NOTICE OF RULEMAKING HEARING

The State Licensing Authority of the Colorado Department of Revenue, Marijuana Enforcement Division, will consider the promulgation of additions and amendments to its Rules as authorized by Article XVIII, Section 16 of the Colorado Constitution, the Retail Marijuana Code, sections 12-43.4-101 et seq., C.R.S. ("Retail Code"), and the Medical Marijuana Code, sections 12-43.3-101et seq., C.R.S. ("Medical Code"). For specific information and language concerning the proposed changes and new rules, please refer to the contents of this Notice and to the initial partial proposed rules that are set forth following this notice and are also at the Colorado Department of Revenue, Marijuana Enforcement Division's website at:

https://www.colorado.gov/pacific/enforcement/2017-med-rulemaking

STATUTORY AUTHORITY FOR RULEMAKING

The State Licensing Authority promulgates these rules pursuant to the authority granted in the Medical Code, The Retail Code, Article XVIII, Section 16 of the Colorado Constitution, and section 24-4-103, C.R.S., of the Administrative Procedure Act.

SUBJECT OF RULEMAKING

An initial portion of the proposed rules are attached to and incorporated in this Notice. As they are ready draft rules will also be posted on the Colorado Department of Revenue, Marijuana Enforcement Division's website at:

https://www.colorado.gov/pacific/enforcement/2017-med-rulemaking

The full set of proposed rules will be posted no later than 5:00 p.m. on Monday, October 9, 2017. Other relevant information regarding this rulemaking also will be posted on the Division's website. In addition, the initial partial proposed rules attached to this Notice are fully incorporated herein.

The State Licensing Authority will consider the promulgation of the following list of new rules and existing rules with changes proposed. This list is not exhaustive, and the State Licensing Authority may consider an addition or amendment to any medical or retail rule. See 1 CCR 212-1 (current medical marijuana rules) and 1 CCR 212-2 (current retail marijuana rules). For specific information and language concerning the proposed changes, please refer to the initial partial proposed rules that are set forth with this notice, at the Colorado Department of Revenue, Marijuana Enforcement Division's website, and on the Colorado Secretary of State website.

Please take note that in addition to the subject matters addressed in the initial partial proposed rules, the State Licensing Authority will consider additional rules consistent with any subject matter needed to implement and interpret the Retail Code, the Medical Code, and Article XVIII, Section 16 of the Colorado Constitution. The rulemaking hearing will include but will not be limited to modifications required due to statutory changes adopted during the 2017 legislative session. Some of those proposed modifications will be quite substantial, particularly those related to House Bill 2017-1367.

The State Licensing Authority initiated public meetings of representative groups of participants with an interest in the subject of the rule-making ("stakeholder meetings"), which began **August 31, 2017** and will continue through **September 22, 2017**. More information related to these meetings can be found at: https://www.colorado.gov/pacific/enforcement/2017-med-rulemaking

Each stakeholder meeting has been noticed on the Division's website. Any changes to stakeholder meetings will be further noticed on the Division's website at least 24 hours in advance. The stakeholder meetings may relate to any of the proposed rule changes. The written and recorded materials from the stakeholder meetings will be included in the rulemaking record.

The State Licensing Authority expects the initial partial proposed rules will be amended during the stakeholder meeting process and that new rules may be drafted. The attached and incorporated initial partial proposed rules are only intended to provide interested persons with the initial proposed drafts of some of the permanent rules. The subjects of other proposed rules not included in the initial partial proposed rules are set forth in this Notice and will be included in the full set of proposed rules to be posted by **Monday, October 9, 2017**.

RULES TO BE CONSIDERED FOR AMENDMENT OR ADOPTION PURSUANT TO THE MEDICAL CODE

M 100 Series – General Applicability

M 103 – Definitions

Additional definitions:

The State Licensing Authority will consider additional amendments to the definitions including definitions related to new legislation and to other rules under consideration during these rulemaking proceedings. Other definitions may be modified for clarification. Some but not all of the proposed new definitions are included in the initial attached proposed rules. Others will be included in the full set of proposed rules to be posted by October 9, 2017.

*Other general rules from this Series may be adopted or amended.

M 200 Series – Licensing and Interests

All M 200 Series rules are under consideration for procedural and substantive amendments. All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

M 300 Series – The Licensed Premises

All M 300 Series rules are under consideration for procedural and substantive amendments. All proposed changes to this Series are not included in initial attached

proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

M 400 Series - Medical Marijuana Center

All M 400 Series rules are under consideration for procedural and substantive amendments. All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

M 500 Series – Optional Premises Cultivation Operation Facilities

All M 500 Series rules are under consideration for procedural and substantive amendments. All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

M 600 Series - Medical Marijuana-Infused Products Manufacturers

All M 600 Series rules are under consideration for procedural and substantive amendments. All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

M 700 Series - Medical Marijuana Testing Facilities

All M 700 Series rules are under consideration for procedural and substantive amendments. All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

M 800 Series – Transportation and Storage

All M 800 Series rules are under consideration for procedural and substantive amendments. All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

M 900 Series – Business Records and Reporting

All M 900 Series rules are under consideration for procedural and substantive amendments. All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

M 1000 Series - Labeling, Packaging, and Products Safety

All M 1000 Series rules are under consideration for procedural and substantive amendments. It is anticipated that the M 1000 Series will be repealed and replaced by the M 1001.1 Series, but that there may be a period of overlap. All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

M 1001-1 Series – Labeling, Packaging, and Product Safety (New)

M 1001-1 - Packaging and Labeling Responsibility - All Intended Uses Except Immature Plants (New)

M 1002-1 – Labeling Requirements: All Intended Uses Except Seeds and Immature Plants (New)

M 1003-1 – Additional Labeling Requirements – Inhaled Products (New)

M 1004-1 – Additional Labeling Requirements – Edible Retail Marijuana Products (New)

M 1005-1 - Additional Labeling Requirements - Skin and Body Products (Topical, Suppositories and Transdermal) (New)

M 1006-1 – Labeling Requirements – Seeds and Immature Plants (New)

M 1007-1 – Packaging Requirements – All Intended Uses Except Immature Plants (New)

M 1008-1 – Additional Packaging Requirements – Edible Retail Marijuana Products (New)

M 1009-1 – Packaging Requirements and Responsibility – Immature Plants (New)

All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

*Other rules governing labeling, packaging and product safety may be adopted or amended.

M 1100 Series - Signage, Marketing, and Advertising

*Rules governing signage, marketing, and advertising may be adopted or amended.

M 1200 Series – Enforcement

*Rules governing enforcement may be adopted or amended.

M 1300 Series – Discipline

*Rules governing discipline may be adopted or amended.

M 1400 Series - Division, Local Jurisdiction, and Law Enforcement Procedures

*Rules governing Division, local jurisdiction, and law enforcement procedures may be adopted or amended.

M 1500 Series - Medical Marijuana Testing Program

All M 1500 Series rules are under consideration for procedural and substantive amendments. All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

M 1600 Series - Medical Marijuana Transporters

All M 1600 Series rules are under consideration for procedural and substantive amendments. All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

M 1700 Series – Medical Marijuana Operators

All M 1700 Series rules are under consideration for procedural and substantive amendments. All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

M 1800 Series - Medical Marijuana Transfers to Unlicensed Medical Marijuana Research Facilities and Pesticide Manufacturers (New)

M 1801 – Medical Research Facilities (New)

M 1802 – Pesticide Manufacturers (New)

All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

*Other rules governing medical marijuana transfers to unlicensed medical marijuana research facilities and pesticide manufacturers may be adopted or amended.

M 1900 Series – Research and Development Licensees (New)

M 1901 – Research and Development Licensees: License Privileges (New)

M 1902 – Research and Development Licensees: General Limitations and Prohibited Acts (New)

M 1903 – Research and Development Licensees: Inventory Tracking (New)

M 1904 – Research and Development Licensees: Health and Safety Regulations (New)

M 1905 – Research and Development Licensees: Testing (New)

M 1906 - Research and Development Licensees: Production Management and Possession Limits (New)

All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

*Other rules governing research and development licensees (which term includes both types of research and development licensees created by House Bill 17-1367) may be adopted or amended.

Any other rules necessary to implement the Medical Code may be amended or adopted.

RULES TO BE CONSIDERED FOR AMENDMENT OR ADOPTION TO THE RETAIL CODE

R 100 Series - General Applicability

R 103 – Definitions

Additional definitions:

The State Licensing Authority will consider additional amendments to the definitions including definitions related to new legislation and to other rules under consideration during these rulemaking proceedings. Other definitions may be modified for clarification. Some but not all of the proposed new definitions are included in the initial attached proposed rules. Others will be included in the full set of proposed rules to be posted by October 9, 2017.

*Other general rules from this Series may be adopted or amended.

R 200 Series – Licensing and Interests

All R 200 Series rules are under consideration for procedural and substantive amendments. All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

R 300 Series – The Licensed Premises

All R 300 Series rules are under consideration for procedural and substantive amendments. All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

R 400 Series – Retail Marijuana Stores

All R 400 Series rules are under consideration for procedural and substantive amendments. All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

R 500 Series – Retail Marijuana Cultivation Facilities

All R 500 Series rules are under consideration for procedural and substantive amendments. All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

R 600 Series - Retail Marijuana Products Manufacturing Facilities

All R 600 Series rules are under consideration for procedural and substantive amendments. All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

R 700 Series – Retail Marijuana Testing Facilities

All R 700 Series rules are under consideration for procedural and substantive amendments. All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

R 800 Series – Transportation and Storage

All R 800 Series rules are under consideration for procedural and substantive amendments. All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

R 900 Series – Business Records and Reporting

All R 900 Series rules are under consideration for procedural and substantive amendments. All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

R 1000 Series – Labeling, Packaging, and Products Safety

All R 1000 Series rules are under consideration for procedural and substantive amendments. It is anticipated that the R 1000 Series will be repealed and replaced by the R 1001.1 Series, but that there may be a period of overlap. All proposed changes to this

Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

R 1001-1 Series – Labeling, Packaging, and Product Safety (New)

R 1001-1 - Packaging and Labeling Responsibility - All Intended Uses Except Immature Plants (New)

R 1002-1 – Labeling Requirements: All Intended Uses Except Seeds and Immature Plants (New)

R 1003-1 – Additional Labeling Requirements – Inhaled Products (New)

R 1004-1 – Additional Labeling Requirements – Edible Retail Marijuana Products (New)

R 1005-1 – Additional Labeling Requirements – Skin and Body Products (Topical, Suppositories and Transdermal) (New)

R 1006-1 – Labeling Requirements – Seeds and Immature Plants (New)

R 1007-1 – Packaging Requirements – All Intended Uses Except Immature Plants (New)

R 1008-1 – Additional Packaging Requirements – Edible Retail Marijuana Products (New)

R 1009-1 – Packaging Requirements and Responsibility – Immature Plants (New)

All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

*Other rules governing labeling, packaging and product safety may be adopted or amended.

R 1100 Series - Signage, Marketing, and Advertising

*Rules governing signage, marketing, and advertising may be adopted or amended.

R 1200 Series – Enforcement

*Rules governing enforcement may be adopted or amended.

R 1300 Series - Discipline

*Rules governing discipline may be adopted or amended.

R 1500 Series – Retail Marijuana Testing Program

All R 1500 Series rules are under consideration for procedural and substantive amendments. All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

R 1600 Series – Retail Marijuana Transporters

All R 1600 Series rules are under consideration for procedural and substantive amendments. All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

R 1700 Series – Retail Marijuana Operators

All R 1700 Series rules are under consideration for procedural and substantive amendments. All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

R 1800 Series – Retail Marijuana Transfers to Unlicensed Medical Marijuana Research Facilities and Pesticide Manufacturers (New)

R 1801 – Medical Research Facilities (New)

R 1802 – Pesticide Manufacturers (New)

All proposed changes to this Series are not included in initial attached proposed rules but will be included in the full set of proposed rules to be posted by October 9, 2017.

*Other rules governing retail marijuana transfers to unlicensed medical marijuana research facilities and pesticide manufacturers or otherwise implementing House Bill 17-1367 may be adopted or amended.

Any other rules necessary to implement the Retail Code may be adopted or amended.

RULEMAKING RECORD AND PUBLIC PARTICIPATION

- 1. Official Rulemaking Record. The official record for purposes of the rulemaking hearing to be held on October 16, 2017, will include the written and recorded materials from the stakeholder meetings and any written comments or oral testimony submitted or presented.
- 2. Written Comments. The State Licensing Authority encourages interested parties to submit written comments on the proposed rules, including alternate proposals, by September 25, 2017, so that the State Licensing Authority can review comments prior to the rulemaking hearing. Written comments will also be accepted after that date. The deadline to submit written comments is 5:00 P.M. on October 16, 2017.

The State Licensing Authority will accept all written comments but strongly encourages written comments to be submitted on the Marijuana Enforcement Division Suggested Revision to Rules Form (Rule Form). A copy of the form is attached to this notice. The form may also be found at: https://www.colorado.gov/pacific/enforcement/2017-med-rulemaking

Please print, complete, and save the Rule Form as a separate document and then submit the Rule Form via e-mail. Written comments and completed Rule Forms may be emailed to: dor-medrulecomments@state.co.us. In addition, you may submit completed Rule Forms to:

Marijuana Enforcement Division Re: Rules 1707 Cole Boulevard, Ste. 300 Lakewood, CO 8040

Written comments will be accepted at the rulemaking hearing.

3. <u>Oral Comments</u>. In its discretion, the State Licensing Authority may also afford interested parties an opportunity to make brief oral presentations at the rulemaking hearing.

The State Licensing Authority strongly encourages written comments

Oral presentations will likely be limited to two minutes or less per person. Individuals will not be allowed to cede their time to another person (for instance, one person speaking on behalf of five people will not be given ten minutes to speak). Organized groups of individuals are urged to identify one spokesperson and to be concise. The State Licensing Authority encourages interested parties to avoid duplicating previously-submitted material and testimony.

CONTINUES ON NEXT PAGE

HEARING SCHEDULE

Date: Monday, October 16, 2016 Time: 9:00 a.m. – 5:00 p.m.

Place: Gaming Commission Room

17301 W. Colfax Avenue Golden, CO 80401

Location of the rulemaking hearing will also be posted on the Department of Revenue's website and the Secretary of State's website.

The hearing may be continued at such place and time as the State Licensing Authority may announce.

The State Licensing Authority shall deliberate upon the rulemaking record including oral testimony and written submissions presented as well as applicable law. The State Licensing Authority will adopt such rules as in its judgment are justified by the rulemaking record and applicable law.

If you are an individual with a disability who needs a reasonable accommodation in order to participate in this rulemaking hearing, please contact Cindy Perkins at Cindy.Perkins@state.co.us no later than **September 25, 2017**.

Dated this 15th day of September 2017.

THE COLORADO DEPARTMENT OF REVENUE, STATE LICENSING AUTHORITY, MARIJUANA ENFORCEMENT DIVISION

Michael S. Hartman, State Licensing Authority

Colorado Department of Revenue

Partial Proposed Rules Accompanying Notice of Permanent Rulemaking¹

- 1. Partial proposed rules for legislation implementation: HB17-1034; SB17-187; SB17-192
- 2. Partial proposed rules for labeling and packaging
- 3. Partial proposed rules for legislation implementation: HB17-1367
- 4. Other general partial proposed rules

¹ Partial proposed rules accompanying the Notice of Permanent Rulemaking are in the order presented at each stakeholder meeting.

Partial proposed rules for legislation implementation HB17-1034; SB17-187; SB17-192

Department of Revenue
Marijuana Enforcement Division
MEDICAL MARIJUANA RULES

LEGISLATION IMPLEMENTATION WORK GROUP

Basis and Purpose - M 206

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-305, 12-43.3-310(7), and 12-43.3-310(13), and section 12-43.3-305, C.R.S. The purpose of this rule is to clarify the application process for changing location of a Licensed Premises.

M 206 - Changing Location of the Licensed Premises: Medical Marijuana Businesses

- A. <u>Application Required to Change Location of Licensed Premises</u>
 - A Direct Beneficial Interest Owner or other authorized representative of a Medical Marijuana Business must make application to the Division for permission to change location of its Licensed Premises.
 - 2. Such application shall:
 - a. Be made upon current forms prescribed by the Division;
 - b. Be complete in every material detail and include remittance of all applicable fees;
 - c. Be submitted at least 30 days prior to the proposed change;
 - d. Explain the reason for requesting such change;
 - e. Be supported by evidence that the application complies with any local licensing authority requirements; and
 - f. Contain a report of the relevant local licensing authority(-ies) in which the Medical Marijuana Business is to be situated, which report shall demonstrate the approval of the local licensing authority(-ies) with respect to the new location.

B. Permit Required Before Changing Location

- No change of location shall be permitted until after the Division considers the application, and such additional information as it may require, and issues to the Applicant a permit for such change.
- 2. The permit shall be effective on the date of issuance, and the Licensee shall, within 120 days, change the location of its business to the place specified therein and at the same time cease to operate a Medical Marijuana Business at the former location. At no time may a Medical Marijuana Business operate or exercise any of the privileges granted pursuant to the license in both locations. For good cause shown, the 120 day deadline may be extended for an additional 90 days. If the Licensee does not change the location of its business within the time period granted by the Division, including any extension, the Licensee shall submit a new application, pay the requisite fees and receive a new permit prior to completing any change of the location of the business.

- 3. The permit shall be conspicuously displayed at the new location, immediately adjacent to the license to which it pertains.
- 4. No change of location will be allowed except to another place within the same city, town, county or city and county in which the license as originally issued was to be exercised.

C. General Requirements

- 1. An application for change of location to a different local licensing authority shall follow the same procedures as an application for a new Medical Marijuana Business license except that —only the cThe Change of Llocation application Application Ffee will be charged at the time of application; all —but—other —except that—licensing fees will not be assessed until the license is renewed. See Rules M 201 Application Process and M 210 Schedule of Other Application Fees: All Licensees.
- An Applicant for change of location within the same local licensing authority shall file a change of location application with the Division and pay the requisite change of location fee. See Rule M 21007 Schedule of Other Application Fees; All Licenses Application Fees: Medical Marijuana Businesses.

Basis and Purpose - M 210

The statutory authority for this rule is found at subsections 12-43.3-202(1)(a), 12-43.3-202(1)(b)(l), 12-43.3-202(2)(a)(XVI), and 12-43.3-202(2)(a)(XX), and sections 12-43.3-104, 12-43.3-310, 12-43.3-401, 12-43.3-501, and 12-43.3-502, 12-43.3-1101, and 12-43.3-1102, C.R.S. The purpose of this rule is to establish basic requirements for all Division applications and help the regulated community understand procedural licensing requirements.

M 210 - Schedule of Other Application Fees: All Licensees

- A. <u>Other Application Fees</u>. The following other application fees apply:
 - 1. Transfer of Ownership New Owners \$1,600.00
 - 2. Transfer of Ownership Reallocation of Ownership \$1,000.00
 - 3. Change of Corporation or LLC Structure \$800.00/Person
 - 4. Change of Trade Name \$50.00
 - 5. Change of Location Application Fee Same Local Jurisdiction Only \$500.00
 - 6. Modification of Licensed Premises \$100.00
 - 7. Duplicate Business License \$20.00
 - 8. Duplicate Occupational License \$20.00
 - 9. Off Premises Storage Permit \$1,500.00
 - 10. Medical Marijuana Transporter Off Premises Storage Permit \$2,200.00
 - 11. Responsible Vendor Program Provider Application Fee: \$850.00

- 12. Responsible Vendor Program Provider Renewal Fee: \$350.00
- 13. Responsible Vendor Program Provider Duplicate Certificate Fee: \$50.00
- B. <u>When Other Application Fees Are Due</u>. All other application fees are due at the time the application and/or request is submitted.
- C. Subpoena Fee See Rule M 106 Subpoena Fees

Basis and Purpose - M 231

The statutory authority for this rule is found at subsections 12-43.3-201(4), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-310(4), 12-43.3-310(7), and 24-18-105(3), and sections 12-43.3-104, 12-43.3-306, 12-43.3-307, 12-43.307.5, 12-43.3-401 and 24-76.5-101 *et. seq*, C.R.S. The purpose of this rule is clarify the qualifications for licensure, including, but not limited to, the requirement for a fingerprint-based criminal history record check for all Direct Beneficial Interest Owners, contractors, employees, and other support staff of licensed entities.

M 231 - Qualifications for Licensure and Residency

- A. Any Applicant may be required to establish his or her identity and age by any document required for a determination of Colorado residency, United States citizenship or lawful presence.
- B. Maintaining Ongoing Licensing Qualification: Duty to Report Offenses. An Applicant or Licensee shall notify the Division in writing of any felony criminal charge and felony conviction against such person within ten days of such person's arrest, felony summons, and within ten days of the disposition of any arrest or summons. Failure to make proper notification to the Division may be grounds for disciplinary action. Applicants and Licensees shall notify the Division within ten days of any other event that renders the Applicant or Licensee no longer qualified under these rules. Licensees shall cooperate in any investigation conducted by the Division. This duty to report includes, but is not limited to, deferred sentences or judgments that are not sealed. If the Division lawfully finds a disqualifying event and an Applicant asserts that the record was sealed, the Division may require the Applicant to provide proof from a court evidencing the sealing of the case.
- C. <u>Application Forms Accessible to Law Enforcement and Licensing Authorities</u>. All application forms supplied by the Division and filed by an Applicant for licensure shall be accessible by the State Licensing Authority, local licensing authorities, and any state or local law enforcement agent.
- D. <u>Associated Key Licenses</u>. Each Direct Beneficial Interest Owner who is a natural person, including but not limited to each officer, director, member or partner of a Closely Held Business Entity, must apply for and hold at all times a valid Associated Key License. Except that these criteria shall not apply to Qualified Limited Passive Investors, who are not required to hold Associated Key Licenses. Each such Direct Beneficial Interest Owner must establish that he or she meets the following criteria before receiving an Associated Key License:
 - 1. The Applicant has paid the annual application and licensing fees;
 - 2. The Applicant's criminal history indicates that he or she is of Good Moral Character;
 - 3. The Applicant is not employing, or financed in whole or in part by any other Person whose criminal history indicates that he or she is not of Good Moral Character;

3

- 4. The Applicant is at least 21 years of age;
- 5. The Applicant has paid all taxes, interest, or penalties due the Department of Revenue relating to a Medical Marijuana Business or Retail Marijuana Establishment, if applicable;
- 6. The Applicant is not currently subject to and has not discharged a sentence for a conviction of a felony in the five years immediately preceding his or her application date;
- 7. The Applicant meets qualifications for licensure that directly and demonstrably relate to the operation of a Medical Marijuana Business.
- 8. The Applicant is not currently subject to and has not discharged a sentence for a conviction of a felony pursuant to any state or federal law regarding the possession, distribution, manufacturing, cultivation, or use of a controlled substance in the ten years immediately preceding his or her application date or five years from May 28, 2013, whichever is longer; except that the State Licensing Authority may grant a license to a person if the Applicant has a state felony conviction based on possession or use of marijuana or marijuana concentrate that would not be a felony of the Applicant were convicted of the offense on the date he or she applied for licensure'
- 9. The Applicant does not employ another person who does not have a valid Occupational License issued pursuant to either the Medical Code or Retail Code;
- 10. The Applicant is not a sheriff, deputy sheriff, police officer, or prosecuting officer, or an officer or employee of the State Licensing Authority or a local licensing authority;
- 11. The Applicant has not been a State Licensing Authority employee with regulatory oversight responsibilities for individuals, Retail Marijuana Establishments and/or Medical Marijuana Businesses licensed by the State Licensing Authority in the six months immediately preceding the date of the Applicant's application:
- 12. The premises that the Applicant proposes to be licensed is not currently licensed as a retail food establishment or wholesale food registrant;
- 13. The Applicant either:
 - a. Has been a resident of Colorado for at least one year prior to the date of the application, or
 - b. Has been a United States citizen since a date prior to the date of the application and has received a Finding of Suitability from the Division prior to filing the application. See Rule M 231.1 Finding of Suitability, Residency and Reporting Requirements for Direct Beneficial Interest Owners; Rule M 232 Factors Considered When Determining Residency and Citizenship: Individuals.
- 14. For Associated Key Licensees who are owners of a Closely Held Business Entity, the Applicant is a United States citizen.
- E. <u>Occupational Licenses</u>. An Occupational License Applicant who is not applying for an Associated Key License must establish that he or she meets the following criteria before receiving an Occupational License:
 - 1. The Applicant has paid the annual application and licensing fees;
 - 2. The Applicant's criminal history indicates that he or she is of Good Moral Character;

- 3. The Applicant is at least 21 years of age;
- 4. An Applicant is currently a resident of Colorado. See Rule M 232 Factors Considered When Determining Residency and Citizenship: Individuals;
- 5. The Applicant has paid all taxes, interest, or penalties due the Department of Revenue relating to a Medical Marijuana Business or Retail Marijuana Establishment;
- 6. The Applicant is not currently subject to and has not discharged a sentence for a conviction of a felony in the five years immediately preceding his or her application date;
- 7. The Applicant meets qualifications for licensure that directly and demonstrably relate to the operation of a Medical Marijuana Business.
- 8. The Applicant is not currently subject to and has not discharged a sentence for a conviction of a felony pursuant to any state or federal law regarding the possession, distribution, manufacturing, cultivation, or use of a controlled substance in the ten years immediately preceding his or her application date or five years from May 28, 2013, whichever is longer; except that the State Licensing Authority may grant a license to a person if the person has a state felony conviction based on possession or use of marijuana or marijuana concentrate that would not be a felony of the person were convicted of the offense on the date he or she applied for licensure.
- 9. The Applicant is not a sheriff, deputy sheriff, police officer, or prosecuting officer, or an officer or employee of the State Licensing Authority or a local licensing authority; and
- 10. The Applicant has not been a State Licensing Authority employee with regulatory oversight responsibilities for occupational licensees, Medical Marijuana Businesses and/or Retail Marijuana Establishments licensed by the State Licensing Authority in the six months immediately preceding the date of the Applicant's application.
- F. <u>Current Medical Marijuana Occupational Licensees.</u>
 - An individual who holds a current, valid Occupational License issued pursuant to the Medical Code may also work in a Retail Marijuana Establishment; no separate Occupational License is required.
 - 2. An individual who holds a current, valid Occupational License issued pursuant to the Retail Code after July 1, 2015 may also work in a Medical Marijuana Business; no separate Occupational License is required.
- G. <u>Associated Key License Privileges</u>. A person who holds an Associated Key License must associate that license separately with each Medical Marijuana Business or Retail Marijuana Establishment with which the person is associated by submitting a form approved by the Division. A person who holds an Associated Key License may exercise the privileges of a licensed employee in any licensed Medical Marijuana Business or Retail Marijuana Establishment in which they are not an owner so long as the person does not exercise privileges of ownership.
- H. Qualified Limited Passive Investor. An Applicant who wishes to be a Qualified Limited Passive Investor and hold an interest in a Medical Marijuana Business as a Direct Beneficial Interest Owner must establish that he or she meets the following criteria before the ownership interest will be approved:
 - 1. He or she is a natural person;

Initial Draft – For Discussion Purposes Only Legislation Implementation Work Group 8/31/17

- 2. The Applicant qualifies under Rule R 231.2(B);
- 3. He or she has been a United States citizen since a date prior to the date of the application, and
- 4. He or she has signed an affirmation of passive investment.
- I. Workforce Training or Development Residency Exempt Occupational License. An Applicant who wishes to obtain a workforce development or training exemption to the license residency requirement may only apply for a Support License and must:
 - 1. Submit a complete application on the Division's approved forms;
 - 2. Establish he or she meets the licensing criteria of Rule M 231(E)(1)-(3) and 231(E)(5)-(10) for Occupational Licensees; and
 - 3. Provide a complete Workforce Training or Development Affirmation form executed under penalty of perjury.

Department of Revenue
Marijuana Enforcement Division
MEDICAL MARIJUANA RULES

LEGISLATION IMPLEMENTATION WORK GROUP

M 600 Series - Medical Marijuana-Infused Products Manufacturers

Basis and Purpose - M 601

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(l) and 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(l)(A-F), , 12-43.3-406(1)(c), and 12-43.3-406(4)(b), and section 12-43.3-404, C.R.S. The purpose of this rule is to establish that it is unlawful for a Medical Marijuana-Infused Products Manufacturer to exercise any privileges other than those granted by the State Licensing Authority and to clarify the license privileges.

M 601 - Medical Marijuana-Infused Products Manufacturer: License Privileges

- A. <u>Privileges Granted</u>. A Medical Marijuana-Infused Products Manufacturer shall only exercise those privileges granted to it by the State Licensing Authority.
- B. <u>Licensed Premises</u>. A separate license is required for each specific business or business entity and geographical location. A Retail Marijuana Products Manufacturing Facility may share a location with a commonly owned Medical Marijuana-Infused Products Manufacturer. However, a separate license is required for each specific business or business entity, regardless of geographical location.
- C. <u>Sales Restricted</u>. A Medical Marijuana-Infused Products Manufacturer may sell: (1) its own Medical Marijuana-Infused Product to Medical Marijuana Centers or another Medical Marijuana-Infused Products Manufacturer, (2) Medical Marijuana that was not cultivated at its own Optional Premises Cultivation to another Medical Marijuana-Infused Products Manufacturer, and (3) Medical Marijuana Concentrate to a Medical Marijuana Center or another Medical Marijuana-Infused Products Manufacturer.
- D. <u>Manufacture of Medical Marijuana-Infused Product Authorized</u>. A Medical Marijuana-Infused Products Manufacturer may manufacture, prepare, package, and label Medical Marijuana-Infused Product, whether in concentrated form or that are comprised of Medical Marijuana and other ingredients intended for use or consumption, such as edible products, ointments, or tinctures.
- E. <u>Location Prohibited</u>. A Medical Marijuana-Infused Products Manufacturer may not manufacture, prepare, package, store, or label Medical Marijuana-Infused Product in a location that is operating as a retail food establishment or a wholesale food registrant.

F. Samples Provided for Testing.

- 1. This rule M 601(F)(1) is repealed effective July 1, 2016. A Medical Marijuana-Infused Products Manufacturer may provide samples of its Medical Marijuana-Infused Product to a Retail Marijuana Testing Facility that has obtained an Occupational License to test and research Medical Marijuana for testing and research purposes. The Medical Marijuana-Infused Products Manufacturer shall maintain the testing results as part of its business books and records. See Rule M 901 Business Records Required.
- 1.5. This rule M 601(F)(1.5) is effective beginning July 1, 2016. A Medical Marijuana-Infused Products Manufacturer may provide samples of its Medical Marijuana-Infused Product to

a Medical Marijuana Testing Facility for testing and research purposes. The Medical Marijuana-Infused Products Manufacturer shall maintain the testing results as part of its business books and records. See Rule M 901 – Business Records Required.

- G. <u>Authorized Marijuana Transport</u>. A Medical Marijuana-Infused Products Manufacturer is authorized to utilize a licensed Medical Marijuana Transporter for transportation of its Medical Marijuana-Infused Product 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-Infused Products Manufacturer from transporting its own Medical Marijuana.
- H. A Medical Marijuana-Infused Products Manufacturer may compensate its employees using performance-based incentives.

Basis and Purpose - M 602

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XVII.6) and (XX), 12-43.3-404(3), and 12-43.3-406(1)(a) C.R.S. The Medical Code sets forth minimum requirements for written agreements between Medical Marijuana-Infused Products Manufacturers and Medical Marijuana Centers. Specifically, the written agreements must set forth the total amount of Medical Marijuana obtained from a Medical Marijuana Center licensee to be used in the manufacturing process, and the total amount of Medical Marijuana-Infused Product to be manufactured from the Medical Marijuana obtained from the Medical Marijuana Center. This rule clarifies that the Division must approve such written agreements to ensure they meet those requirements.

M 602 - Medical Marijuana-Infused Products Manufacturer: General Limitations or Prohibited Acts

- A. <u>Contract Required</u>. Any contract required pursuant to section 12-43.3-404(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 M 901 Business Records and Reporting.
- B. <u>Packaging and Labeling Standards Required</u>. A Medical Marijuana-Infused Products Manufacturer is prohibited from selling Medical Marijuana-Infused Product that are not properly packaged and labeled. See M 1000 Series Labeling, Packaging, and Product Safety and M 1000.1 Series Labeling, Packaging, and Product Safety.
- C. <u>Sale to Consumer Prohibited</u>. A Medical Marijuana-Infused Products Manufacturer is prohibited from selling Medical Marijuana or Medical Marijuana-Infused Product to a consumer.
- D. <u>Consumption Prohibited</u>. A Medical Marijuana-Infused Products Manufacturer shall not permit the consumption of marijuana or marijuana products on its Licensed Premises.
- E. <u>Adequate Care of Perishable Product</u>. A Medical Marijuana-Infused Products Manufacturer must provide adequate refrigeration for perishable Medical Marijuana-Infused Product that will be consumed and shall utilize adequate storage facilities and transport methods.
- F. <u>Homogeneity of Edible Retail Marijuana Product</u>. A Medical Marijuana-Infused Products Manufacturer must ensure that its manufacturing processes are designed so that the cannabinoid content of any Edible Medical Marijuana-Infused Product is homogenous.
- G. A Medical Marijuana-Infused Products Manufacturer shall not sell or give away Medical Marijuana or Medical Marijuana-Infused Product to a Medical Marijuana Transporter, and shall not buy or

receive complimentary Medical Marijuana or Medical Marijuana-Infused Product from a Medical Marijuana Transporter.

H. Cultivated Medical Marijuana Sales Prohibited. A Medical Marijuana-Infused Products
 Manufacturer that also has an Optional Premises Cultivation Operation shall not sell any Medical Marijuana that it cultivates except for the Medical Marijuana contained in its Medical Marijuana-Infused Products or Medical Marijuana Concentrate.

Basis and Purpose - M 603

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XVIII.6) and (XX), and 12-43.3-406(3) and section 12-43.3-404, C.R.S. The purpose of this rule is to require all Medical Marijuana-Infused Products Manufacturers to track all inventory from the point it is received, through any manufacturing processes, to the point of sale or transfer to another Medical Marijuana Business.

M 603 - Medical Marijuana-Infused Products Manufacturer: Inventory Tracking System

- A. <u>Minimum Tracking Requirement</u>. A Medical Marijuana-Infused Products Manufacturer must use the Inventory Tracking System to ensure its inventories are identified and tracked from the point they are transferred from a commonly owned Optional Premises Cultivation Operation, Medical Marijuana Center, <u>or</u>-Medical Marijuana Transporter, <u>or another Medical Marijuana-Infused Products Manufacturer</u> through wholesale transaction or transfer. See also Rule M 309 Medical Marijuana Business: Inventory Tracking System. A Medical Marijuana-Infused Products Manufacturer must have the ability to reconcile its inventory records with the Inventory Tracking System and the associated transaction history and sale receipts. See also Rule M 901 Business Records Required.
 - A Medical Marijuana-Infused Products Manufacturer is prohibited from accepting any Medical Marijuana from any Optional Premises Cultivation Operation—or, Medical Marijuana Transporter or another Medical Marijuana-Infused Products Manufacturer without receiving a valid transport manifest generated from the Inventory Tracking System.
 - 2. A Medical Marijuana-Infused Products Manufacturer must immediately input all Medical Marijuana delivered to the Licensed Premises, accounting for all RFID tags, into the Inventory Tracking System at the time of delivery from a commonly owned Optional Premises Cultivation Operation, a Medical Marijuana Center, or a Medical Marijuana Transporter, or another Medical Marijuana-Infused Products Manufacturer.
 - 3. A Medical Marijuana-Infused Products Manufacturer must reconcile transactions to the Inventory Tracking System at the close of business each day.

Department of Revenue
Marijuana Enforcement Division
MEDICAL MARIJUANA RULES

LEGISLATION IMPLEMENTATION WORK GROUP

M 1700 Series - Medical Marijuana Business Operators

Basis and Purpose - M 1701

The statutory authority for this rule is found at subsections 12-43.3-202(1)(a), 12-43.3-202(1)(b)(l), 12-43.3-202(2)(a)(XX) and 12-43.3-401(d), C.R.S. The purpose of this rule is to establish that it is unlawful for a Medical Marijuana Business Operator registrant to exercise any privileges other than those granted by the State Licensing Authority and to clarify the registrant privileges.

M 1701 - Medical Marijuana Business Operator: License or Registration Privileges

- A. Privileges Granted. A Medical Marijuana Business Operator shall only exercise those privileges granted to it by the Medical 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.
- B. <u>Licensed Premises of the Medical Marijuana Business(es) Operated</u>. A separate <u>license or</u> registration is required for each specific Medical Marijuana Business Operator, and each <u>licensed or such</u>-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. <u>Entities Eligible to Hold Medical Marijuana Business Operator License or Registration</u>. A Medical Marijuana Business Operator <u>license or registration</u> may be held only by a business entity, including, but not limited to, a corporation, limited liability company, partnership or sole proprietorship.
- D. <u>Separate Place of Business</u>. 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 M 1702 and 1704. Possession, storage, use, cultivation, manufacture, sale, distribution, or testing of Medical Marijuana or Medical Marijuana-Infused 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 Direct Beneficial Interest Owners required to hold an Associated Key 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 § 12-43.4-601(1), C.R.S. Similarly, a Medical Marijuana Business Operator and its Direct Beneficial Interest Owners required to hold an Associated Key

License, as well as the officers, agents and employees of the Medical Marijuana Business Operator, may be disciplined for violations committed by the Direct Beneficial Interest 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 Direct Beneficial Interest 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.
- G. Transition from Medical Marijuana Business Operator Registrations to Licenses. The Division will accept applications for Medical Marijuana Business Operator registrations through December 31, 2017. After December 31, 2017, the Division will only accept applications for new or renewal Medical Marijuana Business Operator licenses. Any Medical Marijuana Business Operator registration issued by the Division based on an application submitted on or before December 31, 2017, will be valid for one year from the date of issuance. After December 31, 2017, Medical Marijuana Business Operator registrations will only be available for renewal as Medical Marijuana Business licenses. The Division will not accept applications for new or renewal Medical Marijuana Business registrations after December 31, 2017.
- H. Application of Rules to Registrations. The State Licensing Authority may take any action with respect to a Medical Marijuana Business Operator registration that it could take with respect to a license issued under the Medical Code. In any administrative action involving a Medical Marijuana Business registration, these rules shall be read as including the terms "registered", "registration", "registrant" or any other similar terms as the context requires when applied to a Medical Marijuana Business Operator registration.

Basis and Purpose - M 1702

The statutory authority for this rule is found at subsections 12-43.3-202(1)(a), 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX) and 12-43.3-401(d), 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.

M 1702 - Medical Marijuana Business Operators: General Limitations or Prohibited Acts

- A. Prohibited Financial Interest. A Person who is a Direct Beneficial Interest Owner or an Indirect Beneficial Interest Owner of a Medical Marijuana Business Operator shall not be a Direct Beneficial Interest Owner or Indirect Beneficial Interest Owner of, or otherwise have a direct or indirect financial interest in, a Medical Marijuana Business operated by the Medical Marijuana Business Operator. Except that such Person shall have the right to compensation for services provided in accordance with these rules.
- B. <u>Sale of Marijuana Prohibited</u>. A Medical Marijuana Business Operator is prohibited from selling, distributing, or transferring Medical Marijuana or Medical Marijuana-Infused Product to another Medical Marijuana Business or a consumer, except when acting as an agent of a Medical Marijuana Business(es) operated by the Medical Marijuana Business Operator.
- C. <u>Consumption Prohibited</u>. A Medical Marijuana Business Operator, and its Direct Beneficial Interest Owners, agents and employees, shall not permit the consumption of marijuana or marijuana products at its separate place of business.
- D. <u>Inventory Tracking System</u>. A Medical Marijuana Business Operator, and any of its Direct Beneficial Interest 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. <u>Compliance with Requirements and Limitations Applicable to the Medical Marijuana Business(es)</u>
 <u>Operated.</u> In operating any other Medical Marijuana Business(es), a Medical Marijuana Business
 Operator, and its Direct Beneficial Interest 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 Direct Beneficial Interest Owners who are required to hold Associated Key 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 Direct Beneficial Interest 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 Direct Beneficial Interest 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 Direct Beneficial Interest 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 <u>license or</u> registration of the Medical Marijuana Business Operator, or a specific Direct Beneficial Interest Owner, agent or employee of the Medical Marijuana Business Operator, has expired, or has been suspended or revoked.
- G. <u>Limitations on Use of Documents and Information Obtained from Medical Marijuana Businesses.</u>
 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 Medical 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 Direct Beneficial Interest Owners, Indirect Beneficial Interest Owners, agents or employees, or any Person other than the Medical Marijuana Business it operates.
- H. <u>Form and Structure of Allowable Agreement(s) Between Operators and Owners.</u> Any agreement between a Medical Marijuana Business and a Medical Marijuana Business Operator:

- Must acknowledge that the Medical Marijuana Business Operator, and its Direct Beneficial Interest 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, and any Person associated with the Medical Marijuana Business Operator, shall not be granted, and may not accept:
 - a security interest in the Medical Marijuana Business being operated, or in any assets of the Medical Marijuana Business;
 - 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, and any person associated with 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;
- 4. Shall be contingent on approval by the Division; and
- 5. Shall not be materially amended without advance written approval from the Division.
- I. A Medical Marijuana Business Operator may engage in dual operation of a Medical Marijuana Business and a Retail Marijuana Establishment at a single location, to the extent the Medical Marijuana Business being operated is permitted to do so pursuant to subsection 12-43.4-401(2)(a), C.R.S., and the Medical Marijuana Business Operator shall comply with the rules promulgated pursuant to the Medical Code and the Retail Code, including the requirement of obtaining a valid license as a Retail Marijuana Establishment Operator.

Basis and Purpose - M 1703

The statutory authority for this rule is found at subsections, 12-43.3-202(1)(a), 12-43.3-202(1)(b)(l), 12-43.3-202(2)(a)(XX) and 12-43.3-401(d), C.R.S.. The purpose of this rule is to establish occupational license requirements for the Medical Marijuana Business Operator's Direct Beneficial Interest Owners, agents and employees, including those directly or indirectly engaged in the operation of other Medical Marijuana Business(es).

M 1703 - Medical Marijuana Business Operators: Occupational Licenses for Personnel

A. <u>Occupational Licenses Required</u>. All natural persons who are Direct Beneficial Interest Owners, and all natural persons who are agents and employees, of a Medical Marijuana Business

Operator that are actively engaged, directly or indirectly, in the operation of one or more other Medical Marijuana Business(es), including but not limited to all such persons who will come into contact with Medical Marijuana or Medical Marijuana-Infused Product, who will have to access Limited Access Areas, or who will have access to the Inventory Tracking System account of the Medical Marijuana Business(es) being operated as part of their duties, must have a valid Occupational License.

- 1. <u>Associated Key Licenses</u>. All natural persons who are Direct Beneficial Interest Owners in a Medical Marijuana Business Operator must have a valid Associated Key License, associated with the Medical Marijuana Business Operator registration. Such an Associated Key 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. <u>Key Licenses</u>. All other natural persons who are agents or employees of a Medical Marijuana Business Operator that are actively engaged, directly or indirectly, in the operation of other Medical Marijuana Businesses, must hold a Key License. The Key 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. Occupational Licenses Not Required. Occupational Licenses are not required for Indirect Beneficial Interest Owners of a Medical Marijuana Business Operator, Qualified Limited Passive Investors who are Direct Beneficial Interest Owners of a Medical Marijuana Business Operator, or for natural persons who will not come into contact with Medical Marijuana or Medical Marijuana-Infused Product, 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 the Manager 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 a separate and distinct manager 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 Associated Key License or Key License, as set forth in paragraph A of this rule, and the Medical Marijuana Business shall comply with the reporting provisions of subsection 12-43.4-309(11), C.R.S.

Basis and Purpose - M 1704

The statutory authority for this rule is found at subsections 12-43.3-202(1)(a), 12-43.3-202(1)(b)(l), 12-43.3-202(2)(a)(XX) and 12-43.3-401(d), C.R.S. The purpose of this rule is to establish records retention standards for a Medical Marijuana Business Operators.

M 1704 - Medical Marijuana Business Operators: Business Records Required

- A. <u>General Requirement</u>. A Medical Marijuana Business Operator must maintain all required business records as set forth in Rule R 901 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 or Medical Marijuana-Infused Product 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.

Department of Revenue Marijuana Enforcement Division RETAIL MARIJUANA RULES

LEGISLATION IMPLEMENTATION WORK GROUP

Basis and Purpose - R 231

The statutory authority for this rule is found at subsections 12-43.3-201(4), 12-43.4-202(2)(b), 12-43.4-202(3)(a)(III), and 24-18-105(3), and sections 12-43.4-103, 12-43.4-305, 12-43.4-306 12-43.3-306.5, and 24-76.5-101, et. seq., C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(III). The purpose of this rule is to clarify the qualifications for licensure, including, but not limited to, background investigations for Direct Beneficial Interest Owners, Indirect Beneficial Interest Owners, contractors, employees, and other support staff of licensed entities.

R 231 - Qualifications for Licensure and Residency

- A. Any Applicant may be required to establish his or her identity and age by any document required for a determination of Colorado residency, United States citizenship or lawful presence.
- B. Maintaining Ongoing Licensing Qualification: Duty to Report Offenses. An Applicant or Licensee shall notify the Division in writing of any felony criminal charge and felony conviction against such person within ten days of such person's arrest or felony summons, and within ten days of the disposition of any arrest or summons. Failure to make proper notification to the Division may be grounds for disciplinary action. Applicants and Licensees shall notify the Division within ten days of any other event that renders the Applicant or Licensee no longer qualified under these rules. Licensees shall cooperate in any investigation conducted by the Division. This duty to report includes, but is not limited to, deferred sentences or judgments that are not sealed. If the Division lawfully finds a disqualifying event and an Applicant asserts that the record was sealed, the Division may require the Applicant to provide proof from a court evidencing the sealing of the case.
- C. <u>Application Forms Accessible to Law Enforcement and Licensing Authorities</u>. All application forms supplied by the Division and filed by an Applicant for licensure shall be accessible by the State Licensing Authority, local jurisdictions, and any state or local law enforcement agent.
- D. <u>Associated Key Licenses</u>. Each Direct Beneficial Interest Owner who is a natural person, including but not limited to each officer, director, member or partner of a Closely Held Business Entity, must apply for and hold at all times a valid Associated Key License. Except that these criteria shall not apply to Qualified Limited Passive Investors, who are not required to hold Associated Key Licenses. Each such Direct Beneficial Interest Owner must establish that he or she meets the following criteria before receiving an Associated Key License:
 - 1. The Applicant has paid the annual application and licensing fees;
 - 2. The Applicant's criminal history indicates that he or she is of Good Moral Character;
 - 3. The Applicant is not employing, or financed in whole or in part, by any other Person whose criminal history indicates that he or she is not of Good Moral Character;
 - 4. The Applicant is at least 21 years of age;
 - 5. The Applicant has paid all taxes, interest, or penalties due the Department of Revenue relating to a Retail Marijuana Establishment or Medical Marijuana Business, if applicable;

- 6. The Applicant is not currently subject to and has not discharged a sentence for a conviction of a felony in the five years immediately preceding his or her application date;
- 7. The Applicant meets qualifications for licensure that directly and demonstrably relate to the operation of a Retail Marijuana Establishment.
- 8. The Applicant is not currently subject to or has not discharged a sentence for a conviction of a felony pursuant to any state or federal law regarding the possession, distribution, manufacturing, cultivation, or use of a controlled substance in the ten years immediately preceding his or her application date or five years from May 28, 2013, whichever is longer, except that the State Licensing Authority may grant a license to a Person if the Person has a state felony conviction based on possession or use of marijuana or marijuana concentrate that would not be a felony if the Person were convicted of the offense on the date he or she applied for a license;
- 9. The Applicant does not employ another person who does not have a valid Occupational License issued pursuant to either the Retail Code or the Medical Code.
- 10. The Applicant is not a sheriff, deputy sheriff, police officer, or prosecuting officer, or an officer or employee of the State Licensing Authority or a local licensing authority;
- 11. The Applicant has not been a State Licensing Authority employee with regulatory oversight responsibilities for individuals, Retail Marijuana Establishments and/or Medical Marijuana Businesses licensed by the State Licensing Authority in the six months immediately preceding the date of the Applicant's application;
- 12. The premises that the Applicant proposes to be licensed is not currently licensed as a retail food establishment or wholesale food registrant;
- 13. The Applicant either:
 - a. Has been a resident of Colorado for at least one year prior to the date of the application, or
 - b. Has been a United States citizen since a date prior to the date of the application and has received a Finding of Suitability from the Division prior to filing the application. See Rule R 231.1 Finding of Suitability, Residency and Requirements for Direct Beneficial Interest Owners; Rule R 232 Factors Considered When Determining Residency and Citizenship: Individuals.
- 14. For Associated Key Licensees who are owners of a Closely Held Business Entity, the Applicant is a United States citizen.
- E. <u>Occupational Licenses</u>. An Occupational License Applicant who is not applying for an Associated Key License must establish that he or she meets the following criteria before receiving an Occupational License:
 - 1. The Applicant has paid the annual application and licensing fees;
 - 2. The Applicant's criminal history indicates that he or she is of Good Moral Character;
 - 3. The Applicant is at least 21 years of age;
 - 4. The Applicant is currently a resident of Colorado. See Rule R 232 Factors Considered When Determining Residency and Citizenship: Individuals.

- 5. The Applicant has paid all taxes, interest, or penalties due the Department of Revenue relating to a Medical Marijuana Business or Retail Marijuana Establishment;
- 6. The Applicant is not currently subject to and has not discharged a sentence for a conviction of a felony in the five years immediately preceding his or her application date;
- 7. The Applicant is not currently subject to and has not discharged a sentence for a conviction of a felony pursuant to any state or federal law regarding the possession, distribution, manufacturing, cultivation, or use of a controlled substance in the ten years immediately preceding his or her application date or five years from May 28, 2013, whichever is longer, except that the State Licensing Authority may grant a license to a person if the person has a state felony conviction based on possession or use of marijuana or marijuana concentrate that would not be a felony if the person were convicted of the offense on the date he or she applied for a license;
- 8. The Applicant is not a sheriff, deputy sheriff, police officer, or prosecuting officer, or an officer or employee of the State Licensing Authority or a local jurisdiction; and
- 9. The Applicant has not been a State Licensing Authority employee with regulatory oversight responsibilities for occupational licensees, Retail Marijuana Establishments and/or Medical Marijuana Businesses licensed by the State Licensing Authority in the six months immediately preceding the date of the Applicant's application.
- F. <u>Current Medical Marijuana Occupational Licensees</u>.
 - 1. An individual who holds a current, valid Occupational License issued pursuant to the Medical Code may also work in a Retail Marijuana Establishment; no separate Occupational License is required.
 - 2. An individual who holds a current, valid Occupational License issued pursuant to the Retail Code and these rules shall only work at licensed premises that are exclusively a Retail Marijuana Establishment and shall not work at a Medical Marijuana Business unless he or she also holds a current, valid Occupational License issued pursuant to the Medical Code.
- G. <u>Associated Key License Privileges</u>. A person who holds an Associated Key License must associate that license separately with each Retail Marijuana Establishment or Medical Marijuana Business with which the person is associated by submitting a form approved by the Division. A person who holds an Associated Key License may exercise the privileges of a licensed employee in any licensed Retail Marijuana Establishment or Medical Marijuana Business in which they are not an owner so long as the person does not exercise privileges of ownership.
- H. <u>Qualified Limited Passive Investor</u>. An Applicant who wishes to be a Qualified Limited Passive Investor and hold an interest in a Retail Marijuana Establishment as a Direct Beneficial Interest Owner must establish that he or she meets the following criteria before the ownership interest will be approved:
 - 1. He or she is a natural person;
 - 2. The Applicant qualifies under Rule R 231.2(B);
 - 3. He or she has been a United States citizen since a date prior to the date of the application, and
 - 4. He or she has signed an affirmation of passive investment.

- I. Workforce Training or Development Residency Exempt Occupational License. An Applicant who wishes to obtain a workforce development or training exemption to the license residency requirement may only apply for a Support License and must:
 - 1. Submit a complete application on the Division's approved forms;
 - 2. Establish he or she meets the licensing criteria of Rule R 231(E)(1)-(3) and 231(E)(5)-(9) for Occupational Licensees; and
 - 3. Provide a complete Workforce Training or Development Affirmation form executed under penalty of perjury.

Department of Revenue Marijuana Enforcement Division RETAIL MARIJUANA RULES

LEGISLATION IMPLEMENTATION WORK GROUP

Basis and Purpose - R 1507

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(IV), 12-43.4-202(3)(a)(VII), 12-43.4-202(3)(a)(VIII), 12-43.4-202(3)(a)(XI), 12-43.4-202(3)(a)(XI), 12-43.4-202(3)(b)(III), 12-43.4-202(3)(b)(IX), 12-43.4-202(3)(c)(V), 12-43.4-202(3)(c)(VII), 12-43.4-202(3)(b)(IX), 12-43.4-202(3)(c)(V), 12-43.4-202(3)(c)(VII), 12-43.4-402(4), 12-43.4-403(5), 12-43.4-404(3), and 12-43.4-404(6), 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 Retail Marijuana Sampling and Testing Program.

R 1507 - Retail Marijuana Testing Program - Contaminated Product and Failed Test Results

A. Quarantining of Product

- 1. If the Division has reasonable grounds to believe that a particular Harvest Batch, Production Batch, package or quantity of Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product is contaminated or presents a risk to public safety, then the Division may require a Retail Marijuana Establishment to quarantine it until the completion of the Division's investigation, which may include the receipt of any test results.
- 2. If a Retail Marijuana Establishment is notified by the Division or a Retail Marijuana Testing Facility that a Test Batch failed a contaminant or potency testing, then the Retail Marijuana Establishment shall quarantine any Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product from any package, Harvest Batch or Production Batch combined into that Test Batch and must follow the procedures established pursuant to paragraph B of this rule.
- 3. Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product that has been quarantined pursuant to this rule must be physically separated from all other inventory and may not be sold, wholesaled, transferred or processed into a Retail Marijuana Concentrate or Retail Marijuana Product.
- B. Failed Contaminant Testing: All Contaminant Testing Except Microbial Testing of Retail Marijuana
 Flower or Trim. If a Retail Marijuana Establishment is notified by the Division or a Retail
 Marijuana Testing Facility that a Test Batch failed contaminant testing, then for each package,
 Harvest Batch or Production Batch combined into that Test Batch the Retail Marijuana
 Establishment must either:
 - 1. Destroy and document the destruction of the package, Harvest Batch or Production Batch that it possesses. See Rule R 307 Waste Disposal; or
 - 2. Decontaminate the portion of the package, Harvest Batch or Production Batch that it possesses, if possible, and create two new Test Batches, each containing the requisite number of Samples, and have those Test Batches tested for the identified contaminant by the same or different Retail Marijuana Testing Facility.

- a. If both new Test Batches pass the required contaminant testing, then any Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product from any package, Harvest Batch or Production Batch included in that Test Batch may be sold, wholesaled, transferred or processed into a Retail Marijuana Concentrate or Retail Marijuana Product.
- b. If one or both of the Test Batches do not pass contaminant testing, then the Retail Marijuana Establishment must destroy and document the destruction of the entire portion of the package, Harvest Batch or Production Batch included in that Test Batch that it possesses. See Rule R 307 Waste Disposal.
- B.1. <u>Failed Microbial Contaminant Testing: Microbial Testing of Retail Marijuana Flower or Trim.</u> If a Retail Marijuana Cultivation Facility is notified by the Division or a Retail Marijuana Testing Facility that a Test Batch of Retail Marijuana flower or trim failed microbial testing, then for each package or Harvest Batch combined into that Test Batch the Retail Marijuana Cultivation Facility must either:
 - Destroy and document the destruction of the package or Harvest Batch, See Rule R 307

 Waste Disposal;
 - Decontaminate the portion of the package, Harvest Batch or Production Batch that it
 possesses, if possible, and create two new Test Batches, each containing the requisite
 number of Samples, and have those Test Batches tested for the identified contaminant
 by the same or different Retail Marijuana Testing Facility.
 - a. If both new Test Batches pass the required contaminant testing, then any Retail
 Marijuana flower or trim from any package or Harvest Batch included in that Test

 Batch may be sold, wholesaled, transferred or processed into a Retail Marijuana
 Concentrate or Retail Marijuana Product.
 - b. If one or both of the Test Batches do not pass contaminant testing, then the
 Retail Marijuana Establishment must destroy and document the destruction of the entire portion of the package or Harvest Batch included in that Test Batch that it possesses. See Rule R 307 Waste Disposal; or

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- 32. The Retail Marijuana Cultivation Facility may transfer all packages or Harvest Batches associated with the failed Test Batch to a Retail Marijuana Products Manufacturing Facility for processing the particular Retail Marijuana into a Solvent-Based Retail Marijuana Concentrate.
 - a. The Solvent-Based Retail Marijuana Concentrate shall be manufactured entirely from the Retail Marijuana flower or trim that failed microbial testing.——_No other Retail Marijuana shall be included in the Solvent-Based Retail Marijuana Concentrate manufactured pursuant to subparagraph (B.1)(2) of this rule R 1507.
 - b. The Solvent-Based Retail Marijuana Concentrate that was manufactured out of the Retail Marijuana flower or trim that failed microbial testing shall undergo all required testing for contaminants pursuant to rule R 1501 – Retail Marijuana Testing Program – Contaminant Testing, for potency pursuant to rule R 1503 – Retail Marijuana Testing Program – Potency Testing, and any other testing required or allowed by the Retail Marijuana Rules or Retail Marijuana Code.

- c. If the Solvent-Based Retail Marijuana Concentrate that was manufactured out of the Retail Marijuana flower or trim that failed microbial testing fails contaminant testing, the Retail Marijuana Cultivation Facility shall destroy and document the destruction of the entire portion of the Production Batch(es) associated with the Solvent-Based Retail Marijuana Concentrate that failed contaminant testing, See Rule R 307 – Waste Disposal.
- 43. Nothing in this rule removes or alters the responsibility of the Retail Marijuana Cultivation Facility transferring the Retail Marijuana that failed microbial testing from complying with the requirement to pay excise tax pursuant to rule R 502(E).
- B.2 Failed Microbial Contaminant Testing: Microbial Testing of Retail Marijuana Concentrate or Product. If a Retail Marijuana Cultivation Facility or a Retail Marijuana Products Manufacturing Facility is notified by the Division or a Retail Marijuana Testing Facility that a Test Batch of Retail Marijuana Concentrate or Retail Marijuana Product failed microbial testing, then for each package or Production Batch combined into that Test Batch the Retail Marijuana Cultivation Facility or Retail Marijuana Products Manufacturing Facility must either:
 - Destroy and document the destruction of the package or Production Batch, See Rule R 307 – Waste Disposal;
 - Decontaminate the portion of the package or Production Batch that it possesses, if
 possible, and create two new Test Batches, each containing the requisite number of
 Samples, and have those Test Batches tested for the identified contaminant by the same or different Retail Marijuana Testing Facility.
 - a. If both new Test Batches pass the required contaminant testing, then any Retail
 Concentrate or Retail Marijuana Product from any package or Production Batch included in that Test Batch may be sold, wholesaled, or transferred to a Retail Marijuana Establishment.
 - b. If one or both of the Test Batches do not pass contaminant testing, then the Retail Marijuana Cultivation or Retail Marijuana Products Manufacturing Facility must destroy and document the destruction of the entire portion of the package or Production Batch included in that Test Batch that it possesses. See Rule R 307 Waste Disposal.
- C. <u>Failed Potency Testing.</u> If a Retail Marijuana Establishment is notified by the Division or a Retail Marijuana Testing Facility that a Test Batch of Retail Marijuana Product failed potency testing, then for the package or Production Batch from which that Test Batch was produced the Retail Marijuana Establishment must either:
 - 1. Destroy and document the destruction of the entire portion of the package or Production Batch that it possesses, See Rule R 307 Waste Disposal; or
 - 2. Attempt corrective measures, if possible, and create two new Test Batches and have those Test Batches tested for potency by the same or different Retail Marijuana Testing Facility.
 - a. If both new Test Batches pass potency testing, then any Retail Marijuana Product from the Production Batch included in the Test Batch may be sold, wholesaled or transferred.
 - b. If one or both of the Test Batches fail potency testing, then the Retail Marijuana Products Manufacturing Facility must destroy and document the destruction of

Initial Draft – For Discussion Purposes Only Legislation Implementation Work Group 8/31/17

the entire portion of the package or Production Batch that it possesses. See Rule R 307 – Waste Disposal.

D. <u>Violation Affecting Public Safety.</u> Failure to comply with this rule may constitute a license violation affecting public safety.

Partial proposed rules for labeling and packaging

Department of Revenue Marijuana Enforcement Division RETAIL MARIJUANA RULES

LABELING & PACKAGING WORK GROUP - SELECT DEFINITIONS

"Child-Resistant" means special packaging that is:

- 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. 1700.20 (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 regulation, which is available to the public.
- Opaque so that the packaging does not allow the product to be seen without opening the packaging material;
- Resealable for any product intended for more than a single use or containing multiple servings.

"Container" means a receptacle or vessel that directly holds the Child-Resistant packagesealed that holds package in which Retail Marijuana, Retail Marijuana Concentrate or a-Retail Marijuana Product and any larger receptacle or vessel that holds Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana that has already been placed in a smaller-receptacle or vessel. Each receptacle or vessel must be teach of which are labeled according to the requirements in Rules R 1001 et. seq. or Rules R 1001.1 et.et se seq. is placed for sale to a consumer and that has been labeled according to the requirements set forth in Rules R 10012 et. seq. or Rules R 1001.1 et.et se seq.

-"Edible Retail Marijuana Product" means any Retail Marijuana Product for which the intended use is oral consumption which is intended to be consumed orally, including but not limited to, any type of food, drink, or pill.

"Exit Package" means an <u>Opaque bag or sealed Container package or package</u> provided at the retail point of sale, in which any—Retail Marijuana, <u>Retail Marijuana Concentrate</u> or Retail Marijuana Product already <u>within a Child-Resistant Container is are</u>—placed. <u>The Exit Package shall not be labeled in accordance with Rules R 1001 <u>et</u>, <u>seq.</u> or Rules R 1001.1 <u>et</u>. <u>seq.</u> but may include the Retail Marijuana Store's Identity Statement and/or Standardized Graphic Symbol.</u>

"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.

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

"Liquid Edible Retail Marijuana Product" means an Edible Retail Marijuana Product that is a liquid beverage or food-based product with an oral consumption intended use and intended to be consumed orally, such as a soft drink or cooking sauce.

-"Multiple-Serving Edible Retail Marijuana Product" means an Edible Retail Marijuana Product unit for sale to consumers containing 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

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Edible Retail Marijuana Product shall be considered a Multiple-Serving Edible Retail Marijuana Product.

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

"Resealable" means that the package maintains its Child-Resistant effectiveness for multiple openings.

"Shipping Container" means a hard-sided container with a lid or other enclosure that can be secured in place that, and the container is used solely for the transport of Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product in bulk, or in a quantity for between other Retail Marijuana Establishments.

"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 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 R 605.

"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. The size of a Standardized Serving Of Marijuana shall be no more than 10mg of active THC.

"Total THC" means the sum of the percentage by weight of THCA multiplied by 0.87 plus the percentage by weight of THC i.e., Total THC = (%THCA x 0.877) + %THC.

"Universal Symbol" means the image established by the Division and made available to Licensees through the Division's website indicating the Retail Marijuana or Retail Marijuana Product contains marijuana.

-"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, ice or dry ice.

Department of Revenue Marijuana Enforcement Division RETAIL MARIJUANA RULES

LABELING & PACKAGING WORK GROUP

R 1000 Series - Labeling, Packaging, and Product Safety

Effective Date. Compliance with this R 1000 Series is mandatory until January 1, 2018. During the period January 1, 2018, to June 30, 2018, Licensees have the option of complying with this Rule R 1000 Series or with the Rule R 1000.1 Series, but must be fully compliant with at least one of those two Labeling, Packaging, and Product Safety Series. Beginning July 1, 2018, this Rule R 1000 Series is repealed, and compliance with the R 1000.1 Series is mandatory.

R 1000.1 Series - Labeling, Packaging, and Product Safety

Effective Date. The revised Packaging, Labeling and Product Safety rules set forth in this Rule R 1000.1 Series are effective January 1, 2018, except that during the period January 1, 2018, to June 30, 2018, Licensees have the option of complying with the Rule R 1000 Series or with this Rule R 1000.1 Series, but must be fully compliant with at least one of those two Labeling, Packaging, and Product Safety Series. Beginning July 1, 2018, the Rule R 1000 Series is repealed, and compliance with this R 1000.1 Series is mandatory.

On and after July 1, 2018, all Licensees are required to package and label all Retail Marijuana, Retail Marijuana Concentrate and Retail Marijuana Product according to the Packaging, Labeling, and Product Safety rules in this Rule R 1000.1 Series.

Basis and Purpose - Rule R 1001.1

The statutory authority for this rule is found at subsections 12-43.4-202(1), 12-43.4-202(2)(b), 12-43.4-202(3)(a)(IV), 12-43.4-202(3)(a)(VI), 12-43.4-202(3)(a)(VI), 12-43.4-202(3)(b)(IX), 12-43.4-202(3)(c)(I), 12-43.4-202(3)(c)(III), 12-43.4-202(5), 12-43.4-202(6), 12-43.4-202(6), 12-43.4-202(6), 12-43.4-202(6), 12-43.4-404(1)(6), 12-43.4-404(1)(6), 12-43.4-404(1)(6), 12-43.4-404(7)-(9), and 12-43.4-901(4)(b), 25-4-1614(3)(a), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VI). The purpose of the rules in this series, is to ensure that all Retail Marijuana, Retail Marijuana Concentrate, and Retail Marijuana Product is sold and delivered to lawful consumers in packaging that is not easily opened by children, and that provides consumers with the information necessary to make informed decisions. These rules are in the interest of the health of the people of Colorado and are necessary for the stringent and comprehensive administration of the Retail Code.

Based upon written and oral comments received through numerous rulemaking processes over the years and multiple focus groups with various industry stakeholders, the State Licensing Authority finds that these rules provide necessary information to consumers, promote prevention of underage use, and assist in limiting exposure, accidental consumption by, and diversion to, minors. These rules also aim to reduce duplication and facilitate compliance by moving to an intended use model. The State Licensing Authority finds that use of proper packaging and labeling techniques for all Retail Marijuana, Retail Marijuana Concentrate and Retail Marijuana Product is a public health and safety concern.

The purpose of this rule is to describe the packaging and labeling responsibility of Retail Marijuana Stores, Retail Marijuana Cultivation Facilities and Retail Marijuana Products Manufacturing Facilities.

Packaging and labeling in conformance with the requirements of these rules is a public health and safety concern. It is paramount that all Retail Marijuana Cultivation Facilities, Retail Marijuana Products Manufacturing Facilities and Retail Marijuana Stores ensure accurate, compliant packaging and labeling of all Retail Marijuana, Retail Marijuana Concentrate and Retail Marijuana Products.

Rule R 1001.1 - Packaging and Labeling Responsibility – All Intended Uses Except Immature Plants

- A. Retail Marijuana Cultivation Facility. Other than bulk Retail Marijuana flower or trim and bulk Retail Marijuana Concentrate packaged and labeled in accordance with Rule R 1007.1(F), a Retail Marijuana Cultivation shall not transfer any Retail Marijuana, or Retail Marijuana Concentrate to another Retail Marijuana Establishment unless it has been placed into a Child-Resistant Container and labeled in accordance with this R 1000.1 series so that it is ready for sale to the consumer, except that the Retail Marijuana Store shall affix its license number and the date of sale to the consumer to the outermost Container prior to sale to the consumer. Other than bulk packaged Retail Marijuana flower or trim packaged and labeled in accordance with Rule R 1007.1(F), a Retail Marijuana Cultivation shall not transfer any Retail Marijuana or Retail Marijuana Concentrate to a Medical Research Facility or a Pesticide Manufacturer unless it has been placed into a Child-Resistant Container and labeled in accordance with this R 1000.1 series.
- B. Retail Marijuana Products Manufacturing Facility. Other than bulk Retail Marijuana flower or trim and bulk Retail Marijuana Concentrate packaged and labeled in accordance with Rule R 1007.1(F), a Retail Marijuana Products Manufacturing Facility shall not transfer any Retail Marijuana, Retail Marijuana Product or Retail Marijuana Concentrate to another Retail Marijuana Establishment unless it has been placed into a Child-Resistant Container and labeled in accordance with these R 1000.1 Series rules so that it is ready for sale to the consumer, except that the Retail Marijuana Store shall affix its license number and date of sale to the consumer to the outermost Container prior to sale to the consumer. A Retail Marijuana Products Manufacturing Facility shall not transfer any Retail Marijuana, Retail Marijuana Product or Retail Marijuana Concentrate to a Medical Research Facility or a Pesticide Manufacturer unless it has been placed into a Child-Resistant Container and labeled in accordance with these R 1000.1 Series rules.

C. Retail Marijuana Store.

- 1. Packaging and Labeling Prior to Sale to a Consumer. A Retail Marijuana Store shall ensure that all Retail Marijuana, Retail Marijuana Concentrate and Retail Marijuana Product is placed directly into a Child-Resistant Container prior to sale to a consumer and that a label is affixed to the Container directly containing the Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product. If a Retail Marijuana Store places a Child-Resistant Container containing Retail Marijuana into any other Container, the Retail Marijuana Store shall also ensure that each Container is labeled in accordance with these rules.
- 2. Packaging and Labeling of Bulk Retail Marijuana Flower and Trim or Bulk Retail Marijuana Concentrate. If a Retail Marijuana Store receives bulk Retail Marijuana flower or trim or Retail Marijuana Concentrate from a Retail Marijuana Cultivation Facility or Retail Marijuana Products Manufacturing Facility, the Retail Marijuana Store shall place the Retail Marijuana flower or trim or Retail Marijuana Concentrate into a Child-Resistant Container that does not exceed the sales limit in Rule R 402(C) and affix a label to the Child-Resistant Container directly containing the Retail Marijuana flower or trim or Retail Marijuana Concentrate that includes all information required by these R 1000.1 Series rules.

- 3. <u>Exit Packages Required</u>. A Retail Marijuana Store shall place every Child-Resistant Container into an Opaque Exit Package at the point of sale to the consumer. The Exit Package is not required to be labeled.
- 4. Research Transfers Prohibited. A Retail Marijuana Store shall not sell or transfer any Retail Marijuana, Retail Marijuana Product or Retail Marijuana Concentrate to a Medical Research Facility, a Pesticide Manufacturer or a Research and Development Licensee.
- D. <u>Prohibited Transfers All Retail Marijuana Establishments</u>. A Retail Marijuana Establishment shall not transfer, and another Retail Marijuana Establishment shall not accept nor offer for sale, any Retail Marijuana, Retail Marijuana Product or Retail Marijuana Concentrate that is not packaged and labeled in conformance with the requirements of these rules.
- E. <u>Violation Affecting Public Safety</u>. Any violation of any rule in these R 1000.1 Series may be considered a license violation affecting public safety.

Basis and Purpose - R 1002.1

The statutory authority for this rule is found at subsections 12-43.4-202(1), 12-43.4-202(2)(b), 12-43.4-202(3)(a)(IV), 12-43.4-202(3)(a)(VI), 12-43.4-202(3)(b)(IX), 12-43.4-202(3)(c)(I), 12-43.4-202(3)(c)(III), 12-43.4-202(3)(c)(III), 12-43.4-202(3)(c)(III), 12-43.4-202(3)(c)(III), 12-43.4-202(3)(c)(III), 12-43.4-202(3)(c)(III), 12-43.4-202(3)(c)(III), 12-43.4-202(5), 12-43.4-202(5), 12-43.4-202(6), 12-43.4-20

R 1002.1 - Labeling Requirements: All Intended Uses Except Seeds and Immature Plants

- A. <u>Applicability</u>. The labeling requirements in this Rule R 1002.1 apply to all Containers that contain any Retail Marijuana, Retail Marijuana Concentrate and Retail Marijuana Product regardless of intended use except that this rule does not apply to seeds and Immature Plants. The labeling requirements based on intended use in Rules 1003.1-1005.1 are in addition to, not in lieu of, the requirements of this Rule R 1002.1. See also Rule R 1006.1 Labeling Requirements Seeds and Immature Plants.
- B. <u>Labels Required</u>. Every Container that contains any Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product shall have a label affixed to the Container.
- C. <u>Labels Shall Not Be Designed to Appeal to Children</u>. A Retail Marijuana Establishment shall not place any content on the Container(s) in a manner that reasonably appears to target individuals under the age of 21, including but not limited to, cartoon characters or similar images.
- False or Misleading Statements. The label(s) on the Container(s) shall not include any false or misleading statements.
- E. <u>Trademark Infringement Prohibited</u>. No Container shall be intentionally or knowingly labeled so as to cause a reasonable consumer confusion as to whether the Retail Marijuana, Retail Marijuana

3

Concentrate or Retail Marijuana Product is a trademarked product or labeled in a manner that violates any federal trademark law or regulation.

- F. <u>Health and Benefit Claims</u>. The label(s) on the Container(s) shall not make any claims regarding health or physical benefits to the consumer.
- G. Font Size. Labeling text on the Container(s) must be no smaller than 1/16 of an inch.
- H. <u>Use of English Language</u>. Labeling text on the Container(s) 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.
- I. <u>Unobstructed and Conspicuous</u>. Labeling text on the Container(s) must be unobstructed and conspicuous. A Licensee may affix multiple labels to the Container(s), provided that none of the information required by these rules is obstructed. Labels may be accordion, expandable, extendable or layered to permit labeling of small Containers.
- J. <u>Use of the Word "Candy" and/or "Candies" Prohibited.</u>
 - Licensees shall not use the word(s) "candy" and/or "candies" on the label of Container(s) holding Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product.
 - Notwithstanding the requirements of subparagraph (J)(1), a licensed Retail Marijuana
 Establishment whose Identity Statement contains the word(s) "candy" and/or "candies"
 may place its Identity Statement on the label of the Container(s) holding Retail Marijuana,
 Retail Marijuana Concentrate and/or Retail Marijuana Product.
- K. Information Required on Every Label Regardless of Intended Use (Except for Seeds and Immature Plants). Every Container holding Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product must have a label that includes at least the following information:
 - 1. Required License Number(s). The license number(s) for each of the following:
 - The Retail Marijuana Cultivation Facility(ies) where the Retail Marijuana was grown;
 - ii. If applicable, the Retail Marijuana Cultivation Facility(ies) that produced the Water-Based Retail Marijuana Concentrate;
 - iii. If applicable, the Retail Marijuana Products Manufacturing Facility that produced the Retail Marijuana Product or Retail Marijuana Concentrate; and
 - iv. The Retail Marijuana Store that sold the Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product to the consumer.
 - Batch Numbers. The Harvest Batch Number(s) assigned to the Retail Marijuana or the Production Batch Number(s) assigned to Retail Marijuana Concentrate or Retail Marijuana Product.
 - 3. <u>Statement of Net Contents.</u> Every label must identify the net weight, volume or number of items, using a standard of measure compatible with the Inventory Tracking System, of the Retail Marijuana, Retail Marijuana Concentrate, or Retail Marijuana Product prior to placement in the Container directly containing the Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product:

4

Initial Draft – For Discussion Purposes Only

Labeling and Packaging Work Group 8/31/2017

- 4. <u>Universal Symbol</u>. The Universal Symbol on the front of the Container(s), no smaller than ½ of an inch by ½ of an inch, with the following statement directly below the Universal Symbol: "Contains Marijuana. Keep out of the reach of children."
- 5. Ingredient List Including Major Allergens. A list of all ingredients used to manufacture the Retail Marijuana Concentrate or Retail Marijuana Product including identification of any major allergens contained in the Retail Marijuana Product or Retail 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.
 - 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.

6. Required Warning Statements:

- "This product was produced without regulatory oversight for health, safety, or efficacy."
- ii. "This product has been tested for pesticides, microbials and potency."
- iii. "There may be health risks from use of marijuana including additional risks for women who are pregnant, breastfeeding or planning on becoming pregnant. Use of marijuana may impair your ability to drive a car or operate machinery."
- Required Potency Statement. Each Container shall be labeled with the potency of the Retail Marijuana or Retail Marijuana Concentrate's Total THC expressed as a percentage or Retail Marijuana Product's THC expressed in milligrams and CBD. The potency label shall be either:
 - 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.
- 8. <u>Timing of Effect Statement</u>. A statement of the estimated time after use before the Retail Marijuana, Retail Marijuana Product or Retail Marijuana Concentrate takes effect. Timing of Effect may be stated as a range of times. See also Rule R 1004.1(A.2) Additional Labeling Requirements Edible Retail Marijuana Products, Additional Warning Statement Required.
- Solvent List. A list of all solvents and any other chemicals used to produce any Solvent-Based Retail Marijuana Concentrate that is sold on its own or as a production input in any Retail Marijuana Product.
- <u>Date of Sale</u>. The date the Retail Marijuana Store sells any Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product to the consumer.
- Statement of Intended Use. Every Container shall identify one or more intended use for Retail Marijuana, Retail Marijuana Product and Retail Marijuana Concentrate from the following list:

Comment [AA1]: Add to Medical Rules:

"This product has been tested for pesticides, microbials and potency." or "This product has not been tested."

Comment [AA2]: Add to Medical Rules

Nonorganic Pesticide Disclosure. A complete list of all nonorganic pesticides, fungicides, and herbicides used during the cultivation of Retail Marijuana.

i. Inhaled Product:

- a. Flower or Trim (including pre-rolled joint and kief);
- b. Solvent-Based Concentrate;
- c. Water-Based Retail Marijuana Concentrate;
- d. Vaporizer cartridge.

ii. For Oral Consumption (Edible Retail Marijuana Product):

- a. Food and drink infused with Retail Marijuana;
- b. Food-Based Retail Marijuana Concentrate;
- c. Pills and capsules;
- d. Tinctures.

iii. Skin and Body Products:

- a. Topical;
- b. Suppository;
- c. Transdermal.
- L. No Other Intended Use Permitted. No intended use other than those identified in Rule R 1002.1(K.11) shall be identified on any label without first obtaining formal, written approval from the Division for such additional or new intended use. Licensees shall accurately identify all intended use(s) on the label.
- M. Multiple Intended Uses. Any Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product 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 consumer to use Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product other than in accordance with the intended use(s) identified on the label.

N. <u>Permissive Information</u>.

- Identity Statement. The label may include, but is not required to include, the Identity Statement and/or Standardized Graphic Symbol for:
 - The Retail Marijuana Cultivation Facility(ies) where the Retail Marijuana was grown;
 - ii. The Retail Marijuana Products Manufacturing Facility that manufactured the Retail Marijuana Product or Retail Marijuana Concentrate; and/or
 - iii. The Retail Marijuana Store that sold the Retail Marijuana, Retail Marijuana Product or Retail Marijuana Concentrate.

Other Permissive Information. The labeling requirements in these R 1000.1 Series
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 - R 1003.1

The statutory authority for this rule is found at subsections 12-43.4-202(1), 12-43.4-202(2)(b), 12-43.4-202(3)(a)(IV)(D), 12-43.4-202(3)(a)(VII), 12-43.4-202(3)(b)(IX), 12-43.4-202(c)(VI), 12-43.4-202(f), 12-43.3-402(2)(a), 12-43.4-404(4)(a), and 12-43.4-404(8), C.R.S. The purpose of this rule is to define additional labeling requirements for Retail Marijuana, Retail Marijuana Concentrate and/or Retail Marijuana Product whose intended use is inhalation, and in particular to address potency statement requirements. These labeling requirements are in addition to, not in lieu of, the general labeling requirements in Rule R 1002.1 which apply to all Retail Marijuana (except seeds and Immature plants), Retail Marijuana Concentrate and Retail Marijuana Products regardless of intended use.

R 1003.1 - Additional Labeling Requirements - Inhaled Products

In addition to the labeling requirements in Rule R 1002.1, the label(s) on all inhaled product intended use shall also include:

- A. The potency statement required by Rule R 1002.1(K.7) for: (1) flower (including prerolls), (2) Solvent-Based Concentrate and (3) Mechanical Concentrate shall be stated as the percentage of Total THC and CBD.
- B. The potency statement required by Rule R 1002.1(K.7) for vaporizer cartridges shall be stated as the percentage of Total THC and CBD, and the number of milligrams of THC and CBD per cartridge.

Basis and Purpose - R 1004.1

The statutory authority for this rule is found at subsections 12-43.4-202(1), 12-43.4-202(2)(b), 12-43.4-202(3)(a)(IV), 12-43.4-202(3)(a)(VI), 12-43.4-202(3)(a)(VII), 12-43.4-202(3)(b)(IX), 12-43.4-202(3)(c)(I), 12-43.4-202(3)(c)(III), 12-43.4-202(3)(c)(VI), 12-43.4-202(c)(VI), 12-43.4-202(c.5), 12-43.4-202(f), 12-4

R 1004.1 - Additional Labeling Requirements - Edible Retail Marijuana Products

- A. In addition to the general labeling requirements in Rule R 1002.1, the label(s) on all Edible Retail Marijuana Products, including but not limited to candy, liquids, Retail Marijuana-infused food, pills, capsules and tinctures, shall also include:
 - The potency statement required by Rule R 1002.1(K.7) shall be stated as: (1) milligrams of THC and CBD per serving and (2) milligrams of THC and CBD per Container where the Container contains more than one serving. For example: "The serving size of active THC in this product is X mg, the service size of CBD in this product is X mg, the

total amount of active THC in this Container is X mg and the total amount of CBD in this Container is X mg."

- Additional Warning Statement Required. The following additional warning statement shall be included on the label for all Edible Retail Marijuana Product: "The intoxicating effects of this product may be delayed." See also Rule R 1002.1(K.8) - Labeling Requirements: All Intended Uses Except Seeds and Immature Plants, Timing of Effect Statement.
- 3. Expiration/Use-By Date. A product expiration date, upon which the Edible Retail Marijuana Product will no longer be fit for consumption, or a use-by-date, upon which the oral consumption 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 Retail Marijuana Product, a Licensee shall not alter that expiration or use-by date or affix a new label with a later expiration or use-by date.
- 4. Production Date. The date on which the Edible Retail Marijuana Product was produced.
- 5. <u>Statement Regarding Refrigeration</u>. If an Edible Retail Marijuana Product is perishable, a statement that the oral consumption product must be refrigerated.
- B. <u>Permissive Nutritional Fact Panel</u>. The label also may include, but is 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:
 - For Edible Retail Marijuana Products other than pills, capsules and tinctures and 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;
 - 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.
 - Note that this Rule R 1004.1(B) 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.

Basis and Purpose - R 1005.1

The statutory authority for this rule is found at subsections 12-43.4-202(1), 12-43.4-202(2)(b), 12-43.4-202(3)(a)(IV), 12-43.4-202(3)(a)(VI), 12-43.4-202(3)(b)(IX), 12-43.4-202(3)(c)(II), 12-43.4-202(3)(c)(III), 12-43.4-202(3)(c)(VI), 12-43.4-202(5)(VI), 12-43.4-202(5)(f), 12-43.4-202(5)(g), 12-43.4-202(g), 12-43.4-202

R 1005.1 – Additional Labeling Requirements – Skin and Body Products (Topical, Suppositories and Transdermal)

In addition to the general labeling requirements in Rule R 1002.1, the label(s) on all skin and body product shall also include:

- A. Topical Product Potency Statement. For topical product, the potency statement required by Rule R 1002.1(K.7) shall be stated as the number of milligrams of THC and CBD per Container and per milliliter. For example: "The serving size of active THC in this product is X mg, the serving size of CBD in this product is X mg, the total amount of active THC in this Container is X mg and the total amount of CBD in this Container is X mg."
- B. Suppository and Transdermal Product Potency Statement. For suppository and transdermal product, the potency statement required by Rule R 1002.1(K.7) shall be stated as the number of milligrams of THC and CBD per suppository or transdermal and the total number of milligrams of THC and CBD per Container. For example: "The serving size of active THC in this product is X mg, the serving size of CBD in this product is X mg, the total amount of active THC in this Container is X mg and the total amount of CBD in this Container is X mg."
- C. <u>Expiration/Use-By Date</u>. 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, 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. <u>Production Date</u>. The date on which the skin and body product was produced.

Basis and Purpose - R 1006.1

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(IV), 12-43.4-202(3)(a)(VII), 12-43.4-202(3)(b)(IX), 12-43.4-202(3)(c)(II), 12-43.4-202(3)(c)(III), 12-43.4-202(c)(VII), 12-43.4-202(c)(VII), 12-43.4-202(c)(C)(III), 12-43.4-202(c)(C)(C)(III), 12-43.4-202(c)(C)(C)(C)(C), 12-43.4-202(c)(C)(C)(C)(C), 12-43.4-202(c)(C)(C)(C), 12-43.4-202(c)(C)(C), 12-43.4-20

R 1006.1 - Labeling Requirements - Seeds and Immature Plants

- Labels Required. Every Container holding seeds and any plant pot holding an Immature plant, shall have a label.
- B. <u>False or Misleading Statements</u>. The label(s) shall not include any false or misleading statements.
- C. <u>Health and Benefit Claims</u>. The label(s) shall not make any claims regarding health or physical benefits to the consumer.
- D. <u>Font Size</u>. Labeling text on the labels must be no smaller than 1/16 of an inch.
- E. <u>Use of English Language</u>. Labeling text 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.
- F. <u>Unobstructed and Conspicuous</u>. Labeling text must be unobstructed and conspicuous. A Licensee may affix multiple labels to a Container holding seeds or a plant pot holding an

9

Immature plant, provided that none of the information required by these rules is obstructed. Labels may be accordion, expandable, extendable or layered.

- G. Required Information. All labels on seeds or Immature plants shall include the following required information:
 - 1. Required License Number(s). The license number(s) for each of the following:
 - The Retail Marijuana Cultivation Facility(ies) where the Retail Marijuana was grown; and
 - ii. The Retail Marijuana Store that sold the Retail Marijuana, to the consumer.
 - Statement of Net Contents. Every label on a Container holding seeds shall identify the number of seeds in the Container.
 - 3. <u>Universal Symbol</u>. The Universal Symbol on the front of a Container holding seeds and the front of a plant pot holding 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 out of the reach of children."
 - Required Warning Statements:
 - "This product was produced without regulatory oversight for health, safety, or efficacy."
 - ii. "There may be health risks from use of marijuana including additional risks for women who are pregnant, breastfeeding or planning on becoming pregnant. Use of marijuana may impair your ability to drive a car or operate machinery."
 - No Statement of Intended Use. No intended use shall be identified on the label for seeds or Immature plant labeled according to this Rule.

Basis and Purpose - R 1007.1

The statutory authority for this rule is found at subsections 12-43.4-202(1), 12-43.4-202(2)(b), 12-43.4-202(3)(b)(IX), 12-43.4-202(3)(c)(I), 12-43.4-202(3)(c)(II), 12-43.4-202(f), 12-43.3-402(2)(a), 12-43.4-402(5), 12-43.4-404(1)(e), 12-43.4-404(4)(a), and 12-43.4-404(8), C.R.S. The purpose of this rule is to define the packaging requirements for Retail Marijuana (except Immature plants), Retail Marijuana Concentrate and Retail Marijuana Product regardless of intended use. The State Licensing Authority believes based on written and oral comments it has received through the focus group and rulemaking process that requiring child-resistant packaging is of a state wide concern and would assist in limiting accidental ingestion. The State Licensing Authority wants to ensure the regulated community employs proper packaging techniques for all Retail Marijuana, Retail Marijuana Concentrate and Retail Marijuana Product as this is a public health and safety concern.

R 1007.1 - Packaging Requirements - All Intended Uses Except Immature Plants

- A. <u>General Applicability</u>. These packaging requirements apply to all Retail Marijuana, Retail Marijuana Concentrate and Retail Marijuana Product regardless of intended use except Immature plants. See also Rule R 1009.1 Packaging Requirements and Responsibility– Immature Plants.
- B. <u>Child-Resistant Container Required</u>. The Container directly containing Retail Marijuana, Retail Marijuana Concentrate and Retail Marijuana Product (except for bulk transfers of Retail Marijuana

flower or trim and Retail Marijuana Concentrate) shall be Child-Resistant. All Retail Marijuana, Retail Marijuana Concentrate and Retail Marijuana Product (except for bulk transfers of Retail Marijuana flower or trim and Retail Marijuana Concentrate) shall be placed into the required Child-Resistant Container prior to transfer to a Retail Marijuana Store. Bulk Retail Marijuana flower or trim and Retail Marijuana Concentrate shall be placed into a Child-Resistant Container by the Retail Marijuana Store prior to sale to the consumer.

- A sealed vaporize cartridge or disposable vaporize pen need not itself be Child-Resistant but must be placed into a Child-Resistant Container prior to transfer to a Retail Marijuana Store.
- C. <u>Child Resistant Certificate(s)</u>. Licensee shall maintain a copy of the certificate that each Child-Resistant Container into which the Licensee places Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product complies with the requirements of 16 C.F.R. 1700.20 (1995) for at least: (1) the period of time during which the Licensee uses the Child-Resistant Container, and (2) for one year after the Licensee stops placing Retail Marijuana, Retail Marijuana Concentrate and Retail Marijuana Product into that Child-Resistant Container. All certificates of compliance with 16 C.F.R. 1700.20 (1995) shall be available for inspection upon request by the Division.
 - 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. 1700.20 (1995), which is available to the public for inspection and copying during the Division's regular business hours.
- D. <u>RFID Tags Required</u>. Every Container that holds Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product shall be affixed with an RFID tag.
- E. <u>Containers within Containers</u>. If Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product is placed into a Container that is then placed into a larger Container, each Container must have a label(s) that include all information required by these rules, except that the net contents statement required by Rule R 1002.1(K.3) shall be based upon the weight in the Container that directly contains the Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product and not any larger Container.
- F. <u>Bulk Packaging</u>. Only Retail Marijuana flower or trim and Retail Marijuana Concentrate may be packaged in bulk for transfer to a Retail Marijuana Products Manufacturing Facility or a Retail Marijuana Store. Only Retail Marijuana flower or trim may be packaged in bulk for transfer to a Medical Research Facility or a Pesticide Manufacturer. Retail Marijuana flower or trim bulk packages shall not exceed ten pounds of Retail Marijuana flower or trim. Retail Marijuana Concentrate bulk packages shall not exceed one pound of Retail Marijuana Concentrate. All bulk packaging must include an RFID tag and a label containing all information necessary to permit a Retail Marijuana Store to affix a label to any Container into which bulk Retail Marijuana flower or trim or Retail Marijuana Concentrate is placed prior to sale to the consumer. Bulk packaging labels shall include at least the following information:
 - The license number of the Retail Marijuana Cultivation Facility where the Retail Marijuana was grown;
 - If applicable, the license number of the Retail Marijuana Cultivation Facility(ies) that produced the Water-Based Retail Marijuana Concentrate;
 - 3. If applicable, the license number of the Retail Marijuana Products Manufacturing Facility where the Retail Marijuana Concentrate was produced;

Comment [AA3]: Add to Medical Rules:

All bulk packaging must include an RFID tag and a label containing all information necessary to permit a Research and Development Facility to affix a label to any Container into which bulk Medical Marijuana flower or trim is placed prior to transfer to any Person.

- 4. The Harvest Batch Number(s) assigned to the Retail Marijuana or the Production Batch Number(s) assigned to the Retail Marijuana Concentrate; and
- The net contents, using a standard of measure compatible with the Inventory Tracking System, of the Retail Marijuana or Retail Marijuana Concentrate prior to its placement in the bulk package.
- G. All Other Bulk Packaging Prohibited. Other than Retail Marijuana flower or trim and Retail Marijuana Concentrate that is bulk packaged in accordance with subparagraph (F) above, no Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product shall be transferred to a Retail Marijuana Store, a Medical Research Facility or a Pesticide Manufacturer until it is placed in a Child-Resistant Container and labeled in accordance with these rules so that it is ready for sale to the consumer, except that the Retail Marijuana Store shall affixed its license number and date of sale to the consumer to the outermost Container prior to sale to the consumer.
- H. <u>Trademark Infringement Prohibited</u>. No Retail Marijuana Product shall be intentionally or knowingly packaged so as to cause a reasonable consumer confusion as to whether the Retail Marijuana Product is a trademarked food product or packaged in a manner that violates any federal trademark law or regulation.
- I. <u>Shipping Containers</u>. Licensees may place one or more Containers holding Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product into a Shipping Container prior to transport, provided the Shipping Container has an RFID tag. If a Shipping Container holds multiple Containers, each individual Container shall be affixed with an RFID tag. The Shipping Container is not required to be labeled but each Container placed into the Shipping Container must be labeled as required by these Rules. See Rule R 309 Inventory Tracking System and Rule R 801 Transport of Retail Marijuana and Retail Marijuana Product.

Basis and Purpose - R 1008.1

The statutory authority for this rule is found at subsections 12-43.4-202(1), 12-43.4-202(2)(b), 12-43.4-202(3)(c)(II), 12-43.4-202(3)(c)(III), 12-43.4-202(5), 12

R 1008.1 - Additional Packaging Requirements - Edible Retail Marijuana Products

In addition to the general packaging requirements in Rule R 1007.1, any Container holding Edible Retail Marijuana Product shall meet the following requirements:

- A. <u>Single-Serving Edible Retail Marijuana Product</u>. Every Single-Serving Edible Retail Marijuana Product must be put into a Child-Resistant Container prior to transport to another Retail Marijuana Establishment.
- B. <u>Bundled Single-Serving Edible Retail Marijuana Product</u>. Single-Serving Edible Retail Marijuana Products that are put into a Child-Resistant Container may be bundled into a larger Container so long as the total amount of active THC contained within the larger Container does not exceed 100 milligrams.

Comment [AA4]: Add to Medical Rules:

A complete list of nonorganic pesticides, fungicides, and herbicides used during cultivation.

- C. <u>Multiple-Serving Edible Retail Marijuana Product</u>. Every Multiple-Serving Edible Marijuana Product shall be put into a Child-Resistant Container that maintains its Child-Resistant effectiveness for multiple openings.
- D. <u>Liquid Edible Retail Marijuana Product</u>.
 - Each Liquid Edible Retail Marijuana Product that is a Single-Serving Edible Retail
 Marijuana Product must be packaged in a Child-Resistant Container prior to transport to
 another Retail Marijuana Establishment.
 - Each Liquid Edible Retail Marijuana Product that is a Multiple-Serving Edible Retail Marijuana Product shall be:
 - ii. 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 10mg of active THC per serving, with no more than 100mg of active THC total per Child-Resistant Container; and
 - iii. The measurement component is within the Child-Resistant cap or closure of the bottle and is not a separate component.

Basis and Purpose - R 1009.1

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(b)(IX), 12-43.4-202(3)(c)(III) and 12-43.4-202(f) C.R.S. The purpose of this rule is to define the packaging requirements and responsibility for Immature plants.

R 1009.1 - Packaging Requirements and Responsibility-Immature Plants

- A. <u>Packaging</u>. An Immature plant need only be packaged in a plant pot that is labeled in accordance with the requirements of Rule R 1006.1.
- B. <u>Retail Marijuana Cultivation Facility</u>. A Retail Marijuana Cultivation Facility shall not transfer any Immature plant to another Retail Marijuana Establishment, a Medical Research Facility or a Pesticide Manufacturer unless it is in plant pot and labeled in accordance with Rule R 1006.1.

Partial proposed rules for legislation implementation HB17-1367

Department of Revenue
Marijuana Enforcement Division
MEDICAL MARIJUANA RULES

LEGISLATION IMPLEMENTATION WORK GROUP: HB17-1367 September 14th - 15th. 2017

SELECT DEFINITIONS

M 103 - Definitions

"Affiliated Interest" means any Business Interest related to a Medical Marijuana Business that does not rise to the level of a Financial Interest in a Medical Marijuana Business license. An Affiliated Interest may include, but shall not be limited to, an Indirect Beneficial Interest Owner that is not a Financial Interest, a lease agreement, secured or unsecured loan, or security interest in fixtures or equipment with a direct nexus to the cultivation, manufacture, sale, transportation, or testing, or researching of Medical Marijuana or Medical Marijuana-Infused Products. Except as otherwise provided by these rules, an Affiliated Interest holder shall neither exercise control of nor be positioned so as to enable the exercise of control over the Medical Marijuana Business or its operations. A Medical Marijuana Business shall report each of its Affiliated Interests to the Division with each application for initial licensure, renewal, change of ownership or change of corporate structure.

"Inventory Tracking System" means the required seed-to-sale tracking system that tracks Medical Marijuana from either the seed or immature plant stage until the Medical Marijuana or Medical Marijuana Infused-Product is sold to a customer at a Medical Marijuana Center, used or destroyed by a Research and Development Licensee, transferred to a Medical Research Facility, transferred to a Pesticide Manufacturer, or is-destroyed.

"Licensed Premises" means the premises specified in an application for a license pursuant to the Medical 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, or research Medical Marijuana in accordance with the provisions of the Medical Code and these rules.

"Marijuana Research and Development Cultivation" means a Person that is licensed pursuant to the Medical Code to grow, cultivate, possess, and transfer Medical Marijuana to a Marijuana Research and Development Facility for limited research purposes authorized pursuant to section 12-43.3-407, C.R.S.

"Marijuana Research and Development Facility" means a Person that is licensed pursuant to the Medical Code to possess Medical Marijuana for limited research purposes authorized pursuant to section 12-43.3-407, C.R.S.

"Medical Marijuana Business" means a licensed Medical Marijuana Center, a Medical Marijuana-Infused Products Manufacturer, an Optional Premises Cultivation Operation, a Medical Marijuana Testing Facility, a Medical Marijuana Business Operator, or a Medical Marijuana Transporter, a Marijuana Research and Development Facility, or a Marijuana Research and Development Cultivation.

"Medical Marijuana Business Operator" means an entity that holds a registration from the State Licensing Authority to provide professional operational services to one or more Medical Marijuana Businesses, except for Research and Development Licensees, 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 Transporter" means a Person that is licensed to transport Medical Marijuana and Medical Marijuana-Infused Products 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 and Medical Marijuana-Infused Products at its licensed premises, but is not authorized to sell, give away, buy, or receive complimentary Medical Marijuana or Medical Marijuana-Infused Products under any circumstances. A Medical Marijuana Transporter does not include a Licensee that transports its own Medical Marijuana or Medical Marijuana-Infused Products.

"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 Medical Marijuana Business, a Retail Marijuana Establishment, nor a Licensee.

"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 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 Medical Marijuana; (4) who has applied for and received any necessary license, registration or certifications from the Colorado Department of Agriculture pursuant to the Pesticide Act, sections 35-9-101 et seq., C.R.S. and/or the Pesticide Applicator's 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 Medical Marijuana Business, a Retail Marijuana Establishment, nor a Licensee.

"Public Institution" means any entity established or controlled by the federal government, a state government, or a local government or municipality, including but not limited to institutions of higher education or a public higher education research institution.

"Public Money" means any funds or money obtained by the holder from any governmental entity, including but not limited to research grants.

"Research and Development Licensee" means a Marijuana Research and Development Facility or a Marijuana Research and Development Cultivation.

"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 M 1900 Series – Research and Development Licensees. All research and development conducted by a Research and Development Licensee must be conducted in furtherance of an approved Research Project.

"Sample" means anything collected from a Medical Marijuana Business or a patient participating in an approved clinical or observation study conducted by a Research and Development Licensee that is provided for testing to a Medical Marijuana Testing Facility or a Retail Marijuana Testing Facility in accordance with Rule M 701.5 – Medical Marijuana Testing Facilities: License Privileges. Vendor Registration and Occupational License for Medical Marijuana Testing and Research. The following is a non-exhaustive list of types of Samples: Medical Marijuana, Medical

Marijuana-Infused Product, Medical Marijuana Concentrate, soil, growing medium, water, solvent or swab of a counter or equipment.

SELECT RULES

M 400 SERIES

Basis and Purpose - M 403

The statutory authority for this rule is found at subsections 12-43.3-103(2)(b), 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-310(7), 12-43.3-310(4), 12-43.4-401(4) and sections 12-43.3-402 and 12-43.3-406, 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 Center. This rule also restricts the amount of its inventory a Medical Marijuana Center may sell to other Medical Marijuana Businesses to 30 percent.

The quantity limitations on sales provision is intended to inform stakeholders in order to aid in compliance with a patient's lawful medical marijuana limit. Clarifying the quantity limitations on sales provides Medical Marijuana Centers 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).

M 403 - Medical Marijuana Sales: General Limitations or Prohibited Acts

- A. <u>30 Percent Rule</u>. Pursuant to section 12-43.3-402(4), C.R.S., a Medical Marijuana Center may purchase accept transfers of not more than thirty percent of its total on-hand medical marijuana inventory from another licensed Medical Marijuana Center in Colorado. A Medical Marijuana Center may sell-transfer no more than thirty percent of its total on-hand Medical Marijuana inventory to another Medical Marijuana Center.
 - Total on-hand inventory as used in section 12-43.3-402(4), C.R.S., shall only include Medical Marijuana grown on the Medical Marijuana Center's dedicated Optional Premises Cultivation Operation that has been processed and the total amount or quantity has been accounted for in the licensed Medical Marijuana Center's inventory during the previous calendar year, or in the case of a newly licensed business, its first 12 months of business. For purposes of this rule, a calendar year means January 1st to December 31st.
- B. Medical Marijuana-Infused Products Manufacturers. A Medical Marijuana Center may also contract for the manufacture of Medical Marijuana-Infused Product with Medical Marijuana-Infused Product Licensees utilizing a contract as provided for in Rule M 602 Medical Marijuana-Infused Products Manufacturer: General or Prohibited Acts (Infused Product Contracts). Medical Marijuana distributed to a Medical Marijuana-Infused Products Manufacturer by a Medical Marijuana Center pursuant to such a contract for use solely in Medical Marijuana-Infused Product(s) that are returned to the contracting Medical Marijuana Center shall not be included for purposes of determining compliance with subsection A.
- C. <u>Consumption Prohibited</u>. Licensees shall not permit the consumption of marijuana or a marijuana product on the Licensed Premises.
- D. Quantity Limitations On Sales. A Medical Marijuana Center and its employees are prohibited from selling more than two ounces of Medical Marijuana or its equivalent in Medical Marijuana-Infused Product during a sales transaction to a patient unless that patient has designated the Medical Marijuana Center as its primary center and supplied it with documentation from the patient's physician that allows the patient more than two ounces of Medical Marijuana or its equivalent in

Marijuana-Infused Product. A Medical Marijuana Center is prohibited from selling more than two ounces of Medical Marijuana or its equivalent in Marijuana-Infused Product to any patient who has not registered that Medical Marijuana Center as its primary center.

- E. <u>Licensees May Refuse Sales</u>. Nothing in these rules prohibits a Licensee from refusing to sell Medical Marijuana or Medical Marijuana-Infused Product to a patient.
- F. <u>Storage and Display Limitations</u>. A Medical Marijuana Center shall not display Medical Marijuana and Medical Marijuana-Infused Product outside of a designated Restricted Access Area or in a manner in which Medical Marijuana or Medical Marijuana-Infused Product can be seen from outside the Licensed Premises. Storage of Medical Marijuana and Medical Marijuana-Infused Product shall otherwise be maintained in Limited Access Areas or Restricted Access Area.
- G. <u>Sale of Expired Product Prohibited</u>. A Medical Marijuana Center shall not sell any expired Medical Marijuana-Infused Product.
- G.1 A Medical Marijuana Center shall not sell or give away Medical Marijuana or Medical Marijuana Infused Product to a Medical Marijuana Transporter, and shall not buy, or receive complimentary Medical Marijuana or Medical Marijuana-Infused Product from a Medical Marijuana Transporter.
- G.2 A Medical Marijuana Center shall not compensate its employees using performance-based sales incentives. Performance-based incentives that are not sales-based are acceptable. Examples of performance-based incentives that are not sales-based include recognition for providing quality information to consumers, or the duration of the employee's employment with the Medical Marijuana Center.
- G.3 <u>Edibles Prohibited that are Shaped like a Human, Animal, or Fruit.</u> This paragraph G.3 is effective beginning October 1, 2017.
 - 1. The sale or donation of Edible Medical Marijuana-Infused 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 Medical Marijuana Business. Nothing in this subparagraph (G.3)(2) alters or eliminates a Licensee's obligation to comply with the requirements of rule M 1001.5 Labeling and Packaging Requirements: General Applicability.
 - 3. Edible Medical Marijuana-Infused Products that are geometric shapes and simply fruit flavored are not considered fruit and are permissible; and
 - 4. Edible Medical Marijuana-Infused Products that are manufactured in the shape of a marijuana leaf are permissible.
- H. <u>Violation Affecting Public Safety.</u> Failure to comply with this rule may constitute a license violation affecting public safety.

M 500 SERIES - MEDICAL MARIJUANA OPTIONAL PREMISES CULTIVATION OPERATION

Basis and Purpose - M 501

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(l), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), and 12-43.4-401(4), and sections 12-43.3-310, 12-43.4-402, 12-43.3-403, 12-43.3-404, and 12-43.4-406, C.R.S. The purpose of this rule is to establish that it is unlawful for an Optional Premises Cultivation Operation to exercise any privileges other than those granted by the State Licensing Authority, and to clarify the license privileges.

M 501 - Medical Marijuana Optional Premises Cultivation Operation: License Privileges

- A. <u>Privileges Granted</u>. A Medical Marijuana Optional Premises Cultivation Operation shall only exercise those privileges granted to it by the State Licensing Authority.
- B. <u>Licensed Premises</u>. To the extent authorized by Rule M 304 Medical Marijuana Business and Retail Marijuana Establishment Shared Licensed Premises and Operational Separation, a Medical Marijuana Optional Premises Cultivation Facility may share a location with a commonly-owned Retail Marijuana Cultivation Facility. However, a separate license is required for each specific business entity regardless of geographical location.
- C. <u>Cultivation of Medical Marijuana Authorized</u>. A Medical Marijuana Optional Premises Cultivation Operation may Propagate, cultivate, harvest, prepare, cure, package, store, and label Medical Marijuana, whether in concentrated form or otherwise.
- D. <u>Authorized SalesTransfers</u>. A Medical Marijuana Optional Premises Cultivation Operation may only transfer Medical Marijuana to the Medical Marijuana Center or Medical Marijuana Infused Products Manufacturer it is designated to pursuant to section 12-43.3-403, C.R.S.<u>.</u>
 - 1. An Optional Premises Cultivation Operation is also authorized to transfer Medical

 Marijuana to a Research and Development Licensee, a Medical Research Facility
 pursuant to section 25-1.5-106.5, C.R.S., or Pesticide Manufacturer pursuant to section
 12-43.3-202(1)(h)(II), C.R.S. Before transporting Medical Marijuana to these entities, the
 Medical Marijuana shall first be subject to a documented point-of-sale transaction through
 the Optional Premises Cultivation's designated Medical Marijuana Center.
 - A Medical Marijuana Optional Premises Cultivation Operation is also authorized to transfer by donation Medical Marijuana to a Research and Development Licensee pursuant to this rule and subject to the following condition:
 - a. A Medical Marijuana Optional Premises Cultivation Operation shall not receive any compensation from the Research and Development Licensee or any other Person as a result of a donation of Medical Marijuana.
 - 3. An Optional Premises Cultivation shall not transfer Flowering plants or Vegetative plants to any Person except as authorized pursuant to Rule M 801.
- E. <u>Packaging Processed Medical Marijuana</u>. Processed Medical Marijuana plants shall be packaged in units of ten pounds or less and labeled pursuant to Rule M 1002 Labeling Requirements: General Requirements and securely sealed in a tamper-evident manner.
 - 1. The packages must be transported to the receiving Medical Marijuana Business, Medical Research Facility, or Pesticide Manufacturer within 7 days of receiving notification that the Harvest Batch from the processed Medical Marijuana passed required testing, and recorded as inventory at the receiving Medical Marijuana Business.

- In the event that the Harvest Batch from the processed Medical Marijuana does not pass required testing, the Licensee shall follow the procedures in rule M 1507 for the Harvest Batch. If the Harvest Batch ultimately passes required testing, then the packages of Medical Marijuana associated with the Harvest Batch must be transported to the Medical Marijuana Business within 7 days of receiving notification that the Harvest Batch passed the additional round of testing, and recorded as inventory at the receiving Medical Marijuana Business.
- F. <u>Authorized Marijuana Transport</u>. A Medical Marijuana Optional Premises Cultivation 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 <u>is a licensed Medical Marijuana Business</u> and <u>the transportation order is</u> delivered is a licensed Medical Marijuana Business, <u>Medical Research Facility</u>, <u>or Pesticide Manufacturer</u>. Nothing in this rule prevents a Medical Marijuana Optional Premises Cultivation from transporting its own Medical Marijuana.
- G. A Medical Marijuana Optional Premises Cultivation may compensate its employees using performance-based incentives.

Basis and Purpose - M 503

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(h), 12-43.3-202(2)(a)(XX), and 12-43.3-403(3), C.R.S. The purpose of this rule is to eliminate diversion of Medical Marijuana.

M 503 - Medical Marijuana Optional Premises Cultivation Operation: Inventory Tracking System

- A. Minimum Tracking Requirement. An Optional Premises Cultivation Operation must use the Inventory Tracking System to ensure its inventories are identified and tracked from the point Medical Marijuana is Propagated from seed or cutting to the point when it is delivered to a Medical Marijuana Business, Medical Research Facility, or Pesticide Manufacturer. See also Rule M 309, Medical Marijuana Business: Inventory Tracking System. An Optional Premises Cultivation Operation must have the ability to reconcile its inventory records generated from the Inventory Tracking System and the associated transaction history and sale receipts. See also Rule M 901 Business Records Required.
 - An Optional Premises Cultivation Operation is prohibited from accepting any Medical Marijuana from another Medical Marijuana Optional Premises Cultivation Operation or Medical Marijuana Transporter without receiving a valid transport manifest generated from the Inventory Tracking System.
 - An Optional Premises Cultivation Operation must immediately input all Medical Marijuana delivered to its Licensed Premises and account for all RFID tags into the Inventory Tracking System at the time of delivery from another Medical Marijuana Optional Premises Cultivation Facility or Medical Marijuana Transporter.
 - An Optional Premises Cultivation Operation must reconcile its transaction history and onhand Medical Marijuana to the Inventory Tracking System at the close of business each day.

Basis and Purpose - M 504

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(l), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XV), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to establish minimum health and safety regulation for Optional Premises Cultivation Operations. The rule prohibits an Optional Premises Cultivation Operation from treating or otherwise adulterating Medical Marijuana with

any chemical or other compound whatsoever to alter its color, appearance, weight or smell. This rule also authorizes the State Licensing Authority to require an independent consultant conduct an independent health and sanitary audit of an Optional Premises Cultivation Operation. This rule explains when an independent health and sanitary audit may be deemed necessary and sets forth possible consequences of a Medical Marijuana Business's refusal to cooperate or pay for the audit. The State Licensing Authority intends this rule to help maintain the integrity of Colorado's Medical Marijuana Businesses.

M 600 SERIES - MEDICAL MARIJUANA-INFUSED PRODUCTS MANUFACTURER

M 601 - Medical Marijuana-Infused Products Manufacturer: License Privileges

- A. <u>Privileges Granted</u>. A Medical Marijuana-Infused Products Manufacturer shall only exercise those privileges granted to it by the State Licensing Authority.
- B. <u>Licensed Premises</u>. A separate license is required for each specific business or business entity and geographical location. A Retail Marijuana Products Manufacturing Facility may share a location with a commonly owned Medical Marijuana-Infused Products Manufacturer. However, a separate license is required for each specific business or business entity, regardless of geographical location.
- C. <u>Sales Restricted</u>Authorized Transfers. A Medical Marijuana-Infused Products Manufacturer may transfer enly sell: (1) its own Medical Marijuana-Infused Product and Medical Marijuana
 Concentrate to Medical Marijuana Centers, other Medical Marijuana-Infused Products
 Manufacturers, Research and Development Licensees, Medical Research Facilities, and
 Pesticide Manufacturers, and (2) Medical Marijuana that was not cultivated at its own Optional
 Premises Cultivation to other Medical Marijuana-Infused Products Manufacturers.
 - A Medical Marijuana-Infused Products Manufacturer is also authorized to transfer by donation Medical Marijuana-Infused Products and Medical Marijuana Concentrate to a Research and Development Licensee pursuant to this rule and subject to the following condition:
 - a. A Medical Marijuana-Infused Products Manufacturer shall not receive any compensation from the Research and Development Licensee or any other Person as a result of a donation of Medical Marijuana-Infused Products or Medical Marijuana Concentrate.
- D. <u>Manufacture of Medical Marijuana-Infused Product Authorized</u>. A Medical Marijuana-Infused Products Manufacturer may manufacture, prepare, package, and label Medical Marijuana-Infused Product, whether in concentrated form or that are comprised of Medical Marijuana and other ingredients intended for use or consumption, such as edible products, ointments, or tinctures.
- E. <u>Location Prohibited</u>. A Medical Marijuana-Infused Products Manufacturer may not manufacture, prepare, package, store, or label Medical Marijuana-Infused Product in a location that is operating as a retail food establishment or a wholesale food registrant.

F. Samples Provided for Testing.

1. This rule M 601(F)(1) is repealed effective July 1, 2016. A Medical Marijuana-Infused Products Manufacturer may provide samples of its Medical Marijuana-Infused Product to a Retail Marijuana Testing Facility that has obtained an Occupational License to test and research Medical Marijuana for testing and research purposes. The Medical Marijuana-Infused Products Manufacturer shall maintain the testing results as part of its business books and records. See Rule M 901 – Business Records Required.

- 1.5. This rule M 601(F)(1.5) is effective beginning July 1, 2016. A Medical Marijuana-Infused Products Manufacturer may provide samples of its Medical Marijuana-Infused Product to a Medical Marijuana Testing Facility for testing and research purposes. The Medical Marijuana-Infused Products Manufacturer shall maintain the testing results as part of its business books and records. See Rule M 901 Business Records Required.
- G. <u>Authorized Marijuana Transport</u>. A Medical Marijuana-Infused Products Manufacturer is authorized to utilize a licensed Medical Marijuana Transporter for transportation of its Medical Marijuana-Infused Product so long as the place where transportation orders are taken is a <u>licensed Medical Marijuana Business</u> and the transportation order is delivered is to a licensed Medical Marijuana Business, <u>Medical Research Facility</u>, or <u>Pesticide Manufacturer</u>. Nothing in this rule prevents a Medical Marijuana-Infused Products Manufacturer from transporting its own Medical Marijuana.
- H. A Medical Marijuana-Infused Products Manufacturer may compensate its employees using performance-based incentives.

M 700 SERIES - MEDICAL MARIJUANA TESTING FACILITIES

Basis and Purpose - M 701.5

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XVIII.6), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I)(A), 12-43.3-310(8)(a), 12-43.3-402(6), 12-43.3-404(10), and sections 12-43.3-405 and 12-43.3-406, C.R.S. The purpose of this rule is to establish that it is unlawful for a Medical Marijuana Testing Facility Licensee to exercise any privileges other than those granted by the State Licensing Authority and to clarify the license privileges.

M 701.5 - Medical Marijuana Testing Facilities: License Privileges

- A. <u>Privileges Granted</u>. A Medical Marijuana Testing Facility shall only exercise those privileges granted to it by the State Licensing Authority.
- B. <u>Licensed Premises</u>. A separate License is required for each specific Medical Marijuana Testing Facility and only those privileges granted by the Medical Code and any rules promulgated pursuant to it may be exercised on the Licensed Premises.
- C. <u>Testing of Medical Marijuana and Medical Marijuana Infused-Product Authorized</u>. A Medical Marijuana Testing Facility may accept Samples of Medical Marijuana or Medical Marijuana Infused-Product from Medical Marijuana Businesses for testing and research purposes only. The Division may require a Medical Marijuana Business to submit a sample of Medical Marijuana or Medical Marijuana Infused-Product to a Medical Marijuana Testing Facility upon demand.
- C.5 Testing Medical Marijuana and Medical Marijuana Infused-Product for Patients in Research
 Program. A Medical Marijuana Testing Facility is authorized to accept Samples of Medical
 Marijuana or Medical Marijuana Infused-Product 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 Research and Development Licensee.

- 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 M 405(B) Acceptable Forms of Identification.
- 3. The Medical Marijuana Testing Facility shall require the patient to produce a verification on a form approved by the Division from the Research and Development Licensee that the patient is a participant in an approved clinical or observational Research Project conducted by the Research and Development Licensee and that the testing will be in furtherance of the approved Research Project.
- 4. A primary caregiver may transport Medical Marijuana or Medical Marijuana InfusedProduct on behalf of a patient to Medical Marijuana Testing Facility. A Medical Marijuana
 Testing Facility shall require the following documentation before accepting Medical
 Marijuana or Medical Marijuana Infused-Product 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 M 405(B) Acceptable Forms of Identification; and
 - c. A copy of the Research and Development Licensee'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 Research and Development Licensee and that the testing will be in furtherance of the approved Research Project.
- 5. The Medical Marijuana Testing Facility shall report all testing results to the patient or primary caregiver who submitted the Medical Marijuana or Medical Marijuana Infused-Product and to the Research and Development Licensee that is conducting the study in which the patient is participating. Testing result reporting shall conform with the requirements under these Rules.
- D. <u>Product Development Authorized</u>. A Medical Marijuana Testing Facility may develop Medical Marijuana Infused-Product, but is not authorized to engage in the manufacturing privileges described in section 12-43.3-404, C.R.S. and Rule M 601 Medical Marijuana Infused-Products Manufacturer: License Privileges.
- E. <u>Sending Samples to Another Licensed and Certified Medical Marijuana</u> Testing Facility. A Medical Marijuana Testing Facility may send Samples to another Medical Marijuana Testing Facility for testing. All laboratory reports provided to a Medical Marijuana Business, or to a patient or primary caregiver must identify the Medical Marijuana Testing Facility that actually conducted the test.
- F. <u>Authorized Marijuana Transport</u>. A Medical Marijuana Testing Facility is authorized to utilize a licensed Medical Marijuana Transporter to transport Samples of Medical Marijuana and Medical Marijuana-Infused Product for testing, in accordance with the Medical Marijuana Code and Medical Marijuana Rules, 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 Testing Facility, Medical Marijuana Center, Medical Marijuana Optional Premises Cultivation, or Medical Marijuana-Infused Products Manufacturer to utilize a Medical Marijuana Transporter to transport Samples of Medical Marijuana or Medical Marijuana-Infused Product for testing.

Basis and Purpose - M 702

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XVIII.6), 12-43.3-202(2)(a)(XX), 12-43.3-405, 12-43.3-901, 12-43.4-405, 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.

M 702 - Medical Marijuana Testing Facilities: General Limitations or Prohibited Acts

- A. <u>Prohibited Financial Interest</u>. A Person who is an Owner of an Optional Premises Cultivation, Medical Marijuana Infused-Products Manufacturing Facility, Medical Marijuana Center, Retail Marijuana Cultivation Facility, Retail Marijuana Products Manufacturing Facility, or a Retail Marijuana Store shall not be an Owner of a Medical Marijuana Testing Facility.
- B. <u>Sale of Marijuana Prohibited</u>. A Medical Marijuana Testing Facility is prohibited from selling, distributing, or transferring Retail Marijuana, Retail Marijuana Product, Medical Marijuana, or Medical Marijuana-Infused Product to a Retail Marijuana Establishment, a Medical Marijuana Business, or a consumer, or a patient or primary caregiver, except that a Medical Marijuana Testing Facility may transfer a Sample to another Medical Marijuana Testing Facility.
- C. <u>Destruction of Received Medical Marijuana</u>. 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 M 307 Waste Disposal.
- D. <u>Consumption Prohibited</u>. A Medical Marijuana Testing Facility shall not permit the consumption of marijuana or marijuana products on its Licensed Premises.
- E. <u>Sample Rejection</u>. 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. <u>Medical Marijuana Business Requirements Applicable</u>. 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 its Samples 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 destruction or disposal, including the results of any required tests that are conducted. See also Rule M 309 Medical Marijuana Business: Inventory Tracking System. 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 also Rule M 901 Business Records Required.
- H. <u>Industrial Hemp Testing Prohibited</u>. A Medical Marijuana Testing Facility shall not perform testing on Industrial Hemp.
- I. A Medical Marijuana Testing Facility shall not sell or give away Medical Marijuana or Medical Marijuana-Infused Product to a Medical Marijuana Transporter, and shall not buy, or receive complimentary Medical Marijuana or Medical Marijuana-Infused Product from a Medical Marijuana Transporter.

Basis and Purpose - M 712

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.4-203(2.5)(a)(I), 12-43.3-202(2)(a)(XIV), 12-43.4-202(2)(a)(XI), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(IV), 12-4

M 712 – Medical Marijuana Testing Facilities: Sampling and Testing Program

A. <u>Division Authority</u>. The Division may elect to require that a Test Batch be submitted to a specific Medical Marijuana Testing Facility for testing to verify compliance, perform investigations, compile data or address a public health and safety concern.

B. Test Batches

- 1. <u>Medical Marijuana and Medical Marijuana Concentrate</u>. A Medical Marijuana Testing Facility must establish a standard minimum weight of Medical Marijuana and Medical Marijuana Concentrate that must be included in a Test Batch for every type of test that it conducts.
- 2. <u>Medical Marijuana Infused-Product</u>. A Medical Marijuana Testing Facility must establish a standard number of finished product(s) it requires to be included in each Test Batch of Medical Marijuana Infused-Product for every type of test that it conducts.

C. Rejection of Test Batches and Samples

- 1. A Medical Marijuana Testing Facility may not accept a Test Batch that is smaller than its standard minimum amount.
- 2. A Medical Marijuana Testing Facility may not accept a Test Batch or Sample that it knows was not taken in accordance with these rules or any additional Division sampling procedures or was not collected by Division personnel.
- D. <u>Notification of Medical Marijuana Business</u>. If Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana Infused-Product failed a contaminant test, then the Medical Marijuana Testing Facility must immediately notify the Medical Marijuana Business <u>or patient or primary caregiver</u> that submitted the sample for testing and report the failure in accordance with all Inventory Tracking System procedures.
- E. Permissible Levels of Contaminants. If Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana Infused-Product 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.
 - Microbials

<u>Substance</u>	Acceptable Limits Per Gram	Product to be Tested
-Shiga-toxin producing	< 1 Colony Forming Unit (CFU)	
Escherichia coli (STEC)*- Bacteria		Flower; Medical Marijuana Infused-
Salmonella species* – Bacteria	< 1 Colony Forming Unit (CFU)	Product; Water- and Food-Based
Total Yeast and Mold	< 10 ⁴ Colony Forming Unit (CFU)	Medical Marijuana Concentrates

^{*}Testing facilities should contact the Colorado Department of Public Health and Environment when STEC and Salmonella are detected beyond the acceptable limits

Residual Solvents

Substance	Acceptable Limits Per Gram	Product to be Tested
Butanes	< 5,000 Parts Per Million (PPM)	
Heptanes	< 5,000 Parts Per Million (PPM)	
Benzene**	< 2 Parts Per Million (PPM)	
Toluene**	< 890 Parts Per Million (PPM)	Solvent-Based Medical Marijuana
Hexane**	< 290 Parts Per Million (PPM)	Concentrate
Total Xylenes (m,p, o-xylenes)**	< 2,170 Parts Per Million (PPM)	
Any solvent not permitted for use	None Detected	
pursuant to Rule R 605.		

^{**} Note: These solvents are not approved for use. Due to their possible presence in the solvents approved for use per Rule M 605, limits have been listed here accordingly.

3. Metals

Substance	Acceptable Limits Per Gram	Product to be Tested
Metals (Arsenic, Cadmium, Lead	Lead – Max Limit: < 1.0 ppm	Flower; Water-, Food-, and Solvent-
and Mercury)	Arsenic – Max Limit: < 0.4 ppm	Based Medical Marijuana
	Cadmium – Max Limit: < 0.4 ppm	Concentrates
	Mercury – Max Limit: < 0.2 ppm	

4. Other Contaminants

Pesticide	If testing identifies the use of a banned Pesticide or the improper application of a permitted
	Pesticide, then that Test Batch shall be considered to have failed contaminant testing.
Chemicals	If Test Batch is found to contain levels of any chemical that could be toxic if consumed, then
	the Division may determine that the Test Batch has failed contaminant testing.
Microbials	If Test Batch is found to contain levels of any microbial that could be toxic if consumed, then
	the Division may determine that the Test Batch has failed contaminant testing.

5. <u>Division Notification</u>. A Medical Marijuana Testing Facility must notify the Division 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.

F. Potency Testing

1. <u>Cannabinoids Potency Profiles</u>. A Medical 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 Certification Policy Statement.

2. Reporting of Results

- a. For potency tests on Medical Marijuana and Medical 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.
- b. For potency tests conducted on Medical Marijuana Infused-Product, results must be reported by listing the total number of milligrams contained within a single

Medical Marijuana-Infused Product unit for sale for each cannabinoid and affirming the THC content is homogenous.

- 3. <u>Dried Flower</u>. All potency tests conducted on Medical Marijuana must occur on dried and cured Medical Marijuana that is ready for sale.
- 4. Failed Potency Tests for Medical Marijuana Infused-Product
 - a. If the THC content of a Medical Marijuana Infused-Product is determined through testing not to be homogenous, then it shall be considered to have failed potency testing. A Medical Marijuana Infused-Product shall be considered not to be homogenous if 10% of the infused portion of the Medical Marijuana Infused-Product contains more than 20% of the total THC contained within entire Medical Marijuana Infused-Product.
- 5. Potency Variance. A potency variance of no more than plus or minus 15% is allowed.

M 800 SERIES - TRANSPORT AND STORAGE

Basis and Purpose - M 801

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(h), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XVIII.6) 12-43.3-202(2)(a)(XX) and section 12-43.3-406, C.R.S. The purpose of the rule is to provide clarity as to the requirements associated with the transport and delivery of Medical Marijuana and Medical Marijuana-Infused Product between Licensed Premises. It also prescribes the manner in which licensed entities will track inventory in the transport process to prevent diversionary practices.

M 801 – Transport of Medical Marijuana, Medical Marijuana Vegetative Plants, and Medical Marijuana-Infused Product: All Medical Marijuana Businesses

- A. Persons Authorized to Transport. The only Persons authorized to transport Medical Marijuana, Medical Marijuana Vegetative plants, or Medical Marijuana-Infused Product are those individuals licensed by the State Licensing Authority pursuant to section 12-43.3-401, C.R.S.; including Owners Marijuana_or others holding Occupational Licenses. An individual who does not possess a current and valid Occupational License from the State Licensing Authority may not transport Medical Marijuana, Medical Marijuana Vegetative plants, or Retail-Medical Marijuana-Infused Product between Licensed Premises.
- B. <u>Transport Between Licensed Premises</u>.
 - Medical Marijuana and Medical Marijuana-Infused Product. Medical Marijuana and Medical Marijuana-Infused Product shall only be transported between Licensed Premises; and 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 Medical Marijuana and Medical Marijuana-Infused Product are responsible for ensuring that all Medical Marijuana and Medical Marijuana-Infused Product are secured at all times during transport.
 - Medical Marijuana Vegetative Plants. Medical Marijuana Vegetative plants shall only be transported between Licensed Premises due to an approved change of location pursuant to rule M 206 – Changing Location of Licensed Premises: Medical Marijuana Businesses, or due to a one-time transfer pursuant to rule M 211 – Conversion - Medical Marijuana

Business to Retail Marijuana Establishment. Transportation of Vegetative plants to a permitted off-premises storage facility shall not be allowed.

- C. <u>Inventory Tracking System-Generated Transport Manifest Required</u>. A Licensee may only transport Medical Marijuana, Medical Marijuana Vegetative plants and Medical Marijuana-Infused Product if he or she has a hard 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.
 - Medical Marijuana and Medical Marijuana-Infused Product. A Licensee may transport Medical Marijuana or Medical Marijuana-Infused Product from an originating location to multiple destination locations so long as the transport manifest correctly reflects the specific inventory destined for specific licensed locations, Medical Research Facilities, and/or Pesticide Manufacturers.
 - 2. <u>Medical Marijuana Vegetative Plants</u>. A Licensee shall transport Medical 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, or from a Medical Marijuana Business to a Retail Marijuana Establishment due to a one-time transfer pursuant to rule M 211.
 - Manifest for Transfers to Medical Research Facilities and Pesticide Manufacturers. A
 Licensee may not transport or permit the transportation of Medical Marijuana or Medical
 Marijuana-Infused Products to a Medical Research Facility or Pesticide Manufacturer
 unless an Inventory Tracking System-generated transport manifest has been generated.
- D. <u>Motor Vehicle Required</u>. Transport of Medical Marijuana and Medical Marijuana-Infused Product 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 Medical Marijuana Vegetative plants, Colorado motor vehicle registration is not required.
- E. <u>Documents Required During Transport</u>. Transport of Medical Marijuana, Medical Marijuana Vegetative plants, or Medical Marijuana-Infused Product shall be accompanied by a copy of the originating Medical Marijuana Business's business license, the driver's valid Owner or Occupational License, the driver's valid motor vehicle operator's license, and all required vehicle registration and insurance information.
- F. <u>Use of Colorado Roadways</u>. State law does not prohibit the transport of Medical Marijuana, Medical Marijuana Vegetative plants, and Medical Marijuana-Infused Product 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 Medical Marijuana, Medical Marijuana Vegetative plants, or Medical Marijuana-Infused Product.
- G. <u>Preparation of Medical Marijuana and Medical Marijuana-Infused Product for Transport</u>
 - 1. <u>Final Weighing and Packaging</u>. A Medical Marijuana Business shall comply with the specific rules associated with the final weighing and packaging of Medical Marijuana or Medical Marijuana-Infused Product 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. <u>Preparation in Limited Access Area</u>. Medical Marijuana and Medical Marijuana-Infused Product shall be prepared for transport in a Limited Access Area, including the packing and labeling of Shipping Containers.
- 3. <u>Shipping Containers</u>. Sealed packages or Containers must be placed in Shipping Containers. The contents of Shipping Containers shall be easily accessible and may be inspected by the State Licensing Authority, local licensing authorities, and state and local law enforcement agency for a purpose authorized by the Medical Code or for any other state or local law enforcement purpose.
- G.5 Required RFID Tags for Medical Marijuana Vegetative Plants. Each Medical Marijuana Vegetative plant that is transported pursuant to this rule must have a RFID tag affixed to it prior to transport.
- H. Creation of Records and Inventory Tracking
 - 1. <u>Use of Inventory Tracking System -Generated Transport Manifest.</u>
 - a. Medical Marijuana or Medical Marijuana-Infused Product. Licensees who transport or permit the transportation of Medical Marijuana or Medical Marijuana-Infused Product shall create an Inventory Tracking System-generated transport manifest to reflect inventory that leaves the Licensed Premises for destinations to other Licensed Premiseslocations, Medical Research Facilities, or Pesticide Manufacturers. The transport manifest may either reflect all deliveries for multiple locations within a single trip or separate transport manifests may reflect each single delivery. In either case, no inventory shall be transported without an Inventory Tracking System-generated transport manifest.
 - a.1 <u>Use of a Medical Marijuana Transporter</u>. In addition to subsubparagraph (H)(1)(a), Licensees shall also follow the requirements of this subsubparagraph (H)(1)(a.1) when a Licensee utilizes the services of a Medical Marijuana Transporter.
 - i. When a Medical Marijuana CenterBusiness, Optional Premises Cultivation Operation, Medical Marijuana-Infused Products Manufacturer, or Medical Marijuana Testing Facility utilizes a Medical Marijuana Transporter for transporting its Medical Marijuana or Medical Marijuana-Infused Products, 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 or Medical Marijuana-Infused Products.
 - ii. A Medical Marijuana Transporter is prohibited from being listed as the final destination Licensee.
 - iii. A Medical 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 originating Licensee Medical Marijuana Center, Optional Premises Cultivation Operation, Medical Marijuana-Infused Products Manufacturer, or Medical Marijuana Testing Facility.

- iv. If the Medical Marijuana Transporter is not delivering the originating Licensee's Medical Marijuana or Medical Marijuana- Infused Product directly to the final destination Licensee, the Medical Marijuana Transporter shall communicate to the originating Licensee which of the Medical Marijuana Transporter's Licensed Premises or off-premises storage facilities will receive and temporarily store the Medical Marijuana or Medical Marijuana-Infused Product. The originating Licensee shall input the Medical Marijuana Transporter's location address and license number on the Inventory Tracking System-generated transport manifest.
- b. <u>Medical Marijuana Vegetative Plants.</u>
 - i. Licensees who transport Medical 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 M 206, or a one-time transfer pursuant to rule M 211.
 - ii. 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 M 206, or a one-time transfer pursuant to rule M 211. The Medical Marijuana Transporter shall transport the Medical Marijuana Vegetative Plants directly from the originating Licensed Premises to the final destination Licensed Premises without any stops in between.
- 2. Copy of Transport Manifest to Recipienteiver. A Licensee shall provide a copy of the transport manifest to each Medical 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 receiving Medical 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;
 - Name, location address, and license number of the originating Medical Marijuana Business:
 - c. Name, location address, and license number of the destination Medical Marijuana Business(es) or the destination Retail Marijuana Establishment in the event of a one-time transfer; name and location address of the destination Medical Research Facility; or name and location address of the destination Pesticide Manufacturer:
 - c.1 Name, location address, and license number of the Medical Marijuana Transporter if applicable pursuant to M 801(H)(1)(a.1)(iv).
 - d. Product name and quantities (by weight or unit) of each product to be delivered to each specific destination location(s);
 - e. Arrival date and estimated time of arrival;

- f. Delivery vehicle make and model and license plate number; and
- g. Name, Occupational License number, and signature of the Licensee accompanying the transport.
- I. <u>Inventory Tracking</u>. In addition to all the other tracking requirements set forth in these rules, a Medical Marijuana Business shall be responsible for all the procedures associated with the tracking of inventory that is transported between Licensed Premises. See Rule M 901 Business Records Required.
 - 1. Responsibilities of Originating Licensee.
 - a. Medical Marijuana or Medical Marijuana-Infused Product. Prior to departure, the originating Medical Marijuana Business shall adjust its records to reflect the removal of Medical Marijuana or Medical Marijuana-Infused Product. 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. Medical Marijuana Vegetative Plants. Prior to departure, the originating Optional Premises Cultivation Operation shall adjust its records to reflect the removal of Medical Marijuana Vegetative 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 Recipienteiving Licensee.
 - a. Medical Marijuana or Medical Marijuana-Infused Product. Upon receipt, the receiving Licensee, Medical Research Facility, or Pesticide Manufacturer shall ensure that the Medical Marijuana or Medical Marijuana-Infused Product received are as described in the transport manifest, and If necessary, the receiving Licensee 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 shall comply with all requirements of this subsubparagraph (I)(2)(a) except that they are not required to weigh Medical Marijuana or Medical Marijuana-Infused Products.
 - i. When a Medical Marijuana Business transfers Medical Marijuana or Medical Marijuana-Infused Product to a Medical Research Facility or Pesticide Manufacturer, the originating Licensee is responsible for confirming delivery of the Medical Marijuana or Medical Marijuana-Infused Product in the Inventory Tracking System.
 - b. <u>Medical Marijuana Vegetative Plants</u>. Upon receipt, the receiving Licensee shall ensure that the Medical 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.
 - 3. <u>Discrepancies</u>.

- a. <u>Licensees.</u> A receiving 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. <u>Adequate Care of Perishable Medical Marijuana-Infused Product</u>. A Medical Marijuana Business must provide adequate refrigeration for perishable Medical Marijuana-Infused Product during transport.
- K. In the event Medical Marijuana or Medical Marijuana-Infused Product has failed required testing, has been contaminated, or otherwise presents a risk of cross-contamination to other Medical Marijuana or Medical Marijuana-Infused Product, such Medical Marijuana or Medical Marijuana-Infused Product may only be transported if it is physically segregated and contained in a sealed package that prevents cross-contamination.

M 1500 SERIES - MEDICAL MARIJUANA TESTING PROGRAM

Basis and Purpose - M 1501

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(IV), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XV), 12-43.3-402(6), 12-43.3-402(7), 12-43.3-404(4), and 12-43.3-404(10), C.R.S. 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 Medical Marijuana sampling and testing program.

M 1501 - Medical Marijuana Testing Program - Contaminant Testing

- A. <u>Contaminant Testing Required</u>. Until an Optional Premises Cultivation Operation's and Medical Marijuana-Infused Products Manufacturer's cultivation or production process has been validated under this rule, it shall not wholesale, transfer, or process into a Medical Marijuana Concentrate or Medical Marijuana-Infused Product any Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product unless Samples from the Harvest Batch or Production Batch from which that Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product was derived was tested by a Medical Marijuana Testing Facility for contaminants and passed all contaminant tests required by paragraph C of this rule.
 - 1. Unless otherwise provided herein, Rule M 1501 shall not apply to a Research and Development Licensee. Pursuant to Rule M 1902(A)(1)(i), unless the Medical Marijuana or Medical Marijuana-Infused Product has been subject to contaminant testing required by the Medical Marijuana Code and these rules, a Research and Development Licensee shall disclose to any individual person receiving Medical Marijuana or Medical Marijuana-Infused Product as part of an approved Research Project that the Medical Marijuana or Medical Marijuana-Infused Product has not been subject to mandatory contaminant testing.
- B. Validation of Process Contaminant Testing

- 1. <u>Medical Marijuana</u>. An Optional Premises Cultivation Operation's cultivation process shall be deemed valid regarding Contaminants 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 6 Test Batches that contain Samples from entirely different Harvest Batches.
- 2. Medical Marijuana Concentrate or Medical Marijuana Infused-Product. An Optional Premises Cultivation Operation's or a Medical Marijuana-Infused Products Manufacturer's production process shall be deemed valid regarding contaminants 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 at least four Test Batches that contain Samples from entirely different Production Batches.
- Process Validation is Effective for One Year. Once an Optional Premises Cultivation
 Operation or Medical Marijuana-Infused Products Manufacturer has successfully
 obtained process validation for contaminants, the process validation shall be effective for
 one year from the date of the last passing test required to satisfy the process validation
 requirements.

C. Required Contaminant Tests.

- Microbial Contaminant Testing. Each Harvest Batch of Medical Marijuana and Production Batch of Water- or Food-Based Medical Marijuana Concentrate and Medical Marijuana-Infused Product must be tested for microbial contamination by a Medical Marijuana Testing Facility. The microbial contamination test must include, but need not be limited to, testing to determine the presence of Salmonella sp. and shiga-toxin producing Escherichia coli., and the amount of total yeast and mold.
- 2. Repealed.
- 3. Residual Solvent Contaminant Testing. Each Production Batch of Solvent-Based Medical Marijuana Concentrate produced by a Medical Marijuana-Infused Products Manufacturer must be tested for residual solvent contamination by a Medical Marijuana Testing Facility. The residual solvent contamination test must include, but need not be limited to, testing to determine the presence of, and amounts present of, butane, heptanes, benzene*, toluene*, hexane*, and 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 M 605.
- D. Additional Required Tests. The Division may require additional tests to be conducted on a Harvest Batch or Production Batch prior to an Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer wholesaling, transferring, or processing into a Medical Marijuana Concentrate or Medical Marijuana-Infused Product any Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product from that Harvest Batch or Production Batch. Additional tests may include, but need not be limited to, screening for Pesticide, chemical contaminants or other types of biological contaminants, microbials, molds, metals, or residual solvents.

E. Exemptions

1. <u>Medical Marijuana Concentrate</u>. A Production Batch of Medical Marijuana Concentrate shall be considered exempt from this rule if the Medical Marijuana-Infused Products Manufacturer that produced it does not wholesale or transfer any portion of the Production Batch and uses the entire Production Batch to manufacture Medical

Marijuana-Infused Product, except that a Solvent-Based Medical Marijuana Concentrate must still be submitted for residual solvent contaminant testing.

F. Required Re-Validation - Contaminants.

- 1. <u>Material Change Re-validation</u>. If an Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer makes a Material Change to its cultivation or production process, then it must have the first five Harvest Batches or Production Batches produced using the new standard operating 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 Medical Marijuana Business's process must be re-validated.
 - a. <u>Pesticide</u>. It shall be considered a Material Change if an Optional Premises
 Cultivation begins using a new or different Pesticide during its cultivation process
 and the first five Harvest Batches produced using the new or different Pesticide
 must also be tested for Pesticide.
 - b. <u>Solvents</u>. It shall be considered a Material Change if a Medical Marijuana-Infused Products Manufacturer begins using a new or different solvent or combination of solvents.
 - c. <u>Notification</u>. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer that makes a Material Change must notify the Medical Marijuana Testing Facility that conducts contaminant testing on the first five Harvest Batches or Production Batches produced using the new standard operating procedures.
 - d. Testing Required Prior to Wholesale, Transfer or Processing. When a Harvest Batch or Production Batch is required to be submitted for testing pursuant to this rule, the Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer that produced it may not wholesale, transfer or process into a Medical Marijuana Concentrate or Medical Marijuana-Infused Product any of the Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product from that Harvest Batch or Production Batch.
- 2. Failed Contaminant Testing Re-Validation. If a Sample the Division requires to be tested fails contaminant testing, the Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer shall follow the procedures in paragraph B of rule M 1507 for any package, Harvest Batch, or Production Batch from which the failed Sample was taken. The Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer shall also submit three additional Test Batches of the Medical Marijuana or Medical Marijuana-Infused Product for contaminant testing by a Medical Marijuana Testing Facility within no more than 30 days. If any one of the three submitted Test Batches fails contaminant testing, the Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer shall re-validate its process for contaminants.
- 3. <u>Expiration of Process Validation</u>. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer shall be required to re-validate its process once the one year of process validation expires, or the Medical Marijuana Business shall comply with the requirements of paragraph A of this rule M 1501.
- G. <u>Violation Affecting Public Safety</u>. Failure to comply with this rule may constitute a license violation affecting public safety.

Basis and Purpose - M 1507.1

M 1507.1 - Medical Marijuana Testing Program - Permissible Testing Facilities

Approach for implementation of HB17-1367, Section 7, 12-43-3-202(2.5)(I)(G), C.R.S. and Section 8, 12-43.4-202(3)(a)(IV)(H), C.R.S. remains under discussion.

M 1800 SERIES - NEW SERIES

M 1800 Series – Medical Marijuana Transfers to Unlicensed Medical Research Facilities and Pesticide Manufacturers

M 1801 - Basis and Purpose

The statutory authority for this rule is found at subsection 12-43.3-202(1)(h)(I)-(II) and section 25-1.5-106.5, C.R.S. The purpose of this rule is to establish requirements associated with the transfer of Medical Marijuana and Medical Marijuana-Infused Products to Medical Research Facilities, including requirements for the possession and disposition of Medical Marijuana and Medical Marijuana-Infused Products by Medical Research Facilities.

Rule M 1801 - Medical Research Facilities

- A. Transfers to Medical Research Facilities. An Optional Premises Cultivation Operation may transfer Medical Marijuana to a Medical Research Facility. A Medical Marijuana-Infused Products Manufacturer may transfer Medical Marijuana-Infused Products and Medical Marijuana Concentrate to a Medical Research Facility.
 - Before an Optional Premises Cultivation Operation transports Medical Marijuana to a
 Medical Research Facility, the Medical Marijuana shall first be subject to a documented point-of-sale transaction through the Optional Premises Cultivation's designated Medical Marijuana Center.
 - 2. An Optional Premises Cultivation Operation is authorized to transfer by donation Medical Marijuana to a Medical Research Facility pursuant to Rule M 501.
 - 3. A Medical Marijuana-Infused Products Manufacturer is authorized to transfer by donation Medical Marijuana-Infused Products and Medical Marijuana Concentrate to a Medical Research Facility pursuant to Rule M 601.
- B. Agreement with Medical Research Facility. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer that transfers Medical Marijuana or Medical Marijuana-Infused Products to a Medical Research Facility shall enter into a written agreement with the Medical Research Facility prior to transferring any Medical Marijuana or Medical Marijuana-Infused Products to the Medical Research Facility. The written agreement shall constitute a business record. See Rule M 901. The written agreement shall include the following information:
 - 1. The identity of the Medical Research Facility;
 - 2. The quantity of Medical Marijuana and/or Medical Marijuana-Infused Products 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; and (b) remains authorized to receive the quantity of Medical Marijuana and/or Medical Marijuana-Infused Products that will be transferred to the Medical Research Facility;
- 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,
- The date(s) upon which transfer of the Medical Marijuana and/or Medical Marijuana-Infused Products will occur.
- C. State Board of Health Approval. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer shall not transfer Medical Marijuana or Medical Marijuana-Infused Products 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. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products

 Manufacturer shall not transfer any Medical Marijuana and/or Medical Marijuana-Infused
 Products until the Optional Premises Cultivation Operation or Medical Marijuana-Infused
 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 M 901.
 - 2. Transferring Medical Marijuana and/or Medical Marijuana-Infused Products to a Medical Research Facility before the Medical Research Facility receives approval and funding from the State Board of Health shall be considered a public safety violation.
- D. Inventory Tracking Requirements. An Optional Premises Cultivation Operation or Medical
 Marijuana-Infused Products Manufacturer shall track all Medical Marijuana and/or Medical

 Marijuana-Infused Products in the Inventory Tracking System until it is delivered to a Medical Research Facility.
 - Transport Manifest. A Licensee shall not deliver or permit the delivery of Medical
 Marijuana or Medical Marijuana-Infused Products unless a manifest is generated from the Inventory Tracking System.
 - Complete Manifest. A Licensee shall not relinquish possession or control of Medical
 Marijuana and/or Medical Marijuana-Infused Products to a Medical Research Facility until
 a person authorized by the Medical Research Facility acknowledges receipt of the
 Medical Marijuana and Medical Marijuana-Infused Products by signing the transport
 manifest.
 - 3. No Inventory Tracking Following Delivery. Once Medical Marijuana and/or Medical Marijuana-Infused Products has been transferred by a Licensee to a Medical Research Facility, no further inventory tracking is required.
 - 4. The originating Licensee is responsible for confirming delivery of the Medical Marijuana or Medical Marijuana-Infused Product in the Inventory Tracking System.
- E. Packaging, Labeling, and Testing. An Optional Premises Cultivation Operation or Medical
 Marijuana-Infused Products Manufacturer that transfers Medical Marijuana and/or Medical
 Marijuana-Infused Products to a Medical Research Facility shall package, label, and test all

Medical Marijuana and/or Medical Marijuana-Infused Products in conformance with the Medical Marijuana Rules, 1 CCR 212-1, prior to transferring the Medical Marijuana and/or Medical Marijuana-Infused Products.

- F. Business Records. An Optional Premises Cultivation Operation or Medical Marijuana-Infused
 Products Manufacturer that transfers Medical Marijuana and/or Medical Marijuana-Infused
 Products to a Medical Research Facility shall keep all documents concerning the relationship and
 transfer of any Medical Marijuana and/or Medical Marijuana-Infused Products in accordance with
 Rules M 801 and 901.
- G. Quantity Limitations for Medical Research Facilities. A Medical Research Facility shall not possess at any time a quantity of Medical Marijuana and Medical Marijuana-Infused Products in excess of either 12 Medical Marijuana plants, [HOLD FOR WORK GROUP quantity of finished and infused product related to plant count limit], or the amounts approved by the State Board of Health in approving the Medical Research Facility's research pursuant to section 25-1.5-106.5, C.R.S., whichever is less.
- H. Colorado Department of Public Health and Environment and State Board of Health Oversight.
 The Colorado Department of Public Health and Environment and the State Board of Health are the state agencies with regulatory oversight of Medical Research Facilities, including the authority to approve or deny research grant proposals pursuant to section 25-1.5-106.5, C.R.S.
- I. Disposition of Medical Marijuana. A Medical Research Facility shall destroy all Medical Marijuana and Medical Marijuana-Infused Products following completion of research activities in conformance with the rules or requirements promulgated by the State Board of Health.
- J. Under no circumstance may a Licensee receive or obtain for any purposes Medical Marijuana or Medical Marijuana-Infused Product from a Medical Research Facility.

M 1802 - Basis and Purpose

The statutory authority for this rule is found at subsection 12-43.3-202(1)(h)(I)-(II) and section 25-1.5-106.5, C.R.S. The purpose of this rule is to establish requirements associated with the transfer of Medical Marijuana and Medical Marijuana-Infused Products to Pesticide Manufacturers, including requirements for the possession and disposition of Medical Marijuana and Medical Marijuana-Infused Products by Pesticide Manufacturers.

Rule M 1802 - Pesticide Manufacturers

- A. Transfers to Pesticide Manufacturers. An Optional Premises Cultivation Operation may transfer

 Medical Marijuana to a Pesticide Manufacturer solely for the purpose of research to establish safe
 and effective protocols for the use of pesticides on Medical Marijuana. A Medical MarijuanaInfused Products Manufacturer may transfer Medical Marijuana-Infused Products and Medical
 Marijuana Concentrate to a Pesticide Manufacturer solely for the purpose of research to establish
 safe and effective protocols for the use of pesticides on Medical Marijuana.
 - Before an Optional Premises Cultivation Operation transports Medical Marijuana to a
 Pesticide Manufacturer, the Medical Marijuana shall first be subject to a documented point-of-sale transaction through the Optional Premises Cultivation's designated Medical Marijuana Center.
 - An Optional Premises Cultivation Operation is authorized to transfer by donation Medical Marijuana to a Pesticide Manufacturer pursuant to Rule M 501.

- 3. A Medical Marijuana-Infused Products Manufacturer is authorized to transfer by donation Medical Marijuana-Infused Products and Medical Marijuana Concentrate to a Pesticide Manufacturer pursuant to Rule M 601.
- B. Written Documentation Required. A Licensee shall require, and shall not transfer Medical

 Marijuana or Medical Marijuana-Infused Product prior to receiving, written proof under oath that
 the Pesticide Manufacturer, which documentation shall constitute a business record under Rule M
 901:
 - 1. 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 sea.:
 - 2. Is authorized to do business in Colorado:
 - 3. Is in physical possession of the location in the State of Colorado where its research activities will occur;
 - 4. Has applied for and received any necessary license, registration or certification from the Colorado Department of Agriculture pursuant to the Pesticide Act, sections 35-9-101 et seq., C.R.S. and/or the Pesticide Applicator's Act, sections 35-10-101 et seq., C.R.S.; and,
 - 5. Will conduct pesticide research on the Medical Marijuana and Medical Marijuana-Infused Products to establish safe and effective protocols for the use of pesticides on Medical Marijuana, as evidenced by an affidavit entered into by an authorized person on behalf of the Pesticide Manufacturer.
- C. Agreement with Pesticide Manufacturer. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer that transfers Medical Marijuana and Medical Marijuana-Infused Products to a Pesticide Manufacturer shall enter into a written agreement with the Pesticide Manufacturer prior to transferring any Medical Marijuana or Medical Marijuana-Infused Products to the Pesticide Manufacturer. The written agreement, which shall constitute a business record under Rule M 901, shall include:
 - 1. The identity of the Pesticide Manufacturer;
 - The quantity of Medical Marijuana and/or Medical Marijuana-Infused Products that will be transferred to the Pesticide Manufacturer;
 - 3. The date(s) upon which transfer of the Medical Marijuana and/or Medical Marijuana-Infused Products will occur:
 - 4. An affirmation by the Pesticide Manufacturer that it (a) is registered with the U.S.

 Environmental Protection Agency pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, §§ 7 U.S.C. § 136 et seq., (b) is authorized to do business in Colorado; (c) is in possession of a physical location in the State of Colorado; (d) will conduct its pesticide research in Colorado; (e) is licensed or certified by the Colorado Department of Agriculture pursuant to the Colorado Pesticide Applicator's Act, sections 35-10-101 et seq., C.R.S.; (f) remains authorized to receive the quantity of Medical Marijuana and/or Medical Marijuana-Infused Products that will be transferred to the Pesticide Manufacturer; and (g) the Pesticide Manufacturer will only use the Medical Marijuana and/or Medical Marijuana-Infused Product for the purpose of research to establish safe and effective protocols for the use of pesticides on Medical Marijuana; and,

- 5. An affirmation by the Licensee that it has received written proof the Pesticide

 Manufacturer (a) 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.; (b) is authorized to do business in Colorado;
 (c) is in possession of a physical location in the State of Colorado; (d) will conduct its
 pesticide research in Colorado; (e) is licensed, registered or certified by the Colorado
 Department of Agriculture pursuant to the Pesticide Act, sections 35-9-101 et seq., and/or
 the Pesticide Applicator's Act, sections 35-10-101 et seq., C.R.S.; and (f) remains
 authorized to receive the quantity of Medical Marijuana and/or Medical Marijuana-Infused
 Products that will be transferred to the Pesticide Manufacturer.
- D. Inventory Tracking Requirements. An Optional Premises Cultivation Operation or Medical
 Marijuana-Infused Products Manufacturer shall track all Medical Marijuana and/or Medical
 Marijuana-Infused Products in the Inventory Tracking System until it is delivered to a Pesticide Manufacturer.
 - Transport Manifest. A Licensee shall not deliver or permit the delivery of Medical
 Marijuana or Medical Marijuana-Infused Products unless a manifest is generated from the Inventory Tracking System.
 - 2. Complete Manifest. A Licensee shall not relinquish possession or control Medical Marijuana and/or Medical Marijuana-Infused Products to a Pesticide Manufacturer until a person authorized by the Pesticide Manufacturer acknowledges receipt of the Medical Marijuana and Medical Marijuana-Infused Products by signing the transport manifest.
 - No Inventory Tracking Following Delivery. Once Medical Marijuana and/or Medical
 Marijuana-Infused Products has been transferred by a Licensee to a Pesticide
 Manufacturer, no further inventory tracking is required.
 - 4. The originating Licensee is responsible for confirming delivery of the Medical Marijuana or Medical Marijuana-Infused Product in the Inventory Tracking System.
- E. Packaging, Labeling, and Testing. An Optional Premises Cultivation Operation or Medical

 Marijuana-Infused Products Manufacturer that sells or transfers Medical Marijuana and/or Medical

 Marijuana-Infused Products to a Pesticide Manufacturer shall package, label, and test all Medical

 Marijuana and/or Medical Marijuana-Infused Products in conformance with the Medical Marijuana

 Rules, 1 CCR 212-1, prior to transferring the Medical Marijuana and/or Medical Marijuana-Infused

 Products.
- F. Business Records. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer that transfers Medical Marijuana and/or Medical Marijuana-Infused Products to a Pesticide Manufacturer shall keep all documents concerning the relationship and transfer of any Medical Marijuana and/or Medical Marijuana-Infused Products in accordance with Rules M 801 and 901.
- G. Pesticide Manufacturer Authorized Activities. A Pesticide Manufacturer is only authorized to possess Medical Marijuana and/or Medical Marijuana-Infused Product in order to research the safe and effective protocols for the use of pesticides on medical marijuana.
- H. Quantity Limitations for Pesticide Manufacturer.
 - 1. Plants. A Pesticide Manufacturer shall not possess in excess of 12 Medical Marijuana plants.

- 2. Medical Marijuana and Medical Marijuana-Infused Product. A Pesticide Manufacturer shall not obtain or possess an amount of Medical Marijuana or Medical Marijuana-Infused Product in excess of [HOLD FOR WORK GROUP quantity of finished and infused product related to plant count limit].
- I. <u>Disposition of Medical Marijuana and Medical Marijuana-Infused Products. A Pesticide</u>

 <u>Manufacturer shall destroy all Medical Marijuana and Medical Marijuana-Infused Products</u>
 following completion of research activities.
 - 1. A Pesticide Manufacturer shall destroy Medical Marijuana and Medical Marijuana-Infused Products in conformance with Rule M 307.
 - A Pesticide Manufacturer shall document the destruction of Medical Marijuana and Medical Marijuana-Infused Products, which documentation shall include:
 - Whether the destroyed material was Medical Marijuana and/or Medical Marijuana-Infused Products;
 - ii. The date of destruction;
 - iii. The location of the destruction;
 - iv. The manner in which the Medical Marijuana and/or Medical Marijuana-Infused Products was rendered unusable and unrecognizable;
 - v. The method of final disposition pursuant to Rule M 307(F), 1 CCR 212-2; and,
 - vi. The identity(ies) and contact information of all Person(s) involved in the destruction.
 - A Pesticide Manufacturer shall keep all documentation regarding destruction of Medical Marijuana and/or Medical Marijuana-Infused Products 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 Medical Marijuana Business.
 - 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 Medical Marijuana Business. A violation of this prohibition shall be considered a public safety violation.
- K. Under no circumstance shall a Pesticide Manufacturer receiving Medical Marijuana and/or
 Medical Marijuana-Infused Products from a Licensee to engage in research involving human and/or animal subjects.
 - If a Licensee knows or 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 Medical Marijuana or Medical Marijuana-Infused Products to the Pesticide Manufacturer. A violation of this prohibition shall be considered a public safety violation.
- L. Under no circumstance may a Licensee receive or obtain for any purposes Medical Marijuana or Medical Marijuana-Infused Product from a Pesticide Researcher.

M 1900 SERIES - NEW SERIES

M 1900 Series - Research and Development Licensees

Rule M 1901 – Research and Development Licensees: License Privileges

- A. Privileges Applicable to Any Research and Development Licensee
 - 1. Privileges Granted. A Marijuana Research and Development Licensee shall only exercise those privileges granted to it by the State Licensing Authority.
 - Licensed Premises. A Marijuana Research and Development Licensee may share a Licensed Premises with a commonly-owned Medical Marijuana Testing Facility.
 - i. If a Marijuana Research and Development Licensee shares its Licensed
 Premises with a commonly-owned Medical Marijuana Testing Facility, the
 Licensees shall physically segregate all Medical Marijuana and Medical
 Marijuana-Infused Product used for research purposes in order to prevent
 contamination or any other effect on Medical Marijuana or Medical MarijuanaInfused Product submitted to the Medical Marijuana Testing Facility for testing.
 - 3. Authorized Sources of Medical Marijuana and Medical Marijuana-Infused Product. A
 Research and Development Licensee may receive or obtain Medical Marijuana or
 Medical Marijuana-Infused Product from only the following sources:
 - Donation. An Optional Premises Cultivation Operation and Medical MarijuanaInfused Products Manufacturer may donate Medical Marijuana or Medical
 Marijuana-Infused Products to a Research and Development Licensee. Neither a
 Research and Development Licensee nor any Person acting on its behalf may
 provide any compensation for donated Medical Marijuana or Medical MarijuanaInfused Products.
 - ii. Purchase. A Research and Development Licensee may purchase Medical

 Marijuana or Medical Marijuana-Infused Products from an Optional Premises

 Cultivation Operation or Medical Marijuana-Infused Products Manufacturer.
 - iii. Marijuana Research and Development Cultivations. A Research and Development Licensee may obtain Medical Marijuana from a Marijuana Research and Development Cultivation.
 - 4. Authorized Marijuana Transport. A Research and Development Licensee is authorized to utilize a licensed Medical Marijuana Transporter for transportation of 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 Research and Development Licensee from transporting its own Medical Marijuana.
- B. Privileges Applicable to Marijuana Research and Development Cultivations.
 - Cultivation of Marijuana Authorized. A Marijuana Research and Development Cultivation may propagate, cultivate, harvest, process, prepare, cure, package, store, and label Medical Marijuana for use in research only.
 - Production of Marijuana Concentrate. A Marijuana Research and Development
 Cultivation and an Optional Premises Cultivation Operation are subject to the same restrictions in regard to Medical Marijuana Concentrate production. Therefore, a

Marijuana Research and Development Licensee may produce Medical Marijuana Concentrate only as allowed by, and in conformance with, Rule M 506.

Rule M 1902 - Research and Development Licensees: General Limitations or Prohibited Acts

- A. Restrictions Applicable to Any Research and Development Licensee
 - Packaging and Labeling Standards Required. A Research and Development Licensee is prohibited from transferring Medical Marijuana or Medical Marijuana-Infused Product to a Licensee or any other Person that is not packaged and labeled in accordance with these rules. See M 1000.1 Series – Labeling, Packaging, and Product Safety.
 - i. Unless the Medical Marijuana or Medical Marijuana-Infused Product was subject to contaminant testing required by the Medical Marijuana Code and these rules, a Research and Development Licensee shall disclose to any individual person receiving Medical Marijuana or Medical Marijuana-Infused Product as part of an approved Research Project that the Medical Marijuana or Medical Marijuana-Infused Product has not been subject to mandatory contaminant testing.
 - Transfers to Individuals. A Research and Development Licensee is prohibited from transferring Medical Marijuana or Medical Marijuana-Infused Product to any individual, unless as part of an approved Research Project.
 - 3. Consumption Prohibited. A Research and Development Licensee shall not permit the consumption of marijuana or marijuana products on its Licensed Premises, unless as part of an approved Research Project and the Research and Development Licensee does not share a Licensed Premises with a Medical Marijuana Testing Facility.
 - 4. A Research and Development Licensee shall not sell or give away Medical Marijuana or Medical Marijuana-Infused Product to a Medical Marijuana Transporter, and shall not buy or receive complimentary Medical Marijuana or Medical-Marijuana Infused Product from a Medical Marijuana Transporter.
 - 5. A Research and Development Licensee shall comply with all applicable federal, state, and local law regarding worker health and safety.
 - 6. Performance Incentives. A Research and Development Licensee may not use performance incentives to compensate its employees, agents, or contactors.
 - Licensure and Research Projects. A Research and Development Licensee shall not engage in any research activities until the State Licensing Authority or its delegate approves both (1) its business license application and (2) one or more Research Project(s).
 - i. A Research and Development Licensee shall submit a Research Project
 proposal in conjunction with its business license application. If the initial
 Research Project proposal is not approved, the Research and Development
 Licensee's business license application shall be denied.
 - ii. A Research and Development Licensee may submit additional Research Project proposals at any time during which its license is current and valid.
 - iii. If a Research and Development Licensee's license expires or is suspended or revoked, the Licensee shall immediately cease all research activities.

- iv. A Research and Development Licensee may not renew its business license
 application unless it has one or more ongoing approved Research Projects or it
 submits a new Research Project proposal with its business application renewal
 and which new Research Project proposal is approved.
- B. Restrictions Applicable to Marijuana Research and Development Cultivations.
 - Transfer Restriction. A Marijuana Research and Development Cultivation may only transfer Medical Marijuana or Medical Marijuana-Infused Product to a Research and Development Licensee, a Medical Marijuana Testing Facility for testing, or to any individual person as part of an approved Research Project.
- Restrictions Application to Marijuana Research and Development Facilities.
 - Transfer Restriction. A Marijuana Research and Development Facility may only transfer <u>Medical Marijuana or Medical Marijuana-Infused Product to an individual person as part</u> of an approved Research Project or to a Medical Marijuana Testing Facility for testing.

Rule M 1903 – Research and Development Licensees: Inventory Tracking

- A. Minimum Tracking Requirement. A Research and Development Licensee must use the Inventory Tracking System to ensure its inventories are identified and tracked from the point Medical Marijuana or Medical Marijuana-Infused Product is Propagated or obtained to the point when it is destroyed, used in a Research Project, or, if permitted, delivered to a Research and Development Licensee or a Medical Marijuana Testing Facility. See also Rule M 309, Medical Marijuana Business: Inventory Tracking System. A Research and Development Licensee must have the ability to reconcile its inventory records generated from the Inventory Tracking System and the associated transaction history and sale receipts or other transfer documentation. See also Rule M 901 Business Records Required.
 - A Research and Development Licensee is prohibited from accepting any Medical Marijuana or Medical Marijuana-Infused Product without receiving a valid transport manifest generated from the Inventory Tracking System.
 - A Research and Development Licensee must immediately input all Medical Marijuana or <u>Medical Marijuana-Infused Product delivered to its Licensed Premises and account for all</u> RFID tags into the Inventory Tracking System at the time of delivery.
 - 3. A Research and Development Licensee must reconcile its transaction history and onhand Medical Marijuana and Medical Marijuana-Infused Product to the Inventory Tracking System at the close of business each day.

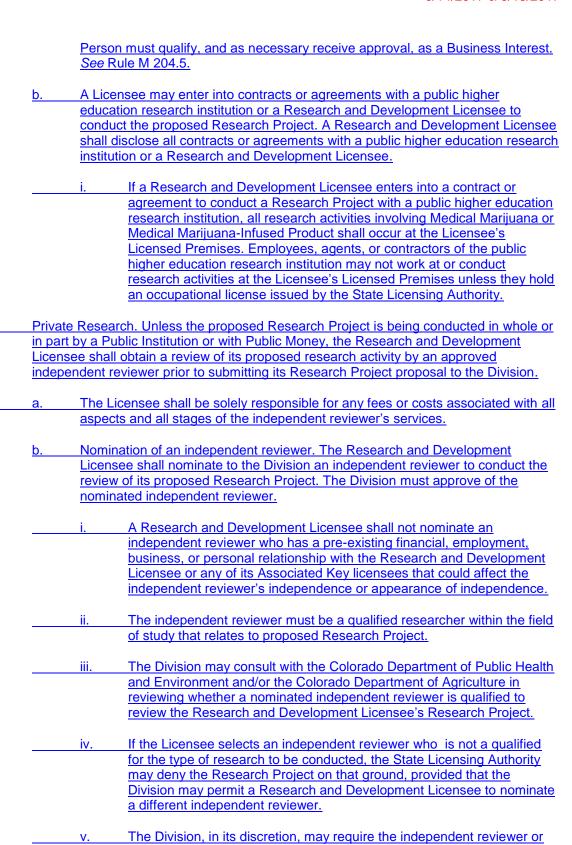
Rule M 1904 - Research and Development Licensees: Project Approval

- A. Project Approval. Prior to engaging in any research activity, a Research and Development

 Licensee shall obtain approval from the Division for a Research Project by submitting a Research

 Project proposal. Any research or development conducted by a Research and Development

 Licensee shall be in furtherance of an approved Research Project.
 - General. A Research and Development Licensee shall seek approval of the Division by submitting its Research Project proposal on the current form supplied by the Division.
 - a. A Licensee shall disclose all Persons who have, are, or will fund the proposed
 Research Project. If any Person funding or intending to fund the proposed activity
 does not hold a license issued by the State Licensing Authority, then such



the Research and Development Licensee 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.
- vi. If a 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 Research and Development Licensee nominates another independent reviewer who is approved by the Division.
- c. Independent Reviewer report. After an independent reviewer nominated by the Research and Development Licensee has been approved by the Division, the Research and Development 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. The compensation paid by the Research and Development 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 M 1903(A) and the reason(s) supporting the reviewer's analysis;
 - v. An assessment of the total quantity of Medical Marijuana and/or Medical Marijuana-Infused Product 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 Licensee is qualified to perform the proposed Research Project, including whether the Licensee's employees are qualified to perform the proposed Research Project;
 - ix. An assessment of whether the Licensee has the appropriate resources and protocols to conduct the proposed Research Project;
 - An assessment of whether the Licensee has the appropriate personnel, expertise, facilities, infrastructure, funding, and other human, animal, or other approvals in place to successfully conduct the Research Project;
 - 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 LICENSEE 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.
- d. The Licensee shall maintain copies of all documents and correspondence sent to or from the independent reviewer. See Rule M 901.
- The Division, in its discretion, may require the independent reviewer or the
 Research and Development Licensee to provide additional information or
 analysis that the Division deems pertinent to its review of the Licensee's
 Research Project proposal.
- f. The State Licensing Authority may decline to approve a Research Project proposal if the independent reviewer, or the Division through further investigation, concludes that:
 - i. The description of the Research Project does not meet the requirements of Section 12-43.3-409, C.R.S. and these rules;
 - ii. The proposed Research Project presents a danger to the public health and/or safety, and/or whether 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 Licensee is not qualified to perform the proposed research;
 - v. The Licensee does not have the appropriate resources and/or protocols to conduct the proposed research;
 - vi. The Licensee lacks the appropriate personnel, expertise, facilities, infrastructure, funding, or other human, animal, or other approvals in place to successfully conduct the Research Project;
 - vii. The independent reviewer cannot meet the certification requirements in this rule; or
 - viii. The Licensee or the proposed Research Project is otherwise not in compliance with the Medical Code or these rules.
- Projects with Public Institutions or Money. If a Research and Development 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 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 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.
- The Scientific Advisory Council shall provide the Division with a report
 recommending whether to grant or deny the proposed project. The Scientific
 Advisory Council's report shall address the following:
 - i. The proposed Research Project's quality, study design, value, or impact;
 - ii. Whether the Licensee has the appropriate personnel, expertise, facilities, infrastructure, funding, and other human, animal, or other approvals in place to successfully conduct the Research Project; and,
 - iii. Whether the amount of marijuana the Licensee proposes to grow or possess is consistent with the proposed Research Project's scope and goals.
- The Licensee shall maintain copies of all documents and correspondence sent to or from the Scientific Advisory Council. See Rule M 901.

Rule M 1905 - Research and Development Licensees: Authorized Research Activities

- A. Authorized Research. A Research and Development Licensee is authorized to engage in the following research at its Licensed Premises:
 - 1. Chemical Potency and Composition Levels.
 - Clinical Investigations of Marijuana-Derived Products.
 - 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.
- B. Pesticide Research. A Research and Development Licensee shall not engage in any research activities involving Pesticides unless the Licensee has applied for and received any necessary license, registration or certification from the Colorado Department of Agriculture pursuant to the Pesticide Act, sections 35-9-101 et seq., C.R.S. and/or the Pesticide Applicator's Act, sections 35-10-101 et seq., C.R.S.
 - A Research and Development Licensee engaged in research activities involving a
 Pesticide shall at all times comply with the Pesticide Act, 35-9-101 et seq., C.R.S.,
 Colorado Pesticide Applicator's Act, sections 35-10-101 et seq., C.R.S., and all Rules promulgated pursuant thereto.
- C. Research Involving Human Subjects. A Research and Development Licensee 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.

- A Research and Development Licensee shall include proof of approval and ongoing oversight and review by an Institutional Review Board as part of its Research Project proposal. Failure to obtain approval by an Institutional Review Board shall be grounds for denial of Research Project proposal research involving human subjects.
- A Research and Development Licensee conducting research involving human subjects
 shall at all times comply with relevant federal and/or state laws and regulations regarding
 research on human subjects, as well as all prevailing ethical standards and requirements
 for research on human subjects.
- 3. A Research and Development Licensee 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 Research and Development Licensee shall comply with U.S. Food and Drug Administration requirements for informed consent, 21 C.F.R. part 50 as part of approval and ongoing oversight and review by an Institutional Review Board.
- D. Research Involving Animals. A Research and Development Licensee shall not conduct any research involving animal subjects unless the Research and Development Licensee is registered with the U.S. Department of Agricultural pursuant to the Animal Welfare Act, 7 U.S.C. §§ 2131 et seq.
 - A Research and Development Licensee 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.
 - A Research and Development Licensee shall at all times treat animals involved in research humanely and consistent with applicable federal and/or state law, as well as all prevailing ethical standards and requirements for research on animals.
- E. Research Involving Testing of Marijuana. A Research and Development Licensee may only engage in research regarding the testing of Medical Marijuana or Medical Marijuana-Infused Products if the following criteria are met:
 - 1. Testing Qualifications. A Research and Development Licensee must meet one of the following standards:
 - a. The Research and Development Licensee also holds a Medical Marijuana
 Testing Facility license and has been certified pursuant to Rule M 703;
 - b. The Research and Development Licensee is accredited to the International
 Organization for Standardization/International Electrotechnical Commission
 17025:2005 Standard, or any subsequent superseding ISO 17025 standard; or
 - c. The Research and Development Licensee is part of an institution of higher
 education whose protocols have been approved by the Colorado Department of Public Health and Environment.
 - 2. A Research and Development Licensee proposing to engage in research regarding the testing Medical Marijuana or Medical Marijuana-Infused Product shall include in its Research Project proposal documentation establishing its testing qualification pursuant to Rule M 1903(F)(1).

- F. No Transfers of Marijuana Used in Research. A Research and Development Licensee shall not transfer to any Person any Medical Marijuana or Medical Marijuana-Infused Product that has been used by the Licensee for research. At the conclusion of its research, a Research and Development Licensee shall destroy all Medical Marijuana or Medical Marijuana-Infused Product used for research in conformance with Rule M 307.
- G. Periodic Reporting. A Research and Development Licensee shall submit to the Division a report regarding the status of approved Research Projects every six (6) months following the Division's approval of its Research Project.
 - 1. The periodic reports shall address the Licensee's compliance and progress with its approved Research Project.
 - 2. The periodic reports shall include any protocol changes, reported protocol deviations, as well as enrollment numbers and adverse events for studies involving human subjects.
 - 3. If the Licensee is conducting its Research Project in whole or in part with a Public Institution or Public Money, the Division shall submit the Licensee's periodic reports to the Scientific Advisory Council for review.
 - 4. If an adverse event occurs, a Research and Development Licensee shall immediately notify the Division of the Adverse Event on the form prepared by the Division.
- H. Project Approval Suspension or Revocation. Research Project approval is subject to revocation or suspension if the Licensee's research has materially diverged from the Licensee's approved Research Project, violates the Medical Marijuana Code or the rules promulgated thereto, or presents a risk to public health and safety. See M 1300 Series.
- I. Reporting of Research Results. A Research and Development Licensee 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 require that a Research and Development Licensee undergo an audit of its research activities.
 - 1. Circumstances Justifying 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 Research and
 Development Licensee 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 Research and
 Development Licensee's research activities present a danger to the public health and/or safety; or
 - The Division has reasonable grounds to believe that the Research and
 Development Licensee has been or is engaged in research activities that have not received prior Division approval.
 - 2. The Division and the Licensee 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. The Research and Development Licensee 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.
- Compliance Required. A Research and Development Licensee must pay for and timely
 cooperate with the State Licensing Authority's requirement that it undergo an
 independent audit research audit in conformance with this Rule.
- K. Violation Affective Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

Rule M 1906 – Research and Development Licensees: Health and Safety Regulations

- A. Local Safety Inspections. A Research and Development Licensee 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 licensing authority restrictions related to Medical 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.
- B. General Sanitary Requirements. A Research and Development 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 Medical Marijuana or Medical Marijuana-Infused Product shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected:
 - 2. That all persons working in direct contact with Medical Marijuana or Medical Marijuana-Infused Product shall conform to hygienic practices while on duty, including but not limited to:
 - a. Maintaining adequate personal cleanliness;
 - Washing hands thoroughly in an adequate hand-washing area(s) before starting work and at any other time when the hands may have become soiled or contaminated;
 - c. 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 and/or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices; and
 - Refraining from having direct contact with Medical Marijuana or Medical
 Marijuana-Infused Product if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.
 - 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 Medical Marijuana is exposed;

- 4. That floors, walls, and ceilings are constructed in such a manner that they may be adequately cleaned and kept clean and kept in good repair;
- That there is adequate lighting in all areas where Medical Marijuana or Medical
 Marijuana-Infused Product is stored and where equipment or utensils are cleaned;
- 6. 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;
- 7. That any buildings, fixtures, and other facilities are maintained in a sanitary condition;
- 8. That toxic cleaning compounds, sanitizing agents, and solvents shall be identified, held, stored and disposed of in a manner that protects against contamination of Medical Marijuana or Medical Marijuana-Infused Product, unless as part of an approved Research Project, and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation or ordinance. All Pesticide must be stored and disposed of in accordance with the information provided on the product's label;
- 9. That all contact surfaces, including utensils and equipment used for the preparation of Medical Marijuana or Medical Marijuana-Infused 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 Research and Development Licensee and used in accordance with labeled instructions:
- 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;
- 11. 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;
- 12. That all operations in the receiving, inspecting, transporting, segregating, preparing, packaging, and storing of Medical Marijuana or Medical Marijuana-Infused Product shall be conducted in accordance with adequate sanitation principles:
- 13. That each Research and Development Licensee shall provide its employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair; and
- 14. That Medical Marijuana or Medical Marijuana-Infused Product that can support the rapid growth of undesirable microorganisms shall be held in a manner that prevents the growth of these microorganisms, unless as part of an approved Research Project.
- C. Pesticide Application. Unless as part of an approved Research Project, a Research and Development Licensee 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.
- D. Application of Other Agricultural Chemicals. Unless as part of an approved Research Project, a
 Research and Development Licensee may only use agricultural chemicals, other than Pesticide,
 in accordance with all applicable federal, state, and local laws, statutes, rules and regulations.
- E. Required Documentation.
 - 1. Marijuana Research and Development Cultivation.
 - i. Standard Operating Procedures. A Marijuana Research and Development

 Cultivation must establish written standard operating procedures for the
 cultivation of Medical Marijuana. The standard operating procedures must at
 least include when, and the manner in which, all Pesticide and other agricultural
 chemicals are to be applied during its cultivation process. A copy of all standard
 operating procedures must be maintained on the Licensed Premises of the
 Marijuana Research and Development Cultivation.
 - ii. Material Change. If a Marijuana Research and Development Cultivation 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.
 - Material Safety Data Sheet. A Research and Development Licensee must obtain a material safety data sheet for any Pesticide or other agricultural chemical used or stored on its Licensed Premises. A Research and Development Licensee must maintain a current copy of the material safety data sheet for any Pesticide or other agricultural chemical on the Licensed Premises where the product is used or stored.
 - Labels of Pesticide and Other Agricultural Chemicals. A Research and Development
 Licensee must have the original label or a copy thereof at its Licensed Premises for all Pesticide and other agricultural chemicals used on its Licensed Premises.
 - 4. Pesticide Application Documentation. A Research and Development Licensee that applies any Pesticide or other agricultural chemical to any portion of a Medical 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 Occupational License number of the individual who applied the Pesticide or other agricultural chemical;
 - <u>Applicator certification number if the applicator is licensed through the</u>
 <u>Department of Agriculture in accordance with the "Pesticides Applicators' Act,"</u>
 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 Medical Marijuana plant(s) that the Pesticide or other agricultural chemical(s) was applied to or if applied to all plants throughout the Licensed Premises, a statement to that effect; and
- i. The total amount of each Pesticide or other agricultural chemical applied.
- F. Prohibited Chemicals. The following chemicals shall not be used on a Research and Development Licensee's Licensed Premises, unless as part of an approved Research Project. Possession of chemicals and/or containers from these chemicals upon the Licensed Premises shall be a violation of this rule, unless as part of an approved Research Project. Prohibited chemicals are:

Chemical Name

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

DDD

CAE750 CALCIUM ARSENATE [2ASH3O4.2CA] 7778-44-1 **CAMPHECHLOR** 8001-35-2 **CAPTAFOL** 2425-06-1 **CARBOFURAN** 1563-66-2 **CARBON TETRACHLORIDE** <u>56-23-5</u> **CHLORDANE** <u>57-74-9</u> **CHLORDECONE (KEPONE)** <u>143-50-0</u> **CHLORDIMEFORM** 6164-98-3 **CHLOROBENZILATE** 510-15-6 CHLOROMETHOXYPROPYLMERCURIC ACETATE [CPMA] EDF-<u>183</u> **COPPER ARSENATE** 10103-61-4 2,4-D, ISOOCTYL ESTER 25168-26-7 **DAMINOZIDE** 1596-84-5

72-54-8 **DDT** 50-29-3 DI(PHENYLMERCURY)DODECENYLSUCCINATE [PMDS] EDF-187 1,2-DIBROMO-3-CHLOROPROPANE (DBCP) <u>96-12-8</u> **1,2-DIBROMOETHANE** 106-93-4 **1,2-DICHLOROETHANE** 107-06-2 **DIELDRIN** <u>60-57-1</u> 4,6-DINITRO-O-CRESOL <u>534-52-1</u> DINITROBUTYL PHENOL 88-85-7 **ENDRIN** 72-20-8 **EPN** 2104-64-5 **ETHYLENE OXIDE 75-21-8 FLUOROACETAMIDE** <u>640-19-7</u> **GAMMA-LINDANE** <u>58-89-9</u> **HEPTACHLOR**

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76-44-8
HEXACHLOROBENZENE
<u>118-74-1</u>
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
<u>1836-75-5</u>
OCTAMETHYLDIPHOSPHORAMIDE
<u>152-16-9</u>
PARATHION
<u>56-38-2</u>
PENTACHLOROPHENOL
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87-86-5

PHENYLMERCURIC OLEATE [PMO]

EDF-185

PHOSPHAMIDON

13171-21-6

PYRIMINIL

<u>53558-25-1</u>

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

<u>95-95-4</u>

VINYL CHLORIDE

<u>75-01-4</u>

- G. The use of Dimethylsulfoxide (DMSO) on a Research and Development Licensee's Licensed

 Premises shall be prohibited and possession of DMSO upon the Licensed Premises is prohibited, unless as part of an approve Research Project.
- H. Adulterants. Unless as part of an approved Research Project, a Research and Development
 Licensee may not treat or otherwise adulterate Medical Marijuana or Medical Marijuana-Infused
 Product with any chemical or other compound whatsoever to alter its color, appearance, weight or smell.
- I. Independent Health and Sanitary Audit
 - 1. State Licensing Authority May Require a Health and Sanitary Audit
 - a. When the State Licensing Authority determines a health and sanitary audit by an independent consultant is necessary, it may require a Research and Development Licensee to undergo such an audit. The scope of the audit may include, but need not be limited, to whether the Research and Development Licensee is in compliance with the requirements set forth in this rule and other applicable public health or sanitary laws and regulations.
 - In such instances, the Division may attempt to mutually agree upon the selection of the independent consultant with a Research and Development Licensee.
 However, the Division always retains the authority to select the independent consultant regardless of whether mutual agreement can be reached.
 - c. The Research and Development Licensee will be responsible for all costs associated with the independent health and sanitary audit.
 - 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:
 - A Research and Development Licensee does not provide requested records
 related to the use of Pesticide or other agricultural chemicals during in the
 cultivation process;
 - b. The Division has reasonable grounds to believe that the Research and
 Development Licensee 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;
 - The Division has reasonable grounds to believe that the Research and
 Development Licensee was the cause or source of contamination of Medical Marijuana or Medical Marijuana-Infused Product; or
 - Multiple Harvest Batches or Production Batches produced by the Research and Development failed contaminant testing.
 - 3. Compliance Required. A Research and Development Licensee 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.
 - 4. Suspension of Operations

- a. 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 Research and Development Licensee's license. See Rule M 1302 – Disciplinary Process: Summary Suspensions.
- b. Prior to or following the issuance of such an order, the Research and
 Development Licensee 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.
 - i. 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 M 1302 Disciplinary Process: Summary Suspensions.
 - ii. If an agreement to suspend operations is reached, then the Research and Development Licensee may continue to care for its inventory and conduct any necessary internal business operations but it may not sell, transfer or wholesale Medical Marijuana or Medical Marijuana-Infused Product to other Medical Marijuana Business during the period of time specified in the agreement.
- J. Violation Affecting Public Safety. Failure to comply with this rule may constitute a license violation affecting public safety.

Rule M 1907 - Research and Development Licensees: Testing

- A. Samples on Demand. A Research and Development Licensee shall, upon request of the Division, submit a sufficient quantity of Medical Marijuana or Medical Marijuana-Infused Product to a Medical Marijuana Testing Facility for testing. The Division will notify the Licensee of the results of the analysis. See Rule M. 309 Medical Marijuana Business: Inventory Tracking System and Rule M 901 Business Records Required.
- B. Samples Provided for Testing.
 - A Research and Development Licensee may provide Samples of its Medical Marijuana or Medical Marijuana-Infused Product to a Medical Marijuana Testing Facility for testing purposes. The Research and Development Licensee shall maintain the testing results as part of its business books and records. See Rule M 901 – Business Records Required.

Rule M 1908 – Research and Development Licensees: Production Management and Possession Limits

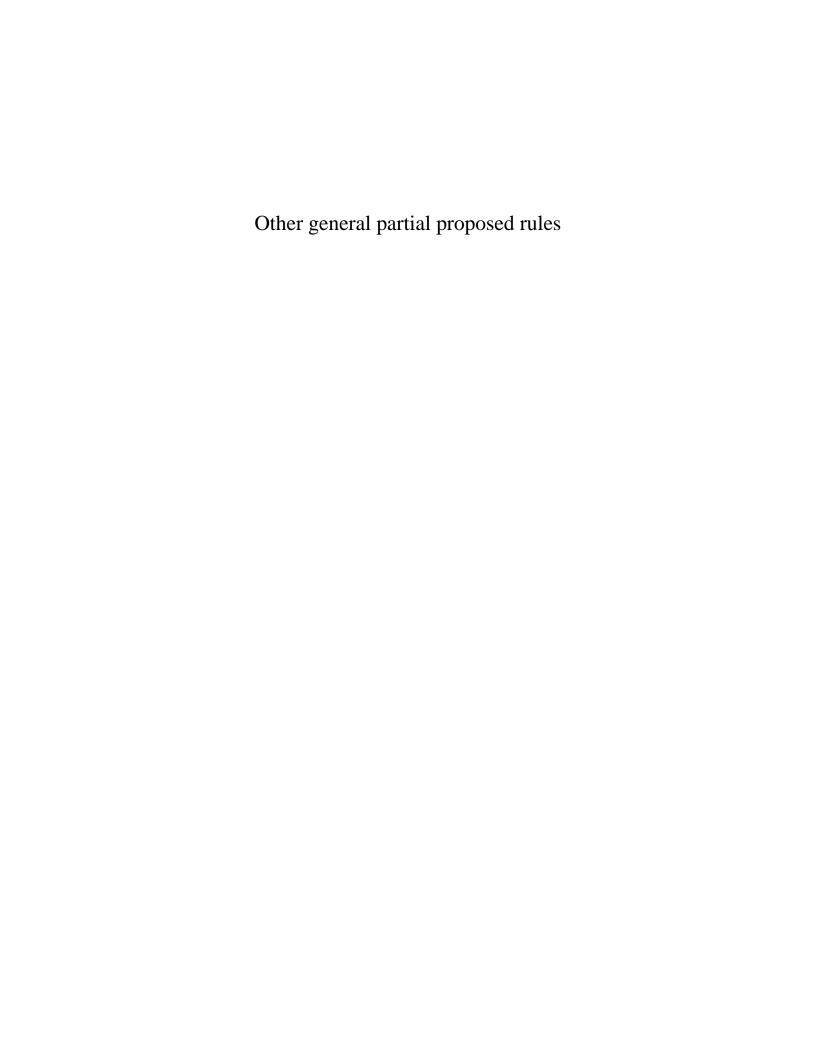
- A. Marijuana for Transfer. A Marijuana Research and Development Cultivation that cultivates

 Medical Marijuana for transfer to Marijuana Research and Development Cultivations or Marijuana

 Research and Development Facilities may not have more than five hundred Medical Marijuana plants on its Licensed Premises.
 - A Research and Development Cultivation Licensee 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 Research and Development Licensee.

- B. Marijuana for Research. A Research and Development Licensee shall only possess for research the amount of Medical Marijuana or Medical Marijuana-Infused Product approved by the Division for each of the Licensee's Research Projects, the total amount of which shall not at any time exceed [HOLD FOR WORK GROUP quantity of finished and infused product related to plant count limitation above].
- C. Separation of Marijuana Used in Research. A Marijuana Research and Development Cultivation shall physically separate all Medical Marijuana used in the Licensee's own approved Research Project from Medical Marijuana to be transferred to other Research and Development Licensees for approved Research Projects.



DEPARTMENT OF REVENUE

Marijuana Enforcement Division

MEDICAL MARIJUANA RULES

1 CCR 212-1

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

M 100 Series - General Applicability

M 103 - Definitions

<u>Definitions</u>. The following definitions of terms, in addition to those set forth in section 12-43.3-104, C.R.S., shall apply to all rules promulgated pursuant to the Medical Code, unless the context requires otherwise:

"Affiliated Interest" means any Business Interest related to a Medical Marijuana Business that does not rise to the level of a Financial Interest in a Medical Marijuana Business license. An Affiliated Interest may include, but shall not be limited to, an Indirect Beneficial Interest Owner that is not a Financial Interest, an indirect financial interest, a lease agreement, secured or unsecured loan, or security interest in fixtures or equipment with a direct nexus to the cultivation, manufacture, sale, transportation, or testing of Medical Marijuana or Medical Marijuana-Infused Products. Except as otherwise provided by these rules, an Affiliated Interest holder shall neither exercise control of nor be positioned so as to enable the exercise of control over the Medical Marijuana Business or its operations. A Medical Marijuana Business shall report each of its Affiliated Interests to the Division with each application for initial licensure, renewal, change of ownership or change of corporate structure.

"Associated Key License" means an Occupational License for an individual who is a Direct Beneficial Interest Owner of the Medical Marijuana Business, other than a Qualified Limited Passive Investor, and any Person who controls or is positioned so as to enable the exercise of control over a Medical Marijuana Business. Each shareholder, officer, director, member, or partner of a Closely Held Business Entity that is a Direct Beneficial Interest Owner and any Person who controls or is positioned so as to enable the exercise of control over a Medical Marijuana Business must hold an Associated Key License.

"Commercially Reasonable Royalty" means a right to compensation in the form of a royalty payment for the use of product-specific intellectual property. A Commercially Reasonable Royalty must be limited to specific intellectual property the Commercially Reasonable Royalty Interest Holder owns or is otherwise authorized to license. A Commercially Reasonable Royalty will not be approved where it could cause reasonable consumer confusion or violate any federal copyright, trademark or patent law or regulation. The Commercially Reasonably Royalty shall provide for compensation to the Commercially Reasonable Royalty Holder as a percentage of gross revenue or gross profit. The royalty payment must be at a reasonable percentage rate. To determine whether the percentage rate is reasonable, the Division will consider the totality of the circumstances, including but not limited to the following factors:

- 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.

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Deleted: product or line of products and provide compensation to the Commercially Reasonable Royalty Holder as a percentage of gross revenue or gross profit generated from sales of the particular product or line of products.

- 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.
- Deleted: manufactured
- 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.
- The established or projected profitability of the product made using the intellectual property; its commercial success; and its current popularity.
- 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.
- 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.

"Finished, Marijuana" means post-harvest Medical Marijuana including flower and trim that has completed the curing and drying process or has been harvested for more than sixty (60) days.

"Flowering" means the reproductive state of the Cannabis plant in which there are physical signs of flower or budding out of the nodes in the stem.

"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-Infused 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.

"Immature Plant" means a nonflowering Medical Marijuana plant that is no more than four inches wide or four inches tall produced from a cutting, clipping or seedling and that is in a growing container that is no larger than two inches wide and two inches tall that is sealed on the sides and bottom. 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."

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"Medical Marijuana" means marijuana that is grown and sold pursuant to the Medical Code and includes seeds and Immature Plants. <u>Unless the context otherwise requires</u>, <u>Medical Marijuana</u> Concentrate is considered Medical Marijuana and is included in the term "Medical Marijuana."

"Medical Marijuana Business Operator" means an entity that holds a registration or license from the State Licensing Authority to provide professional operational services to one or more Medical Marijuana Businesses 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. The Medical Code and rules apply to all Medical Marijuana Business Operators regardless of whether such operator holds a registration or license. Any reference to "license" or "licensee" shall mean "registration" or "registrant" when applied to a Medical Marijuana Business Operator that holds a registration issued by the State Licensing Authority.

"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 and Heat/Pressure Based

"Permitted Economic Interest" means an Agreement to obtain an ownership interest in a Retail Marijuana Establishment or Medical Marijuana Business when the holder of such interest 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 and obtaining a license as a <u>Direct Beneficial Interest Owner under the Retail Code or Medical Code. A Permitted Economic Interest holder is an Indirect Beneficial Interest Owner.</u>

"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 Establishment. "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. Unless the context otherwise requires, Retail Marijuana Concentrate is considered Retail Marijuana and is included in the term "Retail Marijuana."

"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.

"Transfer" means to grant, convey, hand over, assign, sell, exchange, donate, or barter, in any manner or by any means, with or without consideration, any Retail Marijuana or Retail Marijuana Product from one licensee to another licensee or to a consumer. A Transfer includes the movement of Retail Marijuana or Retail Marijuana Product 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 on the Inventory Tracking System, even if no physical movement of the Retail Marijuana or Retail Marijuana Product occurs.

"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.

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M 200 Series - Licensing and Interests

Basis and Purpose - M 201

The statutory authority for this rule is found at subsections 12-43.3-202(1)(a), 12-43.3-202(1)(b)(l), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XXI), 12-43.3-301(3), and 12-43.3-401(1)(a)-(e), and sections 12-43.3-104, 12-43.3-305, 12-43.3-306, 12-43.3-307.5, 12-43.3-310, 12-43.3-311, 12-43.3-313, 12-43.3-401, and 24-76.5-103, C.R.S. The purpose of this rule is to establish that only materially complete applications for licenses or registrations, accompanied by all required fees, will be accepted and processed by the Division. The purpose of this rule is also to clarify that when an initial application is materially complete, but the Division determines further information is required before the application can be fully processed, the Applicant must provide the additional requested information within the time frame provided by the Division. Otherwise, the Division cannot act on the application in a timely manner, and the application may be denied.

M 201 - Application Process

A. General Requirements

- 1. All applications for licenses or registrations authorized pursuant to subsections 12-43.3-401(1)(a)-(g), C.R.S., shall be made upon current forms prescribed by the Division.
- A license or registration issued to a Medical Marijuana Business or an individual constitutes a revocable privilege. The burden of proving an Applicant's qualifications for licensure or registration rests at all times with the Applicant.
- 3. Each application shall identify the local licensing authority.
- Applicants must submit a complete application to the Division before it will be accepted or considered.
 - a. All applications must be complete and accurate in every material detail.
 - b. All applications must include all attachments or supplemental information required by the current forms supplied by the Division.
 - c. All applications must be accompanied by a full remittance for the whole amount of the application and license fees. See Rules M 207 Schedule of Application Fees: Medical Marijuana Businesses; M 208 Schedule of Business License and Registration Fees: Medical Marijuana Businesses; M 209 Schedule of Business Renewal License and Registration Fees: Medical Marijuana Businesses; M 235 Schedule of License Fees: Individuals; M 236 Schedule of Renewal License Fees: Individuals.
 - d. All applications must include all information required by the Division related to the Applicant's proposed Direct Beneficial Interest Owners, Indirect Beneficial Interest Owners and Qualified Limited Passive Investors, and all other direct and indirect financial interests in the Applicant.
 - e. At a minimum, each Applicant for a new license or registration shall provide, at the time of application, the following information:

- For each Associated Key License Applicant, evidence of proof of lawful presence, citizenship, if applicable, residence, if applicable, and Good Moral Character as required by the current forms prescribed by the Division;
- For each Medical Marijuana Business Applicant and each Associated Key License Applicant, all requested information concerning financial and management associations and interests of other Persons in the business;
- iii. If the Applicant for any license pursuant to the Medical Code is a Closely Held Business Entity it shall submit with the application:
 - The Associated Key License applications for all of its shareholders, members, partners, officers and directors who do not already hold an Associated Key License;
 - B. If the Closely Held Business Entity is a corporation, a copy of its articles of incorporation or articles of organization; evidence of authorization from the Colorado Secretary of State to do business within this State, and for each shareholder: his or her name, mailing address, state of residence and certification of Colorado residency for at least one officer and all officers with day-to-day operational control over the business;
 - C. If the Closely Held Business Entity is a limited liability company, a copy of its articles of <u>organization</u> and its operating agreement; evidence of authorization from the Colorado Secretary of State to do business within this State, and for each member: his or her name, mailing address, state of residence and certification of Colorado residency for at least one officer and all officers with day-to-day operational control over the business;
 - D. If the Closely Held Business Entity is a general partnership, limited partnership, limited liability partnership, or limited liability limited partnership, a copy of the partnership agreement and, for each partner, his or her name, mailing address and state of residency and certification of Colorado residency for at least one officer and all officers with day-to-day operational control over the business.
- iv. For each Medical Marijuana Business Applicant and each Associated Key License Applicant, documentation establishing compliant return filing and payment of taxes related to any Medical Marijuana Business or Retail Marijuana Establishment in which such Applicant is, or was, required to file and pay taxes;
- For each Medical Marijuana Business Applicant and each Associated Key License Applicant, documentation verifying and confirming the funds used to start and/or sustain the operation of the medical or retail marijuana business were lawfully earned or obtained;
- vi. Accurate floor plans for the premises to be licensed; and

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- vii. The deed, lease, sublease, contract, or other document(s) governing the terms and conditions of occupancy of the premises to be licensed.
- 5. All applications to reinstate a license or registration will be deemed an application for a new license or registration. This includes, but is not limited to, Associated Key licenses that have expired, Medical Marijuana Business licenses or registrations that have been expired for more than 90 days, licenses or registrations that have been voluntarily surrendered, and licenses that have been revoked.
- 6. The Division may refuse to accept an incomplete application.

B. Additional Information May Be Required

- Upon request by the Division, an Applicant shall provide any additional information required to process and fully investigate the application. The additional information must be provided to the Division no later than seven days after the request is made unless otherwise specified by the Division.
- 2. An Applicant's failure to provide the requested evidence or information by the Division deadline may be grounds for denial of the application.
- C. <u>Information Must Be Provided Truthfully</u>. All Applicants shall submit information to the Division in a full, faithful, truthful, and fair manner. The Division may recommend denial of an application where the Applicant made misstatements, omissions, misrepresentations, or untruths in the application or in connection with the Applicant's background investigation. This type of conduct may be considered as the basis for additional administrative action against the Applicant and it may also be the basis for criminal charges against the Applicant.
- D. <u>Application Forms Accessible</u>. All application forms supplied by the Division and filed by an Applicant for a license, including attachments and any other documents associated with the investigation, may be used for a purpose authorized by the Medical Code, the Retail Code, of for any other state or local law enforcement purpose or as otherwise required by law.
- E. Division Application Management and Local Licensure.
 - 1. If the Division grants a license before the local licensing authority approves the application or grants a local license, the license will be conditioned upon local approval. Such condition will not be viewed as a denial pursuant to the Administrative Procedure Act. If the local licensing authority denies the application, the state license will be revoked.
 - An Applicant is prohibited from operating a Medical Marijuana Business prior to obtaining all necessary licenses, registrations or approvals from both the State Licensing Authority and the local licensing authority.
 - Each Financial Interest is void and of no effect unless and until approved by the Division.

 A Financial Interest shall not exercise any privilege associated with the proposed interest until approved by the Division. Any violation of this requirement may be considered a license or registration violation affecting public safety.

Deleted: 1. For each application for a new Medical Marijuana Business, the Applicant shall submit the original application and one identical copy. The Division will retain the original application for a new Medical Marijuana Business and will send the copy to the local licensing authority.¶

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M 202 - Repealed effective January 1, 2017.

Basis and Purpose - M 202.1

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XVII), 12-43.3-202(2)(a)(XXI), 12-43.3-202(2)(a)(XXI), and sections 12-43.3-104, 12-43.3-305 and 12-43.3-306, 12-43.3-307.5, 12-43.3-310 and 12-43.3-313 C.R.S. The purpose of this rule is to clarify the process to be followed when a Medical Marijuana Business applies to obtain financing or otherwise have a relationship with an Indirect Beneficial Interest Owner. This rule establishes that only materially complete Medical Marijuana Business applications for Indirect Beneficial Interest Owners, accompanied by all required fees, will be accepted and processed by the Division. This rule also clarified that when an initial application is materially complete and accepted, but the Division determines further information is required before the application can be fully processed, the Medical Marijuana Business Applicant must provide the additional requested information within the time frame provided by the Division. Otherwise, the Division cannot act on the application in a timely manner and the Medical Marijuana Business' application may be denied. The rule also sets forth requirements for the contents of the contract or Agreement between Medical Marijuana Businesses and Indirect Beneficial Interest Owners, which reflect basic legal requirements surrounding the relationship between the parties.

M 202.1 – Applications, Agreements, Contracts and Certifications Required for Indirect Beneficial Interest Owners: Medical Marijuana Businesses

- A. Medical Marijuana Business Initiates Process. The Medical Marijuana Business seeking to obtain financing or otherwise establish any type of relationship with an Indirect Beneficial Interest Owner, including a Permitted Economic Interest, a Commercially Reasonably Royalty Interest Holder, a Profit-Sharing Plan Employee, or a Qualified Institutional Investor, must file all required documents with the Division, including any supplemental documents requested by the Division in the course of its review of the application.
- B. <u>General Requirements</u>. The Medical Marijuana Business seeking approval of an Indirect Beneficial Interest Owner must meet the following requirements:
 - All applications for approval of an Indirect Beneficial Interest Owner shall be made upon current forms prescribed by the Division.
 - The burden of proving that a proposed Indirect Beneficial Interest Owner is qualified to hold such an interest rests at all times with the Medical Marijuana Business submitting the application.
 - The Medical Marijuana Business applying for approval of any type of Indirect Beneficial Interest Owner must submit a complete application to the Division before it will be accepted or considered.
 - 4. All applications must be complete and accurate in every material detail.
 - All applications must include all attachments or supplemental information required by the current forms supplied by the Division.
 - 6. All applications must be accompanied by a full remittance of the required fees.
 - 7. The Division may refuse to accept an incomplete application.
 - 8. The proposed holder of the Indirect Beneficial Interest is not a publicly traded company.

- 9. Additional Information May Be Required
 - a. Upon request by the Division, a Medical Marijuana Business applying to have any type of Indirect Beneficial Interest Owner shall provide any additional information required to process and fully investigate the application. The additional information must be provided to the Division no later than seven days after the request is made unless otherwise specified by the Division.
 - b. Failure to provide the requested information by the Division's deadline may be grounds for denial of the application.
- C. Information Must Be Provided Truthfully. A Medical Marijuana Business applying for approval of any type of Indirect Beneficial Interest Owner shall submit information to the Division in a full, faithful, truthful, and fair manner. The Division may recommend denial of an application where any party made misstatements, omissions, misrepresentations or untruths in the application or in connection with the background investigation of the proposed Indirect Beneficial Interest Owner. This type of conduct may be considered as the basis for additional administrative action against the Medical Marijuana Business and it may also be the basis for criminal charges against either the Medical Marijuana Business Applicant or the Indirect Beneficial Interest Owner.
- D. <u>Application Forms Accessible</u>. All application forms supplied by the Division and filed by an Applicant for a license, including attachments and any other documents associated with the investigation, may be used for a purpose authorized by the Medical Code, the Retail Code or for any other state or local law enforcement purpose or as otherwise required by law.
- E. <u>Approval of Financial Interest</u>. Each Financial Interest in a Medical Marijuana Business is void and of no effect unless and until approved by the Division. Any amendment of a Financial Interest is also void and of no effect unless and until approved by the Division.
- F. Ongoing Qualification and Violation Affecting Public Safety. If at any time the Division finds any Indirect Beneficial Interest Owner is not qualified, or is no longer qualified, the Division may require the Medical Marijuana Business to terminate its relationship with and financial ties to the Indirect Beneficial Interest Owner within a specified time period. Failure to terminate such relationship and financial ties within the specified time period may constitute a violation affecting public safety and be a basis for administrative action against the Medical Marijuana Business.
- G. Permitted Economic Interest Holder Requirements. At the time of application, a Medical Marijuana Business seeking to obtain approval of a Permitted Economic Interest shall provide evidence to establish that the natural person seeking to become a Permitted Economic Interest holder is a lawful resident of the United States and shall provide documentation verifying and confirming the funds used for the Permitted Economic Interest were lawfully earned or obtained.
- H. Permitted Economic Interest Agreement Requirements. The Medical Marijuana Business Applicant seeking to obtain financing from a Permitted Economic Interest must submit a copy of the Agreement between the Medical Marijuana Business and the person seeking to hold a Permitted Economic Interest. The following requirements apply to all Agreements:
 - 1. The Agreement must be complete, and must fully incorporate all terms and conditions.

- 2. The following provisions must be included in the Agreement:
 - a. Any interest in a Medical Marijuana Business, whether held by a Permitted Economic Interest or any other person, must be acquired in accordance with the provisions of the Medical Code and/or Retail Code, as applicable, and the rules promulgated thereunder. The issuance of any Agreement or other interest in violation thereof shall be void. The Permitted Economic Interest holder shall not provide funding to the Medical Marijuana Business until the Permitted Economic Interest is approved by the Division.
 - b. No Agreement or other interest issued by the Medical Marijuana Business and no claim or charge therein or thereto shall be transferred except in accordance with the provisions of the Medical Code and/or Retail Code as applicable, and the rules promulgated thereunder. Any transfer in violation thereof shall be void.
 - c. The Medical Marijuana Business and the Permitted Economic Interest holder must sign an affirmation of passive investment on a form approved by the Division.
 - d. The Medical Marijuana Business must initiate any process to convert a Permitted Economic Interest to a Direct Beneficial Interest Owner and the process to convert the Permitted Economic Interest into a Direct Beneficial Interest Owner must be completed prior to the expiration or termination of the Agreement. The holder of the Permitted Economic Interest must meet all qualifications for licensure and ownership pursuant to the Medical Code and/or Retail Code and any rules promulgated thereunder prior to conversion of the Permitted Economic Interest to a Direct Beneficial Interest Owner.
 - e. At the election of the Medical Marijuana Business, if the holder of the Permitted Economic Interest is not qualified for licensure as a Direct Beneficial Interest Owner but is qualified as a holder of the Permitted Economic Interest, and the Permitted Economic Interest is also approved by the Division then the Permitted Economic Interest may remain in force and effect for as long as it remains approved by the Division under the Medical Code and/or Retail Code as applicable, and any rules promulgated thereunder.
 - f. The Permitted Economic Interest holder shall disclose in writing to the Division and to the Medical Marijuana Business any and all disqualifying events, within ten days after occurrence of the event, that could lead to a finding that the holder no longer qualifies to hold the Permitted Economic Interest and/or that could lead to a denial of licensure pursuant to the Medical Code and/or Retail Code and any rules promulgated thereunder.
 - g. The Medical Marijuana Business shall disclose in writing to the Division any and all disqualifying events, within ten days after receiving notice of the event, which could lead to a finding that the holder is no longer qualified to hold the Permitted Economic Interest and/or that could lead to a denial of licensure pursuant to the Medical Code and/or Retail Code as applicable, and any rules promulgated thereunder.

- h. A Permitted Economic Interest holder's or a Medical Marijuana Business' failure to make required disclosures may be grounds for administrative action including but not limited to denial of a subsequent request to convert the Permitted Economic Interest into an ownership interest in the Medical Marijuana Business. Failure to make required disclosures may lead to a finding that the Permitted Economic Interest is no longer approved, and a requirement that the Medical Marijuana Business terminate its relationship with the Permitted Economic Interest holder.
- i. The Permitted Economic Interest holder agrees and acknowledges that it has no entitlement or expectation of being able to invest in, or have a relationship with, the Medical Marijuana Business unless and until the Division determines the Permitted Economic Interest is approved. The Permitted Economic Interest holder agrees and acknowledges that its relationship with the Medical Marijuana Business is contingent upon Division approval. The Permitted Economic Interest holder understands and acknowledges that approval by the Division is wholly discretionary and the Division may, at any time, deny approval of the Permitted Economic Interest or find that the Permitted Economic Interest is no longer qualified. The Permitted Economic Interest Holder agrees and acknowledges it has no entitlement to or expectation of the Division approving the Permitted Economic Interest. The Permitted Economic Interest holder further agrees that any administrative or judicial review of a determination by the Division regarding the qualification or approval of the Permitted Economic Interest will only occur through licensing or enforcement proceedings involving the Medical Marijuana Business. The Permitted Economic Interest holder further agrees and acknowledges that the Permitted Economic Interest holder shall only be entitled to notice of a denial or administrative action concerning the Medical Marijuana Business if the denial or administrative action is based upon, or directly related to, the qualifications or actions of the Permitted Economic Interest holder. The Permitted Economic Interest holder also agrees and acknowledges that the Permitted Economic Interest holder may only request leave to intervene in an administrative proceeding against the Medical Marijuana Business, pursuant to subsection 24-4-105(2)(c), C.R.S., if the administrative proceeding is based upon, or directly related to, the qualifications or actions of the Permitted Economic Interest holder. Furthermore, the Permitted Economic Interest holder agrees and acknowledges that the Permitted Economic Interest holder may only seek judicial review of an action against the Medical Marijuana Business, pursuant to subsection 24-4-106(4), C.R.S., if the administrative action is based upon, or directly related to, the qualifications or actions of the Permitted Economic Interest Holder. THE PERMITTED ECONOMIC INTEREST HOLDER KNOWINGLY, FREELY, AND VOLUNTARILY WAIVES ANY RIGHT OR CLAIM TO SEEK ANY INDEPENDENT REVIEW OF APPROVAL OR DENIAL OF THE PERMITTED ECONOMIC INTEREST BY THE DIVISION, OR OF AN ADMINISTRATIVE ACTION AGAINST THE MEDICAL MARIJUANA BUSINESS, THAT IS BASED UPON, OR DIRECTLY RELATED TO, THE QUALIFICATIONS OR ACTIONS OF THE PERMITTED ECONOMIC INTEREST, AND EXPRESSLY AGREES THAT THE ONLY ADMINISTRATIVE OR JUDICIAL REVIEW OF SUCH A DETERMINATION OR ACTION WILL OCCUR THROUGH A LICENSING OR ENFORCEMENT PROCEEDING FOR THE MEDICAL MARIJUANA BUSINESS.
- Commercially Reasonable Royalty Interest Contract Requirements. A Medical Marijuana
 Business seeking to utilize the intellectual property of a Commercially Reasonable Royalty

Interest Holder must submit a copy of the contract between the Medical Marijuana Business and the Person seeking to hold a Commercially Reasonable Royalty Interest. The following requirements apply to all such contracts:

- The contract must be complete, and must fully incorporate all terms and conditions.
- 2. The following provisions must be included in the contract:
 - a. Any interest in a Medical Marijuana Business, whether held by a Commercially Reasonable Royalty Interest Holder or any other person, must be acquired in accordance with the provisions of the Medical Code and/or Retail Code, as applicable, and the rules promulgated thereunder. The issuance of any contract or other interest in violation thereof shall be void.
 - b. No contract, royalty or other interest issued by the Medical Marijuana Business and no claim or charge therein or thereto shall be transferred except in accordance with the provisions of the Medical Code and/or Retail Code as applicable, and the rules promulgated thereunder. Any transfer in violation thereof shall be void.
 - c. The Medical Marijuana Business and the Commercially Reasonable Royalty Interest Holder must sign an affirmation of passive investment on a form approved by the Division.
 - d. The Commercially Reasonable Royalty Interest Holder shall disclose in writing to the Division and to the Medical Marijuana Business any and all disqualifying events, within ten days after occurrence of the event, that could lead to a finding that the Commercially Reasonable Royalty Interest Holder is not qualified to hold the Commercially Reasonable Royalty Interest.
 - e. The Medical Marijuana Business shall disclose in writing to the Division any and all disqualifying events, within ten days after receiving notice of the event, which would lead to a finding that the Commercially Reasonable Royalty Interest Holder is not qualified to hold the Commercially Reasonable Royalty Interest.
 - f. A Commercially Reasonable Royalty Interest Holder's or a Medical Marijuana Business' failure to make required disclosures may lead to a finding that the Commercially Reasonable Royalty Interest is not approved, or is no longer approved, and may lead to a requirement that the Medical Marijuana Business terminate its relationship with the Commercially Reasonable Royalty Interest Holder.
 - g. The Commercially Reasonable Royalty Interest Holder agrees and acknowledges that its relationship with the Medical Marijuana Business is contingent upon Division approval throughout the entire term of its relationship with the Medical Marijuana Business. The Commercially Reasonable Royalty Interest Holder understands and acknowledges that approval by the Division is wholly discretionary and the Division may, at any time, find that the Commercially Reasonable Royalty Interest Holder does not qualify or no longer qualifies. The Commercially Reasonable Royalty Interest Holder agrees and acknowledges it has no entitlement to or expectation to approval of the Commercially Reasonable Royalty Interest.

- The Commercially Reasonable Royalty Interest Holder further agrees that any administrative or judicial review of a determination by the Division approving or denying the Commercially Reasonable Royalty will only occur through licensing or enforcement proceedings involving the Medical Marijuana Business. The Commercially Reasonable Royalty Interest Holder further agrees and acknowledges that the Commercially Reasonable Royalty Interest Holder shall only be entitled to notice of a denial or administrative action concerning the Medical Marijuana Business if the denial or administrative action is based upon, or directly related to, the qualifications or actions of the Commercially Reasonable Royalty Interest Holder. The Commercially Reasonable Royalty Interest Holder also agrees and acknowledges that the Commercially Reasonable Royalty Interest Holder may only request leave to intervene in an administrative proceeding against the Medical Marijuana Business, pursuant to subsection 24-4-105(2)(c), C.R.S., if the administrative proceeding is based upon, or directly related to, the qualifications or actions of the Commercially Reasonable Royalty Interest Holder. Furthermore, the Commercially Reasonable Royalty Interest Holder agrees and acknowledges that the Commercially Reasonable Royalty Interest Holder may only seek judicial review of an action against the Medical Marijuana Business, pursuant to subsection 24-4-106(4), C.R.S., if the administrative action is based upon, or directly related to, the qualifications or actions of the Commercially Reasonable Royalty Interest Holder. THE COMMERCIALLY REASONABLE ROYALTY INTEREST HOLDER KNOWINGLY, FREELY, AND VOLUNTARILY WAIVES ANY RIGHT OR CLAIM TO SEEK ANY INDEPENDENT REVIEW OF APPROVAL OR DENIAL OF THE COMMERCIALLY REASONABLE ROYALTY INTEREST BY THE DIVISION, OR OF AN ADMINISTRATIVE ACTION AGAINST THE MEDICAL MARIJUANA BUSINESS, THAT IS BASED UPON, OR DIRECTLY RELATED TO, THE QUALIFICATIONS OR ACTIONS OF THE COMMERCIALLY REASONABLE ROYALTY INTEREST HOLDER, AND EXPRESSLY AGREES THAT THE ONLY ADMINISTRATIVE OR JUDICIAL REVIEW OF SUCH A DETERMINATION OR ACTION WILL OCCUR THROUGH A LICENSING OR ENFORCEMENT PROCEEDING FOR THE MEDICAL MARIJUANA BUSINESS.
- i. If the Division determines the Commercially Reasonable Royalty Interest Holder is not in compliance with the Medical Code, the Retail Code, or these rules, then the recipient shall discontinue use of such Commercially Reasonable Royalty Interest Holder's intellectual property within thirty (30) days of the Division finding. The recipient shall not pay any remuneration to a Commercially Reasonable Royalty Interest Holder that does not qualify under the Medical Code and these rules, including but not limited to Rule M 231.2(B).
- J. Profit-Sharing Plan Documents. A Medical Marijuana Business offering licensed employees a share of the profits through a Profit-Sharing Plan must submit a list of all proposed participants in the Profit-Sharing Plan along with their names, addresses and occupational license numbers and submit a copy of all documentation regarding the Profit-Sharing Plan in connection with the Medical Marijuana Business' application:

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- The documents establishing the Profit-Sharing Plan must be complete and must fully incorporate all terms and conditions.
- The following provisions must be included in the documents establishing the Profit-Sharing Plan:
 - a. Any interest in a Medical Marijuana Business, whether held by a Profit-Sharing Plan Employee or any other person, must be acquired in accordance with the provisions of the Medical Code and/or Retail Code, as applicable, and the rules promulgated thereunder. The issuance of any contract or other interest in violation thereof shall be void. Any distributions from a Profit-Sharing Plan must be made in cash, not in the form of stock or other equity interests in the Medical Marijuana Business.
 - b. No contract or other interest issued by the Medical Marijuana Business and no claim or charge therein or thereto shall be transferred except in accordance with the provisions of the Medical Code and/or Retail Code as applicable, and the rules promulgated thereunder. Any transfer in violation thereof shall be void.
 - c. The Medical Marijuana Business shall disclose in writing to the Division any and all disqualifying events, within ten days after receiving notice of the event, which would lead to a finding that any Profit-Sharing Plan Employee does not qualify under the Medical Code and these rules, including but not limited to Rule M 231.2(B), to participate in the Profit-Sharing Plan.
 - d. A Profit-Sharing Plan Employee shall disclose in writing to the Division and to the Medical Marijuana Business any and all disqualifying events, within ten days after occurrence of the event that could lead to a finding that the Profit-Sharing Plan Employee does not qualify or no longer qualifies under the Medical Code and these rules, including but not limited to Rule M 231.2(B), to participate in the Profit-Sharing Plan.
 - e. A Medical Marijuana Business' or a Profit-Sharing Plan Employee's failure to make required disclosures may lead to a finding that the Profit-Sharing Plan is not approved, and may lead to a requirement that the Medical Marijuana Business terminate or modify the Profit-Sharing Plan.
 - f. The Profit-Sharing Plan Employee agrees and acknowledges that its relationship with the Medical Marijuana Business is contingent upon Division approval throughout the entire term of its relationship with the Medical Marijuana Business. The Profit-Sharing Plan Employee understands and acknowledges that approval by the Division is wholly discretionary and the Division may, at any time, deny approval of the Profit-Sharing Plan. The Profit-Sharing Plan Employee agrees and acknowledges he or she has no entitlement to or expectation to Division approval of the Profit-Sharing Plan or the Profit-Sharing Plan Employee's participation in the plan. The Profit-Sharing Plan Employee further agrees that any administrative or judicial review of a determination by the Division approving or denying the Profit-Sharing Plan or the Profit-Sharing Plan Employee will only occur through licensing or enforcement proceedings involving the Medical Marijuana Business. Each Profit-Sharing Plan Employee further agrees and acknowledges that the Profit-Sharing Plan Employee shall only be entitled to notice of a denial or administrative action concerning the Medical Marijuana Business if the denial or administrative action is based upon, or directly related to, the qualifications or actions of the Profit-Sharing Plan Employee. The Profit-Sharing Plan Employee also agrees and acknowledges

that the Profit-Sharing Plan Employee may only request leave to intervene in an administrative proceeding against the Medical Marijuana Business, pursuant to subsection 24-4-105(2)(c), Č.R.S., if the administrative proceeding is based upon, or directly related to, the qualifications or actions of the Profit-Sharing Plan Employee. Furthermore, the Profit Sharing Plan Employee agrees and acknowledges that the Profit-Sharing Plan Employee may only seek judicial review of an action against the Medical Marijuana Business, pursuant to subsection 24-4-106(4), C.R.S., if the administrative action is based upon, or directly related to, the qualifications or actions of the Profit-Sharing Plan Employee. THE PROFIT-SHARING PLAN EMPLOYEE KNOWINGLY, FREELY, AND VOLUNTARILY WAIVES ANY RIGHT OR CLAIM TO SEEK ANY INDEPENDENT REVIEW OF APPROVAL OR DENIAL OF THE PROFIT-SHARING PLAN OR THE PROFIT-SHARING PLAN EMPLOYEE BY THE DIVISION, OR OF AN ADMINISTRATIVE ACTION AGAINST THE MEDICAL MARIJUANA BUSINESS, THAT IS BASED UPON, OR DIRECTLY RELATED TO, THE PROFIT-SHARING PLAN OR THE PROFIT-SHARING PLAN EMPLOYEE'S QUALIFICATIONS OR ACTIONS OF THE PROFIT-SHARING PLAN EMPLOYEE, AND EXPRESSLY AGREES THAT THE ONLY ADMINISTRATIVE OR JUDICIAL REVIEW OF SUCH A DETERMINATION OR ACTION WILL OCCUR THROUGH A LICENSING OR ENFORCEMENT PROCEEDING FOR THE MEDICAL MARIJUANA BUSINESS.

- K. <u>Qualified Institutional Investor Requirements</u>. Before a Medical Marijuana Business may permit a Qualified Institutional Investor to own any portion of the Medical Marijuana Business, the Medical Marijuana Business must submit the following documentation to the Division in connection with the Medical Marijuana Business' application:
 - A description of the Qualified Institutional Investor's business and a statement as to why
 the Qualified Institutional Investor meets the definition of Qualified Institutional Investor in
 Rule R 103 and subsection 12-43.3-307.5(7), C.R.S.
 - A certification made under oath and the penalty of perjury by the Qualified Institutional Investor:
 - a. That the ownership interests were acquired and are held for investment purposes only and were acquired and are held in the ordinary course of business as a Qualified Institutional Investor and not for the purposes of causing, directly or indirectly, the election of a majority of the board of directors, any change in the corporate charter, bylaws, management, policies, or operations of a Medical Marijuana Business.
 - b. That the Qualified Institutional Investor is bound by and shall comply with the Medical Code and the rules adopted pursuant thereto, is subject to the jurisdiction of the courts of Colorado, and consents to Colorado as the choice of forum in the event any dispute, question, or controversy arises regarding the Qualified Institutional Investor's relationship with the Medical Marijuana Business or activities pursuant to the Medical Code and rules adopted pursuant thereto.
 - c. The Qualified Institutional Investor agrees and acknowledges that its relationship with the Medical Marijuana Business is contingent upon Division approval throughout the entire term of its relationship with the Medical Marijuana Business. The Qualified Institutional Investor understands and acknowledges that approval by the Division is wholly discretionary and the Division may, at any time, deny approval of the Qualified Institutional Investor. The Qualified Institutional Investor agrees and acknowledges it has no entitlement to or

expectation to Division approval of the Qualified Institutional Investor. The Qualified Institutional Investor further agrees that any administrative or judicial review of a determination by the Division approving or denying the Qualified Institutional Investor will only occur through licensing or enforcement proceedings involving the Medical Marijuana Business. The Qualified Institutional Investor further agrees and acknowledges that the Qualified Institutional Investor shall only be entitled to notice of a denial or administrative action concerning the Medical Marijuana Business if the denial or administrative action is based upon, or directly related to, the qualifications or actions of the Qualified Institutional Investor. The Qualified Institutional Investor also agrees and acknowledges that the Qualified Institutional Investor may only request leave to intervene in an administrative proceeding against the Medical Marijuana Business, pursuant to subsection 24-4-105(2)(c), C.R.S., if the administrative proceeding is based upon, or directly related to, the qualifications or actions of the Commercially Reasonable Royalty Interest Holder. Furthermore, the Qualified Institutional Investor agrees and acknowledges that the Qualified Institutional Investor may only seek judicial review of an action against the Medical Marijuana Business, pursuant to subsection 24-4-106(4), C.R.S., if the administrative action is based upon, or directly related to, the qualifications or actions of the Commercially Reasonable Royalty Interest Holder. THE QUALIFIED INSTITUTIONAL INVESTOR KNOWINGLY, FREELY, AND VOLUNTARILY WAIVES ANY RIGHT OR CLAIM TO SEEK ANY INDEPENDENT REVIEW OF APPROVAL OR DENIAL OF THE COMMERCIALLY REASONABLE INTEREST BY THE DIVISION, OR OF AN ADMINISTRATIVE ACTION AGAINST THE MEDICAL MARIJUANA BUSINESS, THAT IS BASED UPON, OR DIRECTLY RELATED TO, THE QUALIFICATIONS OR ACTIONS OF THE COMMERCIALLY REASONABLE ROYALTY INTEREST HOLDER, AND EXPRESSLY AGREES THAT THE ONLY ADMINISTRATIVE OR JUDICIAL REVIEW OF SUCH A DETERMINATION OR ACTION WILL OCCUR THROUGH A LICENSING OR ENFORCEMENT PROCEEDING FOR THE MEDICAL MARIJUANA BUSINESS.

- An explanation of the basis of the signatory's authority to sign the certification and to bind the Qualified Institutional Investor to its terms.
- 3. The name, address, telephone number and any other information requested by the Division as required on its approved forms for the officers and directors, or their equivalent, of the Qualified Institutional Investor as well as those Persons that have direct control over the Qualified Institutional Investor's ownership interest in the Medical Marijuana Business.
- The name, address, telephone number and any other information requested by the
 Division as required on its approved forms for each Person who has the power to direct
 or control the Qualified Institutional Investor's voting of its shares in the Medical
 Marijuana Business.
- The name of each Person that beneficially owns 5 percent or more of the Qualified Institutional Investor's voting securities or other equivalent.
- 6. A list of the Qualified Institutional Investor's affiliates.
- A list of all regulatory agencies with which the Qualified Institutional Investor files periodic reports, and the name, address, and telephone number of the individual, if known, to contact at each agency regarding the Qualified Institutional Investor.

- 8. A disclosure of all criminal or regulatory sanctions imposed during the preceding 10 years and of any administrative or court proceedings filed by any regulatory agency during the preceding 5 years against the Qualified Institutional Investor, its affiliates, any current officer or director, or any former officer or director whose tenure ended within the preceding 12 months. As to a former officer or director, such information need be provided only to the extent that it relates to actions arising out of or during such person's tenure with the Qualified Institutional Investor or its affiliates.
- A copy of any filing made under 16 U.S.C § 18a with respect to the acquisition or proposed acquisition of an ownership interest in the Medical Marijuana Business.
- 10. Any additional information requested by the Division.

The statutory authority for this rule is found at subsections 12-43.3-104(1), 12-43.3-104(1.7), 12-43.3-104(12.4), 12-43.3-104(14.3), 12-43.3-202(1)(b)(l), 12-43.3-202(1)(e), $\frac{12-43.3-202(2)(a)(l)}{12-43.3-202(2)(a)(l)}$, 12-43.3-202(2)(a)(XX), 12-43.3-202(2)(a)(XX), 12-43.3-202(2)(a)(XX), 12-43.3-313 and 12-43.3-301(7), (8)(a) and (11), and 12-43.3-601(1), and sections 12-43.3-307.5, 12-43.3-313 and 12-43.3-301, C.R.S. The purpose of this rule is to provide clarity regarding the nature of a Direct Beneficial Interest Owner and an Indirect Beneficial Interest Owner, and to clarify what factors the State Licensing Authority generally considers regarding the same. The Division will review all relevant information to determine ownership of a Medical Marijuana Business.

M 204 - Ownership Interests of a License: Medical Marijuana Businesses

A. <u>Licenses Held By Direct Beneficial Interest Owners</u>. Each Medical Marijuana Business License must be held by its Direct Beneficial Interest Owner(s). Each natural person other than a Qualified Limited Passive Investor must hold an Associated Key License. A Direct Beneficial Interest Owner shall not be a publicly traded company.

B. 100% Ownership.

- The sum of the percentages of ownership of all Direct Beneficial Interest Owners of a Medical Marijuana Business and Qualified Institutional Investors must equal 100%.
 - Qualified Institutional Investors may hold ownership interests, in the aggregate, of 30% or less in the Medical Marijuana Business.
 - A Qualified Limited Passive Investor must be a natural person who is a United States citizen and may hold an ownership interest of less than five percent in the Medical Marijuana Business.
 - c. Each Direct Beneficial Interest Owner, including but not limited to each officer, director, managing member, or partner of a Medical Marijuana Business, must hold a current and valid Associated Key License. See Rule M 233 Retail Code or Medical Code Occupational Licenses Required. Except that this requirement shall not apply to Qualified Limited Passive Investors.
 - d. With the exception of Qualified Institutional Investors, only Direct Beneficial Interest Owners may hold a partnership interest, limited or general, a joint venture interest, or ownership of a share or shares in a corporation or a limited liability company which is licensed.

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- e. In the event of the death, disability, disqualification, divestment, termination, or revocation of the license of a Direct Beneficial Interest Owner or of approval of a Qualified Institutional Investor, a Medical Marijuana Business shall have 45 days to submit a change of ownership application to the Division detailing the Licensee's plan for redistribution of ownership among the remaining Direct Beneficial Interest Owners and Qualified Institutional Investors. Such plan is subject to approval by the Division. If a change of ownership application is not timely submitted, the Medical Marijuana Business and its Associated Key Licensee(s) may be subject to administrative action.
- C. At Least One Associated Key License Required. No Medical Marijuana Business may operate or be licensed unless it has at least one Associated Key Licensee that is a Direct Beneficial Interest Owner who has been a Colorado resident for at least one year prior to application. Any violation of this requirement may be considered a license violation affecting public safety.
- D. Loss Of Occupational License As An Owner Of Multiple Businesses. If an Associated Key License is suspended or revoked as to one Medical Marijuana Business or Retail Marijuana Establishment, that Owner's Occupational License shall be suspended or revoked as to any other Medical Marijuana Business or Retail Marijuana Establishment in which that Person possesses an ownership interest. See Rule M 233 Medical Code or Retail Code Occupational Licenses Required.
- E. <u>Management Companies</u>. Any Person contracted to manage the overall operation of a Licensed Premises must hold a Medical Marijuana Operator license.
- F. Role of Managers. Associated Key Licensees may hire managers, and managers may be compensated on the basis of profits made, gross or net. A Medical Marijuana Business license may not be held in the name of a manager who is not a Direct Beneficial Interest Owner. A manager who does not hold an Associated Key License as a Direct Beneficial Interest Owner of the Medical Marijuana Business, must hold a Key License as an employee of the Medical Marijuana Business. Any change in manager must be reported to the Division and any local licensing authority before the new manager begins managing the Medical Marijuana Business. Additionally, a Medical Marijuana Operator may include management services as part of the operational services provided to a Medical Marijuana Business. A Medical Marijuana Business and its Direct Beneficial Interest Owners may be subject to license denial or administrative action, including but not limited to, fine, suspension or revocation of their license(s), based on the acts and omissions of any manager, Medical Marijuana Business. Operator, or agents and employees thereof engaged in the operations of the Medical Marijuana Business.
- G. Prohibited Third-Party Acts. No Licensee may employ, contract with, hire, or otherwise engage 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.
 - A Licensee is responsible for all actions and omissions of any Person the Licensee employs, contracts with, hires, or otherwise engages, 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 acts and/or omissions of any Person the Licensee employs, contracts with, hires, or otherwise engages, 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.

Basis and Purpose - M 204.5

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(I), 12-43.3-202(2)(a)(XXI), 12-43.3-202(2)(a)(XXI) and 12-43.3-202(3)(a)(XXI) and sections 12-43.3-104, 12-43.3-305, 12-43.3-307, 12-43.3-307, 12-43.3-309, 12-43.3-310, 12-43.3-311 and 12-43.3-313, C.R.S. The purpose of this rule is to clarify the application, review and approval process for various types of Business Interests. The Division will review all relevant information to determine ownership of, interests in, and control of a Medical Marijuana Business.

M 204.5 - Disclosure, Approval and Review of Business Interests

- A. <u>Business Interests</u>. A Medical Marijuana Business shall disclose all Business Interests at the time of initial application and at the time of each renewal application. Business Interests include Financial Interests and Affiliated Interests. Any Financial Interest must be pre-approved by the Division. It shall be unlawful to fail to completely report all Business Interests in each license issued. It shall be unlawful for a person other than a Financial Interest holding an Associated Key License to exercise control over a Medical Marijuana Business or to be positioned so as to enable the exercise of control over a Medical Marijuana Business. Except that a Qualified Institutional Investor and a Qualified Limited Passive Investor may vote his, her or its shares in the Medical Marijuana Business.
- B. <u>Financial Interests</u>. A Medical Marijuana Business shall not permit any Person to hold or exercise a Financial Interest in the Medical Marijuana Business unless and until such Person's Financial Interest has been approved by the Division. If a Medical Marijuana Business wishes to permit a Person to hold or exercise a Financial Interest, and that Person has not been previously approved in connection with an application for the Medical Marijuana Business, the Medical Marijuana Business shall submit a change of ownership or financial interest form approved by the Division. A Financial Interest shall include:
 - 1. Any Direct Beneficial Interest Owner;
 - The following types of Indirect Beneficial Interest Owners:
 - A Commercially Reasonable Royalty Interest Holder who receives more than 30
 percent of the gross revenue or gross profit from sales of the product or line of
 products subject to the royalty; and
- b. A Permitted Economic Interest holder.
 - 3. Control. Any other Person who exercises control or is positioned so as to enable the exercise of control over the Medical Marijuana Business must hold an Associated Key License. A natural person who exercises control or is positioned so as to enable the exercise of control over a Medical Marijuana Business shall include but shall not be limited to a natural person who:
 - Bears the risk of loss and opportunity for profit; Bears the risk of loss and opportunity for profit;
 - Has final decision making authority over any material aspect of the operation of the Medical Marijuana Business;
 - Manages the overall operations of a Medical Marijuana Business or its Licensed Premises, or who manages a material portion of the Medical Marijuana Business or its Licensed Premises;

- d. Guarantees the Medical Marijuana Business' debts or production levels;
- e. Is a beneficiary of the Medical Marijuana Business' insurance policies;
- f. Receives the majority of the Medical Marijuana Business' profits as compared to other recipients of the Medical Marijuana Business' profits; or
- g. Acknowledges liability for the Medical Marijuana Business' federal, state or local taxes
- C. <u>Affiliated Interests</u>. A Medical Marijuana Business shall disclose all Affiliated Interests in connection with each application for licensure, renewal or reinstatement of the Medical Marijuana Business. The Division may conduct such background investigation as it deems appropriate regarding Affiliated Interests. An Affiliated Interest shall include any Person who does not hold a Financial Interest in the Medical Marijuana Business and who has any of the following relationships with the Medical Marijuana Business:
 - 1. The following Indirect Beneficial Interest Owners:
 - A Commercially Reasonable Royalty Interest Holder who receives 30 percent or less of the gross revenue or gross profit from sales of the product or line of products subject to the royalty;
 - b. A Profit Sharing Plan Employee; and
 - c. A Qualified Institutional Investor,
 - 2. Any other Person who holds any other disclosable interest in the Medical Marijuana Business other than a Financial Interest. Such disclosable interests shall include but shall not be limited to an indirect financial interest. a lease agreement, a secured or unsecured loan, or security interest in fixtures or equipment with a direct nexus to the cultivation, manufacture, sale, transportation, or testing of Medical Marijuana or Medical Marijuana Products. If the Division determines any Person disclosed as an Affiliated Interest should have been pre-approved as a Financial Interest, approval and further background investigation may be required. Additionally, the failure to seek pre-approval of a Financial Interest holder may form the basis for license denial or administrative action against the Medical Marijuana Business.
- D. <u>Secured Interest In Marijuana Prohibited</u>. No Person shall at any time hold a secured interest in Medical Marijuana or Medical Marijuana Products.

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(l), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-305, 12-43.3-310(7), and 12-43.3-310(13), and section 12-43.3-305, C.R.S. The purpose of this rule is to clarify the application process for changing location of a Licensed Premises.

M 206 - Changing Location of the Licensed Premises: Medical Marijuana Businesses

A. Application Required to Change Location of Licensed Premises

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- A Direct Beneficial Interest Owner or other authorized representative of a Medical Marijuana Business must make application to the Division for permission to change location of its Licensed Premises.
- 2. Such application shall:
 - a. Be made upon current forms prescribed by the Division;
 - b. Be complete in every material detail and include remittance of all applicable fees;
 - c. Be submitted at least 30 days prior to the proposed change;
 - d. Explain the reason for requesting such change;
 - e. Be supported by evidence that the application complies with any local licensing authority requirements; and
 - f. Contain a report of the relevant local licensing authority(-ies) in which the Medical Marijuana Business is to be situated, which report shall demonstrate the approval of the local licensing authority(-ies) with respect to the new location.

B. <u>Permit Required Before Changing Location</u>

- No change of location shall be permitted until after the Division considers the application, and such additional information as it may require, and issues to the Applicant a permit for such change.
- 2. The permit shall be effective on the date of issuance, and the Licensee shall, within 120 days, change the location of its business to the place specified therein and at the same time cease to operate a Medical Marijuana Business at the former location. At no time may a Medical Marijuana Business operate or exercise any of the privileges granted pursuant to the license in both locations. For good cause shown, the 120 day deadline may be extended for an additional 120 days. If the Licensee does not change the location of its business within the time period granted by the Division, including any extension, the Licensee shall submit a new application, pay the requisite fees and receive a new permit prior to completing any change of the location of the business.
- 3. The permit shall be conspicuously displayed at the new location, immediately adjacent to the license to which it pertains.

C. General Requirements

- An application for change of location to a different local licensing authority shall follow the same procedures as an application for a new Medical Marijuana Business license, except that licensing fees will not be assessed until the license is renewed. See Rule M 201 – Application Process.
- An Applicant for change of location within the same local licensing authority shall file a change of location application with the Division and pay the requisite change of location fee. See Rule M 207 - Schedule of Application Fees: Medical Marijuana Businesses.

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The statutory authority for this rule is found at subsections 12-43.3-202(1)(a), 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a), and 12-43.3-202(2)(a), and 12-43.3-202(2)(a), and sections 12-43.3-104, 12-43.3-104, 12-43.3-104, 12-43.3-104, 12-43.3-104, 12-43.3-104, 12-43.3-104, 12-43.3-104, and 12-43.3-104, and

M 210 - Schedule of Other Application Fees: All Licensees

- A. Other Application Fees. The following other application fees apply:
 - 1. Transfer of Ownership New Owners \$1,600.00
 - 2. Transfer of Ownership Reallocation of Ownership \$1,000.00
 - 3. Change of Corporation or LLC Structure \$800.00,
 - 4. Change of Trade Name \$50.00
 - 5. Change of Location Application Fee Same Local Jurisdiction Only \$500.00
 - 6. Modification of Licensed Premises \$100.00
 - 7. Duplicate Business License \$20.00
 - 8. Duplicate Occupational License \$20.00
 - 9. Off Premises Storage Permit \$1,500.00
 - 10. Medical Marijuana Transporter Off Premises Storage Permit \$2,200.00
 - 11. Responsible Vendor Program Provider Application Fee: \$850.00
 - 12. Responsible Vendor Program Provider Renewal Fee: \$350.00
 - 13. Responsible Vendor Program Provider Duplicate Certificate Fee: \$50.00
- B. When Other Application Fees Are Due. All other application fees are due at the time the application and/or request is submitted.
- C. Subpoena Fee See Rule M 106 Subpoena Fees

Basis and Purpose - M 231.1

The statutory authority for this rule is found at subsections 12-43.3-201(4), 12-43.3-202(1)(b)(l), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-310(4), 12-43.3-310(7), and 24-18-105(3), and sections 12-43.3-104, 12-43.3-307, 12-43.3-307.5, 12-43.3-313, 12-43.3-401, 24-76.5-101 et. seq, and, C.R.S. The purpose of this rule is to clarify the qualifications for Direct Beneficial Interest Owners.

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M 231.1 – Finding of Suitability, Residency and Reporting Requirements for Direct Beneficial Interest Owners

- A. <u>Finding of Suitability Non-Resident Direct Beneficial Interest Owners</u>. A natural person, owner, shareholder, director, officer, member or partner of an entity that intends to apply to become a Direct Beneficial Interest Owner who has not been a resident of Colorado for at least one year prior to the application shall first submit a request to the State Licensing Authority for a finding of suitability to become a Direct Beneficial Interest Owner as follows:
 - A request for a finding of suitability for a non-resident natural person shall be submitted on the forms prescribed by the State Licensing Authority.
 - A natural person or all owners, shareholders, directors, officers, members or partners of
 an entity who have not been a resident of Colorado for at least one year shall obtain a
 finding of suitability prior to submitting an application to become a Direct Beneficial
 Interest Owner to the State Licensing Authority.
 - 3. A finding of suitability is valid for one year from the date it is issued by the Division. If more than one year has passed since the Division issued a finding of suitability to a natural person, owner, shareholder, director, officer, member or partner of an entity that intends to apply to become a Direct Beneficial Interest Owner who has not been a resident of Colorado for at least one year prior to the application, then such applicant shall submit a new request for a finding of suitability to the State Licensing Authority and obtain a new finding of suitability before submitting any application to become a Direct Beneficial Interest Owner to the State Licensing Authority.
 - A non-Colorado resident's failure to obtain a finding of suitability within the year prior to submission of an application to become a Direct Beneficial Interest Owner to the State Licensing Authority shall be grounds for denial of the application.

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- B. <u>Number of Permitted Direct Beneficial Interest Owners.</u>
 - A Medical Marijuana Business may be comprised of an unlimited number of Direct Beneficial Interest Owners that have been residents of Colorado for at least one year prior to the date of the application.
 - 2. On and after January 1, 2017, a Medical Marijuana Business that is comprised of one or more Direct Beneficial Interest Owners who have not been Colorado residents for at least one year is limited to no more than fifteen Direct Beneficial Interest Owners, each of whom is a natural person. Further, a Medical Marijuana Business that is comprised of one or more Direct Beneficial Interest Owners who have not been Colorado residents for at least one year shall have at least one officer who is a Colorado resident. All officers with day-to-day operational control over a Medical Marijuana Business must be Colorado residents for at least one year, must maintain their Colorado residency during the period while they have day-to-day operational control over the Medical Marijuana Business and shall be licensed as required by the Medical Code. Rule 231 Qualifications for Licensure and Residency: Individuals.
- C. <u>Notification of Change of Residency.</u> A Medical Marijuana Establishment with more than fifteen Direct Beneficial Interest Owners shall provide thirty days prior notice to the Division of any Direct Beneficial Interest Owners' intent to change their residency to a residency outside Colorado. A Medical Marijuana Business with no more than fifteen Direct Beneficial Interest Owners shall notify the Division of the change of residency of any Direct Beneficial Interest Owner at the time of its license renewal. Failure to provide timely notice pursuant to this rule may lead to

administrative action against the Medical Marijuana Business and its Direct Beneficial Interest Owners.

D. A Direct Beneficial Interest Owner shall not be a publicly traded company.

M 304 [REPEALED]

Basis and Purpose - M 304.1

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I)(A)-(F), 12-43.4-104(1)(a)(V), 12-43.4-202(2)(b), 12-43.4-401(2), and 12-43.4-404(2), C.R.S. and sections 12-43.3-406, 12-43.4-405 and 12-43.4-406, 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 Licensed Retail Marijuana Establishment, and to ensure the proper separation of a Medical Marijuana Business operation from Retail Marijuana Establishment operation.

M 304.1 – Medical Marijuana Business and Retail Marijuana Establishment – Shared Licensed Premises and Operational Separation

- A. Co-Located Medical Marijuana Centers and Retail Marijuana Stores
 - Medical Marijuana Center that does not authorize patients under the age of 21. A Medical
 Marijuana Center that prohibits Medical Marijuana patients under the age of 21 years
 from being 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 Center and Retail Marijuana Store are commonly owned;
 - c. The Medical Marijuana Center and Retail Marijuana Store shall maintain physical or virtual separation between (i) Medical Marijuana, Medical Marijuana-Infused Products and other inventory and (ii) Retail Marijuana, Retail Marijuana Products and other inventory;
 - d. The Medical Marijuana Center and Retail Marijuana Store shall maintain separate displays between (i) Medical Marijuana, Medical Marijuana-Infused Products and other inventory and (ii) Retail Marijuana, Retail Marijuana Products and other inventory, but the displays may be on the same sale floor.
 - e. Record-keeping, inventory tracking, packaging and labeling for the Medical

 Marijuana Center and Retail Marijuana Store shall enable the Division and local
 licensing authority to clearly distinguish the inventories and business transactions
 of the Medical Marijuana Center from the inventories and business transactions
 of the Retail Marijuana Store.; and
 - f. The Medical Marijuana Center shall post and maintain signage that clearly conveys that persons under the age of 21 years may not enter.:
 - Medical Marijuana Center that authorizes patients under the age of 21. A Medical Marijuana Center that authorizes Medical Marijuana patients under the age of 21 years to be on the premises may operate in the same location with a Retail Marijuana Store under the following conditions:
 - The relevant local licensing authority and local jurisdiction permit a dual operation at the same location:

- b. The Medical Marijuana Center and the Retail Marijuana Store are commonly owned;
- The Medical Marijuana Center and the Retail Marijuana Store maintain physical separation, including separate entrances and exits, between all portions of the Licensed Premises where sales occur;
- d. No point of sale operations occur at any time outside the physically separated Licensed Premises;
- e. All Medical Marijuana and Medical Marijuana-Infused Product in a Restricted
 Access Area must be physically separated from all Retail Marijuana and Retail
 Marijuana Product in a Restricted Access Area, and such physical separation
 must include separate entrances and exits;
- f. Any display shall be located in the physically separated sales The Medical Marijuana Center and Retail Marijuana Store must occur in portions of the Licensed Premises where sales occur:
- g. In addition to the physically separated sales and display areas, the Medical Marijuana Center and Retail Marijuana Store shall maintain physical or virtual separation for storage of Medical Marijuana, Medical Marijuana-Infused Products and other inventory from storage of Retail Marijuana, Retail Marijuana Products and other inventory; and
- h. Record-keeping, inventory tracking, packaging and labeling for the Medical

 Marijuana Center and Retail Marijuana Store shall enable the Division and local
 licensing authority to clearly distinguish the inventories and business transactions
 of the Medical Marijuana Center from the inventories and business transactions
 of the Retail Marijuana Store.
- B. Co-located Optional Premises Cultivation Operation and Retail Marijuana Cultivation Facility. An Optional Premises Cultivation Operation and a Retail Marijuana Cultivation Facility may share a single Licensed Premises and operate at the same location under the following circumstances:
 - The relevant local licensing authority and local jurisdiction permit a dual operation at the same location;
 - The Optional Premises Cultivation Operation and the Retail Marijuana Cultivation Facility are commonly owned;
 - 3. The co-located Optional Premises Cultivation Operation and Retail Marijuana Cultivation
 Facility shall maintain either physical or virtual separation between Medical Marijuana
 and Retail Marijuana; and
 - 4. Record keeping, inventory tracking, packaging and labeling for the Optional Premises Cultivation Operation and Retail Marijuana Cultivation Facility must enable the Division and relevant local licensing authority to clearly distinguish the inventories and business transactions of the Optional Premises Cultivation Operation from the Retail Marijuana Cultivation Facility.
- C. Co-located Medical Marijuana-Infused Products Manufacturer and Retail Marijuana Products

 Manufacturer. A Medical Marijuana-Infused Products Manufacturer and a Retail Marijuana

<u>Products Manufacturing Facility may share a single Licensed Premises and operate at the same</u> location under the following circumstances:

- The relevant local licensing authority and local jurisdiction permit a dual operation at the same location;
- The Medical Marijuana-Infused Products Manufacturer and the Retail Marijuana Products
 Manufacturing Facility are commonly owned;
- 3. The Medical Marijuana-Infused Products Manufacturer and Retail Marijuana Products
 Manufacturing Facility shall maintain either physical or virtual separation between (i)
 Medical Marijuana, Medical Marijuana-Infused Products and other inventory and (ii)
 Retail Marijuana, Retail Marijuana Products and other inventory; except that nothing in
 this rule prohibits a co-located Retail Marijuana Establishment and Medical Marijuana
 Business from sharing raw ingredients in bulk, for example flour or sugar, except that
 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-Infused Products Manufacturer and Retail Marijuana Products Manufacturing Facility must enable the Division and local licensing authority to clearly distinguish the inventories and business transactions of the Medical Marijuana-Infused Product Manufacturer from the Retail Marijuana Product Manufacturing Facility.
- D. Co-located Medical Marijuana Testing Facility and Retail Marijuana Products Manufacturer. 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:
 - The relevant local licensing authority and local licensing jurisdiction permit dual operation at the same location;
 - The Medical Marijuana Testing Facility and Retail Marijuana Products Manufacturer 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-Infused Products and other inventory and (ii) Retail Marijuana, Retail Marijuana Products and other 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 to clearly distinguish the inventories and business transactions of the Medical Marijuana Testing Facility from the Retail Marijuana Testing Facility.
- E. Co-Located 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:
 - The relevant local licensing authority and local licensing jurisdiction permit dual operation at the same location;
 - The Medical Marijuana Transporter and Retail Marijuana Transporter are identically owned;

- The Medical Marijuana Transporter and Retail Marijuana Transporter shall maintain
 either physical or virtual separation between (i) Medical Marijuana, Medical Marijuana Infused Products and other inventory and (ii) Retail Marijuana, Retail Marijuana Products
 and other 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 to clearly distinguish the inventories and business transactions of the Medical Marijuana Transporter from the Retail Marijuana Transporter.
- F. Violation of this rule may be considered a license violation affecting public safety.

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(X), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to ensure adequate control of the Licensed Premises and the Medical Marijuana and Medical Marijuana-Infused Product contained therein. This rule also establishes the minimum guidelines for security requirements for alarm systems, and commercial locking mechanisms for maintaining adequate security.

M 305 - Security Alarm Systems and Lock Standards

- A. <u>Security Alarm Systems Minimum Requirements</u>
 - Each Licensed Premises shall have a Security Alarm System, installed by an Alarm Installation Company, on all perimeter entry points and perimeter windows.
 - 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.
 - The Licensees 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 M 901 – Business Records Required.
 - 4. Upon request, Licensees shall make available to agents of the Division or relevant local licensing authority or other state or local law enforcement agency, for a purpose authorized by the Medical Code or any other state or local law enforcement purpose, all information related to Security Alarm Systems, Monitoring, and alarm activity.
 - 5. Any outdoor Optional Premises Cultivation Facility, or greenhouse cultivation, is a Limited Access Area and must meet all of the requirements for Security Alarm Systems described in this rule. An outdoor or greenhouse Optional Premises 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 an Optional Premises Cultivation Facility located in an indoor Licensed Premises so it can be fully secured and alarmed. The fencing requirements shall, at a minimum include, perimeter fencing designed to prevent the general public from entering the Limited Access Areas that meets at least the following requirements:

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The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I)(A)-(F), 12-43.4-104(1)(a)(V), 12-43.4-202(2)(b), 12-43.4-401(2), and 12-43.4-404(2), C.R.S. and sections 12-43.3-406, 12-43.4-405 and 12-43.4-406, 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 Licensed Retail Marijuana Establishment, and to ensure the proper separation of a Medical Marijuana Business operation from Retail Marijuana Establishment operation.¶

M 304 – Medical Marijuana Business and Retail Marijuana Establishment – Shared Licensed Premises and Operational Separation¶

- A. Licensed Premises General Requirements¶
 1. A Medical Marijuana Center that prohibits patients under the age of 21 years to be on the Licensed Premises may also hold a Retail Marijuana Store license and operate a dual retail business operation on the same Licensed Premises if the relevant local licensing authority permits a dual operation at the same location and the two are commonly owned.¶
- 2. A Medical Marijuana Center that authorizes medical marijuana patients under the age of 21 years to be on the premises is prohibited from sharing its Licensed Premises with a Retail Marijuana Establishment. Even when the two are commonly owned, the two shall maintain distinctly separate Licensed Premises; including, but not limited to, separate sales and storage areas, separate entrances and exits, separate inventories, separate point-of-sale operations, and separate record-keeping.¶
- 3. An Optional Premises Cultivation Operation and a Retail Marijuana Cultivation Facility may share a single Licensed Premises in order to operate a dual cultivation business operation, if the relevant licensing authority permits a dual operation at the same location and the two are commonly owned.
- 4. A Medical Marijuana-Infused Products
 Manufacturer Business Licensee and a Retail
 Marijuana Products Manufacturing Facility may share a
 single Licensed Premises to operate a dual
 manufacturing business operation, if the relevant local
 licensing authority permits a dual operation at the same
 location and the two are commonly owned.¶
- 5. A Medical Marijuana Testing Facility Licensee and a Retail Marijuana Testing Facility Licensee may share a single Licensed Premises to operate a dual testing business operation at the same location if the relevant local licensing authority permits dual operation at the same location and the two are identically owned.
- 6. A Medical Marijuana Transporter Licensee and a Retail Marijuana Transporter Licensee may share a single Licensed Premises to operate a dual ... [1]

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- a. The fencing material shall be metal chain link of heavy gauge thickness or another similarly secure material but may not be wood. All support polls shall be steel and securely anchored.
 - b. The fence must measure at least 8 feet from the ground to the top of the fence.
 - All entry gates must measure at least 8 feet from the ground to the top of the
 entry gate and shall be constructed of metal chain link of a heavy gauge
 thickness or a similarly secure material but may not be wood.

B. <u>Lock Standards – Minimum Requirement</u>

- At all points of ingress and egress, the Licensee shall ensure the use of a commercialgrade, non-residential door locks.
- Any outdoor Optional Premises Cultivation Facility, or greenhouse cultivation, must meet all of the requirements for the lock standards described in this rule.

Basis and Purpose - M 306

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(X), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to ensure adequate control of the Licensed Premises and the Medical Marijuana and Medical Marijuana-Infused Product contained therein. This rule also establishes the minimum guidelines for security requirements for video surveillance systems for maintaining adequate security.

Basis and Purpose - M 307

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XII), 12-43.3-202(1)(b)(XV), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to establish sanitary requirements for Medical Marijuana Businesses.

M 307 - Waste Disposal

- A. <u>All Applicable Laws Apply</u>. Medical Marijuana and Medical Marijuana-Infused Product waste must be stored, secured and managed in accordance with all applicable state and local statutes, regulations, ordinances or other requirements.
- B. <u>Liquid Waste</u>. Liquid waste from Medical Marijuana Businesses shall be disposed of in compliance all applicable federal, state and local laws, regulations, rules and other requirements.
- C. <u>Chemical, Dangerous and Hazardous Waste</u>. Disposal of chemical, dangerous or hazardous waste must be conducted in a manner consistent with federal, state and local laws, regulations, rules or other requirements. This may include, but is not limited to, the disposal of all Pesticide or other chemicals used in the cultivation process, certain solvents or other chemicals used in the production of Medical Marijuana Concentrate or any Medical Marijuana soaked in a Flammable Solvent for purposes of producing a Medical Marijuana Concentrate.
- D. <u>Waste Must Be Made Unusable and Unrecognizable</u>. Medical Marijuana and Medical Marijuana-Infused Product waste must be made unusable and Unrecognizable prior to leaving the Licensed Premises.

- E. <u>Methods to Make Waste Unusable and Unrecognizable</u>. Medical Marijuana and Medical Marijuana-Infused Product waste shall be rendered unusable and Unrecognizable through one of the following methods:
 - Grinding 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:
 - 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

Other wastes approved by the State Licensing Authority that will render the Medical Marijuana and Medical Marijuana-Infused Product waste unusable and Unrecognizable as marijuana,

- F. <u>After Waste is Made Unusable and Unrecognizable</u>. After the Medical Marijuana and Medical Marijuana-Infused Product waste is made unusable and Unrecognizable, then the rendered waste shall be:
 - Disposed of at a solid waste site and disposal facility that has a Certificate of Designation from the local governing body;
 - Deposited at a compost facility that has a Certificate of Designation from the Department of Public Health and Environment, if required; or
 - 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 Department of Public Health and Environment.
- G. <u>Proper Disposal of Waste</u>. A Licensee shall not dispose of Medical Marijuana and Medical Marijuana-Infused Product waste in an unsecured waste receptacle not in possession and control of the Licensee.
- H. <u>Inventory Tracking Requirements</u>
 - 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 materials are identified, weighed and tracked while on the Licensed Premises until disposed of.
 - All Medical Marijuana waste must be weighed before leaving any Medical Marijuana Business. A scale used to weigh Medical Marijuana waste prior to entry into the Inventory

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Tracking System shall be tested and approved in accordance with 35-14-127, C.R.S. See Rule M 309 – Medical Marijuana Business: Inventory Tracking System.

- 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 Marijuana. See Rule M 901 – 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 Medical Marijuana plant prior to harvest, which must include weighing and documenting all waste. Unless required by an Inventory Tracking System procedure, records of waste produced prior to harvest must be maintained on the Licensed Premises. All waste, whether produced prior or subsequent to harvest, must be disposed of in accordance with this rule and be made unusable and unrecognizable.

Basis and Purpose - M 309

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX), 12-43.3-403(2), and 12-43.4-104(1)(a)(III) 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 Medical Marijuana and Medical Marijuana-Infused Product from either seed or immature plant stage until the Medical Marijuana or Medical Marijuana-Infused Product is sold to the patient 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 Medical Marijuana or Medical Marijuana-Infused Product. Through the use of RFID technology, an Optional Premises Cultivation facility will tag either the seed or immature plant with an individualized number which will follow the Medical Marijuana through all phases of production and final sale to a patient. This will allow the State Licensing Authority and the Inventory Tracking System user the ability to monitor and track Medical Marijuana and Medical Marijuana-Infused Product. 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 Medical Marijuana and Medical Marijuana-Infused Product to eliminate diversion, inside and outside of the state, and to ensure that all marijuana grown, processed, sold and disposed of in the Medical Marijuana market is transparently accounted for. An existing Medical Marijuana Business must have an active and functional Inventory Tracking System account on or before December 31, 2013 or it may not excise the privileges of its license.

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 Medical Marijuana inventory.

M 309 - Medical Marijuana Business: Inventory Tracking System

- A. Inventory Tracking System Required. A Medical Marijuana Business is required to use the Inventory Tracking System as the primary inventory tracking system of record. A Medical Marijuana Business without an Inventory Tracking System account that is activated and functional shall not operate or exercise any privileges of a license. Medical Marijuana Businesses converting to or adding a Retail Marijuana Establishment must follow the inventory transfer guidelines detailed in Rule R 309 (D) below.
- B. <u>Inventory Tracking System Access Inventory Tracking System Administrator</u>

- Inventory Tracking System Administrator Required. A Medical Marijuana Business must have at least one individual Owner who is an Inventory Tracking System Administrator. A Medical Marijuana Business may also designate additional Owners and occupationally licensed employees to obtain Inventory Tracking System Administrator accounts.
- 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.
- C. Inventory Tracking System Access Inventory Tracking System User Accounts. A Medical Marijuana Business may designate licensed Owners and employees who hold a valid Occupational License as an Inventory Tracking System User. A Medical Marijuana Business shall ensure that all Owners and Occupational 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.
- Medical Marijuana Business License Conversions Declaring Inventory Prior to Exercising Licensed Privileges as a Medical Marijuana Business
 - 1. Medical Marijuana Inventory Transfer to Retail Marijuana Establishments.
 - a. This rule M 309(D)(1)(a) is repealed effective July 1, 2016. Prior to July 1, 2016, each Medical Marijuana Business that is either converting to or adding a Retail Marijuana Establishment license must create a Retail Marijuana Inventory Tracking System account for each license it is converting or adding. A Medical Marijuana Business must transfer all relevant Medical Marijuana inventory into the Retail Marijuana Establishment's Inventory Tracking System account and affirmatively declare those items as Retail Marijuana and Retail Marijuana Product.
 - b. Beginning July 1, 2016:
 - i. The the only allowed transfer of marijuana between a Medical Marijuana Business and Retail Marijuana Establishment is Medical Marijuana and Medical Marijuana Concentrate that was produced at the Optional Premises Cultivation Operation, from the Optional Premises Cultivation Operation to a Retail Marijuana Cultivation Facility.
 - ii. Each Optional Premises Cultivation Operation 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. An Optional Premises Cultivation Operation 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 Establishment.
- v. All other transfers are prohibited, including but not limited to transfers from a Medical Marijuana Center or Medical Marijuana-Infused Products Manufacturer to any Retail Marijuana Establishment.
- 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.

E. RFID Tags Required

- Authorized Tags Required and Costs. Licensees are required to use RFID tags issued by a Division-approved vendor that is authorized to provision RFID tags for the Inventory Tracking System. Each licensee is responsible for the cost of all RFID tags and any associated vendor fees.
- 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 Medical
 Marijuana Business must ensure it has an adequate supply of RFID tags to properly tag
 Medical Marijuana and Medical Marijuana-Infused Product as required by the Inventory
 Tracking System. An RFID tag must be physically attached to every plant being cultivated
 that is greater than four inches all or four inches wide. An RFID tag must be assigned to
 all Finished Marijuana, Medical Marijuana Concentrate and Medical Marijuana-Infused
 Product. See also M 801(G.5) Required RFID Tags; M 1007-1(H) Shipping
 Containers.

 Reuse of RFID Tags Prohibited. A Licensee shall not reuse any RFID tag that has already been affixed or assigned to any Finished Marijuana, Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product.

F. General Inventory Tracking System Use

 Reconciliation with Inventory. All inventory tracking activities at a Medical Marijuana Business must be tracked through use of the Inventory Tracking System. A Licensee must reconcile all on-premises and in-transit Medical Marijuana and Medical Marijuana-Infused Product inventories each day in the Inventory Tracking System at the close of business

Common Weights and Measures.

- A Medical Marijuana Business must utilize a standard of measurement that is supported by the Inventory Tracking System to track all Medical Marijuana and Medical Marijuana-Infused Product.
- A scale used to weigh such product prior to entry into the Inventory Tracking System shall be tested and approved in accordance with 35-14-127, C.R.S.
- 3. <u>Inventory Tracking System Administrator and User Accounts Security and Record</u>
 - A Medical Marijuana Business shall maintain an accurate and complete list of all Inventory Tracking System Administrators and Inventory Tracking System Users

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for each Licensed Premises. A Medical Marijuana Business shall update this list when a new Inventory Tracking System User is trained. A Medical 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 Medical 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.
- A Medical Marijuana Business is accountable for all actions employees take while logged into the Inventory Tracking System or otherwise conducting Medical Marijuana or Medical Marijuana-Infused Product 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 Medical Marijuana or Medical Marijuana-Infused Product inventory tracking activities, and must maintain compliant with all relevant laws.

4. <u>Secondary Software Systems Allowed</u>

- Nothing in this rule prohibits a Medical 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.
- 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 Medical Marijuana Business must preserve original Inventory Tracking System data when transferred to and from a secondary application(s). Secondary software applications must use Inventory Tracking System data as the primary source of data and must be compatible with updating to the Inventory Tracking System.

G. Conduct While Using Inventory Tracking System

- Misstatements or Omissions Prohibited. A Medical 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 Medical 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.
- <u>Use of Another User's Login Prohibited</u>. Individuals entering data into the Inventory Tracking System shall only use that individual's Inventory Tracking System account.
- Loss of System Access. If at any point a Medical Marijuana Business loses access to the Inventory Tracking System for any reason, the Medical Marijuana Business must keep and maintain comprehensive records detailing all Medical Marijuana and Medical Marijuana-Infused Product tracking inventory activities that were conducted during the loss of access. See Rule M 901 – Business Records Required. Once access is restored,

all Medical Marijuana and Medical Marijuana-Infused Product inventory tracking activities that occurred during the loss of access must be entered into the Inventory Tracking System. A Medical Marijuana Business must document when access to the system was lost and when it was restored. A Medical Marijuana Business shall not transport any Medical Marijuana or Medical Marijuana-Infused Product to another Medical Marijuana Business until such time as access is restored and all information is recorded into the Inventory Tracking System.

H. System Notifications

- Compliance Notifications. A Medical 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 Medical Marijuana Business resolves the compliance issues detailed in the notification.
- Informational Notifications. A Medical 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.
- 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.
- J. <u>Inventory Tracking System Procedures Must Be Followed</u>. A Medical Marijuana Business must utilize the Inventory Tracking System in conformance with these rules and Inventory Tracking System procedures, including but not limited to:
 - Properly indicating the creation of a Production Batch including the assigned Production
 Batch Number:
 - 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;
 - Properly indicating that a Test Batch is being used as part of achieving process validation;
 - Accurately indicting the METRC category for all Medical Marijuana, Medical Marijuana
 Concentrate and Medical Marijuana-Infused Product; and
 - Accurately including a note explaining the reason for any destruction of plants or adjustment of weights to Inventory Tracking System packages.

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The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I)(A)-(F), 12-43.4-104(1)(a)(V), 12-43.4-202(2)(b), 12-43.4-401(2), and 12-43.4-404(2), C.R.S. and sections 12-43.3-406, 12-43.4-405 and 12-43.4-406, 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 Licensed Retail Marijuana Establishment, and to ensure the proper separation of a Medical Marijuana Business operation from Retail Marijuana Establishment operation.

M 304 – Medical Marijuana Business and Retail Marijuana Establishment – Shared Licensed Premises and Operational Separation

A. Licensed Premises – General Requirements[RH1]

- A Medical Marijuana Center that prohibits patients under the age of 21 years to be on the Licensed Premises may also hold a Retail Marijuana Store license and operate a dual retail business operation on the same Licensed Premises if the relevant local licensing authority permits a dual operation at the same location and the two are commonly owned.
- 2. A Medical Marijuana Center that authorizes medical marijuana patients under the age of 21 years to be on the premises is prohibited from sharing its Licensed Premises with a Retail Marijuana Establishment. Even when the two are commonly owned, the two shall maintain distinctly separate Licensed Premises; including, but not limited to, separate sales and storage areas, separate entrances and exits, separate inventories, separate point-of-sale operations, and separate record-keeping.
- 3. An Optional Premises Cultivation Operation and a Retail Marijuana Cultivation Facility may share a single Licensed Premises in order to operate a dual cultivation business operation, if the relevant licensing authority permits a dual operation at the same location and the two are commonly owned.
- 4. A Medical Marijuana-Infused Products Manufacturer Business Licensee and a Retail Marijuana Products Manufacturing Facility may share a single Licensed Premises to operate a dual manufacturing business operation, if the relevant local licensing authority permits a dual operation at the same location and the two are commonly owned.
- 5. A Medical Marijuana Testing Facility Licensee and a Retail Marijuana Testing Facility Licensee may share a single Licensed Premises to operate a dual testing business operation at the same location if the relevant local licensing authority permits dual operation at the same location and the two are identically owned.
- 6. A Medical Marijuana Transporter Licensee and a Retail Marijuana Transporter Licensee may share a single Licensed Premises to operate a dual transporting, logistics, and temporary storage business operation at the same location if the relevant local licensing authority permits dual operation at the same location and the two are identically owned.

B. <u>Separation of Co-located Licensed Operations</u>

1. <u>Cultivation Operations</u>. A Person operating an Optional Premises Cultivation Operation and a Retail Marijuana Cultivation Facility shall maintain either physical or virtual separation of the facilities, marijuana plants, and marijuana inventory. Record keeping for the business operations and labeling of products must enable the Division and relevant

local licensing authority to clearly distinguish the inventories and business transactions of Medical Marijuana Business from the Retail Marijuana Establishment.

- 2. <u>Manufacturing Operations</u>. A Person operating a Medical Marijuana-Infused Products Manufacturer Business and Retail Marijuana Products Manufacturing Facility shall maintain either physical or virtual separation of the facilities, product ingredients, product manufacturing, and final product inventory. Record keeping for the business operations and labeling of products must enable the Division and local licensing authority to clearly distinguish the inventories and business transactions of Medical Marijuana-Infused Product from Retail Marijuana Product.
- 3. Raw Ingredients May Be Shared. Nothing in this rule prohibits a co-located Retail Marijuana Establishment and Medical Marijuana Business from sharing raw ingredients in bulk, for example flour or sugar, except that Retail Marijuana and Medical Marijuana may not be shared under any circumstances.
- 4. Retail Store and Medical Center Operations: No Patients Under The Age of 21 Years. Persons operating a Medical Marijuana Center that specifically prohibits the admittance of patients under the age of 21 years and a Retail Marijuana Store may share their Licensed Premises. Such a Medical Marijuana Center Licensee must post signage that clearly conveys that persons under the age of 21 years may not enter. Under these circumstances and upon approval of the State Licensing Authority, the Medical Marijuana Center and the Retail Marijuana Store may share the same entrances and exits. Also under these circumstances, Medical Marijuana and Retail Marijuana and Medical Marijuana-Infused Product and Retail Marijuana Product must be separately displayed on the same sale floor. Record keeping for the business operations of both must allow the Division and relevant local licensing authority to clearly distinguish the inventories and business transactions of Medical Marijuana and Medical Marijuana-Infused Product from Retail Marijuana and Retail Marijuana Product. Violation of the restrictions in this rule by co-located Medical Marijuana Centers and Retail Marijuana Establishments may be considered a license violation affecting public safety.
- 5. Retail Stores and Medical Marijuana Centers: Patients Under The Age of 21 Years. A colocated Medical Marijuana Center and Retail Marijuana Store shall maintain separate Licensed Premises, including entrances and exits, inventory, point of sale operations, and record keeping if the Medical Marijuana Center serves patients under the age of 21 years or permits admission of patients under the age of 21 years on its premises.
- 6. <u>Testing Facilities</u>. A co-located Medical Marijuana Testing Facility and Retail Marijuana Testing Facility shall maintain either physical or virtual separation of the facilities and marijuana and products being tested. Record keeping for the business operations and labeling of products must enable the Division and local licensing authority to clearly distinguish the inventories and business transactions of Medical Marijuana and Medical Marijuana-Infused Product and Retail Marijuana and Retail Marijuana Product.
- 6.1. Transporters. A co-located Medical Marijuana Transporter and Retail Marijuana Transporter shall maintain either physical or virtual separation of the facilities and Medical Marijuana, Medical Marijuana-Infused Products, Retail Marijuana, and Retail Marijuana Products being transported and stored. Record keeping for the business operations and storage of products must enable the Division and local licensing authority to clearly distinguish the inventories and business transactions of Medical Marijuana and Medical Marijuana-Infused Product and Retail Marijuana and Retail Marijuana Product.
- 7. <u>Clear Separation of Inventory</u>. A Person who operates both a Medical Marijuana Business and Retail Marijuana Establishment within one location is required to maintain separate and distinct inventory tracking processes for Medical and Retail Marijuana

inventories. The inventories must be clearly tagged or labeled so that the products can be reconciled to a particular Medical Marijuana Business or a Retail Marijuana Establishment.

M 400 Series - Medical Marijuana Centers

Basis and Purpose - M 401

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I)(A-F),12-43.3-310(7), 12-43.3-310(4), and sections 12-43.3-402 and 12-43.3-406, C.R.S. The purpose of this rule is to establish that it is unlawful for a Medical Marijuana Center Licensee to exercise any privileges other than those granted by the State Licensing Authority, and to clarify the license privileges.

M 401 - Medical Marijuana Center: License Privileges

- Privileges Granted. A Medical Marijuana Center shall only exercise those privileges granted to it by the State Licensing Authority.
- B. <u>Licensed Premises</u>. To the extent authorized by Rule M 304 Medical Marijuana Business and Retail Marijuana Establishment Shared Licensed Premises and Operational Separation, a Medical Marijuana Center may share a location with a commonly-owned Retail Marijuana Store. However, a separate license is required for each specific business or business entity, regardless of geographical location.
- C. <u>Authorized Sources of Medical Marijuana</u>. A Medical Marijuana Center may only sell Medical Marijuana that it has purchased from another Medical Marijuana Center or that the center has cultivated itself, after first obtaining an Optional Premises Cultivation Operation License. See Rule M 501 Optional Premises Cultivation Operation: License Privileges.

D. <u>Authorized Sources of Medical Marijuana-Infused Product Inventory.</u> A Medical Marijuana Center may sell Medical Marijuana-Infused Product that it has purchased from a Medical Marijuana-Infused Products Manufacturer, so long as each product are pre-packaged and labeled upon purchase from the manufacturer.

- E. <u>Samples Provided for Testing</u>.
 - 1. Repealed.
 - 1.5. A Medical Marijuana Center may provide Samples of its products to a Medical Marijuana Testing Facility for testing and research purposes. The Medical Marijuana Center shall maintain the testing results as part of its business books and records. See Rule M 901 – Business Records Required.
- F. <u>Authorized On-Premises Storage</u>. A Medical Marijuana Center 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.
- G. Authorized Marijuana Transport. A Medical Marijuana Center is authorized to utilize a licensed Medical Marijuana Transporter for transportation of its Medical Marijuana and Medical Marijuana-Infused Product 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 Center from transporting its own Medical Marijuana and Medical Marijuana-Infused Product.

Basis and Purpose - M 402

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The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(1), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-310(7), and 12-43.3-310(4), C.R.S. The purpose of this rule is to establish that a Medical Marijuana Center can only grow Medical Marijuana in its Optional Premises Cultivation Operation for a patient that has designated that Medical Marijuana Center as being his or her primary center. The rule also helps to ensure that Medical Marijuana plants designated to a particular patient are only being grown at one Medical Marijuana Center.

M 402 - Registration of a Primary Medical Marijuana Center

- A. Patient Designation Required. A Medical Marijuana Center may possess only the amount of Medical Marijuana and number of plants permitted by Rule M 403(A.5) for each patient who has designated the Medical Marijuana Center as being his or her primary center. A patient's designation of a Medical Marijuana Center as his or her primary center in accordance with these Rules establishes the center registration requirements set forth in sections 12-43.3-901(4)(e), and 25-1.5-106(8)(f), C.R.S.
- B. Change Only Allowed Every 30 Days. A Medical Marijuana Center shall not register a patient as being the patient's primary center if the patient has designated another Medical Marijuana Center as his or her primary center in the preceding 30 days. The Medical Marijuana Center and its employees must require a patient to sign in writing that he or she has not designated another Medical Marijuana Center as his or her primary center before growing Medical Marijuana plants on behalf of the patient.
- C. <u>Required Questions</u>. A Medical Marijuana Center must maintain a written record of the following questions and their answers at the time a patient indicates a desire to designate said center as his or her primary center:
 - 1. Questions to the patient:
 - a. Which Medical Marijuana Center is currently the patient's primary center; and
 - How many plants is the patient's current primary center is cultivating for that patient.
 - Questions to the current primary center:
 - a. How many plants is the Medical Marijuana Center cultivating for the patient; and
 - b. How many of the patient's plants has the Medical Marijuana Center harvested.
- D. <u>Documents Required.</u> The new primary center shall maintain written authorization from the patient and any relative plant count waivers to support the number of plants designated for that patient and copies of the patient's registry card and proof of identification. See also Rule M 901 Business Records Required.
- E. <u>Violation of Public Safety</u>. Notwithstanding the provisions in M 402 (B), it may be considered a violation of public safety for a Medical Marijuana Center and its employees to become a patient's primary center when the patient already had designated one or more other Medical Marijuana Centers as his or her primary center.

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Basis and Purpose - M 403

The statutory authority for this rule is found at subsections 12-43.3-103(2)(b), 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-310(7), 12-43.3-310(4), 12-43.4-401(4) and sections 12-43.3-402 and 12-43.3-406, 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 Center. This rule also restricts the amount of its inventory a Medical Marijuana Center may sell to other Medical Marijuana Businesses to 30 percent.

The quantity limitations on sales provision is intended to inform stakeholders in order to aid in compliance with a patient's lawful medical marijuana limit. Clarifying the quantity limitations on sales provides Medical Marijuana Centers 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).

M 403 - Medical Marijuana Sales: General Limitations or Prohibited Acts

- A. 30 Percent Rule. Pursuant to section 12-43.3-402(4), C.R.S., a Medical Marijuana Center may purchase not more than thirty percent of its total on-hand medical marijuana inventory from another licensed Medical Marijuana Center in Colorado. A Medical Marijuana Center may sell no more than thirty percent of its total on-hand Medical Marijuana inventory to another Medical Marijuana Center.
 - a. Total on-hand inventory as used in section 12-43.3-402(4), C.R.S., means the total amount of Medical Marijuana that a Medical Marijuana Center received from its dedicated Optional Premises Cultivation Operation and any other Medical Marijuana Center in the preceding twelve months.
 - A Medical Marijuana Center may apply for a temporary waiver from the requirements set forth in this rule and section 12-43.3-402(4), C.R.S. under the following circumstances:
 - A Medical Marijuana Center that suffers a catastrophic event related to its total on-hand inventory; examples of a catastrophic event include, but are not limited to: blight, crop failure, crop contamination, or natural disasters; or
 - To a new Medical Marijuana Center Licensee for a period not to exceed ninety days from the commencement of the first cultivation activities.
- A.5 On-hand Inventory. For purposes of section 12-43.3-901(4)(e), C.R.S., a Medical Marijuana

 Center may possess both six (6) Medical Marijuana plants and two (2) ounces of Medical

 Marijuana for each patient who has registered the Medical Marijuana Center as his or her primary

 Medical Marijuana Center.
 - A Medical Marijuana Center may exceed the six (6) Medical Marijuana plant and two (2) ounces of Medical Marijuana per-patient limits for patients registered with the Medical Marijuana Center who are authorized to exceed the six (6) Medical Marijuana plant and two (2) ounces of Medical Marijuana limits.
 - A Medical Marijuana Center shall not exceed the six (6) Medical Marijuana plant and two
 (2) ounces of Medical Marijuana per-patient limits unless it obtains and maintains documentation from the registered patient's physician authorizing the patient to exceed the six (6) Medical Marijuana plant and two (2) ounces of Medical Marijuana limits.

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- c. A Medical Marijuana Center shall not possess under any circumstance Medical Marijuana plants and Medical Marijuana in excess of the total amount of Medical Marijuana plants and Medical Marijuana that its registered patients are authorized to possess.
- d. Finished Marijuana Jocated at the Medical Marijuana Center's dedicated Optional
 Premises Cultivation Operation shall count as on-hand inventory of the Medical
 Marijuana Center
- B. Medical Marijuana-Infused Products Manufacturers. A Medical Marijuana Center may also contract for the manufacture of Medical Marijuana Concentrate or Medical Marijuana-Infused Product with Medical Marijuana-Infused Product Licensees utilizing a contract as provided for in Rule M 602 Medical Marijuana-Infused Products Manufacturer: General or Prohibited Acts (Infused Product Contracts). Medical Marijuana distributed to a Medical Marijuana-Infused Products Manufacturer by a Medical Marijuana Center pursuant to such a contract for use solely in Medical Marijuana-Infused Product(s) that are returned to the contracting Medical Marijuana Center shall not be included for purposes of determining compliance with subsection A.
- Consumption Prohibited. Licensees shall not permit the consumption of marijuana or a marijuana product on the Licensed Premises.
- D. Quantity Limitations On Sales. During a single transaction to a patient, a Medical Marijuana Center and its employees are prohibited from selling:
 - More than two ounces of Medical Marijuana unless the patient designated the Medical
 Marijuana Center as his or her primary center and supplied it with documentation from
 the patient's physician allowing the patient more than two ounces of Medical Marijuana;
 - More than the patient's extended ounce count to a patient who designated the Medical
 Marijuana Center as his or her primary center and supplied it with documentation from
 the patient's physician allowing the patient more than two ounces of Medical Marijuana;
 - More than six Jmmature Plants unless the patient has designated the Medical Marijuana
 Center as his or her primary center and supplied it with documentation from the patient's physician allowing the patient more than six plants;
 - d. More than half of the patient's extended plant count to a patient who has designated the Medical Marijuana Center as his or her primary center and supplied it with documentation from the patient's physician allowing the patient more than six Plants.
- Por purposes of Rule M 403(D), a single transaction to a patient includes multiple sales to the same patient during the same business day where the Medical Marijuana Center employee knows or reasonably should know that such sale would result in the patient possessing more than the quantities of Medical Marijuana or Immature Plants set forth above.
- E. <u>Licensees May Refuse Sales</u>. Nothing in these rules prohibits a Licensee from refusing to sell Medical Marijuana or Medical Marijuana-Infused Product to a patient.
- F. <u>Storage and Display Limitations</u>. A Medical Marijuana Center shall not display Medical Marijuana and Medical Marijuana-Infused Product outside of a designated Restricted Access Area or in a manner in which Medical Marijuana or Medical Marijuana-Infused Product can be seen from outside the Licensed Premises. Storage of Medical Marijuana and Medical Marijuana-Infused Product shall otherwise be maintained in Limited Access Areas or Restricted Access Area.

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- G. <u>Sale of Expired Product Prohibited</u>. A Medical Marijuana Center shall not sell any expired Medical Marijuana-Infused Product.
- G.1 A Medical Marijuana Center shall not sell or give away Medical Marijuana or Medical Marijuana-Infused Product to a Medical Marijuana Transporter, and shall not buy, or receive complimentary Medical Marijuana or Medical Marijuana-Infused Product from a Medical Marijuana Transporter.
- G.2 A Medical Marijuana Center shall not compensate its employees using performance-based sales incentives. Performance-based incentives that are not sales-based are acceptable. Examples of performance-based incentives that are not sales-based include recognition for providing quality information to consumers, or the duration of the employee's employment with the Medical Marijuana Center.
- G.3 <u>Edibles Prohibited that are Shaped like a Human, Animal, or Fruit.</u> This paragraph G.3 is effective beginning October 1, 2017.
 - The sale or donation of Edible Medical Marijuana-Infused Products in the following shapes is prohibited:
 - a. The distinct shape of a human, animal, or fruit; or
 - A shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings.
 - The prohibition on human, animal, and fruit shapes does not apply to the logo of a licensed Medical Marijuana Business. Nothing in this subparagraph (G.3)(2) alters or eliminates a Licensee's obligation to comply with the requirements of Rule M 1001.5 Labeling and Packaging Requirements: General Applicability or Rule M 1000-1 Series Packaging, Labeling and Product Safety.
 - Edible Medical Marijuana-Infused Products that are geometric shapes and simply fruit flavored are not considered fruit and are permissible; and
 - Edible Medical Marijuana-Infused Products that are manufactured in the shape of a marijuana leaf are permissible.
- H. <u>Violation Affecting Public Safety.</u> Failure to comply with this rule may constitute a license violation affecting public safety.

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(l), 12-43.3-202(1)(h), 12-43.3-202(2)(a)(XX), and 12-43.3-402(1)(b), C.R.S. The purpose of this rule is to require all Medical Marijuana-Centers to track all inventory from the point it is received to the point of Transfer to another Medical Marijuana Center.

M 406 - Medical Marijuana Center: Inventory Tracking System

A. Minimum Tracking Requirement. Medical Marijuana Centers must use the Inventory Tracking System to ensure its Medical Marijuana and Medical Marijuana-Infused Product are identified and tracked from the point of Transfer from an Optional Premises Cultivation Operation, Medical Marijuana-Infused Products Manufacturer, or Medical Marijuana Transporter through the point of sale. See also Rule M 309 – Inventory Tracking System. Medical Marijuana Center: Inventory

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Tracking System. The Medical Marijuana Center must have the ability to reconcile its inventory records with the Inventory Tracking System and the associated transaction history and sale receipts. See also Rule M 901 – Business Records Required.

- A Medical Marijuana Center is prohibited from accepting any Medical Marijuana or Medical Marijuana-Infused Product from an Optional Premises Cultivation Operation, Medical Marijuana-Infused Products Manufacturer, or Medical Marijuana Transporter without receiving a valid transport manifest generated from the Inventory Tracking System.
- A Medical Marijuana Center must immediately input all Medical Marijuana or Medical Marijuana-Infused Product delivered to the Licensed Premises, accounting for all RFID tags, into the Inventory Tracking System at the time of delivery from an Optional Premises Cultivation Operation, Medical Marijuana-Infused Products Manufacturer, or Medical Marijuana Transporter.
- 3. A Medical Marijuana Center must immediately account for all Medical Marijuana Transferred to another Medical Marijuana Center in the Inventory Tracking System.
- A Medical Marijuana Center must reconcile transactions from their point of sale processes and on-hand inventory to the Inventory Tracking System at the close of business each day.

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M 500 Series - Medical Marijuana Optional Premises Cultivation Operation: License Privileges

Basis and Purpose - M 501

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XXI), and 12-43.4-401(4), and sections 12-43.3-310, 12-43.4-402, 12-43.3-403, 12-43.3-404, and 12-43.4-406, C.R.S. The purpose of this rule is to establish that it is unlawful for an Optional Premises Cultivation Operation to exercise any privileges other than those granted by the State Licensing Authority, and to clarify the license privileges.

M 501 - Medical Marijuana Optional Premises Cultivation Operation: License Privileges

- Privileges Granted. A Medical Marijuana Optional Premises Cultivation Operation shall only exercise those privileges granted to it by the State Licensing Authority.
- B. <u>Licensed Premises</u>. To the extent authorized by Rule M 304 Medical Marijuana Business and Retail Marijuana Establishment Shared Licensed Premises and Operational Separation, a Medical Marijuana Optional Premises Cultivation Facility may share a location with a commonly-owned Retail Marijuana Cultivation Facility. However, a separate license is required for each specific business entity regardless of geographical location.
- C. <u>Cultivation of Medical Marijuana Authorized</u>. A Medical Marijuana Optional Premises Cultivation Operation may Propagate, cultivate, harvest, prepare, cure, package, store, and label Medical Marijuana, whether in concentrated form or otherwise.
- D. <u>Authorized Transfers</u>, A Medical Marijuana Optional Premises Cultivation Operation may only Transfer Medical Marijuana to the Medical Marijuana Center or Medical Marijuana Infused Products Manufacturer it is designated to pursuant to section 12-43.3-403, C.R.S.
- E. <u>Packaging Processed Medical Marijuana</u>. Processed Medical Marijuana plants shall be packaged in units of ten pounds or less and labeled pursuant to Rule M 1002 Labeling Requirements: General Requirements or Rules M 1000-1 Labeling, Packaging, and Product Safety et. seq. and securely sealed in a tamper-evident manner.
 - The packages must be transported to the receiving Medical Marijuana Business within 7 days of receiving notification that the Harvest Batch from the processed Medical Marijuana passed required testing, and recorded as inventory at the receiving Medical Marijuana Business.
 - 2. In the event that the Harvest Batch from the processed Medical Marijuana does not pass required testing, the Licensee shall follow the procedures in rule M 1507 for the Harvest Batch. If the Harvest Batch ultimately passes required testing, then the packages of Medical Marijuana associated with the Harvest Batch must be transported to the Medical Marijuana Business within 7 days of receiving notification that the Harvest Batch passed the additional round of testing, and recorded as inventory at the receiving Medical Marijuana Business.
- F. <u>Authorized Marijuana Transport.</u> A Medical Marijuana Optional Premises Cultivation 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 Optional Premises Cultivation from transporting its own Medical Marijuana.

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- G. A Medical Marijuana Optional Premises Cultivation may compensate its employees using performance-based incentives.
- H. Authorized Sources of Medical Marijuana Seeds and Immature Plants. A Medical Marijuana Optional Premises Cultivation Operation shall only obtain Medical Marijuana seeds or Immature, Plants from its own Medical Marijuana or from another Medical Marijuana Business as long as there is first a documented point of sale transaction at that Optional Premises Cultivation Operation's designated Medical Marijuana Center or Medical Marijuana-Infused Products Manufacturer.

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Basis and Purpose - M 502

The statutory authority for this rule is found at subsections 12-43.3-103(2)(b), 12-43.3-202(1)(b)(I), 12-43.3-202(2)(e), 12-43.3-202(2)(e), 12-43.3-202(2)(e), and 12-43.3-202(2)(e), and sections 12-43.3-310, 12-43.3-402, 12-43.3-403 and 12-43.3-406, 12-43.3-201, C.R.S. The purpose of this rule is to clarify what activity is or is not allowed at an Optional Premises Cultivation Operation.

M 502 – Medical Marijuana Optional Premises Cultivation Operation: General Limitations or Prohibited Acts

A. <u>Transfer Restriction</u>. An Optional Premises Cultivation Operation may only <u>Transfer Medical</u> Marijuana to its commonly-owned Medical Marijuana Center or to a <u>Medical Marijuana-Infused</u> <u>Products Manufacturer</u>.

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B. Packaging and Labeling Standards Required. An Optional Premises Cultivation Operation is prohibited from selling Medical Marijuana that is not packaged and labeled in accordance with these rules. See Rules M 1001.5 et. seq. – Labeling, Packaging and Product Safety and Rules M 1000-1 et. seq. – Labeling, Packaging and Product Safety.

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 Sale to Patient Prohibited. An Optional Premises Cultivation Operation is prohibited from selling Medical Marijuana to a patient.

 D. <u>Consumption Prohibited</u>. An Optional Premises Cultivation Operation shall not permit the consumption of marijuana or marijuana products on its Licensed Premises.

- E. <u>Sales and Gifts to Transporters Prohibited.</u> A Medical Marijuana Optional Premises Cultivation shall not sell or give away Medical Marijuana or Medical Marijuana-Infused Product to a Medical Marijuana Transporter, and shall not buy or receive complimentary Medical Marijuana or Medical-Marijuana Infused Product from a Medical Marijuana Transporter.
- F. Inventory Limit. An Optional Premises Cultivation Operation shall not possess more plants than its commonly-owned Medical Marijuana Center is authorized to possess. See Rule M 403(A.5) – Medical Marijuana Sales: General Limitations or Prohibited Acts.

Basis and Purpose - M 504

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(l), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XV), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to establish minimum health and safety regulation for Optional Premises Cultivation Operations. The rule prohibits an Optional Premises Cultivation Operation from treating or otherwise adulterating Medical Marijuana with any chemical or other compound whatsoever to alter its color, appearance, weight or smell. This rule also authorizes the State Licensing Authority to require an independent consultant conduct an independent

health and sanitary audit of an Optional Premises Cultivation Operation. This rule explains when an independent health and sanitary audit may be deemed necessary and sets forth possible consequences of a Medical Marijuana Business's refusal to cooperate or pay for the audit. The State Licensing Authority intends this rule to help maintain the integrity of Colorado's Medical Marijuana Businesses.

M 504 - Optional Premises Cultivation Operation: Health and Safety Regulations

- A. <u>Local Safety Inspections</u>. An Optional Premises Cultivation Operation 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 licensing authority restrictions related to Medical 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.
- B. <u>General Sanitary Requirements.</u> An Optional Premises Cultivation Operation 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 Medical Marijuana shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected:
 - That all persons working in direct contact with Medical 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 and at any other time when the hands may have become soiled or contaminated:
 - c. 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 and/or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices; and
 - d. Refraining from having direct contact with Medical 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.
 - 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 Medical Marijuana is exposed;
 - That floors, walls, and ceilings are constructed in such a manner that they may be adequately cleaned and kept clean and kept in good repair;
 - That there is adequate lighting in all areas where Medical Marijuana is stored and where equipment or utensils are cleaned;

- 6. 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;
- 7. That any buildings, fixtures, and other facilities are maintained in a sanitary condition;
- 8. That toxic cleaning compounds, sanitizing agents, and solvents shall be identified, held, stored and disposed of in a manner that protects against contamination of Medical Marijuana or Medical Marijuana Concentrate, and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation or ordinance. All Pesticide must be stored and disposed of in accordance with the information provided on the product's label:
- 9. That all contact surfaces, including utensils and equipment used for the preparation of Medical Marijuana or Medical 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 an Optional Premises Cultivation Operation and used in accordance with labeled instructions;
- 10. 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 subject to approval of the Water Quality Control Division and local water provider;
- 11. 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;
- 12. That all operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of Medical Marijuana or Medical Marijuana-Infused Product shall be conducted in accordance with adequate sanitation principles;
- That each Optional Premises Cultivation Operation shall provide its employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair; and
- 14. That Medical Marijuana that can support the rapid growth of undesirable microorganisms shall be held in a manner that prevents the growth of these microorganisms.
- C. <u>Pesticide Application</u>. An Optional Premises Cultivation Operation 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.
- D. <u>Application of Other Agricultural Chemicals</u>. An Optional Premises Cultivation Operation may only use agricultural chemicals, other than Pesticide, in accordance with all applicable federal, state, and local laws, statutes, rules and regulations.

E. Required Documentation

 Standard Operating Procedures. An Optional Premises Cultivation Operation must establish written standard operating procedures for the cultivation, harvest, drying, curing, packaging and storing of Medical Marijuana. The standard operating procedures must also include when, and the manner in which, all Pesticide and other agricultural chemicals are to be applied during its cultivation process. A copy of all standard operating procedures must be maintained on the Licensed Premises of the Optional Premises Cultivation Operation.

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- Material Change. If an Optional Premises Cultivation Operation 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. <u>Material Safety Data Sheet</u>. An Optional Premises Cultivation Operation must obtain a material safety data sheet for any Pesticide or other agricultural chemical used or stored on its Licensed Premises. An Optional Premises Cultivation Operation must maintain a current copy of the material safety data sheet for any Pesticide or other agricultural chemical on the Licensed Premises where the product is used or stored.
- Labels of Pesticide and Other Agricultural Chemicals. An Optional Premises Cultivation
 Operation 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. An Optional Premises Cultivation Operation that applies any Pesticide or other agricultural chemical to any portion of a Medical 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 Occupational License number of the individual who applied the Pesticide or other agricultural chemical;
 - 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;
 - The restricted entry interval from the product label of any Pesticide or other agricultural chemical(s) applied;

- h. The RFID tag number of the Medical Marijuana plant(s) that the Pesticide or other agricultural chemical(s) was applied to or if applied to all plants throughout the Licensed Premises, a statement to that effect; and
- i. The total amount of each Pesticide or other agricultural chemical applied.
- F. <u>Prohibited Chemicals</u>. The following chemicals shall not be used in Medical Marijuana cultivation. Possession of chemicals and/or containers from these chemicals upon the Licensed Premises shall be a violation of this rule. Prohibited chemicals are:

Chemical Name

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

<u>DDT</u>

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

<u>EPN</u>

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

<u>METHAMIDOPHOS</u>

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

- G. The use of Dimethylsulfoxide (DMSO) in the production of Medical Marijuana shall be prohibited and possession of DMSO upon the Licensed Premises is prohibited.
- H. <u>Adulterants</u>. An Optional Premises Cultivation Operation may not treat or otherwise adulterate Medical Marijuana with any chemical or other compound whatsoever to alter its color, appearance, weight or smell.
- I. Independent Health and Sanitary Audit
 - 1. State Licensing Authority May Require A Health and Sanitary Audit
 - a. When the State Licensing Authority determines a health and sanitary audit by an independent consultant is necessary, it may require an Optional Premises Cultivation Operation to undergo such an audit. The scope of the audit may include, but need not be limited, to whether the Optional Premises Cultivation Operation is in compliance with the requirements set forth in this rule and other applicable public health or sanitary laws and regulations.
 - In such instances, the Division may attempt to mutually agree upon the selection
 of the independent consultant with an Optional Premises Cultivation Operation.
 However, the Division always retains the authority to select the independent
 consultant regardless of whether mutual agreement can be reached.
 - The Optional Premises Cultivation Operation will be responsible for all costs associated with the independent health and sanitary audit.
 - 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:
 - An Optional Premises Cultivation Operation does not provide requested records related to the use of Pesticide or other agricultural chemicals during in the cultivation process:
 - The Division has reasonable grounds to believe that the Optional Premises
 Cultivation Operation 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;
 - The Division has reasonable grounds to believe that the Optional Premises
 Cultivation Operation was the cause or source of contamination of Medical
 Marijuana or Medical Marijuana Concentrate; or
 - d. Multiple Harvest Batches or Production Batches produced by the Optional Premises Cultivation Operation failed contaminant testing.
 - Compliance Required. An Optional Premises Cultivation Operation 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.
 - 4. Suspension of Operations
 - 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 Optional Premises Cultivation Operation's license. See Rule M 1302 – Disciplinary Process: Summary Suspensions.

- b. Prior to or following the issuance of such an order, Optional Premises Cultivation Operation 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.
 - 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 M 1302 – Disciplinary Process: Summary Suspensions.
 - ii. If an agreement to suspend operations is reached, then the Optional Premises Cultivation Operation may continue to care for its inventory and conduct any necessary internal business operations but it may not Transfer Medical Marijuana or Medical Marijuana Concentrate to other Medical Marijuana Business during the period of time specified in the agreement.
- J. <u>Violation Affecting Public Safety</u>. Failure to comply with this rule may constitute a license violation affecting public safety.

Basis and Purpose - M 505

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I)(A-F),12-43.3-402(6), and 12-43.3-404(10), C.R.S. The purpose of this rule is to permit laboratory testing of Medical Marijuana and establish minimum health and safety regulation for Optional Premises Cultivation Operation. The State Licensing Authority intends this rule to help maintain the integrity of Colorado's Medical Marijuana Businesses.

Basis and Purpose - M 506

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XX), and 12-43.3-202(2.5)(a)(1)(A) through (F), C.R.S. The purpose of this rule is to establish the categories of Medical Marijuana Concentrate that may be produced at an Optional Premises Cultivation Operation and standards for the production of those concentrate.

M 506 - Optional Premises Cultivation Operation: Medical Marijuana Concentrate Production

A. Permitted Production of Certain Categories of Medical Marijuana Concentrate. An Optional Premises Cultivation Operation may only produce Water-Based Medical Marijuana Concentrate on its Licensed Premises and only in an area clearly designated for concentrate production on the current diagram of the Licensed Premises. See Rule M 901- Business Records Required. No other method of production or extraction for Medical Marijuana Concentrate may be conducted within the Licensed Premises of an Optional Premises Cultivation Operation unless the Owner(s) of the Optional Premises Cultivation Operation also has a valid Medical Marijuana-Infused 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

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- B. <u>Safety and Sanitary Requirements for Concentrate Production</u>. If an Optional Premises Cultivation Operation produces Water-Based Medical Marijuana Concentrate, then all areas in which those concentrate are produced and all Owners and Occupational Licensees engaged in the production of those concentrate shall be subject to all of requirements imposed upon a Medical Marijuana-Infused Products Manufacturer that produces Medical Marijuana Concentrate, including general requirements. See Rule M 604 Medical Marijuana-Infused Products Manufacturer: Health and Safety Regulations and Rule M 605 Medical Marijuana-Infused Products Manufacturer: Medical Marijuana Concentrate Production.
- C. Possession of Other Categories of Medical Marijuana Concentrate.
 - It shall be considered a violation of this rule if an Optional Premises Cultivation Operation
 possesses a Medical Marijuana Concentrate other than a Water-Based Medical
 Marijuana Concentrate on its Licensed Premises unless the Owner(s) of the Optional
 Premises Cultivation Operation also has a valid Medical Marijuana-Infused Products
 Manufacturer license.
 - 2. Notwithstanding subparagraph (C)(1) of this rule M 505, an Optional Premises Cultivation Operation 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-Infused Products Manufacturing Facility for processing into a Solvent-Based Medical Marijuana Concentrate, and the Medical Marijuana-Infused Products Manufacturing Facility Transfers the resultant Solvent-Based Medical Marijuana Concentrate back to the originating Optional Premises Cultivation Operation.
 - The Optional Premises Cultivation Operation shall comply with all requirements in rule M 1507(B.1) when having Solvent-Based Medical Marijuana Concentrate manufactured out of Medical Marijuana flower or trim that failed microbial testing.
 - b. The Optional Premises Cultivation Operation is responsible for submitting the Solvent-Based Medical Marijuana Concentrate for all required testing for contaminants pursuant to rule M 1501 Medical Marijuana Testing Program Contaminant Testing, for potency pursuant to rule M 1503 Medical Marijuana Testing Program Potency Testing, and any other testing required or allowed by the Medical Marijuana Rules or Medical Marijuana Code.

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M 600 Series - Medical Marijuana-Infused Products Manufacturers

Basis and Purpose - M 601

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(l) and 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(l)(A-F), , 12-43.3-406(1)(c), and 12-43.3-406(4)(b), and section 12-43.3-404, C.R.S. The purpose of this rule is to establish that it is unlawful for a Medical Marijuana-Infused Products Manufacturer to exercise any privileges other than those granted by the State Licensing Authority and to clarify the license privileges.

M 601 - Medical Marijuana-Infused Products Manufacturer: License Privileges

- Privileges Granted. A Medical Marijuana-Infused Products Manufacturer shall only exercise those
 privileges granted to it by the State Licensing Authority.
- B. <u>Licensed Premises</u>. A separate license is required for each specific business or business entity and geographical location. A Retail Marijuana Products Manufacturing Facility may share a location with a commonly owned Medical Marijuana-Infused Products Manufacturer. However, a separate license is required for each specific business or business entity, regardless of geographical location.
- C. <u>Transfer Restricted.</u> A Medical Marijuana-Infused Products Manufacturer may <u>Transfer</u> (1) its own Medical Marijuana-Infused Product to Medical Marijuana Centers or another <u>Medical Marijuana-Infused Products Manufacturer</u>, (2) <u>Medical Marijuana that was not cultivated at its own Optional Premises Cultivation to another Medical Marijuana-Infused Products Manufacturer</u>, and (3) <u>Medical Marijuana Concentrate to a Medical Marijuana Center or another Medical Marijuana-Infused Products Manufacturer</u>.
- D. Manufacture of Medical Marijuana-Infused Product Authorized. A Medical Marijuana-Infused Products Manufacturer may manufacture, prepare, package, and label Medical Marijuana-Infused Product, whether in concentrated form or that are comprised of Medical Marijuana and other ingredients intended for use or consumption, such as edible products, ointments, or tinctures.
- E. <u>Location Prohibited</u>. A Medical Marijuana-Infused Products Manufacturer may not manufacture, prepare, package, store, or label Medical Marijuana-Infused Product in a location that is operating as a retail food establishment or a wholesale food registrant.
- F. Samples Provided for Testing.
 - This rule M 601(F)(1) is repealed effective July 1, 2016. A Medical Marijuana-Infused Products Manufacturer may provide samples of its Medical Marijuana-Infused Product to a Retail Marijuana Testing Facility that has obtained an Occupational License to test and research Medical Marijuana for testing and research purposes. The Medical Marijuana-Infused Products Manufacturer shall maintain the testing results as part of its business books and records. See Rule M 901 Business Records Required.
 - 1.5. This rule M 601(F)(1.5) is effective beginning July 1, 2016. A Medical Marijuana-Infused Products Manufacturer may provide samples of its Medical Marijuana-Infused Product to a Medical Marijuana Testing Facility for testing and research purposes. The Medical Marijuana-Infused Products Manufacturer shall maintain the testing results as part of its business books and records. See Rule M 901 Business Records Required.
- G. <u>Authorized Marijuana Transport</u>. A Medical Marijuana-Infused Products Manufacturer is authorized to utilize a licensed Medical Marijuana Transporter for transportation of its Medical

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Marijuana-Infused Product 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-Infused Products Manufacturer from transporting its own Medical Marijuana.

 H. A Medical Marijuana-Infused Products Manufacturer may compensate its employees using performance-based incentives.

Basis and Purpose - M 602

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XVII.6) and (XX), 12-43.3-404(3), and 12-43.3-406(1)(a) C.R.S. The Medical Code sets forth minimum requirements for written agreements between Medical Marijuana-Infused Products Manufacturers and Medical Marijuana Centers. Specifically, the written agreements must set forth the total amount of Medical Marijuana obtained from a Medical Marijuana Center licensee to be used in the manufacturing process, and the total amount of Medical Marijuana-Infused Product to be manufactured from the Medical Marijuana obtained from the Medical Marijuana Center. This rule clarifies that the Division must approve such written agreements to ensure they meet those requirements.

M 602 - Medical Marijuana-Infused Products Manufacturer: General Limitations or Prohibited Acts

- A. <u>Contract Required</u>. Any contract required pursuant to section 12-43.3-404(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 M 901 Business Records and Reporting.
- B. <u>Packaging and Labeling Standards Required</u>. A Medical Marijuana-Infused Products Manufacturer is prohibited from selling Medical Marijuana-Infused Product that are not properly packaged and labeled. See M 1000 Series Labeling, Packaging, and Product Safety and M 1000.1 Series Labeling, Packaging, and Product Safety.
- C. <u>Sale to Consumer Prohibited.</u> A Medical Marijuana-Infused Products Manufacturer is prohibited from selling Medical Marijuana or Medical Marijuana-Infused Product to a consumer.
- D. <u>Consumption Prohibited</u>. A Medical Marijuana-Infused Products Manufacturer shall not permit the consumption of marijuana or marijuana products on its Licensed Premises.
- E. <u>Adequate Care of Perishable Product.</u> A Medical Marijuana-Infused Products Manufacturer must provide adequate refrigeration for perishable Medical Marijuana-Infused Product that will be consumed and shall utilize adequate storage facilities and transport methods.
- F. <u>Homogeneity of Edible Retail Marijuana Product</u>. A Medical Marijuana-Infused Products Manufacturer must ensure that its manufacturing processes are designed so that the cannabinoid content of any Edible Medical Marijuana-Infused Product is homogenous.
- G. A Medical Marijuana-Infused Products Manufacturer shall not sell or give away Medical Marijuana or Medical Marijuana-Infused Product to a Medical Marijuana Transporter, and shall not buy or receive complimentary Medical Marijuana or Medical Marijuana-Infused Product from a Medical Marijuana Transporter.
- Cultivated Medical Marijuana Sales Prohibited. A Medical Marijuana-Infused Products
 Manufacturer that also has an Optional Premises Cultivation Operation shall not sell any Medical Marijuana that it cultivates except for the Medical Marijuana contained in its Medical Marijuana-Infused Products or Medical Marijuana Concentrate.

Basis and Purpose - M 603

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XVIII.6) and (XX), and 12-43.3-406(3) and section 12-43.3-404, C.R.S. The purpose of this rule is to require all Medical Marijuana-Infused Products Manufacturers to track all inventory from the point it is received, through any manufacturing processes, to the point of sale or Transfer to another Medical Marijuana Business.

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Basis and Purpose - M 604

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XIV),12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.3-202(2.5)(a)(III)(A)&(B), and section 12-43.3-404, C.R.S. The purpose of this rule is to establish minimum health and safety regulations for Medical Marijuana-Infused Products Manufacturers. It requires all Owners and Occupational Licensees to attend a food handler training course prior to manufacturing any Edible Medical Marijuana Product. This rule also authorizes the State Licensing Authority to require that an independent consultant conduct an independent food safety audit of a Medical Marijuana Infused-Products Manufacturing Facility. This rule explains when an independent food safety audit may be deemed necessary and sets forth possible consequences of a Medical Marijuana-Infused Products Manufacture's refusal to cooperate or pay for the audit. It sets forth general standards and basic sanitary requirements for Medical Marijuana-Infused Products Manufacturers. It covers the physical premises where the products are made as well as the individuals handling the products. The State Licensing Authority modeled this rule after those adopted by the Colorado Department of Public Health and Environment. The State Licensing Authority intends this rule to help maintain the integrity of Colorado's Medical Marijuana Businesses and the safety of the public. Product safety requirements are being adopted to aid in making Medical Marijuana-Infused Products more readily identifiable to the general public outside of packaging as containing Medical Marijuana. While product safety requirements are stated in this rule, nothing in the requirements interferes with a manufacturer's ability to determine portions for its products or to provide a mechanism with the product for accurately measuring a portion.

M 604 - Medical Marijuana-Infused Products Manufacturer: Health and Safety Regulations

A. Training

- Prior to engaging in the manufacture of any Edible Medical Marijuana-Infused Product each Owner or Occupational 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:
 - 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-Infused Products Manufacturer must obtain documentation evidencing that each Owner or Occupational 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 or Occupational Licensee is engaged in the manufacturing of an Edible Medical Marijuana-Infused Product.

B. General Standards

- A Medical Marijuana-Infused Products Manufacturer may be subject to inspection 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 Medical Marijuana. An annual fire safety inspection may result in the required installation of fire suppression devices, or other means necessary for adequate fire safety.
- A Medical Marijuana-Infused Products Manufacturer that manufacturers Edible Medical Marijuana-Infused Product shall comply with all kitchen-related health and safety standards of the relevant local licensing authority 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. General Sanitary Requirements. 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 preparation surfaces for Medical Marijuana or Medical Marijuana-Infused Product shall be excluded from any operations which may be expected to result in such 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/or in Medical Marijuana-Infused Product preparation areas and where good sanitary practices require employees to wash and/or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices;
 - That all persons working in direct contact with preparation of Medical Marijuana or Medical Marijuana-Infused Product 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 a Medical Marijuana Concentrate or manufacture of a Medical Marijuana-Infused Product and at any other time when the hands may have become soiled or contaminated; and

- c. Refraining from having direct contact with preparation of Medical Marijuana or Medical Marijuana-Infused Product if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.
- 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 Medical Marijuana or Medical Marijuana-Infused Product;
- 5. 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 Medical Marijuana or Medical Marijuana-Infused Product are exposed;
- That floors, walls, and ceilings are constructed in such a manner that they may be adequately cleaned and kept clean and kept in good repair;
- That there is adequate safety-type lighting in all areas where Medical Marijuana or Medical Marijuana-Infused Product are processed or stored and where equipment or utensils are cleaned;
- That the Licensed Premises 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;
- 9. That any buildings, fixtures, and other facilities are maintained in a sanitary condition;
- 10. That all contact surfaces, including utensils and equipment used for the preparation of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused 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 in a Medical Marijuana-Infused Products Manufacturer and used in accordance with labeled instructions;
- 11. That toxic cleaning compounds, sanitizing agents, solvents used in the production of Medical Marijuana Concentrate and other chemicals shall be identified, held, stored and disposed of in a manner that protects against contamination of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product, and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation or ordinance;
- 12. 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;
- 13. 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;

- 14. That each Medical Marijuana-Infused Products Manufacturer shall provide its employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair;
- 15. That all operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of Medical Marijuana or Medical Marijuana-Infused Product shall be conducted in accordance with adequate sanitation principles;
- 16. That Medical Marijuana or Medical Marijuana-Infused Product that can support the rapid growth of undesirable microorganisms shall be held in a manner that prevents the growth of these microorganisms; and
- 17. That storage and transport of finished Medical Marijuana-Infused Product shall be under conditions that will protect products against physical, chemical, and microbial contamination as well as against deterioration of any container.

C.5. Product Safety.

Paragraph (C.5) is effective beginning October 1, 2016.

- 1. A Medical Marijuana-Infused Products Manufacturer that manufactures Edible Medical Marijuana-Infused Product shall create and maintain standard production procedures and detailed manufacturing processes for each Edible Medical Marijuana-Infused 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.
- A Medical Marijuana-Infused Products Manufacturer may determine a standard portion of THC for each Edible Medical Marijuana-Infused Product it manufactures. If a Medical Marijuana-Infused Products Manufacturer determines a standard portion for an Edible Medical Marijuana-Infused Product, that information must be documented in the product's standard production procedure.
- 3. For each Edible Medical Marijuana-Infused Product, the total amount of active THC contained within the product must be documented in the standard production procedures.
- 4. Universal Symbol Marking Requirements.
 - The following categories of Edible Medical Marijuana-Infused Products shall be marked, stamped, or otherwise imprinted with the Universal Symbol directly on the Medical Marijuana-Infused Product in a manner to cause the Universal Symbol to be distinguishable and easily recognizable.
 - 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:

- Be marked, stamped, or otherwise imprinted on at least one side of the Edible Medical Marijuana-Infused Product;
- ii. Be centered either horizontally or vertically on the Edible Medical Marijuana-Infused Product; and
- iii. If centered horizontally on the Edible Medical Marijuana-Infused Product, the height and width of the Universal Symbol shall be of a size that is at least 25% of the product's width, but not less than ¼ inch by ¼ inch; or
- iv. If centered vertically on the Edible Medical Marijuana-Infused 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. If a Medical Marijuana-Infused Products Manufacturer elects to determine portions for an Edible Medical Marijuana-Infused Product, then the Universal Symbol shall be applied to each portion in accordance with the requirements of subsubparagraph (C.5)(4)(b) of this rule M 604. 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 '%' by '%''.
- d. Edible Medical Marijuana-Infused Products that are liquids, loose bulk goods (e.g. granola, cereals, popcorn), or powders, are exempt from the Universal Symbol marking requirements provided that they comply with the labeling and Container requirements of rule M 1004.5 – Packaging and Labeling Requirements of a Medical Marijuana Infused-Product by a Medical Marijuana Infused Products Manufacturer or R 1008-1 – Additional Packaging Requirements – Edible Retail Marijuana Products.
- Remanufactured Products Prohibited. A Medical Marijuana-Infused Products
 Manufacturer shall not utilize a commercially manufactured food product as its Edible
 Medical Marijuana-Infused Product. The following exceptions to this prohibition apply:
 - a. A food product that was commercially manufactured specifically for use by the Medical Marijuana-Infused 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-Infused Products Manufacturer.
 - b. Commercially manufactured food products may be used as ingredients in a Medical Marijuana-Infused Products Manufacturer's Edible Medical Marijuana-Infused 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-Infused Product, and (2) the Medical Marijuana-Infused Products Manufacturer does not state or advertise to the consumer that the final Edible Medical Marijuana-Infused Product contains the commercially manufactured food product.
- Trademarked Food Products. Nothing in this rule alters or eliminates a Medical
 Marijuana-Infused Products Manufacturer's responsibility to comply with the trademarked
 food product provisions required by the Medical Code per 12-43.3-404(11)(a-c), C.R.S.
- 7. <u>Edibles Prohibited that are Shaped like a Human, Animal, or Fruit</u>. This subparagraph (C.5)(7) is effective beginning October 1, 2017.

- The production, sale, and donation of Edible Medical Marijuana-Infused Products in the following shapes is prohibited:
 - The distinct shape of a human, animal, or fruit; or
 - A shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings.
- The prohibition on human, animal, and fruit shapes does not apply to the logo of a licensed Medical Marijuana Business. Nothing in this subsubparagraph (C.5)(7)(b) alters or eliminates a Licensee's obligation to comply with the requirements of rule M 1001.5 – Labeling and Packaging Requirements: General Applicability or R 1000-1 Series – Labeling, Packaging, and Product Safety.
- Edible Medical Marijuana-Infused Products that are geometric shapes and simply fruit flavored are not considered fruit and are permissible; and
- d. Edible Medical Marijuana-Infused Products that are manufactured in the shape of a marijuana leaf are permissible.

D. Standard Operating Procedures

- A Medical Marijuana-Infused Products Manufacturer must have written standard operating procedures for each category of Medical Marijuana Concentrate and type of Medical Marijuana-Infused Product that it produces.
 - All standard operating procedures for the production of a Medical Marijuana Concentrate must follow the requirements in Rule M 605.
 - b. A copy of all standard operating procedures must be maintained on the Licensed Premises of the Medical Marijuana-Infused Products Manufacturer.
- If a Medical Marijuana-Infused Products Manufacturer makes a Material Change to its standard Medical Marijuana Concentrate or Medical Marijuana-Infused 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.
- E. Additives. A Medical Marijuana-Infused Products Manufacturer shall not include any Additive that is toxic within a Medical Marijuana-Infused Product; nor include any Additive for the purposes of making the product more addictive, appealing to children or misleading to patients.
- F. DMSO. The use of Dimethylsulfoxide ("DMSO") in the production of Medical Marijuana

 Concentrate or Medical Marijuana-Infused Product shall be prohibited and possession of DMSO

 upon the Licensed Premises is prohibited.

G. Independent Health and Sanitary Audit

- 1. State Licensing Authority May Require An Independent Health and Sanitary Audit
 - a. When the State Licensing Authority determines a health and sanitary audit by an independent consultant is necessary, it may require a Medical Marijuana-Infused Products Manufacturer to undergo such an audit. The scope of the audit may include, but need not be limited, to whether the Medical Marijuana-Infused

Products Manufacturer is in compliance with the requirements set forth in this rule or other applicable food handling laws, rules or regulations and in compliance with the concentrate production rules in Rule M 605 or other applicable laws, rules and regulations.

- b. In such instances, the Division may attempt to mutually agree upon the selection of the independent consultant with a Medical Marijuana-Infused Products Manufacturer. However, the Division always retains the authority to select the independent consultant regardless of whether mutual agreement can be reached
- The Medical Marijuana-Infused Products Manufacturer will be responsible for all direct costs associated with the independent health and sanitary audit.
- 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:
 - A Medical Marijuana-Infused Products Manufacturer does not provide requested records related to the food handling training required for Owners and Occupational Licensees engaged in the production of Edible Medical Marijuana-Infused Products to the Division;
 - A Medical Marijuana-Infused Products Manufacturer does not provide requested records related to the production of Medical Marijuana Concentrate, including but not limited to, certification of its Licensed Premises, equipment or standard operating procedures, training of Owners or employees, or Production Batch specific records;
 - c. The Division has reasonable grounds to believe that the Medical Marijuana-Infused Products Manufacturer is in violation of one or more of the requirements set forth in this rule or Rule M 605; or
 - d. The Division has reasonable grounds to believe that the Medical Marijuana-Infused Products Manufacturer was the cause or source of contamination of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product; or
 - e. Multiple Production Batches of Medical Marijuana Concentrate or Medical Marijuana-Infused Product produced by the Medical Marijuana-Infused Products Manufacturer failed contaminant testing.
- Compliance Required. A Medical Marijuana-Infused Products Manufacturer 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.

4. <u>Suspension of Operations</u>

a. 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 Medical Marijuana-Infused Products Manufacturer's license. See Rule M 1302 – Disciplinary Process: Summary Suspensions.

- b. Prior to or following the issuance of such an order, the Medical Marijuana-Infused Products Manufacturer 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.
 - 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 M 1302 – Disciplinary Process: Summary Suspensions.
 - iii. If an agreement to suspend operations is reached, then the Medical Marijuana-Infused Products Manufacturer may continue to care for its inventory and conduct any necessary internal business operations but it may not Transfer or wholesale Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product to another Medical Marijuana Business during the period of time specified in the agreement. Depending on the condition of the Licensed Premises and required remedial measures, the Division may permit a Medical Marijuana-Infused Products Manufacturer to produce Medical Marijuana Concentrate or manufacture Medical Marijuana-Infused Product while operations have been suspended.

H. Violation Affecting Public Safety. Failure to comply with this rule may constitute a license violation affecting public safety.

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Basis and Purpose - M 605

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XV) and 12-43.3-202(2)(a)(XX), 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-Infused 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.

M 605 – Medical Marijuana-Infused Products Manufacturer: Medical Marijuana Concentrate Production.

- A. <u>Permitted Categories of Medical Marijuana Concentrate Production</u>
 - A Medical Marijuana-Infused Products Manufacturer may produce Water-Based Medical Marijuana Concentrate and Food-Based Medical Marijuana Concentrate.
 - A Medical Marijuana-Infused Products Manufacturer may also produce Solvent-Based Medical Marijuana Concentrate using only the following solvents: butane, propane, CO2, ethanol, isopropanol, acetone heptane and pentane. The use of any other solvent is expressly prohibited unless and until it is approved by the Division.
 - Beginning on July 1, 2014, a Medical Marijuana-Infused 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. <u>General Applicability</u>. A Medical Marijuana-Infused Products Manufacturer that engages in the production of Medical Marijuana Concentrate, regardless of the method of extraction or category of concentrate being produced, must:

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- 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 M 901- Business Records Required.
- 2. Ensure that all applicable sanitary rules are followed. See M 604.
- Ensure that the standard operating procedure for each method used to produce a
 Medical Marijuana Concentrate on its Licensed Premises 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 M 307 – Waste Disposal.
- Establish written and documentable quality control procedures designed to maximize safety for Owners and Occupational Licensees and minimize potential product contamination
- Establish written emergency procedures to be followed by Owners or Occupational 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 on its Licensed Premises. The training manual must include, but need not be limited to, the following topics:
 - All standard operating procedures for each method of concentrate production used at that Licensed Premises;
 - b. The Medical Marijuana-Infused Products Manufacturer's quality control procedures:
 - c. The emergency procedures for that Licensed Premises;
 - d. The appropriate use of any necessary safety or sanitary equipment;
 - e. The hazards presented by all solvents used within the Licensed Premises as described in the material 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
 - Any additional periodic cleaning required to comply with all applicable sanitary rules.

- Provide adequate training to every Owner or Occupational Licensee prior to that individual undertaking any step in the process of producing a Medical Marijuana Concentrate
 - 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 or Occupational 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 or Occupational Licensee can safely produce a Medical Marijuana Concentrate. See Rule M 901- Business Records Required
 - c. The Owner or Occupational 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 M 901- Business Records Required.
- Maintain clear and comprehensive records of the name, signature and Owner or Occupational 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 M 901- Business Records Required.
- C. Water-Based Medical Marijuana Concentrate_Food-Based Medical Marijuana Concentrate and Heat/Pressure Based Retail Marijuana Concentrate. Medical Marijuana-Infused Products Manufacturer that engages in the production of a Water-Based Medical Marijuana Concentrate_a Food-Based Medical Marijuana Concentrate or Heat/Pressure Based Retail Marijuana Concentrate must:

Ensure that all equipment, counters and surfaces used in the production of a Water-Based Medical Marijuana Concentrate_a Food-Based Medical Marijuana Concentrate or a Heat/Pressure Based 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.

Ensure that all equipment, counters, and surfaces used in the production of a Water-Based Medical Marijuana Concentrate a Food-Based Medical Marijuana Concentrate or a Heat/Pressure Based Retail Marijuana Concentrate are thoroughly cleaned after the completion of each Production Batch.

 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 CO₂.

4. Ensure that the appropriate safety or sanitary equipment, including personal protective equipment, is provided to, and appropriately used by, each Owner or Occupational Licensee engaged in the production of a Water-Based Medical Marijuana Concentrate or a Heat/Pressure Based Retail Marijuana Concentrate.

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- 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.
- 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 foodgrade.
- 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 Water-Based Medical Marijuana Concentrate a Food-Based Medical Marijuana Concentrate or a Heat/Pressure Based Retail Marijuana Concentrate.

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- Solvent-Based Medical Marijuana Concentrate. A Medical Marijuana-Infused Products
 Manufacturer that engages in the production of Solvent-Based Medical Marijuana Concentrate
 must:
 - 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. <u>Flammable Solvent Determinations</u>. 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:
 - 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. <u>CO₂ Solvent Determination</u>. If CO₂ is used as solvent at the Licensed Premises, then the Industrial Hygienist or Professional Engineer must determine whether a CO₂ gas monitoring system must be installed within the room in which Medical

Marijuana Concentrate are to be produced or CO_2 is stored, and if required the system's specifications, in accordance with applicable laws, rules and regulations.

- c. <u>Exhaust System Determination</u>. 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. <u>Material Change</u>. If a Medical Marijuana-Infused 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. <u>Manufacturer's Instructions</u>. The Industrial Hygienist or Professional Engineer may review and consider any information provided to the Medical Marijuana-Infused 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-Infused 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 on the Licensed Premises.
- 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;
- 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

- If the system is UL or ETL listed, then a Medical Marijuana-Infused 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-Infused 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-Infused 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. <u>Ethanol or Isopropanol</u>. A Medical Marijuana-Infused 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.
- Ensure that all solvents used in the extraction process are food-grade or at least 99% pure;
 - a. A Medical Marijuana-Infused Products Manufacturer must obtain a material safety data sheet for each solvent used or stored on the Licensed Premises. A Medical Marijuana-Infused Products Manufacturer must maintain a current copy of the material safety data sheet and a receipt of purchase for all solvents used or to be used in an extraction process. See Rule M 901- Business Records Required.
 - b. A Medical Marijuana-Infused Products Manufacturer is prohibited from using denatured alcohol to produce a Medical Marijuana Concentrate.
- 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-Infused 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;
- Ensure that the appropriate safety and sanitary equipment, including personal protective
 equipment, is provided to, and appropriately used by, each Owner or Occupational
 Licensee engaged in the production of a Solvent-Based Medical Marijuana Concentrate;
 and
- Ensure that a trained Owner or Occupational 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-Infused 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.
- F. <u>Violation Affecting Public Safety</u>. Failure to comply with this rule may constitute a license violation affecting public safety.

M 900 Series - Business Records

Basis and Purpose - M 901

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XVII), and 12-43.3-202(2)(a)(XX), C.R.S. This rule explains what business records a Licensee must maintain. It also clarifies that such records must be made available to the Division on demand. Rule R 901.B was added due to written commentary received from an industry representative.

M 901 - Business Records Required

A. <u>General Requirements</u>

- A Medical Marijuana Business must maintain the information required in this rule in a format that is readily understood by a reasonably prudent business person.
- Each Medical 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.
 - On premises records: The Medical Marijuana Business' books and records for the preceding six months (or complete copies of such records) must be maintained on its 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:
 - Current Employee List This list must provide the full name and Occupational License number of each employee and all non-employee Owners, who work at a Medical Marijuana Business.
 - i. Each Licensed Premises shall enter the full name and Occupational 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.
 - Secure Facility Information For its Licensed Premises and any associated permitted off-premises storage facility, a Medical Marijuana Business must maintain the business contact information for vendors that maintain video surveillance systems and Security Alarm Systems.
 - Licensed Premises Diagram of all approved Limited Access Areas and any permitted off-premises storage facilities.
 - Advertising Records All records related to Advertising and marketing, including, but not limited to, audience composition data.
 - Visitor Log List of all visitors entering Limited Access Areas or Restricted
 Access Areas.

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- f. Waste log Comprehensive records regarding all waste material that accounts for, reconciles, and evidences all waste activity related to the disposal of marijuana.
- g. Surveillance logs Surveillance logs as required by Rule M 306.
- n, Identity Statement and Standardized Graphic. 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. A Licensee may elect to have its Identity Statement also serve as its Standardized Graphic Symbol for purposes of complying with this rule.
- All records normally retained for tax purposes.
- . All other records required by these Rules.
- B. <u>Loss of Records and Data</u>. 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.
- Violation Affecting Public Safety. Violation of this rule may constitute a license violation affecting public safety.
- D. Records Related to Inventory Tracking. A Medical Marijuana Business must maintain accurate and comprehensive inventory tracking records that account for, reconcile, and evidence all inventory activity for Medical Marijuana from either seed or Immature Plant stage until the Medical Marijuana or Medical Marijuana-Infused Product is destroyed or sold to another Medical Marijuana Business or a patient.
- E. Records Related to Transport. A Medical Marijuana Business must maintain adequate records for the transport of all activities related to Medical Marijuana and Medical Marijuana-Infused Product. See Rule M 801 – Transport of Medical Marijuana or Medical Marijuana-Infused Product.
- F. <u>Provision of Requested Records to the Division</u>. A Licensee must provide on-demand access to on-premises records following a request from the Division during normal business hours of apparent operation, and must provide access to off-premises records within three business days following a request from the Division.

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M 1700 Series - Medical Marijuana Business Operators

Basis and Purpose - M 1702

The statutory authority for this rule is found at subsections 12-43.3-202(1)(a), 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX) and 12-43.3-401(d), 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.

M 1702 - Medical Marijuana Business Operators: General Limitations or Prohibited Acts

- A. <u>Financial Interest</u>. A Person who is a Direct Beneficial Interest Owner or an Indirect Beneficial Interest Owner of a Medical Marijuana Business Operator <u>may also be a Direct Beneficial Interest Owner, an Indirect Beneficial Interest Owner or otherwise hold a direct or indirect financial interest in another Medical Marijuana Business so long as that interest complies with all other requirements of these rules. A Medical Marijuana Business may be operated by a Medical Marijuana Business Operator where each has one or more Direct Beneficial Interest Owners or Indirect Beneficial Interest Owners in common. A Person <u>may receive compensation for services provided by a Medical Marijuana Business Operator</u> in accordance with these rules.</u>
- B. <u>Sale of Marijuana Prohibited</u>. A Medical Marijuana Business Operator is prohibited from selling, distributing, or transferring Medical Marijuana or Medical Marijuana-Infused Product to another Medical Marijuana Business or a consumer, except when acting as an agent of a Medical Marijuana Business(es) operated by the Medical Marijuana Business Operator.
- C. <u>Consumption Prohibited</u>. A Medical Marijuana Business Operator, and its Direct Beneficial Interest 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 Direct Beneficial Interest 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. <u>Compliance with Requirements and Limitations Applicable to the Medical Marijuana Business(es)</u>
 <u>Operated.</u> In operating any other Medical Marijuana Business(es), a Medical Marijuana Business
 Operator, and its Direct Beneficial Interest 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 Direct Beneficial Interest Owners who are required to hold Associated Key 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.
 - The Direct Beneficial Interest 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.
 - At least one Direct Beneficial Interest 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

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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 Direct Beneficial Interest 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 registration of the Medical Marijuana Business Operator, or a specific Direct Beneficial Interest Owner, agent or employee of the Medical Marijuana Business Operator, has expired, or has been suspended or revoked.
- G. <u>Limitations on Use of Documents and Information Obtained from Medical Marijuana Businesses</u>. 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 Medical 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 Direct Beneficial Interest Owners, Indirect Beneficial Interest Owners, agents or employees, or any Person other than the Medical Marijuana Business it operates.
- H. <u>Form and Structure of Allowable Agreement(s) Between Operators and Owners.</u> Any agreement between a Medical Marijuana Business and a Medical Marijuana Business Operator:
 - Must acknowledge that the Medical Marijuana Business Operator, and its Direct Beneficial Interest 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;
 - 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:
 - 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:
 - 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;

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- The Medical Marijuana Business Operator shall not guarantee the Medical Marijuana Business's debts or production levels.
- 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;
- 4. Shall be contingent on approval by the Division; and
- 5. Shall not be materially amended without advance written approval from the Division.
- A Medical Marijuana Business Operator may engage in dual operation of a Medical Marijuana Business and a Retail Marijuana Establishment at a single location, to the extent the Medical Marijuana Business being operated is permitted to do so pursuant to subsection 12-43.4-401(2)(a), C.R.S., and the Medical Marijuana Business Operator shall comply with the rules promulgated pursuant to the Medical Code and the Retail Code, including the requirement of obtaining a valid license as a Retail Marijuana Establishment Operator.

Basis and Purpose - M 1703

The statutory authority for this rule is found at subsections, 12-43.3-202(1)(a), 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX) and 12-43.3-401(d), C.R.S.. The purpose of this rule is to establish occupational license requirements for the Medical Marijuana Business Operator's Direct Beneficial Interest Owners, agents and employees, including those directly or indirectly engaged in the operation of other Medical Marijuana Business(es).

M 1703 - Medical Marijuana Business Operators: Occupational Licenses for Personnel

- A. Required Occupational Licenses.
 - 1. <u>Associated Key Licenses</u>. All natural persons who are Direct Beneficial Interest Owners in a Medical Marijuana Business Operator must have a valid Associated Key License, associated with the Medical Marijuana Business Operator <u>license or</u> registration. Such an Associated Key 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. Key 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 or supervision, of other Medical Marijuana Businesses, must hold a Key License. The Key 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.
 - 3. Occupational Licenses. All other natural persons who are agents and employees of a Medical Marijuana Business Operator that are actively engaged, directly or indirectly, in the operation of one or more other Medical Marijuana Business(es), including but not limited to all agents or employees who will come into contact with Medical Marijuana or Medical Marijuana-Infused Product, who will have to access Limited Access Areas, or who will have access to the Inventory Tracking System account of the Medical Marijuana Business(es) being operated, must have a valid Occupational License.
- B. Occupational Licenses Not Required. Occupational Licenses are not required for Indirect
 Beneficial Interest Owners of a Medical Marijuana Business Operator, Qualified Limited Passive

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Deleted: Occupational Licenses Required. All natural persons who are Direct Beneficial Interest Owners, and all natural persons who are agents and employees, of a Medical Marijuana Business Operator that are actively engaged, directly or indirectly, in the operation of one or more other Medical Marijuana Business(es), including but not limited to all such persons who will come into contact with Medical Marijuana or Medical Marijuana-Infused Product, who will have to access Limited Access Areas, or who will have access to the Inventory Tracking System account of the Medical Marijuana Business(es) being operated as part of their duties, must have a valid Occupational License.

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Investors who are Direct Beneficial Interest Owners of a Medical Marijuana Business Operator, or for natural persons who will not come into contact with Medical Marijuana or Medical Marijuana-Infused Product, 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. <u>Designation of the Manager of a Medical Marijuana Business Operated by a Medical Marijuana Business Operator</u>. 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 a separate and distinct manager 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 Associated Key License or Key License, as set forth in paragraph A of this rule, and the Medical Marijuana Business shall comply with the reporting provisions of subsection 12-43.4-309(11), C.R.S.

DEPARTMENT OF REVENUE

Marijuana Enforcement Division

RETAIL MARIJUANA RULES

1 CCR 212-2

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

R 100 Series - General Applicability

Basis and Purpose - R 101

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), and 12-43.4-901(2)(a), C.R.S. Any Person who buys, sells, transfers, gives away, or acquires Retail Marijuana outside the requirements of the Retail Code is engaging in illegal activity pursuant to Colorado law. This rule clarifies that those engaged in the business of possessing, cultivating, dispensing, or selling Retail Marijuana must be properly licensed to be in compliance with Colorado law.

<u>R 101 – Engaging in Business</u>

No person shall engage in the business of cultivating, possessing, selling, or offering to sell Retail Marijuana, or Retail Marijuana Product unless said Person is duly licensed by the State Licensing Authority and the relevant local licensing authority(-ies).

R 103 - Definitions

"Affiliated Interest" means any Business Interest related to a Retail Marijuana Establishment that does not rise to the level of a Financial Interest in a Retail Marijuana Establishment license. An Affiliated Interest may include, but shall not be limited to, an Indirect Beneficial Interest Owner that is not a Financial Interest, an indirect financial interest, a lease agreement, secured or unsecured loan, or security interest in fixtures or equipment with a direct nexus to the cultivation, manufacture, sale, transportation, or testing of Retail Marijuana or Retail Marijuana Products. Except as otherwise provided by these rules, an Affiliated Interest holder shall neither exercise control of nor be positioned so as to enable the exercise of control over the Retail Marijuana Establishment or its operations. A Retail Marijuana Establishment shall report each of its Affiliated Interests to the Division with each application for initial licensure, renewal, change of ownership or change of corporate structure.

"Associated Key License" means an Occupational License for an individual who is a Direct Beneficial Interest Owner of the Retail Marijuana Establishment, other than a Qualified Limited Passive Investor, and any Person who controls or is positioned so as to enable the exercise of control over a Retail Marijuana Establishment. Each shareholder, officer, director, member, or partner of a Closely Held Business Entity that is a Direct Beneficial Interest Owner and any Person who controls or is positioned so as to enable the exercise of control over a Retail Marijuana Business Establishment must hold an Associated Key License.

"Commercially Reasonable Royalty" means a right to compensation in the form of a royalty payment for the use of intellectual property. A Commercially Reasonable Royalty must be limited to specific intellectual property the Commercially Reasonable Royalty Interest Holder owns or is otherwise authorized to license. A Commercially Reasonable Royalty will not be approved where it could cause reasonable consumer confusion or violate any federal copyright, trademark or

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patent law or regulation. The Commercially Reasonably Royalty shall provide for compensation to the Commercially Reasonable Royalty Holder as a percentage of gross revenue or gross profit. The royalty payment must be at a reasonable percentage rate. To determine whether the percentage rate is reasonable, the Division will consider the totality of the circumstances, including but not limited to the following factors:

- 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.
- The established or projected profitability of the product made using the intellectual property; its commercial success; and its current popularity.
- 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.
- 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.

"Flowering" means the reproductive state of the Cannabis plant in which there are physical signs of flower budding out of the nodes in the stem.

Heat/Pressure Based Retail Marijuana Concentrate means a 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

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Manufacturing Facility and can be used alone or on a Production Batch that also includes Water-Based Retail Marijuana Concentrate or Solvent-Based Retail Marijuana Concentrate.

"Immature Plant" means a nonflowering Retail Marijuana plant that is no more than four inches wide or four inches high 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

"Key License" means an Occupational License for an individual who performs duties that are key to the Retail Marijuana Establishment's operation and have the highest level of responsibility. Examples of individuals who need this type of license include, but are not limited to, managers and bookkeepers but do not include an Owner.

allowable plant count, but must be fully accounted for in the Inventory Tracking System.

"Medical Marijuana" means marijuana that is grown and sold pursuant to the Medical Code and includes seeds and Immature Plants. <u>Unless the context otherwise requires, Medical Marijuana</u>
Concentrate is considered Medical Marijuana and is included in the term "Medical Marijuana."

"Medical Marijuana Business" means a Medical Marijuana Center, a Medical Marijuana-Infused Product Manufacturer, an Optional Premises Cultivation Operation, a Medical Marijuana Testing Facility, a Medical Marijuana Business Operator, or a Medical Marijuana Transporter.

"Medical Marijuana Business Operator" means an entity that holds a registration or license from the State Licensing Authority to provide professional operational services to one or more Medical Marijuana Businesses 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. The Medical Code and rules apply to all Medical Marijuana Business Operators regardless of whether such operator holds a registration or license. Any reference to "licensee" or "licensee" shall mean "registration" or "registrant" when applied to a Medical Marijuana Business Operator that holds a registration issued by the State Licensing Authority.

"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 and Heat/Pressure Based Medical Marijuana Concentrate and Heat/Pressure Based Medical Marijuana Concentrate.

"Occupational License" means a license granted to an individual by the State Licensing Authority pursuant to section 12-43.3-401 or 12-43.4-401, C.R.S. <u>An Occupational License may be an Associated Key License</u>, a Key License or a Support License.

"Permitted Economic Interest" means an Agreement to obtain an ownership interest in a Retail Marijuana Establishment or Medical Marijuana Business when the holder of such interest 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 and obtaining a license as a Direct Beneficial Interest Owner, under the Retail Code or Medical Code. A Permitted Economic Interest holder is an Indirect Beneficial Interest Owner.

"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

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to Retail Marijuana Concentrate, that is cultivated, manufactured, distributed, or sold by a licensed Retail Marijuana Establishment. "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. Unless the context otherwise requires, Retail Marijuana Concentrate is considered Retail Marijuana and is included in the term "Retail Marijuana."

"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.

"Support License" means a license for an individual who performs duties that support the Retail Marijuana Establishment's operations. While a Support Licensee must conduct himself or herself professionally, he or she has limited decision making authority and always fall under the supervision of an Associated Key Licensee. Examples of individuals who need this type of license include, but are not limited to, sales clerks or cooks.

"Transfer" means to grant, convey, hand over, assign, sell, exchange, donate, or barter, in any manner or by any means, with or without consideration, any Retail Marijuana or Retail Marijuana Product from one licensee to another licensee or to a consumer. A Transfer includes the movement of Retail Marijuana or Retail Marijuana Product 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 on the Inventory Tracking System, even if no physical movement of the Retail Marijuana or Retail Marijuana Product occurs.

"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.

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R 200 Series - Licensing and Interests

Basis and Purpose - R 201

The statutory authority for this rule is found at subsections 12-43.4-104(2)(a), 12-43.4-202(2)(b), 12-43.4-202(3)(a)(II), 12-43.4-202(3)(a)(III), 12-43.4-202(3)(a)(XX), 12-43.4-202(3)(b)(IX), and 12-43.4-304(1), and sections 12-43.4-103, 12-43.4-306.5, 12-43.4-309, 12-43.4-312, 12-43.4-401, and 24-76.5-101, et seq., C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(III). The purpose of this rule is to establish that only materially complete applications for licenses, accompanied by all required fees, will be accepted and processed by the Division. The purpose of the rule is also to clarify that when an initial application is materially complete and accepted, but the Division determines further information is required before the application can be fully processed, the Applicant must provide the additional requested information within the time frame provided by the Division. Otherwise, the Division cannot act on the application in a timely manner, and the application may be denied.

R 201 - Application Process

A. General Requirements

- All applications for licenses authorized pursuant to subsections 12-43.4-401(1)(a)-(g), C.R.S., shall be made upon current forms prescribed by the Division.
- A license issued to a Retail Marijuana Establishment or an individual constitutes a
 revocable privilege. The burden of proving an Applicant's qualifications for licensure rests
 at all times with the Applicant.
- 3. Each application shall identify the relevant local jurisdiction.
- Applicants must submit a complete application to the Division before it will be accepted or considered.
 - a. All applications must be complete and accurate in every material detail.
 - b. All applications must include all attachments or supplemental information required by the current forms supplied by the Division.
 - c. All applications must be accompanied by a full remittance of the application and relevant license fees for each applicant and each premise. See Rules R 207 Schedule of Application Fees: Retail Marijuana Establishments, R 208 Schedule of Business License Fees: Retail Marijuana Establishments, R 209 Schedule of Business License Renewal Fees: Retail Marijuana Establishments, R 234 Schedule of License Fees: Individuals, and R 235 Schedule of Renewal Fees: Individuals.
 - d. All applications must include all information required by the Division related to the Applicant's proposed Direct Beneficial Interest Owners, Indirect Beneficial Interest Owners and Qualified Limited Passive Investors, and all other direct and indirect financial interests in the Applicant.
 - At a minimum, each Applicant for a new license shall provide, at the time of application, the following information:

- For each Associated Key License Applicant, evidence of proof of lawful presence, citizenship, if applicable, residence, if applicable, and Good Moral Character as required by the current forms prescribed by the Division;
- For each Retail Marijuana Establishment Applicant and each Associated Key License Applicant, all requested information concerning financial and management associations and interests of other Persons in the business;
- iii. If the Applicant for any license pursuant to the Retail Code is a Closely Held Business Entity it shall submit with the application:
 - The Associated Key License applications for all of its shareholders, members, partners, officers and directors who do not already hold an Associated Key License;
 - B. If the Closely Held Business Entity is a corporation, a copy of its articles of incorporation or articles of organization; evidence of authorization from the Colorado Secretary of State to do business within this State, for each shareholder: his or her name, mailing address, state of residence and certification of Colorado residency for at least one officer and all officers with day-to-day operational control over the business;
 - C. If the Closely Held Business Entity is a limited liability company, a copy of its articles of <u>organization</u> and its operating agreement; evidence of authorization from the Colorado Secretary of State to do business within this State, for each member: his or her name, mailing address, state of residence and certification of Colorado residency for at least one officer and all officers with day-to-day operational control over the business;
 - D. If the Closely Held Business Entity is a general partnership, limited partnership, limited liability partnership, or limited liability limited partnership, a copy of the partnership agreement and, for each partner, his or her name, mailing address and state of residency and certification of Colorado residency for at least one officer and all officers with day-to-day operational control over the business.
- iv. For each Retail Marijuana Establishment Applicant and each Associated Key License Applicant, documentation establishing compliant return filing and payment of taxes related to any Medical Marijuana Business or Retail Marijuana Establishment in which such Applicant is, or was, required to file and pay taxes;
- v. For each Retail Marijuana Establishment Applicant and each Associated Key License Applicant, documentation verifying and confirming the funds used to start and/or sustain the operation of the medical or retail marijuana business were lawfully earned or obtained.
- vi. Accurate floor plans for the premises to be licensed; and

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- viii. The deed, lease, sublease, contract, or other document(s) governing the terms and conditions of occupancy of the premises to be licensed.
- 5. All applications to reinstate a license will be deemed applications for new licenses. This includes, but is not limited to, Associated Key licenses that have expired, Retail Marijuana Establishment licenses that have been expired for more than 90 days, licenses that have been voluntarily surrendered, licenses for which local licensing approval was not obtained within 12 months, and licenses that have been revoked.
- 6. The Division may refuse to accept or consider an incomplete application.

B. Additional Information May Be Required

- Upon request by the Division, an Applicant shall provide any additional information required to process and fully investigate the application. The additional information must be provided to the Division no later than seven days after the request is made unless otherwise specified by the Division.
- 2. An Applicant's failure to provide the requested information by the Division deadline may be grounds for denial of the application.
- C. Information Must Be Provided Truthfully. All Applicants shall submit information to the Division in a full, faithful, truthful, and fair manner. The Division may recommend denial of an application where the Applicant made misstatements, omissions, misrepresentations or untruths in the application or in connection with the Applicant's background investigation. This type of conduct may be considered as the basis for additional administrative action against the Applicant and it may also be the basis for criminal charges against the Applicant.
- D. <u>Application Forms Accessible</u>. All application forms supplied by the Division and filed by an Applicant for a license, including attachments and any other documents associated with the investigation, may be used for a purpose authorized by the Medical Code, the Retail Code or for any other state or local law enforcement purpose or as otherwise required by law.

E. Division Application Management and Local Licensure.

- The Division will either approve or deny a complete application between 45 days and 90 days of its receipt.
- For each application for a new Retail Marijuana Establishment, the Applicant shall submit
 the original application and one identical copy. The Division will retain the original
 application for a new Retail Marijuana Establishment and will send the copy and half the
 application fee to the relevant local jurisdiction within seven days of receiving the
 application.
- 3. If the Division grants a license before the relevant local jurisdiction approves the application or grants a local license, the license will be conditioned upon local approval. Such a condition will not be viewed as a denial pursuant to the Administrative Procedure Act. If the local jurisdiction denies the application, the state license will be revoked.
- 4. The Applicant has one year from the date of licensing by the State Licensing Authority to obtain approval or licensing through the relevant local jurisdiction. Should the Applicant fail to obtain local jurisdiction approval or licensing within the specified period, the state license shall expire and may not be renewed.

- An Applicant is prohibited from operating a Retail Marijuana Establishment prior to obtaining all necessary licenses or approvals from both the State Licensing Authority and the relevant local jurisdiction.
- 6. Each Financial Interest is void and of no effect unless and until approved by the Division. A Financial Interest shall not exercise any privilege associated with the proposed interest until approved by the Division. Any violation of this requirement may be considered a license violation affecting public safety.

R 202 - Repealed Effective January 1, 2017.

Basis and Purpose - R 202.1

The statutory authority for this rule is found at subsections, 12-43.4-104(2)(a), 12-43.4-202(2)(a), 12-43.4-202(2)(b), 12-43.4-202(3)(a)(II), 12-43.4-202(3)(a)(III), 12-43.4-202(3)(a)(XX), 12-43.4-202(3)(b)(IX), 12-43.4-306.5, and 12-43.4-309(2), and sections 12-43.4-103 and 12-43.4-312, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(III). The purpose of this rule is to clarify the process to be followed when a Retail Marijuana Establishment applies to obtain financing or otherwise have a relationship with an Indirect Beneficial Interest Owner. The rule establishes that only materially complete Retail Marijuana Establishment applications for Indirect Beneficial Interest Owners, accompanied by all required fees, will be accepted and processed by the Division. The rule also clarifies that when an initial application is materially complete and accepted, but the Division determines further information is required before the application can be fully processed, the Retail Marijuana Establishment Applicant must provide the additional requested information within the time frame provided by the Division. Otherwise, the Division cannot act on the application in a timely manner, and the Retail Marijuana Establishment's application may be denied. The rule sets forth requirements for the contents of the contract or Agreement between Retail Marijuana Establishments and Indirect Beneficial Interest Owners, which reflect basic legal requirements surrounding the relationship between the parties.

R 202.1 – Applications, Agreements, Contracts and Certifications Required for Indirect Beneficial Interest Owners: Retail Marijuana Establishments

- A. <u>Retail Marijuana Establishment Initiates Process</u>. The Retail Marijuana Establishment seeking to obtain financing or otherwise establish any type of relationship with an Indirect Beneficial Interest Owner, including a Permitted Economic Interest, a Commercially Reasonable Royalty Interest Holder, a Profit-Sharing Plan Employee, or a Qualified Institutional Investor, must file all required documents with the Division, including any supplemental documents requested by the Division in the course of its review of the application.
- B. <u>General Requirements</u>. The Retail Marijuana Establishment seeking approval of an Indirect Beneficial Interest Owner must meet the following requirements:
 - All applications for approval of an Indirect Beneficial Interest Owner shall be made upon current forms prescribed by the Division.
 - The burden of proving that a proposed Indirect Beneficial Interest Owner is qualified to hold such an interest rests at all times with the Retail Marijuana Establishment submitting the application.
 - The Retail Marijuana Establishment applying for approval of any type of Indirect Beneficial Interest Owner must submit a complete application to the Division before it will be accepted or considered.

- 4. All applications must be complete and accurate in every material detail.
- 5. All applications must include all attachments or supplemental information required by the current forms supplied by the Division.
- 6. All applications must be accompanied by a full remittance of the required fees.
- 7. The Division may refuse to accept an incomplete application.
- 8. The proposed holder of the Indirect Beneficial Interest is not a publicly traded company.
- 9. Additional Information May Be Required
 - a. Upon request by the Division, a Retail Marijuana Establishment applying to have any type of Indirect Beneficial Interest Owner shall provide any additional information required to process and fully investigate the application. The additional information must be provided to the Division no later than seven days after the request is made unless otherwise specified by the Division.
 - Failure to provide the requested information by the Division's deadline may be grounds for denial of the application.
- C. Information Must Be Provided Truthfully. A Retail Marijuana Establishment applying for approval of any type of Indirect Beneficial Interest Owner shall submit information to the Division in a full, faithful, truthful, and fair manner. The Division may recommend denial of an application where any party made misstatements, omissions, misrepresentations or untruths in the application or in connection with the background investigation of the proposed Indirect Beneficial Interest Owner. This type of conduct may be considered as the basis for additional administrative action against the Retail Marijuana Establishment and it may also be the basis for criminal charges against either the Retail Marijuana Establishment Applicant or the Indirect Beneficial Interest Owner.
- D. <u>Application Forms Accessible</u>. All application forms supplied by the Division and filed by an Applicant for a license, including attachments and any other documents associated with the investigation, may be used for a purpose authorized by the Medical Code, the Retail Code or for any other state or local law enforcement purpose or as otherwise required by law.
- E. <u>Approval of Financial Interest</u>. Each Financial Interest in a Retail Marijuana Establishment is void and of no effect unless and until approved by the Division. Any amendment of a Financial Interest is also void and of no effect unless and until approved by the Division.
- F. Ongoing Qualification and Violation Affecting Public Safety. If at any time the Division finds any Indirect Beneficial Interest Owner is not qualified, or is no longer qualified, the Division may require the Retail Marijuana Establishment to terminate its relationship with and financial ties to the Indirect Beneficial Interest Owner within a specified time period. Failure to terminate such relationship and financial ties within the specified time period may constitute a violation affecting public safety and be a basis for administrative action against the Retail Marijuana Establishment.
- G. <u>Permitted Economic Interest Holder Requirements</u>. At the time of application, a Retail Marijuana Establishment seeking to obtain approval of a Permitted Economic Interest shall provide evidence to establish that the natural person seeking to become a Permitted Economic Interest holder is a lawful resident of the United States and shall provide documentation verifying and confirming the funds used for the Permitted Economic Interest were lawfully earned or obtained.

- H. Permitted Economic Interest Agreement Requirements. The Retail Marijuana Establishment Applicant seeking to obtain financing from a Permitted Economic Interest must submit a copy of the Agreement between the Retail Marijuana Establishment and the person seeking to hold a Permitted Economic Interest. The following requirements apply to all Agreements:
 - 1. The Agreement must be complete, and must fully incorporate all terms and conditions.
 - 2. The following provisions must be included in the Agreement:
 - a. Any interest in a Retail Marijuana Establishment, whether held by a Permitted Economic Interest or any other person, must be acquired in accordance with the provisions of the Medical Code and/or Retail Code, as applicable, and the rules promulgated thereunder. The issuance of any Agreement or other interest in violation thereof shall be void. The Permitted Economic Interest holder shall not provide funding to the Retail Marijuana Establishment until the Permitted Economic Interest is approved by the Division.
 - b. No Agreement or other interest issued by the Retail Marijuana Establishment and no claim or charge therein or thereto shall be transferred except in accordance with the provisions of the Medical Code and/or Retail Code as applicable, and the rules promulgated thereunder. Any transfer in violation thereof shall be void.
 - The Retail Marijuana Establishment and the Permitted Economic Interest holder must sign an affirmation of passive investment on a form approved by the Division.
 - d. The Retail Marijuana Establishment must initiate any process to convert a Permitted Economic Interest to a Direct Beneficial Interest Owner and the process to convert the Permitted Economic Interest into a Direct Beneficial Interest Owner must be completed prior to the expiration or termination of the Agreement. The holder of the Permitted Economic Interest must meet all qualifications for licensure and ownership pursuant to the Medical Code and/or Retail Code and any rules promulgated thereunder prior to conversion of the Permitted Economic Interest to a Direct Beneficial Interest Owner.
 - e. At the election of the Retail Marijuana Establishment, if the holder of the Permitted Economic Interest is not qualified for licensure as a Direct Beneficial Interest Owner but is qualified as a holder of the Permitted Economic Interest, and the Permitted Economic Interest is also approved by the Division then the Permitted Economic Interest may remain in force and effect for as long as it remains approved by the Division under the Medical Code and/or Retail Code as applicable, and any rules promulgated thereunder.
 - f. The Permitted Economic Interest holder shall disclose in writing to the Division and to the Retail Marijuana Establishment any and all disqualifying events, within ten days after occurrence of the event, that could lead to a finding that the holder no longer qualifies to hold the Permitted Economic Interest and/or that could lead to a denial of licensure pursuant to the Medical Code and/or Retail Code and any rules promulgated thereunder.
 - g. The Retail Marijuana Establishment shall disclose in writing to the Division any and all disqualifying events, within ten days after receiving notice of the event, which could lead to a finding that the holder is no longer qualified to hold the Permitted Economic Interest and/or that could lead to a denial of licensure

pursuant to the Medical Code and/or Retail Code as applicable, and any rules promulgated thereunder.

- h. A Permitted Economic Interest holder's or a Retail Marijuana Establishment's failure to make required disclosures may be grounds for administrative action including but not limited to denial of a subsequent request to convert the Permitted Economic Interest into an ownership interest in the Retail Marijuana Establishment. Failure to make required disclosures may lead to a finding that the Permitted Economic Interest is no longer approved, and a requirement that the Retail Marijuana Establishment terminate its relationship with the Permitted Economic Interest holder.
 - The Permitted Economic Interest holder agrees and acknowledges that it has no entitlement or expectation of being able to invest in, or have a relationship with, the Retail Marijuana Establishment unless and until the Division determines the Permitted Economic Interest is approved. The Permitted Economic Interest holder agrees and acknowledges that its relationship with the Retail Marijuana Establishment is contingent upon Division approval. The Permitted Economic Interest holder understands and acknowledges that approval by the Division is wholly discretionary and the Division may, at any time, deny approval of the Permitted Economic Interest or find that the Permitted Economic Interest is no longer qualified. The Permitted Economic Interest Holder agrees and acknowledges it has no entitlement to or expectation of the Division approving the Permitted Economic Interest. The Permitted Economic Interest holder further agrees that any administrative or judicial review of a determination by the Division regarding the qualification or approval of the Permitted Economic Interest will only occur through licensing or enforcement proceedings involving the Retail Marijuana Establishment. The Permitted Economic Interest holder further agrees and acknowledges that the Permitted Economic Interest holder shall only be entitled to notice of a denial or administrative action concerning the Retail Marijuana Establishment if the denial or administrative action is based upon, or directly related to, the qualifications or actions of the Permitted Economic Interest holder. The Permitted Economic Interest holder also agrees and acknowledges that the Permitted Economic Interest holder may only request leave to intervene in an administrative proceeding against the Retail Marijuana Establishment, pursuant to subsection 24-4-105(2)(c), C.R.S., if the administrative proceeding is based upon, or directly related to, the qualifications or actions of the Permitted Economic Interest holder. Furthermore, the Permitted Economic Interest holder agrees and acknowledges that the Permitted Economic Interest holder may only seek judicial review of an action against the Retail Marijuana Establishment, pursuant to subsection 24-4-106(4), C.R.S., if the administrative action is based upon, or directly related to, the qualifications or actions of the Permitted Economic Interest Holder. THE PERMITTED ECONOMIC INTEREST HOLDER KNOWINGLY, FREELY, AND VOLUNTARILY WAIVES ANY RIGHT OR CLAIM TO SEEK ANY INDEPENDENT REVIEW OF APPROVAL OR DENIAL OF THE PERMITTED ECONOMIC INTEREST BY THE DIVISION, OR OF AN ADMINISTRATIVE ACTION AGAINST THE RETAIL MARIJUANA ESTABLISHMENT, THAT IS BASED UPON, OR DIRECTLY RELATED TO, THE QUALIFICATIONS OR ACTIONS OF THE PERMITTED ECONOMIC INTEREST, AND EXPRESSLY AGREES THAT THE ONLY ADMINISTRATIVE OR JUDICIAL REVIEW OF SUCH

A DETERMINATION OR ACTION WILL OCCUR THROUGH A LICENSING OR ENFORCEMENT PROCEEDING FOR THE RETAIL MARIJUANA ESTABLISHMENT.

- I. <u>Commercially Reasonable Royalty Interest Contract Requirements.</u> A Retail Marijuana Establishment seeking to utilize the intellectual property of a Commercially Reasonable Royalty Interest Holder must submit a copy of the contract between the Retail Marijuana Establishment and the Person seeking to hold a Commercially Reasonable Royalty Interest. The following requirements apply to all such contracts:
 - 1. The contract must be complete, and must fully incorporate all terms and conditions.
 - 2. The following provisions must be included in the contract:
 - a. Any interest in a Retail Marijuana Establishment, whether held by a Commercially Reasonable Royalty Interest Holder or any other person, must be acquired in accordance with the provisions of the Medical Code and/or Retail Code, as applicable, and the rules promulgated thereunder. The issuance of any contract or other interest in violation thereof shall be void.
 - b. No contract, royalty or other interest issued by the Retail Marijuana Establishment and no claim or charge therein or thereto shall be transferred except in accordance with the provisions of the Medical Code and/or Retail Code as applicable, and the rules promulgated thereunder. Any transfer in violation thereof shall be void.
 - c. The Retail Marijuana Establishment and the Commercially Reasonable Royalty Interest Holder must sign an affirmation of passive investment on a form approved by the Division.
 - d. The Commercially Reasonable Royalty Interest Holder shall disclose in writing to the Division and to the Retail Marijuana Establishment any and all disqualifying events, within ten days after occurrence of the event, that could lead to a finding that the Commercially Reasonable Royalty Interest Holder is not qualified to hold the Commercially Reasonable Royalty Interest.
 - e. The Retail Marijuana Establishment shall disclose in writing to the Division any and all disqualifying events, within ten days after receiving notice of the event, which would lead to a finding that the Commercially Reasonable Royalty Interest Holder is not qualified to hold the Commercially Reasonable Royalty Interest.
 - f. A Commercially Reasonable Royalty Interest Holder's or a Retail Marijuana Establishment's failure to make required disclosures may lead to a finding that the Commercially Reasonable Royalty Interest is not approved, or is no longer approved, and may lead to a requirement that the Retail Marijuana Establishment terminate its relationship with the Commercially Reasonable Royalty Interest Holder.
 - g. The Commercially Reasonable Royalty Interest Holder agrees and acknowledges that its relationship with the Retail Marijuana Establishment is contingent upon Division approval throughout the entire term of its relationship with the Retail Marijuana Establishment. The Commercially Reasonable Royalty Interest Holder understands and acknowledges that approval by the Division is wholly discretionary and the Division may, at any time, find that the Commercially

Reasonable Royalty Interest Holder does not qualify or no longer qualifies. The Commercially Reasonable Royalty Interest Holder agrees and acknowledges it has no entitlement to or expectation to approval of the Commercially Reasonable Royalty Interest.

- h. The Commercially Reasonable Royalty Interest Holder further agrees that any administrative or judicial review of a determination by the Division approving or denying the Commercially Reasonable Royalty will only occur through licensing or enforcement proceedings involving the Retail Marijuana Establishment. The Commercially Reasonable Royalty Interest Holder further agrees and acknowledges that the Commercially Reasonable Royalty Interest Holder shall only be entitled to notice of a denial or administrative action concerning the Retail Marijuana Establishment if the denial or administrative action is based upon, or directly related to, the qualifications or actions of the Commercially Reasonable Royalty Interest Holder. The Commercially Reasonable Royalty Interest Holder also agrees and acknowledges that the Commercially Reasonable Royalty Interest Holder may only request leave to intervene in an administrative proceeding against the Retail Marijuana Establishment, pursuant to subsection 24-4-105(2)(c), C.R.S., if the administrative proceeding is based upon, or directly related to, the qualifications or actions of the Commercially Reasonable Royalty Interest Holder. Furthermore, the Commercially Reasonable Royalty Interest Holder agrees and acknowledges that the Commercially Reasonable Royalty Interest Holder may only seek judicial review of an action against the Retail Marijuana Establishment, pursuant to subsection 24-4-106(4), C.R.S., if the administrative action is based upon, or directly related to, the qualifications or actions of the Commercially Reasonable Royalty Interest Holder. THE COMMERCIALLY REASONABLE ROYALTY INTEREST HOLDER KNOWINGLY, FREELY, AND VOLUNTARILY WAIVES ANY RIGHT OR CLAIM TO SEEK ANY INDEPENDENT REVIEW OF APPROVAL OR DENIAL OF THE COMMERCIALLY REASONABLE ROYALTY INTEREST BY THE DIVISION, OR OF AN ADMINISTRATIVE ACTION AGAINST THE RETAIL MARIJUANA ESTABLISHMENT, THAT IS BASED UPON, OR DIRECTLY RELATED TO, THE QUALIFICATIONS OR ACTIONS OF THE COMMERCIALLY REASONABLE ROYALTY INTEREST HOLDER, AND EXPRESSLY AGREES THAT THE ONLY ADMINISTRATIVE OR JUDICIAL REVIEW OF SUCH A DETERMINATION OR ACTION WILL OCCUR THROUGH A LICENSING OR ENFORCEMENT PROCEEDING FOR THE RETAIL MARIJUANA ESTABLISHMENT.
- If the Division determines the Commercially Reasonable Royalty Interest Holder is not in compliance with the Retail Code, the Medical Code or these rules, then the recipient shall discontinue use of such Commercially Reasonable Royalty Interest Holder's intellectual property within thirty (30) days of the Division finding. The recipient shall not pay any remuneration to a Commercially Reasonable Royalty Interest Holder that does not qualify under the Retail Code and these rules, including but not limited to Rule R 231.2(B).
- j. The Commercially Reasonable Royalty Interest Holder shall neither exercise control over nor be positioned so as to enable the exercise of control over the Retail Marijuana Establishment. Notwithstanding the foregoing, a Commercially Reasonable Royalty Interest Holder may influence the marketing, advertising, labeling and display of any.product.or line of products for which the Commercially Reasonably Royalty Interest exists so long as such influence is not inconsistent with the Retail Code, the Medical Code or these rules.

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- J. <u>Profit-Sharing Plan Documents</u>. A Retail Marijuana Establishment offering licensed employees a share of the profits through a Profit-Sharing Plan must submit a list of all proposed participants in the Profit-Sharing Plan along with their names, addresses and occupational license numbers and submit a copy of all documentation regarding the Profit-Sharing Plan in connection with the Retail Marijuana Establishment's application:
 - The documents establishing the Profit-Sharing Plan must be complete and must fully incorporate all terms and conditions.
 - The following provisions must be included in the documents establishing the Profit-Sharing Plan:
 - a. Any interest in a Retail Marijuana Establishment, whether held by a Profit-Sharing Plan Employee or any other person, must be acquired in accordance with the provisions of the Medical Code and/or Retail Code, as applicable, and the rules promulgated thereunder. The issuance of any contract or other interest in violation thereof shall be void.
 - b. No contract or other interest issued by the Retail Marijuana Establishment and no claim or charge therein or thereto shall be transferred except in accordance with the provisions of the Medical Code and/or Retail Code as applicable, and the rules promulgated thereunder. Any transfer in violation thereof shall be void. Any distributions from a Profit-Sharing Plan must be made in cash, not in the form of stock or other equity interests in the Retail Marijuana Establishment.
 - c. The Retail Marijuana Establishment shall disclose in writing to the Division any and all disqualifying events, within ten days after receiving notice of the event, which would lead to a finding that any Profit-Sharing Plan Employee does not qualify under the Retail Code and these rules, including but not limited to Rule R 231.6(B), to participate in the Profit-Sharing Plan.
 - d. A Profit-Sharing Plan Employee shall disclose in writing to the Division and to the Retail Marijuana Establishment any and all disqualifying events, within ten days after occurrence of the event that could lead to a finding that the Profit-Sharing Plan Employee does not qualify or no longer qualifies under the Retail Code and these rules, including but not limited to Rule R 231.2(B), to participate in the Profit-Sharing Plan.
 - e. A Retail Marijuana Establishment's or a Profit-Sharing Plan Employee's failure to make required disclosures may lead to a finding that the Profit-Sharing Plan is not approved, and may lead to a requirement that the Retail Marijuana Establishment terminate or modify the Profit-Sharing Plan.
 - f. The Profit-Sharing Plan Employee agrees and acknowledges that its relationship with the Retail Marijuana Establishment is contingent upon Division approval throughout the entire term of its relationship with the Retail Marijuana Establishment. The Profit-Sharing Plan Employee understands and acknowledges that approval by the Division is wholly discretionary and the Division may, at any time, deny approval of the Profit-Sharing Plan. The Profit-Sharing Plan Employee agrees and acknowledges he or she has no entitlement to or expectation to Division approval of the Profit-Sharing Plan or the Profit-Sharing Plan Employee's participation in the plan. The Profit-Sharing Plan Employee further agrees that any administrative or judicial review of a determination by the Division approving or denying the Profit-Sharing Plan or the Profit-Sharing Plan Employee will only occur through licensing or enforcement

proceedings involving the Retail Marijuana Establishment. Each Profit-Sharing Plan Employee further agrees and acknowledges that the Profit-Sharing Plan Employee shall only be entitled to notice of a denial or administrative action concerning the Retail Marijuana Establishment if the denial or administrative action is based upon, or directly related to, the qualifications or actions of the Profit-Sharing Plan Employee. The Profit-Sharing Plan Employee also agrees and acknowledges that the Profit-Sharing Plan Employee may only request leave to intervene in an administrative proceeding against the Retail Marijuana Establishment, pursuant to subsection 24-4-105(2)(c), C.R.S., if the administrative proceeding is based upon, or directly related to, the qualifications or actions of the Profit-Sharing Plan Employee. Furthermore, the Profit Sharing Plan Employee agrees and acknowledges that the Profit-Sharing Plan Employee may only seek judicial review of an action against the Retail Marijuana Establishment, pursuant to subsection 24-4-106(4), C.R.S., if the administrative action is based upon, or directly related to, the qualifications or actions of the Profit-Sharing Plan Employee. THE PROFIT-SHARING PLAN EMPLOYEE KNOWINGLY, FREELY, AND VOLUNTARILY WAIVES ANY RIGHT OR CLAIM TO SEEK ANY INDEPENDENT REVIEW OF APPROVAL OR DENIAL OF THE PROFIT-SHARING PLAN OR THE PROFIT-SHARING PLAN EMPLOYEE BY THE DIVISION, OR OF AN ADMINISTRATIVE ACTION AGAINST THE RETAIL MARIJUANA ESTABLISHMENT, THAT IS BASED UPON, OR DIRECTLY RELATED TO, THE PROFIT-SHARING PLAN OR THE PROFIT-SHARING PLAN EMPLOYEE'S QUALIFICATIONS OR ACTIONS OF THE PROFIT-SHARING PLAN EMPLOYEE, AND EXPRESSLY AGREES THAT THE ONLY ADMINISTRATIVE OR JUDICIAL REVIEW OF SUCH A DETERMINATION OR ACTION WILL OCCUR THROUGH A LICENSING OR ENFORCEMENT PROCEEDING FOR THE RETAIL MARIJUANA ESTABLISHMENT.

- K. <u>Qualified Institutional Investor Requirements</u>. Before a Retail Marijuana Establishment may permit a Qualified Institutional Investor to own any portion of the Retail Marijuana Establishment, the Retail Marijuana Establishment must submit the following documentation to the Division in connection with the Retail Marijuana Establishment's application:
 - A description of the Qualified Institutional Investor's business and a statement as to why
 the Qualified Institutional Investor meets the definition of Qualified Institutional Investor in
 Rule R 103 and subsection 12-43.4-306.5(7), C.R.S.
 - A certification made under oath and the penalty of perjury by the Qualified Institutional Investor:
 - a. That the ownership interests were acquired and are held for investment purposes only and were acquired and are held in the ordinary course of business as a Qualified Institutional Investor and not for the purposes of causing, directly or indirectly, the election of a majority of the board of directors, any change in the corporate charter, bylaws, management, policies, or operations of a Retail Marijuana Establishment.
 - b. That the Qualified Institutional Investor is bound by and shall comply with the Retail Code and the rules adopted pursuant thereto, is subject to the jurisdiction of the courts of Colorado, and consents to Colorado as the choice of forum in the event any dispute, question, or controversy arises regarding the Qualified Institutional Investor's relationship with the Retail Marijuana Establishment or activities pursuant to the Retail Code and rules adopted pursuant thereto.

- The Qualified Institutional Investor agrees and acknowledges that its relationship with the Retail Marijuana Establishment is contingent upon Division approval throughout the entire term of its relationship with the Retail Marijuana Establishment. The Qualified Institutional Investor understands and acknowledges that approval by the Division is wholly discretionary and the Division may, at any time, deny approval of the Qualified Institutional Investor. The Qualified Institutional Investor agrees and acknowledges it has no entitlement to or expectation to Division approval of the Qualified Institutional Investor. The Qualified Institutional Investor further agrees that any administrative or judicial review of a determination by the Division approving or denying the Qualified Institutional Investor will only occur through licensing or enforcement proceedings involving the Retail Marijuana Establishment. The Qualified Institutional Investor further agrees and acknowledges that the Qualified Institutional Investor shall only be entitled to notice of a denial or administrative action concerning the Retail Marijuana Establishment if the denial or administrative action is based upon, or directly related to, the qualifications or actions of the Qualified Institutional Investor. The Qualified Institutional Investor also agrees and acknowledges that the Qualified Institutional Investor may only request leave to intervene in an administrative proceeding against the Retail Marijuana Establishment, pursuant to subsection 24-4-105(2)(c), C.R.S., if the administrative proceeding is based upon, or directly related to, the qualifications or actions of the Qualified Institutional Investor. Furthermore, the Qualified Institutional Investor agrees and acknowledges that the Qualified Institutional Investor may only seek judicial review of an action against the Retail Marijuana Establishment, pursuant to subsection 24-4-106(4), C.R.S., if the administrative action is based upon, or directly related to, the qualifications or actions of the Qualified Institutional Investor. THE QUALIFIED INSTITUTIONAL INVESTOR KNOWINGLY, FREELY, AND VOLUNTARILY WAIVES ANY RIGHT OR CLAIM TO SEEK ANY INDEPENDENT REVIEW OF APPROVAL OR DENIAL OF THE QUALIFIED INSTITUTIONAL INVESTOR BY THE DIVISION, OR OF AN ADMINISTRATIVE ACTION AGAINST THE RETAIL MARIJUANA ESTABLISHMENT, THAT IS BASED UPON, OR DIRECTLY RELATED TO, THE QUALIFICATIONS OR ACTIONS OF THE QUALIFIED INSTITUTIONAL INVESTOR, AND EXPRESSLY AGREES THAT THE ONLY ADMINISTRATIVE OR JUDICIAL REVIEW OF SUCH A DETERMINATION OR ACTION WILL OCCUR THROUGH A LICENSING OR ENFORCEMENT PROCEEDING FOR THE RETAIL MARIJUANA ESTABLISHMENT.
- An explanation of the basis of the signatory's authority to sign the certification and to bind the Qualified Institutional Investor to its terms.
- 3. The name, address, telephone number and any other information requested by the Division as required on its approved forms for the officers and directors, or their equivalent, of the Qualified Institutional Investor as well as those Persons that have direct control over the Qualified Institutional Investor's ownership interest in the Retail Marijuana Establishment.
- 4. The name, address, telephone number and any other information requested by the Division as required on its approved forms for each Person who has the power to direct or control the Qualified Institutional Investor's voting of its shares in the Retail Marijuana Establishment.

- The name of each Person that beneficially owns 5 percent or more of the Qualified Institutional Investor's voting securities or other equivalent.
- 6. A list of the Qualified Institutional Investor's affiliates.
- A list of all regulatory agencies with which the Qualified Institutional Investor files periodic reports, and the name, address, and telephone number of the individual, if known, to contact at each agency regarding the Qualified Institutional Investor.
- 8. A disclosure of all criminal or regulatory sanctions imposed during the preceding 10 years and of any administrative or court proceedings filed by any regulatory agency during the preceding 5 years against the Qualified Institutional Investor, its affiliates, any current officer or director, or any former officer or director whose tenure ended within the preceding 12 months. As to a former officer or director, such information need be provided only to the extent that it relates to actions arising out of or during such person's tenure with the Qualified Institutional Investor or its affiliates.
- A copy of any filing made under 16 U.S.C § 18a with respect to the acquisition or proposed acquisition of an ownership interest in the Retail Marijuana Establishment.
- 10. Any additional information requested by the Division.

Basis and Purpose - R 204

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(l), 12-43.4-202(3)(a)(IX), 12-43.4-202(3)(a)(XV), 12-43.4-202(3)(a)(XX), 12-43.4-202(3)(b)(IX), and 12-43.4-601(1) and sections 12-43.4-103, 12-43.4-306.5, 12-43.4-309, 12-43.4-312, and 12-43.4-901, C.R.S. The purpose of this rule is to provide clarity regarding the nature of a Direct Beneficial Interest Owner and an Indirect Beneficial Interest Owner, and to clarify what factors the State Licensing Authority generally considers regarding the same. The Division will review all relevant information to determine ownership of a Retail Marijuana Establishment.

R 204 - Ownership Interests of a License: Retail Marijuana Establishments

- A. <u>Licenses Held By Direct Beneficial Interest Owners</u>. Each Retail Marijuana Establishment License must be held by its Direct Beneficial Interest Owner(s). Each natural person other than a Qualified Limited Passive Investor must hold an Associated Key license. A Direct Beneficial Interest Owner shall not be a publicly traded company.
- B. 100% Ownership.
 - The sum of the percentages of ownership of all Direct Beneficial Interest Owners of a Retail Marijuana Establishment and Qualified Institutional Investors must equal 100%.
 - Qualified Institutional Investors may hold ownership interests, in the aggregate, of 30% or less in the Retail Marijuana Establishment.
 - A Qualified Limited Passive Investor must be a natural person who is a United States citizen and may hold an ownership interest of less than five percent in the Retail Marijuana Establishment.
 - c. Each Direct Beneficial Interest Owner, including but not limited to each officer, director, managing member, or partner of a Retail Marijuana Establishment, must hold a current and valid Associated Key License. See Rule R 233 Retail Code

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- or Medical Code Occupational Licenses Required. Except that this requirement shall not apply to Qualified Limited Passive Investors.
- d. With the exception of Qualified Institutional Investors, only Direct Beneficial Interest Owners may hold a partnership interest, limited or general, a joint venture interest, or ownership of a share or shares in a corporation or a limited liability company which is licensed.
- e. In the event of the death, disability, disqualification, divestment, termination, or revocation of the license of a Direct Beneficial Interest Owner or of approval of a Qualified Institutional Investor, a Retail Marijuana Establishment shall have 45 days to submit a change of ownership application to the Division detailing the Licensee's plan for redistribution of ownership among the remaining Direct Beneficial Interest Owners and Qualified Institutional Investors. Such plan is subject to approval by the Division. If a change of ownership application is not timely submitted, the Retail Marijuana Establishment and its Associated Key Licensee(s) may be subject to administrative action.
- C. <u>At Least One Associated Key License Required</u>. No Retail Marijuana Establishment may operate or be licensed unless it has at least one Associated Key Licensee that is a Direct Beneficial Interest Owner who has been a Colorado resident for at least one year prior to application. Any violation of this requirement may be considered a license violation affecting public safety.
- D. Loss Of Occupational License As An Owner Of Multiple Businesses. If an Associated Key License is suspended or revoked as to one Retail Marijuana Establishment or Medical Marijuana Business, that Associated Key License, shall be suspended or revoked as to any other Retail Marijuana Establishment or Medical Marijuana Business in which that Person possesses an ownership interest. See Rule R 233 Retail Code or Medical Code Occupational Licenses Required.
- E. <u>Management Companies</u>. Any Person contracted to manage the overall operation of a Licensed Premises must hold a Retail Marijuana Operator license.
- F. Role of Managers. Associated Key Licensees may hire managers, and managers may be compensated on the basis of profits made, gross or net. A Retail Marijuana Establishment license may not be held in the name of a manager who is not a Direct Beneficial Interest Owner. A manager who does not hold an Associated Key License as a Direct Beneficial Interest Owner of the Retail Marijuana Establishment, must hold a Key License as an employee of the Retail Marijuana Establishment. Any change in manager must be reported to the Division within seven (7) days of the change. Additionally, a Retail Marijuana Operator may include management services as part of the operational services provided to a Retail Marijuana Establishment. A Retail Marijuana Establishment and its Direct Beneficial Interest Owners may be subject to license denial or administrative action including, but not limited to, fine, suspension or revocation of their license(s) based on the acts or omissions of any manager, Retail Marijuana Establishment Operator, or agents and employees thereof engaged in the operations of the Retail Marijuana Establishment.
- G. Prohibited Third-Party Acts. No Licensee may employ, contract with, hire, or otherwise engage 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.
 - A Licensee is responsible for all actions and omissions of any Person the Licensee employs, contracts with, hires, or otherwise engages, including but not limited to an

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employee, agent, or independent contractor, to perform any act or conduct on the Licensee's behalf or for the Licensee's benefit.

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 acts and/or omissions of any Person the Licensee employs, contracts with, hires, or otherwise engages, 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.

Basis and Purpose - R 204.5

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(I), 12-43.3-202(3)(a)(III), 12-43.4-202(3)(a)(XIV.5), 12-43.4-202(3)(a)(XX), 12-43.4-202(3)(b)(V), 12-43.4-202(3)(b)(VII), 12-43.4-202(3)(b)(VII), 12-43.4-202(3)(b)(IIX), and sections 12-43.4-103, 12-43.4-304, 12-43.4-306, 12-43.4-306, 12-43.4-308, 12-43.4-309, and 12-43.4-312, C.R.S. The purpose of this rule is to clarify the application, review and approval process for various types of Business Interests. The Division will review all relevant information to determine ownership of, interests in, and control of a Retail Marijuana Establishment.

R 204.5 - Disclosure, Approval and Review of Business Interests

- A. <u>Business Interests</u>. A Retail Marijuana Establishment shall disclose all Business Interests at the time of initial application and at the time of each renewal application. Business Interests include Financial Interests and Affiliated Interests. Any Financial Interest must be pre-approved by the Division. It shall be unlawful to fail to completely report all Business Interests in each license issued. It shall be unlawful for a person other than a Financial Interest holding an Associated Key License to exercise control over a Retail Marijuana Establishment or to be positioned so as to enable the exercise of control over a Retail Marijuana Establishment. Except that a Qualified Institutional Investor and a Qualified Limited Passive Investor may vote his, her or its shares in the Retail Marijuana Establishment.
- B. <u>Financial Interests</u>. A Retail Marijuana Establishment shall not permit any Person to hold or exercise a Financial Interest in the Retail Marijuana Establishment unless and until such Person's Financial Interest has been approved by the Division. If a Retail Marijuana Establishment wishes to permit a Person to hold or exercise a Financial Interest, and that Person has not been previously approved in connection with an application for the Retail Marijuana Establishment, the Retail Marijuana Establishment shall submit a change of ownership or financial interest form approved by the Division. A Financial Interest shall include:
 - Any Direct Beneficial Interest Owner;
 - 2. The following types of Indirect Beneficial Interest Owners:
 - A Commercially Reasonable Royalty Interest Holder who receives more than 30
 percent of the gross revenue or gross profit from sales of the product or line of
 products subject to the royalty; and
 - b. A Permitted Economic Interest holder.
 - 3. Control. Any other Person who exercises control or is positioned so as to enable the exercise of control over the Retail Marijuana Establishment must hold an Associated Key License. A natural person who exercises control or is positioned so as to enable the exercise of control over a Retail Marijuana Establishment shall include but shall not be limited to a natural person who:

- Bears the risk of loss and opportunity for profit;
- b. Has final decision making authority over any material aspect of the operation of the Retail Marijuana Establishment;
- c. Manages the overall operations of a Retail Marijuana Establishment or its Licensed Premises, or who manages a material portion of the Retail Marijuana Establishment or its Licensed Premises;
- d. Guarantees the Retail Marijuana Establishment's debts or production levels;
- e. Is a beneficiary of the Retail Marijuana Establishment's insurance policies;
- f. Receives the majority of the Retail Marijuana Establishment's profits as compared to other recipients of the Retail Marijuana Establishment's profits; or
- g. Acknowledges liability for the Retail Marijuana Establishment's federal, state or
- C. Affiliated Interests. A Retail Marijuana Establishment shall disclose all Affiliated Interests in connection with each application for licensure, renewal or reinstatement of the Retail Marijuana Establishment. The Division may conduct such background investigation as it deems appropriate regarding Affiliated Interests. An Affiliated Interest shall include any Person who does not hold a Financial Interest in the Retail Marijuana Establishment and who has any of the following relationships with the Retail Marijuana Establishment:
 - 1. The following Indirect Beneficial Interest Owners:
 - A Commercially Reasonable Royalty Interest Holder who receives 30 percent or less of the gross revenue or gross profit from sales of the product or line of products subject to the royalty;
 - b. A Profit-Sharing Plan Employee; and
 - c. A Qualified Institutional Investor.
 - Any other Person who holds any other disclosable interest in the Retail Marijuana
 Establishment other than a Financial Interest. Such disclosable interests shall include but
 shall not be limited to an indirect financial interest, a lease agreement, a secured or
 unsecured loan, or security interest in fixtures or equipment with a direct nexus to the
 cultivation, manufacture, sale, transportation, or testing of Retail Marijuana or Retail
 Marijuana Products.
 - 3. If the Division determines any Person disclosed as an Affiliated Interest should have been pre-approved as a Financial Interest, approval and further background investigation may be required. Additionally, the failure to seek pre-approval of a Financial Interest holder may form the basis for license denial or administrative action against the Retail Marijuana Establishment.
- D. <u>Secured Interest In Marijuana Prohibited</u>. No Person shall at any time hold a secured interest in Retail Marijuana or Retail Marijuana Products

Basis and Purpose - R 206

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(2)(e), and 12-43.4-202(3)(a)(I), 12-43.4-309(6), 12-43.4-309(12) and section 12-43.4-304, 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 clarify the application process for changing location of a Licensed Premises.

R 206 - Changing Location of Licensed Premises: Retail Marijuana Establishments

A. <u>Application Required to Change Location of Licensed Premises</u>

- A Direct Beneficial Interest Owner or other authorized representative of a Retail Marijuana Establishment must make application to the Division for permission to change location of its Licensed Premise.
- 2. Such application shall:
 - a. Be made upon current forms prescribed by the Division;
 - b. Be complete in every material detail and include remittance of all applicable fees;
 - c. Be submitted at least 30 days prior to the proposed change;
 - d. Explain the reason for requesting such change;
 - e. Be supported by evidence that the application complies with the relevant local jurisdiction requirements; and
 - f. Contain a report of the relevant local jurisdiction(s) in which the Retail Marijuana Establishment is to be situated, which report shall demonstrate the approval of the local jurisdiction(s) with respect to the new location. If the relevant local jurisdiction elects not to approve or deny a change of location of Licensed Premises application, the local jurisdiction must provide written notification acknowledging receipt of the application.

B. Permit Required Before Changing Location

- No change of location shall be permitted until after the Division considers the application, and such additional information as it may require, and issues to the Applicant a permit for such change.
- 2. The permit shall be effective on the date of issuance, and the Licensee shall, within 120 days, change the location of its business to the place specified therein and at the same time cease to operate a Retail Marijuana Establishment at the former location. At no time may a Retail Marijuana Establishment operate or exercise any of the privileges granted pursuant to the license in both locations. For good cause shown, the 120 day deadline may be extended for an additional 120 days. If the Licensee does not change the location of its business within the time period granted by the Division, including any extension, the Licensee shall submit a new application, pay the requisite fees and receive a new permit prior to completing any change of the location of the business.
- The permit shall be conspicuously displayed at the new location, immediately adjacent to the license to which it pertains.

C. General Requirements

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- An application for change of location to a different local jurisdiction shall follow the same procedures as an application for a new Retail Marijuana Establishment license, except that licensing fees will not be assessed until the license is renewed. See Rule R 202 -Process for Issuing a New License: Retail Marijuana Establishments.
- An Applicant for change of location within the same local jurisdiction shall file a change of location application with the Division and pay the requisite change of location fee. See Rule R 207 - Schedule of Application Fees: Retail Marijuana Establishments.

Basis and Purpose - R 210

The statutory authority for this rule is found at subsections 12-43.4-202(2)(a), 12-43.3-1101, 12-43.3-1102, 12-43.4-202(2)(b), 12-43.4-202(3)(a)(II), and 12-43.4-304(1), and sections 12-43.4-103, 12-43.4-103, 12-43.3-501, 12-43.3-501, 12-43.3-502 and 12-43.4-501, 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 basic requirements for all Division applications and help the regulated community understand procedural licensing requirements.

R 210 - Schedule of Other Application Fees: All Licensees

- A. <u>Other Application Fees.</u> The following application fees apply:
 - 1. Transfer of Ownership New Owners \$1,600.00
 - 2. Transfer of Ownership Reallocation of Ownership \$1,000.00
 - 3. Change of Corporation or LLC Structure \$800.00,
 - 4. Change of Trade Name \$50.00
 - 5. Change of Location Application Fee Same Local Jurisdiction Only \$500.00
 - 6. Modification of Licensed Premises \$100.00
 - 7. Duplicate Business License \$20.00
 - 8. Duplicate Occupational License \$20.00
 - 9. Off Premises Storage Permit \$1,500.00
 - 10. Retail Marijuana Transporter Off Premises Storage Permit \$2,200.00
 - 11. Responsible Vendor Program Provider Application Fee: \$850.00
 - 12. Responsible Vendor Program Provider Renewal Fee: \$350.00
 - 13. Responsible Vendor Program Provider Duplicate Certificate Fee: \$50.00
- B. When Other Application Fees Are Due. All other application fees are due at the time the application and/or request is submitted.
- C. Subpoena Fee See Rule M 106 Subpoena Fees

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Basis and Purpose - R 231.1

The statutory authority for this rule is found at subsections 12-43.3-201(4), 12-43.4-202(2)(b), 12-43.4-202(3)(a)(III) and 24-18-105(3), 12-43.4-202(3)(a)(XX), and sections 12-43.4-103, 12-43.4-304, 12-43.4-305, 12-43.4-306.5 and 24-76.5-101, et. seq., C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(III). The purpose of this rule is to clarify the qualifications for Direct Beneficial Interest Owners.

R 231.1 – Finding of Suitability, Residency and Reporting Requirements for Direct Beneficial Interest Owners

- A. <u>Finding of Suitability Non-Resident Direct Beneficial Interest Owners.</u> A natural person, owner, shareholder, director, officer, member or partner of an entity that intends to apply to become a Direct Beneficial Interest Owner who has not been a resident of Colorado for at least one year prior to the application shall first submit a request to the State Licensing Authority for a finding of suitability to become a Direct Beneficial Interest Owner as follows:
 - A request for a finding of suitability for a non-resident natural person shall be submitted on the forms prescribed by the Division.
 - A natural person or all owners, shareholders, directors, officers, members or partners of
 an entity who have not been a resident of Colorado for at least one year shall obtain a
 finding of suitability prior to submitting an application to become a Direct Beneficial
 Interest Owner to the State Licensing Authority.
 - A finding of suitability is valid for one year from the date it is issued by the Division. If more than one year has passed since the Division first issued a finding of suitability to a natural person, owner, shareholder, director, officer, member or partner of an entity that intends to apply to become a Direct Beneficial Interest Owner who has not been a resident of Colorado for at least one year prior to the application, then such applicant shall submit a new request for finding of suitability to the State Licensing Authority and obtain a new finding of suitability before submitting any application to become a Direct Beneficial Interest Owner to the State Licensing Authority.
 - 4. A non-Colorado resident's failure to obtain a finding of suitability within the year prior to submission of an application to become a Direct Beneficial Interest Owner to the State Licensing Authority shall be grounds for denial of the application.
- B. <u>Number of Permitted Direct Beneficial Interest Owners.</u>
 - A Retail Marijuana Establishment may be comprised of an unlimited number of Direct Beneficial Interest Owners that have been residents of Colorado for at least one year prior to the date of the application.
 - On and after January 1, 2017, a Retail Marijuana Establishment that is comprised of one or more Direct Beneficial Interest Owners who have not been Colorado residents for at least one year is limited to no more than fifteen Direct Beneficial Interest Owners, each of whom is a natural person. Further, a Retail Marijuana Establishment that is comprised of one or more Direct Beneficial Interest Owners who have not been Colorado residents for at least one year shall have at least one officer who is a Colorado resident. All officers with day-to-day operational control over a Retail Marijuana Establishment must be Colorado residents for at least one year, must maintain their Colorado residency during the period while they have day-to-day operational control over the Retail Marijuana

Deleted: A non-Colorado resident's failure to obtain a finding of suitability prior to submitting an application to become a Direct Beneficial Interest Owner to the State Licensing Authority shall be grounds for denial of the application.

Establishment and shall be licensed as required by the Retail Code. Rule 231 – Qualifications for Licensure and Residency: Individuals.

- C. Notification of Change of Residency. A Retail Marijuana Establishment with more than fifteen Direct Beneficial Interest Owners shall provide thirty days prior notice to the Division of any Direct Beneficial Interest Owners' intent to change their residency to a residency outside Colorado. A Retail Marijuana Establishment with no more than fifteen Direct Beneficial Interest Owners shall notify the Division of the change of residency of any Direct Beneficial Interest Owner at the time of its license renewal. Failure to provide timely notice pursuant to this rule may lead to administrative action against the Retail Marijuana Establishment and its Direct Beneficial Interest Owners.
- D. A Direct Beneficial Interest Owner shall not be a publicly traded company.

M 304 [REPEALED]

Basis and Purpose - M 304.1

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I)(A)-(F), 12-43.4-104(1)(a)(V), 12-43.4-202(2)(b), 12-43.4-401(2), and 12-43.4-404(2), C.R.S. and sections 12-43.3-406, 12-43.4-405 and 12-43.4-406, 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 Licensed Retail Marijuana Establishment, and to ensure the proper separation of a Medical Marijuana Business operation from Retail Marijuana Establishment operation.

M 304.1 – Medical Marijuana Business and Retail Marijuana Establishment – Shared Licensed Premises and Operational Separation

- A. Co-Located Medical Marijuana Centers and Retail Marijuana Stores
 - Medical Marijuana Center that does not authorize patients under the age of 21. A Medical Marijuana Center that prohibits Medical Marijuana patients under the age of 21 years from being 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 Center and Retail Marijuana Store are commonly owned;
 - The Medical Marijuana Center and Retail Marijuana Store shall maintain physical or virtual separation between (i) Medical Marijuana, Medical Marijuana-Infused Products and other inventory and (ii) Retail Marijuana, Retail Marijuana Products and other inventory;
 - d. The Medical Marijuana Center and Retail Marijuana Store shall maintain separate displays between (i) Medical Marijuana, Medical Marijuana-Infused Products and other inventory and (ii) Retail Marijuana, Retail Marijuana Products and other inventory, but the displays may be on the same sale floor.
 - e. Record-keeping, inventory tracking, packaging and labeling for the Medical

 Marijuana Center and Retail Marijuana Store shall enable the Division and local
 licensing authority to clearly distinguish the inventories and business transactions
 of the Medical Marijuana Center from the inventories and business transactions
 of the Retail Marijuana Store.; and
 - f. The Medical Marijuana Center shall post and maintain signage that clearly conveys that persons under the age of 21 years may not enter.:
 - Medical Marijuana Center that authorizes patients under the age of 21. A Medical Marijuana Center that authorizes Medical Marijuana patients under the age of 21 years to be on the premises may operate in the same location with a Retail Marijuana Store under the following conditions:
 - The relevant local licensing authority and local jurisdiction permit a dual operation at the same location:

- The Medical Marijuana Center and the Retail Marijuana Store are commonly owned;
- The Medical Marijuana Center and the Retail Marijuana Store maintain physical separation, including separate entrances and exits, between all portions of the Licensed Premises where sales occur;
- d. No point of sale operations occur at any time outside the physically separated Licensed Premises;
- e. All Medical Marijuana and Medical Marijuana-Infused Product in a Restricted
 Access Area must be physically separated from all Retail Marijuana and Retail
 Marijuana Product in a Restricted Access Area, and such physical separation
 must include separate entrances and exits;
- f. Any display shall be located in the physically separated sales The Medical Marijuana Center and Retail Marijuana Store must occur in portions of the Licensed Premises where sales occur;
- g. In addition to the physically separated sales and display areas, the Medical Marijuana Center and Retail Marijuana Store shall maintain physical or virtual separation for storage of Medical Marijuana, Medical Marijuana-Infused Products and other inventory from storage of Retail Marijuana, Retail Marijuana Products and other inventory; and
- h. Record-keeping, inventory tracking, packaging and labeling for the Medical

 Marijuana Center and Retail Marijuana Store shall enable the Division and local
 licensing authority to clearly distinguish the inventories and business transactions
 of the Medical Marijuana Center from the inventories and business transactions
 of the Retail Marijuana Store.
- B. Co-located Optional Premises Cultivation Operation and Retail Marijuana Cultivation Facility. An Optional Premises Cultivation Operation and a Retail Marijuana Cultivation Facility may share a single Licensed Premises and operate at the same location under the following circumstances:
 - The relevant local licensing authority and local jurisdiction permit a dual operation at the same location;
 - The Optional Premises Cultivation Operation and the Retail Marijuana Cultivation Facility are commonly owned;
 - 3. The co-located Optional Premises Cultivation Operation and Retail Marijuana Cultivation
 Facility shall maintain either physical or virtual separation between Medical Marijuana
 and Retail Marijuana; and
 - 4. Record keeping, inventory tracking, packaging and labeling for the Optional Premises Cultivation Operation and Retail Marijuana Cultivation Facility must enable the Division and relevant local licensing authority to clearly distinguish the inventories and business transactions of the Optional Premises Cultivation Operation from the Retail Marijuana Cultivation Facility.
- C. Co-located Medical Marijuana-Infused Products Manufacturer and Retail Marijuana Products

 Manufacturer. A Medical Marijuana-Infused Products Manufacturer and a Retail Marijuana

<u>Products Manufacturing Facility may share a single Licensed Premises and operate at the same</u> location under the following circumstances:

- The relevant local licensing authority and local jurisdiction permit a dual operation at the same location;
- The Medical Marijuana-Infused Products Manufacturer and the Retail Marijuana Products
 Manufacturing Facility are commonly owned;
- 3. The Medical Marijuana-Infused Products Manufacturer and Retail Marijuana Products
 Manufacturing Facility shall maintain either physical or virtual separation between (i)
 Medical Marijuana, Medical Marijuana-Infused Products and other inventory and (ii)
 Retail Marijuana, Retail Marijuana Products and other inventory; except that nothing in
 this rule prohibits a co-located Retail Marijuana Establishment and Medical Marijuana
 Business from sharing raw ingredients in bulk, for example flour or sugar, except that
 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-Infused Products Manufacturer and Retail Marijuana Products Manufacturing Facility must enable the Division and local licensing authority to clearly distinguish the inventories and business transactions of the Medical Marijuana-Infused Product Manufacturer from the Retail Marijuana Product Manufacturing Facility.
- D. Co-located Medical Marijuana Testing Facility and Retail Marijuana Products Manufacturer. 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:
 - The relevant local licensing authority and local licensing jurisdiction permit dual operation at the same location;
 - The Medical Marijuana Testing Facility and Retail Marijuana Products Manufacturer 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-Infused Products and other inventory and (ii) Retail Marijuana, Retail Marijuana Products and other 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 to clearly distinguish the inventories and business transactions of the Medical Marijuana Testing Facility from the Retail Marijuana Testing Facility.
- E. Co-Located 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:
 - The relevant local licensing authority and local licensing jurisdiction permit dual operation at the same location;
 - The Medical Marijuana Transporter and Retail Marijuana Transporter are identically owned;

- The Medical Marijuana Transporter and Retail Marijuana Transporter shall maintain
 either physical or virtual separation between (i) Medical Marijuana, Medical Marijuana Infused Products and other inventory and (ii) Retail Marijuana, Retail Marijuana Products
 and other 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 to clearly distinguish the inventories and business transactions of the Medical Marijuana Transporter from the Retail Marijuana Transporter.
- F. Violation of this rule may be considered a license violation affecting public safety.

Basis and Purpose – R 305

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b) and 12-43.4-202(3)(a)(V), 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 Retail Marijuana and Retail Marijuana Product contained therein. This rule also establishes the minimum guidelines for security requirements for alarm systems and commercial locking mechanisms for maintaining adequate security.

R 305 - Security Alarm Systems and Lock Standards

- A. <u>Security Alarm Systems Minimum Requirements.</u> The following Security Alarm Systems and lock standards apply to all Retail Marijuana Establishments.
 - 1. Each Licensed Premises shall have a Security Alarm System, installed by an Alarm Installation Company, on all perimeter entry points and perimeter windows.
 - 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.
 - 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 R 901 – Business Records Required.
 - 4. Upon request, Licensees shall make available to agents of the Division or relevant local jurisdiction or state or local law enforcement agency, for a purpose authorized by the Retail 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 Retail Marijuana Cultivation Facility, or greenhouse cultivation, is a Limited Access Area and must meet all of the requirements for Security Alarm Systems described in this rule. An outdoor or greenhouse 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 Retail Marijuana Cultivation Facility located in an indoor Licensed Premises 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 that meets at least the following minimum requirements:

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The statutory authority for this rule is found at subsections 12-43.3-202(1)(b), 12-43.4-104(1)(a)(V), 12-43.4-202(2)(b), 12-43.3-202(2.5)(a)(I)(A)-(F), 12-43.4-401(2), and 12-43.4-404(2), and sections 12-43.3-406, 12-43.4-405, and 12-43.4-406, C.R.S. The purpose of this rule is to establish guidelines for the manner in which a Medical Marijuana Licensee may share its existing Licensed Premises with a Licensed Retail Marijuana Establishment, and to ensure the proper separation of a medical marijuana operation from Retail Marijuana Establishment operation.¶ R 304 – Medical Marijuana Business and Retail Marijuana Establishment – Shared Licensed

- Premises and Operational Separation¶
 A. Licensed Premises General Requirements¶
- A Medical Marijuana Center that prohibits patients under the age of 21 years to be on the Licensed Premises may also hold a Retail Marijuana Store license and operate a dual retail business operation on the same Licensed Premises if the relevant local jurisdiction permits a dual operation at the same location and the two are commonly owned.
- 2. A Medical Marijuana Center that authorizes medical marijuana patients under the age of 21 years to be on the premises is prohibited from sharing its Licensed Premises with a Retail Marijuana Establishment. Even when the two are commonly owned, the two shall maintain distinctly separate Licensed Premises; including, but not limited to, separate sales and storage areas, separate entrances and exits, separate inventories, separate point-of-sale operations, and separate record-keeping.¶
- 3. An Optional Premises Cultivation Operation and a Retail Marijuana Cultivation Facility may share a single Licensed Premises in order to operate a dual cultivation business operation if the relevant local jurisdiction permits a dual operation at the same location and the two are commonly owned.¶
- 4. A Medical Marijuana-Infused Products
 Manufacturer may also apply to also hold a Retail
 Marijuana Products Manufacturing Facility License and
 operate a dual manufacturing business on the same
 Licensed Premises, if the relevant local jurisdiction
 permits a dual operation at the same location and the
 two are commonly owned.¶
- 5. A Medical Marijuana Testing Facility Licensee and a Retail Marijuana Testing Facility Licensee may share a single Licensed Premises to operate a dual testing business operation at the same location if the relevant local jurisdiction permits dual operation at the same location and the two are identically owned.¶
- 6. A Medical Marijuana Transporter Licensee and a Retail Marijuana Transporter Licensee may share a single Licensed Premises to operate a dual transporting, logistics, and temporary storage business operation at the same location if the relevant local ... [1]

Deleted: This shall include, at a minimum, perimeter fencing designed to prevent the general public from entering the Limited Access Areas.

- The fencing material shall be metal chain link of heavy gauge thickness or another similarly secure material but may not be wood. All support posts shall be steel and securely anchored.
 - b. The fence must measure at least 8 feet from the ground to the top of the fence.
 - All entry gates must measure at least 8 feet from the ground to the top of the
 entry gate and shall be constructed of metal chain link of a heavy gauge
 thickness or a similarly secure material but may not be wood.

B. <u>Lock Standards – Minimum Requirement</u>

- At all points of ingress and egress, the Licensee shall ensure the use of a commercialgrade, non-residential door locks.
- Any outdoor Retail Marijuana Cultivation Facility, or greenhouse cultivation, must meet all
 of the requirements for the lock standards described in this rule.

Basis and Purpose - R 306

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b),12-43.4-202(2)(d), and 12-43.4-202(3)(a)(V), and section 12-43.4-701, 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 Retail Marijuana and Retail Marijuana Product contained therein. This rule also establishes the minimum guidelines for security requirements for video surveillance systems for maintaining adequate security.

R 307 - Waste Disposal

- A. <u>All Applicable Laws Apply.</u> Retail Marijuana and Retail Marijuana Product waste must be stored, secured, locked, and managed in accordance with all applicable federal, state, and local statutes, regulations, ordinances, or other requirements.
- B. <u>Liquid Waste</u>. Liquid waste from Retail Marijuana Establishments shall be disposed of in compliance with all applicable federal, state and local laws, regulations, rules and other requirements.
- C. <u>Chemical, Dangerous and Hazardous Waste.</u> 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 Retail Marijuana Concentrate or any Retail Marijuana soaked in a Flammable Solvent for purposes of producing a Retail Marijuana Concentrate.
- Waste Must Be Made Unusable and Unrecognizable. Retail Marijuana and Retail Marijuana
 Product waste must be made unusable and Unrecognizable prior to leaving the Licensed Premises.
- E. Methods to Make Waste Unusable and Unrecognizable. Retail Marijuana and Retail Marijuana Product waste shall be rendered unusable and Unrecognizable through one of the following methods:
 - Grinding 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:

- 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;

from the local governing body;

 Other wastes approved by the Division that will render the Retail Marijuana waste unusable and Unrecognizable; and

F. After Waste is Made Unusable and Unrecognizable. Licensees shall not dispose of Retail

Marijuana waste in an unsecured waste receptacle not in possession and control of the Licensee.

After the Retail Marijuana waste is made unusable and Unrecognizable, then the rendered waste shall be:

- shall be:Disposed of at a solid waste site and disposal facility that has a Certificate of Designation
- Deposited at a compost facility that has a Certificate of Designation from the Department of Public Health and Environment, if required; or
- 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 Department of Public Health and Environment.
- G. <u>Proper Disposal of Waste.</u> A Licensee shall not dispose of Retail Marijuana and Retail Marijuana Product waste in an unsecured waste receptacle not in possession and control of the Licensee.
- H. <u>Inventory Tracking Requirements</u>
 - 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 materials are identified, weighed and tracked while on the Licensed Premises until disposed of.
 - All Retail Marijuana waste must be weighed before leaving any Retail Marijuana
 Establishment. A scale used to weigh Retail Marijuana waste prior to entry into the
 Inventory Tracking System shall be tested and approved in accordance with 35-14-127,
 C.R.S. See Rule R 309 Retail Marijuana Establishments: Inventory Tracking System,
 - 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 Marijuana. See Rule R 901 – Business Records Required.
 - A Licensee is required to maintain accurate and comprehensive records regarding any
 waste material produced through the trimming or pruning of a Retail Marijuana plant prior

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to harvest, which must include weighing and documenting all waste. Unless required by an Inventory Tracking System procedure, records of waste produced prior to harvest must be maintained on the Licensed Premises. All waste, whether produced prior or subsequent to harvest, must be disposed of in accordance with this rule and be made unusable and unrecognizable.

Basis and Purpose - R 309

The statutory authority for this rule is found at subsections 12-43.4-104(1)(a)(III)12-43.4-201(1), 12-43.4-202(2)(b), 12-43.4-402(1)(e), 12-43.4-402(4), 12-43.4-403(2)(d), and 12-43.4-404(1)(b), 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 Retail Marijuana and Retail Marijuana Product from either seed or immature plant stage until the Retail Marijuana or Retail Marijuana Product is sold to the customer 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 Retail Marijuana or Retail Marijuana Product. Through the use of RFID technology, a Retail Marijuana Cultivation Facility will tag either the seed or immature plant with an individualized number, which will follow the Retail Marijuana through all phases of production and final sale to a consumer. This will allow the State Licensing Authority and the Inventory Tracking System user the ability to monitor and track Retail Marijuana and Retail Marijuana Product 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 Retail Marijuana to eliminate diversion, inside and outside of the state, and to ensure that all marijuana grown, processed, sold and disposed of in the Retail 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 Retail Marijuana inventory.

R 309 – Retail Marijuana Establishments: Inventory Tracking System,

A. Inventory Tracking System Required. A Retail Marijuana Establishment is required to use the Inventory Tracking System as the primary inventory tracking system of record. A Retail Marijuana Establishment 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 Establishment must follow the inventory transfer guidelines detailed in Rule R 309(C) below.

B. <u>Inventory Tracking System Access - Inventory Tracking System Administrator</u>

- Inventory Tracking System Administrator Required. A Retail Marijuana Establishment
 must have at least one individual Owner who is an Inventory Tracking System
 Administrator. A Retail Marijuana Establishment may also designate additional Owners
 and occupationally licensed employees to obtain Inventory Tracking System
 Administrator accounts.
- Training for Inventory Tracking System Administrator Account. In order to obtain a
 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.

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- 3. Inventory Tracking System Access Inventory Tracking System User Accounts. A Retail Marijuana Establishment may designate licensed Owners and employees who hold valid Occupational Licenses as Inventory Tracking System Users. A Retail Marijuana Establishment shall ensure that all Owners and Occupational License 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 Establishment
 - 1. Medical Marijuana Inventory Transfer to Retail Marijuana Establishments.
 - a. This rule R 309(C)(1)(a) is repealed effective July 1, 2016. Prior to July 1, 2016, each Medical Marijuana Business that is either converting to or adding a Retail Marijuana Establishment license must create a Retail Marijuana Inventory Tracking System account for each license it is converting or adding. A Medical Marijuana Business must transfer all relevant Medical Marijuana inventory into the Retail Marijuana Establishment's Inventory Tracking System accounts and affirmatively declare those items as Retail Marijuana and Retail Marijuana Product.
 - b. Beginning July 1, 2016:
 - The the only allowed transfer of marijuana between a Medical Marijuana Business and Retail Marijuana Establishment is Medical Marijuana and Medical Marijuana Concentrate that was produced at the Optional Premises Cultivation Operation, from the Optional Premises Cultivation Operation to a Retail Marijuana Cultivation Facility.
 - Each Optional Premises Cultivation Operation 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. An Optional Premises Cultivation Operation 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 Establishment.
 - v. All other transfers are prohibited, including but not limited to transfers from a Medical Marijuana Center or Medical Marijuana-Infused Products Manufacturer to any Retail Marijuana Establishment.
 - 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

- Authorized Tags Required and Costs. Licensees are required to use RFID tags issued by a Division-approved vendor that is authorized to provision RFID tags for the Inventory Tracking System. Each licensee is responsible for the cost of all RFID tags and any associated vendor fees.
- 2. <u>Use of RFID Tags Required</u>. A Licensee is responsible to ensure its inventories are properly tagged where the Inventory Tracking System requires RFID tag use. A Retail Marijuana Establishment must ensure it has an adequate supply of RFID tags to properly tag Retail Marijuana and Retail Marijuana Product as required by the Inventory Tracking System. An RFID tag must be physically attached to every plant being cultivated that is greater than four inches tall or four inches wide. An RFID tag must be assigned to all Harvested Marijuana, Retail Marijuana Concentrate and Retail Marijuana Product. See also R 801(G.5) Required RFID Tags; R 1007-1(H) Shipping Containers.

E. General Inventory Tracking System Use

Reconciliation with Inventory. All inventory tracking activities at a Retail Marijuana
 Establishment must be tracked through use of the Inventory Tracking System. A
 Licensee must reconcile all on-premises and in-transit Retail Marijuana and Retail
 Marijuana Product inventories each day in the Inventory Tracking System at the close of
 business.

2. Common Weights and Measures.

- A Retail Marijuana Establishment must utilize a standard of measurement that is supported by the Inventory Tracking System to track all Retail Marijuana and Retail Marijuana Product.
- b. A scale used to weigh product prior to entry into the Inventory Tracking System system shall be tested and approved in accordance with 35-14-127, C.R.S.

3. <u>Inventory Tracking System Administrator and User Accounts – Security and Record</u>

- a. A Retail Marijuana Establishment shall maintain an accurate and complete list of all Inventory Tracking System Administrators and Inventory Tracking System Users for each Licensed Premises. A Retail Marijuana Establishment shall update this list when a new Inventory Tracking System User is trained. A Retail Marijuana Establishment 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 Retail Marijuana Establishment 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.
- A Retail Marijuana Establishment is accountable for all actions employees take while logged into the Inventory Tracking System or otherwise conducting Retail Marijuana or Retail Marijuana Product inventory tracking activities.
- Each individual user is also accountable for all of his or her actions while logged into the Inventory Tracking System or otherwise conducting Retail Marijuana or

Retail Marijuana Product inventory tracking activities, and shall maintain compliance with all relevant laws.

4. Secondary Software Systems Allowed

- a. Nothing in this rule prohibits a Retail Marijuana Establishment from using separate software applications to collect information to be used by the business including secondary inventory tracking or point of sale systems.
- 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 Retail Marijuana establishment 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

- Misstatements or Omissions Prohibited. A Retail Marijuana Establishment 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 Retail Marijuana Establishment 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.
- <u>Use of Another User's Login Prohibited</u>. 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 Retail Marijuana Establishment loses access to the Inventory Tracking System for any reason, the Retail Marijuana Establishment must keep and maintain comprehensive records detailing all Retail Marijuana and Retail Marijuana Product tracking inventory activities that were conducted during the loss of access. See Rule R 901 Business Records Required. Once access is restored, all Retail Marijuana and Retail Marijuana Product inventory tracking activities that occurred during the loss of access must be entered into the Inventory Tracking System. A Retail Marijuana Establishment must document when access to the system was lost and when it was restored. A Retail Marijuana Establishment shall not transport any Retail Marijuana or Retail Marijuana Product to another Retail Marijuana Establishment until such time as access is restored and all information is recorded into the Inventory Tracking System.

G. System Notifications

- Compliance Notifications. A Retail Marijuana Establishment 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 Retail Marijuana Establishment resolves the compliance issues detailed in the notification.
- Informational Notifications. A Retail Marijuana Establishment 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. <u>Lawful Activity Required</u>. 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. <u>Inventory Tracking System Procedures Must Be Followed.</u> A Retail Marijuana Establishment must utilize Inventory Tracking System in conformance with these rules and Inventory Tracking System procedures, including, but not limited to:
 - Properly indicating the creation of a Production Batch including the assigned Production Batch Number;
 - 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;
 - Properly indicating that a Test Batch is being used as part of achieving process validation;
 - 5. Accurately indicting the METRC category for all Medical Marijuana, Medical Marijuana

 Concentrate and Medical Marijuana-Infused Product; and
 - Accurately including a note explaining the reason for any destruction of plants or adjustment of weights to Inventory Tracking System packages.

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Basis and Purpose - R 304

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b), 12-43.4-104(1)(a)(V), 12-43.4-202(2)(b), 12-43.3-202(2.5)(a)(I)(A)-(F), 12-43.4-401(2), and 12-43.4-404(2), and sections 12-43.3-406, 12-43.4-405, and 12-43.4-406, C.R.S. The purpose of this rule is to establish guidelines for the manner in which a Medical Marijuana Licensee may share its existing Licensed Premises with a Licensed Retail Marijuana Establishment, and to ensure the proper separation of a medical marijuana operation from Retail Marijuana Establishment operation.

R 304 – Medical Marijuana Business and Retail Marijuana Establishment – Shared Licensed Premises and Operational Separation

A. Licensed Premises – General Requirements[RH1]

- 1. A Medical Marijuana Center that prohibits patients under the age of 21 years to be on the Licensed Premises may also hold a Retail Marijuana Store license and operate a dual retail business operation on the same Licensed Premises if the relevant local jurisdiction permits a dual operation at the same location and the two are commonly owned.
- 2. A Medical Marijuana Center that authorizes medical marijuana patients under the age of 21 years to be on the premises is prohibited from sharing its Licensed Premises with a Retail Marijuana Establishment. Even when the two are commonly owned, the two shall maintain distinctly separate Licensed Premises; including, but not limited to, separate sales and storage areas, separate entrances and exits, separate inventories, separate point-of-sale operations, and separate record-keeping.
- 3. An Optional Premises Cultivation Operation and a Retail Marijuana Cultivation Facility may share a single Licensed Premises in order to operate a dual cultivation business operation if the relevant local jurisdiction permits a dual operation at the same location and the two are commonly owned.
- 4. A Medical Marijuana-Infused Products Manufacturer may also apply to also hold a Retail Marijuana Products Manufacturing Facility License and operate a dual manufacturing business on the same Licensed Premises, if the relevant local jurisdiction permits a dual operation at the same location and the two are commonly owned.
- 5. A Medical Marijuana Testing Facility Licensee and a Retail Marijuana Testing Facility Licensee may share a single Licensed Premises to operate a dual testing business operation at the same location if the relevant local jurisdiction permits dual operation at the same location and the two are identically owned.
- 6. A Medical Marijuana Transporter Licensee and a Retail Marijuana Transporter Licensee may share a single Licensed Premises to operate a dual transporting, logistics, and temporary storage business operation at the same location if the relevant local jurisdiction permits dual operation at the same location and the two are identically owned.

B. <u>Separation of Co-located Licensed Operations</u>

<u>Cultivation Operations.</u> A Licensee that operates an Optional Premises Cultivation
 Operation and a Retail Marijuana Cultivation Facility shall maintain either physical or
 virtual separation of the facilities, marijuana plants, and marijuana inventory. Record keeping for the business operations and labeling of product must enable the Division and

- relevant local jurisdictions to clearly distinguish the inventories and business transactions of the Medical Marijuana Business from the Retail Marijuana Establishment.
- 2. <u>Manufacturing Operations.</u> A Licensee that operates a Medical Marijuana-Infused Products Manufacturer and Retail Marijuana Products Manufacturing Facility shall maintain either physical or virtual separation of the facilities, product ingredients, product manufacturing, and final product inventory. Record-keeping for the business operations and labeling of products must enable the Division and Local Jurisdictions/Local Licensing Authorities to clearly distinguish the inventories and business transactions of Medical Marijuana-Infused Product from Retail Marijuana Product.
- 3. Raw Ingredients May Be Shared. Nothing in this rule prohibits a co-located Retail Marijuana Establishment and Medical Marijuana Business from sharing raw ingredients in bulk, for example flour or sugar, except that Retail Marijuana and Medical Marijuana may not be shared under any circumstances.
- 4. Retail Store and Medical Center Operations: No Patients Under The Age of 21 Years. Persons operating a Medical Marijuana Center that prohibits the admittance of patients under the age of 21 years and a Retail Marijuana Store may share their Licensed Premises. Such a Medical Marijuana Center Licensee must post signage that clearly conveys that persons under the age of 21 years may not enter. Under these circumstances, and upon approval of the State Licensing Authority, the Medical Marijuana Center and the Retail Marijuana Store may share the same entrances and exits. Also under these circumstances, Medical Marijuana and Retail Marijuana and Medical Marijuana-Infused Product and Retail Marijuana Product must be separately displayed on the same sale floor. Record-keeping for the business operations of both must enable the Division and relevant local jurisdictions to clearly distinguish the inventories and business transactions of Medical Marijuana and Medical Marijuana-Infused Products from Retail Marijuana and Retail Marijuana Product. Violation of the restrictions in this rule by co-located Medical Marijuana Centers and Retail Marijuana Stores may be considered a license violation affecting public safety.
- 5. Retail Stores and Medical Marijuana Centers: Patients Under The Age of 21 Years. A colocated Medical Marijuana Center and Retail Marijuana Store shall maintain separate Licensed Premises, including entrances and exits, inventory, point of sale operations, and record keeping if the Medical Marijuana Center serves patients under the age of 21 years or permits admission of patients under the age of 21 years on its Licensed Premises.
- 6. <u>Testing Facilities</u>. A co-located Medical Marijuana Testing Facility and Retail Marijuana Testing Facility shall maintain either physical or virtual separation of the facilities and marijuana and products being tested. Record keeping for the business operations and labeling of products must enable the Division and local licensing authority to clearly distinguish the inventories and business transactions of Medical Marijuana and Medical Marijuana-Infused Product and Retail Marijuana and Retail Marijuana Product.
- 6.1. Transporters. A co-located Medical Marijuana Transporter and Retail Marijuana Transporter shall maintain either physical or virtual separation of the facilities and Medical Marijuana, Medical Marijuana-Infused Products, Retail Marijuana, and Retail Marijuana Products being transported and stored. Record keeping for the business operations and storage of products must enable the Division and local licensing authority to clearly distinguish the inventories and business transactions of Medical Marijuana and Medical Marijuana-Infused Product and Retail Marijuana and Retail Marijuana Product.
- 7. <u>Clear Separation of Inventory.</u> A Licensee that operates both a Medical Marijuana Business and Retail Marijuana Establishment within one location is required to maintain

separate and distinct inventory tracking processes for Medical Marijuana and Retail Marijuana inventories. The inventories must be clearly tagged or labeled so that the product can be reconciled to a particular Medical Marijuana Business or a Retail Marijuana Establishment.

R 400 Series - Retail Marijuana Stores

Basis and Purpose - R 401

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(b)(IX), 12-43.4-309(7)(a), and 12-43.4-901(4)(f), and sections 12-43.4-402 and 12-43.4-406, C.R.S. The purpose of this rule is to establish that it is unlawful for a Retail Marijuana Store to exercise any privileges other than those granted by the State Licensing Authority, and to clarify the license privileges.

R 401 - Retail Marijuana Store: License Privileges

- Privileges Granted. A Retail Marijuana Store shall only exercise those privileges granted to it by the State Licensing Authority.
- B. <u>Licensed Premises</u>. To the extent authorized by Rule R 304 Medical Marijuana Business and Retail Marijuana Establishment Shared Licensed Premises and Operational Separation, a Retail Marijuana Store may share a location with a commonly-owned Medical Marijuana Center. However, a separate license is required for each specific business or business entity, regardless of geographical location.
- C. <u>Authorized Sources of Retail Marijuana</u>. A Retail Marijuana Store may only sell Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product that was obtained from another Retail Marijuana Establishment,
- D. Repealed.
- E. <u>Samples Provided for Testing</u>. 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 R 901 – Business Records Required.
- F. <u>Authorized On-Premises Storage</u>. 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.
- G. <u>Authorized Marijuana Transport.</u> A Retail Marijuana Store is authorized to utilize a licensed Retail Marijuana Transporter for transportation of its Retail Marijuana and Retail Marijuana Product so long as the place where transportation orders are taken and delivered is a licensed Retail Marijuana Establishment. Nothing in this rule prevents a Retail Marijuana Store from transporting its own Retail Marijuana and Retail Marijuana Product.

Basis and Purpose - R 402

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(VIII), 12-43.4-202(3)(a)(IX), 12-43.4-202(3)(a)(X), 12-43.4-202(3)(a)(I), 12-43.4-202(3)(b)(IX), 12-43.4-401(4), 12-43.4-901(1), and 12-43.4-901(4)(c) and 12-43.4-901(1), and 12-43.4-901(1), subsections 12-43.4-105 and 12-43.4-402, 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)(V). 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

Deleted: that it has purchased from a Retail Marijuana Cultivation Facility or that the retailer has cultivated itself, after first obtaining a Retail Marijuana Cultivation Facility License. See Rule R 501 – Retail Marijuana Cultivation Facility: License Privileges

Deleted: Authorized Sources of Retail Marijuana Product. A Retail Marijuana Store may only sell Retail Marijuana Product that it has purchased from a Retail Marijuana Products Manufacturing Facility, so long as such product is pre-packaged and labeled upon purchase from the manufacturer. House Bill 14-1361. The equivalencies have been determined through utilizing findings of a study that the House Bill authorized. The study, "Marijuana Equivalency in Portion and Dosage," was authored by the Marijuana Policy Group and is available on the Division's website. The study was presented to a group of stakeholders during a public meeting as part of the rulemaking process. Although there was disagreement among stakeholders regarding what the equivalencies should be, the general consensus was that the equivalencies must be simple and straightforward, which would facilitate regulatory compliance and serve public safety.

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).

R 402 - Retail Marijuana Sales: General Limitations or Prohibited Acts

- A. <u>Sales to Persons Under 21 Years</u>. Licensees are prohibited from selling, giving, or distributing Retail Marijuana or Retail Marijuana Product to persons under 21 years of age.
- B. <u>Age Verification</u>. Prior to initiating the sale of Retail Marijuana or Retail Marijuana Product, 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. Repealed.
 - 1.5. Repealed
 - Repealed.
 - 3. A Retail Marijuana Store and its employees are prohibited from selling more than one ounce of Retail Marijuana flower or its equivalent in Retail Marijuana Concentrate or Retail Marijuana Product in a single transaction to a consumer. A single transaction includes multiple sales to the same consumer during the same business day where the Retail Marijuana Store employee knows or reasonably should know that such sale would result in that consumer possessing more than one ounce of marijuana.
 - 4. 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 sales. For all other Retail Marijuana Products or Retail Marijuana Concentrate, the following equivalency applies for the one ounce quantity sales limit:
 - 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.
- <u>Licensees May Refuse Sales.</u> Nothing in these rules prohibits a Licensee from refusing to sell Retail Marijuana or Retail Marijuana Product to a customer.

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- E. <u>Sales over the Internet</u>. A Licensee is prohibited from selling Retail Marijuana or Retail Marijuana Product over the internet. Any <u>Transfer</u> of Retail Marijuana and Retail Marijuana Product must occur within the Retail Marijuana Store's Licensed Premises.
- F. <u>Purchases Only Within Restricted Access Area</u>. A customer must be physically present within the Restricted Access Area of the Retail Marijuana Store's Licensed Premises to purchase Retail Marijuana or Retail Marijuana Product.
- G. <u>Evidence of Excise Tax Paid.</u> A Retail Marijuana Store is prohibited from accepting Retail Marijuana from a Retail Marijuana Cultivation Facility or Retail Marijuana Manufacturing Facility unless the Retail Marijuana Store Licensee has received evidence that any applicable excise tax due pursuant to Article 28.8 of Title 39, C.R.S., was paid.
- H. Prohibited Items. A Retail Marijuana Store is prohibited from selling or giving away any consumable product that is not a Retail Marijuana 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.
- I. <u>Free Product Prohibited</u>. A Retail Marijuana Store may not give away Retail Marijuana or Retail Marijuana Product to a consumer for any reason.
- J. <u>Nicotine or Alcohol Prohibited</u>. A Retail Marijuana Store is prohibited from selling Retail Marijuana or Retail Marijuana Product 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.
- K. <u>Consumption Prohibited</u>. A Licensee shall not permit the consumption of marijuana or marijuana product on the Licensed Premises.
- Storage and Display Limitations.
 - A Retail Marijuana Store shall not display Retail Marijuana and Retail Marijuana Product outside of a designated Restricted Access Area or in a manner in which Retail Marijuana or Retail Marijuana Product can be seen from outside the Licensed Premises. Storage of Retail Marijuana and Retail Marijuana Product shall otherwise be maintained in Limited Access Areas or Restricted Access Area.
 - 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.
 - 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.
- M. <u>Sale of Expired Product Prohibited</u>. A Retail Marijuana Store shall not sell any expired Retail Marijuana Product.
- N. A Retail Marijuana Store shall not sell or give away Retail Marijuana or Retail Marijuana Product to a Retail Marijuana Transporter, and shall not buy or receive complimentary Retail Marijuana or Retail Marijuana Product from a Retail Marijuana Transporter.
- A Retail Marijuana Store shall not compensate its employees using performance-based sales incentives. Performance-based incentives that are not sales-based are acceptable. Examples of

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performance-based incentives that are not sales-based include recognition for providing quality information to consumers, or the duration of the employee's employment with the Retail Marijuana Store.

- P. Edibles Prohibited that are Shaped like a Human, Animal, or Fruit. This paragraph (P) is effective beginning October 1, 2017.
 - 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
 - A shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings.
 - The prohibition on human, animal, and fruit shapes does not apply to the logo of a licensed Retail Marijuana Establishment. Nothing in this subparagraph (P)(2) alters or eliminates a Licensee's obligation to comply with the requirements of Rule R 1001 Labeling and Packaging Requirements: General Applicability or Rule R 1000-1 Series Labeling, Packaging, and Product Safety.
 - Edible Retail Marijuana Products that are geometric shapes and simply fruit flavored are not considered fruit and are permissible; and
 - Edible Retail Marijuana Products that are manufactured in the shape of a marijuana leaf are permissible
- Q. Research Transfers Prohibited. A Retail Marijuana Store shall not Transfer any Retail Marijuana, Retail Marijuana Product or Retail Marijuana Concentrate to a Medical Research Facility, a Pesticide Manufacturer or a Research and Development Licensee.

Basis and Purpose - R 405

The statutory authority for this rule is found at subsections 12-43.4-202(1), 12-43.4-202(2)(b), and 12-43.4-402(1)(e), C.R.S. The purpose of this rule is to establish a Retail Marijuana Store's obligation to account for and track all inventories on the Licensed Premises from the point of Transfer from a Retail Marijuana Cultivation Facility, Retail Marijuana Products Manufacturing Facility, or Retail Marijuana Transporter to the point of sale.

R 405 - Retail Marijuana Store: Inventory Tracking System

- A. Minimum Tracking Requirement. A Retail Marijuana Store must use Inventory Tracking System to ensure its inventories are identified and tracked from the point of Transfer to or from another Retail Marijuana Establishment through the point of sale, or otherwise disposed of. See also Rule R 309 Retail Marijuana Establishment: Inventory Tracking System. The Retail Marijuana Store must have the ability to reconcile its inventory records with the Inventory Tracking System and the associated transaction history and sale receipts. See also Rule R 901 Business Records Required.
 - A Retail Marijuana Store is prohibited from accepting any Retail Marijuana, Retail
 <u>Marijuana Concentrate</u> or Retail Marijuana Product from another Retail Marijuana
 <u>Establishment without receiving a valid transport manifest generated from the Inventory Tracking System.</u>

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- A Retail Marijuana Store must immediately input all Retail Marijuana Retail Marijuana Concentrate and Retail Marijuana Product delivered to its Licensed Premises, accounting for all RFID tags, into the Inventory Tracking System at the time of delivery from another Retail Marijuana Establishment. All delivered Retail Marijuana must be weighed and the scale used shall be tested and approved in accordance with measurement standards established in 35-14-127, C.R.S. A Retail Marijuana Store must account for all variances.
- A Retail Marijuana Store must reconcile transactions from their point of sale processes and on-hand inventory to the Inventory Tracking System at the close of business each day

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R 500 Series - Retail Marijuana Cultivation Facilities

Basis and Purpose - R 501

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(b)(IX), and 12-43.4-401(4), and sections 12-43.4-403 and 12-43.4-406, C.R.S. The purpose of this rule is to establish that it is unlawful for a Retail Marijuana Cultivation Facility to exercise any privileges other than those granted by the State Licensing Authority and to clarify the license privileges.

R 501 - Retail Marijuana Cultivation Facility: License Privileges

- A. <u>Privileges Granted</u>. A Retail Marijuana Cultivation Facility shall only exercise those privileges granted to it by the State Licensing Authority.
- B. <u>Licensed Premises</u>. To the extent authorized by Rule R 304 Medical Marijuana Business and Retail Marijuana Establishment Shared Licensed Premises and Operational Separation, a Retail Marijuana Cultivation Facility may share a location with a commonly-owned Optional Premises Cultivation Operation. However, a separate license is required for each specific business or business entity, regardless of geographical location.
- C. <u>Cultivation of Retail Marijuana Authorized</u>. A Retail Marijuana Cultivation Facility may Propagate, cultivate, harvest, prepare, cure, package, store, and label Retail Marijuana, whether in concentrated form or otherwise.
- D. <u>Authorized Transfer</u>, A Retail Marijuana Cultivation Facility may only <u>Transfer</u>, Retail Marijuana to another Retail Marijuana Establishment.
- E. <u>Authorized On-Premises Storage</u>. 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.
- F. <u>Samples Provided for Testing</u>. 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.
- G. <u>Authorized Marijuana Transport.</u> 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 Establishment. Nothing in this rule prevents a Retail Marijuana Cultivation Facility from transporting its own Retail Marijuana.
- Performance Based Incentives. A Retail Marijuana Cultivation Facility may compensate its employees using performance-based incentives.
- I. Authorized Sources of Retail Marijuana Seeds and Immature Plants. A Retail Marijuana Cultivation Facility shall only obtain Medical Marijuana seeds or Immature Plants from its own Retail Marijuana or from another Retail Marijuana Business Establishment.

Basis and Purpose - R 502

Deleted: Sales

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Deleted: a Retail Marijuana Store, Retail Marijuana Products Manufacturing Facility, and other Retail Marijuana Cultivation Facility(-ies).

Deleted: Medical

Deleted: Licensee

901(2)(a), 12-43.4-901(4)(c) and 12-43.4-901(4)(g), and sections 12-43.4-403 and 12-43.4-406, 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.

R 502 - Retail Marijuana Cultivation Facility: General Limitations or Prohibited Acts

- A. Temporary Limitations
 - 1. Repealed.
 - Repealed
- B. Packaging and Labeling Standards Required. A Retail Marijuana Cultivation Facility is prohibited from selling Retail Marijuana that is not packaged and labeled in accordance with these rules. See Rules R 1001 Packaging Requirements: General Requirements and R 1002 Labeling Requirements: General Requirements or Rule 1000-1 Series Labeling, Packaging, and Product Safety.
- Sale to Consumer Prohibited. A Retail Marijuana Cultivation Facility is prohibited from selling Retail Marijuana to a consumer.
- D. <u>Consumption Prohibited</u>. A Retail Marijuana Cultivation Facility shall not permit the consumption of marijuana or marijuana products on its Licensed Premises.
- E. <u>Excise Tax Paid.</u> A Retail Marijuana Cultivation Facility shall remit any applicable excise tax due pursuant to Article 28.8 of Title 39, C.R.S., and shall provide verification to purchasers of the Retail Marijuana that any required excise tax was, or will be, paid.
- F. <u>Sales and Gifts to Transporters Prohibited.</u> A Retail Marijuana Cultivation Facility shall not sell or give away Retail Marijuana or Retail Marijuana Product to a Retail Marijuana Transporter, and shall not buy or receive complimentary Retail Marijuana or Retail Marijuana Product from a Retail Marijuana Transporter.

Basis and Purpose - R 503

The statutory authority for this rule is found at subsections 12-43.4-202(1), 12-43.4-202(2)(b), 12-43.4-202(3)(b)(IX) and 12-43.4-403(4), C.R.S. The purpose of this rule is to establish a Retail Marijuana Cultivation Facility's obligation to account for and track all inventories on the Licensed Premises from seed or cutting to Transfer to other Retail Marijuana Establishments.

R 503 - Retail Marijuana Cultivation Facility: Inventory Tracking System

- A. Minimum Tracking Requirement. A Retail Marijuana Cultivation Facility must use the Inventory Tracking System to ensure its inventories are identified and tracked from the point Retail Marijuana is Propagated from seed or cutting to the point when it is delivered to a Retail Marijuana Establishment. See also Rule R 309 –Inventory Tracking System. A Retail Marijuana Cultivation Facility must have the ability to reconcile its Retail Marijuana inventory with the Inventory Tracking System and the associated transaction history and sale receipts. See also Rule R 901 Business Records Required.
- B. <u>Transport of Retail Marijuana Without Transport Manifest Prohibited</u>. A Retail Marijuana Cultivation Facility is prohibited from transporting any Retail Marijuana without a valid transport manifest generated by the Inventory Tracking System.

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C. Accepting Retail Marijuana Without Transport Manifest Prohibited. Retail Marijuana Cultivation
Facility is prohibited from accepting any Retail Marijuana from another Retail Marijuana

Establishment without receiving a valid transport manifest generated from the Inventory Tracking System.

Deleted: Cultivation Facility or Retail Marijuana Transporter

D. <u>Input Into Inventory Tracking System Required</u>. A Retail Marijuana Cultivation Facility must immediately input all Retail Marijuana delivered to its Licensed Premises, accounting for all RFID tags, into the Inventory Tracking System at the time of delivery from another Retail Marijuana Establishment

Deleted: Cultivation Facility

E. <u>Inventory Must Be Reconciled Daily</u>. A Retail Marijuana Cultivation Facility must reconcile its transaction history and on-hand inventory to the Inventory Tracking System at the close of business each day.

Basis and Purpose - R 504

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(X), 12-43.4-202(3)(a)(XI), 12-43.4-202(3)(a)(XII), and 12-43.4-202(3)(b)(IX), C.R.S. The purpose of this rule is to establish minimum health and safety regulation for Retail Marijuana Cultivation Facilities. The rule prohibits a Retail Marijuana Cultivation Facility from treating or otherwise adulterating Retail Marijuana with any chemical or other compound whatsoever to alter its color, appearance, weight or smell. This rule also authorizes the State Licensing Authority to require an independent consultant to conduct a health and sanitary audit of a Retail Marijuana Cultivation Facility. This rule explains when an independent health and sanitary audit may be deemed necessary and sets forth possible consequences of a Retail Marijuana Establishment's refusal to cooperate or pay for the audit.

R 504 - Retail Marijuana Cultivation Facility: Health and Safety Regulations

- A. <u>Local Safety Inspections.</u> A Retail Marijuana Cultivation Facility 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 Retail Marijuana. An annual fire safety inspection may result in the required installation of fire suppression devices, or other means necessary for adequate fire safety.
- B. <u>General Sanitary Requirements.</u> A Retail Marijuana Cultivation Facility 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 Retail Marijuana shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected:
 - 2. That all persons working in direct contact with Retail Marijuana shall conform to hygienic practices while on duty, including but not limited to:
 - a. Maintaining adequate personal cleanliness;
 - Washing hands thoroughly in an adequate hand-washing area(s) before starting work, prior to engaging in the production of a Retail Marijuana Concentrate, and at any other time when the hands may have become soiled or contaminated;

- c. 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 and/or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices; and
- Refraining from having direct contact with Retail 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.
- 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 Retail Marijuana is exposed;
- That floors, walls, and ceilings are constructed in such a manner that they may be adequately cleaned and kept clean and kept in good repair;
- That there is adequate lighting in all areas where Retail Marijuana are stored or sold, and where equipment or utensils are cleaned;
- 6. 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:
- 7. That any buildings, fixtures, and other facilities are maintained in a sanitary condition;
- 8. That toxic cleaning compounds, sanitizing agents, solvents and other chemicals shall be identified, held, stored and disposed of in a manner that protects against contamination of Retail Marijuana or Retail Marijuana Concentrate, and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation or ordinance. All Pesticide must be stored and disposed of in accordance with the information provided on the product's label:
- 9. That all contact surfaces, including utensils and equipment used for the preparation of Retail Marijuana or 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 Retail Marijuana Cultivation Facility and used in accordance with labeled instructions;
- 10. 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 subject to approval of the Water Quality Control Division of the local water provider;
- 11. 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;

- That all operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of Retail Marijuana or Retail Marijuana Product shall be conducted in accordance with adequate sanitation principles;
- That each Retail Marijuana Cultivation Facility shall provide its employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair; and
- 14. That Retail Marijuana that can support the rapid growth of undesirable microorganisms shall be held in a manner that prevents the growth of these microorganisms.
- C. <u>Pesticide Application.</u> A Retail Marijuana Cultivation Facility may only use Pesticide in accordance with the "Pesticide Act," section 35-9-101 et seq., C.R.S., "Pesticides Applicators' Act," section 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.
- D. <u>Application of Other Agricultural Chemicals.</u> A Retail Marijuana Cultivation Facility may only use agricultural chemicals, other than Pesticide, in accordance with all applicable federal, state, and local laws, statutes, rules and regulations.

E. Required Documentation

- Standard Operating Procedures. A Retail Marijuana Cultivation Facility must establish
 written standard operating procedures for the cultivation, harvest, drying, curing,
 packaging and storing of Retail Marijuana. The standard operating procedures must also
 include when, and the manner in which, all Pesticide and other agricultural chemicals are
 to be applied during its cultivation process. A copy of all standard operating procedures
 must be maintained on the Licensed Premises of the Retail Marijuana Cultivation Facility.
- Material Change. If a Retail Marijuana Cultivation Facility makes a Material Change to its standard operating procedures, it must document the change and revise its standard operating procedures accordingly. Records detailing the Material Change must be maintained on the Licensed Premises of the Retail Marijuana Cultivation Facility.
- Material Safety Data Sheet. A Retail Marijuana Cultivation Facility must obtain a material safety data sheet for any Pesticide or other agricultural chemical used or stored on its Licensed Premises. A Retail Marijuana Cultivation Facility must maintain a current copy of the material safety data sheet for any Pesticide or other agricultural chemical on the Licensed Premises where the product is used or stored.
- Labels of Pesticide and Other Agricultural Chemicals. A 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. <u>Pesticide Application Documentation.</u> A Retail Marijuana Cultivation Facility that applies any Pesticide or other agricultural chemical to any portion of a Retail 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:
 - The name, signature and Occupational License number of the individual who applied the Pesticide or other agricultural chemical;

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- Applicator certification number if the applicator is licensed through the Department of Agriculture in accordance with the "Pesticides Applicators' Act," section 35-10-101 et seq., C.R.S.;
- c. The date and time of the application;
- 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;
- The restricted entry interval from the product label of any Pesticide or other agricultural chemical(s) applied;
- h. The RFID tag number of the Retail Marijuana plant(s) to which the Pesticide or other agricultural chemical(s) were applied, or, if the Pesticide or other agricultural chemical(s) were applied to all plants throughout the Licensed Premises, a statement to that effect; and
- i. The total amount of each Pesticide or other agricultural chemical applied.
- F. <u>Prohibited Chemicals.</u> The following chemicals shall not be used in Retail Marijuana cultivation. Possession of chemicals and/or containers from these chemicals upon the Licensed Premises shall be a violation of this rule. Prohibited chemicals are:

Chemical Name

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

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

126-15-8

485-31-4

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

<u>DDD</u>

72-54-8

<u>DDT</u>

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

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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
<u>OCTAMETHYLDIPHOSPHORAMIDE</u>
152-16-9
PARATHION
56-38-2
<u>PENTACHLOROPHENOL</u>
87-86-5
PHENYLMERCURIC OLEATE [PMO]
EDF-185
PHOSPHAMIDON
13171-21-6
<u>PYRIMINIL</u>
53558-25-1
SAFROLE
94-59-7

TERPENE POLYCHLORINATES (STROBANE6)

8001-50-1

THALLIUM(I) SULFATE

SODIUM ARSENATE

SODIUM ARSENITE

13464-38-5

7784-46-5 <u>2,4,5-T</u> 93-76-5 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

- G. <u>DMSO.</u> The use of Dimethylsulfoxide ("DMSO") in the production of Retail Marijuana shall be prohibited and possession of DMSO upon the Licensed Premises is prohibited.
- H. <u>Adulterants.</u> A Retail Marijuana Cultivation Facility may not treat or otherwise adulterate Retail Marijuana with any chemical or other compound whatsoever to alter its color, appearance, weight or smell
- I. Independent Health and Sanitary Audit
 - 1. State Licensing Authority May Require A Health and Sanitary Audit
 - a. When the State Licensing Authority determines a health and sanitary audit by an independent consultant is necessary, it may require a Retail Marijuana Cultivation Facility to undergo such an audit. The scope of the audit may include, but need not be limited to, whether the Retail Marijuana Cultivation Facility is in compliance with the requirements set forth in this rule and other applicable public health or sanitary laws and regulations.
 - In such instances, the Division may attempt to mutually agree upon the selection
 of the independent consultant with a Retail Marijuana Cultivation Facility.
 However, the Division always retains the authority to select the independent
 consultant regardless of whether mutual agreement can be reached.
 - c. The Retail Marijuana Cultivation Facility will be responsible for all costs associated with the independent health and sanitary audit.
 - 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:
 - A Retail Marijuana Cultivation Facility does not provide requested records related to the use of Pesticide or other agricultural chemicals during in the cultivation process;

- b. The Division has reasonable grounds to believe that the Retail Marijuana Cultivation Facility 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;
- The Division has reasonable grounds to believe that the Retail Marijuana
 Cultivation Facility was the cause or source of contamination of Retail Marijuana
 or Retail Marijuana Concentrate; or
- d. Multiple Harvest Batches or Production Batches produced by the Retail Marijuana Cultivation Facility failed contaminant testing.
- Compliance Required. A Retail Marijuana Cultivation Facility 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.

4. Suspension of Operations

- a. 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 Retail Marijuana Cultivation Facility's license. See Rule R 1302 – Disciplinary Process: Summary Suspensions.
- b. Prior to or following the issuance of such an order, the Retail Marijuana Cultivation Facility 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.
 - 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 R 1302 – Disciplinary Process: Summary Suspensions.
 - ii. If an agreement to suspend operations is reached, then the Retail Marijuana Cultivation Facility may continue to care for its inventory and conduct any necessary internal business operations but it may not Transfer, or wholesale Retail Marijuana or Retail Marijuana Concentrate to any other Retail Marijuana Establishment during the period of time specified in the agreement.

 J. <u>Violation Affecting Public Safety.</u> Failure to comply with this rule may constitute a license violation affecting public safety.

Basis and Purpose - R 505

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(VIII), 12-43.4-202(3)(a)(XI), and 12-43.4-202(3)(b)(IX), and sections 12-43.4-403 and 12-43.4-405, 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.

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R 505 - 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 for concentrate production on the current diagram of the Licensed Premises. See Rule R 901- 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 Owner(s) of the Retail Marijuana Cultivation Facility also has a valid Retail Marijuana Products Manufacturing Facility 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. <u>Safety and Sanitary Requirements for Concentrate Production.</u> If a Retail Marijuana Cultivation Facility produces Retail Marijuana Concentrate, then all areas in which the Retail Marijuana Concentrate are produced and all Owners and Occupational Licensees engaged in the production of the Retail Marijuana Concentrate shall be subject to all of the requirements imposed upon a Retail Marijuana Products Manufacturing Facility that produces Retail Marijuana Concentrate, including all general requirements. See Rule R 604– Health and Safety Regulations: Retail Marijuana Products Manufacturing Facility and Rule R 605 Retail Marijuana Products Manufacturing Facility: Retail Marijuana Concentrate Production.
- C. <u>Possession of Other Categories of Retail Marijuana Concentrate.</u>
 - 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 Owner(s) of the Retail Marijuana
 Cultivation Facility also has a valid Retail Marijuana Products Manufacturing Facility
 license
 - 2. Notwithstanding subparagraph (C)(1) of this rule R 505, 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 Manufacturing Facility Transfers the resultant Solvent-Based Retail Marijuana Concentrate back to the originating Retail Marijuana Cultivation Facility.
 - The Retail Marijuana Cultivation Facility shall comply with all requirements in rule R 1507(B.1) when having Solvent-Based Retail Marijuana Concentrate manufactured out of Retail Marijuana flower or trim that failed microbial testing.
 - The Retail Marijuana Cultivation Facility is responsible for submitting the Solvent-Based Retail Marijuana Concentrate for all required testing for contaminants pursuant to rule R 1501 Retail Marijuana Testing Program Contaminant Testing, for potency pursuant to rule R 1503 Retail Marijuana Testing Program Potency Testing, and any other testing required or allowed by the Retail Marijuana Rules or Retail 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 R 502(E).

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Basis and Purpose - R 506

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(I-II), 12-43.4-202(3)(b)(IX), and 12-43.4-202(4)(a) and (b) and sections 12-43.4-103, 12-43.4-104, and 12-43.4-104. C.R.S.

The rule establishes a means by which to manage the overall production of retail marijuana. The intent of this rule is to encourage responsible production to meet demand for retail 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 continuation of the sale of illegal marijuana.

The State Licensing Authority intends to replace or revise this rule's production management provisions as early as January 2017 by transitioning to an output-based production management model. 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 Store(s) has been incorporated in the production management rules as a means to address this production management concern.

R 506 - Retail Marijuana Cultivation Facility: Production Management

- Applicability. This rule is effective beginning November 30, 2015 and shall apply to all Retail
 Marijuana Cultivation Facility Licensees.
- B. One Retail Cultivation License per Licensed Premises.
 - Only one Retail Marijuana Cultivation Facility License shall be permitted at each licensed premises. Each licensed premises must be located at a distinct address recognized by the local jurisdiction.
 - Existing Retail Marijuana Cultivation Facilities that have Multiple Cultivation Licenses at the Licensed Premises. Upon the first renewal at the Retail Marijuana Cultivation Facility, all of the Retail Marijuana Cultivation Facility's licenses will be collapsed into one surviving license, and fees shall be prorated for the non-expiring licenses. The maximum authorized plant count shall also collapse into the surviving license.
- C. <u>Production Management</u>.
 - 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 increments of 3,600 plants. A Retail Marijuana Cultivation Facility Licensee shall be allowed to increase its maximum authorized plant count one increment of 3,600 plants at a time upon application and approval by the Division pursuant to the requirements of paragraph (E) of this rule R 506.
- iii. A Retail Marijuana Cultivation Facility may apply to increase its authorized plant count by two increments of 3,600 plants (7,200 plants total) every six months once it reaches Tier 5. It is within the Division's discretion to determine whether or not to grant the requested two 3,600 plant increase. In making its determination, the Division will consider documents submitted by the Retail Marijuana Cultivation. By way of example and not limitation, supporting documents may include documents establishing:
 - (1) That the Retail Marijuana Cultivation has consistently cultivated an amount of plants that is at or near its maximum authorized plant count, and has Transferred at least 90% of the inventory it produced during that time period to another Retail Marijuana Establishment;
 - (2) That the Retail Marijuana Cultivation currently has possession of sufficient space to grow the requested two 3,600 plant increments;
 - (3) That the Retail Marijuana Cultivation is co-owned with one or more Retail Marijuana Stores and in the preceding six months, notwithstanding that the Retail Marijuana Cultivation cultivated all, or nearly all, of its authorized plant count, the Retail Marijuana Cultivation and/or the Retail Marijuana Store obtained Retail Marijuana from one or more unrelated Retail Marijuana Cultivations; and
 - (4) That the Retail Marijuana Cultivation has contracts for the sale of Retail Marijuana in the next six months supporting the requested two 3,600 plant increments.
- 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. As of November 30, 2015, a Retail Marijuana Cultivation Facility license that was associated with a Retail Marijuana Products Manufacturing Facility shall be authorized to cultivate no more than 1,800 plants at any given time. If such a Retail Marijuana Cultivation Facility Licensee submitted a plant count waiver application prior to August 31, 2015 and it was subsequently approved, the license shall be authorized to cultivate the maximum number of plants at any given time in the corresponding production management tier pursuant to subparagraph (C)(1) of this rule R 506.
- 4. Each Retail Marijuana Cultivation Facility with a license(s) granted before November 30, 2015 shall be authorized to cultivate the same number of plants that it was authorized to cultivate prior to November 30, 2015. Pursuant to subparagraph (B)(2) of this rule R 506, for any Retail Marijuana Cultivation Facility that has multiple licenses, the total plant count authorized in sum across those licenses shall apply to the entire Retail Marijuana Cultivation Facility and shall be collapsed into one license upon renewal.
- In connection with the license renewal process for Retail Marijuana Cultivation Facilities that are authorized to cultivate more than 1,800 plants, the Division will review the

purchases, sales, and cultivated plant count of the Retail Marijuana Cultivation Facility Licensee during the preceding licensing term. 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 if the Licensee sold less than 70% of what it produced during the six months prior to the application for renewal. When determining whether to reduce the maximum authorized plant count, the Division may consider the following factors including but not limited to:

- Cultivation and production history including whether the plants/inventory suffered a catastrophic event during the licensing period;
- b. Transfer, sales, and excise tax payment history;
- c. Existing inventory and inventory history;
- d. Sales contracts; and
- Any other factors relevant to ensuring responsible cultivation, production, and inventory management.

D. <u>Inventory Management</u>.

- Inventory Management for Retail Cultivation Facilities that have one or two harvest seasons a year. Beginning February 1, 2015, a Retail Marijuana Cultivation Facility that harvests once or twice a year may not accumulate Harvested Marijuana in excess of the total amount of inventory the Licensee produced that was Transferred to another Retail Marijuana Establishment in the previous year.
- 2. Inventory Management for Retail Cultivation Facilities that have two or more harvest seasons a year. Beginning February 1, 2015, a Retail Marijuana Cultivation Facility that harvests more than twice a year may not accumulate Harvested Marijuana in excess of the total amount of inventory the Licensee produced that was Transferred to another Retail Marijuana Establishment in the previous six months.

E. Application for Additional Plants.

- After accruing at least two quarters of sales, 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 Licensee shall provide documentation demonstrating that for at least six consecutive months prior to the tier increase application, it has consistently cultivated an amount of plants that is at or near its maximum authorized plant count, and has Transferred at least 85% of the inventory it produced during that time period to another Retail Marijuana Establishment, and any other information requested to aid the Division in its evaluation of the tier increase application.
- 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 R 208 – Schedule of Business License Fees: Retail Marijuana Establishments.
- 3. 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

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fee at license renewal. See rule R 209 – Schedule of Business License Renewal Fees: Retail Marijuana Establishments.

- F. Maximum Allowed Retail Marijuana Cultivation Facility Licenses.
 - 1. A Person with an Interest in Three or More Retail Marijuana Cultivation Facility Licenses. For every multiple of three Retail Marijuana Cultivation Facility licenses a person has an interest in, the person must have a controlling interest in at least one Retail Marijuana Store. For example: (1) a person with an interest in three, four, or five Retail Marijuana Cultivation Facility licenses also must have a controlling interest in at least one Retail Marijuana Store; (2) a person with an interest in six, seven, or eight Retail Marijuana Cultivation Facility licenses also must have a controlling interest in at least two Retail Marijuana Stores; (3) a person with an interest in nine, ten, or eleven Retail Marijuana Cultivation Facility licenses also must have a controlling interest in at least three Retail Marijuana Stores; etc.
 - 2. A Person with an Interest in Less than Three Retail Marijuana Cultivation Facility Licenses. The person shall not be required to have an interest 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.

R 600 Series - Retail Marijuana Products Manufacturing Facilities

Basis and Purpose - R 601

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-306(1)(j), 12-43.4-309(7)(a), 12-43.4-404(1)(a), 12-43.4-404(1)(b), 12-43.4-404(6), 12-43.4-406(1)(c), and 12-43.4-406(4)(b), C.R.S. The purpose of this rule is to establish that it is unlawful for a Retail Marijuana Products Manufacturing Facility to exercise any privileges other than those granted by the State Licensing Authority and to clarify the license privileges.

R 601 - Retail Marijuana Products Manufacturing Facilities: License Privileges

- A. <u>Privileges Granted</u>. A Retail Marijuana Products Manufacturing Facility shall only exercise those privileges granted to it by the State Licensing Authority.
- B. <u>Licensed Premises</u>. A separate license is required for each specific business or business entity and geographical location. A Retail Marijuana Products Manufacturing Facility may share a location with a commonly owned Medical Marijuana-Infused Products Manufacturer. However, a separate license is required for each specific business or business entity, regardless of geographical location.
- C. <u>Transfers Restricted.</u> A Retail Marijuana Products Manufacturing Facility may only <u>Transfer Retail Marijuana Concentrate or Retail Marijuana Product to Retail Marijuana Stores to other Retail Marijuana Products Manufacturing Facilities and to Retail Marijuana Testing Facility.</u>
- D. <u>Manufacture of Retail Marijuana Product Authorized.</u> A Retail Marijuana Products Manufacturing Facility may manufacture, prepare, package, store, and label Retail Marijuana Product, whether in concentrated form or that are comprised of marijuana and other ingredients intended for use or consumption, such as edible products, ointments, or tinctures.
- E. <u>Location Prohibited.</u> A Retail Marijuana Products Manufacturing Facility may not manufacture, prepare, package, store, or label Retail Marijuana Product in a location that is operating as a retail food establishment or a wholesale food registrant.
- F. <u>Samples Provided for Testing.</u> A Retail Marijuana Products Manufacturing Facility may provide samples of its Retail Marijuana Product to a Retail Marijuana Testing Facility for testing and research purposes. The Retail Marijuana Products Manufacturing Facility shall maintain the testing results as part of its business books and records.
- G. <u>Authorized Marijuana Transport.</u> A Retail Marijuana Products Manufacturing Facility is authorized to utilize a licensed Retail Marijuana Transporter for transportation of its Retail Marijuana Product so long as the place where transportation orders are taken and delivered is a licensed Retail Marijuana Establishment. Nothing in this rule prevents a Retail Marijuana Products Manufacturing Facility from transporting its own Retail Marijuana.
- A Retail Marijuana Products Manufacturing Facility may compensate its employees using performance-based incentives.

Basis and Purpose - R 604

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(IV)(A), 12-43.4-202(3)(a)(VI), 12-43.4-202(3)(a)(VII), 12-43.4-202(3)(a)(VII), 12-43.4-202(3)(a)(XII), 12-43.4-202(3)(b)(IX), 12-43.4-202(3)(c)(V), 12-43.4-202(3)(c)(VII), 12-43.4-202(3)(c)(VIII), 12-43.4-202(3)(c)(VI

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202(3)(c)(IX)(A)-(B), and 12-43.4-202(3)(c.5)(I), and section 12-43.4-404, 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 minimum health and safety regulation for Retail Marijuana Products Manufacturing Facilities. It requires all Owners and Occupational Licensees to demonstrate an understanding of basic food handling safety practices or attend a food handler training course prior to manufacturing any Edible Retail Marijuana Product. It sets forth general standards and basic sanitary requirements for Retail Marijuana Products Manufacturing Facilities. It covers the physical premises where the products are made as well as the individuals handling the products. 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 of Public Health and Environment. This rule also authorizes the State Licensing Authority to require an independent consultant to conduct a health and sanitary audit of a Retail Marijuana Products Manufacturing Facility. This rule explains when a heath and sanitary audit may be deemed necessary and sets forth possible consequences of a Retail Marijuana Establishment's refusal to cooperate or pay for the audit. This rule also establishes requirements for each Edible Retail Marijuana Product manufactured by a Retail Marijuana Products Manufacturing Facility. Product safety requirements were adopted to aid in making Edible Retail Marijuana Products more readily identifiable to the general public outside of their packaging as containing marijuana. 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.

R 604 - Retail Marijuana Products Manufacturing Facility: Health and Safety Regulations

A. Training

- Prior to engaging in the manufacture of any Edible Retail Marijuana Product each Owner or Occupational 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:
 - 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).
- A Retail Marijuana Products Manufacturing Facility must obtain documentation evidencing that each Owner and each Occupational 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 or Occupational Licensee is engaged in the manufacturing of an Edible Retail Marijuana Product.

B. General Standards

- A Retail Marijuana Products Manufacturing Facility may be subject to inspection 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 Retail Marijuana. An annual fire safety inspection may result in the required installation of fire suppression devices, or other means necessary for adequate fire safety.
- A Retail Marijuana Products Manufacturing Facility that manufacturers edible Retail
 Marijuana Product shall comply with all kitchen-related health and safety standards of the
 relevant 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. Product Safety

Paragraph C is repealed effective October 1, 2016. Licensees shall refer to paragraph (C.5) of this rule for product safety requirements beginning October 1, 2016.

- A Retail Marijuana Products Manufacturing Facility that manufactures Edible Retail Marijuana Product shall comply fully with paragraph C of this rule no later than February 1, 2015.
- 2. A Retail Marijuana Products Manufacturing Facility that manufactures Edible Retail Marijuana Product shall create and maintain standard production procedures and detailed manufacturing processes for each Edible Retail Marijuana Product it manufactures. These procedures and processes must be documented and made available on the licensed premises for inspection by the Marijuana Enforcement Division, the Colorado Department of Public Health & Environment, and local licensing authorities.
- 3. The size of a Standardized Serving Of Marijuana shall be no more than 10mg of active THC. A Retail Marijuana Products Manufacturing Facility 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 for sale shall contain more than 100 milligrams of active THC.
- 4. 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.
- Multiple-Serving Edible Retail Marijuana Product. A Retail Marijuana Products Manufacturing Facility 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. 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.

6. If an 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 easily separable, then the product must contain no more than 10 mg of active THC per unit of sale, and the Retail Marijuana Products Manufacturing Facility must ensure that the product complies with subparagraph (B)(2)(a) of rule R 1004.5.

C.5. <u>Product Safety</u>.

Paragraph (C.5) is effective beginning October 1, 2016.

- 1. A Retail Marijuana Products Manufacturing Facility that manufactures Edible Retail Marijuana Product shall create and maintain standard production procedures and detailed manufacturing processes for each 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. The size of a Standardized Serving Of Marijuana shall be no more than 10mg of active THC. A Retail Marijuana Products Manufacturing Facility 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 for sale shall contain more than 100 milligrams of active THC.
- 3. 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.
- 4. Each single Standardized Serving Of Marijuana shall be marked, stamped, or otherwise imprinted with the Universal Symbol directly on at least one side of the Edible Retail Marijuana Product in a manner to cause the Universal Symbol to be distinguishable and easily recognizable. The Universal Symbol marking shall:
 - Be centered either horizontally or vertically on each Standardized Serving Of Marijuana; and
 - b. If centered horizontally on a serving, the height and width of the Universal Symbol shall be of a size that is at least 25% of the serving's width, but not less than $\frac{1}{4}$ inch by $\frac{1}{4}$ inch; or
 - c. If centered vertically on a serving, the height and width of the Universal Symbol shall be of a size that is at least 25% of the serving's height, but not less than $\frac{1}{4}$ inch by $\frac{1}{4}$ inch.
- Notwithstanding the requirement of subparagraph (C.5)(4), an Edible Retail Marijuana Product shall contain no more than 10 mg of active THC per Container and the Retail Marijuana Products Manufacturing Facility must ensure that the product complies with subparagraph (A)(2) of rule R 1004 or subparagraphs (A)-(C) of rule R 1008-1 when:
 - 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

- b. 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 easily separable.
- 6. The following categories of Edible Retail Marijuana Product are considered to be per se practicable to mark with the Universal Symbol:
 - a. Chocolate
 - b. Soft confections
 - c. Hard confections or lozenges
 - d. Consolidated baked goods (e.g. cookie, brownie, cupcake, granola bar)
 - e. Pressed pills and capsules
- The following categories of Edible Retail Marijuana Product are considered to be per se impracticable to mark with the Universal Symbol:
 - a. Repealed.
 - b. Loose bulk goods (e.g. granola, cereals, popcorn)
 - c. Powders
- 8. Repealed.
- 8.1. <u>Liquid Edible Retail Marijuana Product</u>.
 - a. Pursuant to 12-43.4-404(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 (C.5)(5) of this rule R 604 that requires Edible Retail Marijuana Products that are impracticable to mark with the Universal Symbol to contain 10mg or less active THC per Container.
 - b. This exemption permits the manufacture and sale of Multi-Serving Liquid Edible Retail Marijuana Products so long as the product is:
 - 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 10mg of active THC per serving, with no more than 100mg of active THC total per Container; and
 - ii. The measurement component is within the Child-Resistant cap or closure of the bottle and is not a separate component.
- 9. <u>Multiple-Serving Edible Retail Marijuana Product.</u>
 - a. A Retail Marijuana Products Manufacturing Facility 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.

- 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.
- c. 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 (C.5)(4) of this rule R 604.
- d. A Multiple-Serving Edible Retail Marijuana Product that is a Liquid Edible Retail Marijuana Product shall comply with the requirements in subsubparagraph (C.5)(8.1)(b) of this rule R 604 and is exempt from subsubparagraphs a-c of this subparagraph (C.5)(9).
- Remanufactured Products Prohibited. A Retail Marijuana Product Manufacturing Facility shall not utilize a commercially manufactured food product as its Edible Retail Marijuana Product. The following exceptions to this prohibition apply:
 - a. A food product that was commercially manufactured specifically for use by the Retail Marijuana Product Manufacturing Facility 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 Retail Marijuana Product Manufacturing Facility.
 - b. Commercially manufactured food products may be used as ingredients in a Retail Marijuana Product Manufacturing Facility's 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 Retail Marijuana Product, and (2) the Retail Marijuana Product Manufacturing Facility does not state or advertise to the consumer that the final Edible Retail Marijuana Product contains the commercially manufactured food product.
- 11. <u>Trademarked Food Products</u>. Nothing in this rule alters or eliminates a Retail Marijuana Product Manufacturing Facility's responsibility to comply with the trademarked food product provisions required by the Retail Code per 12-43.4-404(1)(e)(I-III), C.R.S.
- Edibles Prohibited that are Shaped like a Human, Animal, or Fruit. This subparagraph (C.5)(12) is effective beginning October 1, 2017.
 - a. The production and sale of Edible Retail Marijuana Products in the following shapes is prohibited:
 - i. The distinct shape of a human, animal, or fruit; or
 - A shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings.

- b. The prohibition on human, animal, and fruit shapes does not apply to the logo of a licensed Retail Marijuana Establishment. Nothing in this subsubparagraph (C.5)(12)(b) alters or eliminates a Licensee's obligation to comply with the requirements of Rule R 1001 – Labeling and Packaging Requirements: General Applicability or Rule R 1000-1 Series – Labeling, Packaging, and Product Safety.
- c. Edible Retail Marijuana Products that are geometric shapes and simply fruit flavored are not considered fruit and are permissible; and
- Edible Retail Marijuana Products that are manufactured in the shape of a marijuana leaf are permissible.
- D. <u>General Sanitary Requirements.</u> 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 preparation surfaces for Retail Marijuana or Retail Marijuana Product shall be excluded from any operations which may be expected to result in such 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/or in Retail Marijuana Product preparation areas and where good sanitary practices require employees to wash and/or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices;
 - That all persons working in direct contact with preparation of Retail Marijuana or Retail
 Marijuana Product shall conform to hygienic practices while on duty, including but not
 limited to:
 - a. Maintaining adequate personal cleanliness;
 - Washing hands thoroughly in an adequate hand-washing area(s) before starting work, prior to engaging in the production of a Retail Marijuana Concentrate or manufacture of a Retail Marijuana Product and at any other time when the hands may have become soiled or contaminated; and
 - c. Refraining from having direct contact with preparation of Retail Marijuana or Retail Marijuana Product if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.
 - 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 Retail Marijuana or Retail Marijuana Product;
 - 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 Retail Marijuana or Retail Marijuana Product are exposed;

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- That floors, walls, and ceilings are constructed in such a manner that they may be adequately cleaned and kept clean and kept in good repair;
- 7. That there is adequate safety-type lighting in all areas where Retail Marijuana or Retail Marijuana Product are processed or stored and where equipment or utensils are cleaned;
- That the Licensed Premises 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;
- 9. That any buildings, fixtures, and other facilities are maintained in a sanitary condition;
- 10. That all contact surfaces, including utensils and equipment used for the preparation of Retail Marijuana, Retail Marijuana Concentrate or Retail 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 in a Retail Marijuana Products Manufacturing Facility and used in accordance with labeled instructions;
- 11. That toxic cleaning compounds, sanitizing agents, solvents used in the production of Retail Marijuana concentrate and other chemicals shall be identified, held, stored and disposed of in a manner that protects against contamination of Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product, and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation or ordinance;
- 12. 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:
- 13. 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;
- 14. That each Retail Marijuana Products Manufacturing Facility shall provide its employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair;
- 15. That all operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of Retail Marijuana or Retail Marijuana Product shall be conducted in accordance with adequate sanitation principles;
- 16. That Retail Marijuana or Retail Marijuana Product that can support the rapid growth of undesirable microorganisms shall be held in a manner that prevents the growth of these microorganisms; and
- 17. That storage and transport of finished Retail Marijuana Product shall be under conditions that will protect products against physical, chemical, and microbial contamination as well as against deterioration of any container.

E. <u>Standard Operating Procedures</u>

- A Retail Marijuana Products Manufacturing Facility must have written standard operating procedures for each category of Retail Marijuana Concentrate and type of Retail Marijuana Product that it produces.
 - a. All standard operating procedures for the production of a Retail Marijuana Concentrate must follow the requirements in Rule R 605.
 - b. A copy of all standard operating procedures must be maintained on the Licensed Premises of the Retail Marijuana Products Manufacturing Facility.
- If a Retail Marijuana Products Manufacturing Facility makes a Material Change to its standard Retail Marijuana Concentrate 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
- F. <u>Additives.</u> A Retail Marijuana Products Manufacturing Facility shall not include any Additive that is toxic within a Retail Marijuana Product; nor include any Additive for the purposes of making the product more addictive, appealing to children or misleading to consumers.
- G DMSO. The use of Dimethylsulfoxide ("DMSO") in the production of Retail Marijuana Concentrate
 or Retail Marijuana Product shall be prohibited and possession of DMSO upon the Licensed
 Premises is prohibited.
- H. Independent Health and Sanitary Audit

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- 1. State Licensing Authority May Require An Independent Health and Sanitary Audit
 - a. When the State Licensing Authority determines a health and sanitary audit by an independent consultant is necessary, it may require a Retail Marijuana Products Manufacturing Facility to undergo such an audit. The scope of the audit may include, but need not be limited to, whether the Retail Marijuana Products Manufacturing Facility is in compliance with the requirements set forth in this rule or other applicable food handling laws, rules or regulations or compliance with the concentrate production rules in Rule R 605 or other applicable laws, rules and regulations.
 - b. In such instances, the Division may attempt to mutually agree upon the selection of the independent consultant with a Retail Marijuana Products Manufacturing Facility. However, the Division always retains the authority to select the independent consultant regardless of whether mutual agreement can be reached.
 - The Retail Marijuana Products Manufacturing Facility will be responsible for all costs associated with the independent health and sanitary audit.
- 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:

- A Retail Marijuana Products Manufacturing Facility does not provide requested records related to the food handling training required for Owners or Occupational Licensees engaged in the production of Edible Retail Marijuana Product to the Division;
- A Retail Marijuana Products Manufacturing Facility does not provide requested records related to the production of Retail Marijuana Concentrate, including but not limited to, certification of its Licensed Premises, equipment or standard operating procedures, training of Owners or Occupational Licensees, or Production Batch specific records;
- The Division has reasonable grounds to believe that the Retail Marijuana Products Manufacturing Facility is in violation of one or more of the requirements set forth in this rule or Rule R 605;
- d. The Division has reasonable grounds to believe that the Retail Marijuana Products Manufacturing Facility was the cause or source of contamination of Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product; or
- e. Multiple Production Batches of Retail Marijuana Concentrate or Retail Marijuana Product produced by the Retail Marijuana Products Manufacturing Facility failed contaminant testing.
- Compliance Required. A Retail Marijuana Products Manufacturing Facility 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.

4. Suspension of Operations

- a. 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 Retail Marijuana Products Manufacturing Facility's license. See Rule R 1302 – Disciplinary Process: Summary Suspensions.
- b. Prior to or following the issuance of such an order, the Retail Marijuana Products Manufacturing Facility 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.
 - 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 R 1302 – Disciplinary Process: Summary Suspensions.
 - ii. If an agreement to suspend operations is reached, then the Retail Marijuana Products Manufacturing Facility may continue to care for its inventory and conduct any necessary internal business operations but it may not Transfer or wholesale Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product to another Retail Marijuana Establishment during the period of time specified in the agreement.

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Depending on the condition of the Retail Marijuana Products Manufacturing Facility and required remedial measures, the Division may permit a Retail Marijuana Products Manufacturing Facility to produce Retail Marijuana Concentrate or manufacture Retail Marijuana Product while operations have been suspended.

Violation Affecting Public Safety. Failure to comply with this rule may constitute a license violation affecting public safety.

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Basis and Purpose - R 605

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(VIII), 12-43.4-202(3)(a)(XI), and 12-43.4-2-2(3)(b)(IX), 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 Manufacturing Facility 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.

R 605 –Retail Marijuana Products Manufacturing Facility: Retail Marijuana Concentrate Production.

- A. Permitted Categories of Retail Marijuana Concentrate Production
 - A Retail Marijuana Products Manufacturing Facility may produce Water-Based Retail Marijuana Concentrate, Food-Based Retail Marijuana Concentrate and Heat/Pressure Based Retail Marijuana Concentrate.

A Retail Marijuana Products Manufacturing Facility may also produce Solvent-Based Retail Marijuana Concentrate using only the following solvents: butane, propane, CO₂, ethanol, isopropanol, acetone, heptane and pentane. The use of any other solvent is expressly prohibited unless and until it is approved by the Division.

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- Beginning on July 1, 2014, a Retail Marijuana Products Manufacturing Facility 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. <u>General Applicability.</u> A Retail Marijuana Products Manufacturing Facility that engages in the production of Retail Marijuana Concentrate, regardless of the method of extraction or category of concentrate being produced, must:
 - 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 R 901- Business Records Required.
 - Ensure that all applicable sanitary rules are followed. See R 604.
 - Ensure that the standard operating procedure for each method used to produce a Retail
 Marijuana Concentrate on its Licensed Premises 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;

- 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 R 307 – Waste Disposal.
- Establish written and documentable quality control procedures designed to maximize safety for Owners and Occupational Licensees and minimize potential product contamination.
- 5. Establish written emergency procedures to be followed by Owners or Occupational 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 on its Licensed Premises. The training manual must include, but need not be limited to, the following topics:
 - All standard operating procedures for each method of concentrate production used at that Licensed Premises;
 - The Retail Marijuana Products Manufacturing Facility's quality control procedures;
 - c. The emergency procedures for that Licensed Premises;
 - d. The appropriate use of any necessary safety or sanitary equipment;
 - e. The hazards presented by all solvents used within the Licensed Premises as described in the material 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.
- Provide adequate training to every Owner or Occupational Licensee prior to that individual undertaking any step in the process of producing a Retail Marijuana Concentrate.
 - 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 or Occupational 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 or Occupational Licensee can safely produce a Retail Marijuana Concentrate. See Rule R 901- Business Records Required.

- c. The Owner or Occupational 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 R 901- Business Records Required.
- Maintain clear and comprehensive records of the name, signature and Owner or Occupational 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 R 901- 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 Manufacturing Facility that engages in the production of a Water-Based Retail Marijuana Concentrate Based Retail Marijuana Concentrate or a Heat/Pressure Based Retail Marijuana Concentrate must:

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Ensure that all equipment, counters and surfaces used in the production of a Water-Based Retail Marijuana Concentrate or a Heat/Pressure Based Retail Marijuana Concentrate or a Heat/Pressure Based 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.

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Ensure that all equipment, counters, and surfaces used in the production of a Water-Based Retail Marijuana Concentrate or a
 <u>Heat/Pressure Based Retail Marijuana Concentrate</u> are thoroughly cleaned after the completion of each Production Batch.

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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 CO₂.

4. Ensure that the appropriate safety or sanitary equipment, including personal protective equipment, is provided to, and appropriately used by, each Owner or Occupational Licensee engaged in the production of a Water-Based Retail Marijuana Concentrate or Heat/Pressure Based Retail Marijuana Concentrate.
Concentrate.

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- 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.
- 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 foodaredo.
- 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 Water-Based Retail Marijuana Concentrate a Food-Based Retail Marijuana Concentrate or a Heat/Pressure Based Retail Marijuana Concentrate.

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- D. <u>Solvent-Based Retail Marijuana Concentrate.</u> A Retail Marijuana Products Manufacturing Facility that engages in the production of Solvent-Based Retail Marijuana Concentrate must:
 - 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. <u>Flammable Solvent Determinations.</u> 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:
 - 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. <u>CO2 Solvent Determination.</u> If CO₂ is used as solvent at the Licensed Premises, then the Industrial Hygienist or Professional Engineer must determine whether a CO₂ gas monitoring system must be installed within the room in which Retail Marijuana Concentrate is to be produced or CO₂ is stored, and if required the system's specifications, in accordance with applicable laws, rules and regulations.
 - c. <u>Exhaust System Determination.</u> 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. <u>Material Change.</u> If a Retail Marijuana Products Manufacturing Facility 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.
- Manufacturer's Instructions. The Industrial Hygienist or Professional Engineer may review and consider any information provided to the Retail Marijuana Products Manufacturing Facility 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 Manufacturing Facility 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.
- 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;
- Ensure that the room in which Solvent-Based Retail Marijuana Concentrate shall be produced must contain an emergency eye-wash station;
- 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.
 - If the system is UL or ETL listed, then a Retail Marijuana Products Manufacturing Facility may use the system in accordance with the manufacturer's instructions.
 - iii. If the system is UL or ETL listed but the Retail Marijuana Products Manufacturing Facility 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 Manufacturing Facility 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. <u>Ethanol or Isopropanol.</u> A Retail Marijuana Products Manufacturing Facility 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.
- Ensure that all solvents used in the extraction process are food-grade or at least 99% pure;
 - A Retail Marijuana Products Manufacturing Facility must obtain a material safety data sheet for each solvent used or stored on the Licensed Premises. A Retail Marijuana Products Manufacturing Facility must maintain a current copy of the material safety data sheet and a receipt of purchase for all solvents used or to be used in an extraction process. See Rule R 901- Business Records Required.
 - b. A Retail Marijuana Products Manufacturing Facility is prohibited from using denatured alcohol to produce a Retail Marijuana Concentrate.
- 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 Manufacturing Facility store more Flammable Solvent on its Licensed Premises than the maximum amount established for that Licensed Premises by the Industrial Hygienist or Professional Engineer;
- Ensure that the appropriate safety and sanitary equipment, including personal protective equipment, is provided to, and appropriately used by, each Owner or Occupational Licensee engaged in the production of a Solvent-Based Retail Marijuana Concentrate;
- Ensure that a trained Owner or Occupational 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. <u>Ethanol and Isopropanol.</u> If a Retail Marijuana Products Manufacturing Facility 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.
- F. <u>Violation Affecting Public Safety.</u> Failure to comply with this rule may constitute a license violation affecting public safety.

R 900 Series - Business Records

Basis and Purpose - R 901

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(XII), and 12-43.4-701(1), and section 12-43.4-310, 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. Rule R 901.B was added due to written commentary received from an industry representative.

R 901 - Business Records Required

A. General Requirements

- A Retail Marijuana Establishment must maintain the information required in this rule in a format that is readily understood by a reasonably prudent business person.
- Each Retail Marijuana Establishment 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.
 - On premises records: The Retail Marijuana Establishment'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 Occupational License number of each employee and all non-employee Owners, who work at a Retail Marijuana Establishment.
 - i. Each Licensed Premises shall enter the full name and Occupational 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 Retail Marijuana Establishment must maintain the business contact information for vendors that maintain video surveillance systems and Security Alarm Systems.
 - Advertising Records All records related to Advertising and marketing, including, but not limited to, audience composition data.
 - Licensed Premises Diagram of all approved Limited Access Areas and any permitted off-premises storage facilities.
 - e. Visitor Log List of all visitors entering Limited Access Areas or Restricted Access Areas.

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Waste log - Comprehensive records regarding all waste material that accounts
for, reconciles, and evidences all waste activity related to the disposal of
marijuana.

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Surveillance logs – Surveillance logs as required by Rule M 306.

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Identity Statement and Standardized Graphic. 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. A Licensee may elect to have its Identity Statement also serve as its Standardized Graphic Symbol for purposes of complying with this rule.

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____All records normally retained for tax purposes.

All other records required by these Rules.

- B. <u>Loss of Records and Data</u>. 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.
- Violation Affecting Public Safety. Violation of this rule may constitute a license violation affecting public safety.
- D. Records Related to Inventory Tracking. A Retail Marijuana Establishment must maintain accurate and comprehensive inventory tracking records that account for, reconcile and evidence all inventory activity for Retail Marijuana from either seed or immature plant stage until the Retail Marijuana or Retail Marijuana Product is destroyed or sold to another Retail Marijuana Establishment or a consumer.
- E. <u>Records Related to Transport</u>. A Retail Marijuana Establishment must maintain adequate records for the transport of all Retail Marijuana and Retail Marijuana Product. See Rule R 801 – Transport of Retail Marijuana and Retail Marijuana Product.
- F. <u>Provision of Any Requested Record to the Division</u>. 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.

R 1700 Series - Retail Marijuana Establishment Operators

Basis and Purpose - R 1702

The statutory authority for this rule is found at subsections 12-43.4-202(1), 12-43.4-202(2)(b), 12-43.4-202(3)(a)(XVIII), 12-43.4-202(3)(b)(IX), and sections 12-43.4-407 and 12-43.4-901, 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 Establishment Operator.

R 1702 - Retail Marijuana Establishment Operators: General Limitations or Prohibited Acts

- A. Financial Interest. A Person who is a Direct Beneficial Interest Owner or an Indirect Beneficial Interest Owner of a Retail Marijuana Establishment Operator may also be a Direct Beneficial Interest Owner, an Indirect Beneficial Interest Owner or otherwise hold, a direct or indirect financial interest in another Retail Marijuana Establishment so long as that interest complies with all other requirements of these rules. A Retail Marijuana Establishment may be operated by a Retail Marijuana Business Operator where each has one or more Direct Beneficial Interest Owners or Indirect Beneficial Interest Owners in common. A Person may receive compensation for services provided by a Retail Marijuana Business Operator in accordance with these rules.
- B. <u>Sale of Marijuana Prohibited.</u> A Retail Marijuana Establishment Operator is prohibited from selling, distributing, or transferring Retail Marijuana or Retail Marijuana Product to another Retail Marijuana Establishment or a consumer, except when acting as an agent of a Retail Marijuana Establishment(s) operated by the Retail Marijuana Establishment Operator.
- C. <u>Consumption Prohibited</u>. A Retail Marijuana Establishment Operator, and its Direct Beneficial Interest 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 Establishment Operator, and any of its Direct Beneficial Interest Owners, agents or employees engaged in the operation of the Retail Marijuana Establishment(s) it operates, must use the Inventory Tracking System account of the Retail Marijuana Establishment(s) it operates, in accordance with all requirements, limitations and prohibitions applicable to the Retail Marijuana Establishment(s) it operates.
- E. Compliance with Requirements and Limitations Applicable to the Retail Marijuana

 Establishment(s) Operated. In operating any other Retail Marijuana Establishment(s), a Retail

 Marijuana Establishment Operator, and its Direct Beneficial Interest Owners who are required to

 hold Associated Key Licenses, as well as the agents and employees of the Retail Marijuana

 Establishment Operator, shall comply with all requirements, limitations and prohibitions applicable

 to the type(s) of Retail Marijuana Establishment(s) 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 Establishment may grant access to its Inventory Tracking System account to the Direct Beneficial Interest Owners, agents and employees of a Retail Marijuana Establishment Operator having duties related to Inventory Tracking System activities of the Retail Marijuana Establishment(s) being operated.
 - The Direct Beneficial Interest Owners, agents and employees of a Retail Marijuana Establishment Operator granted access to a Retail Marijuana Establishment's Inventory Tracking System account, shall comply with all Inventory Tracking System rules.
 - At least one Direct Beneficial Interest Owner of a Retail Marijuana Establishment being operated by a Retail Marijuana Establishment Operator <u>must</u> be an Inventory <u>Tracking</u>

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System Trained Administrator for the Retail Marijuana Establishment'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 Establishment Operator's Direct Beneficial Interest Owners, agents and employees:

- When its contract with the Retail Marijuana Establishment Operator expires by its terms:
- b. When its contract with the Retail Marijuana Establishment Operator is terminated by any party; or
- c. When it is notified that the License of the Retail Marijuana Establishment Operator, or a specific Direct Beneficial Interest Owner, agent or employee of the Retail Marijuana Establishment Operator, has expired, or has been suspended or revoked.
- G. <u>Limitations on Use of Documents and Information Obtained from Retail Marijuana</u>
 <u>Establishments.</u> A Retail Marijuana Establishment Operator, and its agents and employees, shall maintain the confidentiality of documents and information obtained from the other Retail Marijuana Establishment(s) it operates, and shall not use or disseminate documents or information obtained from a Retail Marijuana Establishment it operates for any purpose not authorized by the Retail 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 Establishment to promote the interests of the Retail Marijuana Establishment Operator or its Direct Beneficial Interest Owners, Indirect Beneficial Interest Owners, agents or employees, or any Person other than the Retail Marijuana Establishment it operates.
- H. <u>Form and Structure of Allowable Agreement(s) Between Operators and Owners.</u> Any agreement between a Retail Marijuana Establishment and a Retail Marijuana Establishment Operator:
 - Must acknowledge that the Retail Marijuana Establishment Operator, and its Direct Beneficial Interest Owners, agents and employees who are engaged, directly or indirectly, in operating the Retail Marijuana Establishment, are agents of the Retail Marijuana Establishment being operated, and must not disclaim an agency relationship.;
 - May provide for the Retail Marijuana Establishment Operator to receive direct remuneration from the Retail Marijuana Establishment, including a portion of the profits of the Retail Marijuana Establishment being operated, subject to the following limitations:
 - The portion of the profits to be paid to the Retail Marijuana Establishment
 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 Establishment
 being operated;
 - b. The Retail Marijuana Establishment Operator, shall not be granted, and may not accept:
 - i. a security interest in the Retail Marijuana Establishment being operated, or in any assets of the Retail Marijuana Establishment;
 - 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 Establishment being operated, or a future or contingent right to the same, including but not limited to options or warrants;

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- The Retail Marijuana Establishment Operator, shall not guarantee the Retail Marijuana Establishment's debts or production levels.
- 3. Shall permit the Retail Marijuana Establishment being operated to terminate the contract with the Retail Marijuana Establishment Operator at any time, with or without cause;
- 4. Shall be contingent on approval by the Division; and
- 5. Shall not be materially amended without advance written approval from the Division.
- I. A Retail Marijuana Establishment Operator may engage in dual operation of a Retail Marijuana Establishment and a Medical Marijuana Business at a single location, to the extent the Retail Marijuana Establishment being operated is permitted to do so pursuant to subsection 12-43.4-401(2)(a), C.R.S., and the Retail Marijuana Establishment Operator shall comply with the rules promulgated pursuant to the Medical Code and the Retail Code, including the requirement of obtaining a valid registration as a Medical Marijuana Business Operator.

Basis and Purpose - R 1703

The statutory authority for this rule is found at subsections, 12-43.4-202(3)(a)(XVIII), 12-43.4-202(3)(b)(IX), 12-43.4-309(11), and 12-43.4-401(1)(e) C.R.S. The purpose of this rule is to establish occupational license requirements for the Retail Marijuana Establishment Operator's Direct Beneficial Interest Owners, agents and employees, including those directly or indirectly engaged in the operation of other Retail Marijuana Establishment(s).

R 1703 - Retail Marijuana Establishment Operators: Occupational Licenses for Personnel

A. Required Occupational Licenses.

- Associated Key Licenses. All natural persons who are Direct Beneficial Interest Owners in a Retail Marijuana Establishment Operator must have a valid Associated Key License, associated with the Retail Marijuana Establishment Operator License. Such an Associated Key License shall satisfy all licensing requirements for work related to the business of the Retail Marijuana Establishment Operator and for work performed on behalf of, or at the Licensed Premises of, the Retail Marijuana Establishment(s) operated by the Retail Marijuana Establishment Operator.
- 2. Key Licenses. All other natural persons who are agents or employees of a Retail Marijuana Establishment Operator that are actively engaged, directly or indirectly, in the management or supervision of other Retail Marijuana Establishments, must hold a Key License. The Key License shall satisfy all licensing requirements for work related to the business of the Retail Marijuana Establishment Operator and for work at the Licensed Premises of, or on behalf of, the Retail Marijuana Establishment(s) operated by the Retail Marijuana Establishment Operator.
- 3. Occupational Licenses. All natural persons who are agents and employees of a Retail

 Marijuana Establishment Operator that are actively engaged, directly or indirectly, in the operation of one or more other Retail Marijuana Establishment(s), including but not limited to all agents or employees who will come into contact with Retail Marijuana or Retail Marijuana Product, who will have to access Limited Access Areas, or who will have access to the Inventory Tracking System account of the Retail Marijuana

 Establishment(s) being operated as part of their duties, must have a valid Occupational License.
- B. <u>Occupational Licenses Not Required</u>. Occupational Licenses are not required for Indirect Beneficial Interest Owners of a Retail Marijuana Establishment Operator, Qualified Limited

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Passive Investors who are Direct Beneficial Interest Owners of a Retail Marijuana Establishment Operator, or for natural persons who will not come into contact with Retail Marijuana or Retail Marijuana Product, will not have access Limited Access Area(s) of the Retail Marijuana Establishment(s) being operated, and will not have access to the Inventory Tracking System account of the Retail Marijuana Establishment(s) being operated.

C. <u>Designation of the Manager of a Retail Marijuana Establishment Operated by a Retail Marijuana Establishment Operator.</u> If a Retail Marijuana Establishment Operator is contracted to manage the overall operations of a Retail Marijuana Establishment's Licensed Premises, the Retail Marijuana Establishment shall designate a separate and distinct manager on the Licensed Premises who is an officer, agent or employee of the Retail Marijuana Establishment Operator, which shall be a natural person with a valid Associated Key License or Key License, as set forth in paragraph A of this rule, and the Retail Marijuana Establishment shall comply with the reporting provisions of subsection 12-43.4-309(11), C.R.S.