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 and Regulations 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/2016-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 posted on the Colorado Department of Revenue, Marijuana Enforcement Division's website at:

https://www.colorado.gov/pacific/enforcement/2016-med-rulemaking. The full set of proposed rules will be posted no later than 5:00 p.m. on Friday, August 26, 2016. 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. 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 2016 legislative session. Some of those proposed modifications will be quite substantial, particularly those related to Senate Bill 2016-040 and House Bill 16-1261, and those changes are not included in the initial partial proposed rules but will be included in the full set of proposed rules to be posted by August 26, 2016.

The State Licensing Authority will conduct meetings of representative groups of participants with an interest in the subject of the rule-making ("stakeholder meetings") beginning the week of July 25, 2016. More information related to these meetings can be found at:

https://www.colorado.gov/pacific/enforcement/2016-med-rulemaking. Each stakeholder meeting will be 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 August 26, 2016.

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 licensing, ownership and financial interests, operators, and definitions related to new legislation and to other rules under consideration during these rulemaking proceedings. 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 August 26, 2016.

*Other general rules may be adopted or amended.

M 200 Series – Licensing and Interests

All M 200 Series rules are under consideration for procedural and substantive amendments in order to implement legislation passed in the 2016 legislative session including but not limited to Senate Bill 16-040, House Bill 16-1211, and House Bill 16-1261, or any other subject matter needed to implement and interpret the Medical Code. It is anticipated that the amendments and additions to the M 200 Series will be substantial. The 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 August 26, 2016. The proposed changes will be the focus of extensive discussion during stakeholder meetings.

*Other rules related to licensing and interests may be adopted or amended.

M 300 Series - The Licensed Premises

M 301 – The Licensed Premises

M 302 – Possession of Licensed Premises

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

^{*}Other rules governing the Licensed Premises may be adopted or amended.

M 400 Series – Medical Marijuana Center

M 401 – Medical Marijuana Center: License Privileges

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

M 406 – Medical Marijuana Center: Inventory Tracking System

M 500 Series – Optional Premises Cultivation Operation Facilities

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

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

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

*Other rules governing Optional Premises Cultivation Operation Facilities may be adopted or amended.

M 600 Series - Medical Marijuana-Infused Products Manufacturers

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

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

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

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

*Other rules governing Medical Marijuana-Infused Products Manufacturers may be adopted or amended.

M 700 Series – Medical Marijuana Testing Facilities

M 704 – Medical Marijuana Testing Facilities: Personnel

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

*Other rules governing Medical Marijuana Testing Facilities may be amended or adopted.

M 800 Series – Transportation and Storage

M 801 – Transport of Medical Marijuana and Medical Marijuana-Infused Products: All Medical Marijuana Businesses (Re-named)

M 802 – Off-Premises Storage of Medical Marijuana and Medical Marijuana-Infused Product : All Medical Marijuana Businesses (Re-named)

*Other rules governing transportation and storage of Medical Marijuana and Medical Marijuana-Infused Products may be adopted or amended.

^{*}Other rules governing Medical Marijuana Centers may be adopted or amended.

M 900 Series - Business Records and Reporting

M 905 – Department Information Access (New)

*Other rules governing business records and reporting may be adopted or amended.

M 1000 Series - Labeling, Packaging, and Products Safety

*Rules governing packaging and may be adopted or amended.

M 1100 Series - Signage, Marketing, and Advertising

M 1101 - General Requirement: False and Misleading Statements (Repealed)

M 1102 – Advertising General Requirement: No Deceptive, False or Misleading Statements (New)

M 1103 – The Term "Minor" as Used in the Medical Code and These Rules (New)

M 1104 – Advertising: Television (New)

M 1105 – Advertising: Radio (New)

M 1106 – Advertising: Print Media (New)

M 1107 – Advertising: Internet (New)

M 1108 – Advertising: Targeting Out-of-State Persons Prohibited (New)

M 1109 – Signage and Advertising: No Safety Claims Because Regulated by State Licensing Authority (New)

M 1110 – Signage and Advertising: No Safety Claims Because Tested by a Medical Marijuana Testing Facility (New)

M 1111 – Signage and Advertising: Outdoor Advertising (New)

M 1112 - Signage and Advertising: No Content That Targets Minors (New)

M 1113 – Advertising: Advertising via Marketing Directed Toward Location-Based Devices (New)

M 1114 – Pop-Up Advertising (New)

M 1115 – Advertising: Event Sponsorship (New)

*Other 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

M 1302 – Summary Suspensions (Re-named)

M 1304 – Administrative Hearings

*Other 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

M 1501 - Medical Marijuana Testing Program - Contaminant Testing

M 1502 – Medical Marijuana Testing Program - Mandatory Testing

M 1504 - Medical Marijuana Testing Program - Sampling Procedures

*Other rules governing the medical marijuana testing program may be adopted or amended.

M 1600 Series - Retail Marijuana Transporters (New)

M 1601 – Medical Marijuana: License Privileges (New)

M 1602 – Medical Marijuana: General Limitations or Prohibited Acts (New)

M 1603 – Medical Marijuana: Inventory Tracking System (New)

M 1604 – Medical Marijuana: Health and Safety Regulations (New)

*Other rules governing Transporters may be adopted or amended.

M 1700 Series – Medical Marijuana Operators (New)

* Rules governing Medical Marijuana Operators will be adopted.

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 licensing, ownership and financial interests, operators, and definitions related to new legislation and to other rules under consideration during these rulemaking proceedings. 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 August 26, 2016.

*Other general rules may be adopted or amended.

R 200 Series – (Re-named) Licensing and Interests

All M 200 Series rules are under consideration for procedural and substantive amendments in order to implement legislation passed in the 2016 legislative session including but not limited to Senate Bill 16-040, House Bill 16-1211, and House Bill 16-1261, or any other subject matter needed to implement and interpret the Retail Code and Article XVIII, Section 16 of the Colorado Constitution. It is anticipated that the amendments and additions to the R 200 Series will be substantial. The 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 August 26, 2016. The proposed changes will be the focus of extensive discussion during stakeholder meetings.

*Other rules governing licensing may be adopted or amended.

R 300 Series – The Licensed Premises

- R 301 Limited Access Areas
- R 302 Possession of Licensed Premises
- R 304 Medical Marijuana Business and Retail Marijuana Establishment Shared Licensed Premises and Operational Separation
- *Other rules governing the Licensed Premises may be adopted or amended.

R 400 Series – Retail Marijuana Stores

- R 401 Retail Marijuana Store: License Privileges
- R 402 Retail Marijuana Sales: General Limitations or Prohibited Acts
- R 404 Acceptable Forms of Identification for Retail Sales
- R 405 Retail Marijuana Store: Inventory Tracking System
- *Other rules governing Retail Marijuana Stores may be adopted or amended.

R 500 Series – Retail Marijuana Cultivation Facilities

- R 501 Retail Marijuana Cultivation Facility: License Privileges
- R 502 Retail Marijuana Cultivation Facility: General Limitations or Prohibited Acts
- R 503 Retail Marijuana Cultivation Facility: Inventory Tracking System
- *Other rules governing Retail Marijuana Cultivation Facilities may be adopted or amended.

R 600 Series – Retail Marijuana Products Manufacturing Facilities

- R 601 Retail Marijuana Products Manufacturing Facilities: License Privileges
- R 602 Retail Marijuana Products Manufacturing Facility: General Limitations or Prohibited Acts
- R 603 Retail Marijuana Products Manufacturing Facility: Inventory Tracking System
- R 604 Retail Marijuana Products Manufacturing Facility: Health and Safety Regulations
- *Other rules governing Retail Marijuana Products Manufacturing Facilities may be adopted or amended.

R 700 Series – Retail Marijuana Testing Facilities

- R 703 Retail Marijuana Testing Facilities: Certification Requirements
- R 704 Retail Marijuana Testing Facilities: Personnel
- R 712 Retail Marijuana Testing Facilities: Mandatory Sampling and Testing Program

^{*}Other rules governing Retail Marijuana Testing Facilities may be adopted or amended.

R 800 Series – Transportation and Storage

R 801 – Transport of Retail Marijuana and Retail Marijuana Product: All Retail Marijuana Establishments (Re-named)

R 802 – Off-Premises Storage of Retail Marijuana and Retail Marijuana Product (Renamed)

*Other rules governing the transportation and storage of Retail Marijuana may be adopted or amended.

R 900 Series – Business Records and Reporting

R 905 – Department Information Access

*Other rules governing business records and reporting may be adopted or amended.

R 1000 Series - Labeling, Packaging, and Products Safety

R 1004 – Packaging and Labeling Requirements of a Retail Marijuana Product by a Retail Marijuana Products Manufacturing Facility

R 1005.5 - Packaging and Labeling of Retail Marijuana by a Retail Marijuana Store

R 1006 – Packaging and Labeling of Retail Marijuana Product by a Retail Marijuana Store

R 1007.5 – Packaging and Labeling of Retail Marijuana Concentrates by a Retail Marijuana Store

*Other rules governing labeling and packaging 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

*Other rules governing enforcement may be adopted or amended.

R 1300 Series – Discipline

R 1302 – Summary Suspensions (Re-named)

R 1304 – Administrative Hearings

*Other rules governing discipline may be adopted or amended.

R 1500 Series - Retail Marijuana Testing Program

R 1501 – Retail Marijuana Testing Program – Contaminant Testing

R 1502 - Retail Marijuana Testing Program - Mandatory Testing

R 1504 – Retail Marijuana Testing Program – Retail Marijuana Testing Program:

Sampling Procedures

*Other rules governing the retail marijuana testing program may be adopted or amended.

R 1600 Series – Retail Marijuana Transporters (New)

R 1601 – Retail Marijuana Transporter: License Privileges (New)

R 1602 – Retail Marijuana Transporter: General Limitations or Prohibited Acts (New)

R 1603 – Retail Marijuana Transporter: Inventory Tracking System (New)

R 1604 – Retail Marijuana Transporter: Health and Safety Regulations (New)

R 1700 Series – Retail Marijuana Operators (New)

* Rules governing Retail Marijuana Operators will be adopted.

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 September 2, 2016, 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 August 10, 2015, 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 Friday, September 2, 2016.

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/2016-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 455 Sherman Street, Suite 390 Denver, CO 80203

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.

^{*}Other rules governing Transporters may be adopted or amended.

The State Licensing Authority strongly encourages written comments

If allowed, 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.

HEARING SCHEDULE

Date: September 2, 2016 Time: 9:00 a.m. – 5:00 p.m.

Place: Ralph L. Carr Colorado Judicial Center

1300 Broadway, Rooms 1 A, B & C

Denver, CO 80203

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 testimony and written submissions presented at this hearing, as well as applicable legal provisions and any related matters properly submitted before the hearing record is closed. Pursuant to said hearing, in the above-entitled matter at the time and place aforesaid, or at any adjourned meeting, the State Licensing Authority will adopt such rules as in its judgment are justified by the rulemaking record and applicable legal provisions.

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 August 12, 2016.

Dated this 15th day of July, 2016.

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

Barbara J. Brohl, State Licensing Authority

Colorado Department of Revenue



This form must be completed in its entirety prior to submission for consideration by the Division

Last Name:	First Name:	
Company/Organization:		
Date: Contact Phone Number: Check if you would like your email address to be	Email Address:e added to the Division's rulemaking notification distribution list	
Rule Number and/or Name:	Rule Section:	
Suggested wording for the rule:		



This form must be completed in its entirety prior to submission for consideration by the Division

Basic justification for the suggested change:	
Examples of when the current rule caused a problem/confusion:	
01	
Please provide real life examples	
Please provide real life examples	
Please provide real life examples	
Please provide real life examples	
Please provide real life examples	



This form must be completed in its entirety prior to submission for consideration by the Division

	ct/benefit the industry:		· · · · · · · · · · · · · · · · · · ·
1			
Explain how the change would affect	ct/benefit the Marijuana Er	nforcement Division:	
	•		



This form must be completed in its entirety prior to submission for consideration by the Division

Explain how the change would affect/benefit the public:				
List any documents or informational sources you have to support the proposed rule change:				

Completed rule revision suggestion forms will be included in the permanent rulemaking public record.

Please return this completed form to: <u>dor_medrulecomments@state.co.us</u> or by mailing it to the following address:

Marijuana Enforcement Division Re: Rules 455 Sherman Street, Suite 390 Denver, CO 80203

M 100 Series - General Applicability

Basis and Purpose – M 103

The statutory authority for this rule is found at subsection 12-43.3-202(1)(b)(I), C.R.S. The purpose of this rule is to provide necessary definitions of terms used throughout the rules. Defined terms are capitalized where they appear in the rules, to let the reader know to refer back to these definitions. When a term is used in a conventional sense, and not intended to be a defined term, it is not capitalized.

With regard to the definition of Child-Resistant, the State Licensing Authority relied extensively upon written commentary provided by a public health agency within a Colorado hospital, which had conducted a health impact assessment of packaging regulations, looking at accidental ingestion of medical marijuana. The assessment was supported by others in the public, including industry representatives and a physician specializing in medical toxicology.

With regard to the definition of Restricted Access Area, the State Licensing Authority relied extensively upon written commentary provided by a consumer advocate.

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:

"Advertising" means the act of providing consideration for the publication, dissemination, solicitation, or circulation of visual, oral, or written communication, to induce directly or indirectly any Person to patronize a particular a Medical Marijuana Business, or to purchase particular Medical Marijuana or a Medical Marijuana-Infused Product. "Advertising" includes marketing, but does not include packaging and labeling. "Advertising" proposes a commercial transaction or otherwise constitutes commercial speech.

"Agreement" means any unsecured convertible debt option, option agreement, warrant, or at the Division's discretion, other document that establishes a right for a person to obtain a Permitted Economic Interest that might convert to an ownership interest in a Retail Marijuana Establishment or Medical Marijuana Business.

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

"Applicant" means a Person that has submitted an application pursuant to these rules that was accepted by the Division for review but has not been approved or denied by the State Licensing Authority.

"Associated Key License" means an Occupational License for an individual who is an Owner of the Medical Marijuana Business.

"Batch Number" means any distinct group of numbers, letters, or symbols, or any combination thereof, assigned by a Medical Marijuana Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer to a specific Harvest Batch or Production Batch of Medical Marijuana.

"Child-Resistant" means special packaging that is:

- a. Designed or constructed to be significantly difficult for children under five years of age to open and not difficult for normal adults to use properly as defined by 16 C.F.R. 1700.20 (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.
- b. Opaque so that the packaging does not allow the product to be seen without opening the packaging material;
- c. Resealable for any product intended for more than a single use or containing multiple servings.

"Container" means the sealed package in which Medical Marijuana or a Medical Marijuana-Infused Product is placed for sale to a patient and that has been labeled according to the requirements set forth in Rules M 1002 *et.* seq.

"Denied Applicant" means any Person whose application for licensure pursuant to the Medical Code has been denied.

"Department" means the Colorado Department of Revenue.

"Director" means the Director of the Marijuana Enforcement Division.

"Division" means the Marijuana Enforcement Division.

"Edible Medical Marijuana-Infused Product" means any Medical Marijuana-Infused Product that is intended to be consumed orally, including but not limited to, any type of food, drink, or pill.

"Executive Director" means the Executive Director of the Department of Revenue.

"Exit Package" means a sealed Container or package provided at the retail point of sale, in which any Medical Marijuana or Medical Marijuana-Infused Product already within a Container are placed.

"Final Agency Order" means an Order of the State Licensing Authority issued in accordance with the Medical Code and the State Administrative Procedure Act. The State Licensing Authority will issue a Final Agency Order following review of the Initial Decision and any exceptions filed thereto or at the conclusion of the declaratory order process. A Final Agency Order is subject to judicial review.

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

"Flowering" means the reproductive state of *Cannabis* in which the plant in a light cycle intended to stimulate production of flowers, trichromes, and cannabinoids characteristic of marijuana.

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

"Good Cause" for purposes of denial of an initial, renewal or reinstatement license application or certification, or for purposes of discipline of a license or certification, means:

a. The Licensee or Applicant has violated, does not meet, or has failed to comply with any of the terms, conditions, or provisions of the Medical Code, any rules

promulgated pursuant it, or any supplemental relevant state or local law, rule, or regulation;

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

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

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

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

"Immature plant" means a nonflowering Medical Marijuana plant that is no taller than eight inches and no wider than eight inches 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.

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

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

- A. The special studies and training of such individuals shall be sufficient in the cognate sciences to provide the ability and competency to:
 - Anticipate and recognize the environmental factors and stresses associated with work and work operations and to understand their effects on individuals and their well-being;
 - Evaluate on the basis of training and experience and with the aid of quantitative measurement techniques the magnitude of such environmental factors and stresses in terms of their ability to impair human health and well-being;
 - Prescribe methods to prevent, eliminate, control, or reduce such factors and stresses and their effects.
- B. Any individual who has practiced within the scope of the meaning of industrial hygiene for a period of not less than five years immediately prior to July 1, 1997, is exempt from the degree requirements set forth in the definition above.

C. Any individual who has a two-year associate of applied science degree in environmental science from an accredited college or university and in addition not less than four years practice immediately prior to July 1, 1997, within the scope of the meaning of industrial hygiene is exempt from the degree requirements set forth in the definition above.

"Initial Decision" means a decision of a hearing officer in the Department following a licensing, disciplinary, or other administrative hearing.

"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 or is destroyed.

"Inventory Tracking System Trained Administrator" means an Owner or an Occupational Licensed Licensee of a Medical Marijuana Business who has attended and successfully completed Inventory Tracking System training and who has completed any additional training required by the Division.

"Inventory Tracking System User" means an Owner or an occupationally licensed Medical Marijuana Business employee who is granted Inventory Tracking System User account access for the purposes of conducting inventory tracking functions in the Inventory Tracking System, who has been successfully trained by Inventory Tracking System Trained Administrator(s) in the proper and lawful use Inventory Tracking System, and who has completed any additional training required by the Division.

"Key License" means an Occupational License for an individual who performs duties that are key to the Medical Marijuana Business' 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.

"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-, or test Medical Marijuana in accordance with the provisions of the Medical Code and these rules.

"Licensee" means any Person licensed or registered pursuant to the Medical Code, including an Occupational Licensee.

"Limited Access Area" means a building, room, or other contiguous area upon the Licensed Premises where Medical Marijuana is grown, cultivated, stored, weighed, packaged, sold, or processed for sale, under control of the Licensee.

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

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

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

"Medical Code" means the Colorado Medical Marijuana Code found at sections 12-43.3-101 et. seq., C.R.S.

"Medical Marijuana" means marijuana that is grown and sold pursuant to the Medical Code and includes seeds and Immature Plants.

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

"Medical Marijuana Business Operator" means an entity or person that is not an Owner and that is registered to provide professional operational services to a Medical Marijuana Business for direct remuneration from the Medical Marijuana Business.

"Medical Marijuana Center" means a Person that is licensed pursuant to the Medical Code to operate a business as described in section 12-43.3-402, C.R.S., and that sells Medical Marijuana to registered patients or primary caregivers as defined in Article XVIII, Section 14 of the Colorado Constitution, but is not a primary caregiver.

"Medical Marijuana 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 Solvent-Based Medical Marijuana Concentrate.

"Medical Marijuana-Infused Product" means a product infused with Medical Marijuana that is intended for use or consumption other than by smoking, including but not limited to edible products, ointments, and tinctures. Such products shall not be considered a food or drug for purposes of the "Colorado Food and Drug Act," part 4 of Article 5 of Title 25, C.R.S.

"Medical Marijuana-Infused Products Manufacturer" means a Person licensed pursuant to the Medical Code to operate a business as described in section 12-43.3-404, C.R.S.

"Medical Marijuana Testing Facility" means a public or private laboratory licensed and certified, or approved by the Division, to conduct research and analyze Medical Marijuana, Medical Marijuana-Infused Products, and Medical Marijuana Concentrate for contaminants and potency.

"Medical Marijuana Transporter" means an entity or person that is licensed to transport Medical Marijuana and Medical Marijuana-Infused Products from one Medical Marijuana Business to another Medical Marijuana Business and to temporarily store the transported Medical Marijuana and Medical Marijuana-Infused Products at its licensed premises. The privileges of the Medical Marijuana Transporter License do not permit a Medical Marijuana Transporter to sell Medical Marijuana or Medical Marijuana-Infused Products under any circumstances.

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

"Monitoring Company" means a Person in the business of providing Monitoring services for a Medical Marijuana Business.

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

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

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

"Optional Premises Cultivation Operation" means a Person licensed pursuant to the Medical Code to operate a business as described in section 12-43.3-403, C.R.S.

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

"Owner" means the Person or Persons whose beneficial interest in the license is such that they bear risk of loss other than as an insurer, and have an opportunity to gain profit from the operation or sale of the establishment. Each individual Owner must have an Associated Key License. Owner includes any other Person that qualifies as an Owner pursuant to Rule M 204. The holder of a suitable Permitted Economic Interest is not an Owner.

"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 an owner under the Retail Code or Medical Code.

"Person" means a natural person, partnership, association, company, corporation, limited liability company, or organization, or a manager, agent, owner, director, servant, officer, or employee thereof; except that "Person" does not include any governmental organization.

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

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

"Professional Engineer" means an individual who is licensed by the State of Colorado as a professional engineer pursuant to 12-25-101 et. seq., C.R.S.

"Proficiency Testing Samples" means performing the same analyses on the same Samples and comparing results to ensure the Samples are homogenous and stable, and also that the set of Samples analyzed are appropriate to test and display similarities and differences in results.

"Propagation" means the reproduction of Medical Marijuana plants by seeds, cuttings or grafting.

"RFID" means Radio Frequency Identification.

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

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

"Restricted Access Area" means a designated and secure area within a Licensed Premises in a Medical Marijuana Center where Medical Marijuana and Medical Marijuana-Infused Product are sold, possessed for sale, and displayed for sale, and where no one without a valid patient registry card is permitted.

"Retail Code" means the Colorado Retail Marijuana Code, found at sections 12-43.4-101 et. seq, C.R.S.

"Retail Marijuana" means all parts of the plant of the genus cannabis whether growing or not, the seeds thereof, the resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or its resin, including 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.

"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 and Solvent-Based Retail Marijuana Concentrate.

"Retail Marijuana Cultivation Facility" means an entity licensed to cultivate, prepare, and package Retail Marijuana and sell Retail Marijuana Retail Marijuana Establishments, but not to consumers.

"Retail Marijuana Establishment" means a Retail Marijuana Store, a Retail Marijuana Cultivation Facility, a Retail Marijuana Products Manufacturing Facility, er a Retail Marijuana Testing Facility, a Retail Marijuana Transporter, or a Retail Marijuana Establishment Operator.

"Retail Marijuana Establishment Operator" means an entity or person that is not an Owner and that is licensed to provide professional operational services to a Retail Marijuana Establishment for direct remuneration from the Retail Marijuana Establishment.

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

"Retail Marijuana Products Manufacturing Facility" means an entity licensed to purchase Retail Marijuana; manufacture, prepare, and package Retail Marijuana Product; and sell Retail Marijuana and Retail Marijuana Product to other Retail Marijuana Products Manufacturing Facilities and to Retail Marijuana Stores, but not to consumers.

"Retail Marijuana Store" means an entity licensed to purchase Retail Marijuana from a Retail Marijuana Cultivation Facility and to purchase Retail Marijuana Product from a Retail Marijuana Products Manufacturing Facility and to sell Retail Marijuana and Retail Marijuana Product to consumers.

"Retail Marijuana Testing Facility" means a public or private laboratory licensed and certified, or approved by the Division, to conduct research and analyze Retail Marijuana, Retail Marijuana Products and Retail Marijuana Concentrate for contaminants and potency.

"Retail Marijuana Transporter" means an entity or person that is licensed to transport Retail Marijuana and Retail Marijuana Products from one Retail Marijuana Establishment to another Retail Marijuana Establishment and to temporarily store the transported Retail Marijuana and Retail Marijuana Products at its licensed premises. The privileges of the Retail Marijuana

<u>Transporter License do not permit a Retail Marijuana Transporter to sell Retail Marijuana or Retail Marijuana Products under any circumstances.</u>

"Sample" means anything collected from a Medical Marijuana Business that is provided for testing to a Medical Marijuana Testing Facility or a Retail Marijuana Testing Facility in accordance with Rule M 701 – 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.

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

"Shipping Container" means any container or wrapping used solely for the transport of Medical Marijuana or Medical Marijuana-Infused Product in bulk, or in a quantity for other Medical Marijuana Businesses.

"Solvent-Based Medical Marijuana Concentrate" means a Medical Marijuana Concentrate that was produced by extracting cannabinoids from Medical Marijuana through the use of a solvent approved by the Division pursuant to Rule M 605.

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

"State Licensing Authority" means the authority created for the purpose of regulating and controlling the licensing of the cultivation, manufacture, distribution, and sale of Medical Marijuana and Retail Marijuana in Colorado, pursuant to section 12-43.3-201, C.R.S.

"Support License" means a license for an individual who performs duties that support the Medical Marijuana Business' 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.

"THC" means tetrahydrocannabinol.

"THCA" means tetrahydrocannabinolic acid.

"Test Batch" means a group of Samples that are collectively submitted to a Medical Marijuana Testing Facility or a Retail Marijuana Testing Facility for testing purposes in accordance with Rule M 701 – Vendor Registration and Occupational License for Medical Marijuana Testing and Research. A Test Batch may not be a combination of any two or three of the following: Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana Product.

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

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

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

"Water-Based Medical Marijuana Concentrate" means a Medical Marijuana Concentrate that was produced by extracting cannabinoids from Medical Marijuana through the use of only water, ice or dry ice.

M 300 Series - The Licensed Premises

Basis and Purpose – M 301

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), and section 12-43.3-105, C.R.S. The purpose of this rule is to establish regulations governing Limited Access Areas for inside a Licensed Premises. In addition, this rule clarifies that businesses and individuals cannot use the visitor system as a means to employ an individual who does not possess a valid and current Occupational License.

M 301 - Limited Access Areas

A. <u>Proper Display of License Badge</u>. All persons in a Limited Access Area as provided for in section 12-43.3-105, C.R.S., shall be required to hold and properly display a current license badge issued by the Division at all times. Proper display of the license badge shall consist of wearing the badge in a plainly visible manner, at or above the waist, and with the photo of the Licensee visible. The Licensee shall not alter, obscure, damage, or deface the badge in any manner.

B. Visitors in Limited Access Areas

- 1. Prior to entering a Limited Access Area, all visitors, including outside vendors, contractors or others, must obtain a visitor identification badge from management personnel of the Licensee that shall remain visible while in the Limited Access Area.
- 2. Visitors shall be escorted by the Medical Marijuana Business's licensed personnel at all times. No more than five visitors may be escorted by a single employee. Except that trade craftspeople not normally engaged in the business of cultivating, processing or selling Medical Marijuana need not be accompanied on a full-time basis, but only reasonably monitored.
- 2.1 Any crime or violation of the Medical Marijuana Code or the Medical Marijuana
 Rules committed by a visitor that involves any discovered plan or other action
 involving committing theft, burglary, underage sales, diversion of Medical
 Marijuana or Medical Marijuana Infused-Product, or other crime related to the
 operation of the subject Medical Marijuana Business shall be reported to the
 Division in accordance with rule M 904 Medical Marijuana Business Reporting
 Requirements.
- The Licensee shall maintain a log of all visitor activity, for any purpose, within the Limited Access Area and shall make such logs available for inspection by the Division or relevant local licensing authority.
- All visitors admitted into a Limited Access Area must provide acceptable proof of age and must be at least 21 years of age. See Rule M 405 – Acceptable Forms of Identification for Medical Sales.
- 5. The Licensee shall check an acceptable form of identification for all visitors to verify that the name on the identification matches the name in the visitor log. See Rule M 405 Acceptable Forms of Identification for Medical Sales
- 6. A Licensee may not receive consideration or compensation for permitting a visitor to enter a Limited Access Area.

- 7. Use of a visitor badge to circumvent the Occupational License requirements of rule M 233 Medical Code or Retail Code Occupational Licenses Required is prohibited and may constitute a license violation affecting public safety.
- C. Required Signage. All areas of ingress and egress to Limited Access Areas on the Licensed Premises shall be clearly identified by the posting of a sign which shall be not less than 12 inches wide and 12 inches long, composed of letters not less than a half inch in height, which shall state, "Do Not Enter Limited Access Area Access Limited to Licensed Personnel and Escorted Visitors".
- Diagram for Licensing Licensed Premises. All Limited Access Areas shall be clearly identified to the Division or relevant local licensing authority and described by the filing of a diagram of the Licensed Premises reflecting walls, partitions, counters and all areas of ingress and egress. The diagram shall also reflect all Propagation, cultivation, manufacturing, and Restricted Access Areas. See Rule M 901 Business Records Required.
- E. <u>Modification of a Limited Access Area</u>. A Licensee's proposed modification of designated Limited Access Areas shall be approved by Division or local licensing authorities. See Rule M 303 Changing, Altering, or Modifying Licensed Premises.
- F. <u>Law Enforcement Personnel Authorized</u>. Notwithstanding the requirements of subsection A of this rule, nothing shall prohibit investigators and employees of the Division, authorities from local licensing authority or any state or local law enforcement agency, for a purpose authorized by the Medical Code or for any other state or local law enforcement purpose, from entering a Limited Access Area upon presentation of official credentials identifying them as such.

Basis and Purpose - M 302

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX), and 12-43.3-308(1)(b), C.R.S. The purpose of this rule is to establish and clarify the means by which the Licensee can establish lawful possession of the Licensed Premises.

M 302 - Possession of Licensed Premises

- A. <u>Evidence of Lawful Possession</u>. Persons licensed pursuant to sections 12-43.3-402, 12-43.3-403, er-12-43.3-404, 12-43.3-405, or 12-43.3-406, C.R.S., or those making application for such licenses, must demonstrate proof of lawful possession of the premises to be licensed or Licensed Premises. Evidence of lawful possession consists of properly executed deeds of trust, leases, or other written documents acceptable to the State Licensing Authority and local licensing authorities.
- B. Relocation Prohibited. The Licensed Premises shall only be those geographical areas that are specifically and accurately described in executed documents verifying lawful possession. Licensees are not authorized to relocate to other areas or units within a building structure without first filing a change of location application and obtaining approval from the Division and the local licensing authority. Licensees shall not add additional contiguous units or areas, thereby altering the initially-approved premises, without filing an Application to modify the Licensed Premises on current forms prepared by the Division, including any applicable processing fee. See Rule M 303 Changing, Altering, or Modifying Licensed Premises.
- C. <u>Subletting Not Authorized</u>. Licensees are not authorized to sublet any portion of a Licensed Premises for any purpose, unless all necessary applications to modify the

existing Licensed Premises to accomplish any subletting have been approved by the Division and local licensing authority.

Basis and Purpose – M 304

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. 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. <u>Licensed Premises – General Requirements</u>

- 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. Manufacturing Operations. 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 co-located 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.
- Testing Facilities. 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 12-43.3-402, 12-43.3-406(1)(c) and 12-43.3-406(4)(b), 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

- A. <u>Privileges Granted</u>. 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 an Optional Premises Cultivation Operation 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>.

- This rule M 401(E)(1) is repealed effective July 1, 2016. A Medical Marijuana Center may provide Samples of its products for testing and research purposes to a Retail Marijuana Testing Facility that has obtained a vendor registration and an Occupational License to test and research Medical Marijuana 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.
- 1.5. This rule M 401(E)(1.5) is effective beginning July 1, 2016. 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 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), and 12-43.3-310(4), and section 12-43.3-201, 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.
 - 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 incentives.
- H. <u>Violation Affecting Public Safety.</u> Failure to comply with this rule may constitute a license violation affecting public safety.

Basis and Purpose - M 406

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), and 12-43.3-202(2)(a)(XX), 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 sale or 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 they are transferred from an Optional Premises Cultivation Operation, or 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 Tracking System. The Retail Marijuana Store 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 R-M 901 Business Records Required.
 - 1. A Medical Marijuana Center is prohibited from accepting any Medical Marijuana or Medical Marijuana-Infused Product from an Optional Premises Cultivation Operation, or Medical Marijuana-Infused Products Manufacturer, or Medical

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

- 2. 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. er Medical Marijuana-Infused Products Manufacturer, or Medical Marijuana Transporter.
- 3. A Medical Marijuana Center must immediately account for all Medical Marijuana sold or transferred to another Medical Marijuana Center in the Inventory Tracking System.
- 4. 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.

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)(XX), 12-43.3-310(7), and 12-43.3-310(4), 12-43.3-406(1)(c), and 12-43.3-406(4)(b), 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 Sales</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 and securely sealed in a tamper-evident manner.
 - The packages must be transported to the <u>receiving</u> Medical Marijuana Business within 48 hours <u>of receiving notification that the Harvest Batch from the processed Medical Marijuana passed required testing</u>, 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 48 hours of receiving notification that the Harvest Batch passed the additional round of testing, and recorded as inventory at the receiving Medical Marijuana Business.
- F. Authorized Marijuana Transport. 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.

G. A Medical Marijuana Optional Premises Cultivation may compensate its employees using performance-based incentives.

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(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), and section 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 transfer Medical Marijuana to its commonly-owned Medical Marijuana Center<u>or to a Medical Marijuana Transporter</u>.
- B. <u>Packaging and Labeling Standards Required</u>. 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 Packaging Requirements: General Requirements and M 1002 Labeling Requirements: General Requirements.
- C. <u>Sale to Patient Prohibited</u>. 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. A Medical Marijuana Optional Premises Cultivation shall not sell or give away Medical Marijuana to a Medical Marijuana Transporter, and shall not buy or receive complimentary Medical Marijuana from a Medical Marijuana Transporter.

Basis and Purpose - M 503

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I) and 12-43.3-202(2)(a)(XX), 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. <u>Minimum Tracking Requirement</u>. 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. 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.
 - 2. 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.

3. An Optional Premises Cultivation Operation must reconcile its transaction history and on-hand Medical Marijuana to the Inventory Tracking System at the close of business each day.

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)(I) and 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I)(A-F), and section-12-43.3-404, 12-43.3-406(1)(c), and 12-43.3-406(4)(b), 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 only sell its own Medical Marijuana-Infused Product to Medical Marijuana Centers.
- 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.
 - 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. Authorized Marijuana Transport. 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)(XX), and 12-43.3-404(3), 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.
- 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.

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I) and 12-43.3-202(2)(a)(XX), 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. Minimum Tracking Requirement. 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, or Medical Marijuana Center, or Medical Marijuana Transporter 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 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, or to a Medical Marijuana Center, or a Medical Marijuana Transporter.
 - 3. A Medical Marijuana-Infused Products Manufacturer must reconcile transactions to the Inventory Tracking System at the close of business each day.

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

- 1. Prior to engaging in the manufacture of any Edible Medical Marijuana-Infused Product each Owner or Occupational Licensee must:
 - 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

- 1. 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.
- 2. 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. <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 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;
 - 3. 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;
 - 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;
 - 6. 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 Medical Marijuana or Medical Marijuana-Infused Product are processed or stored and where equipment or utensils are cleaned;
 - 8. 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.
- 2. 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. <u>Universal Symbol Marking Requirements</u>.
 - a. 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 1/4" by 1/4".
- 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 Child-Resistant Container packaging requirements of rule M 1004.5.
- 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.
- 6. <u>Trademarked Food Products</u>. 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. Edibles Prohibited that are Shaped like a Human, Animal, or Fruit. This subparagraph (C.5)(7) is effective beginning October 1, 2017.
 - a. The production and sale of Edible Medical Marijuana-Infused Products in the following shapes is prohibited:
 - i. The distinct shape of a human, animal, or fruit; or
 - ii. A shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings.
 - b. Edible Medical Marijuana-Infused Products that are geometric shapes and simply fruit flavored are not considered fruit and are permissible; and

c. Edible Medical Marijuana-Infused Products that are manufactured in the shape of a marijuana leaf are permissible.

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

- 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.
 - a. All standard operating procedures for the production of a Medical Marijuana Concentrate must follow the requirements in Rule M 605.
 - 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. <u>Independent Health and Sanitary Audit</u>

- 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.
 - c. 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. 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;
- 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.
 - ii. 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 sell, 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.

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

M 700 Series - Medical Marijuana Testing Facilities

Basis and Purpose – M 704

The statutory authority for this rule is found at subsection 12-43.3-202(2.5)(a)(I) and section 12-43.3-405, C.R.S. The purpose of this rule is to establish personnel standards for the operation of a Medical Marijuana Testing Facility.

M 704 - Medical Marijuana Testing Facilities: Personnel

This rule shall be effective on July 1, 2016.

- A. <u>Laboratory Director</u>. The laboratory director is responsible for the overall analytical operation and quality of the results reported by the Medical Marijuana Testing Facility, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurately, and proficiently and for assuring compliance with the standards set forth in this rule.
 - 1. The laboratory director may also serve as a supervisory analyst or testing analyst, or both, for a Medical Marijuana Testing Facility.
 - 2. The laboratory director for a Medical Marijuana Testing Facility must meet one of the following qualification requirements:
 - a. The laboratory director must be a Medical Doctor (M.D.) licensed to
 practice medicine in Colorado and have at least three years of full-time
 laboratory experience in a regulated laboratory environment performing
 analytical scientific testing in which the testing methods were recognized
 by an accrediting body; or
 - The laboratory director must hold a doctoral degree in one of the natural sciences and have at least three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body; or
 - c. The laboratory director must hold a master's degree in one of the natural sciences and have at least five years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body.
- B. What the Laboratory Director May Delegate. The laboratory director may delegate the responsibilities assigned under this rule to a qualified supervisory analyst, provided that such delegation is made in writing and a record of the delegation is maintained. See Rule M 901 Business Records Required. Despite the designation of a responsibility, the laboratory director remains responsible for ensuring that all duties are properly performed.
- C. <u>Responsibilities of the Laboratory Director</u>. The laboratory director must:
 - 1. Ensure that the Medical Marijuana Testing Facility has adequate space, equipment, materials, and controls available to perform the tests reported;

- 2. Establish and adhere to a written standard operating procedure used to perform the tests reported:
- 3. Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;
- 4. Ensure that the physical location and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards;
- 5. Ensure that the test methodologies selected have the capability of providing the quality of results required for the level of testing the laboratory is certified to perform;
- 6. Ensure that validation and verification test methods used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;
- 7. Ensure that testing analysts perform the test methods as required for accurate and reliable results:
- 8. Ensure that the laboratory is enrolled in a Division approved proficiency testing program;
- 9. Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;
- 10. Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;
- Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and that test results are reported only when the system is functioning properly;
- 12. Ensure that reports of test results include pertinent information required for interpretation;
- 13. Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation of said results;
- 14. Employ a sufficient number of laboratory personnel who meet the qualification requirements and provide appropriate consultation, properly supervise, and ensure accurate performance of tests and reporting of test results:
- 15. Ensure that prior to testing any samples, all testing analysts receive the appropriate training for the type and complexity of tests performed, and have demonstrated and documented that they can perform all testing operations reliably to provide and report accurate results;
- 16. Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to

- assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;
- 17. Ensure that an approved standard operating procedure manual is available to all personnel responsible for any aspect of the testing process; and
- 18. Specify, in writing, the responsibilities and duties of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or laboratory director review is required prior to reporting test results.
- C.5 Change in Laboratory Director. In the event that the laboratory director leaves employment at the Medical Marijuana Testing Facility, the Medical Marijuana Testing Facility shall:
 - Provide written notice to the Colorado Department of Public Health and
 Environment and the Marijuana Enforcement Division within seven days of the laboratory director's departure; and
 - Designate an interim laboratory director within seven days of the laboratory director's departure. At a minimum, the interim laboratory director must meet the qualifications of a supervisory analyst.
 - 3. The Medical Marijuana Testing Facility must hire a permanent laboratory director within 45 days from the date of the previous laboratory director's departure, unless the Medical Marijuana Testing Facility receives a written waiver from the Division Director.
- D. <u>Supervisory Analyst</u>. Supervisory analysts must meet one of the qualifications for a laboratory director or have at least a bachelor's degree in one of the natural sciences and three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body. A combination of education and experience may substitute for the three years of full-time laboratory experience.

E. Laboratory Testing Analyst

- Educational Requirements. An individual designated as a testing analyst must meet one of the qualifications for a laboratory director or supervisory analyst or have at least a bachelor's degree in one of the natural sciences and one year of full-time experience in laboratory testing.
- 2. <u>Responsibilities</u>. In order to independently perform any test for a Medical Marijuana Testing Facility, an individual must at least meet the educational requirements for a testing analyst.

Basis and Purpose - M 712

 Subsection 16(5)(a)(VII). The purpose of this rule is to establish the portion of the Division's mandatory testing and random sampling program that is applicable to Medical Marijuana Testing Facilities. The allowable plus or minus 15% potency variance has been included in the rule pursuant to the mandate of Senate Bill 15-260. Section 1 of the bill required the State Licensing Authority to establish an acceptable potency variance. The acceptable potency variance has been set at plus or minus 15% to comport with the potency variance mandated by the Retail Code.

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

This rule shall be effective on July 1, 2016.

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

- Medical Marijuana and Medical Marijuana Concentrate. 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

- A Medical Marijuana Testing Facility may not accept a Test Batch that is smaller than its standard minimum amount.
- 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 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.
 - 1. Microbials

Substance	Acceptable Limits Per Gram	Product to be Tested
-Shiga-toxin producing Escherichia coli (STEC)*- Bacteria	< 1 Colony Forming Unit (CFU)	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	Medical Marijuana Concentrates
	(CFU)	

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

2. Residual Solvents

Substance	Acceptable Limits Per Gram	Product to be Tested
Butanes	< 800-5,000 Parts Per Million	
	(PPM)	
Heptanes	< 500-5,000 Parts Per Million	
	(PPM)	Solvent-Based Medical Marijuana
Benzene**	< 42 Parts Per Million (PPM)	Concentrate
Toluene**	< 4890 Parts Per Million (PPM)	
Hexane**	< 10290 Parts Per Million	
	(PPM)	
Total Xylenes (m,p, o-xylenes)**	< 42,170 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

<u>Substance</u>	Acceptable Limits Per Gram	Product to be Tested
Metals (Arsenic, Cadmium, Lead	Lead – Max Limit: < 10 ppm	Flower; Water-, Food-, and Solvent-
and Mercury)	Arsenic – Max Limit: < 10 ppm	Based Medical Marijuana
	Cadmium – Max Limit: <4.1 ppm	Concentrates; and Medical Marijuana-
	Mercury – Max Limit: <2.0 ppm	Infused Product

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.
Molds, Mildew,	If a Test Batch is found to contain levels of any mold, mildew, or filth that could be toxic if
and Filth	consumed, then that Test Batch shall be considered to have 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.
- 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. <u>Potency Variance.</u> 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), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of the rule is to provide clarity as to the requirements associated with the <u>transport and</u> 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 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 Marijuana 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. 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. Inventory Tracking System-Generated Transport Manifest Required. 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 Marijuana <u>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.

- 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. Preparation of Medical Marijuana and Medical Marijuana-Infused Product for Transport
 - <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. Shipping Containers. All Shipping Containers must be affixed with an RFID tag prior to transport. Sealed packages or Containers may be placed in larger Shipping Containers, so long as such Shipping Containers are labeled with type and amount of Medical Marijuana or Medical Marijuana-Infused Product contained therein. 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. <u>Medical Marijuana or Medical Marijuana-Infused Product</u>. Licensees who transport 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 locations. 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.

- b. Medical Marijuana Vegetative Plants. 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.
- Copy of Transport Manifest to Receiver. A Licensee shall provide a copy of the transport manifest to each Medical Marijuana Business 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.
- 3. The Inventory Tracking System-generated transport manifest shall include the following:
 - a. Departure date and approximate time of departure;
 - b. Name, location address, and license number of the originating Medical Marijuana Business;
 - 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;
 - 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.
 - 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.
- Responsibilities of Receiving Licensee.
 - a. Medical Marijuana or Medical Marijuana-Infused Product. Upon receipt, the receiving Licensee shall ensure that the Medical Marijuana or Medical Marijuana-Infused Product received are as described in the transport manifest and shall immediately adjust its records to reflect the receipt of inventory. The scale used to weigh product being received shall be tested and approved in accordance with measurement standards established in 35-14-127,, C.R.S. Entries to the inventory records shall note the Inventory Tracking System-generated transport manifest and shall be easily reconciled, by product name and quantity, with the applicable transport manifest.
 - b. Medical Marijuana Vegetative Plants. 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 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.
- 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.

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), and 12-43.3-202(2)(a)(XX), 12-43.3-406(2). C.R.S. The purpose of this rule is to establish that Medical Marijuana and Medical Marijuana-Infused Product may not be stored outside of Licensed Premises unless the Licensee obtains an off-premises storage permit. Rule 802.G was amended to require Medical Marijuana Businesses to submit proof of local approval or acknowledgement with an application for an off-premises storage facility. This change was made due to comments received from local government.

M 802 – Off-Premises Storage of Medical Marijuana and Medical Marijuana-Infused Product: All Medical Marijuana Businesses

- A. Off-premises Storage Permit Authorized. A Licensee may only store Medical Marijuana or Medical Marijuana-Infused Product in its Licensed Premises or in its one permitted off-premises storage facility. Except that Medical Marijuana Transporters are allowed to have more than one permitted off-premises storage facility.
- B. <u>Permitting</u>. To obtain a permit for an off-premises storage facility, a Medical Marijuana Business must apply on current Division forms and pay any applicable fees. <u>A Medical Marijuana Transporter may only apply for and hold an off-premises storage permit in a local jurisdiction that permits the operation of Medical Marijuana Centers.</u>
- C. <u>Extension of Licensed Premises</u>. A permitted off-premises storage facility shall constitute an extension of the Medical Marijuana Business' Licensed Premises and be subject to all to the conditions and restrictions established in Rule M 301 Limited Access Areas.
- D. <u>Limitation on Inventory to be Stored</u>. The Licensee-A Medical Marijuana Center, Medical Marijuana-Infused Products Manufacturer, and an Optional Premises Cultivation

 Operation may only have upon the permitted off-premises storage facility Medical Marijuana or Medical Marijuana-Infused Product that are part of https://licensees.org/red/li
- E. <u>Restrictions</u>. The permitted off-premises storage facility may be utilized for storage only. A Licensee may not sell, cultivate, manufacture, process, test, or consume any Medical Marijuana or Medical Marijuana-Infused Product within the premises of the permitted off-premises storage facility.
- F. <u>Display of Off-premises Storage Permit and License</u>. The off-premises storage facility permit and a copy of the Medical Marijuana Business' license must be displayed in a prominent place within the permitted off-premises storage facility.
- G. Local Licensing Authority Approval
 - 1. Prior to submitting an application for an off-premises storage facility permit, the Licensee must obtain approval from the relevant local licensing authority.
 - 2. A copy of the relevant local licensing authority's approval must be submitted by the Licensee in conjunction with its application for an off-premises storage facility.
 - 3. No Medical Marijuana or Medical Marijuana-Infused Product may be stored within a permitted storage facility until the relevant local licensing authority has been provided a copy of the off-premises storage facility permit.
 - 4. Any off-premises storage permit issued by the Division shall be conditioned upon the Medical Marijuana Business' receipt of all required local approvals.
- H. <u>Security in Storage Facility</u>. A permitted off-premises storage facility must meet all video and security requirements applicable to a Licensed Premises.
- I. <u>Transport to or from a Permitted Off-premises Storage Facility</u>. A Medical Marijuana Business must comply with Rule M 801 Transport of Medical Marijuana and Medical Marijuana-Infused Product when transporting any Medical Marijuana or Medical Marijuana-Infused Product to <u>and from</u> a permitted off-premises storage facility.

- J. Inventory Tracking. In addition to all the other tracking requirements set forth in these rules, a Medical Marijuana Business shall utilize the Inventory Tracking System to track its inventories from the point of transfer to or from a permitted off-premises storage facility. See Rules M 901 Business Records Required and M 309- Medical Marijuana Business: Inventory Tracking System.
- K. <u>Inventory Tracking System Access and Scale</u>. Every permitted off-premises storage facility must have an Inventory Tracking System terminal and a scale tested and approved in accordance with measurement standards established in 35-14-127,, C.R.S.
- L. <u>Adequate Care of Perishable Medical Marijuana-Infused Product</u>. A Medical Marijuana Business must provide adequate refrigeration for perishable Medical Marijuana-Infused Product and shall utilize adequate storage facilities and transport methods.
- M. <u>Consumption Prohibited</u>. A Medical Marijuana Business shall not permit the consumption of marijuana or marijuana products on the premises of its permitted off-premises storage facility.

M 900 Series - Business Records

Basis and Purpose – M 905

The statutory authority for this rule is found at subsections 12-43.3-202(1)(d), 12-43.3-202(2)(a)(XVII), 12-43.3-202(2)(a)(XVIII) and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to clarify the Division's authority to provide taxation divisions within the Department copies of or access to reports or other information obtained from or regarding a Licensee, for the purpose of ensuring accurate and complete filing of tax returns and payment of sales and income taxes required by Title 39 of the Colorado Revised Statutes. Such information sharing is for a purpose authorized by the Medical Code.

M 905 - Department Information Access

- A. Department Access to Reports or Other Information. The Division may provide taxation divisions within the Department copies of or access to reports or other information obtained from or regarding a Licensee for the purpose of ensuring accurate and complete filing of tax returns and payment of sales and income taxes required by Title 39 of the Colorado Revised Statutes.
- B. Confidentiality. Reports or other information provided to or accessed by taxation divisions within the Department for the purpose of ensuring accurate and complete filing of tax returns and payment of sales and income taxes required by Title 39 of the Colorado Revised Statutes shall be considered part of the Department's investigation pursuant to subsection 39-21-113(4)(a), C.R.S., and the Division shall continue to maintain such records and information in its possession or control as confidential pursuant to subsection 12-43.3-202(1)(d)., C.R.S.

M 1100 Series - Signage and Advertising

Basis and Purpose - M 1101

The statutory authority for this rule is found at subjections 12-43.3-202(1)(b)(l), 12-43.3-202(1)(a)(VI), 12-43.3-202(2)(a)(VII), 12-43.3-202(2)(a)(XX), and 12-43.3-901(4)(b), C.R.S. The purpose of this rule is to clearly delineate that Licensees are not permitted to make false or misleading statements.

M 1101 - General Requirement: False and Misleading Statements

- A. No Medical Marijuana Business shall display upon or in proximity to, or referring to the Licensed Premises, use, publish or exhibit, or permit to be used, or published, any sign, advertisement, display, notice, symbol or other device which are inconsistent with the local laws and regulations in which the licensee operates.
- B. No Medical Marijuana Business shall display upon or in proximity to, or referring to the Licensed Premises, use, publish or exhibit, or permit to be used, or published, any sign, advertisement, display, notice, symbol or other device which uses misleading, deceptive, or false advertising.

Repealed.

Basis and Purpose – M 1102

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2.5)(a)(II), and 12-43.3-901(4)(b), C.R.S. The purpose of this rule is to clearly delineate that a Medical Marijuana Business is not permitted to make deceptive, false, or misleading statements in Advertising materials or on any product or document provided to a consumer.

M 1102 - Advertising General Requirement: No Deceptive, False or Misleading Statements

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

Basis and Purpose M 1103

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(l), 12-43.3-202(2.5)(a)(II), and 12-43.3-901(4)(b), C.R.S. The purpose of this rule is to clarify the definition of the term "minor" as used in the Medical Code and these rules.

M 1103 – The Term "Minor" as Used in the Medical Code and These Rules

The term "minor" as used in the Medical Code and these rules means an individual under the age of 18.

Basis and Purpose - M 1104

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I) and 12-43.3-202(2.5)(a)(II), C.R.S. The purpose of this rule is to clarify the restrictions applicable to television Advertising.

The operation of Medical Marijuana Businesses in Colorado is authorized solely within the narrow confines of the Colorado Revised Statutes, Title 12, Article 43.3, Sections 101 et seg. The statutorily

mandated regulatory scheme governing Medical Marijuana Businesses must include rules establishing restrictions on the advertising and display of marijuana and marijuana product. Through House Bill 16-1363 passed in 2016, the Colorado General Assembly provided further direction regarding mandated advertising restrictions. See §12-43.3-202(2.5)(a)(II), C.R.S. The Medical Code requires the State Licensing Authority to promulgate rules on the subject of signage, marketing and advertising restrictions that include but are not limited to a prohibition on mass-market campaigns that have a high likelihood of reaching minors. See §12-43.3-202(2.5)(a)(II), C.R.S. Previously, rulemaking on the same signage, marketing and advertising and requirements was mandated by the legislative regulatory scheme governing Retail Marijuana Establishments. In that rulemaking process the State Licensing Authority received extensive comments reflecting the strong influence advertising has on minors' decision-making with regard to substance use and abuse. To ensure equal compliance and enforcement across both regulated industries of Medical and Retail Marijuana, the State Licensing Authority is adopting the same standards for rules regulating the signage, marketing and advertising of Medical Marijuana, that were adopted for Retail Marijuana. These rules apply to Advertising as defined in Rule M 103. Advertising includes marketing but not labeling. Advertising includes only those promotions, positive statements or endorsements that are obtained in exchange for consideration. The State Licensing Authority will continue to evaluate the best way to implement the state legislative directive to establish appropriate advertising restrictions for this evolving industry, and will in particular continue to monitor and evaluate advertising, marketing and signage to protect the interests of those under the age of 18 and to prevent underage use of marijuana.

M 1104 - Advertising: Television

- A. Television Defined. As used in this rule, the term "television" means a system for transmitting visual images and sound that are reproduced on screens, and includes broadcast, cable, on-demand, satellite, or internet programming. Television includes any video programming downloaded or streamed via the internet.
- B. Television Advertising. A Medical Marijuana Business shall not utilize television

 Advertising unless the Medical Marijuana Business has reliable evidence that no more than 30 percent of the audience for the program on which the Advertising is to air is reasonably expected to be under the age of 18.

Basis and Purpose – M 1105

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I) and 12-43.3-202(2.5)(a)(II), C.R.S. The purpose of this rule is to clarify the restrictions applicable to radio Advertising.

The operation of Medical Marijuana Businesses in Colorado is authorized solely within the narrow confines of the Colorado Revised Statutes, Title 12, Article 43.3, Sections 101 et seq. The statutorily mandated regulatory scheme governing Medical Marijuana Businesses must include rules establishing restrictions on the advertising and display of marijuana and marijuana product. Through House Bill 16-1363 passed in 2016, the Colorado General Assembly provided further direction regarding mandated advertising restrictions. See §12-43.3-202(2.5)(a)(II), C.R.S. The Medical Code requires the State Licensing Authority to promulgate rules on the subject of signage, marketing and advertising restrictions that include but are not limited to a prohibition on mass-market campaigns that have a high likelihood of reaching minors. See §12-43.3-202(2.5)(a)(II), C.R.S. Previously, rulemaking on the same signage, marketing and advertising and requirements was mandated by the legislative regulatory scheme governing Retail Marijuana Establishments. In that rulemaking process the State Licensing Authority received extensive comments reflecting the strong influence advertising has on minors' decision-making with regard to substance use and abuse. To ensure equal compliance and enforcement across both regulated industries of Medical and Retail Marijuana, the State Licensing Authority is adopting the same standards for rules regulating the signage, marketing and advertising of Medical Marijuana, that were adopted for Retail Marijuana. These rules apply to Advertising as defined in Rule M 103. Advertising includes marketing but not labeling. Advertising includes only those promotions, positive statements or endorsements that are obtained in exchange for consideration. The State Licensing Authority will

continue to evaluate the best way to implement the state legislative directive to establish appropriate advertising restrictions for this evolving industry, and will in particular continue to monitor and evaluate advertising, marketing and signage to protect the interests of those under the age of 18 and to prevent underage use of marijuana.

M 1105 – Advertising: Radio

- A. Radio Defined. As used in this rule, the term "radio" means a system for transmitting sound without visual images, and includes broadcast, cable, on-demand, satellite, or internet programming. Radio includes any audio programming downloaded or streamed via the internet.
- B. Radio Advertising. A Medical Marijuana Business shall not engage in radio Advertising unless the Medical Marijuana Business has reliable evidence that no more than 30 percent of the audience for the program on which the Advertising is to air is reasonably expected to be under the age of 18.

Basis and Purpose - M 1106

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I) and 12-43.3-202(2.5)(a)(II), C.R.S. The purpose of this rule is to clarify the restrictions applicable to Advertising in print media.

The operation of Medical Marijuana Businesses in Colorado is authorized solely within the narrow confines of the Colorado Revised Statutes, Title 12, Article 43.3, Sections 101 et seq. The statutorily mandated regulatory scheme governing Medical Marijuana Businesses must include rules establishing restrictions on the advertising and display of marijuana and marijuana product. Through House Bill 16-1363 passed in 2016, the Colorado General Assembly provided further direction regarding mandated advertising restrictions. See §12-43.3-202(2.5)(a)(II), C.R.S. The Medical Code requires the State Licensing Authority to promulgate rules on the subject of signage, marketing and advertising restrictions that include but are not limited to a prohibition on mass-market campaigns that have a high likelihood of reaching minors. See §12-43.3-202(2.5)(a)(II), C.R.S. Previously, rulemaking on the same signage, marketing and advertising and requirements was mandated by the legislative regulatory scheme governing Retail Marijuana Establishments. In that rulemaking process the State Licensing Authority received extensive comments reflecting the strong influence advertising has on minors' decision-making with regard to substance use and abuse. To ensure equal compliance and enforcement across both regulated industries of Medical and Retail Marijuana, the State Licensing Authority is adopting the same standards for rules regulating the signage, marketing and advertising of Medical Marijuana, that were adopted for Retail Marijuana. These rules apply to Advertising as defined in Rule M 103. Advertising includes marketing but not labeling. Advertising includes only those promotions, positive statements or endorsements that are obtained in exchange for consideration. The State Licensing Authority will continue to evaluate the best way to implement the state legislative directive to establish appropriate advertising restrictions for this evolving industry, and will in particular continue to monitor and evaluate advertising, marketing and signage to protect the interests of those under the age of 18 and to prevent underage use of marijuana.

M 1106 - Advertising: Print Media

A Medical Marijuana Business shall not engage in Advertising in a print publication unless the Medical Marijuana Business has reliable evidence that no more than 30 percent of the publication's readership is reasonably expected to be under the age of 18.

Basis and Purpose – M 1107

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I) and 12-43.3-202(2.5)(a)(II), C.R.S. The purpose of this rule is to clarify the restrictions applicable to Advertising on the internet.

The operation of Medical Marijuana Businesses in Colorado is authorized solely within the narrow confines of the Colorado Revised Statutes, Title 12, Article 43.3, Sections 101 et seq. The statutorily mandated regulatory scheme governing Medical Marijuana Businesses must include rules establishing restrictions on the advertising and display of marijuana and marijuana product. Through House Bill 16-1363 passed in 2016, the Colorado General Assembly provided further direction regarding mandated advertising restrictions. See §12-43.3-202(2.5)(a)(II), C.R.S. The Medical Code requires the State Licensing Authority to promulgate rules on the subject of signage, marketing and advertising restrictions that include but are not limited to a prohibition on mass-market campaigns that have a high likelihood of reaching minors. See §12-43.3-202(2.5)(a)(II), C.R.S. Previously, rulemaking on the same signage. marketing and advertising and requirements was mandated by the legislative regulatory scheme governing Retail Marijuana Establishments. In that rulemaking process the State Licensing Authority received extensive comments reflecting the strong influence advertising has on minors' decision-making with regard to substance use and abuse. To ensure equal compliance and enforcement across both regulated industries of Medical and Retail Marijuana, the State Licensing Authority is adopting the same standards for rules regulating the signage, marketing and advertising of Medical Marijuana, that were adopted for Retail Marijuana. These rules apply to Advertising as defined in Rule M 103. Advertising includes marketing but not labeling. Advertising includes only those promotions, positive statements or endorsements that are obtained in exchange for consideration. The State Licensing Authority will continue to evaluate the best way to implement the state legislative directive to establish appropriate advertising restrictions for this evolving industry, and will in particular continue to monitor and evaluate advertising, marketing and signage to protect the interests of those under the age of 18 and to prevent underage use of marijuana.

M 1107 – Advertising: Internet

A Medical Marijuana Business shall not engage in Advertising via the internet unless the Medical Marijuana Business has reliable evidence that no more than 30 percent of the audience for the internet web site is reasonably expected to be under the age of 18. See also Rule M 1114 – Pop-Up Advertising.

Basis and Purpose – M 1108

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I) and 12-43.3-202(2.5)(a)(II), C.R.S. The purpose of this rule is to clarify the restrictions applicable to Advertising in a medium designed to target out-of-state residents.

The operation of Medical Marijuana Businesses in Colorado is permitted solely within the narrow confines of the Colorado Revised Statutes, Title 12, Article 43.3, Sections 101 et seq. Colorado has authorized the regulated growth and sale of Medical Marijuana, and it has done so in the context of a longstanding federal ban on such activities. The State Licensing Authority finds that it is essential to regulate Medical Marijuana in the state of Colorado in a manner that does not negatively impact the ability of other states or the federal government to enforce their drug laws. The State Licensing Authority finds that the below restrictions on Advertising as defined in these Medical Marijuana rules are critical to prevent the diversion of Medical Marijuana outside of the state. The State Licensing Authority will continue to monitor and evaluate the best way to implement the state legislative directive to establish appropriate Advertising restrictions for this evolving industry.

M 1108 – Advertising: Targeting Out-of-State Persons Prohibited

A Medical Marijuana Business shall not engage in Advertising that specifically targets Persons located outside the state of Colorado.

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2.5)(a)(II), 12-43.3-402(a)(II)&(III), and 12-43.3-901(4)(b), C.R.S. The purpose of this rule is to clarify the Advertising restrictions applicable to safety claims that are by nature misleading, deceptive, or false.

M 1109 – Signage and Advertising: No Safety Claims Because Regulated by State Licensing Authority

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

Basis and Purpose – M 1110

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2.5)(a)(II), and 12-43.3-901(4)(b), C.R.S. The purpose of this rule is to clarify the Advertising restrictions applicable to safety claims that are by nature misleading, deceptive, or false.

M 1110 - Signage and Advertising: No Safety Claims Because Tested by a Medical Marijuana Testing Facility

A Medical Marijuana Business may advertise that its products have been tested by a Medical Marijuana Testing Facility, but shall not engage in Advertising or utilize signage that asserts its products are safe because they are tested by a Medical Marijuana Testing Facility.

Basis and Purpose – M 1111

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I) and 12-43.3-202(2.5)(a)(II), C.R.S. The purpose of this rule is to clarify the restrictions applicable to outdoor Advertising and signage.

The operation of Medical Marijuana Businesses in Colorado is authorized solely within the narrow confines of the Colorado Revised Statutes, Title 12, Article 43.3, Sections 101 et seq. The statutorily mandated regulatory scheme governing Medical Marijuana Businesses must include rules establishing restrictions on the advertising and display of marijuana and marijuana product. Through House Bill 16-1363 passed in 2016, the Colorado General Assembly provided further direction regarding mandated advertising restrictions. See §12-43.3-202(2.5)(a)(II), C.R.S. The Medical Code requires the State Licensing Authority to promulgate rules on the subject of signage, marketing and advertising restrictions that include but are not limited to a prohibition on mass-market campaigns that have a high likelihood of reaching minors. See §12-43.3-202(2.5)(a)(II), C.R.S. Previously, rulemaking on the same signage, marketing and advertising and requirements was mandated by the legislative regulatory scheme governing Retail Marijuana Establishments. In that rulemaking process the State Licensing Authority received extensive comments reflecting the strong influence advertising has on minors' decision-making with regard to substance use and abuse. To ensure equal compliance and enforcement across both regulated industries of Medical and Retail Marijuana, the State Licensing Authority is adopting the same standards for rules regulating the signage, marketing and advertising of Medical Marijuana, that were adopted for Retail Marijuana. These rules apply to Advertising as defined in Rule M 103. Advertising includes marketing but not labeling. Advertising includes only those promotions, positive statements or endorsements that are obtained in exchange for consideration. The State Licensing Authority will continue to evaluate the best way to implement the state legislative directive to establish appropriate advertising restrictions for this evolving industry, and will in particular continue to monitor and evaluate advertising, marketing and signage to protect the interests of those under the age of 18 and to prevent underage use of marijuana.

M 1111 - Signage and Advertising: Outdoor Advertising

- A. Local Ordinances. In addition to any requirements within these rules, a Medical Marijuana
 Business shall comply with any applicable local ordinances regulating signs and Advertising.
- B. Outdoor Advertising Generally Prohibited. Except as otherwise provided in this rule, it shall be unlawful for any Medical Marijuana Business to engage in Advertising that is visible to members of the public from any street, sidewalk, park or other public place, including Advertising utilizing any of the following media: any billboard or other outdoor general Advertising device; any sign mounted on a vehicle, any hand-held or other portable sign; or any handbill, leaflet or flier directly handed to any person in a public place, left upon a motor vehicle, or posted upon any public or private property without the consent of the property owner.
- C. Exception. The prohibitions set forth in this rule shall not apply to any fixed sign that is located on the same zone lot as a Medical Marijuana Business and that exists solely for the purpose of identifying the location of the Medical Marijuana Business and otherwise complies with any applicable local ordinances.

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I) and 12-43.3-202(2.5)(a)(II), C.R.S. The purpose of this rule is to prohibit signage and Advertising that has a high likelihood of reaching individuals under the age of 18.

The operation of Medical Marijuana Businesses in Colorado is authorized solely within the narrow confines of the Colorado Revised Statutes, Title 12, Article 43.3, Sections 101 et seq. The statutorily mandated regulatory scheme governing Medical Marijuana Businesses must include rules establishing restrictions on the advertising and display of marijuana and marijuana product. Through House Bill 16-1363 passed in 2016, the Colorado General Assembly provided further direction regarding mandated advertising restrictions. See §12-43.3-202(2.5)(a)(II), C.R.S. The Medical Code requires the State Licensing Authority to promulgate rules on the subject of signage, marketing and advertising restrictions that include but are not limited to a prohibition on mass-market campaigns that have a high likelihood of reaching minors. See §12-43.3-202(2.5)(a)(II), C.R.S. Previously, rulemaking on the same signage, marketing and advertising and requirements was mandated by the legislative regulatory scheme governing Retail Marijuana Establishments. In that rulemaking process the State Licensing Authority received extensive comments reflecting the strong influence advertising has on minors' decision-making with regard to substance use and abuse. To ensure equal compliance and enforcement across both regulated industries of Medical and Retail Marijuana, the State Licensing Authority is adopting the same standards for rules regulating the signage, marketing and advertising of Medical Marijuana, that were adopted for Retail Marijuana. These rules apply to Advertising as defined in Rule M 103. Advertising includes marketing but not labeling. Advertising includes only those promotions, positive statements or endorsements that are obtained in exchange for consideration. The State Licensing Authority will continue to evaluate the best way to implement the state legislative directive to establish appropriate advertising restrictions for this evolving industry, and will in particular continue to monitor and evaluate advertising, marketing and signage to protect the interests of those under the age of 18 and to prevent underage use of marijuana.

M 1112 - Signage and Advertising: No Content That Targets Minors

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

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(l) and 12-43.3-202(2.5)(a)(II)(F), C.R.S. The purpose of this rule is to clarify the Advertising restrictions applicable to marketing directed toward location-based devices.

The operation of Medical Marijuana Businesses in Colorado is authorized solely within the narrow confines of the Colorado Revised Statutes, Title 12, Article 43.3, Sections 101 et seq. The statutorily mandated regulatory scheme governing Medical Marijuana Businesses must include rules establishing restrictions on the advertising and display of marijuana and marijuana product. Through House Bill 16-1363 passed in 2016, the Colorado General Assembly provided further direction regarding mandated advertising restrictions. See §12-43.3-202(2.5)(a)(II), C.R.S. The Medical Code requires the State Licensing Authority to promulgate rules on the subject of signage, marketing and advertising restrictions that include but are not limited to a prohibition on mass-market campaigns that have a high likelihood of reaching minors. See §12-43.3-202(2.5)(a)(II), C.R.S. Previously, rulemaking on the same signage, marketing and advertising and requirements was mandated by the legislative regulatory scheme governing Retail Marijuana Establishments. In that rulemaking process the State Licensing Authority received extensive comments reflecting the strong influence advertising has on minors' decision-making with regard to substance use and abuse. To ensure equal compliance and enforcement across both regulated industries of medical and Retail Marijuana, the State Licensing Authority is adopting the same standards for rules regulating the signage, marketing and advertising of Medical Marijuana, that were adopted for Retail Marijuana. These rules apply to Advertising as defined in Rule M 103. Advertising includes marketing but not labeling. Advertising includes only those promotions, positive statements or endorsements that are obtained in exchange for consideration. The State Licensing Authority will continue to evaluate the best way to implement the state legislative directive to establish appropriate advertising restrictions for this evolving industry, and will in particular continue to monitor and evaluate advertising, marketing and signage to protect the interests of those under the age of 18 and to prevent underage use of marijuana.

M 1113 - Advertising: Advertising via Marketing Directed Toward Location-Based Devices

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

Basis and Purpose - M 1114

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I) and 12-43.3-202(2.5)(a)(II)(C), C.R.S. The purpose of this rule is to clarify the Advertising restrictions applicable to pop-up Advertising.

The operation of Medical Marijuana Businesses in Colorado is authorized solely within the narrow confines of the Colorado Revised Statutes, Title 12, Article 43.3, Sections 101 et seq. The statutorily mandated regulatory scheme governing Medical Marijuana Businesses must include rules establishing restrictions on the advertising and display of marijuana and marijuana product. Through House Bill 16-1363 passed in 2016, the Colorado General Assembly provided further direction regarding mandated advertising restrictions. See §12-43.3-202(2.5)(a)(II), C.R.S. The Medical Code requires the State Licensing Authority to promulgate rules on the subject of signage, marketing and advertising restrictions that include but are not limited to a prohibition on mass-market campaigns that have a high likelihood of reaching minors. See §12-43.3-202(2.5)(a)(II), C.R.S. Previously, rulemaking on the same signage, marketing and advertising and requirements was mandated by the legislative regulatory scheme governing Retail Marijuana Establishments. In that rulemaking process the State Licensing Authority received extensive comments reflecting the strong influence advertising has on minors' decision-making with regard to substance use and abuse. To ensure equal compliance and enforcement across both regulated industries of Medical and Retail Marijuana, the State Licensing Authority is adopting the same

standards for rules regulating the signage, marketing and advertising of Medical Marijuana, that were adopted for Retail Marijuana. These rules apply to Advertising as defined in Rule M 103. Advertising includes marketing but not labeling. Advertising includes only those promotions, positive statements or endorsements that are obtained in exchange for consideration. The State Licensing Authority will continue to evaluate the best way to implement the state legislative directive to establish appropriate advertising restrictions for this evolving industry, and will in particular continue to monitor and evaluate advertising, marketing and signage to protect the interests of those under the age of 18 and to prevent underage use of marijuana.

M 1114 - Pop-Up Advertising

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

Basis and Purpose – M 1115

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I) and 12-43.3-202(2.5)(a)(II), C.R.S. The purpose of this rule is to clarify the Advertising restrictions applicable to event sponsorship.

The operation of Medical Marijuana Businesses in Colorado is authorized solely within the narrow confines of the Colorado Revised Statutes, Title 12, Article 43.3, Sections 101 et seq. The statutorily mandated regulatory scheme governing Medical Marijuana Businesses must include rules establishing restrictions on the advertising and display of marijuana and marijuana product. Through House Bill 16-1363 passed in 2016, the Colorado General Assembly provided further direction regarding mandated advertising restrictions. See §12-43.3-202(2.5)(a)(II), C.R.S. The Medical Code requires the State Licensing Authority to promulgate rules on the subject of signage, marketing and advertising restrictions that include but are not limited to a prohibition on mass-market campaigns that have a high likelihood of reaching minors. See §12-43.3-202(2.5)(a)(II), C.R.S. Previously, rulemaking on the same signage. marketing and advertising and requirements was mandated by the legislative regulatory scheme governing Retail Marijuana Establishments. In that rulemaking process the State Licensing Authority received extensive comments reflecting the strong influence advertising has on minors' decision-making with regard to substance use and abuse. To ensure equal compliance and enforcement across both regulated industries of Medical and Retail Marijuana, the State Licensing Authority is adopting the same standards for rules regulating the signage, marketing and advertising of Medical Marijuana, that were adopted for Retail Marijuana. These rules apply to Advertising as defined in Rule M 103. Advertising includes marketing but not labeling. Advertising includes only those promotions, positive statements or endorsements that are obtained in exchange for consideration. The State Licensing Authority will continue to evaluate the best way to implement the state legislative directive to establish appropriate advertising restrictions for this evolving industry, and will in particular continue to monitor and evaluate advertising, marketing and signage to protect the interests of those under the age of 18 and to prevent underage use of marijuana.

M 1115 - Advertising: Event Sponsorship

A Medical Marijuana Business may sponsor a charitable, sports, or similar event, but a Medical Marijuana Business shall not engage in Advertising at, or in connection with, such an event unless the Medical Marijuana Business has reliable evidence that no more than 30 percent of the audience at the event and/or viewing Advertising in connection with the event is reasonably expected to be under the age of 18.

M 1300 Series - Discipline

Basis and Purpose – M 1302

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(V), 12-43.3-202(a)(XIX), 12-43.3-202(2)(a)(XX), and 24-4-104(4)(a), and sections 12-43.3-601 and 24-4-105, C.R.S. The purpose of this rule is to set forth the process for summary suspensions when the State Licensing Authority has cause to immediately suspend a license prior to and pending a hearing and final agency action. Summary suspension will be imposed when the State Licensing Authority has reason to believe and finds that a Licensee has been guilty of a deliberate and willful violation of any applicable law or regulation, or that the public health, safety, or welfare imperatively requires emergency action. The rule ensures proper due process for Licensees when their licenses are temporarily or summarily suspended by requiring prompt initiation of disciplinary proceedings after such suspensions. The purpose of the modifications to this rule is to clarify that the hearing following the Order of Summary Suspension concerns the allegations set forth in the Order to Show Cause.

M 1302 - Disciplinary Process: Summary Suspensions

A. How a Summary Suspension Action is Initiated

- When the State Licensing Authority has reasonable grounds to believe and finds that a Licensee has been guilty of a deliberate and willful violation of any applicable law or regulation, or that the public health, safety, or welfare imperatively requires emergency action it shall serve upon the Licensee a Summary Suspension Order that temporarily or summarily suspends the license.
- 2. The Summary Suspension Order shall identify the nature of the State Licensing Authority's basis for the summary suspension. The Summary Suspension Order shall also provide an advisement that the License may be subject to further discipline or revocation following a hearing on an Order to Show Causeshould the charges contained in the notice be sustained following a hearing.
- 3. Proceedings for suspension or revocation shall be promptly instituted and determined after the Summary Suspension Order is issued in accordance with the following procedure:
 - a. 4. After the Summary Suspension Order is issued, the State Licensing Authority shall <u>promptly</u> issue and serve upon the Licensee an Order to Show Cause (administrative citation) as to why the Licensee's license should not be suspended, revoked, restricted, fined or subject to other disciplinary sanction.
 - <u>b.</u> 5. The Order to Show Cause shall identify the statute, rule, regulation, or order allegedly violated, and the facts alleged to constitute the violation. The Order to Show Cause shall also provide an advisement that the license could be suspended, revoked, restricted, fined or subject to ther disciplinary sanction should the charges contained in the Order to Show Cause notice be sustained upon final hearing.
 - <u>C.</u> The Order to Show Cause shall be filed with the Department's Hearings
 Division. The hearing on the allegations set forth in the Order to Show
 Cause shall be expedited to the extent practicable and will be conducted in accordance with Rule M 1304 Administrative Hearings.

- Unless lifted by the State Licensing Authority, the Summary Suspension Order shall remain in effect until issuance of a Final Agency Order.
- B. <u>Duration of Summary Suspension-Hearings</u>. <u>Unless lifted by the State Licensing</u>
 <u>Authority, the Summary Suspension Order shall remain in effect until issuance of a Final Agency Order. Summary suspension hearings will be expedited to the extent practicable and will be conducted in accordance with Rule M 1304 Administrative Hearings.</u>

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(c), 12-43.3-202(1)(d), 12-43.3-202(2)(a)(V), 12-43.3-202(a)(XIX), and 12-43.3-202(2)(a)(XX), and sections 12-43.3-601 and 24-4-105, C.R.S. The purpose of this rule is to establish what entity conducts the administrative hearings, the procedures governing administrative hearings, and other general hearings issues. The purpose of the modifications to this rule is to clarify that the hearing following the Order of Summary Suspension concerns the allegations set forth in the Order to Show Cause, and to clarify that an answer is required only for two types of administrative notices: an Order to Show Cause and a Notice of Grounds for Denial.

M 1304 - Administrative Hearings

A. General Procedures

- 1. Hearing Location. Hearings will generally be conducted by the Department's of Revenue, Hearings Division. Unless the hearing officer orders a change of location based on good cause, as described in this rule, hearings generally will be conducted at a location in the greater Denver metropolitan area to be determined by the hearing officer. Under unusual circumstances where justice, judicial economy and convenience of the parties would be served, hearings may be held in other locations in the state of Colorado.
- 2. <u>Scope of Hearing Rules</u>. This rule shall be construed to promote the just and efficient determination of all matters presented.
- 3. Right to Legal Counsel. Any Denied Applicant or Respondent has a right to legal counsel throughout all processes described in rules associated with the denial of an application and disciplinary action. Such counsel shall be provided solely at the Denied Applicant's or Respondent's expense.

B. Requesting a Hearing

1. A Denied Applicant that has been served with a Notice of Denial may request a hearing within 60 days of the service of the Notice of Denial by making a written request for a hearing to the Division. The request must be submitted by United States mail or by hand delivery. Email or fax requests will not be considered. The request must be sent to:

> Marijuana Enforcement Division Attn: Hearing Request 455 Sherman Street, Suite 390 Denver, CO 80203

The written request for a hearing must be received by the Division within the time stated in the Notice of Denial. An untimely request for hearing will not be considered.

- 2. A Denied Applicant that timely requests a hearing following issuance of a Notice of Denial shall be served with a Notice of Grounds for Denial, and shall be entitled to a hearing regarding the matters addressed therein.
- 3. A Respondent that has been served with an Order to Show Cause shall be entitled to a hearing regarding the matters addressed therein.

C. When a Responsive Pleading is Required

- 1. A Respondent shall file a written answer with the Hearings Division and the Division within 30 days after the date of mailing of any administrative notice or Order to Show Cause. The written answer shall comply with the requirements of Rule 8 of the Colorado Rules of Civil Procedure. If a Respondent fails to file a required answer, the hearing officer, upon motion, may enter a default against that Person pursuant to section 24-4-105(2)(b), C.R.S. For good cause, as described in this rule, shown, the hearing officer may set aside the entry of default within ten days after the date of such entry.
- A Denied Applicant shall file a written answer with the Hearings Division and the Division within 30 days after the date of mailing of any administrative notice or Notice of Grounds for Denial. The written answer shall comply with the requirements of Rule 8 of the Colorado Rules of Civil Procedure. If a Denied Applicant fails to file a required answer, the hearing officer, upon motion, may enter a default against that Person pursuant to section 24-4-105(2)(b), C.R.S. For good cause, as described in this rule, shown, the hearing officer may set aside the entry of default within ten days after the date of such entry.

D. Hearing Notices

- Notice to Set. The Division shall send a notice to set a hearing to the Denied Applicant or Respondent in writing by first-class mail to the last mailing address of record.
- 2. Notice of Hearing. The Hearings Division shall notify the Division and Denied Applicant or Respondent of the date, place, time and nature of the hearing regarding denial of the license application or whether discipline should be imposed against the Respondent's license at least 30 days prior to the date of such hearing, unless otherwise agreed to by both parties. This notice shall be sent to the Denied Applicant or Respondent in writing by first-class mail to the last mailing address of record. Hearings shall be scheduled and held as soon as is practicable.
 - a. <u>If an Order of Summary Suspension has issued, the hearing on the Order to Show Cause Summary suspension hearings will be scheduled and held promptly.</u>
 - b. Continuances may be granted for good cause, as described in this rule, shown. A motion for a continuance must be timely.
 - c. For purposes of this rule, good cause may include but is not limited to: death or incapacitation of a party or an attorney for a party; a court order staying proceedings or otherwise necessitating a continuance; entry or substitution of an attorney for a party a reasonable time prior to the hearing, if the entry or substitution reasonably requires a postponement of the hearing; a change in the parties or pleadings sufficiently significant

to require a postponement; a showing that more time is clearly necessary to complete authorized discovery or other mandatory preparation for the hearing; or agreement of the parties to a settlement of the case which has been or will likely be approved by the final decision maker. Good cause normally will not include the following: unavailability of counsel because of engagement in another judicial or administrative proceeding, unless the other proceeding was involuntarily set subsequent to the setting in the present case; unavailability of a necessary witness, if the witness' testimony can be taken by telephone or by deposition; or failure of an attorney or a party timely to prepare for the hearing.

E. <u>Prehearing Matters Generally</u>

- 1. <u>Prehearing Conferences Once a Hearing is Set</u>. Prehearing conferences may be held at the discretion of the hearing officer upon request of any party, or upon the hearing officer's own motion. If a prehearing conference is held and a prehearing order is issued by the hearing officer, the prehearing order will control the course of the proceedings. Such prehearing conferences may occur by telephone.
- 2. <u>Depositions</u>. Depositions are generally not allowed; however, a hearing officer has discretion to allow a deposition if a party files a written motion and can show why such deposition is necessary to prove its case. When a hearing officer grants a motion for a deposition, C.R.C.P. 30 controls. Hearings will not be continued because a deposition is allowed unless (a) both parties stipulate to a continuance and the hearing officer grants the continuance, or (b) unless the hearing officer grants a continuance over the objection of any party in accordance with subsections (D)(2)(b) and (c) of this rule.
- 3. Prehearing Statements Once a Hearing is Set. Prehearing Statements are required and unless otherwise ordered by the hearing officer, each party shall file with the hearing officer and serve on each party a prehearing statement no later than seven calendar days prior to the hearing. Parties shall also exchange exhibits at that time. Parties shall not file exhibits with the hearing officer. Parties shall exchange exhibits by the date on which prehearing statements are to be filed. Prehearing statements shall include the following information:
 - a. <u>Witnesses</u>. The name, mailing address, and telephone number of any witness whom the party may call at hearing, together with a detailed statement of the expected testimony.
 - b. Experts. The name, mailing address, and brief summary of the qualifications of any expert witness a party may call at hearing, together with a statement that details the opinions to which each expert is expected to testify. These requirements may be satisfied by the incorporation of an expert's resume or report containing the required information.
 - c. <u>Exhibits</u>. A description of any physical or documentary evidence to be offered into evidence at the hearing. Exhibits should be identified as follows: Division using numbers and Denied Applicant or Respondent using letters.
 - d. <u>Stipulations</u>. A list of all stipulations of fact or law reached, as well as a list of any additional stipulations requested or offered to facilitate disposition of the case.

- 4. Prehearing Statements Binding. The information provided in a party's prehearing statement shall be binding on that party throughout the course of the hearing unless modified to prevent manifest injustice. New witnesses or exhibits may be added only if: (1) the need to do so was not reasonably foreseeable at the time of filing of the prehearing statement; (2) it would not unduly prejudice other parties; and (3) it would not necessitate a delay of the hearing.
- 5. <u>Consequence of Not Filing a Prehearing Statement Once a Hearing is Set</u>. If a party does not timely file a prehearing statement, the hearing officer may impose appropriate sanctions including, but not limited to, striking proposed witnesses and exhibits.

F. Conduct of Hearings

- 1. The hearing officer shall cause all hearings to be electronically recorded.
- 2. The hearing officer may allow a hearing, or any portion of the hearing, to be conducted in real time by telephone or other electronic means. If a party is appearing by telephone, the party must provide actual copies of the exhibits to be offered into evidence at the hearing to the hearing officer when the prehearing statement is filed.
- 3. The hearing officer shall administer oaths to all witnesses at hearing. The hearing officer may question any witness.
- 4. The hearing, including testimony and exhibits, shall be open to the public unless otherwise ordered by the hearing officer in accordance with a specific provision of law.
 - a. Reports and other information that would otherwise be confidential pursuant to Subsection 12-43.3-202(1)(d), C.R.S., may be introduced as exhibits at hearing. Such exhibits shall not be sealed from public inspection unless confidential pursuant to a provision of law other than Subsection 12-43.3-202(1)(d), C.R.S.
 - b. Any party may move the hearing officer to seal an exhibit or order other appropriate relief if necessary to safeguard the confidentiality of evidence, if such evidence is confidential pursuant to a specific provision of law other than Subsection 12-43.3-202(1)(d), C.R.S.

5. Court Rules.

- a. To the extent practicable, the Colorado Rules of Evidence apply. Unless the context requires otherwise, whenever the word "court," "judge," or "jury" appears in the Colorado Rules of Evidence, such word shall be construed to mean a hearing officer. A Hearing officer has discretion to consider evidence not admissible under such rules, including but not limited to hearsay evidence, pursuant to section 24-4-105(7), C.R.S.
- b. To the extent practicable, the Colorado Rules of Civil Procedure apply. However, Colorado Rules of Civil Procedure 16 and 26-37 do not apply, although parties are encouraged to voluntarily work together to resolve the case, simplify issues, and exchange information relevant to the case prior to a hearing. Unless the context otherwise requires, whenever the

word "court" appears in a rule of civil procedure, that word shall be construed to mean a hearing officer.

6. <u>Exhibits</u>.

- All documentary exhibits must be paginated by the party offering the exhibit into evidence.
- b. The Division shall use numbers to mark its exhibits.
- The Denied Applicant or Respondent shall use letters to mark its exhibits.
- 7. The hearing officer may proceed with the hearing or enter default judgment if any party fails to appear at hearing after proper notice.
- G. <u>Post Hearing</u>. After considering all the evidence, the hearing officer shall determine whether the proponent of the order has proven its case by a preponderance of the evidence, and shall make written findings of evidentiary fact, ultimate conclusions of fact, conclusions of law, and a recommendation. These written findings shall constitute an Initial Decision subject to review by the State Licensing Authority pursuant to the Colorado Administrative Procedure Act and as set forth in Rule M 1306 Administrative Hearing Appeals/Exceptions to Initial Decision.
- H. No Ex Parte Communication. Ex parte communication shall not be allowed at any point following the formal initiation of the hearing process. A party or counsel for a party shall not initiate any communication with a hearing officer or the State Licensing Authority, or with conflicts counsel representing the hearing officer or State Licensing Authority, pertaining to any pending matter unless all other parties participate in the communication or unless prior consent of all other parties (and any pro se parties) has been obtained. Parties shall provide all other parties with copies of any pleading or other paper submitted to the hearing officer or the State Licensing Authority in connection with a hearing or with the exceptions process.
- I. <u>Marijuana Enforcement Division Representation</u>. The Division shall be represented by the Colorado Department of Law.

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), 12-43.3-402(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

Rule M 1501 shall be effective beginning July 1, 2016.

A. Contaminant Testing Required. 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.

B. Validation of Process – Contaminant Testing

- Medical Marijuana. 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.
- 3. 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 and amounts present of Salmonella sp., and shiga-toxin producing Escherichia coli., and the amount of total yeast and mold.

2. <u>Biological Contaminant Testing.</u>

- a. Mold and Mildew Contaminant Testing. Each Harvest Batch of Medical Marijuana and Production Batch of Medical Marijuana Concentrate and Medical Marijuana Infused-Product must be visually inspected, in addition to other required mold testing, by a Medical Marijuana Testing Facility for toxic amounts of mold and mildew contamination.
- b. <u>Filth Contaminant Testing</u>. Each Harvest Batch of Medical Marijuana must be visually inspected by a Medical Marijuana Testing Facility for toxic amounts of filth.
- 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, filth or residual solvents.

E. Exemptions

Medical Marijuana Concentrate. 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.
- Expiration of Process Validation. 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 1502

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)(XII), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(A)(A)(A)(A)(A)(A)

M 1502 - Medical Marijuana Testing Program - Mandatory Testing

Rule M 1502 shall be effective beginning July 1, 2016.

- A. Required Sample Submission. A Medical Marijuana Business may be required by the Division to submit a Sample(s) of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product it possesses to a Medical Marijuana Testing Facility at any time regardless of whether its process has been validated and without notice.
 - Samples collected pursuant to this rule may be tested for potency or contaminants which may include, but may not be limited to, Pesticide, microbials, molds, metals, filth, residual solvents, biological contaminants, and chemical contaminants.
 - 2. When a Sample(s) is required to be submitted for testing, the Medical Marijuana Business may not sell, 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 from the package, Harvest Batch or Production Batch from which the Sample was taken, unless or until it passes all required testing.
- B. <u>Methods for Determining Required Testing.</u>
 - 1. <u>Random Testing</u>. The Division may require Samples to be submitted for testing through any one or more of the following processes: random process, risk-based process or other internally developed process, regardless of whether a Medical Marijuana Business's process has been validated.
 - 2. <u>Inspection or Enforcement Tests</u>. The Division may require a Medical Marijuana Business to submit a Sample for testing if the Division has reasonable grounds to believe that:
 - a. Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product is contaminated or mislabeled;
 - b. A Medical Marijuana Business is in violation of any product safety, health or sanitary law, rule or regulation; or
 - c. The results of a test would further an investigation by the Division into a violation of any law, rule or regulation.
 - 3. <u>Beta Testing</u>. The Division may require a Medical Marijuana Business to submit Samples from certain randomly selected Harvest Batches or Production Batches for potency or contaminant testing prior to implementing mandatory testing.
- C. <u>Minimum Testing Standards</u>. The testing requirements contained in the M 1500 series are the minimum required testing standards. Medical Marijuana Businesses are responsible for receiving enough testing on any Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana Infused-Product they produce to ensure the marijuana consumables are safe for human consumption.
- D. <u>Additional Sample Types</u>. The Division may also require a Medical Marijuana Business to submit Samples comprised of items other than Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product to be tested for contaminants which may include, but may not be limited to, Pesticide, microbials, molds, metals, filth, residual

solvents, biological contaminants, and chemical contaminants. The following is a non-exhaustive list of the types of Samples that may be required to be submitted for contaminant testing:

- 1. Specific plant(s) or any portion of a plant(s),
- 2. Any growing medium, water or other substance used in the cultivation process,
- 3. Any water, solvent or other substance used in the processing of a Medical Marijuana Concentrate,
- 4. Any ingredient or substance used in the manufacturing of a Medical Marijuana-Infused Product; or
- 5. Swab of any equipment or surface.
- E. <u>Violation Affecting Public Safety</u>. Failure to comply with this rule may constitute a license violation affecting public safety.

Basis and Purpose – M 1504

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)(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 sampling procedures and rules for the Division's Medical Marijuana sampling and testing program.

M 1504 - Medical Marijuana Testing Program - Sampling Procedures

Rule M 1504 shall be effective beginning July 1, 2016.

A. <u>Collection of Samples</u>

- Sample Collection. All Samples submitted for testing pursuant to this rule must be collected by Division personnel or in accordance with the Division's sampling policy.
- Sample Selection. The Division may elect, at its sole direction, to assign Division personnel to collect Samples. A Medical Marijuana Business, its Owners and employees shall not attempt to influence the Samples selected by Division personnel.
- 3. Adulteration or Alteration Prohibited. A Licensee or its agent shall not adulterate or alter, or attempt to adulterate or alter, any Medical Marijuana or Medical Marijuana-Infused Product, or any Samples of the Medical Marijuana or Medical Marijuana-Infused Product, for the purpose of circumventing contaminant testing detection limits or potency testing requirements. A violation of this subparagraph (A)(3) shall be considered a license violation affecting public safety.
- B. <u>Samples for Test Batches of Medical Marijuana and Medical Marijuana Concentrate</u>. Each Test Batch of Medical Marijuana or Medical Marijuana Concentrate must be comprised of a representative selection of Samples.

- Minimum Number of Samples. At a minimum, each Test Batch of Medical Marijuana or Medical Marijuana Concentrate must be comprised of at least the following number of separately taken Samples:
 - a. For Test Batches comprised of Harvest Batches or Production Batches weighing up to 10 pounds, eight separate Samples must be taken.
 - b. For Test Batches comprised of Harvest Batches or Production Batches weighing more than 10 pounds but less than 20 pounds, 12 separate Samples must be taken.
 - For Test Batches comprised of Harvest Batches or Production Batches weighing 20 pounds or more but less than 30 pounds, 15 separate Samples must be taken.
 - d. For Test Batches comprised of Harvest Batches or Production Batches weighing 30 pound or more but less than 40 pounds, 18 separate Samples must be taken.
 - e. For Test Batches comprised of Harvest Batches or Production Batches weighing 40 pounds or more but less than 100 pounds, 23 separate Samples must be taken.
 - f. For Test Batches comprised of Harvest Batches or Production Batches weighing 100 pounds or more, 29 separate Samples must be taken.
- 2. <u>Multiple Harvest Batches or Production Batches</u>. If more than one Harvest Batch or Production Batch is combined into a single Test Batch, then that Test Batch must include at least one Sample from each Harvest Batch or Production Batch.
- C. Samples for Test Batches of Medical Marijuana-Infused Product.
 - 1. <u>Finished Product</u>. Test Batches of Medical Marijuana-Infused Product must be comprised of finished product that is packaged for sale.
 - 2. <u>Multiple Production Batches</u>. If more than one Production Batch of Medical Marijuana-Infused Product is combined into a single Test Batch, then that Test Batch must include at least one finished product that is packaged for sale from each Production Batch combined into that Test Batch.
- D. Medical Marijuana Testing Facility Selection. The Division will generally permit a Medical Marijuana Business to select which Medical Marijuana Testing Facility will test a Sample collected pursuant to this rule. However, the Division may elect, at is sole discretion, to assign a Medical Marijuana Testing Facility to test the Sample.
- E. <u>Violation Affecting Public Safety</u>. Failure to comply with this rule may constitute a license violation affecting public safety.

M 1600 Series – Medical Marijuana Transporters

Basis and Purpose - M 1601

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), and 12-43.3-406, C.R.S. The purpose of this rule is to establish that it is unlawful for a Medical Marijuana Transporter to exercise any privileges other than those granted by the State Licensing Authority and to clarify the license privileges.

M 1601 – Medical Marijuana Transporter: License Privileges

- A. Privileges Granted. A Medical Marijuana Transporter shall only exercise those privileges granted to it by the State Licensing Authority.
- B. Licensed Premises. A separate license is required for each specific business or business entity and geographical location. A Medical Marijuana Transporter may share a location with an identically owned Retail Marijuana Transporter. However, a separate license is required for each specific business or business entity, regardless of geographical location.
- C. Transportation of Medical Marijuana and Medical Marijuana-Infused Product Authorized.

 A Medical Marijuana Transporter may take transportation and delivery orders, receive, transport, temporarily store, and deliver Medical Marijuana and Medical Marijuana-Infused Product.
- D. Authorized Sources of Medical Marijuana and Medical Marijuana-Infused Product. A
 Medical Marijuana Transporter may only transport and store Medical Marijuana and

 Medical Marijuana-Infused Product that it received directly from the originating Medical Marijuana Business.
- E. Authorized On-Premises Storage. A Medical Marijuana Transporter is authorized to store transported Medical Marijuana and Medical Marijuana-Infused Product on its Licensed Premises or permitted off-premises storage facility. All transported Medical Marijuana and Medical Marijuana-Infused Product must be secured in a Limited Access Area or Restricted Access Area, and tracked consistently with the inventory tracking rules.

Basis and Purpose - M 1602

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(l), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XVIII.6), 12-43.3-202(2)(a)(XX), and 12-43.3-406, C.R.S. The purpose of this rule is to clarify those acts that are limited in some fashion or prohibited by a Medical Marijuana Transporter.

M 1602 – Medical Marijuana Transporter: General Limitations or Prohibited Acts

- A. Sales Prohibited. A Medical Marijuana Transporter is prohibited from buying, selling, or giving away Medical Marijuana or Medical Marijuana-Infused Product, or from receiving complimentary Medical Marijuana or Medical Marijuana-Infused Product.
- B. Licensed Premises Required. A Medical Marijuana Transporter shall maintain a

 Licensed Premises. The Licensed Premises shall be in a local jurisdiction that authorizes the operation of Medical Marijuana Centers. If a Medical Marijuana Transporter Licensed Premises is co-located with a Retail Marijuana Transporter Licensed Premises, then the combined Licensed Premises shall be in a local jurisdiction that authorizes the operation of both Medical Marijuana Centers and Retail Marijuana Stores.

- C. Off-Premises Storage Permit. A Medical Marijuana Transporter may maintain one or more permitted off-premises storage facilities. See rule M 802 Off-Premises Storage of Medical Marijuana and Medical Marijuana-Infused Product: All Medical Marijuana Businesses.
- D. Storage Duration. A Medical Marijuana Transporter shall not store Medical Marijuana or Medical Marijuana-Infused Product for longer than 72 hours from receiving it at its Licensed Premises or off-premises storage facility. The allowable 72-hour duration begins regardless of which of the Medical Marijuana Transporter's premises receives the Medical Marijuana or Medical Marijuana-Infused Product first.
- E. Control of Medical Marijuana and Medical Marijuana-Infused Product. A Medical Marijuana Transporter is responsible for the Medical Marijuana and Medical Marijuana-Infused Product once it takes control of the Medical Marijuana and Medical Marijuana-Infused Product and until the Medical Marijuana Transporter delivers it to the receiving Medical Marijuana Business. For purposes of this rule, taking control of the Medical Marijuana and Medical Marijuana-Infused Product means removing it from the originating Medical Marijuana Business's Licensed Premises and placing the Medical Marijuana and Medical Marijuana-Infused Product in the transport vehicle.
- F. Location of Orders Taken and Delivered. A Medical Marijuana Transporter is permitted to take orders on the Licensed Premises of any Medical Marijuana Business to transport Medical Marijuana and Medical Marijuana-Infused Product. The Medical Marijuana Transporter shall deliver the Medical Marijuana and Medical Marijuana-Infused Product to the Licensed Premises of a licensed Medical Marijuana Business.
- G. Consumption Prohibited. A Licensee shall not permit the consumption of marijuana or marijuana product on the Licensed Premises.

Basis and Purpose - M 1603

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)(XV), 12-43.3-202(2)(a)(XVIII.6), 12-43.3-202(2)(a)(XX), and 12-43.3-406(3) C.R.S. The purpose of this rule is to establish a Medical Marijuana Transporter's obligation to account for and track all Medical Marijuana and Medical Marijuana-Infused Product on the Licensed Premises from the point they are transferred from the originating Medical Marijuana Business to the destination Medical Marijuana Business.

M 1603 – Medical Marijuana Transporter: Inventory Tracking System

A. Minimum Tracking Requirement. A Medical Marijuana Transporter must use the Inventory Tracking System to ensure its transported Medical Marijuana and Medical Marijuana-Infused Product are identified and tracked from the point they are transferred from a Medical Marijuana Business when the Medical Marijuana Transporter takes control of the Medical Marijuana and Medical Marijuana-Infused Product by removing it from the originating Medical Marijuana Business's Licensed Premises and placing the Medical Marijuana and Medical Marijuana-Infused Product in the Medical Marijuana Transporter's transport vehicle, through delivery to the destination Medical Marijuana Business. See also Rule R 309 —Inventory Tracking System. A Medical Marijuana and Medical Marijuana-Infused Product with the Inventory Tracking System and the associated transaction history and transportation order receipts. See also Rule M 901 — Business Records Required.

- A Medical Marijuana Transporter is prohibited from accepting any Medical
 Marijuana or Medical Marijuana-Infused Product from another Medical Marijuana
 Business without receiving a valid transport manifest generated from the Inventory Tracking System.
- 2. A Medical Marijuana Transporter must immediately input all Medical Marijuana and Medical Marijuana-Infused Product received at its Licensed Premises or off-premises storage facility, accounting for all RFID tags, into the Inventory Tracking System at the time of receiving the Medical Marijuana or Medical Marijuana-Infused Product.
- 3. A Medical Marijuana Transporter must reconcile transactions to the Inventory Tracking System at the close of business each day.

Basis and Purpose – M 1604

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)(XV), 12-43.3-202(2)(a)(XVIII.6), and 12-43.3-202(2)(a)(XX), C.R.S. It sets forth general standards and basic sanitary requirements for Medical Marijuana Transporters. It covers the physical premises where the products are weighed and stored as well as the individuals handling the products. This rule also authorizes the State Licensing Authority to require an independent consultant to conduct a health and sanitary audit of a Medical Marijuana Transporter's Licensed Premises. This rule explains when an independent health and sanitary audit may be deemed necessary and sets forth possible consequences of a Medical Marijuana Transporter's refusal to cooperate or pay for the audit. The State Licensing Authority intends for this rule to reduce any product contamination, which will benefit both the Licensees and consumers. Overall, the State Licensing Authority intends this rule to help maintain the integrity of Colorado's Medical Marijuana Businesses and the safety of the public.

M 1604 – Medical Marijuana Transporter: Health and Safety Regulations

- A. Local Safety Inspections. A Medical Marijuana Transporter's Licensed Premises 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.
- B. Sanitary Conditions. A Medical Marijuana Transporter shall take all reasonable measures and precautions to ensure the following:
 - 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 and Medical Marijuana-Infused Product, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected;
 - That hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Hand-washing facilities shall be located in the Licensed Premises and where good sanitary practices require employees to wash 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 Medical Marijuana or Medical
 Marijuana-Infused Product shall conform to hygienic practices while on duty, including but not limited to:
 - 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; 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.
- 4. That litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where Medical Marijuana or Medical Marijuana-Infused Product are exposed;
- 5. 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;
- 6. That there is adequate lighting in all areas where Medical Marijuana or Medical Marijuana-Infused Product are stored or weighed, and where equipment or utensils are cleaned;
- 7. That the Licensee provides adequate screening or other protection against the entry of pests. Rubbish shall be disposed of so as to minimize the development of odor and minimize the potential for the waste becoming an attractant, harborage, or breeding place for pests;
- 8. That any buildings, fixtures, and other facilities are maintained in a sanitary condition;
- 9. That toxic cleaning compounds, sanitizing agents, and other chemicals shall be identified, held, stored and disposed of in a manner that protects against contamination of 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;
- 10. 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;
- 11. That each employee is provided with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair; and
- 12. 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.
- C. 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 Medical Marijuana Transporter to undergo such an audit. The scope of the audit may include, but need not be limited to, whether the Medical Marijuana Transporter is in compliance with the requirements set forth in this rule and other applicable health, sanitary or food handling 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
 Transporter. However, the Division always retains the authority to select the independent consultant regardless of whether mutual agreement can be reached.
- c. The Medical Marijuana Transporter 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. The Division has reasonable grounds to believe that the Medical
 Marijuana Transporter 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; or
 - b. The Division has reasonable grounds to believe that the Medical
 Marijuana Transporter was the cause or source of contamination of
 Medical Marijuana, Medical Marijuana Concentrate or Medical
 Marijuana-Infused Product.
- 3. Compliance Required. A Medical Marijuana Transporter 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 Medical Marijuana Transporter's license.

 See Rule M 1302 Summary Suspensions.
 - b. Prior to or following the issuance of such an order, the Medical Marijuana
 Transporter 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 Summary Suspensions.

- ii. If an agreement to suspend operations is reached, then the Medical Marijuana Transporter may continue to care for its stored or transported Medical Marijuana and Medical Marijuana-Infused Product and conduct any necessary internal business operations.
- D. Violation Affecting Public Safety. Failure to comply with this rule may constitute a license violation affecting public safety.