements, and
  - 6. Transfer limits to consumers.

#### **Basis and Purpose – 6-110**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(2)(g), 44-10-203(2)(h), 44-10-203(4)(b), 44-10-203(1)(j), 44-10-401(2)(b)(l), 44-10-701(1)(a), 44-10-701(3)(d) and (f), and 44-10-601, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsections 16(3)(a), 16(5)(a)(V) and 16(5)(a)(VIII). The purpose of this rule is to clarify those acts that are limited in some fashion, or prohibited, by a licensed Retail Marijuana Store.

Regarding quantity limitations on sales, equivalencies for Retail Marijuana Concentrate and Retail Marijuana Product to Retail Marijuana flower have been included in this rule pursuant to the mandate of House Bill 14-1361. The establishment of equivalencies also provides information to stakeholders including Licensees, the general public, and law enforcement to aid in the enforcement of and compliance with the lawful personal possession limit of one ounce or less of marijuana. Setting these equivalencies provides Retail Marijuana Stores and their employees with necessary information to avoid being complicit in a patron acquiring more marijuana than is lawful to possess under the Colorado Constitution pursuant to Article XVIII, Subsection 16(3)(a).

This Rule 6-110 was previously Rule R 402, 1 CCR 212-2.

### **6-110 – Retail Marijuana Sales: General Limitations or Prohibited Acts**

- A. Sales to Persons Under 21 Years. Licensees are prohibited from Transferring, giving, or distributing Retail Marijuana to persons under 21 years of age. Licensees are prohibited from permitting a person under the age of 21 years of age from entering the Restricted Access Area.
- B. Age Verification. Prior to initiating the Transfer of Retail Marijuana, a Licensee must verify that the purchaser has a valid government-issued photo identification showing that the purchaser is 21 years of age or older.
- C. Quantity Limitations On Sales.
  - 1. A Retail Marijuana Store and its employees are prohibited from Transferring more than one ounce of Retail Marijuana flower or its equivalent in Retail Marijuana Concentrate or Retail Marijuana Product or more than six Retail Marijuana seeds in a single transaction to a consumer. A single transaction includes multiple Transfers to the same consumer during the same business day where the Retail Marijuana Store employee knows or reasonably should know that such Transfer would result in that consumer possessing more than one ounce of marijuana. In determining the imposition of any penalty for violation of this Rule 6-110(C), the State Licensing Authority will consider any mitigating and aggravating factors set forth in Rule 8-235(C).
  - 2. Equivalency. Non-edible, non-psychoactive Retail Marijuana Products including ointments, lotions, balms, and other non-transdermal topical products are exempt from the one-ounce quantity limit on Transfers. For all other Retail Marijuana Products or Retail Marijuana Concentrate, the following equivalency applies for the one ounce quantity Transfer limit:
    - a. One ounce of Retail Marijuana flower shall be equivalent to eight grams of Retail Marijuana Concentrate.
    - b. One ounce of Retail Marijuana flower shall be equivalent to 80 ten-milligram servings of THC in Retail Marijuana Product.
- D. Licensees May Refuse Sales. Nothing in these rules prohibits a Licensee from refusing to Transfer Retail Marijuana to a consumer.

- E. Sales over the Internet. A Licensee is prohibited from selling Retail Marijuana over the internet. Any Transfer of Retail Marijuana must occur within the Retail Marijuana Store's Restricted Access Area. Only a Licensee holding a valid delivery permit may make sales over the internet or deliver to a private residence.
- F. Delivery Outside Colorado Prohibited. A Retail Marijuana Store holding a valid delivery permit shall not deliver Retail Marijuana to an address that is outside the state of Colorado.
- G. Prohibited Items. A Retail Marijuana Store is prohibited from selling or giving away any consumable product that is not a Retail Marijuana Product or an Industrial Hemp Product including, but not limited to, cigarettes or tobacco products, alcohol beverages, and food products or non-alcohol beverages that are not Retail Marijuana Product.
- H. Free Product Prohibited. A Retail Marijuana Store may not give away Retail Marijuana to a consumer for any reason.
- I. Nicotine or Alcohol Prohibited. A Retail Marijuana Store is prohibited from Transferring Retail Marijuana that contain nicotine or alcohol, if the sale of the alcohol would require a license pursuant to Articles 46 or 47 of Title 12, C.R.S.
- J. Storage and Display Limitations.
1. A Retail Marijuana Store shall not display Retail Marijuana outside of a designated Restricted Access Area or in a manner in which Retail Marijuana can be seen from outside the Licensed Premises. Storage of Retail Marijuana shall otherwise be maintained in Limited Access Areas or Restricted Access Area.
  2. Any Retail Marijuana Concentrate displayed in a Retail Marijuana Store must include the potency of the concentrate on a sign next to the name of the product.
    - a. The font on the sign must be large enough for a consumer to reasonably see from the location where a consumer would usually view the concentrate.
    - b. The potency displayed on the sign must be within plus or minus fifteen percent of the concentrate's actual potency.
- K. Transfer of Expired Product Prohibited. A Retail Marijuana Store shall not Transfer any expired Retail Marijuana Product to a consumer.
- L. Transfer Restriction.
1. Sampling Units. A Retail Marijuana Store may not possess or Transfer Sampling Units.
  2. Research Transfers Prohibited. A Retail Marijuana Store shall not Transfer any Retail Marijuana to a Medical Research Facility, a Pesticide Manufacturer, or a Marijuana Research and Development Facility.
- M. Edibles Prohibited that are Shaped like a Human, Animal, or Fruit.
1. The sale of Edible Retail Marijuana Products in the following shapes is prohibited:
    - a. The distinct shape of a human, animal, or fruit; or

- b. A shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings.
  2. The prohibition on human, animal, and fruit shapes does not apply to the logo of a licensed Retail Marijuana Business. Nothing in this subparagraph (M)(2) alters or eliminates a Licensee's obligation to comply with the requirements of the 3-1000 Series Rules – Labeling, Packaging, and Product Safety.
  3. Edible Retail Marijuana Products that are geometric shapes and simply fruit flavored are not considered fruit and are permissible; and
  4. Edible Retail Marijuana Products that are manufactured in the shape of a marijuana leaf are permissible.
- N. Adverse Event Reporting. A Retail Marijuana Store that Transfers Audited Product and/or Alternative Use Product must report any adverse event related to an Audited Product and/or Alternative Use Product directly to the Retail Marijuana Products Manufacturer that Transferred the Audited Product or Alternative Use Product to the Retail Marijuana Store. The report must be submitted within forty-eight (48) hours after learning of the adverse event by the Retail Marijuana Store. For purposes of this Rule, adverse event means any untoward medical occurrence associated with the use of marijuana—this could include any unfavorable and unintended sign (including a hospitalization, emergency department visit, doctor's visit, abnormal laboratory finding), symptom or disease temporally associated with the use of a marijuana product, and may include concerns or reports on the quality or possible adverse reactions to a specific Audited Product or Alternative Use Product. To the extent known after reasonable diligence to ascertain the information, the report to the Retail Marijuana Products Manufacturer must contain the name and contact information of the complainant, the date the complaint was received, the nature of the complaint, and the name and Production Batch number of the Audited Product or Alternative Use Product.
- O. Research Transfers Prohibited. A Retail Marijuana Store shall not Transfer any Retail Marijuana to a Medical Research Facility, a Pesticide Manufacturer, or a Marijuana Research and Development Facility.
- P. Corrective and Preventive Action. This paragraph P shall be effective January 1, 2021. A Retail Marijuana Store 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. See Rule 3-905. The written procedures shall include requirements, as appropriate, for:
  1. What constitutes a Nonconformance in the Licensee's business operation;
  2. 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;
  3. Investigating the root cause of Nonconformances relating to product, processes, and the quality system;
  4. Identifying the action(s) needed to correct and prevent recurrence of Nonconformance and other quality problems;

5. Verifying the Corrective Action or Preventive Action to ensure that such action is effective and does not adversely affect finished products;
6. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;
7. 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
8. Submitting relevant information on identified quality problems and Corrective Action and Preventive Action documentation, and confirming the result of the evaluation, for management review.

Q. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

### **Basis and Purpose – 6-115**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(z), and 44-10-202(3)(h), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsections 16(5)(a)(V) and 16(5)(a)(VIII). The purpose of this rule is to establish that a Retail Marijuana Store must control and safeguard access to certain areas where Retail Marijuana and Retail Marijuana Product will be sold to the general public and prevent the diversion of Retail Marijuana and Retail Marijuana Product to people under 21 years of age. This Rule 6-115 was previously Rule R 403, 1 CCR 212-2.

### **6-115 – Point of Sale: Restricted Access Area**

- A. Identification of Restricted Access Area. All areas where Retail Marijuana are sold, possessed for sale, displayed, or dispensed for sale shall be identified as a Restricted Access Area and shall be clearly identified by the posting of a sign which shall be not less than 12 inches wide and 12 inches long, composed of letters not less than a half inch in height, which shall state, “Restricted Access Area – No One Under 21 Years of Age Allowed.”
- B. Consumers in Restricted Access Area. The Restricted Access Area must be supervised by a Licensee at all times when consumers are present to ensure that only persons who are 21 years of age or older are permitted to enter. When allowing a customer access to a Restricted Access Area, Owner Licensees and Employee Licensees shall make reasonable efforts to limit the number of consumers in relation to the number of Owners Licensees and Employee Licensees in the Restricted Access Area at any time.
- C. Display of Retail Marijuana. The display of Retail Marijuana for sale is allowed only in Restricted Access Areas. Any product displays that are readily accessible to the consumer must be supervised by the Owner Licensee or Employee Licensees at all times when consumers are present.
- D. Pregnancy Warning. Retail Marijuana Stores must post, at all times and in a prominent place inside the Restricted Access Area, a warning that is at minimum three inches high and six inches wide that reads:

**WARNING:** Using marijuana, in any form, while you are pregnant or breastfeeding passes THC to your baby and may be harmful to your baby. There is no known safe amount of marijuana use during pregnancy or breastfeeding.



## 6-200 Series – Retail Marijuana Cultivation Facilities

### Basis and Purpose – 6-205

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(h), 44-10-203(2)(j), 44-10-203(2)(r), 44-10-203(3)(c), 44-10-401(2)(b)(II), and 44-10-602, C.R.S. The purpose of this rule is to establish the license privileges granted by the State Licensing Authority to a Retail Marijuana Cultivation Facility. This Rule 6-205 was previously Rule R 501, 1 CCR 212-2.

### 6-205 – Retail Marijuana Cultivation Facility: License Privileges

- A. Licensed Premises. To the extent authorized by Rule 3-215 – Regulated Marijuana Businesses: Shared Licensed Premises and Operational Separation, a Retail Marijuana Cultivation Facility may share, and operate at, the same Licensed Premises with a commonly owned Medical Marijuana Cultivation Facility. However, a separate license is required for each specific business or business entity, regardless of geographical location. In addition, a Retail Marijuana Cultivation Facility may share, and operate at, the same Licensed Premises as a Marijuana Research and Development Facility so long as:
1. Each business or business entity holds a separate license;
  2. The Marijuana Research and Development Facility obtains an R&D Co-Location Permit;
  3. Both the Marijuana Research and Development Facility and the Retail Marijuana Cultivation Facility comply with all terms and conditions of the R&D Co-Location Permit; and
  4. Both the Marijuana Research and Development Facility and the Retail Marijuana Cultivation Facility comply with all applicable rules. See 5-700 Series Rules.
- B. Cultivation of Retail Marijuana Authorized. A Retail Marijuana Cultivation Facility may Propagate, cultivate, harvest, prepare, cure, package, store, and label Retail Marijuana, whether in concentrated form or otherwise.
- C. Authorized Transfers. A Retail Marijuana Cultivation Facility may only Transfer Retail Marijuana and Water-Based Retail Marijuana Concentrate to another Retail Marijuana Business.
1. A Retail Marijuana Cultivation Facility is also authorized to Transfer Retail Marijuana and Water-Based Retail Marijuana Concentrate to a Medical Research Facility pursuant to section 25-1.5-106.5, C.R.S., or Pesticide Manufacturer pursuant to section 44-10-202(1)(a)(II), C.R.S. and these Rules.
  2. A Retail Marijuana Cultivation Facility shall not Transfer Flowering plants or Vegetative plants to any Person except as authorized pursuant to Rule 3-605.
  3. A Retail Marijuana Cultivation Facility may Transfer Sampling Units of Retail Marijuana or Retail Marijuana Concentrate to a designated Sampling Manager in accordance with the restrictions set forth in section 44-10-602(6), C.R.S., and Rule 6-225.
  4. A Retail Marijuana Cultivation Facility may Transfer Retail Marijuana or Retail Marijuana Concentrate to another Retail Marijuana Cultivation Facility prior to testing required by these rules for the purpose of decontamination only after all other steps outlined in the Retail Marijuana Cultivation Facility's standard operating procedures have been completed, including but not limited to drying, curing, and trimming.

- D. Authorized On-Premises Storage. A Retail Marijuana Cultivation Facility is authorized to store inventory on the Licensed Premises. All inventory stored on the Licensed Premise must be secured in a Limited Access Area and tracked consistently with the inventory tracking rules.
- E. Samples Provided for Testing. A Retail Marijuana Cultivation Facility may provide Samples of its Retail Marijuana to a Retail Marijuana Testing Facility for testing and research purposes. The Retail Marijuana Cultivation Facility shall maintain the testing results as part of its business books and records. See Rule R 901 – Business Records Required.
- F. Authorized Marijuana Transport. A Retail Marijuana Cultivation Facility is authorized to utilize a licensed Retail Marijuana Transporter for transportation of its Retail Marijuana so long as the place where transportation orders are taken and delivered is a licensed Retail Marijuana Business. Nothing in this Rule prevents a Retail Marijuana Cultivation Facility from transporting its own Retail Marijuana.
- G. Performance-Based Incentives. A Retail Marijuana Cultivation Facility may compensate its employees using performance-based incentives, including sales-based performance-based incentives. However, a Retail Marijuana Cultivation Facility may not compensate a Sampling Manager using Sampling Units. See Rule 6-225 – Sampling Unit Protocols.
- H. Authorized Sources of Retail Marijuana Seeds and Immature Plants. A Retail Marijuana Cultivation Facility shall only obtain Retail Marijuana seeds or Immature Plants from its own Retail Marijuana, properly Transferred Medical Marijuana cultivated at a Medical Marijuana Cultivation Facility with at least one identical Controlling Beneficial Owner, or properly transferred from another Retail Marijuana Business pursuant to the inventory tracking requirements in the 3-800 Series Rules.
- I. Centralized Distribution Permit. A Retail Marijuana Cultivation Facility may apply to the State Licensing Authority for a Centralized Distribution Permit for authorization to temporarily store Retail Marijuana Concentrate and Retail Marijuana Product received from a Retail Marijuana Products Manufacturer for the sole purpose of Transfer to commonly owned Retail Marijuana Stores.
1. For purposes of a Centralized Distribution Permit only, the term “commonly owned” means at least one natural person has a minimum of five percent ownership in both the Retail Marijuana Cultivation Facility possessing a Centralized Distribution Permit and the Retail Marijuana Store to which the Retail Marijuana Concentrate and Retail Marijuana Product will be Transferred.
  2. To apply for a Centralized Distribution Permit, a Retail Marijuana Cultivation Facility may submit an addendum to its new or renewal application or a separate addendum prior to a renewal application on forms prepared by the Division to request a Centralized Distribution Permit. The Retail Marijuana Cultivation Facility shall send a copy of its Centralized Distribution Permit addendum to the Local Licensing Authority in the jurisdiction in which the Centralized Distribution Permit is proposed at the same time it submits the addendum to the State Licensing Authority.
  3. A Retail Marijuana Cultivation Facility that has been issued a Centralized Distribution Permit and has obtained all required approvals from the local licensing jurisdiction where it is located, if any, may accept Transfers of Retail Marijuana Concentrate and Retail Marijuana Product from a Retail Marijuana Products Manufacturer for the sole purpose of temporary storage and Transfer to commonly owned Retail Marijuana Stores.

- a. A Retail Marijuana Cultivation Facility may only accept Retail Marijuana Concentrate and Retail Marijuana Product that is packaged and labeled for sale to a consumer pursuant to the 3-1000 Series Rules.
  - b. A Retail Marijuana Cultivation Facility storing Retail Marijuana Concentrate and Retail Marijuana Product pursuant to a Centralized Distribution Permit shall not store such Retail Marijuana Concentrate or Retail Marijuana Product on the Retail Marijuana Cultivation Facility's Licensed Premises for more than 90 days from the date of receipt.
  - c. All Transfers of Retail Marijuana Concentrate and Retail Marijuana Product by a Retail Marijuana Cultivation Facility shall be without consideration.
4. All security and surveillance requirements that apply to a Retail Marijuana Cultivation Facility apply to activities conducted pursuant to the privileges of a Centralized Distribution Permit.
- J. Transition Permit. A Retail Marijuana Cultivation Facility may only operate at two geographical locations pursuant to Rule 2-255(D).

### **Basis and Purpose – 6-210**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(f), 44-10-203(2)(h), 44-10-203(2)(j), 44-10-701(2)(a), 44-10-602, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(V). The purpose of this rule is to clarify those acts that are limited in some fashion, or prohibited, by a Retail Marijuana Cultivation Facility. This Rule 6-210 was previously Rule R 502, 1 CCR 212-2.

### **6-210 – Retail Marijuana Cultivation Facility: General Limitations or Prohibited Acts**

- A. Packaging and Labeling Standards Required. A Retail Marijuana Cultivation Facility is prohibited from Transferring Retail Marijuana that is not packaged and labeled in accordance with these rules. See 3-1000 Series Rules – Labeling, Packaging, and Product Safety.
- B. Transfer to Consumer Prohibited. A Retail Marijuana Cultivation Facility is prohibited from Transferring Retail Marijuana to a consumer. This prohibition does not apply to Transfers to a Sampling Manager that comply with section 44-10-602(6), C.R.S., and Rule 6-225.
- C. Excise Tax Paid. A Retail Marijuana Cultivation Facility shall remit any applicable excise tax due pursuant to Article 28.8 of Title 39, C.R.S.
- D. Corrective and Preventive Action. This paragraph D shall be effective January 1, 2021. A Retail Marijuana Cultivation Facility 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. See Rule 3-905. The written procedures shall include requirements, as appropriate, for:
  - 1. What constitutes a Nonconformance in the Licensee's business operation;
  - 2. 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;

3. Investigating the root cause of Nonconformances relating to product, processes, and the quality system;
4. Identifying the action(s) needed to correct and prevent recurrence of Nonconformance and other quality problems;
5. Verifying the Corrective Action or Preventive Action to ensure that such action is effective and does not adversely affect finished products;
6. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;
7. 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
8. Submitting relevant information on identified quality problems and Corrective Action and Preventive Action documentation, and confirming the result of the evaluation, for management review.

### **Basis and Purpose – 6-215**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(d), 44-10-203(2)(g), 44-10-203(2)(i), 44-10-203(2)(r), 44-10-401(2)(b)(II), and 44-10-602, C.R.S. The purpose of this rule is to establish the categories of Retail Marijuana Concentrate that may be produced at a Retail Marijuana Cultivation Facility and standards for the production of Retail Marijuana Concentrate. This Rule 6-215 was previously Rule R 505, 1 CCR 212-2.

### **6-215 – Retail Marijuana Cultivation Facilities: Retail Marijuana Concentrate Production**

- A. Permitted Production of Certain Categories of Retail Marijuana Concentrate. A Retail Marijuana Cultivation Facility may only produce Water-Based Retail Marijuana Concentrate on its Licensed Premises and only in an area clearly designated as a Limited Access Area. See Rule 3-905-Business Records Required. No other method of production or extraction for Retail Marijuana Concentrate may be conducted within the Licensed Premises of a Retail Marijuana Cultivation Facility unless the Controlling Beneficial Owner(s) of the Retail Marijuana Cultivation Facility also has a valid Retail Marijuana Products Manufacturer license and the room in which Retail Marijuana Concentrate is to be produced is physically separated from all cultivation areas and has clear signage identifying the room.
- B. Safety and Sanitary Requirements for Concentrate Production. If a Retail Marijuana Cultivation Facility produces Retail Marijuana Concentrate, then all areas in which the Retail Marijuana Concentrate are produced and all Controlling Beneficial Owners and Employee Licensees engaged in the production of the Retail Marijuana Concentrate shall be subject to all of the requirements imposed upon a Retail Marijuana Products Manufacturer that produces Retail Marijuana Concentrate, including all general requirements. See 3-300 Series Rules – Health and Safety Regulations and Rule 6-315 – Retail Marijuana Products Manufacturer: Retail Marijuana Concentrate Production.
- C. Possession of Other Categories of Retail Marijuana Concentrate.
  1. It shall be considered a violation of this Rule if a Retail Marijuana Cultivation Facility possesses a Retail Marijuana Concentrate other than a Water-Based Retail Marijuana Concentrate on its Licensed Premises unless: the Controlling Beneficial Owner(s) of the Retail Marijuana Cultivation Facility also has a valid Retail Marijuana Products

Manufacturer license; or the Retail Marijuana Cultivation Facility has been issued a Centralized Distribution Permit and is in possession of the Retail Marijuana Concentrate in compliance with Rule 6-205(l).

2. Notwithstanding subparagraph (C)(1) of this Rule 6-215, a Retail Marijuana Cultivation Facility shall be permitted to possess Solvent-Based Retail Marijuana Concentrate only when the possession is due to the Transfer of Retail Marijuana flower or trim that failed microbial testing to a Retail Marijuana Products Manufacturing Facility for processing into a Solvent-Based Retail Marijuana Concentrate, and the Retail Marijuana Products Manufacturer Transfers the resultant Solvent-Based Retail Marijuana Concentrate back to the originating Retail Marijuana Cultivation Facility.
  - a. The Retail Marijuana Cultivation Facility shall comply with all requirements in Rule 4-135(C) when having Solvent-Based Retail Marijuana Concentrate manufactured out of Retail Marijuana flower or trim that failed microbial testing.
  - b. The Retail Marijuana Cultivation Facility is responsible for submitting the Solvent-Based Retail Marijuana Concentrate for all required testing for contaminants pursuant to Rule 4-120 – Regulated Marijuana Testing Program – Contaminant Testing, for potency pursuant to Rule 4-125 – Regulated Marijuana Testing Program – Potency Testing, and any other testing required or allowed by the Marijuana Rules or the Marijuana Code.
  - c. Nothing in this Rule removes or alters the responsibility of the Retail Marijuana Cultivation Facility that Transfers the Retail Marijuana that failed microbial testing from complying with the requirement to pay excise tax pursuant to Rule 6-210(C).
- D. Production of Alternative Use Product or Audited Product Prohibited. A Retail Marijuana Cultivation Facility shall not produce an Alternative Use Product or Audited Product.
- E. Possession of Alternative Use Product or Audited Product. A Retail Marijuana Cultivation Facility is authorized to possess or Transfer Alternative Use Product and/or Audited Product only if the Retail Marijuana Cultivation Facility received the Alternative Use Product and/or Audited Product pursuant to a Centralized Distribution Permit from a Retail Marijuana Products Manufacturer that is manufacturing and Transferring the Alternative Use Product or Audited Product in accordance with Rule 6-325.

### **Basis and Purpose – 6-220**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(6), 44-10-401(2)(b)(II), and 44-10-602, C.R.S. The rule establishes a means by which to manage the overall production of Retail Marijuana in the state of Colorado. The intent of this rule is to encourage responsible production to meet demand for retail marijuana consumers, while also avoiding overproduction or underproduction. The establishment of production management is necessary to ensure there is not significant under or over production, either of which will increase incentives to engage in diversion and facilitate the continuation of the sale of illegal marijuana.

Existing and prospective licensees should be on notice that the new or revised regulations may impact the production limits provided for in this rule. Additionally, throughout the rulemaking process stakeholders expressed concern over ensuring an adequate amount of licensed Retail Marijuana Stores exist to sell the amount of Retail Marijuana being produced at licensed Retail Marijuana Cultivation Facilities. Scaling the number of interests a Person may hold in Retail Marijuana Cultivation Facility licenses relative to the number of controlling interests the Person has in Retail Marijuana Store(s) has been incorporated in the production management rules as a means to address this production management concern.

The Rule 6-220 was previously Rule R 506, 1 CCR 212-2.

## **6-220 – Retail Marijuana Cultivation Facility: Production Management**

### **A. One Retail Cultivation License per Licensed Premises.**

1. One Retail Marijuana Cultivation License per Licensed Premises. Except as permitted by subparagraph (B)(2) only one Retail Marijuana Cultivation Facility License shall be permitted at each Licensed Premises and each Licensed Premises must be located at a distinct address recognized by the Local Jurisdiction.
2. Collapse after January 1, 2019. After January 1, 2019, collapse of more than one Retail Marijuana Cultivation Facility license at a single Licensed Premises through an approved change of location application shall be permitted if all Retail Marijuana Cultivation Facility licenses for which the collapse is sought meet the following requirements:
  - a. All Retail Marijuana Cultivation Facility licenses sought to be collapsed have been continuously operating for at least 180 days prior to the proposed collapse;
  - b. All Retail Marijuana Cultivation Facility licenses sought to be collapsed have identical Controlling Beneficial Owners holding identical ownership percentages;
  - c. There is no pending administrative action regarding any of the Retail Marijuana Cultivation Facility licenses sought to be collapsed;
  - d. The tier for the surviving Retail Marijuana Cultivation Facility license has not been decreased in the 180 days prior to the change of location application.
  - e. All Retail Marijuana Cultivation Facility Licensees identify the desired surviving license and agree that all other Retail Marijuana Cultivation Facility licenses will be surrendered at the time of collapse; and
  - f. Determining Tier for Surviving License.
    - i. Surviving License Tier Will Not Decrease. The tier for the surviving license will not be decreased as a result of any approved change of location application.
    - ii. Surrendered License is Tier 1 or Tier 2. For the surviving license to increase one tier or one increment of 3,600 plants if already tier 5 or higher, during the 180 days prior to the change of location application, the surrendered license must have cultivated at least 50% of the maximum authorized plant count and transferred at least 85% of the inventory it produced during that time.
    - iii. Surrendered License is Tier 3 or Higher. For the surviving license to increase by the maximum authorized plant count of the surrendered license, during the 180 days prior to the change of location application the surrendered license must have cultivated at least 50% of the maximum authorized plant count and transferred at least 85% of the inventory it produced during that time. If during the 180 days prior to the change of location application, the surrendering license did not cultivate at least 50% of the maximum authorized plant count and transfer at least 85% of the inventory it produced, the surviving license will only increase one tier or one increment of 3,600 plants if already a tier 5 or higher.

- iv. Division Determination of Tier. If a collapse results in a maximum authorized plant count in the middle of a tier, the surviving license's maximum authorized plant count will be rounded up to the top of that tier.

B. Production Management.

1. Production Management Tiers.

- a. Tier 1: 1 - 1,800 plants
- b. Tier 2: 1,801 – 3,600 plants
- c. Tier 3: 3,601 – 6,000 plants
- d. Tier 4: 6,001 – 10,200 plants
- e. Tier 5: 10,201 – 13,800+ plants
  - i. Tier 5 shall not have a cap on the maximum authorized plant count.
  - ii. The maximum authorized plant count above 10,200 plants shall increase in one or two increments of 3,600 plants. A Retail Marijuana Cultivation Facility Licensee shall be allowed to increase its maximum authorized plant count one or two increments of 3,600 plants at a time upon application and approval by the Division pursuant to the requirements of paragraph (E) of this Rule 6-220.

2. All Retail Marijuana Cultivation Facility licenses granted on or after November 30, 2015 shall be authorized to cultivate no more than 1,800 plants at any given time.

3. Immature Plants. For purposes of calculating the maximum number of authorized plants, Immature Plants are excluded.

4. Ground for Denial. The Division may deny an application for additional plants pursuant to paragraph E of this Rule if the Licensee exceeded the authorized plant count during the relevant time period for production.

5. Violation Affecting Public Safety. It may be considered a license violation affecting public safety for a Licensee to exceed the authorized plant count pursuant to these Rules.

C. Inventory Management.

1. Inventory Management for Retail Cultivation Facilities that Have One or Two Harvest Seasons a Year. Beginning the 721<sup>st</sup> day from the commencement of its first cultivation activities, a Retail Marijuana Cultivation Facility that has one or two harvest seasons a year may not accumulate Harvested Marijuana in excess of the total amount of Retail Marijuana flower and trim the Licensee reported as a package in the Inventory Tracking System that was Transferred to another Retail Marijuana Business in the previous 720 days.

2. Inventory Management for Retail Cultivation Facilities That Have More Than Two Harvest Seasons a Year. Beginning the 181<sup>st</sup> day from the commencement of its first cultivation activities, a Retail Marijuana Cultivation Facility that has more than two harvest seasons a year may not accumulate Harvested Marijuana in excess of the total amount of Retail Marijuana flower and trim the Licensee reported as a package in the Inventory Tracking

System that was Transferred to another Retail Marijuana Business in the previous 180 days.

D. Tier Decrease. For Retail Marijuana Cultivation Facilities that are authorized to cultivate more than 1,800 plants, the Division may review the purchases, Transfers, and cultivated plant count of the Retail Marijuana Cultivation Facility Licensee in connection with the license renewal process or after an investigation. Based on the Division's review, the Division may reduce the Licensee's maximum allowed plant count to a lower production management tier pursuant to subparagraph (C)(1) of this Rule. When determining whether to reduce the maximum authorized plant count, the Division may consider the following non-exhaustive factors including but not limited to:

1. The Licensee sold less than 70% of what the inventory it reported as packaged in the Inventory Tracking System during any 180 day review period;
2. On average during the previous 180 days the Licensee actually cultivated less than 90% of the maximum number of plants authorized by the next lower production management tier;
3. Whether the plants/inventory suffered a catastrophic event during the review period;
4. Excise tax payment history;
5. Existing inventory and inventory history;
6. Sales contracts; and
7. Any other factors relevant to ensuring responsible cultivation, production, and inventory management.

E. Application for Additional Plants.

1. Retail Marijuana Cultivation Facilities That Have One or Two Harvest Seasons Per Year.
  - a. After accruing at least one harvest season of Transfers, a Retail Marijuana Cultivation Facility Licensee may apply to the Division for a production management tier increase to be authorized to cultivate the number of plants in the next highest production management tier. The Division may consider the following in determining whether to approve the production management tier increase:
    - i. That during the previous harvest season prior to the tier increase application, it consistently cultivated an average amount of plants that is at least 85% of its maximum authorized plant count;
    - ii. That the Licensee Transferred at least 85% of the inventory it reported as a package in the Inventory Tracking System in the previous 360 days to another Retail Marijuana Business;
    - iii. The Division may also consider Transfers of over 85% of the inventory it reported as a package in the Inventory Tracking System during the previous 360 days, if the Licensee cultivated between 75% and 85% of its maximum authorized plant count; and
    - iv. Any other information requested to aid the Division in its evaluation of the production management tier increase application.



- b. If the Division approves the production management tier increase application, the Licensee shall pay the applicable expanded production management tier fee prior to cultivating the additional authorized plants. See Rule 2-205 –Fees.
- c. For a Licensee with an authorized plant count in tiers 2-5 to continue producing at its expanded authorized plant count, the Licensee shall pay the requisite Retail Marijuana Cultivation Facility license fee and the applicable expanded production management tier fee at license renewal. See Rule 2-205 – Fees.
- d. After accruing one harvest season during which the Retail Marijuana Cultivation Facility Transferred and consistently cultivated the Licensee may apply to increase its authorized plant count by: (a) two production management tiers or (b) if already authorized to cultivate at a production management tier 5, two increments of 3,600 plants (7,200 plants total), every 360 days. It is within the Division’s discretion to determine whether or not to grant the requested two tiers or increments of 3,600 plants (7,200 plants total).
  - i. The Licensee must demonstrate:
    - A. That the Licensee consistently cultivated an average amount of plants that is at least 90% of its maximum authorized plant count; and
    - B. That the Licensee Transferred at least 90% of the inventory it reported as a package in the Inventory Tracking System during that time period to another Retail Marijuana Business.
    - C. If the Retail Marijuana Cultivation Facility cultivated between 80% and 90% of its maximum authorized plant count, the Division may also consider Transfers of over 90% of the inventory it reported as a package in the Inventory Tracking System during that time period and/or Transfers into the Retail Marijuana Cultivation Facility or related Retail Marijuana Store(s).
  - ii. In making its determination, the Division may consider the following exclusive factors:
    - A. The Retail Marijuana Cultivation currently has possession of, or has entered into a written agreement or contract to possess, sufficient space to grow the requested two tiers or two 3,600 plant increments;
    - B. The Retail Marijuana Cultivation Facility cultivated at least 90% of its maximum authorized plant count and during the preceding 360 days the Retail Marijuana Cultivation Facility and/or any commonly owned Retail Marijuana Store Transferred in Retail Marijuana from one or more unrelated Retail Marijuana Cultivation Facility(ies);
    - C. The Retail Marijuana Cultivation has contracts for the sale of Retail Marijuana in the next 360 days supporting the requested two tiers or two increments of 3,600 plants;

- D. An established history of responsible cultivation and Transfer by the Retail Marijuana Cultivation;
- E. Any history of noncompliance with the Retail Code, Marijuana Code, and/or Rules by the Retail Marijuana Cultivation Facility, or any commonly owned Retail Marijuana Business, and/or any investigation of, or administrative action(s) against, the Retail Marijuana Cultivation Facility, or any commonly owned Retail Marijuana Business; or
- F. Any other pertinent facts or circumstances regarding responsible production and inventory management.

2. Retail Marijuana Cultivation Facilities that have more than two harvest seasons per year.

- a. After a 180-day period during which the Retail Marijuana Cultivation Facility Transferred and consistently cultivated, the Licensee may apply to the Division for a production management tier increase to be authorized to cultivate the number of plants in the next highest production management tier. The Division may consider the following in determining whether to approve the production management tier increase:
  - i. That for 180 days prior to the tier increase application, the Licensee consistently cultivated an average amount of plants that is at least 85% of its maximum authorized plant count, and
  - ii. That the Licensee Transferred at least 85% of the inventory it reported as a package in the Inventory Tracking System during that time period to another Retail Marijuana Business.
  - iii. The Division may also consider Transfers of over 85% of the inventory it reported as a package in the Inventory Tracking System during the 180-day time period if the Licensee cultivated between 75% and 85% of its maximum authorized plant count.
  - iv. Any other information requested to aid the Division in its evaluation of the tier increase application.
- b. If the Division approves the production management tier increase application, the Licensee shall pay the applicable expanded production management tier fee prior to cultivating the additional authorized plants. See Rule 2-205 – Fees.
- c. For a Licensee with an authorized plant count in tier 2-5 to continue producing at its expanded authorized plant count, the Licensee shall pay the requisite Retail Marijuana Cultivation Facility license fee and the applicable expanded production management tier fee at license renewal. See Rule 2-205 – Fees.
- d. After accruing 180 days during which the Retail Marijuana Cultivation Facility Transferred and consistently cultivated the Licensee may apply to increase its authorized plant count by: (a) two production management tiers or (b) if already authorized to cultivate at a tier 5, two increments of 3,600 plants (7,200 plants total) every 180 days. It is within the Division's discretion to determine whether or not to grant the requested two tier or two increments of 3,600 plants (7,200 plants total).

- i. The Licensee must demonstrate:
    - A. That the Licensee consistently cultivated an average amount of plants that is at least 90% of its maximum authorized plant count; and
    - B. That the Licensee Transferred at least 90% of the inventory it reported as a package in the Inventory Tracking System during that time period to another Retail Marijuana Business;
    - C. If the Retail Marijuana Cultivation Facility cultivated between 80% and 90% of its maximum authorized plant count, the Division may also consider Transfers of over 90% of the inventory it reported as a package in the Inventory Tracking system during that time period and/or Transfers into the Retail Marijuana Cultivation Facility or related Retail Marijuana Store(s).
  - ii. In making its determination, the Division may consider the following exclusive factors:
    - A. The Retail Marijuana Cultivation currently has possession of, or has entered into a written agreement or contract to possess, sufficient space to grow the requested two tiers or two increments of 3,600 plants;
    - B. The Retail Marijuana Cultivation Facility cultivated at least 90% of its maximum authorized plant count and during the preceding 180 days the Retail Marijuana Cultivation Facility and/or any commonly owned Retail Marijuana Store Transferred in Retail Marijuana from one or more unrelated Retail Marijuana Cultivation Facility(ies);
    - C. The Retail Marijuana Cultivation has entered into a written agreement(s) or contract(s) for the sale of Retail Marijuana in the next 180 days supporting the requested two tiers or two increments of 3,600 plants;
    - D. An established history of responsible cultivation and Transfer by the Retail Marijuana Cultivation;
    - E. Any history of noncompliance with the Retail Code, Marijuana Code, and/or Rules by the Retail Marijuana Cultivation Facility or any commonly owned Retail Marijuana Business(es), and/or any investigation of, or administrative action(s) against, the Retail Marijuana Cultivation Facility or any commonly owned Retail Marijuana Business;
    - F. Any other pertinent facts or circumstances regarding responsible production and inventory management.
3. Application for Tier Increase. Applications for a tier increase that include any artificial increase of plant count, manipulation of Transfer history, or other misrepresentation will be denied. In addition to denial, any artificial increase of plant count, manipulation of

Transfer history, or other misrepresentation is a public safety violation that may result in administrative action.

F. Maximum Allowed Retail Marijuana Cultivation Facility Licenses.

1. A Person that is a Controlling Beneficial Owner in Three or More Retail Marijuana Cultivation Facility Licenses. For every multiple of three Retail Marijuana Cultivation Facility licenses in which a Person is a Controlling Beneficial Owner, the Person must also be a Controlling Beneficial Owner in at least one Retail Marijuana Store. For example: (1) a Person that is a Controlling Beneficial Owner in three, four, or five Retail Marijuana Cultivation Facility licenses also must be a Controlling Beneficial Owner in at least one Retail Marijuana Store; (2) a Person that is a Controlling Beneficial Owner in six, seven, or eight Retail Marijuana Cultivation Facility licenses also must be a Controlling Beneficial Owner in at least two Retail Marijuana Stores; (3) a Person that is a Controlling Beneficial Owner in nine, ten, or eleven Retail Marijuana Cultivation Facility licenses also must be a Controlling Beneficial Owner in at least three Retail Marijuana Stores; etc.
2. A Person that is a Controlling Beneficial Owner in Less than Three Retail Marijuana Cultivation Facility Licenses. A Person that is a Controlling Beneficial Owner in less than three Retail Marijuana Cultivation Facility licenses shall not be required to be a Controlling Beneficial Owner in a Retail Marijuana Store.

- G. The State Licensing Authority, at its sole discretion, may adjust any of the plant limits described in this Rule on an industry-wide aggregate basis for all Retail Marijuana Cultivation Facility Licensees subject to that limitation.

**Basis and Purpose – 6-225**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-401(2)(b)(II), and 44-10-602(6), C.R.S. The purpose of this rule is to establish the circumstances under which a Retail Marijuana Cultivation Facility may provide Sampling Units to a designated Sampling Manager for quality control or product development purposes. In order to maintain the integrity of Colorado's Regulated Marijuana Businesses, this rule establishes limits on the amount of Sampling Units a Sampling Manager may receive in a calendar month and imposes inventory tracking, reporting and recordkeeping requirements on a Retail Marijuana Cultivation Facility that Transfer Sampling Units. This Rule 6-225 was previously Rule R 507, 1 CCR 212-2.

**6-225 – Sampling Unit Protocols**

- A. Designation of Sampling Manager(s). In any calendar month, a Retail Marijuana Cultivation Facility may designate no more than five Sampling Managers in the Inventory Tracking System.
1. Only management personnel of the Retail Marijuana Cultivation Facility who holds an Owner License or an Employee License may be designated as a Sampling Manager.
  2. A person may be designated as a Sampling Manager by more than one Medical Marijuana Business or Retail Marijuana Business.
  3. By virtue of the decision to be designated as a Sampling Manager, the Sampling Manager expressly consents to being identified in the Inventory Tracking System and makes a voluntary decision that any Sampling Units Transferred to the Sampling Manager will be identified in the Inventory Tracking System.

4. A Retail Marijuana Cultivation Facility that wishes to provide Sampling Units to a Sampling Manager shall first establish and provide to each Sampling Manager standard operating procedures that explain the requirements of section 44-10-602(6), C.R.S., the personal possession limits pursuant to section 18-18-406, C.R.S., and the requirements of this Rule 6-225. See *also* Rule 3-905 – Business Records Required. A Retail Marijuana Cultivation Facility shall maintain and update such standard operating procedures as necessary to reflect accurately any changes in the relevant statutes and rules.
- B. Sampling Unit Limits. Only one Sampling Unit may be designated per Harvest Batch or Production Batch. A Sampling Unit shall not be designated until the Harvest Batch or Production Batch has satisfied the testing requirements in the 4-100 Series Rules – Regulated Marijuana Testing Program.
1. A Sampling Unit of Retail Marijuana flower or trim shall not exceed one gram.
  2. A Sampling Unit of Retail Marijuana Concentrate shall not exceed one-quarter of one gram; except that a Sampling Unit of Retail Marijuana Concentrate which has the intended use of being delivered in a vaporized form shall not exceed one-half of one gram.
- C. Excise Tax Requirements. A Retail Marijuana Cultivation Facility must pay excise tax on Sampling Units of Retail Marijuana flower or trim, based on the average market rate of the unprocessed Retail Marijuana.
- D. Transfer Restrictions.
1. No Sampling Unit shall be Transferred unless it is packaged and labeled in accordance with the requirements in the 3-1000 Series Rules – Labeling, Packaging, and Product Safety.
  2. No Sampling Unit shall be Transferred to any individual who is not currently designated in the Inventory Tracking System by the Retail Marijuana Cultivation Facility as a Sampling Manager for the calendar month in which the Transfer occurs.
  3. In any calendar month, a Sampling Manager shall not receive Sampling Units totaling more than one ounce of Retail Marijuana or eight grams of Retail Marijuana Concentrate.
  4. The monthly limit established in subparagraph (D)(3) applies to each Sampling Manager, regardless of the number of Retail Marijuana Businesses with which the Sampling Manager is associated.
  5. A Sampling Manager shall not accept Sampling Units in excess of the monthly limit established in subparagraph (D)(3). Before Transferring any Sampling Units, a Retail Marijuana Cultivation Facility shall verify with the recipient Sampling Manager that the Sampling Manager will not exceed the monthly limits established in subparagraph (D)(3).
  6. A Sampling Manager shall not Transfer any Sampling Unit to any other Person, including but not limited to any other Person designated as a Sampling Manager.
- E. Compensation Prohibited. A Retail Marijuana Cultivation Facility may not use Sampling Units to compensate a Sampling Manager.
- F. On-Premises Consumption Prohibited. A Sampling Manager shall not consume any Sampling Unit on any Licensed Premises.

- G. Acceptable Purposes. Sampling Units shall only be designated and Transferred for the purposes of quality control and product development in accordance with section 44-10-602(6), C.R.S.
- H. Record keeping requirements. A Retail Marijuana Cultivation Facility shall maintain copies of any material documents created regarding the quality control and product development purpose(s) of each Sampling Unit. Such documents shall constitute business records under Rule 3-905 – Business Records Required. At a minimum, a Retail Marijuana Cultivation Facility shall maintain records that show whether a Sampling Unit Transferred to a Sampling Manager is for the purpose of quality control or product development. A Retail Marijuana Cultivation Facility shall also maintain copies of the Retail Marijuana Cultivation Facility’s standard operating procedures provided to Sampling Managers
- I. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

**6-300 Series – Retail Marijuana Products Manufacturing Facilities**

**Basis and Purpose – 6-305**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(2)(g), 44-10-203(2)(i), 44-10-203(2)(y), 44-10-307(1)(j), 44-10-401(2)(b)(III), 44-10-603, C.R.S. The purpose of this rule is to establish the license privileges granted by the State Licensing Authority to a Retail Marijuana Products Manufacturer. This Rule 6-305 was previously Rule R 601, 1 CCR 212-2.

**6-305 – Retail Marijuana Products Manufacturer: License Privileges**

- A. Licensed Premises. A separate license is required for each specific business or business entity and geographical location. A Retail Marijuana Products Manufacturer may share, and operate at, the same Licensed Premises with a commonly owned Medical Marijuana Products Manufacturer. However, a separate license is required for each specific business or business entity, regardless of geographical location. In addition, a Retail Marijuana Products Manufacturer may share, and operate at, the same Licensed Premises as a Marijuana Research and Development Facility so long as:
  - 1. Each business or business entity holds a separate license;
  - 2. The Marijuana Research and Development Facility obtains an R&D Co-Location Permit;
  - 3. Both the Marijuana Research and Development Facility and the Retail Marijuana Products Manufacturer comply with all terms and conditions of the R&D Co-Location Permit; and
  - 4. Both the Marijuana Research and Development Facility and the Retail Marijuana Products Manufacturer comply with all applicable rules. See 5-700 Series Rules.
- B. Authorized Transfers. A Retail Marijuana Products Manufacturer is authorized to Transfer Retail Marijuana as follows:
  - 1. Retail Marijuana Concentrate and Retail Marijuana Product.
    - a. A Retail Marijuana Products Manufacturer may Transfer Retail Marijuana Concentrate or Retail Marijuana Product to Retail Marijuana Stores, other Retail Marijuana Products Manufacturers , Retail Marijuana Testing Facilities, Retail

Marijuana Hospitality and Sales Businesses, Medical Research Facilities, and Pesticide Manufacturers.

- b. A Retail Marijuana Products Manufacturer may Transfer Retail Marijuana Product and Retail Marijuana Concentrate to a Retail Marijuana Cultivation Facility that has been issued a Centralized Distribution Permit.
  - i. Prior to any Transfer pursuant to this Rule 6-305(B)(1)(b), a Retail Marijuana Products Manufacturer shall verify the Retail Marijuana Cultivation Facility possesses a valid Centralized Distribution Permit. See Rule 6-205 – Retail Marijuana Cultivation Facility: License Privileges.
  - ii. For any Transfer pursuant to this Rule 6-305(B)(1)(b), A Retail Marijuana Products Manufacturer shall only Transfer Retail Marijuana Product and Retail Marijuana Concentrate that is packaged and labeled for Transfer to a consumer. See 3-1000 Series Rules.

- 2. Retail Marijuana. A Retail Marijuana Products Manufacturer may Transfer Retail Marijuana to other Retail Marijuana Products Manufacturer, Retail Marijuana Testing Facilities, and Retail Marijuana Stores.
- 3. Sampling Units. A Retail Marijuana Products Manufacturer may also Transfer Sampling Units of its own Retail Marijuana Concentrate or Retail Marijuana Product to a designated Sampling Manager in accordance with the restrictions set forth in section 44-10-603(10), C.R.S., and Rule 6-320.

C. Manufacture of Retail Marijuana Concentrate and Retail Marijuana Product Authorized. A Retail Marijuana Products Manufacturer may manufacture, prepare, package, store, and label Retail Marijuana Concentrate and Retail Marijuana Product, whether in concentrated form or that are comprised of Retail Marijuana and other Ingredients intended for use or consumption, such as Edible Retail Marijuana Products, ointments, or tinctures.

- 1. Industrial Hemp Product Authorized. This subparagraph (C)(1) is effective July 1, 2020. A Retail Marijuana Products Manufacturer that uses Industrial Hemp Product as an Ingredient in the manufacture and preparation of Retail Marijuana Product must comply with this subparagraph (C)(1) of this Rule.
  - a. Prior to accepting and taking possession of any Industrial Hemp Product for use as an Ingredient in a Retail Marijuana Product the Retail Marijuana Products Manufacturer shall verify the following:
    - i. That the Industrial Hemp Product has passed all required testing pursuant to the 4-100 Series Rules at a Retail Marijuana Testing Facility; and
    - ii. That the Person Transferring the Industrial Hemp Product to the Retail Marijuana Products Manufacturer is registered with the Colorado Department of Public Health and Environment pursuant to section 25-5-426, C.R.S.

D. Location Prohibited. A Retail Marijuana Products Manufacturer may not manufacture, prepare, package, store, or label Retail Marijuana Concentrate or Retail Marijuana Product in a location that is operating as a retail food establishment.

- E. Samples Provided for Testing. A Retail Marijuana Products Manufacturer may provide samples of its Retail Marijuana Concentrate or Retail Marijuana Product to a Retail Marijuana Testing Facility for testing and research purposes. The Retail Marijuana Products Manufacturer shall maintain the testing results as part of its business books and records. See Rule 3-905 – Business Records Required.
- F. Authorized Marijuana Transport. A Retail Marijuana Products Manufacturer is authorized to utilize a Retail Marijuana Transporter for transportation of its Retail Marijuana so long as the place where transportation orders are taken is a Retail Marijuana Business and the transportation order is delivered to a Retail Marijuana Business, Medical Research Facility, or Pesticide Manufacturer. Nothing in this Rule prevents a Retail Marijuana Products Manufacturer from transporting its own Retail Marijuana.
- G. Performance-Based Incentives. A Retail Marijuana Products Manufacturer may compensate its employees using performance-based incentives, including sales-based performance-based incentives. However, a Retail Marijuana Products Manufacturer may not compensate a Sampling Manager using Sampling Units. See Rule 6-320 – Sampling Unit Protocols.

### **Basis and Purpose – 6-310**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(f), 44-10-203(2)(g), 44-10-203(2)(h), 44-10-203(2)(i), 44-10-203(2)(y), 44-10-203(3)(d), 44-10-401(2)(b)(III), 44-10-603, and 44-10-701(2)(a), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(V). The purpose of this rule is to clarify those acts that are limited in some fashion or prohibited by a Retail Marijuana Products Manufacturer. This Rule 6-310 was previously Rule R 602, 1 CCR 212-2.

### **6-310 – Retail Marijuana Products Manufacturer: General Limitations or Prohibited Acts**

- A. Packaging and Labeling Standards Required. A Retail Marijuana Products Manufacturer is prohibited from Transferring Retail Marijuana Concentrate or Retail Marijuana Product that are not properly packaged and labeled. See 3-1000 Series Rules – Labeling, Packaging, and Product Safety.
- B. THC Content Container Restriction. Each individually packaged Edible Retail Marijuana Product, even if comprised of multiple servings, may include no more than a total of 100 milligrams of active THC. See Rule 3-1010 – Packaging and Labeling – General Requirements Prior to Transfer to a Consumer.
  - 1. Exception for Bulk Transfers to Retail Marijuana Hospitality and Sales Businesses. An individually packaged Edible Retail Marijuana Product comprised of multiple servings that is Transferred in bulk to a Retail Marijuana Hospitality and Sales Establishment may include more than a total of 100 milligrams of active THC.
    - i. A Retail Marijuana Products Manufacturer shall develop and maintain standard operating procedures, and any additional equipment necessary, to ensure that a Retail Marijuana Hospitality and Sales Business receiving bulk Transfers of Edible Retail Marijuana Product can measure accurately the Edible Retail Marijuana Product in single serving sizes equal to or less than 10 milligrams of active THC per serving.
- C. Transfer to Consumer Prohibited. A Retail Marijuana Products Manufacturer is prohibited from Transferring Retail Marijuana to a consumer. This prohibition does not apply to Transfers to a Sampling Manager that comply with section 44-10-603(10), C.R.S., and Rule 6-320.



- D. Adequate Care of Perishable Product. A Retail Marijuana Products Manufacturer must provide adequate refrigeration for perishable Retail Marijuana Product that will be consumed and shall utilize adequate storage facilities and transport methods.
- E. Homogeneity of Edible Retail Marijuana Product. A Retail Marijuana Products Manufacturer must ensure that its manufacturing processes are designed so that the Cannabinoid content of any Edible Retail Marijuana Product is homogenous.
- F. Use of Ingredients. A Retail Marijuana Products Manufacturer must obtain and maintain certificates of analysis or other records demonstrating the full composition of each Ingredient used in the manufacture of Vaporizer Delivery Devices or Pressurized Metered Dose Inhalers.
- G. Corrective and Preventive Action. This paragraph G shall be effective January 1, 2021. A Retail Marijuana Products 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. See Rule 3-905. The written procedures shall include requirements, as appropriate, for:
1. What constitutes a Nonconformance in the Licensee's business operation.
  2. 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;
  3. Investigating the root cause of Nonconformances relating to product, processes, and the quality system;
  4. Identifying the action(s) needed to correct and prevent recurrence of Nonconformance and other quality problems;
  5. Verifying the Corrective Action or Preventive Action to ensure that such action is effective and does not adversely affect finished products;
  6. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;
  7. 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
  8. Submitting relevant information on identified quality problems and Corrective Action and Preventive Action documentation, and confirming the result of the evaluation, for management review.

### **Basis and Purpose – 6-315**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(g), 44-10-203(2)(i), 44-10-401(2)(b)(III), and 44-10-603, C.R.S. The purpose of this rule is to establish the categories of Retail Marijuana Concentrate that may be produced at a Retail Marijuana Products Manufacturer and establish standards for the production of Retail Marijuana Concentrate. Nothing in this rule authorizes the unlicensed practice of engineering under Article 25 of Title 12, C.R.S. This Rule 6-315 was previously Rule R 605, 1 CR 212-2.

**6-315 – Retail Marijuana Products Manufacturing Facility: Retail Marijuana Concentrate Production.**

A. Permitted Categories of Retail Marijuana Concentrate Production.

1. A Retail Marijuana Products Manufacturer may produce Water-Based Retail Marijuana Concentrate, Food-Based Retail Marijuana Concentrate and Heat/Pressure-Based Retail Marijuana Concentrate.
2. A Retail Marijuana Products Manufacturer may also produce Solvent-Based Retail Marijuana Concentrate using only the following solvents: butane, propane, CO<sub>2</sub>, ethanol, isopropanol, acetone, heptane, ethyl acetate, and pentane. The use of any other solvent is expressly prohibited unless and until it is approved by the Division.
3. A Retail Marijuana Products Manufacturer may submit a request to the Division to consider the approval of solvents not permitted for use under this Rule during the next formal rulemaking.

B. General Applicability. A Retail Marijuana Products Manufacturer that engages in the production of Retail Marijuana Concentrate, regardless of the method of extraction or category of concentrate being produced, must:

1. Ensure that the space in which any Retail Marijuana Concentrate is to be produced is a fully enclosed room and clearly designated on the current diagram of the Licensed Premises. See Rule 3-905- Business Records Required.
2. Ensure that all applicable sanitary rules are followed. See 3-300 Series Rules.
3. Ensure that the standard operating procedure for each method used to produce a Retail Marijuana Concentrate includes, but need not be limited to, step-by-step instructions on how to safely and appropriately:
  - a. Conduct all necessary safety checks prior to commencing production;
  - b. Prepare Retail Marijuana for processing;
  - c. Extract Cannabinoids and other essential components of Retail Marijuana;
  - d. Purge any solvent or other unwanted components from a Retail Marijuana Concentrate,
  - e. Clean all equipment, counters and surfaces thoroughly; and
  - f. Dispose of any waste produced during the processing of Retail Marijuana in accordance with all applicable local, state and federal laws, rules and regulations. See Rule 3-230 – Waste Disposal.
4. Establish written and documentable quality control procedures designed to maximize safety for Owner Licensees and Employee Licensees and minimize potential product contamination.
5. Establish written emergency procedures to be followed by Owner Licensees or Employee Licensees in case of a fire, chemical spill or other emergency.

6. Have a comprehensive training manual that provides step-by-step instructions for each method used to produce a Retail Marijuana Concentrate. The training manual must include, but need not be limited to, the following topics:
    - a. All standard operating procedures for each method of concentrate production used;
    - b. The Retail Marijuana Products Manufacturer's quality control procedures;
    - c. The emergency procedures;
    - d. The appropriate use of any necessary safety or sanitary equipment;
    - e. The hazards presented by all solvents used as described in the safety data sheet for each solvent;
    - f. Clear instructions on the safe use of all equipment involved in each process and in accordance with manufacturer's instructions, where applicable; and
    - g. Any additional periodic cleaning required to comply with all applicable sanitary rules.
  7. Provide adequate training to every Owner Licensee or Employee Licensee prior to that individual undertaking any step in the process of producing a Retail Marijuana Concentrate.
    - a. Adequate training must include, but need not be limited to, providing a copy of the training manual for that Licensed Premises and live, in-person instruction detailing at least all of the topics required to be included in the training manual.
    - b. The individual training an Owner Licensee or Employee Licensee must sign and date a document attesting that all required aspects of training were conducted and that he or she is confident that the Owner Licensee or Employee Licensee can safely produce a Retail Marijuana Concentrate. See Rule 3-905 – Business Records Required.
    - c. The Owner Licensee or Employee Licensee that received the training must sign and date a document attesting that he or she can safely implement all standard operating procedures, quality control procedures, and emergency procedures, operate all closed-loop extraction systems, use all safety, sanitary and other equipment and understands all hazards presented by the solvents to be used within the Licensed Premises and any additional period cleaning required to maintain compliance with all applicable sanitary rules. See Rule 3-905 – Business Records Required.
  8. Maintain clear and comprehensive records of the name, signature and Owner Licensee or Employee License number of every individual who engaged in any step related to the creation of a Production Batch of Retail Marijuana Concentrate and the step that individual performed. See Rule 3-905 – Business Records Required.
- C. Water-Based Retail Marijuana Concentrate, Food-Based Retail Marijuana Concentrate and Heat/Pressure-Based Retail Marijuana Concentrate. A Retail Marijuana Products Manufacturer that engages in the production of a Retail Marijuana Concentrate must:

1. Ensure that all equipment, counters and surfaces used in the production of Retail Marijuana Concentrate is food-grade including ensuring that all counters and surface areas were constructed in such a manner that it reduces the potential for the development of microbials, molds and fungi and can be easily cleaned.
2. Ensure that all equipment, counters, and surfaces used in the production of a Retail Marijuana Concentrate are thoroughly cleaned after the completion of each Production Batch.
3. Ensure that any room in which dry ice is stored or used in processing Retail Marijuana into a Retail Marijuana Concentrate is well ventilated to prevent against the accumulation of dangerous levels of CO<sub>2</sub>.
4. Ensure that the appropriate safety or sanitary equipment, including personal protective equipment, is provided to, and appropriately used by, each Owner Licensee or Employee Licensee engaged in the production of a Retail Marijuana Concentrate.
5. Ensure that only finished drinking water and ice made from finished drinking water is used in the production of a Water-Based Retail Marijuana Concentrate.
6. Ensure that if propylene glycol or glycerin is used in the production of a Food-Based Retail Marijuana Concentrate, then the propylene glycol or glycerin to be used is food-grade.
7. Follow all of the rules related to the production of a Solvent-Based Retail Marijuana Concentrate if a pressurized system is used in the production of a Retail Marijuana Concentrate.

D. Solvent-Based Retail Marijuana Concentrate. A Retail Marijuana Products Manufacturer that engages in the production of Solvent-Based Retail Marijuana Concentrate must:

1. Obtain a report from an Industrial Hygienist or a Professional Engineer that certifies that the equipment, Licensed Premises and standard operating procedures comply with these rules and all applicable local and state building codes, fire codes, electrical codes and other laws. If a Local Jurisdiction has not adopted a local building code or fire code or if local regulations do not address a specific issue, then the Industrial Hygienist or Professional Engineer shall certify compliance with the International Building Code of 2012 (<http://www.iccsafe.org>), the International Fire Code of 2012 (<http://www.iccsafe.org>) or the National Electric Code of 2014 (<http://www.nfpa.org>), as appropriate. Note that this Rule does not include any later amendments or editions to each Code. The Division has maintained a copy of each code, each of which is available to the public;
  - a. Flammable Solvent Determinations. If a Flammable Solvent is to be used in the processing of Retail Marijuana into a Retail Marijuana Concentrate, then the Industrial Hygienist or Professional Engineer must:
    - i. Establish a maximum amount of Flammable Solvents and other flammable materials that may be stored within that Licensed Premises in accordance with applicable laws, rules and regulations;
    - ii. Determine what type of electrical equipment, which may include but need not be limited to outlets, lights and junction boxes, must be installed within the room in which Retail Marijuana Concentrate is to be produced

- or Flammable Solvents are to be stored in accordance with applicable laws, rules and regulations;
- iii. Determine whether a gas monitoring system must be installed within the room in which Retail Marijuana Concentrate is to be produced or Flammable Solvents are to be stored, and if required the system's specifications, in accordance with applicable laws, rules and regulations; and
  - iv. Determine whether fire suppression system must be installed within the room in which Retail Marijuana Concentrate is to be produced or Flammable Solvents are to be stored, and if required the system's specifications, in accordance with applicable laws, rules and regulations.
- b. CO<sub>2</sub> Solvent Determination. If CO<sub>2</sub> is used as solvent at the Licensed Premises, then the Industrial Hygienist or Professional Engineer must determine whether a CO<sub>2</sub> gas monitoring system must be installed within the room in which Retail Marijuana Concentrate is to be produced or CO<sub>2</sub> is stored, and if required the system's specifications, in accordance with applicable laws, rules and regulations.
  - c. Exhaust System Determination. The Industrial Hygienist or Professional Engineer must determine whether a fume vent hood or exhaust system must be installed within the room in which Retail Marijuana Concentrate is to be produced, and if required the system's specifications, in accordance with applicable laws, rules and regulations.
  - d. Material Change. If a Retail Marijuana Products Manufacturer makes a Material Change to its Licensed Premises, equipment or a concentrate production procedure, in addition to all other requirements, it must obtain a report from an Industrial Hygienist or Professional Engineer re-certifying its standard operating procedures and, if changed, its Licensed Premises and equipment as well.
  - e. Manufacturer's Instructions. The Industrial Hygienist or Professional Engineer may review and consider any information provided to the Retail Marijuana Products Manufacturer by the designer or manufacturer of any equipment used in the processing of Retail Marijuana into a Retail Marijuana Concentrate.
  - f. Records Retention. A Retail Marijuana Products Manufacturer must maintain copy of all reports received from an Industrial Hygienist and Professional Engineer on its Licensed Premises. Notwithstanding any other law, rule, or regulation, compliance with this Rule is not satisfied by storing these reports outside of the Licensed Premises. Instead the reports must be maintained on the Licensed Premises until the Licensee ceases production of Retail Marijuana Concentrate on the Licensed Premises.
- 2. Ensure that all equipment, counters and surfaces used in the production of a Solvent-Based Retail Marijuana Concentrate are food-grade and do not react adversely with any of the solvents to be used in the Licensed Premises. Additionally, all counters and surface areas must be constructed in a manner that reduces the potential development of microbials, molds and fungi and can be easily cleaned;
  - 3. Ensure that the room in which Solvent-Based Retail Marijuana Concentrate shall be produced must contain an emergency eye-wash station;

4. Ensure that only a professional grade, closed-loop extraction system capable of recovering the solvent is used to produce Solvent-Based Retail Marijuana Concentrate;
  - a. UL or ETL Listing.
    - i. If the system is UL or ETL listed, then a Retail Marijuana Products Manufacturer may use the system in accordance with the manufacturer's instructions.
    - ii. If the system is UL or ETL listed but the Retail Marijuana Products Manufacturer intends to use a solvent in the system that is not listed in the manufacturer's instructions for use in the system, then, prior to using the unlisted solvent within the system, the Retail Marijuana Products Manufacturer must obtain written approval for use of the non-listed solvent in the system from either the system's manufacturer or a Professional Engineer after the Professional Engineer has conducted a peer review of the system. In reviewing the system, the Professional Engineer shall review and consider any information provided by the system's designer or manufacturer.
    - iii. If the system is not UL or ETL listed, then there must a designer of record. If the designer of record is not a Professional Engineer, then the system must be peer reviewed by a Professional Engineer. In reviewing the system, the Professional Engineer shall review and consider any information provided by the system's designer or manufacturer.
  - b. Ethanol or Isopropanol. A Retail Marijuana Products Manufacturer need not use a professional grade, closed-loop system extraction system capable of recovering the solvent for the production of a Solvent-Based Retail Marijuana Concentrate if ethanol or isopropanol are the only solvents being used in the production process.
5. Ensure that all solvents used in the extraction process are food-grade or at least 99% pure;
  - a. A Retail Marijuana Products Manufacturer must obtain a safety data sheet for each solvent used or stored on the Licensed Premises. A Retail Marijuana Products Manufacturer must maintain a current copy of the safety data sheet and a receipt of purchase for all solvents used or to be used in an extraction process. See Rule 3-905 – Business Records Required.
  - b. A Retail Marijuana Products Manufacturer is prohibited from using denatured alcohol to produce a Retail Marijuana Concentrate, unless the denaturant is an approved solvent listed in Rule 6-315(A)(2) and the alcohol and the denaturant meet all other requirements set forth in this Rule.
6. Ensure that all Flammable Solvents or other flammable materials, chemicals and waste are stored in accordance with all applicable laws, rules and regulations. At no time may a Retail Marijuana Products Manufacturer store more Flammable Solvent on its Licensed Premises than the maximum amount established for that Licensed Premises by the Industrial Hygienist or Professional Engineer;
7. Ensure that the appropriate safety and sanitary equipment, including personal protective equipment, is provided to, and appropriately used by, each Owner Licensee or Employee

Licensee engaged in the production of a Solvent-Based Retail Marijuana Concentrate;  
and

8. Ensure that a trained Owner Licensee or Employee Licensee is present at all times during the production of a Solvent-Based Retail Marijuana Concentrate whenever an extraction process requires the use of pressurized equipment.
- E. Ethanol and Isopropanol. If a Retail Marijuana Products Manufacturer only produces Solvent-Based Retail Marijuana Concentrate using ethanol or isopropanol at its Licensed Premises and no other solvent, then it shall be considered exempt from paragraph D of this Rule and instead must follow the requirements in paragraph C of this Rule. Regardless of which rule is followed, the ethanol or isopropanol must be food grade or at least 99% pure and denatured alcohol cannot be used. The Retail Marijuana Products Manufacturer shall comply with contaminant testing required in Rule 4-120(C)(4).
- F. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

### **Basis and Purpose – 6-320**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(2)(d), 44-10-203(1)(j), 44-10-203(2)(h), 44-10-401(2)(b)(III), and 44-10-603(10), C.R.S. The purpose of this rule is to establish the circumstances under which a Retail Marijuana Products Manufacturer may provide Sampling Units to a designated Sampling Manager for quality control or product development purposes. In order to maintain the integrity of Colorado's regulated Retail Marijuana Businesses, this rule establishes limits on the amount of Sampling Units a Sampling Manager may receive in a calendar month and imposes inventory tracking, reporting and recordkeeping requirements on a Retail Marijuana Products Manufacturer that Transfer Sampling Units. This Rule 6-320 was previously Rule R 606, 1 CCR 212-2.

### **6-320 – Sampling Unit Protocols**

- A. Designation of Sampling Manager(s). In any calendar month, a Retail Marijuana Products Manufacturer may designate no more than five Sampling Managers in the Inventory Tracking System.
1. Only management personnel of the Retail Marijuana Products Manufacturer who holds an Owner License or an Employee License may be designated as a Sampling Manager.
  2. An individual may be designated as a Sampling Manager by more than one Retail Marijuana Business.
  3. By virtue of the decision to be designated as a Sampling Manager, the Sampling Manager expressly consents to being identified in the Inventory Tracking System and makes a voluntary decision that any Sampling Units Transferred to the Sampling Manager will be identified in the Inventory Tracking System.
  4. A Retail Marijuana Products Manufacturer who wishes to provide Sampling Units to a Sampling Manager shall first establish and provide to each Sampling Manager standard operating procedures that explain the requirements of section 44-10-603(10), C.R.S., the personal possession limits pursuant to section 18-18-406, C.R.S., and the requirements of this Rule 6-320. *See also* Rule 3-905 – Business Records Required. A Retail Marijuana Products Manufacturer shall maintain and update such standard operating procedures as necessary to reflect accurately any changes in the relevant statutes and rules.

- B. Sampling Unit Limits. Only one Sampling Unit may be designated per Production Batch. A Sampling Unit shall not be designated until the Production Batch has satisfied the testing requirements in the 4-100 Series Rules – Regulated Marijuana Testing Program.
1. A Sampling Unit of Retail Marijuana Product shall not exceed one Standardized Serving of Marijuana.
  2. A Sampling Unit of Retail Marijuana Concentrate shall not exceed one quarter of one gram; except that a Sampling Unit of Retail Marijuana Concentrate which has the intended use of being delivered in a vaporized form shall not exceed one-half of one gram.
- C. Transfer Restrictions.
1. No Sampling Unit shall be Transferred unless it is packaged and labeled in accordance with the requirements in the 3-1000 Series Rules – Labeling, Packaging, and Product Safety.
  2. No Sampling Unit shall be Transferred to any individual who is not currently designated in the Inventory Tracking System by the Retail Marijuana Products Manufacturer as a Sampling Manger for the calendar month in which the Transfer occurs.
  3. In any calendar month, a Sampling Manager shall not receive Sampling Units totaling more than:
    - a. With respect to Retail Marijuana Product, fourteen Standardized Servings of Marijuana; and
    - b. Eight grams of Retail Marijuana Concentrate.
  4. The monthly limit established in subparagraph (C)(3) applies to each Sampling Manager, regardless of the number of Retail Marijuana Businesses with which the Sampling Manager is associated.
  5. A Sampling Manager shall not accept Sampling Units in excess of the monthly limit established in subparagraph (C)(3). Before Transferring any Sampling Units, a Retail Marijuana Products Manufacturer shall verify with the recipient Sampling Manager that the Sampling Manager will not exceed the monthly limit established in subparagraph (C)(3).
  6. A Sampling Manager shall not Transfer any Sampling Unit to any other Person, including but not limited to any other Person designated as a Sampling Manager.
- D. Compensation Prohibited. A Retail Marijuana Products Manufacturer may not use Sampling Units to compensate a Sampling Manager.
- E. On-Premises Consumption Prohibited. A Sampling Manager shall not consume any Sampling Unit on any Licensed Premises.
- F. Acceptable Purposes. Sampling Units shall only be designated and Transferred for purposes of quality control and product development in accordance with section 44-10-603(10), C.R.S.
- G. Record keeping requirements. A Retail Marijuana Products Manufacturer shall maintain copies of any material documents created regarding the quality control and product development purpose(s) of each Sampling Unit. Such documents shall constitute business records under Rule



3-905 – Business Records Required. At a minimum, a Retail Marijuana Products Manufacturer shall maintain records that show whether a Sampling Unit Transferred to a Sampling Manager is for the purpose of either quality control or product development. A Retail Marijuana Products Manufacturer shall also maintain copies of the Retail Marijuana Products Manufacturer's standard operating procedures provided to Sampling Managers.

- H. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

### **Basis and Purpose – 6-325**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(2)(g), 44-10-203(2)(i), 44-10-203(2)(y), 44-10-203(3)(b), 44-10-203(3)(e), 44-10-401(2)(b)(III), 44-10-603, and 44-10-701(3)(c), C.R.S. The purpose of this rule is to define requirements for manufacture of Audited Product for administration by: (1) metered dose nasal spray, (2) vaginal administration, or (3) rectal administration which may raise public health concerns. This rule defines audit, insurance, minimum product requirements, minimum production process requirements, and pre-production testing requirements for Retail Marijuana Products Manufacturers that manufacture Audited Products. The purpose of this rule further recognizes that Alternative Use Product not within an intended use identified in Rule 3-1015 may raise public health concerns that outweigh its manufacture or Transfer entirely or that require additional safeguards to protect public health and safety prior to manufacturer or Transfer. This rule identifies general requirements for Retail Marijuana Products Manufacturer to seek an Alternative Use Designation from the State Licensing Authority to manufacture any type of Retail Marijuana Product that is not within an intended use identified in Rule 3-1015. This Rule 6-325 was previously Rule R 607, 1 CCR 212-2.

### **6-325 – Retail Marijuana Products Manufacturing Facility: Audited Product and Alternative Use Product**

- A. General Rule. A Retail Marijuana Products Manufacturer shall not Transfer Audited Product to a Retail Marijuana Store, another Retail Marijuana Products Manufacturer, or a Retail Marijuana Cultivation Facility that has obtained a Centralized Distribution Permit except in accordance with all requirements of this Rule 6-325. The requirements of this Rule 6-325 are in addition to all other Rules that apply to Retail Marijuana Products Manufacturers; except where the context otherwise clearly requires this Rule 6-325 controls.
- B. Audited Products – Mandatory Audit Prior to Transfer. Following submission of an independent third-party audit to the Division and, if applicable, to the Local Jurisdiction as required by this Rule, a Retail Marijuana Products Manufacturer may Transfer Audited Product with an intended use of: (1) metered dose nasal spray, (2) vaginal administration, or (3) rectal administration.
1. A written audit report from an independent third-party auditor that was completed within the last 24 months shall be submitted to the Division and, if applicable to the Local Licensing Authority: (i) before the first Transfer of Audited Product to any Retail Marijuana Store, (ii) prior to Transfer of any Audited Product following a Material Change to any standard operating procedure or master formulation record regarding the Audited Product, and (iii) with the Retail Marijuana Products Manufacturer's renewal application if the Retail Marijuana Products Manufacturer will Transfer Audited Product after renewal.
  2. The independent third-party audit shall be performed by either a certified quality auditor or a certified GMP auditor. The Retail Marijuana Products Manufacturer shall be responsible for all costs associated with obtaining the independent third-party audit.
  3. The independent third-party written audit report shall include the following minimum requirements:

- a. The independent third-party auditor's qualifications and an attestation that the certified quality auditor or certified GMP auditor has no conflict of interest;
  - b. Establish that the Retail Marijuana Products Manufacturer and the Audited Product meet all requirements of this Rule 6-325, including but not limited to the specific requirements of this Rule 6-325(C), 6-325(D), 6-325(E), 6-325(G), and 6-325(H);
  - c. Verify the written standard operating procedure(s) for Audited Product include sufficient and detailed step-by-step instructions on how to produce the Audited Product in a manner that prevents contamination and protects the public health and safety;
  - d. Verify, based upon a physical inspection, the manufacture of Audited Product by the Retail Marijuana Products Manufacturer adheres to all applicable standard operating procedures;
  - e. Verify, based upon a physical inspection, of any Licensed Premises that such Licensed Premises complies with the requirements of this Rule 6-325(E), including any Limited Access Area where the Audited Product is to be manufactured;
  - f. Include the independent third-party auditor's findings;
  - g. Include the plan of correction identifying any corrective actions and/or preventative actions implemented as a result of the findings of the independent third-party audit; and
  - h. Include the independent third-party auditor's assessment that the Retail Marijuana Products Manufacturer demonstrated compliance with all requirements of Rule 6-325 and with the requirements of all standard operating procedures, master formulation records, and Batch manufacturing records that apply to the Audited Product.
- C. Products Liability Insurance. Any Retail Marijuana Products Manufacturer that intends to Transfer Audited Product shall first obtain products liability insurance providing coverage for liability arising from manufacture or Transfer of Audited Product and shall provide an unredacted certificate of product liability insurance to the Division and the independent third-party auditor.
- D. Audited Product Requirements. Audited Product shall meet the following minimum product requirements:
- 1. Inactive Ingredients. Audited Product must meet the requirements in Rule 3-335 – Production of Regulated Marijuana Products.
    - a. If the Audited Product contains a fungicidal or bactericidal Ingredient listed in, and with a concentration that is at or below the maximum concentration permitted in, the Federal Food and Drug Administration Inactive Ingredients Database, <https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm>, the Audited Product is not required to undergo microbial contaminant testing required by Rules 4-115 and 4-120.
  - 2. Required Product Development Testing. The Retail Marijuana Products Manufacturer must establish the Audited Product meets the following through independent third-party testing:

- a. The Audited Product must deliver the amount of each cannabinoid identified on the label throughout the entire volume of the Audited Product using the intended delivery device and in accordance with the instructions provided by the Retail Marijuana Products Manufacturer, as demonstrated by testing at a Retail Marijuana Testing Facility.
  - i. For Audited Product with an intended use of metered dose nasal spray, compliance with this requirement shall be established by test results verifying the delivered dose of each cannabinoid identified on the label using the methods described in The United States Pharmacopeia Physical Test and Determination Chapter 601, *Aerosols, Nasal Sprays, Metered-Dose Inhalers, and Dry Powder Inhalers*.
  - ii. For Audited Product with an intended use of either vaginal administration or rectal administration, compliance with this testing requirement shall be established by test results demonstrating that each cannabinoid identified on the label is within +/- 15% of the amount identified on the label.
- b. The expiration date identified on the label of the Audited Product is appropriate when the Audited Product is stored at room temperature, as demonstrated by testing from a Retail Marijuana Testing Facility.
- c. Identification of all non-cannabis derived Ingredients and constituents in the Audited Product at concentrations of 1%, which verification is obtained from one or more of the following:
  - i. Testing by a Retail Marijuana Testing Facility;
  - ii. Testing by a laboratory that is ISO 17025 accredited but is not a Retail Marijuana Testing Facility, except that no Retail Marijuana, Retail Marijuana Concentrate, or Retail Marijuana Product may be Transferred to such a laboratory; and/or
  - iii. One or more certificate(s) of analysis from the manufacturer of any Ingredient or constituent included in the Audited Product.

E. Additional Production Requirements for Audited Product. In addition to all other requirements applicable to Retail Marijuana Products Manufacturer, a Retail Marijuana Products Manufacturer that manufactures and Transfers Audited Product shall meet the following additional requirements:

1. Personnel Training. All personnel directly involved in the manufacture and handling of Audited Product must be trained, must demonstrate competency, and must undergo annual refresher training, which shall be documented and maintained at the Retail Marijuana Products Manufacturer's Licensed Premises. Personnel directly involved in the manufacture and handling of Audited Product must be trained and demonstrate proficiency in hand hygiene, cleaning and sanitizing, performing necessary calculations, measuring and mixing, and documenting the manufacturing process including master formulation records and batch manufacturing records.
2. Facility Requirements. A Retail Marijuana Products Manufacturer must have a space that is specifically designated for the manufacture of Audited Products that is designed and operated to prevent cross contamination from other areas of the Licensed Premises. The

surfaces, walls, floors, fixtures, shelving, work surfaces, and cabinets in this designated area must be non-porous and cleanable.

3. Cleaning and Sanitizing. A Retail Marijuana Products Manufacturer must clean and sanitize surfaces where Audited Product is manufactured and handled on a regular basis and at a minimum, work surfaces and floors must be cleaned and sanitized daily. All other surfaces must be cleaned and sanitized at least every three months. A Retail Marijuana Products Manufacturer must clean and sanitize all surfaces when a spill occurs and when surfaces, floors, and walls are visibly soiled.
4. Hand Hygiene. Hand hygiene is required when entering and re-entering any area where Audited Product is manufactured and handled. Hand hygiene includes washing hands and forearms up to the elbows with soap and water for at least 30 seconds followed by drying completely with disposable towels. Alcohol hand sanitizers alone are not sufficient.
  - a. Gloves are required to be worn for all mixing activities. Other garb such as shoe covers, head and facial hair covers, face masks, and gowns must be worn as appropriate to protect Licensees and/or prevent contamination of the Audited Product.
5. Equipment. Mechanical, electronic, and other types of equipment used in mixing, measuring, or testing of Audited Product must be inspected prior to use and verified for accuracy at the frequency recommended by the manufacturer, and at least annually.
6. Ingredient Quality. All Ingredients used to manufacture Audited Product must be handled and stored in accordance with the manufacturer's instructions. Ingredients that lack a manufacturer's expiration date shall not be used if a reasonable manufacturer would not use the Ingredient or after 1 year from the date of receipt, whichever period is shorter.
7. Master Formulation Record. A master formulation record must be prepared and maintained for each unique Audited product a Retail Marijuana Products Manufacturer manufactures. A master formulation record must include at least the following information:
  - a. Name of the Audited Product;
  - b. Ingredient identities and amounts;
  - c. Specifications on the delivery device (if applicable);
  - d. Complete instructions for preparing the Audited Product, including equipment, supplies, and description of the manufacturing steps;
  - e. Quality control procedures; and
  - f. Any other information needed to describe the Retail Marijuana Products Manufacturer's production and ensure its repeatability.
8. Batch Manufacturing Records. A batch manufacturing record shall be created for each Production Batch of Audited Product. This record shall include at the least the following information:
  - a. Name of the Audited Product;
  - b. Master formulation record reference for the Audited Product;

- c. Date and time of preparation of the Audited Product;
  - d. Production Batch number;
  - e. Signature or initials of individuals involved in each manufacturing step;
  - f. Name, vendor, or manufacturer, Production Batch number, and expiration date of each Ingredient;
  - g. Weight or measurement of each Ingredient;
  - h. Documentation of quality control procedures;
  - i. Any deviations from the master formulation record, and any problems or errors experienced during the manufacture; and
  - j. Total quantity of the Audited Product manufactured.
- F. Audited Product Testing. For each Production Batch, the Audited Product shall undergo all required testing in the 4-100 Series Rules for Retail Marijuana Product and/or Audited Product. See also Rule 4-115 – Regulated Marijuana Testing Program: Sampling and Testing Program.
- G. Packaging and Labeling of Audited Product. Audited Product must be packaged and labeled in accordance with all requirements of the 3-1000 Series Rules regarding packaging and labeling for Transfer to a consumer prior to any Transfer.
- H. Adverse Event Reporting. A Retail Marijuana Products Manufacturer that manufactures Audited Product must maintain a record of all complaints it receives, which may include concerns or reports on the quality or possible adverse reactions to a specific Audited Product. For purposes of this Rule, adverse event means any untoward medical occurrence associated with the use of marijuana—this could include any unfavorable and unintended sign (including a hospitalization, emergency department visit, doctor’s visit, abnormal laboratory finding), symptom or disease temporally associated with the use of a marijuana product. To the extent known after reasonable diligence to ascertain the information, the record must contain the name of the complainant, the date the complaint was received, the nature of the complaint, the steps taken to investigate the complaint, the response to the complaint, and the name and Production Batch number of the Audited Product. Adverse events must also be reported directly to the Colorado Department of Public Health and Environment and the Division within 48 hours of receipt by the Retail Marijuana Products Manufacturer.
- I. Alternative Use Designation – Any Other Method of Consumption or Administration. A Retail Marijuana Products Manufacturer shall not Transfer to a Retail Marijuana Store, another Retail Marijuana Products Manufacturer, or Retail Marijuana Cultivation Facility that has obtained a Centralized Distribution Permit any Retail Marijuana Concentrate or Retail Marijuana Product that is not within any intended use identified in Rule 3-1015(B) until it applies for and receives an Alternative Use Designation from the State Licensing Authority in consultation with the Colorado Department of Public Health and Environment. In the process of applying for an Alternative Use Designation, the Retail Marijuana Products Manufacturer shall work with the Division and the Colorado Department of Public Health and Environment to determine whether the proposed Alternative Use Product may be manufactured in a manner that does not pose a threat to public health and safety when particular independent review factors, safeguards, and tests are in place. The following are minimum requirements for any application for an Alternative Use Designation:
- 1. The Retail Marijuana Products Manufacturer shall identify provisions of this Rule 6-325 that apply to its Alternative Use Product, any proposed additional or alternative

requirements, and how any proposed alternatives protect public health and safety. The Retail Marijuana Products Manufacturer shall also provide any additional information as may be requested by the Division, in consultation with the Colorado Department of Public Health and Environment.

2. The Retail Marijuana Products Manufacturer bears the burden of proving its proposed Alternative Use Product may be manufactured in a manner that does not pose a threat to public health and safety when the identified independent review factors, safeguards, and tests are in place.
  3. A Retail Marijuana Products Manufacturer seeking an Alternative Use Designation shall cooperate with the Division. Failure to cooperate with the Division is grounds for denial of an Alternative Use Designation.
  4. The granting of an Alternative Use Designation shall rest in the discretion of the State Licensing Authority, in consultation with the Colorado Department of Public Health and Environment. The State Licensing Authority may in his or her discretion deny an Alternative Use Designation where the Retail Marijuana Products Manufacturer does not meet the burden established in this Rule 6-325.
- J. Alternative Use Designation – Packaging and Labeling Requirements. If the Division recommends, and the State Licensing Authority grants, an Alternative Use Designation, the State Licensing Authority, in consultation with the Colorado Department of Public Health and Environment shall provide the Retail Marijuana Products Manufacturer the appropriate statement of intended use label to be affixed to the Alternative Use Product, and any additional or distinct packaging and labeling requirements applicable to the Alternative Use Product. See Rules 3-1010 and 3-1015.
- K. Required Records. A Retail Marijuana Products Manufacturer manufacturing or Transferring Audited Product and/or Alternative Use Product shall maintain accurate and comprehensive records on the Licensed Premises regarding the manufacturing process, a list of all active and inactive Ingredients used in the Audited Product and/or Alternative Use Product, and such other documentation as required by this Rule 6-325. See Rule 3-905 – Business Records Required.

### **Basis and Purpose – 5-330**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), 44-10-203(2)(d)(I)-(VI), 44-10-401(2)(b)(III), and 44-10-603, C.R.S. The purpose of this rule is to provide the process by which the Division or a Retail Marijuana Products Manufacturer initiates a product recall, the requirements any recall must meet, and how such recall is terminated.

### **6-330 – Recall of Retail Marijuana Concentrate and Retail Marijuana Product**

- A. Effective Date. This Rule shall be effective January 1, 2021.
- B. A Retail Marijuana Products Manufacturer may voluntarily undertake a recall at any time, or at the request of the Division. A request by the Division is to be directed to the Retail Marijuana Products Manufacturer that Transferred the Retail Marijuana Concentrate or Retail Marijuana Product for sale and that is to be recalled.
1. If a Retail Marijuana Products Manufacturer voluntarily undertakes a recall or the Division requests a recall, the Licensee shall notify the Local Licensing Authority or Local Jurisdiction in which the Retail Marijuana Products Manufacturer is located of such recall.

- C. A Retail Marijuana Products Manufacturer 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. A Retail Marijuana Products Manufacturer must maintain a record of all complaints it receives, which may include concerns or reports in the quality of possible adverse reactions to a specific product. To the extent known after reasonable diligence to ascertain the information, the record must contain the name of the complainant, the purchase date, the location of where the product was purchased, the date the complaint was received, the nature of the complaint, the steps taken to investigate the complaint, the response to the complaint, and the name and Production Batch number of the Retail Marijuana Concentrate or Retail Marijuana Product.
    - a. If an initial assessment indicates a recall may be necessary, the Retail Marijuana Products Manufacturer shall determine the hazard and evaluate the safety concerns with the product and;
      - i. Assure adequate product quarantine steps have occurred for product still in control of the Licensee;
      - ii. Determine the product removal strategy appropriate to the threat and location in commerce; and
      - iii. Report directly to the Colorado Department of Public Health and Environment and the Division immediately after a determination to recall is made.
  2. Identification of Implicated Retail Marijuana Concentrate or Retail Marijuana Product.
    - a. A distribution list shall be prepared as part of the identification process. The distribution list shall, at minimum, identify the following:
      - i. Business name that received the recalled Retail Marijuana Concentrate or Retail Marijuana Product(s);
      - ii. Product ship date(s);
      - iii. Business license number;
      - iv. Business address;
      - v. Business contact name; and
      - vi. Business contact telephone numbers.
    - b. Product information shall include:
      - i. Type of Retail Marijuana Concentrate or Retail Marijuana Product;
      - ii. Product description;
      - iii. Net contents;
      - iv. Production Batch number; and
      - v. The Retail Marijuana Products Manufacturer license number.

- c. Additional Product Information. To the extent known after reasonable diligence to ascertain the information, the recall plan shall include:
    - i. Amount of Retail Marijuana Concentrate or Retail Marijuana Product returned;
    - ii. Amount of Retail Marijuana Concentrate or Retail Marijuana Product Transferred to consumers; and
    - iii. Amount of Retail Marijuana Concentrate or Retail Marijuana Product still in the marketplace.
3. Notification of affected parties.
- a. In the event of a recall, the Retail Marijuana Products Manufacturer shall notify the receiving Licensee(s) of the recalled Retail Marijuana Concentrate or Retail Marijuana Product(s) by providing a recall notice in accordance with the written recall plan. The recall notice shall include:
    - i. Retail Marijuana Concentrate or Retail Marijuana Product type;
    - ii. Reason for recall and hazard involved, if any. If the product is being removed for quality rather than health reasons, the notice may state that the Retail Marijuana Concentrate or Retail Marijuana Product does not meet internal company specifications and is being removed from distribution;
    - iii. Licensed business name that manufactured the Retail Marijuana Concentrate or Retail Marijuana Product;
    - iv. License number of the business that manufactured the Retail Marijuana Concentrate or Retail Marijuana Product;
    - v. The trade name of the business that manufactured the Retail Marijuana Concentrate or Retail Marijuana Product;
    - vi. Retail Marijuana Concentrate or Retail Marijuana Product description;
    - vii. Production Batch number of the Retail Marijuana Concentrate or Retail Marijuana Product;
    - viii. Expiration date of the Retail Marijuana Concentrate or Retail Marijuana Product(s), if applicable;
    - ix. Retail Marijuana Concentrate or Retail Marijuana Product ship date(s);
    - x. Regulated Marijuana Businesses that received the Retail Marijuana Concentrate or Retail Marijuana Product; and
    - xi. Instructions regarding the disposition of the Retail Marijuana Concentrate or Retail Marijuana Product.
  - b. The Retail Marijuana Products Manufacturer shall immediately notify the Division and Colorado Department of Public Health and Environment of the recalled



Retail Marijuana Concentrate or Retail Marijuana Product(s) by providing a recall notice as described above.

- c. Consumers shall be notified by the most effective method available. If appropriate, a press release can be used to notify patients.

4. Removal of affected Retail Marijuana Concentrate or Retail Marijuana Product(s).

- a. Removal. The Retail Marijuana Products Manufacturer shall make all reasonable efforts to remove the affected Retail Marijuana Concentrate or Retail Marijuana Product(s) from commerce.

- i. Retail Marijuana Concentrate or Retail Marijuana Product(s) in commerce shall be detained, segregated, and handled in a manner determined by the originating Retail Marijuana Products Manufacturer.
- ii. Retail Marijuana Concentrate or Retail Marijuana Product(s) that are still in control of the originating Retail Marijuana Products Manufacturer shall be detained and segregated.
- iii. All affected Retail Marijuana Concentrate or Retail Marijuana Product(s) returned shall be clearly labeled, not for sale or distribution, and clearly separated from any other Retail Marijuana Concentrate or Retail Marijuana Product(s).

- b. Product disposition. The final disposition of the Retail Marijuana Concentrate or Retail Marijuana Product shall be determined by the Division. The Division shall notify the Retail Marijuana Products Manufacturer to either:

- i. Destroy and document the destruction of the Retail Marijuana Concentrate or Retail Marijuana Product(s) Inventory Tracking System package or Production Batch pursuant to Rule 3-235; or
- ii. Decontaminate the affected Inventory Tracking System package or Production Batch pursuant to Rule 4-135(B)(2).

- c. Recall effectiveness. The Retail Marijuana Products Manufacturer shall be 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 received the recall notification;
  - B. If the recalled Retail Marijuana Concentrate or Retail Marijuana Product was handled as instructed in the recall notification; and
  - C. If the Retail Marijuana Concentrate or Retail Marijuana Product was further distributed or sold by the receiving Licensee before receipt of the recall notification, and if so, were these additional Licensees notified.

- D. If 100 percent of the affected Retail Marijuana Concentrate or Retail Marijuana Product has been accounted for, then no effectiveness checks are required.
- d. Termination of recall. A recall shall be terminated when the Licensee, or the Division if the recall was requested by the Division, determines that all reasonable efforts have been made to remove or correct the Retail Marijuana Concentrate or Retail Marijuana Product in accordance with the recall plan, and when it is reasonable to assume that the Retail Marijuana Concentrate or Retail Marijuana Product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled Retail Marijuana Concentrate or Retail Marijuana Product. Written notification that a recall is terminated will be issued by the Division.
- i. A recalling Retail Marijuana Products Manufacturer may request termination of its recall by submitting a written request to the Division stating that the recall is effective in accordance with this Rule, and by accompanying the request with a recall status report and a description of the disposition of the recalled Retail Marijuana Concentrate or Retail Marijuana 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 communication and quantity of Retail Marijuana Concentrate or Retail Marijuana Product(s) on hand at the time it was received;
    - C. Number of receiving Licensees that did not respond;
    - D. Number of products returned or corrected by each receiving Licensee contacted and the quantity of Retail Marijuana Concentrate or Retail Marijuana Product(s) accounted for;
    - E. Number and results of the effectiveness checks that were made; and
    - F. Estimated time frame for completion of the recall.

## **6-400 Series – Retail Marijuana Testing Facilities**

### **Basis and Purpose – 6-405**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(a), 44-10-202(1)(b), 44-10-202(1)(c), 44-10-202(4), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(c), 44-10-203(2)(d), 44-10-203(2)(h), 44-10-203(2)(y), 44-10-203(3)(c), 44-10-203(3)(d), 44-10-313(8)(a), 44-10-401(2)(b)(IV), 44-10-604, 35-61-104, and 35-61-105.5, C.R.S. The purpose of this rule is to establish the license privileges granted by the State Licensing Authority to Retail Marijuana Testing Facilities. This Rule 6-405 was previously Rule R 701.

### **6-405 – Retail Marijuana Testing Facilities: License Privileges**

- A. Licensed Premises. A separate License is required for each specific Retail Marijuana Testing Facility and only those privileges granted by the Marijuana Code and any rules promulgated pursuant to it may be exercised on the Licensed Premises.
- B. Testing of Retail Marijuana Authorized. A Retail Marijuana Testing Facility may accept Samples of Retail Marijuana from Retail Marijuana Businesses for testing and research purposes only. The Division may require a Retail Marijuana Business to submit a Sample of Retail Marijuana to a Retail Marijuana Testing Facility upon demand.
- C. Product Development Authorized. A Retail Marijuana Testing Facility may develop Retail Marijuana Product, but is not authorized to engage in the manufacturing privileges described in section 44-10-603, C.R.S., and Rule 6-305 – Retail Marijuana Manufacturing Facilities: License Privileges.
- D. Transferring Samples to Another Licensed and Certified Retail Marijuana Testing Facility. A Retail Marijuana Testing Facility may Transfer Samples to another Retail Marijuana Testing Facility for testing. All laboratory reports provided to or by a Retail Marijuana Business must identify the Retail Marijuana Testing Facility that actually conducted the test.
- E. Testing of Registered and Tracked Industrial Hemp Authorized.
1. A Retail Marijuana Testing Facility may accept and test Industrial Hemp as regulated by Article 61 of Title 35, C.R.S.
  2. Before a Retail Marijuana Testing Facility accepts a sample of Industrial Hemp, the Retail Marijuana Testing Facility shall verify that the Person submitting the sample is registered with the Commissioner of the Colorado Department of Agriculture, pursuant to section 35-61-104, C.R.S.
  3. A Retail Marijuana Testing Facility may only accept samples that are tracked through the radio frequency identification-based inventory tracking system approved by the Commissioner of the Colorado Department of Agriculture, pursuant to section 35-61-105.5, C.R.S.
  4. A Retail Marijuana Testing Facility shall be permitted to test Industrial Hemp only in the category(ies) that the Retail Marijuana Testing Facility is certified to perform testing in pursuant to Rule 6-415 – Retail Marijuana Testing Facilities: Certification Requirements.
  5. In accordance with section 35-61-105.5, C.R.S., a Retail Marijuana Testing Facility shall provide the results of any testing performed on Industrial Hemp to the Person submitting the sample of Industrial Hemp and to the Colorado Department of Agriculture.
  6. Nothing in these rules shall be construed to require a Retail Marijuana Testing Facility to accept and/or test Samples of Industrial Hemp.
- F. Testing of Industrial Hemp Product Authorized.
1. A Retail Marijuana Testing Facility may accept and test samples of Industrial Hemp Products.
  2. Before a Retail Marijuana Testing Facility accepts a sample of Industrial Hemp Product, the Retail Marijuana Testing Facility shall verify that the Person submitting the sample is registered with the Colorado Department of Public Health and Environment pursuant to section 25-5-426, C.R.S.

3. A Retail Marijuana Testing Facility is responsible for entering and tracking samples of Industrial Hemp Product in the inventory tracking system pursuant to the 3-800 Series Rules.
  4. A Retail Marijuana Testing Facility shall be permitted to test Industrial Hemp Product only in the category(ies) that the Retail Marijuana Testing Facility is certified to perform testing in pursuant to Rule 6-415 – Retail Marijuana Testing Facilities: Certification Requirements.
  5. A Retail Marijuana Testing Facility may provide the results of any testing performed on Industrial Hemp Product to the Person submitting the sample of Industrial Hemp Product.
  6. Nothing in these rules shall be construed to require a Retail Marijuana Testing Facility to accept and/or test samples of Industrial Hemp Product.
- G. Authorized Retail Marijuana Transport. A Retail Marijuana Testing Facility is authorized to utilize a licensed Retail Marijuana Transporter to transport Samples of Retail Marijuana for testing, in accordance with the Marijuana Code and Marijuana Rules, between the originating Retail Marijuana Business requesting testing services and the destination Retail Marijuana Testing Facility performing testing services. Nothing in this Rule requires a Retail Marijuana Business to utilize a Retail Marijuana Transporter to transport Samples of Retail Marijuana for testing.

#### **Basis and Purpose – 6-410**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(a), 44-10-202(1)(b), 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(c), 44-10-203(2)(d), 44-10-202(4), 44-10-203(2)(h), 44-10-203(2)(y), 44-10-203(3)(c), 44-10-203(2)(d), 44-10-401(2)(b)(IV), 44-10-604, 44-10-701, 35-61-104, and 35-61-105.5, C.R.S. The purpose of this rule is to clarify those acts that are limited in some fashion, or prohibited, by a Retail Marijuana Testing Facility. This Rule 6-410 was previously Rule R 702, 1 CCR 212-2.

#### **6-410 – Retail Marijuana Testing Facilities: General Limitations or Prohibited Acts**

- A. Prohibited Financial Interest. A Person who is Controlling Beneficial Owner or Passive Beneficial of a Retail Marijuana Cultivation Facility, Retail Marijuana Products Manufacturer, Retail Marijuana Store, Medical Marijuana Store, Medical Marijuana Cultivation Facility, or a Medical Marijuana Products Manufacturer shall not be a Controlling Beneficial Owner or Passive Beneficial Owner of a Retail Marijuana Testing Facility.
- B. Conflicts of Interest. The Retail Marijuana 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 Retail Marijuana Testing Facility’s testing processes or results, or that may diminish public confidence in the competency, impartiality and integrity of the Retail Marijuana Testing Facility’s testing processes or results. At a minimum, employees, owners or agents of a Retail Marijuana Testing Facility who participate in any aspect of the analysis and results of a Sample or Test Batch 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 Retail Marijuana Business that provided the Sample.
- C. Transfer of Retail Marijuana Prohibited. A Retail Marijuana Testing Facility shall not Transfer Retail Marijuana to another Retail Marijuana Business or a consumer, except that a Retail Marijuana Testing Facility may Transfer a Sample to another Retail Marijuana Testing Facility.

- D. Destruction of Received Samples. A Retail Marijuana Testing Facility shall properly dispose of all Samples it receives, that are not Transferred to another Retail Marijuana Testing Facility, after all necessary tests have been conducted and any required period of storage. See Rule 3-230 – Waste Disposal.
- E. Sample Rejection. A Retail Marijuana Testing Facility shall reject any Sample where the condition of the Sample at receipt indicates that that the Sample may have been tampered with.
- F. Retail Marijuana Business Requirements Applicable. A Retail Marijuana Testing Facility shall be considered a Licensed Premises. A Retail Marijuana Testing Facility shall be subject to all requirements applicable to Retail Marijuana Businesses.
- G. Retail Marijuana Testing Facility – Inventory Tracking System Required. A Retail Marijuana Testing Facility must use the Inventory Tracking System to ensure all Test Batches or Samples containing Retail Marijuana are identified and tracked from the point they are Transferred from a Retail Marijuana Business through the point of Transfer or destruction or disposal. A Retail Marijuana Testing Facility that performs testing on Industrial Hemp must use the Inventory Tracking System to ensure all samples of Industrial Hemp are identified and tracked from the point they are Transferred from a cultivator registered with the Commissioner of the Colorado Department of Agriculture, pursuant to section 35-61-104, C.R.S., to the point of Transfer or destruction or disposal. The Inventory Tracking System reporting shall include the results of any tests that are conducted on Retail Marijuana or Industrial Hemp. See *also* Rule 3-805 – Regulated Marijuana Businesses: Inventory Tracking System and Rule 3-825 – Reporting and Inventory Tracking System. The Retail Marijuana Testing Facility must have the ability to reconcile its Sample records with the Inventory Tracking System and the associated transaction history. See *also* Rule 3-905 – Business Records Required and Rule 3-825.
- H. Testing of Unregistered or Untracked Industrial Hemp or Industrial Hemp Products Prohibited.
  - 1. A Retail Marijuana Testing Facility is authorized to accept or test Industrial Hemp only if (1) the entity providing the Samples of Industrial Hemp is regulated by Article 61 of Title 35, C.R.S., (2) the Industrial Hemp is submitted by a registered cultivator, and (3) the Industrial Hemp is tracked through the radio frequency identification-based inventory tracking system approved by the Commissioner of the Colorado Department of Agriculture, pursuant to section 35-61-105.5, C.R.S.
  - 2. A Retail Marijuana Testing Facility is authorized to accept or test Industrial Hemp Product only if (1) the entity providing the Samples of Industrial Hemp Product is registered and regulated pursuant to Article 4 or Title 25, C.R.S., and (2) the Industrial Hemp Product being submitted for testing is tracked in the Inventory Tracking System.

**Basis and Purpose – 6-415**

The statutory authority for this rule includes but is not limited to section 44-10-202(1)(a), 44-10-202(1)(b), 44-10-202(1)(c), 44-10-202(4), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(c), 44-10-203(2)(d), 44-10-203(2)(h), 44-10-203(2)(y), 44-10-203(3)(c), 44-10-203(3)(d), 44-10-401(2)(b)(IV), and 44-10-604, C.R.S. The purpose of this rule is to establish a frame work for certification for Retail Marijuana Testing Facilities. This Rule 6-415 was previously Rule R 703, 1 CCR 212-2.

**6-415 – Retail Marijuana Testing Facilities: Certification Requirements**

- A. Certification Types. If certification in a testing category is required by the Division, then the Retail Marijuana Testing Facility must be certified in the category in order to perform that type of testing.
  - 1. Residual solvents;

2. Microbials;
  3. Mycotoxins;
  4. Pesticides;
  5. THC and other Cannabinoid potency; and
  6. Metals.
- B. In order to obtain a certification for Pesticide testing, a Retail Marijuana Testing Facility must also obtain certification for mycotoxin testing.
- C. Certification Procedures. The Retail Marijuana Testing Facility certification program is contingent upon successful on-site inspection, successful participation in proficiency testing, and ongoing compliance with the applicable requirements in this Rule.
1. Certification Inspection. A Retail Marijuana Testing Facility must be inspected prior to initial certification and annually thereafter by an inspector approved by the Division.
  2. Standards for Certification. A Retail Marijuana Testing Facility must meet standards of performance, as established by these rules, in order to obtain and maintain certification. Standards of performance include but are not limited to: personnel qualifications, standard operating procedure manual, analytical processes, Proficiency Testing, quality control, quality assurance, security, chain of custody, Sample retention, space, records, and results reporting. In addition, a Retail Marijuana Testing Facility must be accredited under the International Organization for Standardization/International Electrotechnical Commission 17025:2005 Standard, or any subsequent superseding ISO/IEC 17025 standard. In order to obtain certification in a testing category from the Division, the Retail Marijuana Testing Facility's scope of accreditation must specify that particular testing category.
    - a. Subsequent to initial approval of a Retail Marijuana Testing Facility License, the Division may grant provisional certification if the Applicant has not yet obtained ISO/IEC 17025:2005 accreditation, but meets all other requirements. Such provisional certification shall be for a period not to exceed twelve months.
    - b. A Retail Marijuana Testing Facility which is not accredited to the ISO/IEC 17025:2005 standard, but obtained certification prior to January 1, 2019, may submit a request for a temporary exemption from the ISO/IEC 17025:2005 accreditation requirement. Such request must be made on Division-approved forms. In order to receive a temporary exemption, a Retail Marijuana Testing Facility must establish good cause, which includes, but is not limited to, circumstances in which the Retail Marijuana Testing Facility has submitted an application for accreditation prior to December 31, 2018, and the application is still pending. A temporary exemption shall not exceed twelve months.
  3. Personnel Qualifications.
    - a. Laboratory Director. A Retail Marijuana Testing Facility must employ, at a minimum, a laboratory director with sufficient education and experience in a regulated laboratory environment in order to obtain and maintain certification. See Rule 6-420 – Retail Marijuana Testing Facilities: Personnel.

- b. Employee Competency. A Retail Marijuana Testing Facility must have a written and documented system to evaluate and document the competency in performing authorized tests for employees. Prior to independently analyzing Samples, testing personnel must demonstrate acceptable performance on precision, accuracy, specificity, reportable ranges, blanks, and unknown challenge samples (proficiency samples or internally generated quality controls).
4. Standard Operating Procedure Manual. A Retail Marijuana Testing Facility must have a written standard operating procedure manual meeting the minimum standards set forth in these rules detailing the performance of all methods employed by the facility used to test the analytes it reports and made available for testing analysts to follow at all times.
  - a. The current laboratory director must approve, sign and date each procedure. If any modifications are made to those procedures, the laboratory director must approve, sign, and date the revised version prior to use.
  - b. A Retail Marijuana Testing Facility must maintain a copy of all standard operating procedures to include any revised copies for a minimum of three years. See Rule 6-450 – Retail Marijuana Testing Facilities: Records Retention, and Rule 3-905 – Business Records Required.
5. Analytical Processes. A Retail Marijuana Testing Facility must maintain a listing of all analytical methods used and all analytes tested and reported. The Retail Marijuana Testing Facility must provide this listing to the Division upon request.
6. Proficiency Testing. A Retail Marijuana Testing Facility must successfully participate in a Division approved Proficiency Testing program in order to obtain and maintain certification.
7. Quality Assurance and Quality Control. A Retail Marijuana Testing Facility must establish and follow a quality assurance and quality control program to ensure sufficient monitoring of laboratory processes and quality of results reported.
8. Security. A Retail Marijuana Testing Facility must be located in a secure setting as to prevent unauthorized persons from gaining access to the testing and storage areas of the laboratory.
9. Chain of Custody. A Retail Marijuana Testing Facility must establish a system to document the complete chain of custody for samples from receipt through disposal.
10. Space. A Retail Marijuana Testing Facility must be located in a fixed structure that provides adequate infrastructure to perform analysis in a safe and compliant manner consistent with federal, state, and local requirements.
11. Records. A Retail Marijuana Testing Facility must establish a system to retain and maintain records for a period not less than three years. See Rules 6-450 – Retail Marijuana Testing Facilities - Records Retention and Rule 3-905 – Business Records Required.
12. Results Reporting. A Retail Marijuana Testing Facility must establish processes to ensure results are reported in a timely and accurate manner. See Rule 3-825 – Reporting and Inventory Tracking System.
13. Conduct While Seeking Certification. A Retail Marijuana Testing Facility, and its agents and employees, shall provide all documents and information required or requested by the

Colorado Department of Public Health and Environment and its employees, and the Division and its employees in a full, faithful, truthful, and fair manner.

- D. Violation Affecting Public Safety. A violation of this Rule may be considered a license violation affecting public safety.

### **Basis and Purpose - 6-420**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(a), 44-10-202(1)(b), 44-10-202(1)(c), 44-10-202(4), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(c), 44-10-203(2)(d), 44-10-203(3)(c), 44-10-203(3)(d), 44-10-401(2)(b)(IV), 44-10-604, C.R.S. The purpose of this rule is to establish personnel standards for the operation of a Retail Marijuana Testing Facility. This Rule 6-420 was previously Rule R 704, 1 CCR 212-2.

### **6-420 – Retail Marijuana Testing Facilities: Personnel**

- A. Laboratory Director. The laboratory director is responsible for the overall analytical operation and quality of the results reported by the Retail Marijuana Testing Facility, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurately, and proficiently and for assuring compliance with the standards set forth in this Rule.
1. The laboratory director may also serve as a supervisory analyst or testing analyst, or both, for a Retail Marijuana Testing Facility.
  2. The laboratory director for a Retail Marijuana Testing Facility must meet one of the following qualification requirements:
    - a. The laboratory director must be a Medical Doctor (M.D.) licensed to practice medicine in Colorado and have at least three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body; or
    - b. The laboratory director must hold a doctoral degree in one of the natural sciences and have at least three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body;
    - c. The laboratory director must hold a master's degree in one of the natural sciences and have at least five years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body; or
    - d. The laboratory director must hold a bachelor's degree in one of the natural sciences and have at least seven years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body.
- B. What the Laboratory Director May Delegate. The laboratory director may delegate the responsibilities assigned under this Rule to a qualified supervisory analyst, provided that such delegation is made in writing and a record of the delegation is maintained. See Rule 3-905 – Business Records Required. Despite the designation of a responsibility, the laboratory director remains responsible for ensuring that all duties are properly performed.
- C. Responsibilities of the Laboratory Director. The laboratory director must:



1. Ensure that the Retail Marijuana Testing Facility has adequate space, equipment, materials, and controls available to perform the tests reported;
2. Establish and adhere to a written standard operating procedure used to perform the tests reported;
3. Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;
4. Ensure that the physical location and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards;
5. Ensure that the test methodologies selected have the capability of providing the quality of results required for the level of testing the laboratory is certified to perform;
6. Ensure that validation and verification test methods used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;
7. Ensure that testing analysts perform the test methods as required for accurate and reliable results;
8. Ensure that the laboratory is enrolled in and successfully participates in a Division approved Proficiency Testing program;
9. Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;
10. Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;
11. Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and that test results are reported only when the system is functioning properly;
12. Ensure that reports of test results include pertinent information required for interpretation;
13. Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation of said results;
14. Employ a sufficient number of laboratory personnel who meet the qualification requirements and provide appropriate consultation, properly supervise, and ensure accurate performance of tests and reporting of test results;
15. Ensure that prior to testing any samples, all testing analysts receive the appropriate training for the type and complexity of tests performed, and have demonstrated and documented that they can perform all testing operations reliably to provide and report accurate results;
16. Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process Samples, perform test procedures and report test results promptly and proficiently, avoid actual and apparent

conflicts of interests, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

17. Ensure that an approved standard operating procedure manual is available to all personnel responsible for any aspect of the testing process; and
  18. Specify, in writing, the responsibilities and duties of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for Sample processing, test performance or results reporting, and whether consultant or laboratory director review is required prior to reporting test results.
- D. Change in Laboratory Director. In the event that the laboratory director leaves employment at the Retail Marijuana Testing Facility, the Retail Marijuana Testing Facility shall:
1. Provide written notice to the Colorado Department of Public Health and Environment and the Division within seven days of the laboratory director's departure; and
  2. Designate an interim laboratory director within seven days of the laboratory director's departure. At a minimum, the interim laboratory director must meet the qualifications of a supervisory analyst.
  3. The Retail Marijuana Testing Facility must hire a permanent laboratory director within 60 days from the date of the previous laboratory director's departure.
  4. Notwithstanding the requirement of subparagraph (D)(3), the Retail Marijuana Testing Facility may submit a waiver request to the Division Director to receive an additional 60 days to hire a permanent laboratory director provided that the Retail Marijuana Testing Facility submits a detailed oversight plan along with the waiver request.
- E. Supervisory Analyst. Supervisory analysts must meet one of the qualifications for a laboratory director or have at least a bachelor's degree in one of the natural sciences and three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body. A combination of education and experience may substitute for the three years of full-time laboratory experience.
- F. Laboratory Testing Analyst.
1. Educational Requirements. An individual designated as a testing analyst must meet one of the qualifications for a laboratory director or supervisory analyst or have at least a bachelor's degree in one of the natural sciences and one year of full-time experience in laboratory testing.
  2. Responsibilities. In order to independently perform any test for a Retail Marijuana Testing Facility, an individual must at least meet the educational requirements for a testing analyst.

### **Basis and Purpose – 6-425**

The statutory authority for this rule includes but is not limited to sections 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(d), 44-10-202(4), 44-10-401(2)(b)(IV), and 44-10-604, C.R.S. The purpose of this rule is to establish standard operating procedure manual standards for the operation of a Retail Marijuana Testing Facility. This Rule 6-425 was previously Rule R 705, 1 CCR 212-2.

### **6-425 –Retail Marijuana Testing Facilities: Standard Operating Procedure Manual**

- A. A standard operating procedure manual must include, but need not be limited to, procedures for:
1. Sample receiving;
  2. Sample accessioning;
  3. Sample storage;
  4. Identifying and rejecting unacceptable Samples;
  5. Recording and reporting discrepancies;
  6. Security of Samples, aliquots and extracts and records;
  7. Validating a new or revised method prior to testing Samples to include: accuracy, precision, analytical sensitivity, analytical specificity (interferences), LOD, LOQ, and verification of the reportable range;
  8. Aliquoting Samples to avoid contamination and carry-over;
  9. Sample retention to assure stability, as follows:
    - a. For Samples that comprise Test Batches submitted for testing other than Pesticide contaminant testing, Sample retention for 14 days;
    - b. For Samples that comprise Test Batches submitted for Pesticide contaminant testing, Sample retention for 90 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 subject tests 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; and

21. Policies and procedures to follow when Samples are requested for referral and testing by another certified Retail Marijuana Testing Facility or an approved local or state agency's laboratory.
22. Testing Industrial Hemp, if the Retail Marijuana Testing Facility tests Industrial Hemp.

### **Basis and Purpose – 6-430**

The statutory authority for this rule includes but is not limited to sections 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(d), 44-10-202(4), 44-10-401(2)(b)(IV), and 44-10-604, C.R.S. The purpose of this rule is to establish analytical processes standards for the operation of a Retail Marijuana Testing Facility. This Rule 6-430 was previously Rule R 706, 1 CCR 212-2.

### **6-430 –Retail Marijuana Testing Facilities: Analytical Processes**

- A. Gas Chromatography (“GC”). A Retail Marijuana Testing Facility using GC must:
  1. Document the conditions of the gas chromatograph, including the detector response;
  2. Perform and document preventive maintenance as required by the manufacturer;
  3. Ensure that records are maintained and readily available to the staff operating the equipment;
  4. Document the performance of new columns before use;
  5. Use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified;
  6. Establish criteria of acceptability for variances between different aliquots and different columns; and
  7. Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system.
- B. Gas Chromatography Mass Spectrometry (“GC/MS”). A Retail Marijuana Testing Facility using GC/MS must:
  1. Perform and document preventive maintenance as required by the manufacturer;
  2. Document the changes of septa as specified in the standard operating procedure;
  3. Document liners being cleaned or replaced as specified in the standard operating procedure;
  4. Ensure that records are maintained and readily available to the staff operating the equipment;
  5. Maintain records of mass spectrometric tuning;
  6. Establish written criteria for an acceptable mass-spectrometric tune;

7. Document corrective actions if a mass-spectrometric tune is unacceptable;
8. Monitor analytic analyses to check for contamination and carry-over;
9. Use selected ion monitoring within each run to assure that the laboratory compare ion ratios and retention times between calibrators, controls and Samples for identification of an analyte;
10. Use an internal standard for qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;
11. Document the monitoring of the response (area or peak height) for the internal standard to ensure consistency overtime of the analytical system;
12. Define the criteria for designating qualitative results as positive;
13. When a library is used to qualitatively identify an analyte, the identity of the analyte must be confirmed before reporting results by comparing the relative retention time and mass spectrum to that of a known standard or control run on the same system; and
14. Evaluate the performance of the instrument after routine and preventive maintenance (e.g. clipping or replacing the column or cleaning the source) prior to analyzing subject Samples.

C. Immunoassays. A Retail Marijuana Testing Facility using Immunoassays must:

1. Perform and document preventive maintenance as required by the manufacturer;
2. Ensure that records are maintained and readily available to the staff operating the equipment;
3. Validate any changes or modifications to a manufacturer's approved assays or testing methods when a Sample is not included within the types of Samples approved by the manufacturer; and
4. Define acceptable separation or measurement units (absorbance intensity or counts per minute) for each assay, which must be consistent with manufacturer's instructions.

D. Thin Layer Chromatography ("TLC"). A Retail Marijuana Testing Facility using TLC must:

1. Apply unextracted standards to each thin layer chromatographic plate;
2. Include in their written procedure the preparation of mixed solvent systems, spray reagents and designation of lifetime;
3. Include in their written procedure the storage of unused thin layer chromatographic plates;
4. Evaluate, establish, and document acceptable performance for new thin layer chromatographic plates before placing them into service;
5. Verify that the spotting technique used precludes the possibility of contamination and carry-over;

6. Measure all appropriate RF values for qualitative identification purposes;
  7. Use and record sequential color reactions, when applicable;
  8. Maintain records of thin layer chromatographic plates; and
  9. Analyze an appropriate matrix blank with each batch of Samples analyzed.
- E. High Performance Liquid Chromatography (“HPLC”). A Retail Marijuana Testing Facility using HPLC must:
1. Perform and document preventive maintenance as required by the manufacturer;
  2. Ensure that records are maintained and readily available to the staff operating the equipment;
  3. Monitor and document the performance of the HPLC instrument each day of testing;
  4. Evaluate the performance of new columns before use;
  5. Create written standards for acceptability when eluting solvents are recycled;
  6. Use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified when available or appropriate for the assay; and
  7. Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system.
- F. Liquid Chromatography Mass Spectroscopy (“LC/MS”). A Retail Marijuana Testing Facility using LC/MS must:
1. Perform and document preventive maintenance as required by the manufacturer;
  2. Ensure that records are maintained and readily available to the staff operating the equipment;
  3. Maintain records of mass spectrometric tuning;
  4. Document corrective actions if a mass-spectrometric tune is unacceptable;
  5. Use an internal standard with each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;
  6. Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system;
  7. Compare two transitions and retention times between calibrators, controls and Samples within each run;
  8. Document and maintain records when changes in source, source conditions, eluent, or column are made to the instrument; and

9. Evaluate the performance of the instrument when changes in: source, source conditions, eluent, or column are made prior to reporting test results.
- G. Other Analytical Methodology. A Retail Marijuana Testing Facility using other methodology or new methodology must:
1. Implement a performance based measurement system for the selected methodology and validate the method following good laboratory practices prior to reporting results. Validation of other or new methodology must include when applicable, but is not limited to:
    - a. Verification of Accuracy
    - b. Verification of Precision
    - c. Verification of Analytical Sensitivity
    - d. Verification of Analytical Specificity
    - e. Verification of the LOD
    - f. Verification of the LOQ
    - g. Verification of the Reportable Range
    - h. Identification of Interfering Substances
  2. Validation of the other or new methodology must be documented.
  3. Prior to use, other or new methodology must have a standard operating procedure approved and signed by the laboratory director.
  4. Testing analysts must have documentation of competency assessment prior to testing Samples.
  5. Any changes to the approved other or new methodology must be revalidated and documented prior to testing Samples.

#### **Basis and Purpose - 6-435**

The statutory authority for this rule includes but is not limited to sections 44-10-202(4), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(d), 44-10-401(2)(b)(IV), and 44-10-604, C.R.S. The purpose of this rule is to establish a proficiency testing program for Retail Marijuana Testing Facilities. This Rule 6-435 was previously Rule R 707, 1 CCR 212-2.

#### **6-435 – Retail Marijuana Testing Facilities: Proficiency Testing**

- A. Proficiency Testing Required. A Retail Marijuana Testing Facility must participate in a Proficiency Testing program for each approved category in which it seeks certification under Rule 6-415 – Retail Marijuana Testing Facilities: Certification Requirements.
- B. Participation in Designated Proficiency Testing Event. If required by the Division as part of certification, the Retail Marijuana Testing Facility must have successfully participated in Proficiency Testing in the category for which it seeks certification, within the preceding 12 months.

- C. Continued Certification. To maintain continued certification, a Retail Marijuana Testing Facility must participate in the designated Proficiency Testing program with continued satisfactory performance as determined by the Division as part of certification. The Division may designate a local agency, state agency, or independent third-party to provide Proficiency Testing.
- D. Analyzing Proficiency Testing Samples. A Retail Marijuana Testing Facility must analyze Proficiency Test Samples using the same procedures with the same number of replicate analyses, standards, testing analysts and equipment as used in its standard operating procedures.
- E. Proficiency Testing Attestation. The laboratory director and all testing analysts who participated in Proficiency Testing must sign corresponding attestation statements.
- F. Laboratory Director Must Review Results. The laboratory director must review and evaluate all Proficiency Testing results.
- G. Remedial Action. A Retail Marijuana Testing Facility must take and document remedial action when a score of less than 100% is achieved on any test during Proficiency Testing. Remedial action documentation must include a review of Samples tested and results reported since the last successful Proficiency Testing event. A requirement to take remedial action does not necessarily indicate unsatisfactory participation in a Proficiency Testing event.
- H. Unsatisfactory Participation in a Proficiency Testing Event. Unless the Retail Marijuana Testing Facility positively identifies at least 80% of the target analytes tested, participation in the Proficiency Testing event will be considered unsatisfactory. A positive identification must include accurate quantitative and qualitative results as applicable. Any false positive result reported will be considered unsatisfactory participation in the Proficiency Testing event.
- I. Consequence of Unsatisfactory Participation in Proficiency Testing Event. Unsatisfactory participation in a Proficiency Testing event may result in limitation, suspension or revocation of Rule 6-415 certification.

#### **Basis and Purpose – 6-440**

The statutory authority for this rule includes but is not limited to sections 44-10-202(4), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(d), 44-10-401(2)(b)(IV), and 44-10-604, C.R.S. The purpose of this rule is to establish quality assurance and quality assurance standards for a Retail Marijuana Testing Facility. This Rule 6-440 was previously Rule R 708, 1 CCR 212-2.

#### **6-440 – Retail Marijuana Testing Facilities: Quality Assurance and Quality Control**

- A. Quality Assurance Program Required. A Retail Marijuana Testing Facility must establish, monitor, and document the ongoing review of a quality assurance program that is sufficient to identify problems in the laboratory preanalytic, analytic and postanalytic systems when they occur and must include, but is not limited to:
  1. Review of instrument preventive maintenance, repair, troubleshooting and corrective actions documentation must be performed by the laboratory director or designated supervisory analyst on an ongoing basis to ensure the effectiveness of actions taken over time;
  2. Review by the laboratory director or designated supervisory analyst of all ongoing quality assurance; and



3. Review of the performance of validated methods used by the Retail Marijuana Testing Facility to include calibration standards, controls and the standard operating procedures used for analysis on an ongoing basis to ensure quality improvements are made when problems are identified or as needed.

B. Quality Control Measures Required. A Retail Marijuana Testing Facility must establish, monitor and document on an ongoing basis the quality control measures taken by the laboratory to ensure the proper functioning of equipment, validity of standard operating procedures and accuracy of results reported. Such quality control measures must include, but shall not be limited to:

1. Documentation of instrument preventive maintenance, repair, troubleshooting and corrective actions taken when performance does not meet established levels of quality;
2. Review and documentation of the accuracy of automatic and adjustable pipettes and other measuring devices when placed into service and annually thereafter;
3. Cleaning, maintaining and calibrating as needed the analytical balances and in addition, verifying the performance of the balance annually using certified weights to include three or more weights bracketing the ranges of measurement used by the laboratory;
4. Annually verifying and documenting the accuracy of thermometers using a NIST traceable reference thermometer;
5. Recording temperatures on all equipment when in use where temperature control is specified in the standard operating procedures manual, such as water baths, heating blocks, incubators, ovens, refrigerators, and freezers;
6. Properly labeling reagents as to the identity, the concentration, date of preparation, storage conditions, lot number tracking, expiration date and the identity of the preparer;
7. Avoiding mixing different lots of reagents in the same analytical run;
8. Performing and documenting a calibration curve with each analysis using at minimum three calibrators throughout the reporting range;
9. For qualitative analyses, analyzing, at minimum, a negative and a positive control with each batch of Samples analyzed;
10. For quantitative analyses, analyzing, at minimum, a negative and two levels of controls that challenge the linearity of the entire curve;
11. Using a control material or materials that differ in either source or, lot number, or concentration from the calibration material used with each analytical run;
12. For multi-analyte assays, performing and documenting calibration curves and controls specific to each analyte, or at minimum, one with similar chemical properties as reported in the analytical run;
13. Analyzing an appropriate matrix blank and control with each analytical run, when available;
14. Analyzing calibrators and controls in the same manner as unknowns;

15. Documenting the performance of calibration standards and controls for each analytical run to ensure the acceptability criteria as defined in the standard operating procedure is met;
16. Documenting all corrective actions taken when unacceptable calibration, control, and standard or instrument performance does not meet acceptability criteria as defined in the standard operating procedure;
17. Maintaining records of validation data for any new or modified methods to include; accuracy, precision, analytical specificity (interferences), LOD, LOQ, and verification of the linear range; and
18. Performing testing analysts that follow the current Standard Operating Procedures Manual for the test or tests to be performed.

#### **Basis and Purpose – 6-445**

The statutory authority for this rule includes but is not limited to sections 44-10-202(4), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(d), 44-10-401(2)(b)(IV), and 44-10-604, C.R.S. The purpose of this rule is to establish chain of custody standards for a Retail Marijuana Testing Facility. In addition, it establishes the requirement that a Retail Marijuana Testing Facility follow an adequate chain of custody for Samples it maintains. This Rule 6-445 was previously Rule R 709, 1 CCR 212-2.

#### **6-445 –Retail Marijuana Testing Facilities: Chain of Custody**

- A. General Requirements. A Retail Marijuana Testing Facility must establish an adequate chain of custody and Sample requirement instructions that must include, but 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 Samples, aliquots, and extracts;
  5. Document all Transfers of Samples, aliquots, and extracts referred to another certified Retail Marijuana 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 Laboratory 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; and
  11. Document the disposal of Samples, aliquots, and extracts.

#### **Basis and Purpose – 6-450**

The statutory authority for this rule includes but is not limited to sections 44-10-202(4), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(d), 44-10-401(2)(b)(IV), and 44-10-604, C.R.S. The purpose of this rule is to establish records retention standards for a Retail Marijuana Testing Facility. This Rule 6-450 was previously Rule R 710, 1 CCR 212-2.

#### **6-450 –Retail Marijuana Testing Facilities: Records Retention**

- A. General Requirement. A Retail Marijuana Testing Facility must maintain all required business records. See Rule 3-905 - Business Records Required.
- B. Specific Business Records Required: Record Retention. A Retail Marijuana Testing Facility must establish processes to preserve records in accordance with Rule 3-905 that includes, but is not limited to;
1. Test Results, including final and amended reports, and identification of analyst and date of analysis;
  2. Quality Control and Quality Assurance Records, including accession numbers, Sample type, and acceptable reference range parameters;
  3. Standard Operating Procedures;
  4. Personnel Records;
  5. Chain of Custody Records;
  6. Proficiency Testing Records; and
  7. Analytical Data to include data generated by the instrumentation, raw data of calibration standards and curves.

#### **Basis and Purpose – 6-455**

The statutory authority for this rule includes but is not limited to sections 44-10-202(4), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(d), 44-10-401(2)(b)(IV), and 44-10-604, C.R.S. The purpose of this rule is to clarify a Retail Marijuana Testing Facility's responsibility to notify the Retail Marijuana Business and accurately report in the inventory tracking system any failed contaminant test result. This Rule 6-455 was previously Rule R 712(D), 1 CCR 212-2.

#### **6-455 – Notification of Retail Marijuana Business**

If Retail Marijuana failed a contaminant test, then the Retail Marijuana Testing Facility must immediately (1) notify the Retail Marijuana Business that submitted the Test Batch or Sample for testing and any Person as directed by an approved Research Project (2) report the failure in accordance with the Inventory Tracking System reporting requirements in Rule 3-825(B).

#### **6-500 Series – Retail Marijuana Transporters**

##### **Basis and Purpose – 6-505**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(h), 44-10-203(2)(n), 44-10-203(3)(c), 44-10-401(2)(b)(V), and 44-10-605, C.R.S. The purpose of this rule is to establish the license privileges granted by the State Licensing Authority to Retail Marijuana Transporters. This Rule 6-505 was previously Rule R 1601, 1 CCR 212-2.

## **6-505 – Retail Marijuana Transporter: License Privileges**

- A. Licensed Premises. A separate license is required for each specific business or business entity and geographical location. A Retail Marijuana Transporter may share a location with an identically owned Medical Marijuana Transporter. However, a separate license is required for each specific business or business entity, regardless of geographical location.
- B. Transportation of Retail Marijuana and Retail Marijuana Product Authorized. A Retail Marijuana Transporter may take transportation orders, receive, transport, temporarily store, and deliver Retail Marijuana to Retail Marijuana Businesses.
- C. Authorized Sources of Retail Marijuana and Retail Marijuana Product. A Retail Marijuana Transporter may only transport and store Retail Marijuana that it received directly from the originating Retail Marijuana Business.
- D. Authorized On-Premises Storage. A Retail Marijuana Transporter is authorized to store transported Retail Marijuana on its Licensed Premises or permitted off-premises storage facility. All transported Retail Marijuana must be secured in a Limited Access Area, and tracked consistently with the inventory tracking rules.
- E. Delivery to Consumers Pursuant to Delivery Permit.
  - 1. Prior to January 2, 2021, all Retail Marijuana Transporters are prohibited from delivering Regulated Marijuana to consumers.
  - 2. After January 2, 2021, only Retail Marijuana Transporters that possess a valid delivery permit may deliver Retail Marijuana pursuant to contracts with Retail Marijuana Stores that also possess valid delivery permits. All deliveries of Retail Marijuana consumers must also comply with all requirements of Rule 3-615.
  - 3. Violation affecting Public Safety. Any violation of paragraph E of this Rule is a license violation affecting public safety.

## **Basis and Purpose – 6-510**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(h), 44-10-203(2)(n), 44-10-203(3)(c), 44-10-401(2)(b)(V), and 44-10-605, C.R.S. The purpose of this rule is to clarify those acts that are limited in some fashion or prohibited by a Retail Marijuana Transporter. This Rule 6-510 was previously Rule R 1602, 1 CCR 212-2.

## **6-510 – Retail Marijuana Transporter: General Limitations or Prohibited Acts**

- A. Sales, Liens, and Secured Interests Prohibited. A Retail Marijuana Transporter is prohibited from buying, selling, or giving away Retail Marijuana or from receiving complimentary Retail Marijuana. A Retail Marijuana Transporter shall not place or hold a lien or secured interest on Retail Marijuana.
- B. Licensed Premises Permitted. A Retail Marijuana Transporter shall maintain a Licensed Premises if it: (1) temporarily stores any Retail Marijuana or (2) modifies any information in the Inventory Tracking System generated transport manifest. The Licensed Premises shall be in a Local Jurisdiction that authorizes the operation of Retail Marijuana Stores. If a Retail Marijuana Transporter Licensed Premises is co-located with a Medical Marijuana Transporter Licensed Premises, then the combined Licensed Premises shall be in a Local Jurisdiction that authorizes the operation of both Retail Marijuana Stores and Medical Marijuana Stores.

- C. Off-Premises Storage Permit. A Retail Marijuana Transporter may maintain one or more permitted off-premises storage facilities. See Rule 3-610 – Off-Premises Storage of Regulated Marijuana: All Regulated Marijuana Businesses.
- D. Storage Duration. A Retail Marijuana Transporter shall not store Retail Marijuana for longer than seven days from receiving it at its Licensed Premises or off-premises storage facility. The total allowable seven day storage duration begins and applies regardless of which of the Retail Marijuana Transporter’s premises receives the Retail Marijuana first, ie. the Retail Marijuana Transporter’s Licensed Premises, or any of its off-premises storage facilities. A Retail Marijuana Transporter with a valid delivery permit may store Retail Marijuana for delivery to consumers pursuant to the delivery permit for no longer than seven days from receipt at its Licensed Premises or off-premises storage facility.
- E. Control of Retail Marijuana. A Retail Marijuana Transporter is responsible for the Retail Marijuana once it takes control of the Retail Marijuana and until the Retail Marijuana Transporter delivers it to the receiving Retail Marijuana Business, Medical Research Facility, Pesticide Manufacturer, or to a consumer pursuant to a valid delivery permit. For purposes of this Rule, taking control of the Retail Marijuana means removing it from the originating Retail Marijuana Business’s Licensed Premises and placing the Retail Marijuana in the transport vehicle or the Delivery Motor Vehicle.
- F. Location of Orders Taken and Delivered. A Retail Marijuana Transporter is permitted to take orders on the Licensed Premises of any Retail Marijuana Business to transport Retail Marijuana between Retail Marijuana Businesses. The Retail Marijuana Transporter shall deliver the Retail Marijuana to the Licensed Premises of a licensed Retail Marijuana Business, a Medical Research Facility, or a Pesticide Manufacturer. A Retail Marijuana Transporter may also delivery Retail Marijuana to consumers pursuant to a contract with a Retail Marijuana Store if it possesses a valid delivery permit.
- G. A Retail Marijuana Transporter shall receive Retail Marijuana from the originating Licensee packaged in the way that it is intended to be delivered to the final destination Licensee, Medical Research Facility, or Pesticide Manufacturer. The Retail Marijuana Transporter shall deliver the Retail Marijuana in the same, unaltered packaging to the final destination Licensee.
- H. A Retail Marijuana Transporter with a valid delivery permit shall receive Retail Marijuana that has been weighed, packaged, prepared, and labeled for delivery on the Licensed Premises of a Retail Marijuana Store or at the Retail Marijuana Store’s off-premises storage facility after receipt of a delivery order. Retail Marijuana cannot be placed into a Delivery Motor Vehicle until after an order has been received and the Retail Marijuana has been packaged and labeled for delivery to the consumer as required by the 3-1000 Series Rules.
- I. A Retail Marijuana Transporter must not deliver Retail Marijuana to consumers while also transporting Regulated Marijuana between Licensed Premises in the Delivery Motor Vehicle.
- J. Opening of Bulk Packages or Containers and Re-Packaging Prohibited. A Retail Marijuana Transporter shall not open Containers of Retail Marijuana. Retail Marijuana Transporters are prohibited from re-packaging Retail Marijuana.
- K. Temperature-Controlled Transport Vehicles. A Retail Marijuana Transporter shall utilize temperature-controlled transport vehicles when necessary to prevent spoilage of the transported Retail Marijuana.
- L. Damaged, Refused, or Undeliverable Retail Marijuana. Any damaged Retail Marijuana that is undeliverable to the final destination Retail Marijuana Business, or any Retail Marijuana that is refused by the final destination Retail Marijuana Business shall be transported back to the originating Retail Marijuana Business. Any Retail Marijuana that cannot be delivered to a

consumer pursuant to a valid delivery permit shall be returned to the originating Retail Marijuana Store or the Retail Marijuana Store's off-premises storage facility within the same business day or pursuant to paragraph D of this Rule.

- M. Transport of Retail Marijuana Vegetative Plants Authorized. Retail Marijuana Vegetative plants may only be transported between Licensed Premises and such transport shall only be permitted due to an approved change of location pursuant to Rule 2-255. Transportation of Vegetative plants to a permitted off-premises storage facility shall not be allowed.

## **6-600 Series – Retail Marijuana Business Operators**

### **Basis and Purpose – 6-605**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(o), 44-10-401(2)(b)(VI), and 44-10-606, C.R.S. The purpose of this rule is to establish the license privileges granted by the State Licensing Authority to Retail Marijuana Business Operators. This Rule 6-605 was previously Rule R 1701, 1 CCR 212-2.

### **6-605 – Retail Marijuana Business Operator: License Privileges**

- A. Privileges Granted. A Retail Marijuana Business Operator shall only exercise those privileges granted to it by the Marijuana Code, the rules promulgated pursuant thereto and the State Licensing Authority. A Retail Marijuana Business Operator may exercise those privileges only on behalf of the Retail Marijuana Business(es) it operates. A Retail Marijuana Business shall not contract to have more than one Retail Marijuana Business Operator providing services to the Retail Marijuana Business at any given time.
- B. Licensed Premises of the Retail Marijuana Business(es) Operated. A separate License is required for each specific Retail Marijuana Business Operator, and each such licensed Retail Marijuana Business Operator may operate one or more other Retail Marijuana Business(es). A Retail Marijuana Business Operator will not have its own Licensed Premises, but shall maintain its own place of business, and may exercise the privileges of a Retail Marijuana Business Operator at the Licensed Premises of the Retail Marijuana Business(es) it operates.
- C. Entities Eligible to Hold Retail Marijuana Business Operator License. A Retail Marijuana Business Operator License may be held only by a business entity, including, but not limited to, a corporation, limited liability company, partnership, or sole proprietorship.
- D. Separate Place of Business. A Retail Marijuana Business Operator shall designate and maintain a place of business separate from the Licensed Premises of any Retail Marijuana Business(es) it operates. A Retail Marijuana Business Operator's separate place of business shall not be considered a Licensed Premises, and shall not be subject to the requirements applicable to the Licensed Premises of other Retail Marijuana Businesses, except as set forth in Rules 6-610 and 6-620. Possession, storage, use, cultivation, manufacture, sale, distribution, or testing of Retail Marijuana is prohibited at a Retail Marijuana Business Operator's separate place of business.
- E. Agency Relationship and Discipline for Violations. A Retail Marijuana Business Operator and each of its Controlling Beneficial Owners required to hold an Owner License, as well as the agents and employees of the Retail Marijuana Business Operator, shall be agents of the Retail Marijuana Business(es) the Retail Marijuana Business Operator is contracted to operate, when engaged in activities related, directly, or indirectly, to the operation of such Retail Marijuana Business(es), including for purposes of taking administrative action against the Retail Marijuana Business being operated. See § 44-10-901(1), C.R.S. Similarly, a Retail Marijuana Business Operator and its Controlling Beneficial Owners required to hold an Owner License, as well as the officers, agents and employees of the Retail Marijuana Business Operator, may be disciplined for

violations committed by the Controlling Beneficial Owners, agents or employees of the Retail Marijuana Business acting under their direction or control. A Retail Marijuana Business Operator may also be disciplined for violations not directly related to a Retail Marijuana Business it is operating.

- F. Compliance with Applicable State and Local Law, Ordinances, Rules, and Regulations. A Retail Marijuana Business Operator, and each of its Controlling Beneficial Owners, agents and employees engaged, directly or indirectly in the operation of the Retail Marijuana Business it operates, shall comply with all state and local laws, ordinances, rules and regulations applicable to the Retail Marijuana Business(es) being operated.

### **Basis and Purpose – 6-610**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(o), 44-10-401(2)(b)(VI), and 44-10-606, C.R.S. The purpose of this rule is to clarify those acts that are limited in some fashion, or prohibited, by a Retail Marijuana Business Operator. This Rule 6-610 was previously Rule R 1702, 1 CCR 212-2.

### **6-610 – Retail Marijuana Business Operators: General Limitations or Prohibited Acts**

- A. Financial Interest. A Person who holds an Owner's Interest in a Retail Marijuana Business Operator may hold an Owner's Interest in another Retail Marijuana Business. A Retail Marijuana Business may be operated by a Retail Marijuana Business Operator where each has one or more Controlling Beneficial Owners or Passive Beneficial Owners in common. A Person may receive compensation for services provided by a Retail Marijuana Business Operator in accordance with these rules.
- B. Sale of Marijuana Prohibited. A Retail Marijuana Business Operator is prohibited from selling, distributing, or transferring Retail Marijuana to another Retail Marijuana Business or a consumer, except when acting as an agent of a Retail Marijuana Business (s) operated by the Retail Marijuana Business Operator.
- C. Consumption Prohibited. A Retail Marijuana Business Operator, and its Controlling Beneficial Owners, Passive Beneficial Owners, agents and employees, shall not permit the consumption of marijuana or marijuana products at its separate place of business.
- D. Inventory Tracking System. A Retail Marijuana Business Operator, and any of its Controlling Beneficial Owners, agents or employees engaged in the operation of the Retail Marijuana Business(es) it operates, must use the Inventory Tracking System account of the Retail Marijuana Business(es) it operates, in accordance with all requirements, limitations and prohibitions applicable to the Retail Marijuana Business(es) it operates.
- E. Compliance with Requirements and Limitations Applicable to the Retail Marijuana Business(es) Operated. In operating any other Retail Marijuana Business, a Retail Marijuana Business Operator, and its Controlling Beneficial Owners who are required to hold Owner Licenses, as well as the agents and employees of the Retail Marijuana Business Operator, shall comply with all requirements, limitations and prohibitions applicable to the type(s) of Retail Marijuana Business(es) being operated, under state and local laws, ordinances, rules, and regulations, and may be disciplined for violation of the same.
- F. Inventory Tracking System Access. A Retail Marijuana Business may grant access to its Inventory Tracking System account to the Controlling Beneficial Owners, agents and employees of a Retail Marijuana Business Operator having duties related to Inventory Tracking System activities of the Retail Marijuana Business(es) being operated.

1. The Controlling Beneficial Owners, agents and employees of a Retail Marijuana Business Operator granted access to a Retail Marijuana Business's Inventory Tracking System account, shall comply with all Inventory Tracking System rules.
  2. At least one Controlling Beneficial Owner of a Retail Marijuana Business being operated by a Retail Marijuana Business Operator must be an Inventory Tracking System Trained Administrator for the Retail Marijuana Business's Inventory Tracking System account. That Inventory Tracking System Trained Administrator shall control access to its Inventory Tracking System account, and shall promptly terminate the access of the Retail Marijuana Business Operator's Controlling Beneficial Owners, agents and employees:
    - a. When its contract with the Retail Marijuana Business Operator expires by its terms;
    - b. When its contract with the Retail Marijuana Business Operator is terminated by any party; or
    - c. When it is notified that the License of the Retail Marijuana Business Operator, or a specific Controlling Beneficial Owner, agent or employee of the Retail Marijuana Business Operator, has expired, or has been suspended or revoked.
- G. Limitations on Use of Documents and Information Obtained from Retail Marijuana Businesses. A Retail Marijuana Business Operator, and its agents and employees, shall maintain the confidentiality of documents and information obtained from the other Retail Marijuana Business(es) it operates, and shall not use or disseminate documents or information obtained from a Retail Marijuana Business it operates for any purpose not authorized by the Marijuana Code and the rules promulgated pursuant thereto, and shall not engage in data mining or other use of the information obtained from a Retail Marijuana Business to promote the interests of the Retail Marijuana Business Operator or its Controlling Beneficial Owners, Passive Beneficial Owners, agents or employees, or any Person other than the Retail Marijuana Business it operates.
- H. Form and Structure of Allowable Agreement(s) Between Operators and Owners. Any agreement between a Retail Marijuana Business and a Retail Marijuana Business Operator:- 1. Must acknowledge that the Retail Marijuana Business Operator, and its Controlling Beneficial Owners, agents and employees who are engaged, directly or indirectly, in operating the Retail Marijuana Business, are agents of the Retail Marijuana Business being operated, and must not disclaim an agency relationship;
- 2. May provide for the Retail Marijuana Business Operator to receive direct remuneration from the Retail Marijuana Business, including a portion of the profits of the Retail Marijuana Business being operated, subject to the following limitations:
  - a. The portion of the profits to be paid to the Retail Marijuana Business Operator shall be commercially reasonable, and in any event shall not exceed the portion of the net profits to be retained by the Retail Marijuana Business being operated;
  - b. The Retail Marijuana Business Operator shall not be granted, and may not accept:
    - i. A security interest in the Retail Marijuana Business being operated, or in any assets of the Retail Marijuana Business;



- ii. An ownership or membership interest, shares, or shares of stock, or any right to obtain any direct or indirect beneficial ownership interest in the Retail Marijuana Business being operated, or a future or contingent right to the same, including but not limited to options or warrants;
    - c. The Retail Marijuana Business Operator shall not guarantee the Retail Marijuana Business's debts or production levels.
  - 3. Shall permit the Retail Marijuana Business being operated to terminate the contract with the Retail Marijuana Business Operator at any time, with or without cause.
- I. A Retail Marijuana Business Operator may engage in dual operation of a Retail Marijuana Business and a Medical Marijuana Business at a single location, to the extent the Retail Marijuana Business being operated is permitted to do so, the Retail Marijuana Business Operator shall comply with the rules promulgated pursuant to the Marijuana Code, including the requirement of obtaining a valid registration as a Medical Marijuana Business Operator.
- J. Any Retail Marijuana Business Operators and the Retail Marijuana Business Operator's Owner Licensee(s) that are appointed by a court to serve as a receiver, personal representative, executor, administrator, guardian, conservator, trustee, or similarly situated Person and take possession of, operate, manage, or control a Retail Marijuana Business must comply with Rule 2-275(F).

### **Basis and Purpose – 6-615**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(2)(o), 44-10-313(12), 44-10-401(2)(b)(VI), and 44-10-401(2)(c) C.R.S. The purpose of this rule is to establish employee license requirements for the Retail Marijuana Business Operator's Controlling Beneficial Owners, agents and employees, including those directly or indirectly engaged in the operation of other Retail Marijuana Business(es). This Rule 6-615 was previously Rule R 1703, 1 CCR 212-2.

### **6-615 – Retail Marijuana Business Operators: Employee Licenses for Personnel**

#### **A. Required Licenses.**

- 1. Owner Licenses. All natural persons who are Controlling Beneficial Owners in a Retail Marijuana Business Operator must have a valid Owner License, associated with the Retail Marijuana Business Operator License. Such an Owner License shall satisfy all licensing requirements for work related to the business of the Retail Marijuana Business Operator and for work performed on behalf of, or at the Licensed Premises of, the Retail Marijuana Business(es) operated by the Retail Marijuana Business Operator.
- 2. Employee Licenses. All other natural persons who are agents or employees of a Retail Marijuana Business Operator that are actively engaged, directly or indirectly, in the management, supervision, or operation of one or more other Retail Marijuana Businesses, including but not limited to all agents or employees who will come into contact with Retail Marijuana, who will have access to Limited Access Areas, or who will have access to the Inventory Tracking System account of the Retail Marijuana Business(es) being operated, must hold a valid Employee License. The Employee License shall satisfy all licensing requirements for work related to the business of the Retail Marijuana Business Operator and for work at the Licensed Premises of, or on behalf of, the Retail Marijuana Business(es) operated by the Retail Marijuana Business Operator.

- B. Employee Licenses Not Required. Employee Licenses are not required for Passive Beneficial Owners of a Retail Marijuana Business Operator, or for natural persons who will not come into contact with Retail Marijuana, will not have access Limited Access Area(s) of the Retail Marijuana Business(es) being operated, and will not have access to the Inventory Tracking System account of the Retail Marijuana Business(es) being operated.
- C. Designation of Management Personnel of a Retail Marijuana Business Operated by a Retail Marijuana Business Operator. If a Retail Marijuana Business Operator is contracted to manage the overall operations of a Retail Marijuana Business's Licensed Premises, the Retail Marijuana Business shall designate a separate and distinct management personnel on the Licensed Premises who is an officer, agent or employee of the Retail Marijuana Business Operator, which shall be a natural person with a valid Owner License or Employee License, as set forth in paragraph A of this Rule, and the Retail Marijuana Business shall comply with the reporting provisions of subsection 44-10-313(12), C.R.S.

**Basis and Purpose – 6-620**

The statutory authority for this rule includes but is not limited to 44-10-202(1)(c), 44-10-203(1)(c), and 44-10-203(1)(j), C.R.S. The purpose of this rule is to establish records retention standards for a Retail Marijuana Business Operators. This Rule 6-620 was previously Rule R 1704, 1 CCR 212-2.

**6-620 – Retail Marijuana Business Operators: Business Records Required**

- A. General Requirement. A Retail Marijuana Business Operator must maintain all required business records as set forth in Rule 3-905 - Business Records Required, except that:
  - 1. A Retail Marijuana Business Operator is not required to maintain secure facility information, diagrams of its designated place of business, or a visitor log for its separate place of business, because a Retail Marijuana Business Operator will not come into contact with Retail Marijuana at its separate place of business; and
  - 2. A Retail Marijuana Business Operator is not required to maintain records related to inventory tracking, or transport, because a Retail Marijuana Business Operator is prohibited from engaging in activities on its own behalf that would require inventory tracking or transport. All records relating to inventory tracking activities and records related to transport pertaining to the Retail Marijuana Business(es) operated by the Retail Marijuana Business Operator shall be maintained at the Licensed Premises of such Retail Marijuana Business(es).
- B. All records required to be maintained shall be maintained at the Retail Marijuana Business Operator's separate place of business, and not at the Licensed Premises of the Retail Marijuana Business(es) it operates.

**6-700 Series – Licensed Hospitality Businesses**

**Basis and Purpose – 6-705**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1), 44-10-203(2)(ff), 44-10-305(2)(b), 44-10-609, and 44-10-610, C.R.S. The purpose of this rule is to establish general provisions for Licensed Hospitality Businesses.

**6-705 – Licensed Hospitality Businesses: General Provisions**

- A. Privileges Granted. A Licensed Hospitality Business shall only exercise those privileges granted pursuant to the Marijuana Code and these Rules.

- B. Local Approval Required. No Licensed Hospitality Business may operate in a Local Jurisdiction that does not have an ordinance or resolution authorizing the operation of that type of Licensed Hospitality Business within the Local Jurisdiction. A Licensed Hospitality Business must comply with any requirements or restrictions on its operations imposed by the Local Jurisdiction's ordinance or resolution.
- C. Liability Insurance Required. Licensed Hospitality Businesses are required to carry general liability insurance. If a Licensed Hospitality Business has not obtained general liability insurance at the time of its initial license application, it must obtain general liability insurance prior to submitting the Licensee's first renewal application.
- D. Responsible Vendor Training Required. All Controlling Beneficial Owners and employees of a Licensed Hospitality Business shall complete annual responsible vendor training that satisfies the requirements of the responsible vendor program established in the 3-500 Series Rules.
- E. No Visible Consumption of Regulated Marijuana. A Licensed Hospitality Business shall ensure that the display and consumption of any marijuana is not visible from outside of its Licensed Premises. The requirement in this paragraph (E) also applies to Licensed Hospitality Businesses that operate in an isolated portion of a Retail Food Establishment. See rule 6-715 – Licensed Hospitality Businesses: Operation Within A Retail Food Establishment.
1. Outdoor Consumption Areas Permitted. A Licensed Hospitality Business may have a Consumption Area outdoors under the following conditions:
    - a. The Licensed Hospitality Business shall ensure that all marijuana is kept out of plain sight and is not visible from a public place without the use of optical aids, such as telescopes or binoculars, or aircraft; and
    - b. The Licensed Hospitality Business shall ensure that the Consumption Area is surrounded by a sight-obscuring wall, fence, hedge, or other opaque or translucent barrier.
- F. Required Signage.
1. Identification of Consumption Area. A Licensed Hospitality Business shall ensure all areas ingress and egress to the Consumption Area(s) be clearly identified by the posting of a sign which shall not be less than 12 inches wide and 12 inches long, composed of letters not less than a half inch in height, which shall state, "Consumption Area – No One Under 21 Years of Age Allowed."
  2. Required Warning. Licensed Hospitality Businesses must post, at all times and in a prominent place inside the Consumption Area, a warning that is at minimum twelve inches high and twelve inches wide that reads as follows:

“Must be 21 or older to enter

Marijuana may only be consumed in designated areas out of public view

No consumption of alcohol or tobacco products on site

We reserve the right to refuse entry or service for reasons including visible intoxication

It is against the law to drive while impaired by marijuana”

- G. Entry By A Person Under 21 Years Prohibited. A Licensed Hospitality Business shall not allow any individual under 21 years of age to enter its Licensed Premises. A Licensed Hospitality Business shall verify that every individual entering the Licensed Premises has a valid government-issued photo identification showing that the individual is 21 years of age or older. See Rule 3-405 – Acceptable Forms of Identification.
- H. Customers in Consumption Area. The Consumption Area must be supervised by a Licensee at all times when consumers are present to ensure that only persons who are 21 years of age or older are permitted to enter. A Licensed Hospitality Business shall reasonably monitor consumers in the Consumption Area to ensure compliance with these 6-700 Series Rules.
- I. Conduct on the Licensed Premises.
1. Consumption By Intoxicated Patrons Prohibited. A Licensed Hospitality Business shall not permit the use or consumption of marijuana by any person displaying any visible signs of intoxication.
  2. Alcohol Consumption Prohibited. No consumption of alcohol is permitted in a Licensed Hospitality Business. A Licensed Hospitality Business is responsible for preventing the consumption of alcohol within its Licensed Premises.
  3. Tobacco Consumption Prohibited. No smoking of tobacco or tobacco products is permitted in a Licensed Hospitality Business. A Licensed Hospitality Business is responsible for preventing the smoking of tobacco and tobacco products within its Licensed Premises.
  4. Employee Consumption Prohibited. No employee of a Licensed Hospitality Business who is on duty may use or consume marijuana. A Licensed Hospitality Business is responsible for preventing the use or consumption of marijuana by on-duty employees within its Licensed Premises.
  5. Flammable Instrument Restrictions. A Licensed Hospitality Business shall not allow the use of the following devices in the Licensed Premises if prohibited by a local ordinance or resolution:
    - a. Any device using liquid petroleum gas;
    - b. A butane torch;
    - c. A butane lighter; or
    - d. Matches.
  6. Orderliness. A Licensed Hospitality Business shall operate the business in a decent, orderly, and respectable manner. A Licensed Hospitality Business shall not knowingly permit any activity or acts of disorderly conduct as defined by and provided for in section 18-9-106, C.R.S., nor shall a Licensed Hospitality Business permit rowdiness, undue noise, or other disturbances or activity offensive to the senses of the average citizen, or to the residents of the neighborhood in which the Licensed Hospitality Business is located.
- J. Free Marijuana Prohibited. A Licensed Hospitality Business may not give away marijuana to a consumer for any reason.

- K. Food Products Permitted. A Licensed Hospitality Business is permitted to sell or give away consumable products that do not contain marijuana under the following circumstances:
1. The Licensed Hospitality Business operates in an isolated portion of a Retail Food Establishment;
  2. A Licensed Hospitality Business that is not a Retail Food Establishment may prepare and serve hot coffee, hot tea, instant hot beverages, and nonpotentially hazardous doughnuts or pastries obtained from sources complying with all laws related to food and food labeling; or
  3. A Licensed Hospitality Business that is not a Retail Food Establishment may sell or give away nonpotentially hazardous prepackaged food and commercially prepared, prepackaged foods requiring no preparation other than the heating of food within its original container or package.
- L. Emergency Entry by Public Safety Personnel. If an emergency requires law enforcement, firefighters, emergency medical service providers, or other public safety personnel to enter the Licensed Premises of a Licensed Hospitality Business, the Licensed Hospitality Business is responsible for ensuring that all consumption and other activities, including sales, if applicable, cease until such personnel have completed their investigation or services and have left the Licensed Premises.
- M. Criminal Activity Reporting Requirements. In addition to other reporting requirements set forth in these Rules, a Licensed Hospitality Business must report directly to the Division any criminal activity requiring an in-person response from law enforcement. Any report required under this Rule must be submitted within 48 hours after an Owner Licensee or Employee Licensee of the Licensed Hospitality Business learns of the event.
- N. Removal of Persons from the Licensed Premises. A Licensed Hospitality Business may remove a person from the Licensed Premises for any reason, including but not limited to, any consumer showing any visible signs of intoxication.
- O. Control and Disposal of Marijuana Left by a Consumer. A Licensed Hospitality Business is responsible for the collection and disposal of any marijuana left on the Licensed Premises by a consumer. When a consumer leaves any marijuana on the Licensed Premises, a Licensed Hospitality Business must promptly collect and remove the marijuana from the Restricted Access Area and either immediately destroy or store and secure the marijuana in a Limited Access Area or an area inaccessible to consumers in accordance with Rule 6-720(A).
1. Marijuana Consumer Waste. In conjunction with the collecting and securing of any remaining marijuana, a Licensed Hospitality Business may segregate any Marijuana Consumer Waste in order to Transfer the Marijuana Consumer Waste for purposes of recycling in accordance with Rule 3-240 – Collection of Marijuana Consumer Waste.
  2. Destruction Required. At, or before, the end of each business day, a Licensed Hospitality Business shall destroy any marijuana left on its Licensed Premises by a consumer in conformance with Rule 3-230 – Waste Disposal. The Licensed Hospitality Business shall document any destruction of Regulated Marijuana in a waste log. See Rule 3-905 – Business Records Required.
- P. Consumer Education Materials. A Licensed Hospitality Business must provide Consumer Education Materials regarding the safe consumption of marijuana. Consumer Education Materials may be made available in print or digital form, may never make claims regarding health or

physical benefits of marijuana, and must be prominently displayed. Consumer Education Materials shall at a minimum include the following statement:

**“WARNING:** Using marijuana, in any form, while you are pregnant or breastfeeding passes THC to your baby and may be harmful to your baby. There is no known safe amount of marijuana use during pregnancy or breastfeeding.

Create a transportation plan ahead of time. Don't operate a vehicle impaired.

Impairing effects of marijuana may be delayed.”

### **Basis and Purpose – 6-710**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1), 44-10-203(2)(ff), 44-10-305(2)(b), 44-10-609, and 44-10-610, C.R.S. The purpose of this rule is to establish additional health and safety regulations for Licensed Hospitality Businesses.

### **6-710 – Licensed Hospitality Businesses: Additional Health and Safety Regulations**

- A. Local Safety Requirements and Inspections. A Licensed Hospitality Business must comply with any safety requirements or required inspections imposed by the Local Jurisdiction's ordinance or resolution which authorizes the Licensed Hospitality Business's operation.
- B. Sanitation of Consumption Equipment. If a Licensed Hospitality Business provides consumers with reusable equipment or devices to aid in the use or consumption of marijuana, the Licensed Hospitality Business shall ensure the equipment or device is sanitized properly. A Licensed Hospitality Business shall maintain standard operating procedures regarding reusable equipment and device sanitation practices. Failure to maintain records and/or sanitize reusable equipment may constitute a license violation affecting public safety.

### **Basis and Purpose – 6-715**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1), 44-10-203(2)(ff), 44-10-305(2)(b), 44-10-609, and 44-10-610, C.R.S. The purpose of this rule is to establish requirements for Licensed Hospitality Businesses operating within a Retail Food Establishment or on the Licensed Premises of any establishment with a license issued pursuant to articles 3, 4, or 5 of Title 44.

### **6-715 – Licensed Hospitality Businesses: Operation Within a Retail Food Establishment**

- A. Alcohol Beverage License Prohibited. A Licensed Hospitality Business shall not operate within a Retail Food Establishment that holds a license or permit issued pursuant to article 3, 4, or 5 of title 44.
  - 1. The Licensed Premises of a Licensed Hospitality Business must be completely separate from, and shall not overlap with, the licensed premises of any license issued pursuant to articles 3, 4, or 5 of Title 44. To be considered completely separate:
    - a. The Licensed Premises of a Licensed Hospitality Business shall not overlap with or share any physical space with, at any time, the licensed premises of a license issued pursuant to articles 3, 4, or 5 of Title 44. Alternating use of the same location at different times by a license issued pursuant to article 10 of Title 44 and a license or permit issued pursuant to article 3, 4, or 5 of Title 44 is prohibited.

- b. The Licensed Premises of a Licensed Hospitality Business may be adjacent to the licensed premises of any license issued pursuant to article 3, 4, or 5 of Title 44, so long as all of the following conditions are met:
  - i. Each has a separate address, which may be separate units within a street address so long as each unit has separate entrances and exits from the other, and consumers may not pass through the licensed premises of one to reach the licensed premises of the other;
  - ii. There is no door, hallway, or passageway by or through which a consumer may pass between the Licensed Premises of a Licensed Hospitality Business and the adjacent licensed premises of any license issued pursuant to articles 3, 4, or 5 of Title 44; and
  - iii. Any window on a shared wall is covered, or rendered opaque or translucent, to ensure the display or consumption of marijuana within a Licensed Hospitality Business is not visible to any person outside the Licensed Premises, including by a person within the adjacent licensed premises of a license issued pursuant to articles 3, 4, or 5 of Title 44.

B. Isolation From Unlicensed Portions of the Retail Food Establishment. A Licensed Hospitality Business that operates within a Retail Food Establishment shall ensure that its Licensed Premises are isolated from the rest of the Retail Food Establishment.

- 1. Consumers may enter the Licensed Premises from the unlicensed portion of the Retail Food Establishment. However, in order to be isolated from the rest of the Retail Food Establishment, the Licensed Premises shall:
  - a. Not overlap with the operations of the Retail Food Establishment; and
  - b. Be separated by a sight-obscuring wall, or other opaque or translucent barrier, and a secure door to ensure only consumers 21 years of age or older are permitted into the Licensed Premises.
- 2. Segregation of Marijuana. A Licensed Hospitality Business shall not store marijuana—either for purposes of sale or destruction—in any location containing other inventory of the Retail Food Establishment.

C. Manufacturing of Regulated Marijuana Products Prohibited. A Licensed Hospitality Business shall ensure that the Retail Food Establishment is not used to manufacture Regulated Marijuana Products or to add marijuana to foods produced or provided at the Retail Food Establishment.

D. Food Service Permitted. Nothing in this Rule 6-715 prohibits employees of the Retail Food Establishment from taking orders for, or serving, foods, produced or provided at the Retail Food Establishment within the Licensed Premises of the Licensed Hospitality Business. Any employee of the Retail Food Establishment who has unescorted access to the Limited Access Area or Restricted Access Area of a Licensed Hospitality Business, or who may handle marijuana for destruction, or any other purpose, shall first obtain an Employee License and Identification Badge.

### **Basis and Purpose – 6-720**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1), 44-10-203(2)(ff), 44-10-305(2)(b), and 44-10-610, C.R.S. The purpose of this rule is to establish requirements for the display of Retail Marijuana on the Licensed Premises of a Retail Marijuana Hospitality and Sales

Business, and to establish that a Retail Marijuana Hospitality and Sales Business must control and safeguard access to certain areas where Retail Marijuana will be sold..

#### **6-720 – Retail Marijuana Hospitality and Sales Businesses Point of Sale: Restricted Access Area**

- A. Display of Retail Marijuana. The display of Retail Marijuana for sale is allowed only in Restricted Access Areas. Any product displays that are readily accessible to the consumer must be supervised by the Owner Licensee or Employee Licensees at all times when consumers are present.

#### **Basis and Purpose – 6-725**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1), 44-10-203(2)(ff), 44-10-305(2)(b), 44-10-609, and 44-10-610, C.R.S. The purpose of this rule is to clarify additional license privileges and restrictions for Retail Marijuana Hospitality and Sales Businesses that do not apply to Marijuana Hospitality Businesses.

#### **6-725 – Retail Marijuana Hospitality and Sales Businesses: Additional License Privileges and Restrictions**

- A. Authorized Sources of Retail Marijuana. A Retail Marijuana Hospitality and Sales Business may only Transfer Retail Marijuana that it obtained from another Retail Marijuana Business.
- B. Restriction on Transfers to Consumers. A Retail Marijuana Hospitality and Sales Business and its employees are prohibited from Transferring Retail Marijuana to a consumer if the Retail Marijuana Hospitality and Sales Business' employee knows or reasonably should know that the consumer does not intend to consume the Retail Marijuana on the Licensed Premises of the Retail Marijuana Hospitality and Sales Business or previously during the same business day the consumer already received the relevant quantity limitation in this Rule. In determining the imposition of any penalty for violation of this Rule 6-725, the State Licensing Authority will consider any mitigating and aggravating factors set forth in Rule 8-235.
- C. Inventory Tracking System Requirements. A Retail Marijuana Hospitality and Sales Business must use the Inventory Tracking System in accordance with the requirements of the 3-800 Series Rules.
- D. Samples Provided for Testing. A Retail Marijuana Hospitality and Sales Business may provide Samples of Retail Marijuana for testing purposes to a Retail Marijuana Testing Facility. The Retail Marijuana Hospitality and Sales Business shall maintain the testing results as part of its business books and records. See Rule 3-905 – Business Records Required.
- E. Authorized On-Premises Storage. A Retail Marijuana Hospitality and Sales Business may store inventory on the Licensed Premises. All inventory stored on the Licensed Premises must be secured in a Limited Access Area or Restricted Access Area, and tracked consistently with the inventory tracking rules. See Rule 3-800 Series Rules – Regulated Marijuana Business: Inventory Tracking System.
- F. Authorized Marijuana Transport. A Retail Marijuana Hospitality and Sales Business is authorized to utilize a licensed Retail Marijuana Transporter for transportation of its Retail Marijuana so long as the place where the transportation orders are taken and delivered is a licensed Retail Marijuana Business. Nothing in this Rule prevents a Retail Marijuana Hospitality and Sales Business from transporting its own Retail Marijuana to the Licensed Premises of its Retail Marijuana Hospitality and Sales Business.



- G. Quantity Limitations on Sales. All Transfers of Retail Marijuana by a Retail Marijuana Hospitality and Sales Business to a consumer shall not exceed the following sales limits:
1. More than two grams of Retail Marijuana flower;
  2. More than one-half of one gram of Retail Marijuana Concentrate; or
  3. A Retail Marijuana Product containing more than 20 milligrams of active THC. For any Transfer of Retail Marijuana Product containing more than 10 milligrams of active THC, the Retail Marijuana Product must be Transferred to a consumer in separate serving sizes containing no more than 10 milligrams of active THC per serving.
- H. Measurement Procedures and Equipment.
1. A Retail Marijuana Hospitality and Sales Business shall develop and maintain standard operating procedures, and any additional equipment necessary, to ensure any Retail Marijuana Product Transferred to a consumer does not exceed the quantity limitation set forth in subparagraph G(3).
  2. A Retail Marijuana Hospitality and Sales Business Transferring Multiple-Serving Edible Retail Marijuana Product or Multiple-Serving Liquid Edible Retail Marijuana Product to a consumer shall provide a measurement device necessary for the consumer to achieve accurate measurements of each serving in increments equal to or less than 10 milligrams of active THC per serving.
- I. Packaging and Labeling.
1. Packaging and Labeling Not Required at Time of Transfer. A Retail Marijuana Hospitality and Sales Business may Transfer Retail Marijuana to a consumer without packaging and labeling so long as the Retail Marijuana Hospitality and Sales Business complies with the requirements of Rule 3-1020. See Rule 3-1020 – Packaging and Labeling: Requirements Prior to Transfer to a Consumer at a Retail Marijuana Hospitality and Sales Business.
  2. Packaging and Labeling Required Before Retail Marijuana Removed from Licensed Premises. A Retail Marijuana Hospitality and Sales Business shall not permit a consumer to leave the Licensed Premises with any unconsumed marijuana unless the Retail Marijuana Hospitality and Sales Business has ensured the, unconsumed marijuana is packaged and labeled in accordance with the requirements of Rule 3-1020. See Rule 3-1020 – Packaging and Labeling: Requirements Prior to Transfer to a Consumer at a Retail Marijuana Hospitality and Sales Business.
- J. Licenses May Refuse Sales. Nothing in these rules prohibits a Licensee from refusing to Transfer Retail Marijuana, Retail Marijuana Concentrate, or Retail Marijuana Product to a consumer.

### **Basis and Purpose – 6-730**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1), 44-10-203(2)(ff), 44-10-305(2)(b), 44-10-609, and 44-10-610, C.R.S. The purpose of this rule is to establish general limitations and prohibited acts for Retail Marijuana Hospitality and Sales Businesses.

### **6-730 – Retail Marijuana Hospitality and Sales Businesses: General Limitations and Prohibited Acts**

- A. Age Verification. Prior to Initiating the Transfer of Retail Marijuana a Licensee must verify that the purchaser has a valid government-issued photo identification showing that the purchaser is 21 years of age or older. See Rule 3-405 – Acceptable Forms of Identification.
- B. Purchases Only Within Restricted Access Area. A consumer must be physically present within the Restricted Access Area of the Retail Marijuana Hospitality and Sales Business's Licensed Premises to purchase Retail Marijuana.
1. Application to Retail Marijuana Hospitality and Sales Businesses Operating in a Retail Food Establishment. The requirement of paragraph (B) also applies to all Retail Marijuana Hospitality and Sales Businesses operating in an isolated portion of the Retail Food Establishment. All Transfers of Retail Marijuana may occur only in the Retail Marijuana Hospitality and Sales Business' Restricted Access Area, and not in any other area of the Retail Food Establishment.
- C. Prohibited Sales and Activity.
1. Sales to Persons Under 21 Years. A Retail Marijuana Hospitality and Sales Business is prohibited from Transferring, giving, or distributing Regulated Marijuana to persons under 21 years of age.
  2. Alternative Use Products. A Retail Marijuana Hospitality and Sales Business shall not Transfer, or permit the use or consumption of, any Alternative Use Product.
  3. Marijuana Not Transferred by the Retail Marijuana Hospitality and Sales Business. A Retail Marijuana Hospitality and Sales Business shall not permit the purchase, use or consumption of any marijuana other than the Retail Marijuana it Transfers pursuant to these rules.
  4. Nicotine or Alcohol. A Retail Marijuana Hospitality and Sales Business is prohibited from Transferring Retail Marijuana that contain nicotine or alcohol, if the sale of alcohol would require a license pursuant to articles 3, 4, or 5 of Title 44, C.R.S.
  5. Transfer of Expired Product. A Retail Marijuana Hospitality and Sales Business shall not Transfer any expired Retail Marijuana Product to a consumer.
  6. Transporter Transfer Restrictions. A Retail Marijuana Hospitality and Sales Business shall not Transfer Retail Marijuana to a Retail Marijuana Transporter, and shall not buy or receive complimentary Retail Marijuana from a Retail Marijuana Transporter.
  7. Possession and Transfer of Sampling Units. A Retail Marijuana Hospitality and Sales Business may not possess or Transfer Sampling Units.
  8. Research Transfers. A Retail Marijuana Hospitality and Sales Business shall not Transfer any Retail Marijuana to a Medical Research Facility, a Pesticide Manufacturer, or a Marijuana Research and Development Facility.
- D. Storage and Display Limitations.
1. A Retail Marijuana Hospitality and Sales Business shall not display Retail Marijuana outside of a designated Restricted Access Area or in a manner in which Retail Marijuana can be seen from outside the Licensed Premises. Storage of Retail Marijuana shall otherwise be maintained in Limited Access Area or Restricted Access Area.

2. Any product displays that are readily accessible to the customer must be supervised by the Owner Licensee or Employee Licensee at all times when consumers are present.
- E. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

### **Basis and Purpose – 6-735**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1), 44-10-203(2)(ff), 44-10-305(2)(b), 44-10-609, and 44-10-610, C.R.S. The purpose of this rule is to establish Limited Access Area and security exemptions and requirements for Marijuana Hospitality Businesses.

### **6-735 – Marijuana Hospitality Business: Limited Access Areas and Security Standards**

- A. Limited Access Area Permitted But Not Required. A Marijuana Hospitality Business is not required to maintain a Limited Access Area as part of the Licensed Premises so long as the Marijuana Hospitality Business demonstrates the following:
1. It has established policies, procedures, and methods to ensure marijuana collected pursuant to Rule 6-705(O) will be secured in an area inaccessible to patrons of the Marijuana Hospitality Business prior to destruction; and
  2. Its surveillance recording equipment is housed in a designated, locked, and secured room or other enclosure with access limited to authorized employees, agents of the Division, and the relevant Local Licensing Authority or Local Jurisdiction, state or local law enforcement agencies for a purpose authorized by the Marijuana Code or for any other state or local law enforcement purpose, and service personnel or contractors.
- B. Security Standards. A Marijuana Hospitality Business shall comply with Rule 3-220 Security Alarm Systems and Lock Standards, except that its Licensed Premises need only be monitored when consumers are on the Licensed Premises or during periods when marijuana collected pursuant to Rule 6-705(O) remains on the Licensed Premises prior to destruction.

### **Basis and Purpose – 6-740**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1), 44-10-203(2)(ff), 44-10-305(2)(b), and 44-10-609, C.R.S. The purpose of this rule is to establish requirements for Marijuana Hospitality Businesses with a Mobile Premises.

### **6-740 – Marijuana Hospitality Business: Requirements for Mobile Premises**

- A. Separate License Required for Each Mobile Premises. Each Mobile Premises requires a separate Marijuana Hospitality Business License.
- B. Consumption Area of the Mobile Premises. The Consumption Area of the Mobile Premises shall exclude the area designed to seat the driver and front seat passenger.
- C. Requirements for Motor Vehicles Designated as Mobile Premises. A Marijuana Hospitality Business must ensure that the motor vehicle serving as the Mobile Premises of a Marijuana Hospitality Business complies with all state and local registration and permitting requirements. At each initial and renewal application, a Marijuana Hospitality Business must provide the Division with the following information regarding its Mobile Premises:
- a. Documentation that the Mobile Premises is owned or leased by the Marijuana Hospitality Business;

- b. The vehicle manufacturer/make, model, and model year associated with the Mobile Premises;
- c. The vehicle identification number (VIN) associated with the Mobile Premises;
- d. The Colorado license plate number and copy of the registration associated with the Mobile Premises;
- e. If applicable, the automatic vehicle identification tag associated with the Mobile Premises; and
- f. A copy of a valid permit issued by the Public Utilities Commission to the Marijuana Hospitality Business.

D. Local Approval Required. A Marijuana Hospitality Business with a Mobile Premises may only operate in Local Jurisdictions that have an ordinance or resolution authorizing the operation of Mobile Premises and for which it holds any required valid local license(s). A Mobile Premises' operation includes, but is not limited to, allowing passengers to consume marijuana and boarding or disembarking the Mobile Premises.

E. Additional Requirements for Mobile Premises. Before receiving a License for a Mobile Premises, a Marijuana Hospitality Business must establish that the Mobile Premises will be able to meet the following requirements:

1. Global position system tracking of the Mobile Premises;
2. Written standard operating procedures that address the logging of the route(s) of each Mobile Premises;
3. Video surveillance inside of the Mobile Premises, including the entry and exit points to the Mobile Premises and driver's area of the vehicle;
4. Proper ventilation within the vehicle, which includes, if marijuana is smoked or vaped in the Licensed Premises, that air is not circulated into the driver's area of the Licensed Premises;
5. Policies and procedures to ensure that no marijuana is possessed or consumed in the area designed to seat the driver and front seat passenger in a motor vehicle designed, maintained, or used primarily for the transportation of persons for compensation;
6. Methods to ensure consumption activity is not visible outside the vehicle;
7. Policies, procedures or other measures to ensure that consumers are prohibited from entering the driver's area of the Mobile Premises; and
8. Display of the Marijuana Hospitality Business license on the dashboard of the Mobile Premises.

F. Separate Place of Business. A Marijuana Hospitality Business with a Mobile Premises shall designate and maintain a fixed place of business in Colorado that is separate from the Mobile Premises. The fixed place of business does not need to be a Licensed Premises. However, if the Marijuana Hospitality Business will transport any marijuana to the separate place of business for purposes of destruction, the separate place of business shall also be a Licensed Premises and is subject to any applicable state and local licensing requirements or restrictions.

1. **Shared Places of Business.** Multiple Marijuana Hospitality Business Licensees with Mobile Premises may share a single separate place of business so long as the Marijuana Hospitality Businesses are identically owned.
  2. **Shared Premises with Another Licensed Hospitality Business.** A Marijuana Hospitality Business with a Mobile Premises may designate the location of another Marijuana Hospitality Business's Licensed Premises as its separate place of business subject to the following conditions:
    - a. The relevant Local Licensing Authority or Local Jurisdiction permit a Marijuana Hospitality Business with a Mobile Premises to designate the location of another Marijuana Hospitality Business's Licensed Premises as its separate place of business;
    - b. The Marijuana Hospitality Businesses are identically owned; and
    - c. Record-keeping shall enable the Division and the Local Licensing Authority or Local Jurisdiction to distinguish clearly the business transactions and operations of each Marijuana Hospitality Business.
- G. **Business Records.** All records required to be maintained by these rules must be maintained at the Marijuana Hospitality Business's separate place of business, and not at the Mobile Premises, except that when the Mobile Premises is in operation it must maintain its current route log on the Mobile Premises.
1. A Marijuana Hospitality Business is not required to maintain records related to inventory tracking because a Marijuana Hospitality Business is prohibited from engaging in Transfers of marijuana.
- H. **Health and Safety Requirements.** A Marijuana Hospitality Business' Mobile Premises shall comply with all relevant requirements in the 3-300 Series Rules. Hand-washing facilities, however, need not be in the Mobile Premises, but may be located in the Marijuana Hospitality Business's separate place of business.
- I. **Operating Restrictions.** A Marijuana Hospitality Business shall ensure that its Mobile Premises does not operate outside of the state of Colorado.

## **Part 7 – Regulated Marijuana Transfers to Unlicensed Medical Research Facilities and Pesticide Manufacturers**

### **Basis and Purpose – 7-105**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-202(1)(a)(I), and 25-1.5-106.5, C.R.S. The purpose of this rule is to establish requirements associated with the Transfer of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana Product to Medical Research Facilities, including requirements for the possession and disposition of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana Product by Medical Research Facilities. This Rule 7-105 was previously Rule M 1801, 1 CCR 212-1.

### **7-105 – Medical Marijuana Transfers to Medical Research Facilities**

- A. **Transfers to Medical Research Facilities.** A Medical Marijuana Cultivation Facility and a Medical Marijuana Products Manufacturer may Transfer Medical Marijuana to a Medical Research Facility pursuant to Rules 5-205 and 5-305.

- B. Agreement with Medical Research Facility. A Medical Marijuana Cultivation Facility or Medical Marijuana Products Manufacturer that Transfers Medical Marijuana to a Medical Research Facility shall enter into a written agreement with the Medical Research Facility prior to Transferring any Medical Marijuana to the Medical Research Facility. The written agreement shall constitute a business record. See Rule 3-905 – Business Records Required. The written agreement shall include the following information:
1. The identity of the Medical Research Facility;
  2. The quantity of Medical Marijuana that will be Transferred to the Medical Research Facility;
  3. An affirmation by the Medical Research Facility that it (a) has received approval and funding from the State Board of Health for the research to be conducted on the marijuana; (b) remains authorized to receive the quantity of Medical Marijuana that will be Transferred to the Medical Research Facility; and (c) will destroy all Medical Marijuana that will be Transferred to the Medical Research Facility, following completion of research activities as required by subsection 25-1.5-106.5(5)(b), C.R.S.;
  4. An affirmation by the Licensee that the Medical Research Facility has provided it with written proof of the State Board of Health’s approval and funding of the Medical Research Facility’s research; and
  5. The date(s) upon which Transfer of the Medical Marijuana will occur.
- C. State Board of Health Approval. A Medical Marijuana Cultivation Facility or Medical Marijuana Products Manufacturer shall not Transfer Medical Marijuana unless and until the State Board of Health approves and funds the Medical Research Facility’s research pursuant to section 25-1.5-106.5, C.R.S.
1. A Medical Marijuana Cultivation Facility or Medical Marijuana Products Manufacturer shall not Transfer any Medical Marijuana until the Medical Marijuana Cultivation Facility or Medical Marijuana Products Manufacturer receives written proof of the State Board of Health’s approval and funding of the Medical Research Facility’s research. The written proof of the State Board of Health’s approval and funding of the Medical Research Facility’s research shall constitute a business record. See Rule 3-905 – Business Records Required.
  2. Transferring Medical Marijuana to a Medical Research Facility before the Medical Research Facility receives approval and funding from the State Board of Health shall be considered a violation affecting public safety.
- D. Inventory Tracking Requirements. A Medical Marijuana Cultivation Facility or Medical Marijuana Products Manufacturer shall track all Medical Marijuana in the Inventory Tracking System until it is delivered to a Medical Research Facility.
1. Transport Manifest. A Licensee shall not deliver or permit the delivery of Medical Marijuana unless a manifest is generated from the Inventory Tracking System. See Rule 3-605(C) – Transport: All Regulated Marijuana Businesses.
  2. Complete Manifest. A Licensee shall not relinquish possession or control of Medical Marijuana to a Medical Research Facility until a natural person authorized by the Medical Research Facility acknowledges receipt of the Medical Marijuana by signing the transport manifest. See Rule 3-605(I).

3. No Inventory Tracking Following Delivery. Once Medical Marijuana has been Transferred by a Licensee to a Medical Research Facility, no further inventory tracking is required.
  4. Licensee Delivery Responsibility. The originating Licensee is responsible for confirming delivery of the Medical Marijuana in the Inventory Tracking System. See Rule 3-605(I).
- E. Packaging, Labeling, and Testing. A Medical Marijuana Cultivation Facility or Medical Marijuana Products Manufacturer that Transfers Medical Marijuana to a Medical Research Facility shall package, label, and test all Medical Marijuana in conformance with these rules, prior to Transferring the Medical Marijuana. See 3-1000 Series Rules – Labeling, Packaging, and Product Safety; 4-100 Series Rules – Regulated Marijuana Testing Program.
  - F. Business Records. A Medical Marijuana Cultivation Facility or Medical Marijuana Products Manufacturer that Transfers Medical Marijuana to a Medical Research Facility shall keep all documents concerning the relationship and Transfer of any Medical Marijuana in accordance with Rules 3-605 and 3-905.
  - G. Quantity Limitations for Medical Research Facilities. A Medical Research Facility shall only use Medical Marijuana for the medical research approved pursuant to section 25-1.5-106.5, C.R.S. A Medical Research Facility shall not possess at any time a quantity of Transferred Medical Marijuana greater than the quantity approved by the research grant awarded to the Medical Research Facility by the State Board of Health. In no event shall the Medical Research Facility possess at any given time more than (i) 12 Medical Marijuana plants and (ii) four pounds of Medical Marijuana or its equivalency in Medical Marijuana Concentrate (512 grams) or Medical Marijuana Product (5,120 Medical Marijuana Products).
  - H. Colorado Department of Public Health and Environment and State Board of Health Administration. The Colorado Department of Public Health and Environment is responsible for the administration of grants to Medical Research Facilities pursuant to section 25-1.5-106.5(2), C.R.S. The Colorado Department of Public Health and Environment, through the Scientific Advisory council, has the authority to review and make recommendations regarding research grant proposals. The State Board of Health has the authority to approve or deny research grant proposals pursuant to section 25-1.5-106.5, C.R.S.
  - I. Disposal of Medical Marijuana. A Medical Research Facility shall destroy all Medical Marijuana pursuant to Rule 3-230 – Waste Disposal following completion of research activities as required by subsection 25-1.5-106.5(5)(b), C.R.S.
  - J. No Transfer to Licensees. Under no circumstance may a Licensee receive or obtain for any purposes Medical Marijuana from a Medical Research Facility.

### **Basis and Purpose – 7-110**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(a)(I), 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), and 25-1.5-106.5(5)(b), C.R.S. The purpose of this rule is to establish requirements associated with the Transfer of Retail Marijuana, Retail Marijuana Concentrate, and Retail Marijuana Product to Medical Research Facilities, including requirements for the possession and disposition of Retail Marijuana, Retail Marijuana Concentrate, and Retail Marijuana Product by Medical Research Facilities. This Rule 7-110 was previously Rule R 1801, 1 CCR 212-2.

### **7-110 – Retail Marijuana Transfers to Medical Research Facilities**

- A. Transfers to Medical Research Facilities. A Retail Marijuana Cultivation Facility or a Retail Marijuana Products Manufacturer may Transfer Retail Marijuana to a Medical Research Facility pursuant to Rules 6-205 and 6-305.

1. Upon Transfer of the Retail Marijuana to the Medical Research Facility, such Retail Marijuana shall be deemed Medical Marijuana.
- B. Agreement with Medical Research Facility. A Retail Marijuana Cultivation Facility or Retail Marijuana Products Manufacturer that Transfers Retail Marijuana to a Medical Research Facility shall enter into a written agreement with the Medical Research Facility prior to Transferring any Retail Marijuana to the Medical Research Facility. The written agreement shall constitute a business record. See Rule 3-905 – Business Records Required. The written agreement shall include the following information:
1. The identity of the Medical Research Facility;
  2. The quantity of Retail Marijuana that will be Transferred to the Medical Research Facility;
  3. An affirmation by the Medical Research Facility that it (a) has received approval and funding from the State Board of Health for the research to be conducted on the marijuana; (b) remains authorized to receive the quantity of Retail Marijuana that will be Transferred to the Medical Research Facility; and (c) will destroy all Retail Marijuana that will be Transferred to the Medical Research Facility, following completion of research activities as required by subsection 25-1.5-106.5(5)(b), C.R.S.;
  4. An affirmation by the Licensee that the Medical Research Facility has provided it with written proof of the State Board of Health’s approval and funding of the Medical Research Facility’s research;
  5. The date(s) upon which Transfer of the Retail Marijuana will occur; and
  6. An acknowledgement that, pursuant to these rules, upon Transfer of the Retail Marijuana to the Medical Research Facility, such Retail Marijuana shall be deemed Medical Marijuana.
- C. State Board of Health Approval. A Retail Marijuana Cultivation Facility or Retail Marijuana Products Manufacturer shall not Transfer Retail Marijuana unless and until the State Board of Health approves and funds the Medical Research Facility’s research pursuant to section 25-1.5-106.5, C.R.S.
1. A Retail Marijuana Cultivation Facility or Retail Marijuana Products Manufacturer shall not Transfer any Retail Marijuana until the Retail Marijuana Cultivation Facility or Retail Marijuana Products Manufacturer receives written proof of the State Board of Health’s approval and funding of the Medical Research Facility’s research. The written proof of the State Board of Health’s approval and funding of the Medical Research Facility’s research shall constitute a business record. See Rule 3-905 – Business Records Required.
  2. Transferring Retail Marijuana to a Medical Research Facility before the Medical Research Facility receives approval and funding from the State Board of Health shall be considered a violation affecting public safety.
- D. Inventory Tracking Requirements. A Retail Marijuana Cultivation Facility or Retail Marijuana Products Manufacturer shall track all Retail Marijuana in the Inventory Tracking System until it is delivered to a Medical Research Facility.
1. Transport Manifest. A Licensee shall not deliver or permit the delivery of Retail Marijuana unless a manifest is generated from the Inventory Tracking System. See Rule 3-605(C) - Transport: All Regulated Marijuana Businesses.



2. Complete Manifest. A Licensee shall not relinquish possession or control of Retail Marijuana to a Medical Research Facility until a natural person authorized by the Medical Research Facility acknowledges receipt of the Retail Marijuana by signing the transport manifest. See Rule 3-605(H).
  3. No Inventory Tracking Following Delivery. Once Retail Marijuana has been Transferred by a Licensee to a Medical Research Facility, no further inventory tracking is required.
  4. Licensee Delivery Responsibility. The originating Licensee is responsible for confirming delivery of the Retail Marijuana in the Inventory Tracking System. See Rule 3-605(J).
- E. Packaging, Labeling, and Testing. A Retail Marijuana Cultivation Facility or Retail Marijuana Products Manufacturer that Transfers Retail Marijuana to a Medical Research Facility shall package, label, and test all Retail Marijuana in conformance with these Retail Marijuana Rules, 1 CCR 212-2, rules prior to Transferring the Retail Marijuana. See 3-1000 Series – Labeling, Packaging, and Product Safety; 4-100 Series Rules – Regulated Marijuana Testing Program.
- F. Business Records. A Retail Marijuana Cultivation Facility or Retail Marijuana Products Manufacturer that Transfers Retail Marijuana to a Medical Research Facility shall keep all documents concerning the relationship and such Transfer of any Retail Marijuana in accordance with Rules 3-605 and 3-905.
- G. Quantity Limitations for Medical Research Facilities. A Medical Research Facility shall only obtain Retail Marijuana for the medical research approved pursuant to section 25-1.5-106.5, C.R.S. A Medical Research Facility shall not possess at any time a quantity of Transferred Retail Marijuana greater than the quantity approved by the research grant awarded to the Medical Research Facility by the State Board of Health. In no event shall the Medical Research Facility possess at any given time more than (i) 12 Retail Marijuana Plants and (ii) four pounds of Retail Marijuana or its equivalency in Retail Marijuana Concentrate (512 grams) or Retail Marijuana Product (5,120 ten-milligram servings of Retail Marijuana Product).
- H. Colorado Department of Public Health and Environment and State Board of Health Administration. The Colorado Department of Public Health and Environment is responsible for the administration of grants to Medical Research Facilities pursuant to section 25-1.5-106.5(2), C.R.S. The Colorado Department of Public Health, through the Scientific Advisory council, has the authority to review and make recommendations regarding research grant proposals. The State Board of Health has the authority to approve or deny research grant proposals pursuant to section 25-1.5-106.5, C.R.S.
- I. Disposal of Medical Marijuana. A Medical Research Facility shall destroy all Transferred Retail Marijuana following completion of research activities as required by subsection 25-1.5-106.5(5)(b), C.R.S.
- J. No Transfer to Licensees. Under no circumstance may a Licensee receive or obtain for any purposes any Transferred Regulated Marijuana from a Medical Research Facility.

### **Basis and Purpose – 7-115**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(a)(II), 44-10-202(1)(c), 44-10-203(1)(c), and 44-10-203(1)(j), C.R.S. The purpose of this rule is to establish requirements associated with the Transfer of Regulated Marijuana and Regulated Marijuana Product to Pesticide Manufacturers, including requirements for the possession and disposition of Regulated Marijuana and Regulated Marijuana Products by Pesticide Manufacturers. This Rule 7-115 was previously Rules M and R 1802, 1 CCR 212-1 and 1 CCR 212-2.

## 7-115 – Pesticide Manufacturers

- A. Transfers to Pesticide Manufacturers. A Medical Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, Retail Marijuana Cultivation Facility, and Retail Marijuana Products Manufacturer may Transfer Regulated Marijuana to a Pesticide Manufacturer solely for the purpose of conducting research to establish safe and effective protocols, including but not limited to establishing efficacy and toxicity, for the use of Pesticides on Regulated Marijuana. See Rules 5-205, 5-305, 6-205, 6-305.
- B. Written Documentation Required. A Licensee shall require, and shall not Transfer Regulated Marijuana prior to receiving, written proof under oath, as evidenced by an affidavit entered into by an authorized person on behalf of the Pesticide Manufacturer, affirming that the Pesticide Manufacturer meets the requirements set forth in subparagraph (C)(4) of this Rule. This documentation shall constitute a business record under Rule 3-905 – Business Records Required.
- C. Agreement with Pesticide Manufacturer. A Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or Retail Marijuana Products Manufacturer that Transfers Regulated Marijuana to a Pesticide Manufacturer shall enter into a written agreement with the Pesticide Manufacturer prior to Transferring any Regulated Marijuana to the Pesticide Manufacturer. The written agreement, which shall constitute a business record under Rule 3-905, shall include:
1. The identity of the Pesticide Manufacturer;
  2. The quantity of Regulated Marijuana that will be Transferred to the Pesticide Manufacturer;
  3. The date(s) upon which Transfer of the Regulated Marijuana will occur;
  4. An affirmation by the Pesticide Manufacturer that it:
    - i. Has an establishment number with the U.S. Environmental Protection Agency pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136 *et seq.*;
    - ii. Is authorized to do business in Colorado;
    - iii. Is in possession of a physical location in the State of Colorado where its research activities will occur;
    - iv. Has applied for and received any necessary license, registration, certification, or permit from the Colorado Department of Agriculture pursuant to the Pesticide Act, sections 35-9-101 *et seq.*, C.R.S. and/or the Pesticide Applicators' Act, sections 35-10-101 *et seq.*, C.R.S.;
    - v. Remains authorized to receive the quantity of Regulated Marijuana that will be Transferred to the Pesticide Manufacturer; and
    - vi. Will only use the Transferred Regulated Marijuana for the purpose of research to establish safe and effective protocols for the use of Pesticides on Regulated Marijuana, which protocols may include but not be limited to establishing efficacy and toxicity; and

5. An affirmation by the Licensee that it has received written proof the Pesticide Manufacturer meets the requirements set forth in subparagraph (C)(4) of this Rule.
- D. Inventory Tracking Requirements. A Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, and Retail Marijuana Products Manufacturer shall track all Regulated Marijuana in the Inventory Tracking System until it is delivered to a Pesticide Manufacturer.
1. Transport Manifest. A Licensee shall not deliver or permit the delivery of Regulated Marijuana unless a manifest is generated from the Inventory Tracking System.
  2. Complete Manifest. A Licensee shall not relinquish possession or control of Regulated Marijuana to a Pesticide Manufacturer until a natural person authorized by the Pesticide Manufacturer acknowledges receipt of the Regulated Marijuana by signing the transport manifest.
  3. No Inventory Tracking Following Delivery. Once Regulated Marijuana has been Transferred by a Licensee to a Pesticide Manufacturer, no further inventory tracking is required.
  4. Licensee Delivery Responsibility. The originating Licensee is responsible for confirming delivery of all Regulated Marijuana in the Inventory Tracking System.
- E. Packaging, Labeling, and Testing. A Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or Retail Marijuana Products Manufacturer that Transfers Regulated Marijuana to a Pesticide Manufacturer shall package, label, and test all Regulated Marijuana in conformance with these rules prior to Transferring the Regulated Marijuana. See – Labeling, Packaging, and Product Safety; – Regulated Marijuana Testing Program.
- F. Business Records. A Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or Retail Marijuana Products Manufacturer that Transfers Regulated Marijuana to a Pesticide Manufacturer shall keep all documents concerning the relationship and Transfer of any Regulated Marijuana in accordance with Rules 3-605 and 3-905.
- G. Pesticide Manufacturer Authorized Activities. A Pesticide Manufacturer is only authorized to possess Transferred Regulated Marijuana in order to conduct research to establish safe and effective protocols, including but not limited to establishing efficacy and toxicity, for the use of Pesticides on Regulated Marijuana.
- H. Quantity Limitations for Pesticide Manufacturer. In no event shall a Pesticide Manufacturer possess at any given time more than (i) 12 Medical Marijuana plants and (ii) four pounds of Medical Marijuana or its equivalency in Medical Marijuana Concentrate (512 grams) or Medical Marijuana Product (5,120 Medical Marijuana Products), and (i) 12 Retail Marijuana plants and (ii) four pounds of Retail Marijuana or its equivalency in Retail Marijuana Concentrate (512 grams) or Retail Marijuana Products (5,120 ten-milligram servings of Retail Marijuana Product).
- I. Disposition of Transferred Regulated Marijuana. A Pesticide Manufacturer shall destroy all Transferred Regulated Marijuana received from a Licensee following completion of research activities.
1. A Pesticide Manufacturer shall destroy Transferred Regulated Marijuana in conformance with Rule 3-230 – Waste Disposal.

2. A Pesticide Manufacturer shall document the destruction of Transferred Regulated Marijuana, which documentation shall include:
    - i. Whether the destroyed material was Transferred Regulated Marijuana;
    - ii. The date of destruction;
    - iii. The location of the destruction;
    - iv. The manner in which the Transferred Regulated Marijuana was rendered unusable and Unrecognizable;
    - v. The method of final disposition pursuant to Rule 3-230; and
    - vi. The identity(ies) and contact information of all Person(s) involved in the destruction.
  3. A Pesticide Manufacturer shall keep all documentation regarding destruction of Transferred Regulated Marijuana for the current year and three preceding calendar years.
- J. No Pesticide on Licensed Premises. Under no circumstance may a Pesticide Manufacturer apply Pesticide(s) for research purposes on the Licensed Premises of a Regulated Marijuana Business.
1. Licensees Shall Not Permit Pesticide on Licensed Premises. Under no circumstance may a Licensee allow or permit the application of Pesticide(s) by a Pesticide Manufacturer for research purposes on the Licensed Premises of a Regulated Marijuana Business.
  2. Violation Affecting Public Safety. A violation of this prohibition shall be considered a violation affecting public safety.
- K. No Human or Animal Subjects. Under no circumstance shall a Pesticide Manufacturer receiving Regulated Marijuana from a Licensee engage in research involving human subjects. Additionally, under no circumstance shall a Pesticide Manufacturer receiving Regulated Marijuana from a Licensee engage in research involving animal subjects, as defined in the Animal Welfare Act, 7 U.S.C. § 2132(g).
1. Licensees Shall Not Permit Human or Animal Subject Research. If a Licensee knows or reasonably should know that a Pesticide Manufacturer intends to engage in or has engaged in marijuana-related research involving human and/or animal subjects, the Licensee shall not Transfer any Regulated Marijuana to the Pesticide Manufacturer.
  2. Violation Affecting Public Safety. A violation of this Rule shall be considered a violation affecting public safety.
- L. No Transfer to Licensees. Under no circumstance may a Licensee receive or obtain for any purposes any Transferred Regulated Marijuana from a Pesticide Manufacturer.

## **Part 8 – Enforcement and Discipline**

### **8-100 Series - Enforcement**

#### **Basis and Purpose –**

The statutory authority for this rule includes but is not limited to sections 44-10-201(4), 44-10-202(1)(c), 44-10-203(1)(e), 44-10-203(1)(f), 44-10-203(1)(g), 44-10-203(1)(j), 44-10-204, and 44-10-902, 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 administrative hold process, the handling of inventory subject to administrative hold and under investigation and the process for voluntary surrender of Regulated Marijuana. This Rule 8-105 was previously Rules M and R 1201, 1 CCR 212-1 and 1 CCR 212-2.

### **8-105 – Duties of Employees of the State Licensing Authority**

#### **A. Duties of Director.**

1. The State Licensing Authority may delegate an act required to be performed by the State Licensing Authority related to the day-to-day operation of the Division to the Director.
2. The Director may authorize Division employees to perform tasks delegated from the State Licensing Authority.
3. The Director or his or her authorized Division employees may consult with any state or local agency for the purpose of the proper administration of these rules or the Marijuana Code.

#### **B. Duties of Division Investigators. The State Licensing Authority, the Department's Senior Director of Enforcement, the Director, and Division investigators shall have all the powers of any peace officer to:**

1. Investigate violations or suspected violations of the Marijuana Code and any rules promulgated pursuant to it. Make arrests, with or without warrant, for any violation of the Marijuana Code, any rules promulgated pursuant to it, Article 18 of Title 18, C.R.S., any other laws or regulations pertaining to Regulated Marijuana in this state, or any criminal law of this state, if, during an officer's exercise of powers or performance of duties pursuant to the Marijuana Code, probable cause exists that a crime related to such laws has been or is being committed;
2. Serve all warrants, summonses, subpoenas, administrative citations, notices or other processes relating to the enforcement of laws regulating Regulated Marijuana;
3. Assist or aid any law enforcement officer in the performance of his or her duties upon such law enforcement officer's request or the request of other local officials having jurisdiction;
4. Inspect, examine, or investigate any premises where the Licensee's Regulated Marijuana is grown, stored, cultivated, manufactured, tested, distributed, or sold, and any books and records in any way connected with any licensed or unlicensed activity;
5. Require any Licensee, upon demand, to permit an inspection of Licensed Premises during business hours or at any time of apparent operation, marijuana equipment, and marijuana accessories, or books and records; and, to permit the testing of or examination of Regulated Marijuana;
6. Require Applicants to submit complete and current applications and fees and other information the Division deems necessary to make licensing decisions and approve material changes made by the Applicant or Licensee;

7. Conduct investigations into the character, criminal history, and all other relevant factors related to suitability of all Applicants and Licensees for Regulated Marijuana licenses and such other Persons with a direct or indirect interest in an Applicant or Licensee, as the State Licensing Authority may require; and
8. Exercise any other power or duty authorized by law.

C. Duties of State Licensing Authority and Division Employees.

1. Employees shall maintain the confidentiality of State Licensing Authority and Division records and information. For confidentiality requirements of State Licensing Authority and Division employees who leave the employment of the State Licensing Authority, see Rule 8-240 - Confidential Information and Former State Licensing Authority Employees.
2. Pursuant to subsection 44-10-201(3), C.R.S., State Licensing Authority employees with regulatory oversight responsibilities for marijuana businesses licensed by the State Licensing Authority shall not work for, represent, or provide consulting services to or otherwise derive pecuniary gain from a marijuana business licensed by the State Licensing Authority or other business entity established for the primary purpose of providing services to the marijuana industry for a period of six months following his or her last day of employment with the State Licensing Authority.
3. Pursuant to subsection 44-10-201(4), C.R.S., disclosure of confidential records or information in violation of the provisions of the Marijuana Code constitutes a class 1 misdemeanor.

**Basis and Purpose – 8-110**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(f), 44-10-202(1)(g), 44-10-203(1)(j), and 44-10-902, 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 administrative hold process, the handling of inventory subject to administrative hold and under investigation and the process for voluntary surrender of Regulated Marijuana. This Rule 8-110 was previously Rules M and R 1202, 1 CCR 212-1 and 1 CCR 212-2.

**8-110 – Requirement for Inspections and Investigations, Searches, Administrative Holds, Voluntary Surrenders and Such Additional Activities as May Become Necessary from Time to Time**

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 Marijuana 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 Marijuana Code and all rules promulgated pursuant to it. 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 investigator 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 Marijuana 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.
3. License Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

**B. Administrative Hold.**

- 1. To prevent destruction of evidence, diversion, or other threats to public safety, while permitting a Licensee to retain its inventory pending further investigation, a Division investigator may order an administrative hold of Regulated Marijuana pursuant to the following procedure:
  - a. If during an investigation or inspection of a Licensee, a Division investigator develops reasonable grounds to believe certain Regulated Marijuana constitute evidence of acts in violation of the Marijuana Code or rules promulgated pursuant to it, or constitute a threat to the public safety, the Division investigator may issue a notice of administrative hold of any such Regulated Marijuana. The notice of administrative hold shall provide a documented description of the Regulated Marijuana to be subject to the administrative hold and a concise statement that is promptly issued and approved by the Director, or his or her designee, regarding the reasons for issuing the administrative hold.
  - b. Following the issuance of a notice of administrative hold, the Division will identify the Regulated Marijuana subject to the administrative hold in the Inventory Tracking System. The Licensee shall continue to comply with all tracking requirements. See Rule 3-805 Regulated Marijuana Businesses: Inventory Tracking System.
  - c. The Licensee shall completely and physically segregate the Regulated Marijuana subject to the administrative hold in a Limited Access Area of the Licensed Premises under investigation, where it shall be safeguarded by the Licensee.
  - d. While the administrative hold is in effect, the Licensee is prohibited from, giving away, Transferring, transporting, or destroying the Regulated Marijuana subject to the administrative hold, except as otherwise authorized by these rules.
  - e. While the administrative hold is in effect, the Licensee must safeguard the Regulated Marijuana subject to the administrative hold, must 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 as set forth in the Marijuana Code and the rules of the State Licensing Authority.

- f. Nothing herein shall prevent a Licensee from voluntarily surrendering Regulated Marijuana that is subject to an administrative hold, except that the Licensee must follow the procedures set forth in paragraph (C) for voluntary surrender of Regulated Marijuana.
- g. Nothing herein shall prevent a Licensee from the continued possession, cultivation or harvesting of the Regulated Marijuana subject to the administrative hold. All Regulated Marijuana subject to an administrative hold must be put into separate Harvest Batches.
- h. At any time after the initiation of the administrative hold, the Division may lift the administrative hold, order the continuation of the administrative hold pending the administrative process, or seek other appropriate relief.

C. Voluntary Surrender of Regulated Marijuana .

- 1. A Licensee, prior to a Final Agency Order and upon mutual agreement with the Division, may elect to voluntarily surrender any Regulated Marijuana to the Division.
  - a. Such voluntary surrender may require destruction of any Regulated Marijuana 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 Licensee must certify that the individual has authority to represent and bind the Licensee.
- 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 Marijuana 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 Marijuana 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 Licensee must certify that the individual has authority to represent and bind the Licensee.

**Basis and Purpose – 8-115**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(f), 44-10-203(1)(g), 44-10-203(1)(j), and 44-10-902. The purpose of this rule is to provide guidance following either an agency decision or under any circumstances where the Licensee is ordered



to surrender and/or destroy unauthorized Regulated Marijuana. This rule also provides guidance as to the need to preserve evidence during agency investigations or subject to agency order. This Rule 8-115 was previously Rules M and R 1203, 1 CCR 212-1 and 1 CCR 212-2.

### **8-115 – Disposition of Unauthorized Regulated Marijuana**

- A. After a Final Agency Order Mandates the Destruction of Regulated Marijuana. If the State Licensing Authority issues a Final Agency Order pursuant to section 44-10-902, C.R.S., that orders the destruction of some or all of the Licensee's unauthorized Regulated, the Licensee may:
1. Voluntarily Surrender. The Licensee may voluntarily surrender to the Division all of its unauthorized Regulated Marijuana that are described in the Final Agency Order in accordance with the provisions of Rule 8-110(C).
  2. Seek A Stay. The Licensee may file a petition for a stay of the Final Agency Order with the Denver district court within 15 days of the date of the Final Agency Order.
  3. Take No Action. If the Licensee does not either (1) voluntarily surrender its unauthorized Regulated Marijuana as set forth in subparagraph (A)(1) of this Rule; or (2) properly seek a stay of the Final Agency Order as set forth in subparagraph (A)(2) of this Rule, the Division will enter upon the Licensed Premises and seize and destroy the unauthorized Regulated Marijuana that are the subject of the Final Agency Order.
- B. General Requirements Applicable To All Licensees Following Final Agency Order To Destroy Unauthorized Regulated Marijuana. The following requirements apply regardless of whether the Licensee voluntarily surrenders its unauthorized Regulated Marijuana seeks a stay of agency action, or takes no action:
1. The 15 day period set forth in section 44-10-902(5), C.R.S., and this Rule shall include holidays and weekends.
  2. During the period of time between the issuance of the Final Agency Order and the destruction of the unauthorized Regulated Marijuana the Licensee shall not sell, destroy, or otherwise let any unauthorized Regulated Marijuana that are subject to the Final Agency Order leave the Licensed Premises, unless specifically authorized by the State Licensing Authority or Court order.
  3. During the period of time between the issuance of the Final Agency Order and the destruction of unauthorized Regulated Marijuana, the Licensee must safeguard any unauthorized Regulated Marijuana in its possession or control and must fully comply with all security requirements including but not limited to surveillance, lock and alarm requirements set forth in the Marijuana Code and the rules of the State Licensing Authority.
  4. Unless the State Licensing Authority otherwise orders, the Licensee may cultivate, water, or otherwise care for any unauthorized Regulated Marijuana that are subject to the Final Agency Order during the period of time between the issuance of the Final Agency order and the destruction of the unauthorized Regulated Marijuana.
  5. If a district attorney notifies the Division that some or all of the unauthorized Regulated Marijuana is involved in an investigation, the Division shall not destroy the unauthorized Regulated Marijuana until approved by the district attorney.

### **Basis and Purpose – 8-120**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(f), 44-10-203(1)(g), 44-10-203(1)(j), and 44-10-203(2)(w), C.R.S. This rule explains that Division investigators may exercise discretion in issuing written warning when, during the course of a compliance check or investigation, the Division investigator identifies a violation(s) of the Marijuana Code or the rules promulgated thereunder. This rule also explains that the Director of the Division may exercise discretion to accept an assurance of voluntary compliance. It also explains the evidentiary value of a written warning or an assurance of voluntary compliance. This Rule 8-120 was previously Rules M and R 1204, 1 CCR 212-1 and 1 CCR 212-2.

### **8-120 – Written Warnings and Assurances of Voluntary Compliance**

- A. Written Warnings. During an investigation, if a Division investigator identifies a violation(s) of the Marijuana Code or the rules promulgated thereunder, the Division investigator may issue a written warning in lieu of recommending immediate 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 Licensee violated the Marijuana Code, or the rules promulgated thereunder.
  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 Marijuana Code, or the rules thereunder.
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 Marijuana Code, and/or the rules promulgated thereunder.
  3. The State Licensing Authority may approve or review an assurance of voluntary compliance.
- C. Not a Disciplinary Action. Neither a written warning nor an assurance of voluntary compliance constitutes a disciplinary action.

### **Basis and Purpose – 8-125**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(b), 44-10-202(1)(c), 44-10-202(5), 44-10-203(1)(e), 44-10-203(1)(g), 44-10-203(1)(j), 44-10-203(2)(l), C.R.S. The purpose of this rule is to establish the circumstances under which the State Licensing Authority may seek from a district court an investigative subpoena and what reasonable efforts the Division may take prior to seeking an investigative subpoena. The Division has encountered circumstances that would have justified such an

investigative subpoena. Establishing the criteria under which the Division may seek an investigative subpoena will provide district courts guidelines under which to evaluate a petition for an investigative subpoena.

### **8-125 – 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 Marijuana Code to obtain documents or information necessary to enforce the Marijuana 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 8-125, “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 – 8-130**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(2)(e), 44-10-203(2)(l), 44-10-203(1)(e), 44-10-203(1)(g), and 44-10-203(2)(w), C.R.S. The purpose of this rule is to establish the circumstances under which the Division may seek from a district court an administrative warrant to search and/or seize marijuana and marijuana products, or other evidence indicating a violation of the Marijuana Code or rules. The Division has encountered circumstances that would have justified such a warrant. Establishing the criteria under which the Division may seek an administrative warrant will give fair notice to the regulated community regarding the types of violations that would lead to a request for an administrative warrant. This Rule 8-130 was previously Rules M and R 1309, 1 CCR 212-1 and 1 CCR 212-2.

### **8-130 – 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 administrative hold or summary suspension has failed to comply with applicable rules; or
  - 3. A Licensee otherwise has acted in a manner demonstrating disregard for the Marijuana Code and the State Licensing Authority’s 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. If the Division seizes marijuana, neither the Division nor the State Licensing Authority shall cultivate or care for any seized marijuana or marijuana products. The Division may seek from the district court an order to destroy any such marijuana or marijuana products.

### **8-200 Series - Discipline**

### **Basis and Purpose – 8-205**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(d), 44-10-203(1)(j), 44-10-203(2)(a), 44-10-203(2)(l), 44-10-701, 44-10-901, and 24-4-105 C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(l). The purpose of this rule is to clarify how the disciplinary process for non-summary license suspensions and license revocations is initiated. This Rule 8-205 was previously Rules M and R 1301, 1 CCR 212-1 and 1 CCR 212-2.

### **8-205 – Disciplinary Process: 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 Marijuana Code, any rule promulgated pursuant to it, or any of its orders, the State Licensing Authority shall issue and serve upon the Licensee an Order to Show Cause (administrative citation) 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 8-220 – 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.**

### **Basis and Purpose – 8-210**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(d), 44-10-203(1)(j), 44-10-203(2)(a), 44-10-203(2)(l), 24-4-104(4)(a), 44-10-701, 44-10-901, and 24-4-105, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(l). The purpose of this rule is to set forth the process for summary suspensions when the State Licensing Authority has cause to immediately suspend a license prior to and pending a hearing and final agency order. Summary suspensions will be imposed when the State Licensing Authority has reason 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, and welfare imperatively require emergency action. The rule ensures proper due process for Licensees when their licenses are temporarily or summarily suspended by requiring prompt initiation of disciplinary proceedings after such suspensions. The purpose of the modifications to this rule is to clarify that the hearing following the Order of Summary Suspension concerns the allegations set forth in the Order to Show Cause. This Rule 8-210 was previously Rules M and R 1302, 1 CCR 212-1 and 1 CCR 212-2.

### **8-210 – Summary Suspensions**

#### **A. How a Summary Suspension Action 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 Licensee 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 in accordance with the following procedure:
  - a. After the Summary Suspension Order is issued, the State Licensing Authority shall promptly 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 shall identify the statute, rule, regulation, or order allegedly violated, and the facts alleged to constitute the violation. The Order to Show Cause shall 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 1304 – Administrative Hearings.

- B. Duration of Summary Suspension. Unless lifted by the State Licensing Authority, the Summary Suspension Order shall remain in effect until issuance of a Final Agency Order.

### **Basis and Purpose – 8-215**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(d), 44-10-203(1)(j), 44-10-203(2)(a), 44-10-203(2)(l), 44-10-701, 44-10-901, 24-4-104(4)(a), and 24-4-105, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(I). The State Licensing Authority recognizes that if Licensees are not able to care for their products during a period of active suspension, then their plants could die, their edible 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, manufactured products, and plants during the suspension (unless the State Licensing Authority does not allow such activity), provided the Licensed Premises and all Regulated Marijuana is adequately secured. In addition, the rule clarifies what activity is always prohibited during such suspension. This Rule 8-215 was previously Rules M and R 1303, 1 CCR 212-1 and 1 CCR 212-2.

### **8-215 – 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 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 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 MARIJUANA LICENSES ISSUED

FOR THESE PREMISES HAVE BEEN

SUSPENDED BY ORDER OF THE STATE LICENSING AUTHORITY

FOR VIOLATION OF THE COLORADO MARIJUANA 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 MARIJUANA LICENSES ISSUED

FOR THESE PREMISES HAVE BEEN

SUSPENDED BY ORDER OF THE STATE LICENSING AUTHORITY

FOR ALLEGED VIOLATION OF THE COLORADO MARIJUANA 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, sampling, acquisition, purchase, testing, Transfer, or transport of Regulated Marijuana on or from the Licensed Premises, nor allow patients or consumers 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 Marijuana on the Licensed Premises. The Licensee must fully account for all such Regulated Marijuana in the Inventory Tracking System. The Licensee must safeguard any Regulated Marijuana 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 Marijuana Code and the rules of the State Licensing Authority.

**C. Removal and Destruction of Regulated Marijuana. Regulated Marijuana shall not be removed from the Licensed Premises or destroyed unless and until:**

1. The provisions described in section 44-10-902, C.R.S., related to the proper destruction of unauthorized marijuana are met, and the State Licensing Authority orders forfeiture and destruction. See *also* Rule 8-115 – Disposition of Unauthorized Regulated Marijuana;

2. The Licensee has voluntarily surrendered the Regulated Marijuana in accordance with Rule 8-110(C) – Voluntary Surrender;
  3. The State Licensing Authority has seized the Regulated pursuant to an Administrative Warrant. See Rule 8-130 – Administrative Warrant.
- D. Renewal. The issuance of a suspension or an Order of Summary Suspension does not relieve the Licensee of the obligation to timely comply with all license renewal requirements.

### **Basis and Purpose – 8-220**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(d), 44-10-203(1)(j), 44-10-203(2)(a), 44-10-203(2)(l), 44-10-204(1)(a), 44-10-701, 44-10-901, 24-4-104, and 24-4-105, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(l). The purpose of this rule is to establish what entity conducts the administrative hearings, the procedures governing administrative hearings, and other general hearings issues. The purpose of the modifications to this rule is to clarify that the hearing following the Order of Summary Suspension concerns the allegations set forth in the Order to Show Cause, and to clarify that an answer is required only for two types of administrative notices: an Order to Show Cause and a Notice of Grounds for Denial. This Rule 8-220 was previously Rules M and R 1304, 1 CCR 212-1 and 1 CCR 212-2.

### **8-220 – Administrative Hearings**

#### **A. General Procedures.**

1. Hearing Location. Hearings will generally be conducted by the Department's Hearings Division. Unless the hearing officer orders a change of location based on good cause, as described in this Rule, hearings generally will be conducted at a location in the greater Denver metropolitan area to be determined by the hearing officer. Under unusual circumstances where justice, judicial economy and convenience of the parties would be served, hearings may be held in other locations in the state of Colorado.
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.

#### **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 the 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.

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 first-class mail to the last mailing address of record.
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 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 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. For purposes of this Rule, good cause 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. Such prehearing conferences may occur by telephone.
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 not 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 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 shall be 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.
  3. The hearing officer shall administer oaths 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 44-10-204(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 8-230 – Administrative Hearing Appeals/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. Marijuana Enforcement Division representation. The Division shall be represented by the Colorado Department of Law.

### **Basis and Purpose – 8-225**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(d), 44-10-203(1)(j), 44-10-203(2)(a), 24-4-105, and 44-10-901, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(I). The purpose of this rule is to establish how all parties, including pro se parties, can obtain subpoenas during the administrative hearing process. This Rule 8-225 was previously Rules M and R 1305, 1 CCR 212-1 and 1 CCR 212-2.

### **8-225 – Administrative Subpoenas**

- A. Informal Exchange of Documents Encouraged. Parties are encouraged to exchange documents relevant to the Notice of Denial or Order to Show Cause prior to requesting subpoenas. In addition, to the extent practicable, parties are encouraged to secure the voluntary presence of witnesses necessary for the hearing prior to requesting subpoenas.
- B. Hearing Officer May Issue Subpoenas.
  1. A party or its counsel may request the hearing officer to issue subpoenas to secure the presence of witnesses or documents necessary for the hearing or a deposition, if one is allowed.
  2. Requests for subpoenas to be issued by the hearing officer must be delivered in person or by mail to the office of the Department of Revenue – Hearings Division, 1881 Pierce St. #106, Lakewood, CO 80214. Subpoena requests must include the return mailing address, and phone and facsimile numbers of the requesting party or its attorney.
  3. Requests for subpoenas to be issued by the hearing officer must be made on a “Request for Subpoena” form authorized and provided by the Hearings Division. A hearing officer shall not issue a subpoena unless the request contains the following information:
    - a. Name of Denied Applicant or Respondent;
    - b. License or application number;
    - c. Case number;
    - d. Date of hearing;
    - e. Location of hearing, or telephone number for telephone check-in;
    - f. Time of hearing;
    - g. Name of witness to be subpoenaed; and
    - h. Mailing address of witness (home or business).

4. A request for a subpoena *duces tecum* must identify each document or category of documents to be produced.
5. Requests for subpoenas shall be signed by the requesting party or its counsel.
6. The hearing officer shall issue subpoenas without discrimination, as set forth in section 24-4-105(5), C.R.S. If the reviewing hearing officer denies the issuance of a subpoena, or alters a subpoena in any material way, specific findings and reasons for such denial or alteration must be made on the record, or by written order incorporated into the record.

C. Service of Subpoenas.

1. Service of any subpoena is the duty of the party requesting the subpoena.
2. All subpoenas must be served at least two business days prior to the hearing.

D. Subpoena Enforcement.

1. Any subpoenaed witness, entity, or custodian of documents may move to quash the subpoena with the Hearing Officer.
2. A hearing officer may quash a subpoena if he or she finds on the record that compliance would be unduly burdensome or impracticable, unreasonably expensive, or is unnecessary.

**Basis and Purpose – 8-230**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(d), 44-10-203(1)(j), 44-10-203(2)(a), 44-10-701, 44-10-901, and 24-4-105, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(I). The purpose of this rule is to establish how parties may appeal a hearing officer's Initial Decision pursuant to the Administrative Procedure Act. This Rule 8-230 was previously Rules M and R 1306, 1 CCR 212-1 and 1 CCR 212-2.

**8-230 – Administrative Hearing Appeals/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, 1375 Sherman Street, 4<sup>th</sup> Floor, Denver, CO 80203.
- 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 – 8-235**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(j), 44-10-203(2)(l), 44-10-701, and 44-10-901(3)(b), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(IX). 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 Marijuana Code, section 18-18-406.3(7), or any other applicable rule. The State Licensing Authority considered the type of violation and the threat of harm to the public versus purely administrative harm when setting the penalty structure. This Rule 8-235 was previously Rules M and R 1307, 1 CCR 212-1 and 1 CCR 212-2.

### **8-235 – Penalties**

- A. Penalty Schedule. The State Licensing Authority will make determinations regarding the type of penalty to impose based on the severity of the violation in the following categories:
  - 1. License Violations Affecting Public Safety. This category of violation is the most severe and may include, but is not limited to, Retail Marijuana sales to persons under the age of 21 years, Medical Marijuana sales to non-patients, consuming marijuana on the Licensed Premises, Regulated Marijuana sales in excess of the relevant sales limitations, permitting the diversion of Regulated Marijuana outside the regulated distribution system, possessing marijuana obtained from outside the regulated distribution system or from an unauthorized source, making misstatements or omissions in the Inventory Tracking System failure to report any transfer required by section 44-10-313(11), knowingly adulterating or altering or attempting to adulterate or alter any Samples of Regulated Marijuana, violations related to co-located Medical Marijuana Businesses and Retail Marijuana Businesses, violations related to R&D Co-Location Permits, failure to maintain books and records to fully account for all transactions of the business, failure to cooperate with Division investigators during the course of a Division investigation, failure to comply with any requirement related to the Transfer of Sampling Units, utilizing advertising material that is misleading, deceptive, or false, advertising violations directly targeting minors, or packaging or labeling violations that directly impact patient or consumer safety. Violations of this nature generally have an immediate impact on the health, safety, and welfare of the public at large. The range of penalties for this category of violation may include license suspension, a fine per individual violation, a fine in lieu of suspension of up to \$100,000, and/or license revocation depending on the mitigating and aggravating circumstances. Sanctions may also include restrictions on the license.
  - 2. License Violations. This category of violation is more severe than a license infraction but generally does not have an immediate impact on the health, safety, and welfare of the public at large. License violations may include but are not limited to, advertising and/or marketing violations, packaging or labeling violations that do not directly impact patient or consumer safety, failing to continuously escort a visitor in a Limited Access Area, failure to maintain minimum security requirements, failure to keep and maintain adequate business books and records, or minor or clerical errors in the Inventory Tracking System. The range of penalties for this category of violation may include license suspension, a fine per individual violation, a fine in lieu of suspension of up to \$50,000, and/or license revocation depending on the mitigating and aggravating circumstances. Sanctions may also include restrictions on the license.

3. License Infractions. This category of violation is the least severe and may include, but is not limited to, failure to display required Identification Badges, visitor badges, unauthorized modifications of the Licensed Premises of a minor nature, or failure to notify the State Licensing Authority of a minor change in ownership. The range of penalties for this category of violation may include license suspension, a fine per individual violation, and/or a fine in lieu of suspension of up to \$10,000 depending on the mitigating and aggravating circumstances. Sanctions may also include restrictions on the license.

B. Other Factors

1. The State Licensing Authority may take into consideration any aggravating and mitigating factors surrounding the violation which could impact the type or severity of penalty imposed.
2. The 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 on a case-by-case basis.
3. For all administrative offenses involving a proposed suspension, a Licensee may petition the State Licensing Authority for permission to pay a monetary fine, within the provisions of section 44-10-901, C.R.S., in lieu of having its license suspended for all or part of the suspension.

C. Mitigating and Aggravating Factors. The State Licensing Authority may consider mitigating and aggravating factors when considering the imposition of a penalty. These factors may include, but are not limited to:

1. Any prior violations that the Licensee has admitted to or was found to have engaged in.
2. Good faith measures by the Licensee to prevent the violation, including the following:
  - a. Proper supervision;
  - b. Regularly-provided and documented employee training, provided the Licensee demonstrates all reasonable training measures were delivered prior to the Division's investigation;
  - c. Standard operating procedures established prior to the Division's investigation, and which include procedures directly addressing the conduct for which imposition of a penalty is being considered; and
  - d. Previously established and maintained responsible-vendor designation pursuant to the 3-500 Series Rules.
3. Licensee's past history of success or failure with compliance checks.
4. Corrective action(s) taken by the Licensee related to the current violation or prior violations.
5. Willfulness and deliberateness of the violation.
6. Likelihood of reoccurrence of the violation.
7. Circumstances surrounding the violation, which may include, but are not limited to:

- a. Prior notification letter to the Licensee that an underage compliance check would be forthcoming.
  - b. The dress or appearance of an underage operative used during an underage compliance check (e.g., the operative was wearing a high school letter jacket).
  - c. Licensee self-reported violation(s) of the Marijuana Code or rules promulgated pursuant to the Marijuana Code.
8. Owner or management personnel is the violator or has directed an employee or other individual to violate the law.

### **Basis and Purpose – 8-240**

The statutory authority for this rule includes but is not limited to sections 44-10-201(3), 44-10-201(4), 44-10-202(1)(c), 44-10-203(1)(j), 44-10-203(2)(l), 44-10-203(2)(m), 44-10-203(1)(e), and 44-10-204(1)(a), C.R.S. The purpose of this rule is to assure Licensees do not use unauthorized confidential information at any time and do not engage the services of former State Licensing Authority or Division employees with regulatory oversight responsibilities for licensed marijuana businesses for the first 6 months following State Licensing Authority or Division employment. This Rule 8-240 was previously Rules M and R 1308, 1 CCR 212-1 and 1 CCR 212-2.

### **8-240 – Confidential Information and Former State Licensing Authority Employees**

- A. Misdemeanor if Disclosed. Disclosure of confidential records or information in violation of the Marijuana Code constitutes a class 1 misdemeanor pursuant to subsection 44-10-201(4), C.R.S.
- 1. Licensees, and employees or agents of Licensees, shall not obtain or utilize confidential information the Licensee, employee or agent is not lawfully entitled to possess and acquire through use or misuse of Division processes or Division-approved systems. For confidentiality requirements of State Licensing Authority and Division employees, see Rule 8-105 – Duties of Employees of the State Licensing Authority.
  - 2. Any Licensee, and any employee or agent of a Licensee, who is authorized to access the Division's Inventory Tracking System and/or have access to confidential information derived from Division sources, shall utilize the confidential information only for a purpose authorized by the Division or these Rules.
  - 3. All Licensees, and all employees and agents of Licensees, shall not use the Inventory Tracking System for any purpose other than tracking the Licensee's Regulated Marijuana and Regulated Marijuana Product.
- B. Six-Month Prohibition from Working with Former State Licensing Authority Employees. State Licensing Authority or Division employees with regulatory oversight responsibilities for Regulated Marijuana Businesses are prohibited from working for, representing, or providing consulting services to or otherwise deriving pecuniary gain from a Licensee for a period of six months following his or her last day of employment with the State Licensing Authority or Division.
- 1. Any Licensee who utilizes, employs, consults, seeks advice from, or contracts with a former employee of the State Licensing Authority or the Division prior to the conclusion of the six-month period shall be in violation of the Marijuana Code.
  - 2. Any Licensee who possesses, utilizes, or re-discloses confidential information obtained from a former State Licensing Authority or Division employee at any time shall be in violation of the Marijuana Code.