



## DEPARTMENT OF REVENUE

### Marijuana Enforcement Division

## MEDICAL MARIJUANA RULES

### 1 CCR 212-1

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

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#### **M 100 Series – General Applicability**

##### **Basis and Purpose – M 101**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-901(2), and 18-18-406(7.5), C.R.S. Any Person who buys, sells, transfers, gives away, or acquires Medical Marijuana outside the requirements the Medical Code is engaging in illegal activity pursuant to Colorado law. This rule clarifies that those engaged in the business of possessing, cultivating, dispensing, or selling Medical Marijuana must be properly licensed to be in compliance with Colorado law.

##### **M 101 – Engaging in Business**

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

##### **Basis and Purpose – M 102**

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 clarify that each rule is independent of the others, so if one is found to be invalid, the remainder will stay in effect. This will give the regulated community confidence in the rules even if one is challenged.

##### **M 102 – Severability**

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

##### **Basis and Purpose – M 103**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a) and 12-43.3-202(2)(a)(XX), C.R.S., section 12-43.3-104, and all of the Medical Code. The purpose of this rule is to provide necessary definitions of terms used throughout the rules. Defined terms are capitalized where they appear in the rules, to let the reader know to refer back to these definitions. When a term is used in a conventional sense, and not intended to be a defined term, it is not capitalized.

##### **M 103 – Definitions**

Definitions. 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 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.

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

“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 for licensure or registration, or for renewal of licensure or registration, pursuant to these rules that was accepted by the Division for review but has not been approved or denied by the State Licensing Authority.

“Associated Key License” means an Occupational License for an individual who is a Direct Beneficial Interest Owner of the Medical Marijuana Business, other than a Qualified Limited Passive Investor. Each shareholder, officer, director, member, or partner of a Closely Held Business Entity that is a Direct Beneficial Interest Owner must hold an Associated Key License.

“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.

“Business Interest” means any Person that holds a Financial Interest or an Affiliated Interest in a Medical Marijuana Business.

“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.

“Closely Held Business Entity” means an “entity” as defined in section 7-90-102, C.R.S., that has no more than fifteen shareholders, officers, directors, members, partners or owners, each of whom are natural persons, each of whom holds an Associated Key License, and each of whom is a United States citizen prior to the date of application. There must be no publicly traded market for interests in the entity. A Closely Held Business Entity and each of the natural persons who are its shareholders, officers, directors, members, partners or owners, are Direct Beneficial Interest Owners. A Closely Held Business Entity is an associated business of the Medical Marijuana Business for which it is a Direct Beneficial Interest Owner.

“Commercially Reasonable Royalty” means a right to compensation in the form of a royalty payment for the use of product-specific intellectual property. A Commercially Reasonable Royalty must be limited to a specific product or line of products and provide compensation to the Commercially Reasonable Royalty Holder as a percentage of gross revenue or gross profit generated from sales of the particular product or line of products. The royalty payment must be at a reasonable percentage rate. To determine whether the percentage rate is reasonable, the Division will consider the totality of the circumstances, including but not limited to the following factors:

- a. The percentage of royalties received by the recipient for the licensing of the intellectual property.
- b. The rates paid by the Licensee for the use of other intellectual property.
- c. The nature and scope of the license, as exclusive or non-exclusive; or as restricted or non-restricted in terms of territory or with respect to whom the manufactured product may be sold.
- d. The licensor’s established policy and marketing program to maintain his intellectual property monopoly by not licensing others or by granting licenses under special conditions designed to preserve that monopoly.
- e. The commercial relationship between the recipient and Licensee, such as, whether they are competitors in the same territory in the same line of business.
- f. The effect of selling the intellectual property in promoting sales of other products of the Licensee; the existing value of the intellectual property to the recipient as a generator of sales of his non-intellectual property items; and the extent of such derivative sales.
- g. The duration of the term of the license for use of the intellectual property.
- h. The established or projected profitability of the product made using the intellectual property; its commercial success; and its current popularity.
- i. The utility and advantages of the intellectual property over products without the intellectual property.

- j. The nature of the intellectual property; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the intellectual property.
- k. The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the intellectual property.
- l. The portion of the realizable profit that should be credited to the intellectual property as distinguished from non-intellectual property elements, the manufacturing process, business risks, or significant features or improvements added by the Licensee.

“Commercially Reasonable Royalty Interest Holder” means a Person that receives a Commercially Reasonable Royalty in exchange for a Licensee’s use of the Commercially Reasonable Royalty Interest Holder’s intellectual property. A Commercially Reasonable Royalty Interest Holder is an Indirect Beneficial Interest Owner.

“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.

“Direct Beneficial Interest Owner” means a natural person or a Closely Held Business entity that owns a share or shares of stock in a licensed Medical Marijuana Business, including the officers, directors, members, or partners of the licensed Medical Marijuana Business or Closely Held Business Entity, or a Qualified Limited Passive Investor. Each natural person that is a Direct Beneficial Interest Owner must hold an Associated Key License. Except that a Qualified Limited Passive Investor need not hold an Associated Key License and shall not engage in activities for which an Occupational License is required.

“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.

“Financial Interest” means any Direct Beneficial Interest Owner, a Commercially Reasonable Royalty Interest Holder who receives more than 30 percent of the gross revenue or gross profit from sales of the product subject to the royalty, a Permitted Economic Interest holder, and any other Person who controls or is positioned so as to enable the exercise of control over the Medical Marijuana Business.

“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 is in a light cycle intended to stimulate production of flowers, trichomes, 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;
- b. The Licensee or Applicant has failed to comply with any special terms or conditions that were placed upon the license pursuant to an order of the State Licensing Authority or the relevant local 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.

“Indirect Beneficial Interest Owner” means a holder of a Permitted Economic Interest, a recipient of a Commercially Reasonable Royalty associated with the use of intellectual property by a Licensee, a Profit-Sharing Plan Employee, a Qualified Institutional Investor, or another similarly situated Person as determined by the State Licensing Authority. An Indirect Beneficial Interest Owner is not a Licensee. The Licensee must obtain Division approval for an Indirect Beneficial Interest Owner that constitutes a Financial Interest before such Indirect Beneficial Interest Owner may exercise any of the privileges of the ownership or interest with respect to the Licensee.

“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 an 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:
  1. 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;
  2. 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;
  3. 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 Associated Key Licensee of a Medical Marijuana Business or an occupationally licensed employee of a Medical Marijuana Business, each of whom has attended and successfully completed Inventory Tracking System training and has completed any additional training required by the Division.

“Inventory Tracking System User” means an Associated Key Licensee of a Medical Marijuana Business or 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. Each Inventory Tracking System User must have 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, transport, 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, a Medical Marijuana Testing Facility, a Medical Marijuana Business Operator, or a Medical Marijuana Transporter.

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

“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 a 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, but is not authorized to sell, give away, buy, or receive complimentary Medical Marijuana or Medical Marijuana-Infused Products under any circumstances. A Medical Marijuana Transporter does not include a Licensee that transports its own Medical Marijuana or Medical Marijuana-Infused Products.

“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, except where the context otherwise requires, a Direct Beneficial Interest 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. A Permitted Economic Interest holder is an Indirect Beneficial Interest Owner.

“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.

“Profit-Sharing Plan” means a profit-sharing plan that is qualified pursuant to 26 U.S.C. § 401 of the Internal Revenue Code and subject to the Employee Retirement Income Security Act, and which provides for employer contributions in the form of cash, but not in the form of stock or other equity interests in a Medical Marijuana Business.

“Profit-Sharing Plan Employee” means an employee holding an Occupational License who receives a share of a Medical Marijuana Business’s profits through a Profit-Sharing Plan. A Profit-Sharing Plan Employee is an Indirect Beneficial Interest Owner.

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

“Qualified Institutional Investor” means:

- a. A bank as defined in Section 3(a) (6) of the Federal Securities Exchange Act of 1934, as amended;
- b. An insurance company as defined in Section 2(a) (17) of the Investment Company Act of 1940, as amended;
- c. An investment company registered under Section 8 of the Investment Company Act of 1940, as amended;
- d. An investment adviser registered under Section 203 of the Investment Advisers Act of 1940, as amended;

- e. Collective trust funds as defined in Section 3(c) (11) of the Investment Company Act of 1940, as amended;
- f. An employee benefit plan or pension fund that is subject to the Employee Retirement Income Security Act of 1974, as amended, excluding an employee benefit plan or pension fund sponsored by a licensed or an intermediary or holding company licensee which directly or indirectly owns five percent or more of a licensee;
- g. A state or federal government pension plan; or
- h. A group comprised entirely of persons specified in (a) through (g) of this definition.

A Qualified Institutional Investor is an Indirect Beneficial Interest Owner.

“Qualified Limited Passive Investor” means a natural person who is a United States citizen and is a passive investor who owns less than a five percent share or shares of stock in a licensed Medical Marijuana Business. A Qualified Limited Passive Investor is a Direct Beneficial Interest Owner.

“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, a Retail Marijuana Testing Facility, a Retail Marijuana Establishment Operator, or a Retail Marijuana Transporter.

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

“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 a 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, but is not authorized to sell, give away, buy, or receive complimentary Retail Marijuana or Retail Marijuana Products under any circumstances. A Retail Marijuana Transporter does not include a Licensee that transports and distributes its own Retail Marijuana or Retail Marijuana Products.

“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 a hard-sided container with a lid or other enclosure that can be secured in place, and the container is 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.

#### **Basis and Purpose – M 104**

The statutory authority for this rule exists in subsections 12-43.3-202(1)(b)(I) and 24-4-105(11), and section 12-43.3-201, C.R.S. The purpose of this rule is to establish a system by which a licensee may request the Division to issue a formal statement of position and, subsequently, petition State Licensing Authority for a declaratory order. Typically, a position statement or declaratory order would address matters that are likely to be applicable to other licensees. The approach is similar to that utilized by other divisions within the Department of Revenue.

**M 104 – Declaratory Orders Concerning the Medical Code**

- A. Who May Request a Statement of Position. Any person as defined in section 24-4-102(12), C.R.S., may request the Division to issue a statement of position concerning the applicability to the petitioner of any provision of the Medical Code, or any regulation of the State Licensing Authority.
- B. Division Response. The Division will determine, in its sound discretion, whether to respond with a written statement of position. Following receipt of a proper request, the Division will respond by issuing a written statement of position or by declining to issue such a statement.
- C. Petition for Declaratory Order. Any person who has properly requested a statement of position, and who is dissatisfied with the Division's response, may petition the State Licensing Authority for a declaratory order pursuant to section 24-4-105(11), C.R.S. The petition shall be filed within 30 days of the Division's response, or may be filed at any time before the Division's response if the Division has not responded within 60 days of receiving a proper request for a statement of position, and shall set forth the following:
1. The name and address of the petitioner.
  2. Whether the petitioner is licensed pursuant to the Medical Code or Retail Code, and if so, the type of license and address of the Licensed Premises.
  3. Whether the petitioner is involved in any pending administrative hearing with the State Licensing Authority or relevant local licensing authority.
  4. The statute, rule, or order to which the petition relates.
  5. A concise statement of all of the facts necessary to show the nature of the controversy or the uncertainty as to the applicability to the petitioner of the statute, rule or order to which the petition relates.
  6. A concise statement of the legal authorities, if any, and such other reasons upon which petitioner relies.
  7. A concise statement of the declaratory order sought by the petitioner.
- D. State Licensing Authority Retains Discretion Whether to Entertain Petition. The State Licensing Authority will determine, in its discretion and without prior notice to the petitioner, whether to entertain any petition. If the State Licensing Authority decides it will not entertain a petition, it shall notify the petitioner in writing of its decision and the reasons for that decision. Any of the following grounds may be sufficient reason to refuse to entertain a petition:
1. The petitioner failed to properly request a statement of position from the Division, or the petition for declaratory order was filed with the State Licensing Authority more than 30 days after the Division's response to the request for statement of position was issued.
  2. A ruling on the petition will not terminate the controversy nor remove uncertainties concerning the applicability to petitioner of the statute, rule or order in question.
  3. The petition involves a subject, question or issue that is currently relevant to a pending hearing before the state or any local licensing authority, an on-going investigation conducted by the Division, or a written complaint filed with the State Licensing Authority.
  4. The petition seeks a ruling on a moot or hypothetical question.

5. Petitioner has some other adequate legal remedy, other than an action for declaratory relief pursuant to Colo. R. Civ. Pro. 57, which will terminate the controversy or remove any uncertainty concerning applicability of the statute, rule or order.
- E. State Licensing Authority May Adopt Division Position Statement. The State Licensing Authority may adopt the Division Position Statement as a Final Agency Action subject to judicial review pursuant to section 24-4-106, C.R.S.
- F. If State Licensing Authority Entertains Petition. If the State Licensing Authority determines that it will entertain the petition for declaratory order, it shall so notify the petitioner within 30 days, and any of the following procedures may apply:
1. The State Licensing Authority may expedite the matter by ruling on the basis of the facts and legal authority presented in the petition, or by requesting the petitioner or the Division to submit additional evidence and legal argument in writing.
  2. In the event the State Licensing Authority determines that an evidentiary hearing is necessary to a ruling on the petition, a hearing shall be conducted in accordance with Rules M 1304 – Administrative Hearings, M 1305 – Administrative Subpoenas, and M 1306 – Administrative Hearing Appeals. The petitioner will be identified as Respondent.
  3. The parties to any proceeding pursuant to this rule shall be the petitioner/Respondent and the Division. Any other interested Person may seek leave of the State Licensing Authority to intervene in the proceeding and such leave may be granted if the State Licensing Authority determines that such intervention will make unnecessary a separate petition for declaratory order by the interested Person.
  4. The declaratory order shall constitute a Final Agency Order subject to judicial review pursuant to section 24-4-106, C.R.S.
- G. Public Inspection. Files of all requests, petitions, statements of position, and declaratory orders will be maintained by the Division. Except with respect to any material required by law to be kept confidential, such files shall be available for public inspection.
- H. Posted on Website. The Division shall post a copy of all statements of position and all declaratory orders on the Division's website.

#### **Basis and Purpose – M 105**

The statutory authority for this rule is found at subsection 12-43.4-202(2)(b), C.R.S. The purpose of this rule is to clarify that any reference to days means calendar days.

#### **M 105 – Computation of Time**

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

#### **Basis and Purpose – M 106**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(l) and 12-43.3-501(4), C.R.S. The purpose of this rule is to establish the basic fees that must be paid at the time of service of any subpoena (including a subpoena for testimony and/or a subpoena duces tecum) upon the State Licensing Authority, and for production of documents pursuant to any such subpoena. This rule also establishes additional fees for meals, mileage, and each day’s testimony. The service fee is not applicable when a subpoena is served by a governmental agency.

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**M 106 – Subpoena Fees**

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

**M 200 Series – Licensing and Interests**

**Basis and Purpose – M 201**

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

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**M 201 – Application Process**

A. General Requirements

1. All applications for licenses or registrations authorized pursuant to subsections 12-43.3-401(1)(a)-(g), C.R.S., shall be made upon current forms prescribed by the Division.
2. A license or registration issued to a Medical Marijuana Business or an individual constitutes a revocable privilege. The burden of proving an Applicant's qualifications for licensure or registration rests at all times with the Applicant.
3. Each application shall identify the local licensing authority.
4. Applicants must submit a complete application to the Division before it will be accepted or considered.
  - a. All applications must be complete and accurate in every material detail.
  - b. All applications must include all attachments or supplemental information required by the current forms supplied by the Division.
  - c. All applications must be accompanied by a full remittance for the whole amount of the application and license fees. See Rules M 207 – Schedule of Application Fees: Medical Marijuana Businesses; M 208 – Schedule of Business License and Registration Fees: Medical Marijuana Businesses; M 209 – Schedule of Business Renewal License and Registration Fees: Medical Marijuana Businesses; M 235 – Schedule of License Fees: Individuals; M 236 – Schedule of Renewal License Fees: Individuals.
  - d. All applications must include all information required by the Division related to the Applicant's proposed Direct Beneficial Interest Owners, Indirect Beneficial Interest Owners and Qualified Limited Passive Investors, and all other direct and indirect financial interests in the Applicant.
  - e. At a minimum, each Applicant for a new license or registration shall provide, at the time of application, the following information:
    - i. For each Associated Key License Applicant, evidence of proof of lawful presence, citizenship, if applicable, residence, if applicable, and Good Moral Character as required by the current forms prescribed by the Division;
    - ii. For each Medical Marijuana Business Applicant and each Associated Key License Applicant, all requested information concerning financial and management associations and interests of other Persons in the business;
    - iii. If the Applicant for any license pursuant to the Medical Code is a Closely Held Business Entity it shall submit with the application:
      - A. The Associated Key License applications for all of its shareholders, members, partners, officers and directors who do not already hold an Associated Key License;

- B. If the Closely Held Business Entity is a corporation, a copy of its articles of incorporation or articles of organization; evidence of authorization from the Colorado Secretary of State to do business within this State, and for each shareholder: his or her name, mailing address, state of residence and certification of Colorado residency for at least one officer and all officers with day-to-day operational control over the business;
  - C. If the Closely Held Business Entity is a limited liability company, a copy of its articles of incorporation and its operating agreement; evidence of authorization from the Colorado Secretary of State to do business within this State, and for each member: his or her name, mailing address, state of residence and certification of Colorado residency for at least one officer and all officers with day-to-day operational control over the business;
  - D. If the Closely Held Business Entity is a general partnership, limited partnership, limited liability partnership, or limited liability limited partnership, a copy of the partnership agreement and, for each partner, his or her name, mailing address and state of residency and certification of Colorado residency for at least one officer and all officers with day-to-day operational control over the business.
- iv. For each Medical Marijuana Business Applicant and each Associated Key License Applicant, documentation establishing compliant return filing and payment of taxes related to any Medical Marijuana Business or Retail Marijuana Establishment in which such Applicant is, or was, required to file and pay taxes;
  - v. For each Medical Marijuana Business Applicant and each Associated Key License Applicant, documentation verifying and confirming the funds used to start and/or sustain the operation of the medical or retail marijuana business were lawfully earned or obtained;
  - vi. Accurate floor plans for the premises to be licensed; and
  - vii. The deed, lease, sublease, contract, or other document(s) governing the terms and conditions of occupancy of the premises to be licensed.
- 5. All applications to reinstate a license or registration will be deemed an application for a new license or registration. This includes, but is not limited to, Associated Key licenses that have expired, Medical Marijuana Business licenses or registrations that have been expired for more than 90 days, licenses or registrations that have been voluntarily surrendered, and licenses that have been revoked.
  - 6. The Division may refuse to accept an incomplete application.
- B. Additional Information May Be Required
- 1. Upon request by the Division, an Applicant shall provide any additional information required to process and fully investigate the application. The additional information must be provided to the Division no later than seven days after the request is made unless otherwise specified by the Division.

2. An Applicant's failure to provide the requested evidence or information by the Division deadline may be grounds for denial of the application.
- C. Information Must Be Provided Truthfully. All Applicants shall submit information to the Division in a full, faithful, truthful, and fair manner. The Division may recommend denial of an application where the Applicant made misstatements, omissions, misrepresentations, or untruths in the application or in connection with the Applicant's background investigation. This type of conduct may be considered as the basis for additional administrative action against the Applicant and it may also be the basis for criminal charges against the Applicant.
- D. Application Forms Accessible. All application forms supplied by the Division and filed by an Applicant for a license, including attachments and any other documents associated with the investigation, may be used for a purpose authorized by the Medical Code, the Retail Code, or for any other state or local law enforcement purpose or as otherwise required by law.
- E. Division Application Management and Local Licensure.
1. For each application for a new Medical Marijuana Business, the Applicant shall submit the original application and one identical copy. The Division will retain the original application for a new Medical Marijuana Business and will send the copy to the local licensing authority.
  2. If the Division grants a license before the local licensing authority approves the application or grants a local license, the license will be conditioned upon local approval. Such condition will not be viewed as a denial pursuant to the Administrative Procedure Act. If the local licensing authority denies the application, the state license will be revoked.
  3. An Applicant is prohibited from operating a Medical Marijuana Business prior to obtaining all necessary licenses, registrations or approvals from both the State Licensing Authority and the local licensing authority.
  4. Each Financial Interest is void and of no effect unless and until approved by the Division. A Financial Interest shall not exercise any privilege associated with the proposed interest until approved by the Division. Any violation of this requirement may be considered a license or registration violation affecting public safety.

**M 201.5 – Repealed effective January 1, 2017.**

**M 202 – Repealed effective January 1, 2017.**

**Basis and Purpose – M 202.1**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XVIII.5), 12-43.3-202(2)(a)(XX), 12-43.3-202(2)(a)(XXI), and sections 12-43.3-104, 12-43.3-305 and 12-43.3-306, 12-43.3-307.5, 12-43.3-310 and 12-43.3-313 C.R.S. The purpose of this rule is to clarify the process to be followed when a Medical Marijuana Business applies to obtain financing or otherwise have a relationship with an Indirect Beneficial Interest Owner. This rule establishes that only materially complete Medical Marijuana Business applications for Indirect Beneficial Interest Owners, accompanied by all required fees, will be accepted and processed by the Division. This rule also clarified that when an initial application is materially complete and accepted, but the Division determines further information is required before the application can be fully processed, the Medical Marijuana Business Applicant must provide the additional requested information within the time frame provided by the Division. Otherwise, the Division cannot act on the application in a timely manner and the Medical Marijuana Business' application may be denied. The rule also sets forth requirements for the contents of the contract or Agreement between Medical Marijuana Businesses and Indirect Beneficial Interest Owners, which reflect basic legal requirements surrounding the relationship between the parties.

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

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

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

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

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

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

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

1. The documents establishing the Profit-Sharing Plan must be complete and must fully incorporate all terms and conditions.
2. The following provisions must be included in the documents establishing the Profit-Sharing Plan:
  - a. Any interest in a Medical Marijuana Business, whether held by a Profit-Sharing Plan Employee or any other person, must be acquired in accordance with the provisions of the Medical Code and/or Retail Code, as applicable, and the rules promulgated thereunder. The issuance of any contract or other interest in violation thereof shall be void. Any distributions from a Profit-Sharing Plan must be made in cash, not in the form of stock or other equity interests in the Medical Marijuana Business.
  - b. No contract or other interest issued by the Medical Marijuana Business and no claim or charge therein or thereto shall be transferred except in accordance with the provisions of the Medical Code and/or Retail Code as applicable, and the rules promulgated thereunder. Any transfer in violation thereof shall be void.
  - c. The Medical Marijuana Business shall disclose in writing to the Division any and all disqualifying events, within ten days after receiving notice of the event, which would lead to a finding that any Profit-Sharing Plan Employee does not qualify under the Medical Code and these rules, including but not limited to Rule M 231.2(B), to participate in the Profit-Sharing Plan.
  - d. A Profit-Sharing Plan Employee shall disclose in writing to the Division and to the Medical Marijuana Business any and all disqualifying events, within ten days after occurrence of the event that could lead to a finding that the Profit-Sharing Plan Employee does not qualify or no longer qualifies under the Medical Code and these rules, including but not limited to Rule M 231.2(B), to participate in the Profit-Sharing Plan.
  - e. A Medical Marijuana Business' or a Profit-Sharing Plan Employee's failure to make required disclosures may lead to a finding that the Profit-Sharing Plan is not approved, and may lead to a requirement that the Medical Marijuana Business terminate or modify the Profit-Sharing Plan.

- f. The Profit-Sharing Plan Employee agrees and acknowledges that its relationship with the Medical Marijuana Business is contingent upon Division approval throughout the entire term of its relationship with the Medical Marijuana Business. The Profit-Sharing Plan Employee understands and acknowledges that approval by the Division is wholly discretionary and the Division may, at any time, deny approval of the Profit-Sharing Plan. The Profit-Sharing Plan Employee agrees and acknowledges he or she has no entitlement to or expectation to Division approval of the Profit-Sharing Plan or the Profit-Sharing Plan Employee's participation in the plan. The Profit-Sharing Plan Employee further agrees that any administrative or judicial review of a determination by the Division approving or denying the Profit-Sharing Plan or the Profit-Sharing Plan Employee will only occur through licensing or enforcement proceedings involving the Medical Marijuana Business. Each Profit-Sharing Plan Employee further agrees and acknowledges that the Profit-Sharing Plan Employee shall only be entitled to notice of a denial or administrative action concerning the Medical Marijuana Business if the denial or administrative action is based upon, or directly related to, the qualifications or actions of the Profit-Sharing Plan Employee. The Profit-Sharing Plan Employee also agrees and acknowledges that the Profit-Sharing Plan Employee may only request leave to intervene in an administrative proceeding against the Medical Marijuana Business, pursuant to subsection 24-4-105(2)(c), C.R.S., if the administrative proceeding is based upon, or directly related to, the qualifications or actions of the Profit-Sharing Plan Employee. Furthermore, the Profit Sharing Plan Employee agrees and acknowledges that the Profit-Sharing Plan Employee may only seek judicial review of an action against the Medical Marijuana Business, pursuant to subsection 24-4-106(4), C.R.S., if the administrative action is based upon, or directly related to, the qualifications or actions of the Profit-Sharing Plan Employee. THE PROFIT-SHARING PLAN EMPLOYEE KNOWINGLY, FREELY, AND VOLUNTARILY WAIVES ANY RIGHT OR CLAIM TO SEEK ANY INDEPENDENT REVIEW OF APPROVAL OR DENIAL OF THE PROFIT-SHARING PLAN OR THE PROFIT-SHARING PLAN EMPLOYEE BY THE DIVISION, OR OF AN ADMINISTRATIVE ACTION AGAINST THE MEDICAL MARIJUANA BUSINESS, THAT IS BASED UPON, OR DIRECTLY RELATED TO, THE PROFIT-SHARING PLAN OR THE PROFIT-SHARING PLAN EMPLOYEE'S QUALIFICATIONS OR ACTIONS OF THE PROFIT-SHARING PLAN EMPLOYEE, AND EXPRESSLY AGREES THAT THE ONLY ADMINISTRATIVE OR JUDICIAL REVIEW OF SUCH A DETERMINATION OR ACTION WILL OCCUR THROUGH A LICENSING OR ENFORCEMENT PROCEEDING FOR THE MEDICAL MARIJUANA BUSINESS.

- K. Qualified Institutional Investor Requirements. Before a Medical Marijuana Business may permit a Qualified Institutional Investor to own any portion of the Medical Marijuana Business, the Medical Marijuana Business must submit the following documentation to the Division in connection with the Medical Marijuana Business' application:

1. A description of the Qualified Institutional Investor's business and a statement as to why the Qualified Institutional Investor meets the definition of Qualified Institutional Investor in Rule R 103 and subsection 12-43.3-307.5(7), C.R.S.
2. A certification made under oath and the penalty of perjury by the Qualified Institutional Investor:

- a. That the ownership interests were acquired and are held for investment purposes only and were acquired and are held in the ordinary course of business as a Qualified Institutional Investor and not for the purposes of causing, directly or indirectly, the election of a majority of the board of directors, any change in the corporate charter, bylaws, management, policies, or operations of a Medical Marijuana Business.
- b. That the Qualified Institutional Investor is bound by and shall comply with the Medical Code and the rules adopted pursuant thereto, is subject to the jurisdiction of the courts of Colorado, and consents to Colorado as the choice of forum in the event any dispute, question, or controversy arises regarding the Qualified Institutional Investor's relationship with the Medical Marijuana Business or activities pursuant to the Medical Code and rules adopted pursuant thereto.
- c. The Qualified Institutional Investor agrees and acknowledges that its relationship with the Medical Marijuana Business is contingent upon Division approval throughout the entire term of its relationship with the Medical Marijuana Business. The Qualified Institutional Investor understands and acknowledges that approval by the Division is wholly discretionary and the Division may, at any time, deny approval of the Qualified Institutional Investor. The Qualified Institutional Investor agrees and acknowledges it has no entitlement to or expectation to Division approval of the Qualified Institutional Investor. The Qualified Institutional Investor further agrees that any administrative or judicial review of a determination by the Division approving or denying the Qualified Institutional Investor will only occur through licensing or enforcement proceedings involving the Medical Marijuana Business. The Qualified Institutional Investor further agrees and acknowledges that the Qualified Institutional Investor shall only be entitled to notice of a denial or administrative action concerning the Medical Marijuana Business if the denial or administrative action is based upon, or directly related to, the qualifications or actions of the Qualified Institutional Investor. The Qualified Institutional Investor also agrees and acknowledges that the Qualified Institutional Investor may only request leave to intervene in an administrative proceeding against the Medical Marijuana Business, pursuant to subsection 24-4-105(2)(c), C.R.S., if the administrative proceeding is based upon, or directly related to, the qualifications or actions of the Commercially Reasonable Royalty Interest Holder. Furthermore, the Qualified Institutional Investor agrees and acknowledges that the Qualified Institutional Investor may only seek judicial review of an action against the Medical Marijuana Business, pursuant to subsection 24-4-106(4), C.R.S., if the administrative action is based upon, or directly related to, the qualifications or actions of the Commercially Reasonable Royalty Interest Holder. THE QUALIFIED INSTITUTIONAL INVESTOR KNOWINGLY, FREELY, AND VOLUNTARILY WAIVES ANY RIGHT OR CLAIM TO SEEK ANY INDEPENDENT REVIEW OF APPROVAL OR DENIAL OF THE COMMERCIALLY REASONABLE INTEREST BY THE DIVISION, OR OF AN ADMINISTRATIVE ACTION AGAINST THE MEDICAL MARIJUANA BUSINESS, THAT IS BASED UPON, OR DIRECTLY RELATED TO, THE QUALIFICATIONS OR ACTIONS OF THE COMMERCIALLY REASONABLE ROYALTY INTEREST HOLDER, AND EXPRESSLY AGREES THAT THE ONLY ADMINISTRATIVE OR JUDICIAL REVIEW OF SUCH A DETERMINATION OR ACTION WILL OCCUR THROUGH A LICENSING OR ENFORCEMENT PROCEEDING FOR THE MEDICAL MARIJUANA BUSINESS.
- d. An explanation of the basis of the signatory's authority to sign the certification and to bind the Qualified Institutional Investor to its terms.

3. The name, address, telephone number and any other information requested by the Division as required on its approved forms for the officers and directors, or their equivalent, of the Qualified Institutional Investor as well as those Persons that have direct control over the Qualified Institutional Investor's ownership interest in the Medical Marijuana Business.
4. The name, address, telephone number and any other information requested by the Division as required on its approved forms for each Person who has the power to direct or control the Qualified Institutional Investor's voting of its shares in the Medical Marijuana Business.
5. The name of each Person that beneficially owns 5 percent or more of the Qualified Institutional Investor's voting securities or other equivalent.
6. A list of the Qualified Institutional Investor's affiliates.
7. A list of all regulatory agencies with which the Qualified Institutional Investor files periodic reports, and the name, address, and telephone number of the individual, if known, to contact at each agency regarding the Qualified Institutional Investor.
8. A disclosure of all criminal or regulatory sanctions imposed during the preceding 10 years and of any administrative or court proceedings filed by any regulatory agency during the preceding 5 years against the Qualified Institutional Investor, its affiliates, any current officer or director, or any former officer or director whose tenure ended within the preceding 12 months. As to a former officer or director, such information need be provided only to the extent that it relates to actions arising out of or during such person's tenure with the Qualified Institutional Investor or its affiliates.
9. A copy of any filing made under 16 U.S.C § 18a with respect to the acquisition or proposed acquisition of an ownership interest in the Medical Marijuana Business.
10. Any additional information requested by the Division.

**M 202.5 – Repealed Effective January 1, 2017.**

**Basis and Purpose – M 203**

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)(XVIII.5), 12-43.3-202(2)(a)(XX), 12.43.3-307(2)(c), and 12-43.3-310(7) and sections 12-43.3-104 and 12-43.3-311, C.R.S. The purpose of this rule is to establish how licenses can be renewed.

**M 203 – Process for Renewing a License: Medical Marijuana Businesses**

**A. General Process for License Renewal**

1. The Division will send a notice for license renewal 90 days prior to the expiration of an existing license by first class mail to the Licensee's mailing address of record.
2. A Licensee may apply for the renewal of an existing license not less than 30 days prior to the license's expiration date. If a Licensee timely applies for the renewal of an existing license, the Division may administratively continue the license beyond the expiration date while it completes the renewal licensing process.

3. If the Licensee files a renewal application within 30 days prior to expiration, the Licensee must provide a written explanation detailing the circumstances surrounding the untimely filing. If the Division accepts the application, then the Division may elect to administratively continue the license beyond the expiration date while it completes the renewal licensing process.
  4. An application for renewal will only be accepted if it is accompanied by:
    - a. The requisite licensing fees. See Rule M 209 - Schedule of Business License Renewal Fees: Medical Marijuana Businesses.
    - b. A copy of the local licensing authority's approval.
  5. Each Direct Beneficial Interest Owner required to have an Associated Key License must be fingerprinted at least every two years, and may be fingerprinted more often at the Division's discretion.
  6. The Division shall perform a limited background check, which may include fingerprinting, regarding Qualified Limited Passive Investors and other Financial Interests that are Indirect Beneficial Interest Owners. If the background check provides reasonable cause for additional investigation, the Division may require additional investigation.
  7. For each renewal application, the Licensee shall submit the original application and one identical copy. The Division will retain the original renewal application and will send the copy to the local licensing authority.
- B. Failure to Receive a Notice for License Renewal. Failure to receive a notice for license renewal does not relieve a Licensee of the obligation to renew all licenses as required.
- C. If License Not Renewed Before Expiration or Administratively Continued. A license is immediately invalid upon expiration if the Licensee has not filed a renewal application and remitted all of the required fees.
1. In the event the license is not renewed prior to expiration, a Medical Marijuana Business may not operate unless it has been administratively continued.
  2. If a former Medical Marijuana Business Licensee files an application within 90 days of expiration of its license with the Division and pays the requisite fees to the Division, the Division may administratively continue the license from the date the application was received until it can complete its renewal application process and investigate the extent to which the Medical Marijuana Business operated with an expired license.
  3. The Division will not renew any Medical Marijuana Business license expired over 90 days prior to submission of the Medical Marijuana Business Licensee's renewal application, nor will it renew any license that has been voluntarily surrendered, or any license that has been revoked. A Medical Marijuana Business license that expired over 90 days prior to submission of the Medical Marijuana Business Licensee's renewal application, a license that has been voluntarily surrendered, and a license that has been revoked may only be reinstated via an application for a new license that is subsequently approved by the Division or the State Licensing Authority.

- D. Licenses Subject to Ongoing Discipline and/or Summary Suspension. Licenses that are the subject of a summary suspension, a disciplinary action, and/or any other administrative action are subject to the requirements of this rule. Licenses that are not timely renewed shall expire. See Rules M 1301 – Disciplinary Process: Non-Summary Suspension and M 1302 – Disciplinary Process: Summary Suspensions.
- E. Closely Held Business Entity Direct Beneficial Interest Owners. Closely Held Business Entity Direct Beneficial Interest Owners must submit a current Division certification form, signed by all Direct Beneficial Interest Owner(s) of the Medical Marijuana Business certifying that each Associated Key License owner of the Closely Held Business Entity has maintained, and currently maintains, United States citizenship.
- F. Indirect Beneficial Interest Owners and Qualified Limited Passive Investors. At the time of renewal, a Medical Marijuana Business shall disclose any and all Indirect Beneficial Interest Owners and Qualified Limited Passive Investors that hold an interest in the Medical Marijuana Business. Additionally, the Medical Marijuana Business must present updated information regarding all Indirect Beneficial Interest Owners and Qualified Limited Passive Investors at the time the Medical Marijuana Business submits its renewal materials:
1. Current Division Indirect Beneficial Interest Owners and Qualified Limited Passive Investors renewal disclosure forms;
  2. Current Division form allowing the Division to investigate any Indirect Beneficial Interest Owner(s) and/or Qualified Limited Passive Investor(s) if the Division deems such investigation necessary. The form shall be signed by all Direct Beneficial Interest Owner(s) of the Medical Marijuana Business;
  3. Permitted Economic Interest holders, at the discretion of the Division, may be required to submit new fingerprints;
  4. Current Division certification form attesting that all Qualified Limited Passive Investor(s) and/or Indirect Beneficial Interest Owner(s) remain qualified under the Medical Code and these rules. The form shall be signed by all Direct Beneficial Interest Owner(s) of the Medical Marijuana Business;
  5. For Permitted Economic Interest Holder, current Division certification form, signed by all Direct Beneficial Interest Owner(s) of the Medical Marijuana Business and the particular Permitted Economic Interest holder, certifying that he or she has maintained, and currently maintains, lawful residence in the United States; and
  6. For Qualified Limited Passive Investors, current Division certification form, signed by all Direct Beneficial Interest Owner(s) of the Medical Marijuana Business and the particular Qualified Limited Passive Investor, certifying that he or she has maintained, and currently maintains, United States citizenship.

#### **Basis and Purpose – M 204**

The statutory authority for this rule is found at subsections 12-43.3-104(1), 12-43.3-104(1.7), 12-43.3-104(12.4), 12-43.3-104(14.3), 12-43.3-202(1)(b)(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)(a)(XXI), and 12-43.3-310(7) and (11), and sections 12-43.3-307.5, 12-43.3-313 and 12-43.3-601, C.R.S. The purpose of this rule is to provide clarity regarding the nature of a Direct Beneficial Interest Owner and an Indirect Beneficial Interest Owner, and to clarify what factors the State Licensing Authority generally considers regarding the same. The Division will review all relevant information to determine ownership of a Medical Marijuana Business.

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**M 204 – Ownership Interests of a License: Medical Marijuana Businesses**

- A. Licenses Held By Direct Beneficial Interest Owners. Each Medical Marijuana Business License must be held by its Direct Beneficial Interest Owner(s). Each natural person other than a Qualified Limited Passive Investor must hold an Associated Key License. A Direct Beneficial Interest Owner shall not be a publicly traded company.
- B. 100% Ownership.
1. The sum of the percentages of ownership of all Direct Beneficial Interest Owners of a Medical Marijuana Business and Qualified Institutional Investors must equal 100%.
    - a. Qualified Institutional Investors may hold ownership interests, in the aggregate, of 30% or less in the Medical Marijuana Business.
    - b. A Qualified Limited Passive Investor must be a natural person who is a United States citizen and may hold an ownership interest of less than five percent in the Medical Marijuana Business.
    - c. Each Direct Beneficial Interest Owner, including but not limited to each officer, director, managing member, or partner of a Medical Marijuana Business, must hold a current and valid Associated Key License. See Rule M 233 – Retail Code or Medical Code Occupational Licenses Required. Except that this requirement shall not apply to Qualified Limited Passive Investors.
    - d. With the exception of Qualified Institutional Investors, only Direct Beneficial Interest Owners may hold a partnership interest, limited or general, a joint venture interest, or ownership of a share or shares in a corporation or a limited liability company which is licensed.
    - e. In the event of the death, disability, disqualification, divestment, termination, or revocation of the license of a Direct Beneficial Interest Owner or of approval of a Qualified Institutional Investor, a Medical Marijuana Business shall have 45 days to submit a change of ownership application to the Division detailing the Licensee's plan for redistribution of ownership among the remaining Direct Beneficial Interest Owners and Qualified Institutional Investors. Such plan is subject to approval by the Division. If a change of ownership application is not timely submitted, the Medical Marijuana Business and its Associated Key Licensee(s) may be subject to administrative action.
- C. At Least One Associated Key License Required. No Medical Marijuana Business may operate or be licensed unless it has at least one Associated Key Licensee that is a Direct Beneficial Interest Owner who has been a Colorado resident for at least one year prior to application. Any violation of this requirement may be considered a license violation affecting public safety.
- D. Loss Of Occupational License As An Owner Of Multiple Businesses. If an Associated Key License is suspended or revoked as to one Medical Marijuana Business or Retail Marijuana Establishment, that Owner's Occupational License shall be suspended or revoked as to any other Medical Marijuana Business or Retail Marijuana Establishment in which that Person possesses an ownership interest. See Rule M 233 – Medical Code or Retail Code Occupational Licenses Required.
- E. Management Companies. Any Person contracted to manage the overall operation of a Licensed Premises must hold a Medical Marijuana Operator license.

- F. Role of Managers. Associated Key Licensees may hire managers, and managers may be compensated on the basis of profits made, gross or net. A Medical Marijuana Business license may not be held in the name of a manager who is not a Direct Beneficial Interest Owner. A manager who does not hold an Associated Key License as a Direct Beneficial Interest Owner of the Medical Marijuana Business, must hold a Key License as an employee of the Medical Marijuana Business. Any change in manager must be reported to the Division and any local licensing authority before the new manager begins managing the Medical Marijuana Business. Additionally, a Medical Marijuana Operator may include management services as part of the operational services provided to a Medical Marijuana Business. A Medical Marijuana Business and its Direct Beneficial Interest Owners may be subject to license denial or administrative action, including but not limited to, fine, suspension or revocation of their license(s), based on the acts and omissions of any manager, Medical Marijuana Business Operator, or agents and employees thereof engaged in the operations of the Medical Marijuana Business.

#### **Basis and Purpose – M 204.5**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(I), 12-43.3-202(2)(a)(XVIII.5), 12-43.3-202(2)(a)(XX), 12-43.3-202(2)(a)(XXI) and 12-43.3-202(3)(a)(XVI) and sections 12-43.3-104, 12-43.3-305, 12-43.3-307, 12-43.3-307.5, 12-43.3-309, 12-43.3-310, 12-43.3-311 and 12-43.3-313, C.R.S. The purpose of this rule is to clarify the application, review and approval process for various types of Business Interests. The Division will review all relevant information to determine ownership of, interests in, and control of a Medical Marijuana Business.

#### **M 204.5 – Disclosure, Approval and Review of Business Interests**

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

3. Control. Any other Person who exercises control or is positioned so as to enable the exercise of control over the Medical Marijuana Business must hold an Associated Key License. A natural person who exercises control or is positioned so as to enable the exercise of control over a Medical Marijuana Business shall include but shall not be limited to a natural person who:
  - a. Bears the risk of loss and opportunity for profit; Bears the risk of loss and opportunity for profit;
  - b. Has final decision making authority over any material aspect of the operation of the Medical Marijuana Business;
  - c. Manages the overall operations of a Medical Marijuana Business or its Licensed Premises, or who manages a material portion of the Medical Marijuana Business or its Licensed Premises;
  - d. Guarantees the Medical Marijuana Business' debts or production levels;
  - e. Is a beneficiary of the Medical Marijuana Business' insurance policies;
  - f. Receives the majority of the Medical Marijuana Business' profits as compared to other recipients of the Medical Marijuana Business' profits; or
  - g. Acknowledges liability for the Medical Marijuana Business' federal, state or local taxes.
  
- C. Affiliated Interests. A Medical Marijuana Business shall disclose all Affiliated Interests in connection with each application for licensure, renewal or reinstatement of the Medical Marijuana Business. The Division may conduct such background investigation as it deems appropriate regarding Affiliated Interests. An Affiliated Interest shall include any Person who does not hold a Financial Interest in the Medical Marijuana Business and who has any of the following relationships with the Medical Marijuana Business:
  1. The following Indirect Beneficial Interest Owners:
    - a. A Commercially Reasonable Royalty Interest Holder who receives 30 percent or less of the gross revenue or gross profit from sales of the product or line of products subject to the royalty;
    - b. A Profit Sharing Plan Employee; and
    - c. A Qualified Institutional Investor.
    - d.
  
  2. Any other Person who holds any other disclosable interest in the Medical Marijuana Business other than a Financial Interest. Such disclosable interests shall include but shall not be limited to a lease agreement, a secured or unsecured loan, or security interest in fixtures or equipment with a direct nexus to the cultivation, manufacture, sale, transportation, or testing of Medical Marijuana or Medical Marijuana Products. If the Division determines any Person disclosed as an Affiliated Interest should have been pre-approved as a Financial Interest, approval and further background investigation may be required. Additionally, the failure to seek pre-approval of a Financial Interest holder may form the basis for license denial or administrative action against the Medical Marijuana Business.

- D. Secured Interest In Marijuana Prohibited. No Person shall at any time hold a secured interest in Medical Marijuana or Medical Marijuana Products.

**Basis and Purpose – M 205**

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)(XVIII.5), 12-43.3-202(2)(a)(XX), 12-43.3-202(2)(a)(XXI), 12-43.3-310(7), 12-43.3-310(11), and sections 12-43.3-104, 12-43.3-305, 12-43.3-306, 12-43.3-309, 12-43.3-406 and 24-76.5-101 et. seq., C.R.S. The purpose of this rule is to establish protocol for ownership transfers. In addition, the rule clarifies that a business cannot use the transfer of ownership process in order to circumvent the administrative disciplinary process and that an ongoing investigation or disciplinary action may: (1) constitute grounds to deny a transfer of ownership request; (2) constitute grounds to delay a transfer of ownership request, or (3) mandate that the new business owner is responsible for any imposed sanction.

**M 205 – Transfer of Ownership and Changes in Business Structure: Medical Marijuana Businesses**

A. General Requirements

1. All applications for transfers of Direct Beneficial Interest Owners or changes in corporate structure by licensed Medical Marijuana Businesses authorized pursuant to section 12-43.3-401, C.R.S., shall be made upon current forms prescribed by the Division. Each application shall identify the relevant local licensing authority.
2. All applications for transfers of ownerships and changes in licensed entities by Medical Marijuana Businesses must include application fees, be complete in every material detail, and be filled out truthfully.
3. All applications for transfers of ownership and changes in licensed entities by Medical Marijuana Businesses must be submitted to the State Licensing Authority or its designee and relevant local licensing authority 30 days prior to any requested transfer or change.
4. Each Applicant for a transfer of ownership shall provide suitable evidence as required by the Division, in accordance with these rules and the Medical Code, of each natural person's proof of lawful presence, citizenship, residence, good character and reputation and verification that funds used to invest in or finance the Medical Marijuana Business were lawfully earned or obtained. Each Applicant shall also provide all requested information concerning financial and management associations and interests of other Persons in the business, Department of Revenue tax payment information, the deed, lease, contract, or other document governing the terms and conditions of occupancy of the Licensed Premises. Nothing in this section is intended to limit the Division's ability to request additional information it deems necessary to determining an Applicant's suitability for licensure.
5. Failure to provide such additional information by the requested deadline may result in denial of the application.
6. The Applicant shall provide the original and one copy of an application for transfer of ownership to the Division. The Division will retain the original application and send the copy to the relevant local licensing authority. See Rule M 1401 - Instructions for Local Licensing Authorities and Law Enforcement Officers.

7. The Division will not approve a transfer of ownership application without first receiving written notification that the Applicant disclosed the transfer of ownership to the relevant local licensing authority. If a local licensing authority elects not to approve or deny a transfer of ownership application, the local licensing authority must provide written notification acknowledging receipt of the application and the State Licensing Authority shall revoke the state-issued license.
8. The Applicant(s), or proposed transferee(s), for any license shall not operate the Medical Marijuana Business identified in the transfer of ownership application until the transfer of ownership request is approved in writing by the Division. A violation of this requirement shall constitute grounds to deny the transfer of ownership request, may be a violation affecting public safety, and may result in disciplinary action against the Applicant's existing license(s), if applicable.
9. All current Direct Beneficial Interest Owner(s), or proposed transferor(s), of the license(s) at issue retain full responsibility for the Medical Marijuana Business identified in the transfer of ownership application until the transfer of ownership request is approved in writing by the Division. A violation of this requirement shall constitute grounds to deny the transfer of ownership request, may be a violation affecting public safety, and may result in disciplinary action against the license(s) of the current Direct Beneficial Interest Owner(s) and/or the Medical Marijuana Business.
10. If a Medical Marijuana Business or any of its Direct Beneficial Interest Owners applies to transfer ownership and is involved in an administrative investigation or administrative disciplinary action, the following may apply:
  - a. The transfer of ownership may be delayed or denied until the administrative action is resolved; or
  - b. If the transfer of ownership request is approved in writing by the Division, the transferee may be responsible for the actions of the Medical Marijuana Business and its prior Direct Beneficial interest Owners, and subject to discipline based upon the same.
11. Licensee Initiates Change of Ownership for Permitted Economic Interests. All individuals holding a Permitted Economic Interest who seek to convert to become a Direct Beneficial Interest Owner are subject to this Rule M 205. The Medical Marijuana Business must initiate the change of ownership process for an individual holding a Permitted Economic Interest who seeks to convert its interest to become a Direct Beneficial Interest Owner. Permitted Economic Interest holders who are not qualified to become a Direct Beneficial Interest Owner shall not be allowed to convert.
12. Medical Marijuana Transporters Not Eligible. Medical Marijuana Transporters are not eligible to apply for change of ownership.

- B. As It Relates to Corporations and Limited Liability Companies
1. If the Applicant is a corporation or limited liability company, it shall submit with the application the names, mailing addresses, and background forms of all of its officers, directors, and Direct and Indirect Beneficial Interest Owners; a copy of its articles of incorporation or articles of organization; and evidence of its authorization to do business within this State. In addition, each Applicant shall submit the names, mailing addresses, and where applicable, certifications of residency or citizenship for all Persons owning any of the outstanding or issued capital stock, or holding a membership interest. No publicly traded company may be identified as the proposed recipient of any ownership interest in a Medical Marijuana Business.
  2. Any proposed transfer of capital stock, regardless of the number of shares of capital stock transferred, shall be reported and approved by the State Licensing Authority or its designee and the local licensing authority at least 30 days prior to such transfer or change.
- C. As It Relates to Partnerships. If the Applicant is a general partnership, limited partnership, limited liability partnership, or limited liability limited partnership, it shall submit with the application the names, mailing addresses, and background forms and, where applicable, certification of residency or citizenship for all of its partners and a copy of its partnership agreement.
- D. As It Relates to Entity Conversions. Any Licensee that qualifies for an entity conversion pursuant to sections 7-90-201, C.R.S., *et. seq.*, shall not be required to file a transfer of ownership application pursuant to section 12-43.3-309, C.R.S., upon statutory conversion, but shall submit a report containing suitable evidence of its intent to convert at least 30 days prior to such conversion. Such evidence shall include, but not be limited to, any conversion documents or agreements for conversion at least ten days prior to the date of recognition of conversion by the Colorado Secretary of State. The Licensee shall submit to the Division the names and mailing addresses of any officers, directors, general or managing partners, and all Direct and Indirect Beneficial Interest Owners.
- E. Approval Required. It may be considered a license violation affecting public safety if a Licensee engages in any transfer of ownership without prior approval from the Division and the relevant local licensing authority.
- F. Applications for Reinstatements Deemed New Applications. The Division will not accept an application for transfer of ownership if the license to be transferred is expired for more than 90 days, is voluntarily surrendered, or is revoked. See Rule M 201 – Application Process.

### **Basis and Purpose – M 206**

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

### **M 206 – Changing Location of the Licensed Premises: Medical Marijuana Businesses**

- A. Application Required to Change Location of Licensed Premises
1. A Direct Beneficial Interest Owner or other authorized representative of a Medical Marijuana Business must make application to the Division for permission to change location of its Licensed Premises.

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

**B. Permit Required Before Changing Location**

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

**C. General Requirements**

1. An application for change of location to a different local licensing authority shall follow the same procedures as an application for a new Medical Marijuana Business license. See Rule M 201 – Application Process.
2. An Applicant for change of location shall file a change of location application with the Division and pay the requisite change of location fee. See Rule M 207 - Schedule of Application Fees: Medical Marijuana Businesses.

**Basis and Purpose – M 207**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(a), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XVIII.5), 12-43.3-202(2)(a)(XX), and 12-43.3-401(1)(a)-(e), and sections, 12-43.3-104, 12-43.3-310, 12-43.3-401, 12-43.3-501, and 12-43.3-502, C.R.S. The purpose of this rule is to clarify the schedules of application fees for Medical Marijuana Business Applicants.

**M 207 – Schedule of Application Fees: Medical Marijuana Businesses**

A. Base Medical Marijuana Application Fees

1. Medical Marijuana Center Application Fees

- a. Type 1 Center (1-300 patients) - \$6,000.00
- b. Type 2 Center (301-500 patients) - \$10,000.00
- c. Type 3 Center (501 or more patients) - \$14,000.00

2. Medical Marijuana-Infused Products Manufacturer Application Fee - \$1,000.00

3. Optional Premises Cultivation Location Application Fee - \$1,000.00

4. Medical Marijuana Testing Facility Application Fee - \$1,000.00

5. Medical Marijuana Transporter Application Fee - \$1,000.00

6. Medical Marijuana Business Operator Registration Application Fee - \$1,000.00

7. Medical Marijuana Businesses Converting to Retail Marijuana Establishments. Medical Marijuana Center Applicants or Licensees that want to convert to Retail Marijuana Establishments should refer to 1 CCR 212-2, Rule R 207 – Schedule of Application Fees: Retail Marijuana Establishments.

B. Medical Marijuana Business Application Fees for Indirect Beneficial Interest Owners, Qualified Limited Passive Investors and Other Affiliated Interests

1. Affiliated Interest that is not an Indirect Beneficial Interest Owner - \$200.00

2. Commercially Reasonable Royalty Interest Holder receiving more than 30 percent of the gross revenue or gross profit from the sales of the product or lines of products subject to the royalty - \$400.00

3. Commercially Reasonable Royalty Interest Holder receiving less than or equal to 30 percent of the gross revenue or gross profit from the sales of the product or lines of product subject to the royalty - \$200.00

4. Permitted Economic Interest - \$400.00

5. Employee Profit Sharing Plan - \$200.00

6. Qualified Limited Passive Investor

- a. Standard limited initial background check - \$75.00

- b. Full background check for reasonable cause - \$125.00
- 7. Qualified Institutional Investor - \$200.00
- C. When Application Fees Are Due. All application fees are due at the time a Medical Marijuana Business submits an application and/or at the time a Medical Marijuana Business submits an application for a new Financial Interest.

**Basis and Purpose – M 208**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(a), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX) and 12-43.3-302(5)(c), 12-3.3-401(1)(a)-(e), and sections 12-43.3-104, 12-43.3-310, and 12-43.3-501, and 12-43.3-502, C.R.S. The purpose of this rule is to establish basic requirements for all Division applications and help the regulated community understand procedural licensing and registration requirements.

**M 208 – Schedule of Business License and Registration Fees: Medical Marijuana Businesses**

- A. Medical Marijuana Center License Fees
  - 1. Type 1 Center (1-300 patients) - \$3,000.00
  - 2. Type 2 Center (301-500 patients) - \$6,000.00
  - 3. Type 3 Center (501 or more patients) - \$8,000.00
- B. Medical Marijuana-Infused Products Manufacturer License Fee- \$1,500.00
- C. Optional Premises Cultivation Location License Fee- \$1,500.00
- D. Medical Marijuana Testing Facility License Fee - \$1,500.00
- E. Medical Marijuana Transporter License Fee - \$4,400.00
- F. Medical Marijuana Business Operator Registration Fee - \$2,200.00
- G. When License and Registration Fees Are Due. All license and registration fees are due at the time an application is submitted.
- H. If Application is Denied. If an application is denied, an Applicant may request that the State Licensing Authority refund the license or registration fee after the denial appeal period has lapsed or after the completion of the denial appeal process, whichever is later

**Basis and Purpose – M 209**

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

**M 209 – Schedule of Business License and Registration Renewal Fees: Medical Marijuana Businesses**

- A. Renewal Fee Amount and Due Date. The renewal fee shall be \$300 for each renewal application. Renewal license and processing fees are due at the time the renewal application is submitted.
- B. Medical Marijuana Center Renewal Fees.
1. Type 1 Center – \$2,000.00
  2. Type 2 Center – \$5,000.00
  3. Type 3 Center – \$7,000.00
  4. Medical Marijuana-Infused Products Manufacturer - \$1,500.00
  5. Optional Premises Cultivation - \$1,500.00
  6. Medical Marijuana Testing Facility - \$1,500.00
- C. Medical Marijuana Transporter License - \$4,400.00
- D. Medical Marijuana Business Operator Registration - \$2,200.00
- E. If Renewal Application is Denied. If an application for renewal is denied, an Applicant may request that the State Licensing Authority refund the license or registration fee after the denial appeal period has lapsed or after the completion of the denial appeal process, whichever is later.

**Basis and Purpose – M 210**

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

**M 210 – Schedule of Other Application Fees: All Licensees**

- A. Other Application Fees. The following other application fees apply:
1. Transfer of Ownership - New Owners - \$1,600.00
  2. Transfer of Ownership - Reallocation of Ownership - \$1,000.00
  3. Change of Corporation or LLC Structure - \$800.00/Person
  4. Change of Trade Name - \$50.00
  5. Change of Location Application Fee - Same Local Jurisdiction Only - \$500.00
  6. Modification of Licensed Premises - \$100.00
  7. Duplicate Business License - \$20.00
  8. Duplicate Occupational License - \$20.00

9. Off Premises Storage Permit - \$1,500.00
  10. Medical Marijuana Transporter Off Premises Storage Permit - \$2,200.00
  11. Responsible Vendor Program Provider Application Fee: \$850.00
  12. Responsible Vendor Program Provider Renewal Fee: \$350.00
  13. Responsible Vendor Program Provider Duplicate Certificate Fee: \$50.00
- B. When Other Application Fees Are Due. All other application fees are due at the time the application and/or request is submitted.
- C. Subpoena Fee - See Rule M 106 – Subpoena Fees

### **Basis and Purpose – M 211**

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX) and 12-43.4-202(4)(b)(I)(A), and sections 12-43.4-104 and 12-43.3-501, C.R.S. The purpose of this rule is to clarify that, with the exception of Medical Marijuana Testing Facilities, Medical Marijuana Business Operators and Medical Marijuana Business Transporters, existing Medical Marijuana Businesses may apply to convert a Medical Marijuana Business License to a Retail Marijuana Establishment License or may apply to obtain one additional license to operate a Retail Marijuana Establishment. It is important to note that the State Licensing Authority considers each license issued as separate and distinct. Each license, whether it is in the same location or not, is fully responsible to maintain compliance with all statutes and rules promulgated regardless of whether or not they are located in a shared address.

A Medical Marijuana Business may only obtain one Retail Marijuana Establishment License, whether it converts the Medical Business License or obtains a Retail Marijuana Establishment License, for each Medical Marijuana Business License it holds. In order to ensure all Retail Marijuana and Retail Marijuana Product are tracked in the Inventory Tracking System and as a condition of licensure, a Medical Marijuana Business must declare in the Inventory Tracking System all Medical Marijuana and Medical Marijuana Infused-Product that are converted for sale as Retail Marijuana or Retail Marijuana Product prior to initiating or allowing any sales. This declaration may be made only once. Beginning July 1, 2016, the only allowed transfer of marijuana between a Medical Marijuana Business and Retail Marijuana Establishment is the transfer of Medical Marijuana and Medical Marijuana Concentrate that was produced at the Optional Premises Cultivation Operation, from the Optional Premises Cultivation Operation to a Retail Marijuana Cultivation Facility. The marijuana subject to the one-time transfer is subject to the excise tax upon the first transfer from the Retail Marijuana Cultivation Facility to another Retail Marijuana Establishment.

The State Licensing Authority received several comments from stakeholders who requested lower fees for Medical Marijuana Businesses that were either converting a Medical Marijuana Business license to a Retail Marijuana Establishment license or obtaining an additional Retail Marijuana Establishment license while retaining the existing Medical Marijuana Business license. The adopted permanent regulations reflect changes to address this concern. Under the rules as adopted, Medical Marijuana Businesses that apply to convert to a Retail Marijuana Establishment license will be required to pay an application fee, but no license fees will be charged until such time as the renewal fees would have been due under the Medical Marijuana Business license term. The Retail Marijuana Establishment license, if approved, would assume the balance of the license term from the Medical Marijuana Business license and have the same expiration date.

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**M 211 – Conversion - Medical Marijuana Business to Retail Marijuana Establishment**

A. Retail Marijuana Establishment Expiration Date

1. A Medical Marijuana Business converting its license to a Retail Marijuana Establishment license shall not be required to pay a license fee at the time of application for conversion.
2. If a Medical Marijuana Business licensee is scheduled to renew its license during the processing of its conversion to a Retail Marijuana Establishment license, the Medical Marijuana Business must complete all renewal applications and pay the requisite renewal licensing fees.
3. A Retail Marijuana Establishment license that was fully converted from a Medical Marijuana Business license will assume the balance of licensing term previously held by the surrendered Medical Marijuana Business license.

B. Medical Marijuana Licensees Applying for Retail Marijuana Establishments. Except for a Medical Marijuana Testing Facility, a Medical Marijuana Business Operator or a Medical Marijuana Business Transporter, a Medical Marijuana Business Licensee in good standing or who had a pending application as of December 10, 2012 that has not yet been denied, and who has paid all applicable fees, may apply for a Retail Marijuana Establishment license in accordance with the Retail Code and these rules on or after October 1, 2013. A Medical Marijuana Business meeting these conditions may apply to convert a Medical Marijuana Business license to a Retail Marijuana Establishment license or may apply for a single Retail Marijuana Establishment of the requisite class of license in the Medical Marijuana Code for each Medical Marijuana Business License not converted.

C. Retail Marijuana Establishment Licenses Conditioned

1. It shall be unlawful for a Retail Marijuana Establishment to operate without being issued a Retail Marijuana Establishment license by the State Licensing Authority and receiving all relevant local jurisdiction approvals. Each Retail Marijuana Establishment license issued shall be conditioned on the Licensee's receipt of all required local jurisdiction approvals and licensing, if required.
2. Each Retail Marijuana Establishment license issued shall be conditioned on the Medical Marijuana Business Licensee's declaration of the amount of Medical Marijuana or Medical Marijuana-Infused Product it intends to transfer from the requisite Medical Marijuana Business for sale as Retail Marijuana or Retail Marijuana Product. A Retail Marijuana Establishment shall not exercise any of the rights or privileges of a Retail Marijuana Establishment Licensee until such time as all such Medical Marijuana and Medical Marijuana-Infused Product are fully transferred and declared in the Inventory Tracking System. See also, Rule R 309 – Inventory Tracking System. Beginning July 1, 2016, the only allowed transfer of marijuana between a Medical Marijuana Business and Retail Marijuana Establishment is the transfer of Medical Marijuana and Medical Marijuana Concentrate that was produced at the Optional Premises Cultivation Operation, from the Optional Premises Cultivation Operation to a Retail Marijuana Cultivation Facility.

**D. One-Time Transfer.**

1. This rule M 211(D)(1) is repealed effective July 1, 2016. Prior to July 1, 2016, once a Retail Marijuana Establishment has declared Medical Marijuana and/or Medical Marijuana-Infused Product as Retail Marijuana or Retail Marijuana Product in the Inventory Tracking System and begun exercising the rights and privileges of the license, no additional Medical Marijuana or Medical Marijuana-Infused Product can be transferred from the Medical Marijuana Business to the relevant Retail Marijuana Establishment at any time.
2. Beginning July 1, 2016, the only allowed transfer of marijuana between a Medical Marijuana Business and a Retail Marijuana Establishment is the transfer of Medical Marijuana and Medical Marijuana Concentrate that was produced at the Optional Premises Cultivation Operation, from the Optional Premises Cultivation Operation to a Retail Marijuana Cultivation Facility. All other transfers are prohibited, including but not limited to transfers from a Medical Marijuana Center or Medical Marijuana-Infused Products Manufacturer to any Retail Marijuana Establishment. Once a Retail Marijuana Establishment has declared Medical Marijuana and Medical Marijuana Concentrate as Retail Marijuana or Retail Marijuana Concentrate in the Inventory Tracking System and begun exercising the rights and privileges of the license, no additional Medical Marijuana or Medical Marijuana Concentrate can be transferred from the Medical Marijuana Business to the relevant Retail Marijuana Establishment at any time.

**M 230 – Repealed Effective January 1, 2017.**

**Basis and Purpose – M 231**

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

**M 231 – Qualifications for Licensure and Residency**

- A. Any Applicant may be required to establish his or her identity and age by any document required for a determination of Colorado residency, United States citizenship or lawful presence.
- B. Maintaining Ongoing Licensing Qualification: Duty to Report Offenses. An Applicant or Licensee shall notify the Division in writing of any felony criminal charge and felony conviction against such person within ten days of such person's arrest, felony summons, and within ten days of the disposition of any arrest or summons. Failure to make proper notification to the Division may be grounds for disciplinary action. Applicants and Licensees shall notify the Division within ten days of any other event that renders the Applicant or Licensee no longer qualified under these rules. Licensees shall cooperate in any investigation conducted by the Division. This duty to report includes, but is not limited to, deferred sentences or judgments that are not sealed. If the Division lawfully finds a disqualifying event and an Applicant asserts that the record was sealed, the Division may require the Applicant to provide proof from a court evidencing the sealing of the case.
- C. Application Forms Accessible to Law Enforcement and Licensing Authorities. All application forms supplied by the Division and filed by an Applicant for licensure shall be accessible by the State Licensing Authority, local licensing authorities, and any state or local law enforcement agent.

- D. Associated Key Licenses. Each Direct Beneficial Interest Owner who is a natural person, including but not limited to each officer, director, member or partner of a Closely Held Business Entity, must apply for and hold at all times a valid Associated Key License. Except that these criteria shall not apply to Qualified Limited Passive Investors, who are not required to hold Associated Key Licenses. Each such Direct Beneficial Interest Owner must establish that he or she meets the following criteria before receiving an Associated Key License:
1. The Applicant has paid the annual application and licensing fees;
  2. The Applicant's criminal history indicates that he or she is of Good Moral Character;
  3. The Applicant is not employing, or financed in whole or in part by any other Person whose criminal history indicates that he or she is not of Good Moral Character;
  4. The Applicant is at least 21 years of age;
  5. The Applicant has paid all taxes, interest, or penalties due the Department of Revenue relating to a Medical Marijuana Business or Retail Marijuana Establishment, if applicable;
  6. The Applicant is not currently subject to and has not discharged a sentence for a conviction of a felony in the five years immediately preceding his or her application date;
  7. The Applicant meets qualifications for licensure that directly and demonstrably relate to the operation of a Medical Marijuana Business.
  8. The Applicant is not currently subject to and has not discharged a sentence for a conviction of a felony pursuant to any state or federal law regarding the possession, distribution, manufacturing, cultivation, or use of a controlled substance in the ten years immediately preceding his or her application date or five years from May 28, 2013, whichever is longer; except that the State Licensing Authority may grant a license to a person if the Applicant has a state felony conviction based on possession or use of marijuana or marijuana concentrate that would not be a felony of the Applicant were convicted of the offense on the date he or she applied for licensure'
  9. The Applicant does not employ another person who does not have a valid Occupational License issued pursuant to either the Medical Code or Retail Code;
  10. The Applicant is not a sheriff, deputy sheriff, police officer, or prosecuting officer, or an officer or employee of the State Licensing Authority or a local licensing authority;
  11. The Applicant has not been a State Licensing Authority employee with regulatory oversight responsibilities for individuals, Retail Marijuana Establishments and/or Medical Marijuana Businesses licensed by the State Licensing Authority in the six months immediately preceding the date of the Applicant's application;
  12. The premises that the Applicant proposes to be licensed is not currently licensed as a retail food establishment or wholesale food registrant;
  13. The Applicant either:
    - a. Has been a resident of Colorado for at least one year prior to the date of the application, or

- b. Has been a United States citizen since a date prior to the date of the application and has received a Finding of Suitability from the Division prior to filing the application. See Rule M 231.1 – Finding of Suitability, Residency and Reporting Requirements for Direct Beneficial Interest Owners; Rule M 232 – Factors Considered When Determining Residency and Citizenship: Individuals.
  14. For Associated Key Licensees who are owners of a Closely Held Business Entity, the Applicant is a United States citizen.
- E. Occupational Licenses. An Occupational License Applicant who is not applying for an Associated Key License must establish that he or she meets the following criteria before receiving an Occupational License:
1. The Applicant has paid the annual application and licensing fees;
  2. The Applicant's criminal history indicates that he or she is of Good Moral Character;
  3. The Applicant is at least 21 years of age;
  4. An Applicant is currently a resident of Colorado. See Rule M 232 – Factors Considered When Determining Residency and Citizenship: Individuals;
  5. The Applicant has paid all taxes, interest, or penalties due the Department of Revenue relating to a Medical Marijuana Business or Retail Marijuana Establishment;
  6. The Applicant is not currently subject to and has not discharged a sentence for a conviction of a felony in the five years immediately preceding his or her application date;
  7. The Applicant meets qualifications for licensure that directly and demonstrably relate to the operation of a Medical Marijuana Business.
  8. The Applicant is not currently subject to and has not discharged a sentence for a conviction of a felony pursuant to any state or federal law regarding the possession, distribution, manufacturing, cultivation, or use of a controlled substance in the ten years immediately preceding his or her application date or five years from May 28, 2013, whichever is longer; except that the State Licensing Authority may grant a license to a person if the person has a state felony conviction based on possession or use of marijuana or marijuana concentrate that would not be a felony of the person were convicted of the offense on the date he or she applied for licensure.
  9. The Applicant is not a sheriff, deputy sheriff, police officer, or prosecuting officer, or an officer or employee of the State Licensing Authority or a local licensing authority; and
  10. The Applicant has not been a State Licensing Authority employee with regulatory oversight responsibilities for occupational licensees, Medical Marijuana Businesses and/or Retail Marijuana Establishments licensed by the State Licensing Authority in the six months immediately preceding the date of the Applicant's application.
- F. Current Medical Marijuana Occupational Licensees.
1. An individual who holds a current, valid Occupational License issued pursuant to the Medical Code may also work in a Retail Marijuana Establishment; no separate Occupational License is required.

2. An individual who holds a current, valid Occupational License issued pursuant to the Retail Code after July 1, 2015 may also work in a Medical Marijuana Business; no separate Occupational License is required.
- G. Associated Key License Privileges. A person who holds an Associated Key License must associate that license separately with each Medical Marijuana Business or Retail Marijuana Establishment with which the person is associated by submitting a form approved by the Division. A person who holds an Associated Key License may exercise the privileges of a licensed employee in any licensed Medical Marijuana Business or Retail Marijuana Establishment in which they are not an owner so long as the person does not exercise privileges of ownership.
- H. Qualified Limited Passive Investor. An Applicant who wishes to be a Qualified Limited Passive Investor and hold an interest in a Medical Marijuana Business as a Direct Beneficial Interest Owner must establish that he or she meets the following criteria before the ownership interest will be approved:
1. He or she is a natural person;
  2. The Applicant qualifies under Rule R 231.2(B);
  3. He or she has been a United States citizen since a date prior to the date of the application, and
  4. He or she has signed an affirmation of passive investment.

#### **Basis and Purpose – M 231.1**

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

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

- A. Finding of Suitability – Non-Resident Direct Beneficial Interest Owners. A natural person, owner, shareholder, director, officer, member or partner of an entity that intends to apply to become a Direct Beneficial Interest Owner who has not been a resident of Colorado for at least one year prior to the application shall first submit a request to the State Licensing Authority for a finding of suitability to become a Direct Beneficial Interest Owner as follows:
1. A request for a finding of suitability for a non-resident natural person shall be submitted on the forms prescribed by the State Licensing Authority.
  2. A natural person or all owners, shareholders, directors, officers, members or partners of an entity who have not been a resident of Colorado for at least one year shall obtain a finding of suitability prior to submitting an application to become a Direct Beneficial Interest Owner to the State Licensing Authority. A non-Colorado resident's failure to obtain a finding of suitability prior to submitting an application to become a Direct Beneficial Interest Owner to the State Licensing Authority shall be grounds for denial of the application.

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

**Basis and Purpose – M 231.2**

The statutory authority for this rule is found at subsections 12-43.3-201(4), 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-202(2)(a)(XXI) and 24-18-105(3), and sections 12-43.3-104, 12-43.3-307.5 and 24-76.5-101 et. seq., C.R.S. The purpose of this rule is to clarify the qualifications for an Indirect Beneficial Interest Owner other than a Permitted Economic Interest.

**M 231.2 – Qualifications for Indirect Beneficial Interest Owners and Qualified Limited Passive Investors**

- A. General Requirements
1. An Applicant applying to become a Commercially Reasonable Royalty Interest holder who receives more than 30 percent of the gross revenue or gross profit from sales of the product or line of products or the holder of a Permitted Economic Interest must be pre-approved by the Division.
  2. An Applicant applying to become an Indirect Beneficial Interest Owner or Qualified Limited Passive Investor shall submit information to the Division in a full, faithful, truthful, and fair manner. The Division may recommend denial of an application where the Applicant made misstatements, omissions, misrepresentations, or untruths in the application. This type of conduct may be considered as the basis of additional administrative action against the Applicant and the Medical Marijuana Business.
  3. The Division may deny the application when the Applicant fails to provide any requested information by the Division's deadline.

4. The Division's determination that an Indirect Beneficial Interest Owner or Qualified Limited Passive Investor is qualified constitutes a revocable privilege held by the Medical Marijuana Business. The burden of proving the Indirect Beneficial Interest Owner or Qualified Limited Passive Investor is qualified rests at all times with the Medical Marijuana Business Applicant. Indirect Beneficial Interest Owners and Qualified Limited Passive Investors are not separately licensed by the Division. Any administrative action regarding an Indirect Beneficial Interest Owner or Qualified Limited Passive Investor may be taken directly against the Medical Marijuana Business.
  5. Permitted Economic Interest Fingerprints Required. Any individual applying to hold his or her first Permitted Economic Interest shall be fingerprinted for a criminal history record check. In the Division's discretion, an individual may be required to be fingerprinted again for additional criminal history record checks.
  6. No publicly traded company can be an Indirect Beneficial Interest Owner or Qualified Limited Passive Investor.
- B. Qualification. The Division may consider the following non-exhaustive list of factors to determine whether an Indirect Beneficial Interest Owner or Qualified Limited Passive Investor is qualified:
1. The Applicant's criminal history indicates that he or she is of Good Moral Character;
  2. The Applicant is at least 21 years of age;
  3. The Applicant has paid all taxes, interest, or penalties due the Department of Revenue relating to a Medical Marijuana Business or Retail Marijuana Establishment, if applicable;
  4. The Applicant is not currently subject to and has not discharged a sentence for a conviction of a felony in the five years immediately preceding his or her application date;
  5. The Applicant is not currently subject to or has not discharged a sentence for a conviction of a felony pursuant to any state or federal law regarding the possession, distribution, manufacturing, cultivation, or use of a controlled substance in the ten years immediately preceding his or her application date or five years from May 28, 2013, whichever is longer, except, in the Division's discretion, a state felony conviction based on possession or use of marijuana or marijuana concentrate that would not be a felony if the Person were convicted of the offense on the date he or she applied may not disqualify an Indirect Beneficial Interest Owner or Qualified Limited Passive Investor;
  6. The Applicant is not a sheriff, deputy sheriff, police officer, or prosecuting officer, or an officer or employee of the State Licensing Authority or a local licensing authority;
  7. The Applicant has not been a State Licensing Authority employee with regulatory oversight responsibilities for individuals, Medical Marijuana Businesses and/or Retail Marijuana Establishments licensed by the State Licensing Authority in the six months immediately preceding the date of the Applicant's application.
  8. The Applicant has provided all documentation requested by the Division to establish qualification to be an Indirect Beneficial Interest Owner.

C. Maintaining Qualification:

1. An Indirect Beneficial Interest Owner or Qualified Limited Passive Investor shall notify the Division in writing of any felony criminal charge and felony conviction against such person within ten days of such person's arrest or felony summons, and within ten days of the disposition of any arrest or summons. Failure to make proper notification to the Division may be grounds for disciplinary action. This duty to report includes, but is not limited to, deferred sentences, prosecutions, or judgments that are not sealed. If the Division lawfully finds a disqualifying event and the individual asserts that the record was sealed, the Division may require the individual to provide proof from a court evidencing the sealing of the case
2. An Indirect Beneficial Interest Owner, Qualified Limited Passive Investor and Medical Marijuana Business shall cooperate in any investigation into whether an Indirect Beneficial Interest Owner or Qualified Limited Passive Investor continues to be qualified that may be conducted by the Division.

- D. Divestiture of Indirect Beneficial Interest Owner or Qualified Limited Passive Investor. If the Division determines an Indirect Beneficial Interest Owner or Qualified Limited Passive Investor is not permitted to hold their interest, the Medical Marijuana Business shall have 60 days from such determination to divest the Indirect Beneficial Interest Owner or Qualified Limited Passive Investor. The Division may extend the 60-day deadline for good cause shown. Failure to timely divest any Indirect Beneficial Interest Owner or Qualified Limited Passive Investor the Division determines is not qualified, or is no longer qualified, may constitute grounds for denial of license or administrative action against the Medical Marijuana Business and/or its Associated Key Licensee(s).

**M 231.5 – Repealed Effective January 1, 2017.**

**Basis and Purpose – M 232**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(I), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-202(2)(a)(XXI), 12-43.3-307.5(2), 12-43.3-310(6), C.R.S. The purpose of this rule is to interpret residency requirements set forth in the Medical Code.

**M 232 – Factors Considered When Determining Residency and Citizenship: Individuals**

This rule applies to individual Applicants who are trying to obtain Medical Marijuana Business licenses. When the State Licensing Authority determines whether an Applicant is a resident, the following factors will be considered:

- A. Primary Home Defined. The location of an Applicant's principal or primary home or place of abode ("primary home") may establish Colorado residency. An Applicant's primary home is that home or place in which a person's habitation is fixed and to which the person, whenever absent, has the present intention of returning after a departure or absence therefrom, regardless of the duration of such absence. A primary home is a permanent building or part of a building and may include, by way of example, a house, condominium, apartment, room in a house, or manufactured housing. No rental property, vacant lot, vacant house or cabin, or other premises used solely for business purposes shall be considered a primary home.
- B. Reliable Indicators That an Applicant's Primary Home is in Colorado. The State Licensing Authority considers the following types of evidence to be generally reliable indicators that a person's primary home is in Colorado.

1. Evidence of business pursuits, place of employment, income sources, residence for income or other tax purposes, age, residence of parents, spouse, and children, if any, leaseholds, situs of personal and real property, existence of any other residences outside of Colorado and the amount of time spent at each such residence, and any motor vehicle or vessel registration;
  2. Duly authenticated copies of the following documents may be taken into account: A current driver's license with address, recent property tax receipts, copies of recent income tax returns where a Colorado mailing address is listed as the primary address, current voter registration cards, current motor vehicle or vessel registrations, and other public records evidencing place of abode or employment; and
  3. Other types of reliable evidence.
- C. Totality of the Evidence. The State Licensing Authority will review the totality of the evidence, and any single piece of evidence regarding the location of a person's primary home is not necessarily determinative.
- D. Other Considerations for Residency. The State Licensing Authority may consider the following circumstances
1. Members of the armed services of the United States or any nation allied with the United States who are on active duty in this state under permanent orders and their spouses;
  2. Personnel in the diplomatic service of any nation recognized by the United States who are assigned to duty in Colorado and their spouses; and
  3. Full-time students who are enrolled in any accredited trade school, college, or university in Colorado. The temporary absence of such student from Colorado, while the student is still enrolled at any such trade school, college, or university, shall not be deemed to terminate their residency. A student shall be deemed "full-time" if considered full-time pursuant to the rules or policy of the educational institution he or she is attending.
- E. Entering Armed Forces Does Not Terminate Residency. An individual who is a Colorado resident pursuant to this rule does not terminate Colorado residency upon entering the armed services of the United States. A member of the armed services on active duty who resided in Colorado at the time the person entered military service and the person's spouse are presumed to retain their status as residents of Colorado throughout the member's active duty in the service, regardless of where stationed or for how long.
- F. Determination of United States Citizenship. Whenever the Medical Code or the rules promulgated pursuant thereto require a Direct Beneficial Interest Owner to be a United States citizen, the Direct Beneficial Interest Owner must provide evidence of United States citizenship as required by the Division in accordance with applicable federal and state statutes and regulations.

### **Basis and Purpose – M 233**

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)(VIII), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-310(7), and section 12-43.3-401(1)(d), C.R.S. The purpose of this rule is to clarify when an individual must be licensed or registered with the Division before commencing any work activity at a Medical Marijuana Business. The rule also sets forth the process for obtaining a license or registration and explains what information may be required before obtaining such license or registration.

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## M 233 – Medical Code or Retail Code Occupational Licenses Required

- A. Medical Code or Retail Code Occupational Licenses and Identification Badges
1. Any person who possesses, cultivates, manufactures, tests, dispenses, sells, serves, transports or delivers Medical Marijuana or Medical Marijuana-Infused Product as permitted by privileges granted under a Medical Marijuana Business license must have a valid Occupational License.
  2. Any person who has the authority to access or input data into the Inventory Tracking System or a Medical Marijuana Business point of sale system must have a valid Occupational License.
  3. Any person within a Restricted Access Area or Limited Access Area that does not have a valid Occupational License shall be considered a visitor and must be escorted at all times by a person who holds a valid Associated Key License or other Occupational License. Failure by a Medical Marijuana Business to continuously escort a person who does not have a valid Occupational License within a Limited Access Area may be considered a license violation affecting the public safety. See Rule M 1307 – Penalties. See also Rule M 301 – Limited Access Areas. Nothing in this provision alters or eliminates a Medical Marijuana Business’s obligation to comply with the Occupational License requirements of paragraph (A) of this rule M 233. Trade craftspeople not normally engaged in the business of cultivating, processing, or selling Medical Marijuana do not need to be accompanied at all times, and instead only reasonably monitored.
- B. Occupational License Required to Commence or Continue Employment. Any person required to be licensed pursuant to these rules shall obtain all required approvals and obtain a Division-issued identification badge before commencing activities permitted by his or her Medical Code or Retail Code Occupational License. See Rules M 231 – Qualifications for Licensure and Residency; M 204 –Ownership Interests of a License: Medical Marijuana Businesses, and M 301 – Limited Access Areas.
- C. Identification Badges Are Property of State Licensing Authority. All identification badges shall remain the property of the State Licensing Authority, and all identification badges shall be returned to the Division upon demand of the State Licensing Authority or the Division.

## M 234 – Repealed (October 30, 2014)

### Basis and Purpose – M 235

The statutory authority for this rule is found at subsections 12-43.3-202(1)(a), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-307.5(5)(a)-(b), and 12-43.3-401(1)(d), and sections 12-43.3-104, 12-43.3-310, 12-43.3-401, 12-43.3-501, and 12-43.3-502, C.R.S. The purpose of this rule is to establish the licensing fees for individuals.

## M 235 – Schedule of Application and License Fees: Individuals

- A. Individual Application and License Fees
1. Direct Beneficial Interest Owner Fees
    - a. Colorado Resident Associated Key License
      - i. Application Fee - \$725.00

- ii. License Fee - \$75.00
    - b. Non-Resident Associated Key License
      - i. Application Fee upon request for finding of suitability - \$4,925.00
      - ii. License Fee following a finding of suitability - \$75.00
  - 2. Occupational Key License
    - i. Application Fee - \$225.00
    - ii. License Fee - \$25.00
  - 3. Occupational Support License
    - i. Application Fee - \$50.00
    - ii. License Fee - \$25.00
- B. When Fees Are Due. Application and License fees are due at the time Applicant submits an application, except for the Non-Resident Associated Key License fee following a finding of suitability. The Non-Resident Associated Key License fee following a finding of suitability is due after an Applicant has been informed by the Division of a finding of suitability and prior to issuance of the Non-Resident Associated Key License.

**Basis and Purpose – M 236**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(a), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), and 12-43.3-401(1)(d), and sections 12-43.3-104, 12-43.3-310, 12-43.3-401, 12-43.3-501, and 12-43.3-502, C.R.S. The purpose of this rule is to establish renewal fees for individuals.

**M 236 – Schedule of Renewal Fees: Individuals**

- A. Individual Renewal Fees
  - 1. Associated Key Renewal Fee - \$500.002.
  - 2. Other Occupational Renewal Fee - \$75.00
- B. When Fees Are Due. Renewal fees are due at the time Applicant submits an application for renewal.

**Basis and Purpose – M 250**

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 12-43.3-305(1), and 12-43.3-305, C.R.S. The purpose of this rule is to clarify that a Licensee must keep its mailing address current with the Division.

**M 250 – Licensee Required to Keep Mailing Address Current with the Division: All Licensees**

- A. Timing of Notification. A Licensee shall inform the Division in writing of any change to its mailing address within 30 days of the change. The Division will not change a Licensee's information without explicit written notification provided by the Licensee or its authorized agent.
- B. Division Communications. Division communications are sent to the last mailing address furnished by an Applicant or a Licensee to the Division.
- C. Failure to Change Address Does Not Relieve Licensee's or Applicant's Obligation. Failure to notify the Division of a change of mailing address does not relieve a Licensee or Applicant of the obligation to respond to a Division communication.
- D. Application and Disciplinary Communications. The State Licensing Authority will send any application, disciplinary or sanction communication, as well as any notice of hearing, to the last mailing address furnished to the Division by the Licensee or Applicant.

**Basis and Purpose – M 251**

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), and sections 12-43.2-306, 24-4-104 and 24-4-105, C.R.S. The purpose of this rule is to establish what factors the State Licensing Authority will consider when denying an application for licensure.

**M 251 – Application Denial and Voluntary Withdrawal: All Licensees**

- A. Applicant Bears Burden of Proving It Meets Licensing Requirements
  - 1. At all times during the application process, an Applicant must be capable of establishing that it is qualified to hold a license.
  - 2. An Applicant that does not cooperate with the Division during the application phase may be denied as a result. For example, if the Division requests additional evidence of qualification and the Applicant does not furnish such evidence by the date requested, the Applicant's application may be denied.
- B. Applicants Must Provide Accurate Information
  - 1. An Applicant must provide accurate information to the Division during the entire Application process.
  - 2. If an Applicant provides inaccurate information to the Division, the Applicant's application may be denied.

C. Grounds for Denial

1. The State Licensing Authority will deny an application from an Applicant that forms a business, including but not limited to a sole proprietorship, corporation, or other business enterprise, with the purpose or intent, in whole or in part, of transporting, cultivating, processing, transferring, or distributing marijuana or marijuana products without receiving prior licenses from all relevant licensing authorities.
2. The State Licensing Authority will deny an application for Good Cause.
3. The State Licensing Authority will deny an application from an Applicant that is statutorily disqualified from holding a license.

D. Voluntary Withdrawal of Application

1. The Division and Applicant may mutually agree to allow the voluntary withdrawal of an application in lieu of a denial proceeding.
2. Applicants must first submit a notice to the Division requesting the voluntary withdrawal of the application. Applicants will submit the notice with the understanding that they were not obligated to request the voluntary withdrawal and that any right to a hearing in the matter is waived once the voluntary withdrawal is approved.
3. The Division will consider the request along with any circumstances at issue with the application in making a decision to accept the voluntary withdrawal. The Division may at its discretion grant the request with or without prejudice or deny the request.
4. The Division will notify the Applicant of its acceptance of the voluntary withdrawal and the terms thereof.
5. If the Applicant agrees to a voluntary withdrawal granted with prejudice, then the Applicant is not eligible to apply again for licensing or approval until after expiration of one year from the date of such voluntary withdrawal.

E. An Applicant May Appeal a Denial

1. An Applicant may appeal a denial pursuant to the Administrative Procedure Act.
2. See also Rules M 1304 – Administrative Hearings, M 1305 – Administrative Subpoenas, and M 1306 – Administrative Hearing Appeals.

**Basis and Purpose – M 252**

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 12-43.3-310(6), C.R.S. The purpose of this rule is to clarify the length of licenses for businesses and individuals.

**M 252 – Length of License: All Licensees Except Retail Marijuana Transporters and Occupational Licenses**

- A. Medical Marijuana Business License. All licenses issued pursuant to the Medical Code and these rules are valid for one year, except that a Medical Marijuana Transporter license and an Occupational License are valid for two years.

- B. License May Be Valid for Less Than Full Term. A License may be valid for less than the applicable license term if surrendered, or if revoked, suspended, or otherwise disciplined.

### **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)(I), 12-43.3-202(2)(a)(X), 12-43.3-202(2)(a)(XI), 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. Proper Display of License Badge. 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 A Medical Marijuana Business and a Licensee employed by the Medical Medical Marijuana Business shall report any discovered plan of or other action by any visitor to commit 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. Such discovered plan or other action shall be reported to the Division in accordance with Rule M 904 – Medical Marijuana Business Reporting Requirements.
  3. 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.
  4. 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”.
- D. 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. Modification of a Limited Access Area. 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. Law Enforcement Personnel Authorized. 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. Evidence of Lawful Possession. Persons licensed pursuant to sections 12-43.3-402, 12-43.3-403, 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 M303 - Changing, Altering, or Modifying Licensed Premises.
- C. Subletting Not Authorized. 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 303

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(X), 12-43.3-202(2)(a)(XX), and 12-43.3-305, C.R.S. The purpose of this rule is to establish guidelines for changing, altering or modifying the Licensed Premises.

### M 303 – Changing, Altering, or Modifying Licensed Premises

- A. Application Required to Alter or Modify Premises. After issuance of a license, the Licensee shall make no physical change, alteration, or modification of the Licensed Premises that materially or substantially alters the Licensed Premises or the usage of the Licensed Premises from the plans originally approved, without the prior written approval of both the Division and relevant licensing authority. The Licensee whose premises are to be materially or substantially changed is responsible for filing an application for approval on current forms provided by the Division.
- B. What Constitutes a Material Change. Material or substantial changes, alterations, or modifications requiring approval include, but are not limited to, the following:
1. Any increase or decrease in the total physical size or capacity of the Licensed Premises;
  2. The sealing off, creation of or relocation of a common entryway, doorway, passage or other such means of public ingress and/or egress, when such common entryway, doorway or passage alters or changes Limited Access Areas, such as the cultivation, harvesting, manufacturing, or sale of Medical Marijuana or Medical Marijuana-Infused Product within the Licensed Premises;
  3. Within a Medical Marijuana Center, the permanent addition of a separate sales counter that creates an additional point-of-sale location, and the permanent addition of a display case, all of which would require the installation of additional video surveillance cameras. See Rule M 306 – Video Surveillance;
  4. The installation or replacement of electric fixtures or equipment, the lowering of a ceiling, or electrical modifications made for the purpose of increasing power usage to enhance cultivation activities; or
  5. The addition or deletion of Optional Premises Cultivation Operation licenses that will be, or have been, combined with other commonly owned cultivation licenses in a common area for the purpose of growing and cultivating Medical Marijuana.
- C. Attachments to Application. The Division and relevant local licensing authority may grant approval for the types of changes, alterations, or modifications described herein upon the filing of an application by the Licensee, and payment of any applicable fee. The Licensee must submit all information requested by the Division including but not limited to, documents that verify the following:
1. The Licensee will continue to have possession of the premises, as changed, by ownership, lease, or rental agreement; and
  2. The proposed change conforms to any local restrictions related to the time, manner, and place of Medical Marijuana Business regulation.

## 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. and sections 12-43.3-406, 12-43.4-405 and 12-43.4-406, C.R.S. The purpose of this rule is to establish guidelines for the manner in which a Medical Marijuana Business may share its existing Licensed Premises with a Licensed Retail Marijuana Establishment, and to ensure the proper separation of a Medical Marijuana Business operation from Retail Marijuana Establishment operation.

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

### A. Licensed Premises – General Requirements

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

1. Cultivation Operations. 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.
6. 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. Clear Separation of Inventory. 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.

**Basis and Purpose – M 305**

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

**M 305 – Security Alarm Systems and Lock Standards**

**A. Security Alarm Systems – Minimum Requirements**

1. Each Licensed Premises shall have a Security Alarm System, installed by an Alarm Installation Company, on all perimeter entry points and perimeter windows.
2. Each Licensee must ensure that all of its Licensed Premises are continuously monitored. Licensees may engage the services of a Monitoring Company to fulfill this requirement.
3. The Licensees shall maintain up to date and current records and existing contracts on the Licensed Premises that describe the location and operation of each Security Alarm System, a schematic of security zones, the name of the Alarm Installation Company, and the name of any Monitoring Company. See Rule M 901 – Business Records Required.
4. Upon request, Licensees shall make available to agents of the Division or relevant local licensing authority or other state or local law enforcement agency, for a purpose authorized by the Medical Code or any other state or local law enforcement purpose, all information related to Security Alarm Systems, Monitoring, and alarm activity.
5. Any outdoor Optional Premises Cultivation Facility, or greenhouse cultivation, is a Limited Access Area and must meet all of the requirements for Security Alarm Systems described in this rule. An outdoor or greenhouse Optional Premises Cultivation Facility must provide sufficient security measures to demonstrate that outdoor areas are not readily accessible by unauthorized individuals. This shall, at a minimum include, perimeter fencing designed to prevent the general public from entering the Limited Access Areas. It shall be the responsibility of the Licensee to maintain physical security in a manner similar to an Optional Premises Cultivation Facility located in an indoor Licensed Premises so it can be fully secured and alarmed.

**B. Lock Standards – Minimum Requirement**

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

**Basis and Purpose – M 306**

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

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**M 306 – Video Surveillance**

- A. Minimum Requirements The following video surveillance requirements shall apply to all Medical Marijuana Businesses:
1. Prior to exercising the privileges of a Medical Marijuana Business, an Applicant must install fully operational video surveillance and camera recording system. The recording system must record in digital format and meet the requirements outlined in this rule.
  2. All video surveillance records and recordings must be stored in a secure area that is only accessible to a Licensee's management staff.
  3. Video surveillance records and recordings must be made available upon request to the Division, the relevant local licensing authority, or any other state or local law enforcement agency for a purpose authorized by the Medical Code or for any other state or local law enforcement purpose.
  4. Video surveillance records and recordings of point-of-sale areas shall be held in confidence by all employees and representatives of the Division, except that the Division may provide such records and recordings to the relevant local licensing authority, or any other state or local law enforcement agency for a purpose authorized by the Medical Code or for any other state or local law enforcement purpose.
- B. Video Surveillance Equipment
1. Video surveillance equipment shall, at a minimum, consist of digital or network video recorders, cameras capable of meeting the recording requirements described in this rule, video monitors, digital archiving devices, and a color printer capable of delivering still photos.
  2. All video surveillance systems must be equipped with a failure notification system that provides prompt notification to the Licensee of any prolonged surveillance interruption and/or the complete failure of the surveillance system.
  3. Licensees are responsible for ensuring that all surveillance equipment is properly functioning and maintained so that the playback quality is suitable for viewing and the surveillance equipment is capturing the identity of all individuals and activities in the monitored areas.
  4. All video surveillance equipment shall have sufficient battery backup to support a minimum of four hours of recording in the event of a power outage.
- C. Placement of Cameras and Required Camera Coverage
1. Camera coverage is required for all Limited Access Areas, point-of-sale areas, security rooms, all points of ingress and egress to Limited Access Areas, all areas where Medical Marijuana or Medical Marijuana-Infused Product is displayed for sale, and all points of ingress/egress to the exterior of the Licensed Premises.
  2. Camera placement shall be capable of identifying activity occurring within 20 feet of all points of ingress and egress and shall allow for the clear and certain identification of any individual and activities on the Licensed Premises.

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

**D. Location and Maintenance of Surveillance Equipment**

1. The surveillance room or surveillance area shall be a Limited Access Area.
2. Surveillance recording equipment must be housed in a designated, locked and secured room or other enclosure with access limited to authorized employees, agents of the Division and relevant local licensing authority, state or local law enforcement agencies for a purpose authorized by the Medical Code or for any other state or local law enforcement purpose, and service personnel or contractors.
3. Licensees must keep a current list of all authorized employees and service Personnel who have access to the surveillance system and/or room on the Licensed Premises. Licensees must keep a surveillance equipment maintenance activity log on the Licensed Premises to record all service activity including the identity of the individual(s) performing the service, the service date and time and the reason for service to the surveillance system.
4. Off-site Monitoring and video recording storage of the Licensed Premises by the Licensee or an independent third-party is authorized as long as standards exercised at the remote location meets or exceeds all standards for on-site Monitoring.

5. Each Medical Marijuana Licensed Premises located in a common or shared building must have a separate surveillance room/area that is dedicated to that specific Licensed Premises. Commonly-owned Medical Marijuana Businesses located in the same local jurisdiction may have one central surveillance room located at one of the commonly owned Licensed Premises which simultaneously serves all of the commonly-owned Medical Marijuana Businesses. The facility that does not house the central surveillance room is required to have a review station, printer, and map of camera placement on the premises. All minimum requirements for equipment and security standards as set forth in the section apply to the review station.
6. Licensed Premises that combine both a Medical Marijuana Business and a Retail Marijuana Establishment may have one central surveillance room located at the shared Licensed Premises. See Rule M 304 – Medical Marijuana Business and Retail Marijuana Establishment: Shared Licensed Premises and Operational Separation.

**E. Video Recording and Retention Requirements**

1. All camera views of all Limited Access Areas must be continuously recorded 24 hours a day. The use of motion detection is authorized when a Licensee can demonstrate that monitored activities are adequately recorded.
2. All surveillance recordings must be kept for a minimum of 40 days and be in a format that can be easily accessed for viewing. Video recordings must be archived in a format that ensures authentication of the recording as legitimately-captured video and guarantees that no alteration of the recorded image has taken place.
3. The Licensee's surveillance system or equipment must have the capabilities to produce a color still photograph from any camera image, live or recorded, of the Licensed Premises.
4. The date and time must be embedded on all surveillance recordings without significantly obscuring the picture. The date and time must be synchronized with any point-of-sale system.
5. Time is to be measured in accordance with the official United States time established by the National Institute of Standards and Technology and the U.S. Naval Observatory at: <http://www.time.gov/timezone.cgi?Mountain/d/-7/java>.
6. After the 40 day surveillance video retention schedule has lapsed, surveillance video recordings must be erased or destroyed prior to sale or transfer of the facility or business to another Licensee, or being discarded or disposed of for any other purpose. Surveillance video recordings may not be destroyed if the Licensee knows or should have known of a pending criminal, civil or administrative investigation or any other proceeding for which the recording may contain relevant information.

**F. Other Records**

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

### Basis and Purpose – M 307

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

### M 307 – Waste Disposal

- A. All Applicable Laws Apply. Medical Marijuana and Medical Marijuana-Infused Product waste must be stored, secured and managed in accordance with all applicable state and local statutes, regulations, ordinances or other requirements.
- B. Liquid Waste. Liquid waste from Medical Marijuana Businesses shall be disposed of in compliance all applicable federal, state and local laws, regulations, rules and other requirements.
- C. Chemical, Dangerous and Hazardous Waste. Disposal of chemical, dangerous or hazardous waste must be conducted in a manner consistent with federal, state and local laws, regulations, rules or other requirements. This may include, but is not limited to, the disposal of all Pesticide or other chemicals used in the cultivation process, certain solvents or other chemicals used in the production of Medical Marijuana Concentrate or any Medical Marijuana soaked in a Flammable Solvent for purposes of producing a Medical Marijuana Concentrate.
- D. Waste Must Be Made Unusable and Unrecognizable. Medical Marijuana and Medical Marijuana-Infused Product waste must be made unusable and Unrecognizable prior to leaving the Licensed Premises.
- E. Methods to Make Waste Unusable and Unrecognizable. Medical Marijuana and Medical Marijuana-Infused Product waste shall be rendered unusable and Unrecognizable through one of the following methods:
  - 1. Grinding and incorporating the marijuana waste with non-consumable, solid wastes listed below such that the resulting mixture is at least 50 percent non-marijuana waste:
    - a. Paper waste;
    - b. Plastic waste;
    - c. Cardboard waste;
    - d. Food waste;
    - e. Grease or other compostable oil waste;
    - f. Bokashi, or other compost activators;
    - g. Other wastes approved by the State Licensing Authority that will render the Medical Marijuana and Medical Marijuana-Infused Product waste unusable and Unrecognizable as marijuana; and
    - h. Soil.
- F. After Waste is Made Unusable and Unrecognizable. After the Medical Marijuana and Medical Marijuana-Infused Product waste is made unusable and Unrecognizable, then the rendered waste shall be:

1. Disposed of at a solid waste site and disposal facility that has a Certificate of Designation from the local governing body;
  2. Deposited at a compost facility that has a Certificate of Designation from the Department of Public Health and Environment; or
  3. Composted on-site at a facility owned by the generator of the waste and operated in compliance with the Regulations Pertaining to Solid Waste Sites and Facilities (6 CCR 1007-2, Part 1) in the Department of Public Health and Environment.
- G. Proper Disposal of Waste. A Licensee shall not dispose of Medical Marijuana and Medical Marijuana-Infused Product waste in an unsecured waste receptacle not in possession and control of the Licensee.
- H. Inventory Tracking Requirements
1. In addition to all other tracking requirements set forth in these rules, a Licensee shall utilize the Inventory Tracking System to ensure its post-harvest waste materials are identified, weighed and tracked while on the Licensed Premises until disposed of.
  2. All Medical Marijuana waste must be weighed before leaving any Medical Marijuana Business. A scale used to weigh Medical Marijuana waste prior to entry into the Inventory Tracking System shall be tested and approved in accordance with 35-14-127, C.R.S. See Rule M 309 – Medical Marijuana Business: Inventory Tracking System.
  3. A Licensee is required to maintain accurate and comprehensive records regarding waste material that accounts for, reconciles, and evidences all waste activity related to the disposal of Marijuana. See Rule M 901 – Business Records Required.
  4. A Licensee is required to maintain accurate and comprehensive records regarding any waste material produced through the trimming or pruning of a Medical Marijuana plant prior to harvest, which must include weighing and documenting all waste. Unless required by an Inventory Tracking System procedure, records of waste produced prior to harvest must be maintained on the Licensed Premises. All waste, whether produced prior or subsequent to harvest, must be disposed of in accordance with this rule and be made unusable and unrecognizable.

### **Basis and Purpose – M 308**

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 C.R.S. The purpose of this rule is to establish hours of operation requirements for Medical Marijuana Businesses. The State Licensing Authority modeled this rule after the Retail Marijuana Establishment Hours of Operation rule, Rule R 308 located in 1 CCR 212-2, and the Colorado Department of Revenue's liquor rules. Based upon written comments and testimony during working groups and public hearings, this rule was amended to remove restrictions on the hours during which initiating the transportation of Medical Marijuana and Medical Marijuana-Infused Product is permitted.

### **M 308 – Selling and Serving Medical Marijuana and Medical Marijuana-Infused Product: Hours of Operation**

- A. Hours of Operation. Medical Marijuana Businesses shall not sell or serve Medical Marijuana or Medical Marijuana-Infused Product at any time other than between the hours of 8:00 am and 12:00 am, Mountain Time, Monday through Sunday.

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

**Basis and Purpose – M 309**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX), 12-43.3-403(2), and 12-43.4-104(1)(a)(III) C.R.S. The purpose of this rule is to establish a system that will allow the State Licensing Authority and the industry to jointly track Medical Marijuana and Medical Marijuana-Infused Product from either seed or immature plant stage until the Medical Marijuana or Medical Marijuana-Infused Product is sold to the patient or destroyed.

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

The State Licensing Authority finds it essential to regulate, monitor, and track all Medical Marijuana and Medical Marijuana-Infused Product to eliminate diversion, inside and outside of the state, and to ensure that all marijuana grown, processed, sold and disposed of in the Medical Marijuana market is transparently accounted for. An existing Medical Marijuana Business must have an active and functional Inventory Tracking System account on or before December 31, 2013 or it may not exercise the privileges of its license.

The State Licensing Authority will engage the industry and provide training opportunities and continue to evaluate the Inventory Tracking System to promote an effective means for this industry to account for and monitor its Medical Marijuana inventory.

**M 309 – Medical Marijuana Business: Inventory Tracking System**

- A. Inventory Tracking System Required. A Medical Marijuana Business is required to use the Inventory Tracking System as the primary inventory tracking system of record. A Medical Marijuana Business without an Inventory Tracking System account that is activated and functional shall not operate or exercise any privileges of a license. Medical Marijuana Businesses converting to or adding a Retail Marijuana Establishment must follow the inventory transfer guidelines detailed in Rule R 309 (D) below.
- B. Inventory Tracking System Access - Inventory Tracking System Administrator
1. Inventory Tracking System Administrator Required. A Medical Marijuana Business must have at least one individual Owner who is an Inventory Tracking System Administrator. A Medical Marijuana Business may also designate additional Owners and occupationally licensed employees to obtain Inventory Tracking System Administrator accounts.
  2. Training for Inventory Tracking System Administrator Account. In order to obtain an Inventory Tracking System Administrator account, a person must attend and successfully complete all required Inventory Tracking System training. The Division may also require additional ongoing, continuing education for an individual to retain his or her Inventory Tracking System Administrator account.

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- C. Inventory Tracking System Access - Inventory Tracking System User Accounts. A Medical Marijuana Business may designate licensed Owners and employees who hold a valid Occupational License as an Inventory Tracking System User. A Medical Marijuana Business shall ensure that all Owners and Occupational Licensees who are granted Inventory Tracking System User account access for the purposes of conducting inventory tracking functions in the system are trained by Inventory Tracking System Administrators in the proper and lawful use of Inventory Tracking System.
- D. Medical Marijuana Business License Conversions - Declaring Inventory Prior to Exercising Licensed Privileges as a Medical Marijuana Business
1. Medical Marijuana Inventory Transfer to Retail Marijuana Establishments.
    - a. This rule M 309(D)(1)(a) is repealed effective July 1, 2016. Prior to July 1, 2016, each Medical Marijuana Business that is either converting to or adding a Retail Marijuana Establishment license must create a Retail Marijuana Inventory Tracking System account for each license it is converting or adding. A Medical Marijuana Business must transfer all relevant Medical Marijuana inventory into the Retail Marijuana Establishment's Inventory Tracking System account and affirmatively declare those items as Retail Marijuana and Retail Marijuana Product.
    - b. Beginning July 1, 2016:
      - i. The the only allowed transfer of marijuana between a Medical Marijuana Business and Retail Marijuana Establishment is Medical Marijuana and Medical Marijuana Concentrate that was produced at the Optional Premises Cultivation Operation, from the Optional Premises Cultivation Operation to a Retail Marijuana Cultivation Facility.
      - ii. Each Optional Premises Cultivation Operation that is either converting to or adding a Retail Marijuana Cultivation Facility license must create a Retail Marijuana Inventory Tracking System account for each license it is converting or adding.
      - iii. An Optional Premises Cultivation Operation must transfer all relevant Medical Marijuana and Medical Marijuana Concentrate into the Retail Marijuana Cultivation Facility's Inventory Tracking System account and affirmatively declare those items as Retail Marijuana or Retail Marijuana Concentrate as appropriate.
      - iv. The marijuana subject to the one-time transfer is subject to the excise tax upon the first transfer from the Retail Marijuana Cultivation Facility to another Retail Marijuana Establishment.
      - v. All other transfers are prohibited, including but not limited to transfers from a Medical Marijuana Center or Medical Marijuana-Infused Products Manufacturer to any Retail Marijuana Establishment.
  2. No Further Transfer Allowed. Once a Licensee has declared any portion of its Medical Marijuana inventory as Retail Marijuana, no further transfers of inventory from Medical Marijuana to Retail Marijuana shall be allowed.

E. RFID Tags Required

1. Authorized Tags Required and Costs. Licensees are required to use RFID tags issued by a Division-approved vendor that is authorized to provision RFID tags for the Inventory Tracking System. Each licensee is responsible for the cost of all RFID tags and any associated vendor fees.
2. Use of RFID Tags Required. A Licensee is responsible to ensure its inventories are properly tagged where the Inventory Tracking System requires RFID tag use. A Medical Marijuana Business must ensure it has an adequate supply of RFID tags to properly tag Medical Marijuana and Medical Marijuana-Infused Product as required by the Inventory Tracking System.

F. General Inventory Tracking System Use

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

4. Secondary Software Systems Allowed

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

G. Conduct While Using Inventory Tracking System

1. Misstatements or Omissions Prohibited. A Medical Marijuana Business and its designated Inventory Tracking System Administrator(s) and Inventory Tracking System User(s) shall enter data into the Inventory Tracking System that fully and transparently accounts for all inventory tracking activities. Both the Medical Marijuana Business and the individuals using the Inventory Tracking System are responsible for the accuracy of all information entered into the Inventory Tracking System. Any misstatements or omissions may be considered a license violation affecting public safety.
2. Use of Another User's Login Prohibited. Individuals entering data into the Inventory Tracking System shall only use that individual's Inventory Tracking System account.
3. Loss of System Access. If at any point a Medical Marijuana Business loses access to the Inventory Tracking System for any reason, the Medical Marijuana Business must keep and maintain comprehensive records detailing all Medical Marijuana and Medical Marijuana-Infused Product tracking inventory activities that were conducted during the loss of access. See Rule M 901 – Business Records Required. Once access is restored, all Medical Marijuana and Medical Marijuana- Infused Product inventory tracking activities that occurred during the loss of access must be entered into the Inventory Tracking System. A Medical Marijuana Business must document when access to the system was lost and when it was restored. A Medical Marijuana Business shall not transport any Medical Marijuana or Medical Marijuana-Infused Product to another Medical Marijuana Business until such time as access is restored and all information is recorded into the Inventory Tracking System.

H. System Notifications

1. Compliance Notifications. A Medical Marijuana Business must monitor all compliance notifications from the Inventory Tracking System. The Licensee must resolve the issues detailed in the compliance notification in a timely fashion. Compliance notifications shall not be dismissed in the Inventory Tracking System until the Medical Marijuana Business resolves the compliance issues detailed in the notification.
2. Informational Notifications. A Medical Marijuana Business must take appropriate action in response to informational notifications received through the Inventory Tracking System, including but not limited to notifications related to RFID billing, enforcement alerts, and other pertinent information.

- I. Lawful Activity Required. Proper use of the Inventory Tracking System does not relieve a Licensee of its responsibility to maintain compliance with all laws, rules, and other requirements at all times.
- J. Inventory Tracking System Procedures Must Be Followed. A Medical Marijuana Business must utilize the Inventory Tracking System in conformance with these rules and Inventory Tracking System procedures

## **M 400 Series – Medical Marijuana Centers**

### **Basis and Purpose – M 401**

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

### **M 401 – Medical Marijuana Center: License Privileges**

- A. Privileges Granted. A Medical Marijuana Center shall only exercise those privileges granted to it by the State Licensing Authority.
- B. Licensed Premises. 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. Authorized Sources of Medical Marijuana. 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. Authorized Sources of Medical Marijuana-Infused Product Inventory. 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. Samples Provided for Testing.
  - 1. Repealed.
  - 1.5. A Medical Marijuana Center may provide Samples of its products to a Medical Marijuana Testing Facility for testing and research purposes. The Medical Marijuana Center shall maintain the testing results as part of its business books and records. See Rule M 901 – Business Records Required.
- F. Authorized On-Premises Storage. A Medical Marijuana Center is authorized to store inventory on the Licensed Premises. All inventory stored on the Licensed Premises must be secured in a Limited Access Area or Restricted Access Area, and tracked consistently with the inventory tracking rules.

- G. Authorized Marijuana Transport. A Medical Marijuana Center is authorized to utilize a licensed Medical Marijuana Transporter for transportation of its Medical Marijuana and Medical Marijuana-Infused Product so long as the place where transportation orders are taken and delivered is a licensed Medical Marijuana Business. Nothing in this rule prevents a Medical Marijuana Center from transporting its own Medical Marijuana and Medical Marijuana-Infused Product.

### **Basis and Purpose – M 402**

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), C.R.S. The purpose of this rule is to establish that a Medical Marijuana Center can only grow Medical Marijuana in its Optional Premises Cultivation Operation for a patient that has designated that Medical Marijuana Center as being his or her primary center. The rule also helps to ensure that Medical Marijuana plants designated to a particular patient are only being grown at one Medical Marijuana Center.

### **M 402 – Registration of a Primary Medical Marijuana Center**

- A. Patient Designation Required. A Medical Marijuana Center may only grow Medical Marijuana plants for patients who have designated the Medical Marijuana Center as being his or her primary center..
- B. Change Only Allowed Every 30 Days. A Medical Marijuana Center shall not register a patient as being the patient's primary center if the patient has designated another Medical Marijuana Center as his or her primary center in the preceding 30 days. The Medical Marijuana Center and its employees must require a patient to sign in writing that he or she has not designated another Medical Marijuana Center as his or her primary center before growing medical marijuana plants on behalf of the patient.
- C. Required Questions. A Medical Marijuana Center must maintain a written record of the following questions and their answers at the time a patient indicates a desire to designate said center as his or her primary center:
1. Questions to the patient:
    - a. Which Medical Marijuana Center is currently the patient's primary center; and
    - b. How many plants is the patient's current primary center is cultivating for that patient.
  2. Questions to the current primary center:
    - a. How many plants is the Medical Marijuana Center cultivating for the patient; and
    - b. How many of the patient's plants has the Medical Marijuana Center harvested.
- D. Other Requirements. The new primary center shall also maintain written authorization from the patient and any relative plant count waivers to support the number of plants designated for that patient.
- E. Violation of Public Safety. Notwithstanding the provisions in M 402 (B), it may be considered a violation of public safety for a Medical Marijuana Center and its employees to become a patient's primary center when the patient already had designated one or more other Medical Marijuana Centers as his or her primary center.

### 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(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-310(7), 12-43.3-310(4), 12-43.4-401(4) and sections 12-43.3-402 and 12-43.3-406, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 14(4). The purpose of this rule is to clarify those acts that are prohibited, or limited in some fashion, by a licensed Medical Marijuana Center. This rule also restricts the amount of its inventory a Medical Marijuana Center may sell to other Medical Marijuana Businesses to 30 percent.

The quantity limitations on sales provision is intended to inform stakeholders in order to aid in compliance with a patient's lawful medical marijuana limit. Clarifying the quantity limitations on sales provides Medical Marijuana Centers and their employees with necessary information to avoid being complicit in a patient acquiring more medical marijuana than is lawful under the Colorado Constitution pursuant to Article XVIII, Subsection 14(4).

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

- A. 30 Percent Rule. Pursuant to section 12-43.3-402(4), C.R.S., a Medical Marijuana Center may purchase not more than thirty percent of its total on-hand medical marijuana inventory from another licensed Medical Marijuana Center in Colorado. A Medical Marijuana Center may sell no more than thirty percent of its total on-hand Medical Marijuana inventory to another Medical Marijuana Center.

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. Consumption Prohibited. 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. Licensees May Refuse Sales. Nothing in these rules prohibits a Licensee from refusing to sell Medical Marijuana or Medical Marijuana-Infused Product to a patient.

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

#### **Basis and Purpose – M 404**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(a)(VII), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to establish that a Medical Marijuana Center must control and safeguard access to certain areas where Medical Marijuana and Medical Marijuana-Infused Product will be sold, and to prevent diversion to non-patients.

**M 404 – Point of Sale: Restricted Access Area**

- A. Identification of Restricted Access Area. All areas where Medical Marijuana or Medical Marijuana-Infused Product are sold, possessed for sale, displayed or dispensed for sale shall be identified as a Restricted Access Area and shall be clearly identified by the posting of a sign which shall be not less than 12 inches wide and 12 inches long, composed of letters not less than a half inch in height, which shall state, “Restricted Access Area – Only Medical Marijuana Patients Allowed.”
- B. Patients in Restricted Access Area. The Restricted Access Area must be supervised by a Licensee at all times when patients are present to ensure that only persons with a valid patient registry card or a caregivers permitted to deliver Medical Marijuana to homebound patients as permitted by section 25-1.5-106(9)(e), C.R.S. When allowing a patient or caregiver access to a Restricted Access Area, Occupational Licensees shall make reasonable efforts to limit the number of patients in relation to the number of Occupational Licensees in the Restricted Access Area at any time.
- C. Display of Medical Marijuana and Medical Marijuana-Infused Products. The display of Medical Marijuana or Medical Marijuana-Infused Product for sale is allowed only in Restricted Access Areas. Any product displays that are readily accessible to the customer must be supervised by the Occupational Licensee at all times when customers are present.

**Basis and Purpose – M 405**

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 12-43.3-402(5), C.R.S. The Medical Code requires Medical Marijuana Center employees to verify that the purchaser has a valid registration card issued pursuant to section 25-1.5-106, C.R.S., and a valid picture identification card that matches the name on the registration card. Accordingly, this rule was adopted to explain exactly what types of picture identification cards can be accepted. Not only will this rule alleviate any confusion on the part of Medical Marijuana Center employees, but it will help reduce the amount of fraudulent transactions, thereby helping to maintain the integrity of Colorado’s Medical Marijuana Businesses.

**M 405 – Acceptable Forms of Identification for Medical Marijuana Sales**

- A. When Sales Allowed. Medical Marijuana Centers shall only sell Medical Marijuana to any patient or caregiver permitted to deliver Medical Marijuana to homebound patients as permitted by section 25-1.5-106(9)(e), C.R.S., if the patient or caregiver can produce:
  - 1. A valid patient registry card and adequate, currently valid proof of identification; or
  - 2. A copy of a current and complete new application for the Medical Marijuana registry that is documented by a certified mail return receipt as having been submitted to the Colorado Department of Public Health and Environment within the preceding thirty-five days and adequate, currently valid proof of identification.
- B. Acceptable Forms of Identification. As long as it contains a picture and date of birth, the kind and type of identification deemed adequate shall be limited to the following:
  - 1. An operator's, chauffeur's or similar type driver's license, issued by any state within the United States, any U.S. Territory;
  - 2. An identification card, issued by any state for the purpose of proof of age using requirements similar to those in sections 42-2-302 and 42-2-303, C.R.S.;
  - 3. A United States military identification card;

4. A passport; or
  5. Enrollment card issued by the governing authority of a federally recognized Indian tribe located in the state of Colorado, if the enrollment card incorporates proof of age requirements similar to sections 42-2-302 and 42-2-303, C.R.S.
- C. Physical Inspection Required. A Licensee must physically view and inspect the patient or caregiver's registry card and proof of identification to confirm the information contained on the documents and also to judge the authenticity of the documents presented.

**Basis and Purpose – M 406**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(l), 12-43.3-202(1)(h), 12-43.3-202(2)(a)(XX), and 12-43.3-402(1)(b), C.R.S. The purpose of this rule is to require all Medical Marijuana-Centers to track all inventory from the point it is received to the point of 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, 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 Medical Marijuana Center must have the ability to reconcile its inventory records with the Inventory Tracking System and the associated transaction history and sale receipts. See also Rule M 901 – Business Records Required.
1. A Medical Marijuana Center is prohibited from accepting any Medical Marijuana or Medical Marijuana-Infused Product from an Optional Premises Cultivation Operation, Medical Marijuana-Infused Products Manufacturer, or Medical Marijuana Transporter without receiving a valid transport manifest generated from the Inventory Tracking System.
  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, 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.

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**Basis and Purpose – M 407**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XV) and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to establish minimum health and safety regulation for Medical Marijuana Centers. It sets forth general standards and basic sanitary requirements for Medical Marijuana Centers. It covers the physical premises where the products are made as well as the individuals handling the products. This rule also authorizes the State Licensing Authority to require an independent consultant conduct a health and sanitary audit of a Medical Marijuana Center. This rule explains when an independent health and sanitary audit may be deemed necessary and sets forth possible consequences of a Medical Marijuana Business's refusal to cooperate or pay for the audit. The State Licensing Authority 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 Centers.

**M 407 - Health and Safety Regulations: Medical Marijuana Center**

- A. Local Safety Inspections. Licensees may be subject to inspection of the Medical Marijuana Center 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. 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 Medical Marijuana and Medical Marijuana-Infused Product shall be excluded from any operations which may be expected to result in contamination until the condition is corrected;
  2. That hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Hand-washing facilities shall be located in the Licensed Premises and where good sanitary practices require employees to wash or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices;
  3. That all persons working in direct contact with Medical Marijuana and Medical Marijuana-Infused Product shall conform to hygienic practices while on duty, including but not limited to:
    - a. Maintaining adequate personal cleanliness;
    - b. Washing hands thoroughly in an adequate hand-washing area(s) before starting work and at any other time when the hands may have become soiled or contaminated; and
    - c. Refraining from having direct contact with Medical Marijuana and 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 and 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 each is kept clean and in good repair;
6. That there is adequate lighting in all areas where Medical Marijuana and Medical Marijuana-Infused Product are stored or sold, and where equipment or utensils are cleaned;
7. That the Licensee provides adequate screening or other protection against the entry of pests. Rubbish shall be disposed of so as to minimize the development of odor and minimize the potential for the waste becoming an attractant, harborage, or breeding place for pests;
8. That any buildings, fixtures, and other facilities are maintained in a sanitary condition;
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 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 Medical Marijuana Center provides its employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair; and
12. That Medical Marijuana and Medical Marijuana-Infused Product that can support the rapid growth of undesirable microorganisms are 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 Center to undergo such an audit. The scope of the audit may include, but need not be limited, to whether the Medical Marijuana Center 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 Center. However, the Division always retains the authority to select the independent consultant regardless of whether mutual agreement can be reached.
  - c. The Medical Marijuana Center will be responsible for all costs associated with the independent health and sanitary audit.

2. 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 Center 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 Center was the cause or source of contamination of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product.
3. Compliance Required. A Medical Marijuana Center 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 Center's license. See Rule M 1302 – Disciplinary Process: Summary Suspensions.
  - b. Prior to or following the issuance of such an order, the Medical Marijuana Center may attempt to come to a mutual agreement with the Division to suspend its operations until the completion of the independent audit and the implementation of any required remedial measures.
    - i. If an agreement cannot be reached or the State Licensing Authority, in its sole discretion, determines that such an agreement is not in the best interests of the public health, safety or welfare, then the State Licensing Authority will promptly institute license suspension or revocation procedures. See Rule M 1302 – Disciplinary Process: Summary Suspensions.
    - ii. If an agreement to suspend operations is reached, then the Medical Marijuana Center may continue to care for its inventory and conduct any necessary internal business operations but it may not sell any Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product to a patient or other Medical Marijuana Business during the period of time specified in the agreement.
5. Violation Affecting Public Safety. Failure to comply with this rule may constitute a license violation affecting public safety.

**Basis and Purpose - M 408**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(X), 12-43.3-202(2)(a)(XIII), 12-43.3-202(2)(a)(XV) and 12-43.3-202(2)(a)(XX), 12-43.3-1101, and 12-43.3-1102, C.R.S. The purpose of this rule is to establish minimum standards for responsible vendor programs that provide training to personnel at Medical Marijuana Centers seeking designation as a “responsible vendor.” It sets forth general standards and basic requirements for responsible vendor programs. This rule also establishes the timeframe for new staff to complete a responsible vendor program and the requirements for recertification. The State Licensing Authority intends this rule to help maintain the integrity of Colorado’s Medical Marijuana Centers.

**M 408 - Medical Marijuana Center: Responsible Vendor Program**

**A. General Standards.**

1. To be designated a “responsible vendor” of Medical Marijuana, Medical Marijuana-Infused Product and Medical Marijuana Concentrate at any licensed Medical Marijuana Center, a Medical Marijuana Center licensee shall comply with this rule.
2. To be designated a “responsible vendor” all Owners, managers and employees involved in the handling and sale of Medical Marijuana, Medical Marijuana Infused-Product or Medical Marijuana Concentrate shall attend and successfully complete a responsible vendor program.
3. Once a licensee is designated a “responsible vendor,” all new employees involved in the handling and sale of Medical Marijuana, Medical Marijuana Infused-Product or Medical Marijuana Concentrate shall successfully complete the training described in this rule within 90 days of hire.
4. After initial successful completion of a responsible vendor program, each Owner, manager and employee of a Medical Marijuana Center shall successfully complete the program once every two years thereafter to maintain designation as a “responsible vendor.”

**B. Certification Training Program Standards.**

1. No owner or employee of a responsible vendor program shall have an interest in a licensed Medical Marijuana Business or Retail Marijuana Establishment.
2. Program providers shall submit their programs to the Division for approval as a responsible vendor program.
3. Program providers shall submit their programs for approval every two years in order to maintain designation as a responsible vendor program.
4. The program shall include at least two hours of instruction time.
5. The program shall be taught in a real-time, interactive classroom setting where the instructor is able to verify the identification of each individual attending the program and certify completion of the program by the individual identified.
6. The program provider shall maintain its training records at its principal place of business during the applicable year and for the following three years. The provider shall make the records available for inspection by the licensing authority upon request during normal business hours.

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7. The program shall provide written documentation of attendance and successful passage of a test on the knowledge of the required curriculum for each attendee.
    - a. Attendees who can speak and write English must successfully pass a written test with a score of 70% or better.
    - b. Attendees who cannot speak or write English may be offered a verbal test, provided that the same questions are given as are on the written test and the results of the verbal test are documented with a passing score of 70% or better.
  8. Program providers shall solicit effectiveness evaluations from individuals who have completed their program.
- C. Certification Training Class Core Curriculum.
1. Discussion concerning marijuana's effect on the human body. Training shall include:
    - a. Marijuana's physical effects based on type of marijuana product;
    - b. The amount of time to feel impairment;
    - c. Visible signs of impairment; and
    - d. Recognizing the signs of impairment.
  2. Sales to minors. Training shall cover all pertinent Colorado law provisions.
  3. Acceptable forms of Identification. Training shall include:
    - a. How to check identification;
    - b. Spotting false identification;
    - c. Patient Registry Cards issued by the department of public health and environment and equivalent patient verification documents;
    - d. Provisions for confiscating fraudulent identifications; and
    - e. Common mistakes made in verification.
  4. Other key state laws and rules affecting owners, managers, and employees. Training shall include:
    - a. Local and state licensing and enforcement;
    - b. Compliance with all Inventory Tracking System regulations;
    - c. Administrative and criminal liability;
    - d. License sanctions and court sanctions;
    - e. Waste disposal;
    - f. Health and safety standards;

- g. Patrons prohibited from bringing marijuana onto licensed premises;
- h. Permitted hours of sale;
- i. Conduct of establishment;
- j. Permitting inspections by state and local licensing and enforcement authorities;
- k. Licensee responsible for activities occurring within licensed premises;
- l. Maintenance of records;
- m. Privacy issues; and
- n. Prohibited purchases.

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

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

- A. Privileges Granted. A Medical Marijuana Optional Premises Cultivation Operation shall only exercise those privileges granted to it by the State Licensing Authority.
- B. Licensed Premises. 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. Cultivation of Medical Marijuana Authorized. 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. Authorized Sales. 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. Packaging Processed Medical Marijuana. Processed Medical Marijuana plants shall be packaged in units of ten pounds or less and labeled pursuant to Rule M 1002 - Labeling Requirements: General Requirements and securely sealed in a tamper-evident manner.
  - 1. The packages must be transported to the receiving Medical Marijuana Business within 7 days of receiving notification that the Harvest Batch from the processed Medical Marijuana passed required testing, and recorded as inventory at the receiving Medical Marijuana Business.

2. In the event that the Harvest Batch from the processed Medical Marijuana does not pass required testing, the Licensee shall follow the procedures in rule M 1507 for the Harvest Batch. If the Harvest Batch ultimately passes required testing, then the packages of Medical Marijuana associated with the Harvest Batch must be transported to the Medical Marijuana Business within 7 days of receiving notification that the Harvest Batch passed the additional round of testing, and recorded as inventory at the receiving Medical Marijuana Business.
- F. 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)(l), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), and 12-43.3-202(2)(a)(XX), and sections 12-43.3-310, 12-43.3-402, 12-43.3-403 and 12-43.3-406, 12-43.3-201, C.R.S. The purpose of this rule is to clarify what activity is or is not allowed at an Optional Premises Cultivation Operation.

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

- A. Transfer Restriction. An Optional Premises Cultivation Operation may only transfer Medical Marijuana to its commonly-owned Medical Marijuana Center or to a Medical Marijuana Transporter.
- B. Packaging and Labeling Standards Required. An Optional Premises Cultivation Operation is prohibited from selling Medical Marijuana that is not packaged and labeled in accordance with these rules. See Rules M 1001 – Packaging Requirements: General Requirements and M 1002 – Labeling Requirements: General Requirements.
- C. Sale to Patient Prohibited. An Optional Premises Cultivation Operation is prohibited from selling Medical Marijuana to a patient.
- D. Consumption Prohibited. 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 or Medical Marijuana-Infused Product to a Medical Marijuana Transporter, and shall not buy or receive complimentary Medical Marijuana or Medical-Marijuana Infused Product from a Medical Marijuana Transporter.

### **Basis and Purpose – M 503**

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

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

- A. Minimum Tracking Requirement. An Optional Premises Cultivation Operation must use the Inventory Tracking System to ensure its inventories are identified and tracked from the point Medical Marijuana is Propagated from seed or cutting to the point when it is delivered to a Medical Marijuana Business. See *a/so* 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 *a/so* Rule M 901 – Business Records Required.
1. 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.

### **Basis and Purpose – M 504**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XV), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to establish minimum health and safety regulation for Optional Premises Cultivation Operations. The rule prohibits an Optional Premises Cultivation Operation from treating or otherwise adulterating Medical Marijuana with any chemical or other compound whatsoever to alter its color, appearance, weight or smell. This rule also authorizes the State Licensing Authority to require an independent consultant conduct an independent health and sanitary audit of an Optional Premises Cultivation Operation. This rule explains when an independent health and sanitary audit may be deemed necessary and sets forth possible consequences of a Medical Marijuana Business's refusal to cooperate or pay for the audit. The State Licensing Authority intends this rule to help maintain the integrity of Colorado's Medical Marijuana Businesses.

### **M 504 – Optional Premises Cultivation Operation: Health and Safety Regulations**

- A. Local Safety Inspections. An Optional Premises Cultivation Operation may be subject to inspection of its Licensed Premises by the local fire department, building inspector, or code enforcement officer to confirm that no health or safety concerns are present. The inspection could result in additional specific standards to meet local licensing authority restrictions related to Medical Marijuana or other local businesses. An annual fire safety inspection may result in the required installation of fire suppression devices, or other means necessary for adequate fire safety.
- B. General Sanitary Requirements. An Optional Premises Cultivation Operation shall take all reasonable measures and precautions to ensure the following:

1. That any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with Medical Marijuana shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected;
2. That all persons working in direct contact with Medical Marijuana shall conform to hygienic practices while on duty, including but not limited to:
  - a. Maintaining adequate personal cleanliness;
  - b. Washing hands thoroughly in an adequate hand-washing area(s) before starting work and at any other time when the hands may have become soiled or contaminated;
  - c. Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Hand-washing facilities shall be located in the Licensed Premises and where good sanitary practices require employees to wash and/or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices; and
  - d. Refraining from having direct contact with Medical Marijuana if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.
3. That litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where Medical Marijuana is exposed;
4. That floors, walls, and ceilings are constructed in such a manner that they may be adequately cleaned and kept clean and kept in good repair;
5. That there is adequate lighting in all areas where Medical Marijuana is stored and where equipment or utensils are cleaned;
6. That the Licensee provides adequate screening or other protection against the entry of pests. Rubbish shall be disposed of so as to minimize the development of odor and minimize the potential for the waste becoming an attractant, harborage, or breeding place for pests;
7. That any buildings, fixtures, and other facilities are maintained in a sanitary condition;
8. That toxic cleaning compounds, sanitizing agents, and solvents shall be identified, held, stored and disposed of in a manner that protects against contamination of Medical Marijuana or Medical Marijuana Concentrate, and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation or ordinance. All Pesticide must be stored and disposed of in accordance with the information provided on the product's label;

9. That all contact surfaces, including utensils and equipment used for the preparation of Medical Marijuana or Medical Marijuana Concentrate shall be cleaned and sanitized as frequently as necessary to protect against contamination. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. Only sanitizers and disinfectants registered with the Environmental Protection Agency shall be used in an Optional Premises Cultivation Operation and used in accordance with labeled instructions;
  10. That the water supply shall be sufficient for the operations intended and shall be derived from a source that is a regulated water system. Private water supplies shall be derived from a water source that is capable of providing a safe, potable, and adequate supply of water to meet the Licensed Premises needs;
  11. That plumbing shall be of adequate size and design and adequately installed and maintained to carry sufficient quantities of water to required locations throughout the plant and that shall properly convey sewage and liquid disposable waste from the Licensed Premises. There shall be no cross-connections between the potable and waste water lines;
  12. That all operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of Medical Marijuana or Medical Marijuana-Infused Product shall be conducted in accordance with adequate sanitation principles;
  13. That each Optional Premises Cultivation Operation shall provide its employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair; and
  14. That Medical Marijuana that can support the rapid growth of undesirable microorganisms shall be held in a manner that prevents the growth of these microorganisms.
- C. Pesticide Application. An Optional Premises Cultivation Operation may only use Pesticide in accordance with the “Pesticide Act” sections 35-9-101 et seq., C.R.S., the “Pesticides Applicators’ Act,” sections 35-10-101 et seq., C.R.S., and all other applicable federal, state, and local laws, statutes, rules and regulations. This includes, but shall not be limited to, the prohibition on detaching, altering, defacing or destroying, in whole or in part, any label on any Pesticide.
- D. Application of Other Agricultural Chemicals. An Optional Premises Cultivation Operation may only use agricultural chemicals, other than Pesticide, in accordance with all applicable federal, state, and local laws, statutes, rules and regulations.
- E. Required Documentation
1. Standard Operating Procedures. An Optional Premises Cultivation Operation must establish written standard operating procedures for the cultivation of Medical Marijuana. The standard operating procedures must at least include when, and the manner in which, all Pesticide and other agricultural chemicals are to be applied during its cultivation process. A copy of all standard operating procedures must be maintained on the Licensed Premises of the Optional Premises Cultivation Operation.
  2. Material Change. If an Optional Premises Cultivation Operation makes a Material Change to its cultivation procedures, it must document the change and revise its standard operating procedures accordingly. Records detailing the Material Change must be maintained on the relevant Licensed Premises.

3. Material Safety Data Sheet. An Optional Premises Cultivation Operation must obtain a material safety data sheet for any Pesticide or other agricultural chemical used or stored on its Licensed Premises. An Optional Premises Cultivation Operation must maintain a current copy of the material safety data sheet for any Pesticide or other agricultural chemical on the Licensed Premises where the product is used or stored.
4. Labels of Pesticide and Other Agricultural Chemicals. An Optional Premises Cultivation Operation must have the original label or a copy thereof at its Licensed Premises for all Pesticide and other agricultural chemicals used during its cultivation process.
5. Pesticide Application Documentation. An Optional Premises Cultivation Operation that applies any Pesticide or other agricultural chemical to any portion of a Medical Marijuana plant, water or feed used during cultivation or generally within the Licensed Premises must document, and maintain a record on its Licensed Premises of, the following information:
  - a. The name, signature and Occupational License number of the individual who applied the Pesticide or other agricultural chemical;
  - b. Applicator certification number if the applicator is licensed through the Department of Agriculture in accordance with the "Pesticides Applicators' Act," sections 35-10-101 et seq., C.R.S.;;
  - c. The date and time of the application;
  - d. The EPA registration number of the Pesticide or CAS number of any other agricultural chemical(s) applied;
  - e. Any of the active ingredients of the Pesticide or other agricultural chemical(s) applied;
  - f. Brand name and product name of the Pesticide or other agricultural chemical(s) applied;
  - g. The restricted entry interval from the product label of any Pesticide or other agricultural chemical(s) applied;
  - h. The RFID tag number of the Medical Marijuana plant(s) that the Pesticide or other agricultural chemical(s) was applied to or if applied to all plants throughout the Licensed Premises, a statement to that effect; and
  - i. The total amount of each Pesticide or other agricultural chemical applied.
- F. Prohibited Chemicals. The following chemicals shall not be used in Medical Marijuana cultivation. Possession of chemicals and/or containers from these chemicals upon the Licensed Premises shall be a violation of this rule. Prohibited chemicals are:

Chemical Name

CAS Registry Number (or EDF Substance ID)

ALDRIN

309-00-2

ARSENIC OXIDE (3)

1327-53-3

ASBESTOS (FRIABLE)

1332-21-4

AZODRIN

6923-22-4

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

118-75-2

BINAPACRYL

485-31-4

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

126-15-8

BROMOXYNIL BUTYRATE

EDF-186

CADMIUM COMPOUNDS

CAE750

CALCIUM ARSENATE [2ASH3O4.2CA]

7778-44-1

CAMPHECHLOR

8001-35-2

CAPTAFOL

2425-06-1

CARBOFURAN

1563-66-2

CARBON TETRACHLORIDE

56-23-5

CHLORDANE

57-74-9

CHLORDECONE (KEPONE)

143-50-0

CHLORDIMEFORM

6164-98-3

CHLOROBENZILATE

510-15-6

CHLOROMETHOXYPROPYLMERCURIC ACETATE [CPMA] EDF-

183

COPPER ARSENATE

10103-61-4

2,4-D, ISOOCTYL ESTER

25168-26-7

DAMINOZIDE

1596-84-5

DDD

72-54-8

DDT

50-29-3

DI(PHENYLMERCURY)DODECENYLSUCCINATE [PMDS] EDF-

187

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

96-12-8

1,2-DIBROMOETHANE

106-93-4

1,2-DICHLOROETHANE

107-06-2

DIELDRIN

60-57-1

4,6-DINITRO-O-CRESOL

534-52-1

DINITROBUTYL PHENOL

88-85-7

ENDRIN

72-20-8

EPN

2104-64-5

ETHYLENE OXIDE

75-21-8

FLUOROACETAMIDE

640-19-7

GAMMA-LINDANE

58-89-9

HEPTACHLOR

76-44-8

HEXACHLOROBENZENE

118-74-1

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

608-73-1

1,3-HEXANEDIOL, 2-ETHYL-

94-96-2

LEAD ARSENATE

7784-40-9

LEPTOPHOS

21609-90-5

MERCURY

7439-97-6

METHAMIDOPHOS

10265-92-6

METHYL PARATHION

298-00-0

MEVINPHOS

7786-34-7

MIREX

2385-85-5

NITROFEN

1836-75-5

OCTAMETHYLDIPHOSPHORAMIDE

152-16-9

PARATHION

56-38-2

PENTACHLOROPHENOL

87-86-5

PHENYLMERCURIC OLEATE [PMO]

EDF-185

PHOSPHAMIDON

13171-21-6

PYRIMINIL

53558-25-1

SAFROLE

94-59-7

SODIUM ARSENATE

13464-38-5

SODIUM ARSENITE

7784-46-5

2,4,5-T

93-76-5

TERPENE POLYCHLORINATES (STROBANE6)

8001-50-1

THALLIUM(I) SULFATE

7446-18-6

2,4,5-TP ACID (SILVEX)

93-72-1

TRIBUTYLTIN COMPOUNDS

EDF-184

2,4,5-TRICHLOROPHENOL

95-95-4

VINYL CHLORIDE

75-01-4

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

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2. 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. An Optional Premises Cultivation Operation does not provide requested records related to the use of Pesticide or other agricultural chemicals during in the cultivation process;
    - b. The Division has reasonable grounds to believe that the Optional Premises Cultivation Operation is in violation of one or more of the requirements set forth in this rule or other applicable public health or sanitary laws, rules or regulations;
    - c. The Division has reasonable grounds to believe that the Optional Premises Cultivation Operation was the cause or source of contamination of Medical Marijuana or Medical Marijuana Concentrate; or
    - d. Multiple Harvest Batches or Production Batches produced by the Optional Premises Cultivation Operation failed contaminant testing.
  3. Compliance Required. An Optional Premises Cultivation Operation must pay for and timely cooperate with the State Licensing Authority's requirement that it undergo an independent health and sanitary audit in accordance with this rule.
  4. Suspension of Operations
    - 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 Optional Premises Cultivation Operation's license. See Rule M 1302 – Disciplinary Process: Summary Suspensions.
    - b. Prior to or following the issuance of such an order, Optional Premises Cultivation Operation may attempt to come to a mutual agreement with the Division to suspend its operations until the completion of the independent audit and the implementation of any required remedial measures.
      - i. If an agreement cannot be reached or the State Licensing Authority, in its sole discretion, determines that such an agreement is not in the best interests of the public health, safety or welfare, then the State Licensing Authority will promptly institute license suspension or revocation procedures. See Rule M 1302 – Disciplinary Process: Summary Suspensions.
      - ii. If an agreement to suspend operations is reached, then the Optional Premises Cultivation Operation may continue to care for its inventory and conduct any necessary internal business operations but it may not sell, transfer or wholesale Medical Marijuana or Medical Marijuana Concentrate to other Medical Marijuana Business during the period of time specified in the agreement.
- J. Violation Affecting Public Safety. Failure to comply with this rule may constitute a license violation affecting public safety.

### Basis and Purpose – M 505

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

### M 505 – Optional Premises Cultivation Operation: Testing

- A. Samples on Demand. Medical Marijuana Optional Premises Cultivation Operation shall, upon request of the Division, submit a sufficient quantity of Medical Marijuana to a Retail or Medical Marijuana Testing Facility to enable laboratory or chemical analysis thereof. The Division will notify the Licensee of the results of the analysis. See Rule M. 309 – Medical Marijuana Business: Inventory Tracking System and Rule M 901 – Business Records Required.
- B. Samples Provided for Testing.
1. This rule M 505(B)(1) is repealed effective July 1, 2016. A Medical Marijuana Optional Premises Cultivation Operation may provide Samples of its Medical Marijuana to a Retail Marijuana Testing Facility with a vendor certification and Occupational License for Medical Marijuana testing and research. See Rule M 701- Vendor Registration and Occupational License for Medical Marijuana Testing and Research. The Optional Premises Cultivation Operation 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 505(B)(1.5) is effective beginning July 1, 2016. A Medical Marijuana Optional Premises Cultivation Operation may provide Samples of its Medical Marijuana to a Medical Marijuana Testing Facility for testing and research purposes. The Optional Premises Cultivation Operation shall maintain the testing results as part of its business books and records. See Rule M 901 – Business Records Required.

### Basis and Purpose – M 506

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

### M 506 – Optional Premises Cultivation Operation: Medical Marijuana Concentrate Production

- A. Permitted Production of Certain Categories of Medical Marijuana Concentrate. An Optional Premises Cultivation Operation may only produce Water-Based Medical Marijuana Concentrate on its Licensed Premises and only in an area clearly designated for concentrate production on the current diagram of the Licensed Premises. See Rule M 901- Business Records Required. No other method of production or extraction for Medical Marijuana Concentrate may be conducted within the Licensed Premises of an Optional Premises Cultivation Operation unless the Owner(s) of the Optional Premises Cultivation Operation also has a valid Medical Marijuana-Infused Products Manufacturer license and the room in which Medical Marijuana Concentrate is to be produced is physically separated from all cultivation areas and has clear signage identifying the room.

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

## **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), , 12-43.3-406(1)(c), and 12-43.3-406(4)(b), and section 12-43.3-404, C.R.S. The purpose of this rule is to establish that it is unlawful for a Medical Marijuana-Infused Products Manufacturer to exercise any privileges other than those granted by the State Licensing Authority and to clarify the license privileges.

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

- A. Privileges Granted. A Medical Marijuana-Infused Products Manufacturer 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 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. Sales Restricted. A Medical Marijuana-Infused Products Manufacturer may only sell its own Medical Marijuana-Infused Product to Medical Marijuana Centers.
- D. Manufacture of Medical Marijuana-Infused Product Authorized. A Medical Marijuana-Infused Products Manufacturer may manufacture, prepare, package, and label Medical Marijuana-Infused Product, whether in concentrated form or that are comprised of Medical Marijuana and other ingredients intended for use or consumption, such as edible products, ointments, or tinctures.
- E. Location Prohibited. A Medical Marijuana-Infused Products Manufacturer may not manufacture, prepare, package, store, or label Medical Marijuana-Infused Product in a location that is operating as a retail food establishment or a wholesale food registrant.
- F. Samples Provided for Testing.
1. This rule M 601(F)(1) is repealed effective July 1, 2016. A Medical Marijuana-Infused Products Manufacturer may provide samples of its Medical Marijuana-Infused Product to a Retail Marijuana Testing Facility that has obtained an Occupational License to test and research Medical Marijuana for testing and research purposes. The Medical Marijuana-Infused Products Manufacturer shall maintain the testing results as part of its business books and records. See Rule M 901 – Business Records Required.
  - 1.5. This rule M 601(F)(1.5) is effective beginning July 1, 2016. A Medical Marijuana-Infused Products Manufacturer may provide samples of its Medical Marijuana-Infused Product to a Medical Marijuana Testing Facility for testing and research purposes. The Medical Marijuana-Infused Products Manufacturer shall maintain the testing results as part of its business books and records. See Rule M 901 – Business Records Required.
- G. 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)(XVII.6) and (XX), 12-43.3-404(3), and 12-43.3-406(1)(a) C.R.S. The Medical Code sets forth minimum requirements for written agreements between Medical Marijuana-Infused Products Manufacturers and Medical Marijuana Centers. Specifically, the written agreements must set forth the total amount of Medical Marijuana obtained from a Medical Marijuana Center licensee to be used in the manufacturing process, and the total amount of Medical Marijuana-Infused Product to be manufactured from the Medical Marijuana obtained from the Medical Marijuana Center. This rule clarifies that the Division must approve such written agreements to ensure they meet those requirements.

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

- A. Contract Required. 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. Packaging and Labeling Standards Required. 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. Sale to Consumer Prohibited. A Medical Marijuana-Infused Products Manufacturer is prohibited from selling Medical Marijuana or Medical Marijuana-Infused Product to a consumer.
- D. Consumption Prohibited. A Medical Marijuana-Infused Products Manufacturer shall not permit the consumption of marijuana or marijuana products on its Licensed Premises.
- E. Adequate Care of Perishable Product. 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. Homogeneity of Edible Retail Marijuana Product. 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.

**Basis and Purpose – M 603**

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

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

- A. 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, 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.
  - 1. 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, 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 Manufacturer'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:
  - a. Have a currently valid ServSafe Food Handler Certificate obtained through the successful completion of an online assessment or print exam; or
  - b. Take a food safety course that includes basic food handling training and is comparable to, or is a course given by, the Colorado State University extension service or a state, county, or district public health agency, and must maintain a status of good standing in accordance with the course requirements, including attending any additional classes if necessary. Any course taken pursuant to this rule must last at least two hours and cover the following subjects:
    - i. Causes of foodborne illness, highly susceptible populations and worker illness;
    - ii. Personal hygiene and food handling practices;
    - iii. Approved sources of food;

- iv. Potentially hazardous foods and food temperatures;
    - v. Sanitization and chemical use; and
    - vi. Emergency procedures (fire, flood, sewer backup).
  2. A Medical Marijuana-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 manufactures Edible Medical Marijuana-Infused Product shall comply with all kitchen-related health and safety standards of the relevant local licensing authority and, to the extent applicable, with all Colorado Department of Public Health and Environment health and safety regulations applicable to retail food establishments, as set forth in 6 CCR 1010-2.

**C. General Sanitary Requirements. The Licensee shall take all reasonable measures and precautions to ensure the following:**

1. That any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with preparation surfaces for Medical Marijuana or Medical Marijuana-Infused Product shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected;
2. That hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Hand-washing facilities shall be located in the Licensed Premises and/or in Medical Marijuana-Infused Product preparation areas and where good sanitary practices require employees to wash and/or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices;
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;
  - b. Washing hands thoroughly in an adequate hand-washing area(s) before starting work, prior to engaging in the production of a Medical Marijuana Concentrate or manufacture of a Medical Marijuana-Infused Product and at any other time when the hands may have become soiled or contaminated; and

- c. Refraining from having direct contact with preparation of Medical Marijuana or Medical Marijuana-Infused Product if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.
4. 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. Universal Symbol Marking Requirements.
  - 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:

- i. 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  $\frac{1}{4}$  inch by  $\frac{1}{4}$  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  $\frac{1}{4}$  inch by  $\frac{1}{4}$  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  $\frac{1}{4}$ " by  $\frac{1}{4}$ ".
  - 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.
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. Trademarked Food Products. Nothing in this rule alters or eliminates a Medical Marijuana-Infused Products Manufacturer's responsibility to comply with the trademarked food product provisions required by the Medical Code per 12-43.3-404(11)(a-c), C.R.S.
7. 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, sale, and donation 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. The prohibition on human, animal, and fruit shapes does not apply to the logo of a licensed Medical Marijuana Business. Nothing in this subparagraph (C.5)(7)(b) alters or eliminates a Licensee's obligation to comply with the requirements of rule M 1001.5 – Labeling and Packaging Requirements: General Applicability.
  - c. Edible Medical Marijuana-Infused Products that are geometric shapes and simply fruit flavored are not considered fruit and are permissible; and
  - d. Edible Medical Marijuana-Infused Products that are manufactured in the shape of a marijuana leaf are permissible.

D. Standard Operating Procedures

- 1. 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.
  - b. A copy of all standard operating procedures must be maintained on the Licensed Premises of the Medical Marijuana-Infused Products Manufacturer.
- 2. 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. Independent Health and Sanitary Audit

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

- c. The Medical Marijuana-Infused Products Manufacturer will be responsible for all direct costs associated with the independent health and sanitary audit.
2. 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;
  - b. A Medical Marijuana-Infused Products Manufacturer does not provide requested records related to the production of Medical Marijuana Concentrate, including but not limited to, certification of its Licensed Premises, equipment or standard operating procedures, training of Owners or employees, or Production Batch specific records;
  - c. The Division has reasonable grounds to believe that the Medical Marijuana-Infused Products Manufacturer is in violation of one or more of the requirements set forth in this rule or Rule M 605; or
  - d. The Division has reasonable grounds to believe that the Medical Marijuana-Infused Products Manufacturer was the cause or source of contamination of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product; or
  - e. Multiple Production Batches of Medical Marijuana Concentrate or Medical Marijuana-Infused Product produced by the Medical Marijuana-Infused Products Manufacturer failed contaminant testing.
3. 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. 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-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.

- i. If an agreement cannot be reached or the State Licensing Authority, in its sole discretion, determines that such an agreement is not in the best interests of the public health, safety or welfare, then the State Licensing Authority will promptly institute license suspension or revocation procedures. See Rule M 1302 – Disciplinary Process: Summary Suspensions.
  - ii. If an agreement to suspend operations is reached, then the 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. Violation Affecting Public Safety. Failure to comply with this rule may constitute a license violation affecting public safety.

#### **Basis and Purpose – M 605**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XV) and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to establish the categories of Medical Marijuana Concentrate that may be produced at a Medical Marijuana-Infused Products Manufacturer and establish standards for the production of those concentrate. Nothing in this rule authorizes the unlicensed practice of engineering under Article 25 of Title 12, C.R.S.

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

- A. Permitted Categories of Medical Marijuana Concentrate Production
  1. A Medical Marijuana-Infused Products Manufacturer may produce Water-Based Medical Marijuana Concentrate and Food-Based Medical Marijuana Concentrate.
  2. A Medical Marijuana-Infused Products Manufacturer may also produce Solvent-Based Medical Marijuana Concentrate using only the following solvents: butane, propane, CO<sub>2</sub>, ethanol, isopropanol, acetone, and heptane. The use of any other solvent is expressly prohibited unless and until it is approved by the Division.
  3. Beginning on July 1, 2014, a Medical Marijuana-Infused Products Manufacturer may submit a request to the Division to consider the approval of solvents not permitted for use under this rule during the next formal rulemaking.
- B. General Applicability. A Medical Marijuana-Infused Products Manufacturer that engages in the production of Medical Marijuana Concentrate, regardless of the method of extraction or category of concentrate being produced, must:
  1. Ensure that the space in which any Medical Marijuana Concentrate is to be produced is a fully enclosed room and clearly designated on the current diagram of the Licensed Premises. See Rule M 901- Business Records Required.

2. Ensure that all applicable sanitary rules are followed. See M 604.
3. Ensure that the standard operating procedure for each method used to produce a Medical Marijuana Concentrate on its Licensed Premises includes, but need not be limited to, step-by-step instructions on how to safely and appropriately:
  - a. Conduct all necessary safety checks prior to commencing production;
  - b. Prepare Medical Marijuana for processing;
  - c. Extract cannabinoids and other essential components of Medical Marijuana;
  - d. Purge any solvent or other unwanted components from a Medical Marijuana Concentrate,
  - e. Clean all equipment, counters and surfaces thoroughly; and
  - f. Dispose of any waste produced during the processing of Medical Marijuana in accordance with all applicable local, state and federal laws, rules and regulations. See Rule M 307 – Waste Disposal.
4. Establish written and documentable quality control procedures designed to maximize safety for Owners and Occupational Licensees and minimize potential product contamination.
5. Establish written emergency procedures to be followed by Owners or Occupational Licensees in case of a fire, chemical spill or other emergency.
6. Have a comprehensive training manual that provides step-by-step instructions for each method used to produce a Medical Marijuana Concentrate on its Licensed Premises. The training manual must include, but need not be limited to, the following topics:
  - a. All standard operating procedures for each method of concentrate production used at that Licensed Premises;
  - b. The Medical Marijuana-Infused Products Manufacturer's quality control procedures;
  - c. The emergency procedures for that Licensed Premises;
  - d. The appropriate use of any necessary safety or sanitary equipment;
  - e. The hazards presented by all solvents used within the Licensed Premises as described in the material safety data sheet for each solvent;
  - f. Clear instructions on the safe use of all equipment involved in each process and in accordance with manufacturer's instructions, where applicable; and
  - g. Any additional periodic cleaning required to comply with all applicable sanitary rules.
7. Provide adequate training to every Owner or Occupational Licensee prior to that individual undertaking any step in the process of producing a Medical Marijuana Concentrate.

- a. Adequate training must include, but need not be limited to, providing a copy of the training manual for that Licensed Premises and live, in-person instruction detailing at least all of the topics required to be included in the training manual.
  - b. The individual training an Owner or Occupational Licensee must sign and date a document attesting that all required aspects of training were conducted and that he or she is confident that the Owner or Occupational Licensee can safely produce a Medical Marijuana Concentrate. See Rule M 901- Business Records Required.
  - c. The Owner or Occupational Licensee that received the training must sign and date a document attesting that he or she can safely implement all standard operating procedures, quality control procedures, and emergency procedures, operate all closed-loop extraction systems, use all safety, sanitary and other equipment and understands all hazards presented by the solvents to be used within the Licensed Premises and any additional period cleaning required to maintain compliance with all applicable sanitary rules. See Rule M 901- Business Records Required.
8. Maintain clear and comprehensive records of the name, signature and Owner or Occupational License number of every individual who engaged in any step related to the creation of a Production Batch of Medical Marijuana Concentrate and the step that individual performed. See Rule M 901- Business Records Required.
- C. Water-Based Medical Marijuana Concentrate and Food-Based Medical Marijuana Concentrate. Medical Marijuana-Infused Products Manufacturer that engages in the production of a Water-Based Medical Marijuana Concentrate or a Food-Based Medical Marijuana Concentrate must:
1. Ensure that all equipment, counters and surfaces used in the production of a Water-Based Medical Marijuana Concentrate or a Food-Based Medical Marijuana Concentrate is food-grade including ensuring that all counters and surface areas were constructed in such a manner that it reduces the potential for the development of microbials, molds and fungi and can be easily cleaned.
  2. Ensure that all equipment, counters, and surfaces used in the production of a Water-Based Medical Marijuana Concentrate or a Food-Based Medical Marijuana Concentrate are thoroughly cleaned after the completion of each Production Batch.
  3. Ensure that any room in which dry ice is stored or used in processing Medical Marijuana into a Medical Marijuana Concentrate is well ventilated to prevent against the accumulation of dangerous levels of CO<sub>2</sub>.
  4. Ensure that the appropriate safety or sanitary equipment, including personal protective equipment, is provided to, and appropriately used by, each Owner or Occupational Licensee engaged in the production of a Water-Based Medical Marijuana Concentrate or Food-Based Medical Marijuana Concentrate.
  5. Ensure that only finished drinking water and ice made from finished drinking water is used in the production of a Water-Based Medical Marijuana Concentrate.
  6. Ensure that if propylene glycol or glycerin is used in the production of a Food-Based Medical Marijuana Concentrate, then the propylene glycol or glycerin to be used is food-grade.

7. Follow all of the rules related to the production of a Solvent-Based Medical Marijuana Concentrate if a pressurized system is used in the production of a Water-Based Medical Marijuana Concentrate or a Food-Based Medical Marijuana Concentrate.
- D. Solvent-Based Medical Marijuana Concentrate. A Medical Marijuana-Infused Products Manufacturer that engages in the production of Solvent-Based Medical Marijuana Concentrate must:
1. Obtain a report from an Industrial Hygienist or a Professional Engineer that certifies that the equipment, Licensed Premises and standard operating procedures comply with these rules and all applicable local and state building codes, fire codes, electrical codes and other laws. If a local jurisdiction has not adopted a local building code or fire code or if local regulations do not address a specific issue, then the Industrial Hygienist or Professional Engineer shall certify compliance with the International Building Code of 2012 (<http://www.iccsafe.org>), the International Fire Code of 2012 (<http://www.iccsafe.org>) or the National Electric Code of 2014 (<http://www.nfpa.org>), as appropriate. Note that this rule does not include any later amendments or editions to each Code. The Division has maintained a copy of each code, which are available to the public;
    - a. Flammable Solvent Determinations. If a Flammable Solvent is to be used in the processing of Medical Marijuana into a Medical Marijuana Concentrate, then the Industrial Hygienist or Professional Engineer must:
      - i. Establish a maximum amount of Flammable Solvents and other flammable materials that may be stored within that Licensed Premises in accordance with applicable laws, rules and regulations.
      - ii. Determine what type of electrical equipment, which may include but need not be limited to outlets, lights, junction boxes, must be installed within the room in which Medical Marijuana Concentrate are to be produced or Flammable Solvents are to be stored in accordance with applicable laws, rules and regulations.
      - iii. Determine whether a gas monitoring system must be installed within the room in which Medical Marijuana Concentrate are to be produced or Flammable Solvents are to be stored, and if required the system's specifications, in accordance with applicable laws, rules and regulations.
      - iv. Determine whether fire suppression system must be installed within the room in which Medical Marijuana Concentrate are to be produced or Flammable Solvents are to be stored, and if required the system's specifications, in accordance with applicable laws, rules and regulations.
    - b. CO<sub>2</sub> Solvent Determination. If CO<sub>2</sub> is used as solvent at the Licensed Premises, then the Industrial Hygienist or Professional Engineer must determine whether a CO<sub>2</sub> gas monitoring system must be installed within the room in which Medical Marijuana Concentrate are to be produced or CO<sub>2</sub> is stored, and if required the system's specifications, in accordance with applicable laws, rules and regulations.

- c. Exhaust System Determination. The Industrial Hygienist or Professional Engineer must determine whether a fume vent hood or exhaust system must be installed within the room in which Medical Marijuana Concentrate are to be produced, and if required the system's specifications, in accordance with applicable laws, rules and regulations.
  - d. Material Change. If a Medical Marijuana-Infused Products Manufacturer makes a Material Change to its Licensed Premises, equipment or a concentrate production procedure, in addition to all other requirements, it must obtain a report from an Industrial Hygienist or Professional Engineer re-certifying its standard operating procedures and, if changed, its Licensed Premises and equipment as well.
  - e. Manufacturer's Instructions. The Industrial Hygienist or Professional Engineer may review and consider any information provided to the Medical Marijuana-Infused Products Manufacturer by the designer or manufacturer of any equipment used in the processing of Medical Marijuana into a Medical Marijuana Concentrate.
  - f. Records Retention. A Medical Marijuana-Infused Products Manufacturer must maintain copy of all reports received from an Industrial Hygienist and Professional Engineer on its Licensed Premises. Notwithstanding any other law, rule or regulation, compliance with this rule is not satisfied by storing these reports outside of the Licensed Premises. Instead the reports must be maintained on the Licensed Premises until the Licensee ceases production of Medical Marijuana Concentrate on the Licensed Premises.
2. Ensure that all equipment, counters and surfaces used in the production of a Solvent-Based Medical Marijuana Concentrate must be food-grade and must not react adversely with any of the solvents to be used in the Licensed Premises. Additionally, all counters and surface areas must be constructed in a manner that reduces the potential development of microbials, molds and fungi and can be easily cleaned;
  3. Ensure that the room in which Solvent-Based Medical Marijuana Concentrate shall be produced must contain an emergency eye-wash station;
  4. Ensure that a professional grade, closed-loop extraction system capable of recovering the solvent is used to produce Solvent-Based Medical Marijuana Concentrate;
    - a. UL or ETL Listing
      - i. If the system is UL or ETL listed, then a Medical Marijuana-Infused Products Manufacturer may use the system in accordance with the manufacturer's instructions.
      - ii. If the system is UL or ETL listed but the Medical Marijuana-Infused Products Manufacturer intends to use a solvent in the system that is not listed in the manufacturer's instructions for use in the system, then, prior to using the unlisted solvent within the system, the Medical Marijuana-Infused Products Manufacturer must obtain written approval for use of the non-listed solvent in the system from either the system's manufacturer or a Professional Engineer after the Professional Engineer has conducted a peer review of the system. In reviewing the system, the Professional Engineer shall review and consider any information provided by the system's designer or manufacturer.

- iii. If the system is not UL or ETL listed, then there must a designer of record. If the designer of record is not a Professional Engineer, then the system must be peer reviewed by a Professional Engineer. In reviewing the system, the Professional Engineer shall review and consider any information provided by the system's designer or manufacturer.
  - b. Ethanol or Isopropanol. A Medical Marijuana-Infused Products Manufacturer Facility need not use a professional grade, closed-loop system extraction system capable of recovering the solvent for the production of a Solvent-Based Medical Marijuana Concentrate if ethanol or isopropanol are the only solvents being used in the production process.
- 5. Ensure that all solvents used in the extraction process are food-grade or at least 99% pure;
  - a. A Medical Marijuana-Infused Products Manufacturer must obtain a material safety data sheet for each solvent used or stored on the Licensed Premises. A Medical Marijuana-Infused Products Manufacturer must maintain a current copy of the material safety data sheet and a receipt of purchase for all solvents used or to be used in an extraction process. See Rule M 901- Business Records Required.
  - b. A Medical Marijuana-Infused Products Manufacturer is prohibited from using denatured alcohol to produce a Medical Marijuana Concentrate.
- 6. Ensure that all Flammable Solvents or other flammable materials, chemicals and waste are stored in accordance with all applicable laws, rules and regulations. At no time may a Medical Marijuana-Infused Products Manufacturer store more Flammable Solvent on its Licensed Premises than the maximum amount established for that Licensed Premises by the Industrial Hygienist or Professional Engineer;
- 7. Ensure that the appropriate safety and sanitary equipment, including personal protective equipment, is provided to, and appropriately used by, each Owner or Occupational Licensee engaged in the production of a Solvent-Based Medical Marijuana Concentrate; and
- 8. Ensure that a trained Owner or Occupational Licensee is present at all times during the production of a Solvent-Based Medical Marijuana Concentrate whenever an extraction process requires the use of pressurized equipment.
- E. Ethanol and Isopropanol. If a Medical Marijuana-Infused Products Manufacturer only produces Solvent-Based Medical Marijuana Concentrate using ethanol or isopropanol at its Licensed Premises and no other solvent, then it shall be considered exempt from the requirements in paragraph D of this rule and instead must follow the requirements in paragraph C of this rule. Regardless of which rule is followed, the ethanol or isopropanol must be food grade or at least 99% pure and denatured alcohol cannot be used.
- F. Violation Affecting Public Safety. 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 701

The statutory basis for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XX), 12-43.3-402(6), and 12-43.3-404(10), C.R.S. The purpose of this rule is to clarify the means by which the Division may utilize to ensure Medical Marijuana and Medical Marijuana-Infused Product are safe for patient consumption and that any Medical Marijuana or Medical Marijuana-Infused Product sold for human consumption do not contain contaminants that are injurious to health, and to help ensure sufficient and correct labeling.

### M 701 – Vendor Registration and Occupational License for Medical Marijuana Testing and Research

A. Rule M 701 is repealed effective July 1, 2016.

#### B. Occupational License For Testing and Research

1. If a Retail Marijuana Testing Facility wishes to test and research Medical Marijuana, it shall first:
  - a. Complete a current Division application, pay all applicable fees and obtain a registration as a vendor;
  - b. Complete a current Division application, pay all applicable fees and obtain an Occupational License for at least one Owner to engage in testing and research.
2. The vendor registration and Occupational License referenced in this rule may only be granted to or held by a Retail Marijuana Testing Facility whose license and certification are current, valid and in good standing.

#### C. Requirements and Violations

1. A Person holding a vendor registration and Occupational License to test and research Medical Marijuana must comply with all requirements in the Retail Marijuana Rules, 700 Series.
2. Any violation of such requirements in connection with testing and research of Medical Marijuana shall constitute a violation of these rules and a violation in connection with the Person's Retail Marijuana Testing Facility license.

### Basis and Purpose – M 701.5

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

### M 701.5 - Medical Marijuana Testing Facilities: License Privileges

A. Privileges Granted. A Medical Marijuana Testing Facility shall only exercise those privileges granted to it by the State Licensing Authority.

- B. Licensed Premises. A separate License is required for each specific Medical Marijuana Testing Facility and only those privileges granted by the Medical Code and any rules promulgated pursuant to it may be exercised on the Licensed Premises.
- C. Testing of Medical Marijuana and Medical Marijuana Infused-Product Authorized. A Medical Marijuana Testing Facility may accept Samples of Medical Marijuana or Medical Marijuana Infused-Product from Medical Marijuana Businesses for testing and research purposes only. The Division may require a Medical Marijuana Business to submit a sample of Medical Marijuana or Medical Marijuana Infused-Product to a Medical Marijuana Testing Facility upon demand.
- D. Product Development Authorized. A Medical Marijuana Testing Facility may develop Medical Marijuana Infused-Product, but is not authorized to engage in the manufacturing privileges described in section 12-43.3-404, C.R.S. and Rule M 601 – Medical Marijuana Infused-Products Manufacturer: License Privileges.
- E. Sending Samples to Another Licensed and Certified Medical Marijuana Testing Facility. A Medical Marijuana Testing Facility may send Samples to another Medical Marijuana Testing Facility for testing. All laboratory reports provided to a Medical Marijuana Business must identify the Medical Marijuana Testing Facility that actually conducted the test.
- F. Authorized Marijuana Transport. A Medical Marijuana Testing Facility is authorized to utilize a licensed Medical Marijuana Transporter to transport Samples of Medical Marijuana and Medical Marijuana-Infused Product for testing, in accordance with the Medical Marijuana Code and Medical Marijuana Rules, between the originating Medical Marijuana Business requesting testing services and the destination Medical Marijuana Testing Facility performing testing services. Nothing in this rule requires a Medical Marijuana Testing Facility, Medical Marijuana Center, Medical Marijuana Optional Premises Cultivation, or Medical Marijuana-Infused Products Manufacturer to utilize a Medical Marijuana Transporter to transport Samples of Medical Marijuana or Medical Marijuana-Infused Product for testing.

### **Basis and Purpose – M 702**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XVIII.6), 12-43.3-202(2)(a)(XX), 12-43.3-405, 12-43.3-901, 12-43.4-405, and 35-61-105.5, C.R.S. The purpose of this rule is to clarify those acts that are limited in some fashion, or prohibited, by a Medical Marijuana Testing Facility.

### **M 702 – Medical Marijuana Testing Facilities: General Limitations or Prohibited Acts**

- A. Prohibited Financial Interest. A Person who is an Owner of an Optional Premises Cultivation, Medical Marijuana Infused-Products Manufacturing Facility, Medical Marijuana Center, Retail Marijuana Cultivation Facility, Retail Marijuana Products Manufacturing Facility, or a Retail Marijuana Store shall not be an Owner of a Medical Marijuana Testing Facility.
- B. Sale of Marijuana Prohibited. A Medical Marijuana Testing Facility is prohibited from selling, distributing, or transferring Retail Marijuana, Retail Marijuana Product, Medical Marijuana, or Medical Marijuana-Infused Product to a Retail Marijuana Establishment, a Medical Marijuana Business, or a consumer, except that a Medical Marijuana Testing Facility may transfer a Sample to another Medical Marijuana Testing Facility.
- C. Destruction of Received Medical Marijuana. A Medical Marijuana Testing Facility shall properly dispose of all Samples it receives, that are not transferred to another Medical Marijuana Testing Facility, after all necessary tests have been conducted and any required period of storage. See Rule M 307 – Waste Disposal.

- D. Consumption Prohibited. A Medical Marijuana Testing Facility shall not permit the consumption of marijuana or marijuana products on its Licensed Premises.
- E. Sample Rejection. A Medical Marijuana Testing Facility shall reject any Sample where the condition of the Sample at receipt indicates that that the sample may have been tampered with.
- F. Medical Marijuana Business Requirements Applicable. A Medical Marijuana Testing Facility shall be considered a Licensed Premises. A Medical Marijuana Testing Facility shall be subject to all requirements applicable to Medical Marijuana Businesses.
- G. Medical Marijuana Testing Facility – Inventory Tracking System Required. A Medical Marijuana Testing Facility must use the Inventory Tracking System to ensure its Samples are identified and tracked from the point they are transferred from a Medical Marijuana Business through the point of destruction or disposal. See also Rule M 309 – Medical Marijuana Business: Inventory Tracking System. The Medical Marijuana Testing Facility must have the ability to reconcile its Sample records with the Inventory Tracking System and the associated transaction history. See also Rule M 901 – Business Records Required.
- H. Industrial Hemp Testing Prohibited. A Medical Marijuana Testing Facility shall not perform testing on Industrial Hemp.
- I. A Medical Marijuana Testing Facility shall not sell or give away Medical Marijuana or Medical Marijuana-Infused Product to a Medical Marijuana Transporter, and shall not buy, or receive complimentary Medical Marijuana or Medical Marijuana-Infused Product from a Medical Marijuana Transporter.

#### **Basis and Purpose – M 703**

The statutory authority for this rule is found at subsection 12-43.3-202(1)(b)(l), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(IV), 12-43.3-202(2)(a)(X), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(l) and section 12-43.3-405, C.R.S. The purpose of this rule is to establish a frame work for certification for Medical Marijuana Testing Facilities.

#### **M 703 – Medical Marijuana Testing Facilities: Certification Requirements**

- A. Certification Types. If certification in a testing category is required by the Division, then the Medical Marijuana Testing Facility must be certified in the category in order to perform that type of testing.
  - 1. Microbials;
  - 2. Residual solvents;
  - 3. Chemical Contaminants;
  - 4. Biological Contaminants; and
  - 5. THC and other Cannabinoid potency.
- B. Certification Procedures. The Medical Marijuana Testing Facility certification program is contingent upon successful on-site inspection, successful participation in proficiency testing, and ongoing compliance with the applicable requirements in this rule.
  - 1. Certification Inspection. A Medical Marijuana Testing Facility must be inspected prior to initial certification and annually thereafter by an inspector approved by the Division.

2. Standards for Certification. A Medical Marijuana Testing Facility must meet standards of performance, as established by these rules, in order to obtain and maintain certification. Standards of performance include but are not limited to: personnel qualifications, standard operating procedure manual, analytical processes, proficiency testing, quality control, quality assurance, security, chain of custody, specimen retention, space, records, and results reporting.
3. Personnel Qualifications
  - a. Laboratory Director. A Medical Marijuana Testing Facility must employ, at a minimum, a laboratory director with sufficient education and experience in a regulated laboratory environment in order to obtain and maintain certification. See Rule M 704 – Retail Marijuana Testing Facilities: Personnel.
  - b. Employee Competency. A Medical Marijuana Testing Facility must have a written and documented system to evaluate and document the competency in performing authorized tests for employees. Prior to independently analyzing samples, testing personnel must demonstrate acceptable performance on precision, accuracy, specificity, reportable ranges, blanks, and unknown challenge samples (proficiency samples or internally generated quality controls).
4. Standard Operating Procedure Manual. A Medical Marijuana Testing Facility must have a written procedure manual meeting the minimum standards set forth in these rules detailing the performance of all methods employed by the facility used to test the analytes it reports and made available for testing analysts to follow at all times.
  - a. The current laboratory director must approve, sign and date each procedure. If any modifications are made to those procedures, the laboratory director must approve, sign and date the revised version prior to use.
  - b. A Medical Marijuana Testing Facility must maintain a copy of all Standard Operating Procedures to include any revised copies for a minimum of three years. See Rule M 901 – Business Records Required.
5. Analytical Processes. A Medical Marijuana Testing Facility must maintain a listing of all analytical methods used and all analytes tested and reported. The Medical Marijuana Testing Facility must provide this listing to the Division upon request.
6. Proficiency Testing. A Medical Marijuana Testing Facility must successfully participate in a Division approved proficiency testing program in order to obtain and maintain certification.
7. Quality Assurance and Quality Control. A Medical Marijuana Testing Facility must establish and follow a quality assurance and quality control program to ensure sufficient monitoring of laboratory processes and quality of results reported.
8. Security. A Medical Marijuana Testing Facility must be located in a secure setting as to prevent unauthorized persons from gaining access to the testing and storage areas of the laboratory.
9. Chain of Custody. A Medical Marijuana Testing Facility must establish a system to document the complete chain of custody for samples from receipt through disposal.

10. Space. A Medical Marijuana Testing Facility must be located in a fixed structure that provides adequate infrastructure to perform analysis in a safe and compliant manner consistent with federal, state and local requirements.
11. Records. A Medical Marijuana Testing Facility must establish a system to retain and maintain records for a period not less than three years.
12. Results Reporting. A Medical Marijuana Testing Facility must establish processes to ensure results are reported in a timely and accurate manner.
13. Conduct While Seeking Certification. A Medical Marijuana Testing Facility, and its agents and employees, shall provide all documents and information required or requested by the Colorado Department of Public Health and Environment and its employees, and the Division and its employees in a full, faithful, truthful, and fair manner. A violation of this rule may be considered a license violation affecting public safety.

#### **Basis and Purpose – M 704**

The statutory authority for this rule is found at subsection 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX), 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**

- A. Laboratory Director. The laboratory director is responsible for the overall analytical operation and quality of the results reported by the Medical Marijuana Testing Facility, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurately, and proficiently and for assuring compliance with the standards set forth in this rule.
  1. The laboratory director may also serve as a supervisory analyst or testing analyst, or both, for a Medical Marijuana Testing Facility.
  2. The laboratory director for a Medical Marijuana Testing Facility must meet one of the following qualification requirements:
    - a. The laboratory director must be a Medical Doctor (M.D.) licensed to practice medicine in Colorado and have at least three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body; or
    - b. The laboratory director must hold a doctoral degree in one of the natural sciences and have at least three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body; 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. Responsibilities of the Laboratory Director. The laboratory director must:
1. Ensure that the Medical Marijuana Testing Facility has adequate space, equipment, materials, and controls available to perform the tests reported;
  2. Establish and adhere to a written standard operating procedure used to perform the tests reported;
  3. Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;
  4. Ensure that the physical location and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards;
  5. Ensure that the test methodologies selected have the capability of providing the quality of results required for the level of testing the laboratory is certified to perform;
  6. Ensure that validation and verification test methods used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;
  7. Ensure that testing analysts perform the test methods as required for accurate and reliable results;
  8. Ensure that the laboratory is enrolled in a Division approved proficiency testing program;
  9. Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;
  10. Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;
  11. Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and that test results are reported only when the system is functioning properly;
  12. Ensure that reports of test results include pertinent information required for interpretation;
  13. Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation of said results;
  14. Employ a sufficient number of laboratory personnel who meet the qualification requirements and provide appropriate consultation, properly supervise, and ensure accurate performance of tests and reporting of test results;

15. Ensure that prior to testing any samples, all testing analysts receive the appropriate training for the type and complexity of tests performed, and have demonstrated and documented that they can perform all testing operations reliably to provide and report accurate results;
  16. Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process 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:
1. 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
  2. Designate an interim laboratory director within seven days of the laboratory director's departure. At a minimum, the interim laboratory director must meet the qualifications of a supervisory analyst.
  3. The Medical Marijuana Testing Facility must hire a permanent laboratory director within 60 days from the date of the previous laboratory director's departure.
  4. Notwithstanding the requirement of subparagraph (C.5)(3), the Medical Marijuana Testing Facility may submit a waiver request to the Division Director to receive an additional 60 days to hire a permanent laboratory director provided that the Medical Marijuana Testing Facility submits a detailed oversight plan along with the waiver request.
- D. Supervisory Analyst. Supervisory analysts must meet one of the qualifications for a laboratory director or have at least a bachelor's degree in one of the natural sciences and three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body. A combination of education and experience may substitute for the three years of full-time laboratory experience.
- E. Laboratory Testing Analyst
1. Educational Requirements. An individual designated as a testing analyst must meet one of the qualifications for a laboratory director or supervisory analyst or have at least a bachelor's degree in one of the natural sciences and one year of full-time experience in laboratory testing.

2. Responsibilities. In order to independently perform any test for a Medical Marijuana Testing Facility, an individual must at least meet the educational requirements for a testing analyst.

### **M 705 – Basis and Purpose**

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 Standard Operating Procedure Manual standards for the operation of a Medical Marijuana Testing Facility.

### **M 705 – Medical Marijuana Testing Facilities: Standard Operating Procedure Manual**

This rule shall be effective on July 1, 2016.

- A. A standard operating procedure manual must include, but need not be limited to, procedures for:
  1. Specimen receiving;
  2. Specimen accessioning;
  3. Specimen storage;
  4. Identifying and rejecting unacceptable specimens;
  5. Recording and reporting discrepancies;
  6. Security of specimens, aliquots and extracts and records;
  7. Validating a new or revised method prior to testing specimens to include: accuracy, precision, analytical sensitivity, analytical specificity (interferences), LOD, LOQ, and verification of the reportable range;
  8. Aliquoting specimens to avoid contamination and carry-over;
  9. Sample retention to assure stability for 90 days;
  10. Disposal of specimens;
  11. The theory and principles behind each assay;
  12. Preparation and identification of reagents, standards, calibrators and controls and ensure all standards are traceable to National Institute of Standards of Technology (“NIST”);
  13. Special requirements and safety precautions involved in performing assays;
  14. Frequency and number of control and calibration materials;
  15. Recording and reporting assay results;
  16. Protocol and criteria for accepting or rejecting analytical procedure to verify the accuracy of the final report;
  17. Pertinent literature references for each method;

18. Current step-by-step instructions with sufficient detail to perform the assay to include equipment operation and any abbreviated versions used by a testing analyst;
19. Acceptability criteria for the results of calibration standards and controls as well as between two aliquots or columns;
20. A documented system for reviewing the results of testing calibrators, controls, standards, and subject tests results, as well as reviewing for clerical errors, analytical errors and any unusual analytical results. Are corrective actions implemented and documented, and does the laboratory contact the requesting entity; and
21. Policies and procedures to follow when specimens are requested for referral and testing by another certified laboratory.

### **M 706 – Basis and Purpose**

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 analytical processes standards for the operation of a Medical Marijuana Testing Facility.

### **M 706 – Medical Marijuana Testing Facilities: Analytical Processes**

This rule shall be effective on July 1, 2016.

- A. Gas Chromatography (“GC”). A Medical Marijuana Testing Facility using GC must:
  1. Document the conditions of the gas chromatograph, including the detector response;
  2. Perform and document preventive maintenance as required by the manufacturer;
  3. Ensure that records are maintained and readily available to the staff operating the equipment;
  4. Document the performance of new columns before use;
  5. Use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified;
  6. Establish criteria of acceptability for variances between different aliquots and different columns; and
  7. Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system.
- B. Gas Chromatography Mass Spectrometry (“GC/MS”). A Medical Marijuana Testing Facility using GC/MS must:
  1. Perform and document preventive maintenance as required by the manufacturer;
  2. Document the changes of septa as specified in the Standard Operating Procedure;
  3. Document liners being cleaned or replaced as specified in the Standard Operating Procedure;

4. Ensure that records are maintained and readily available to the staff operating the equipment;
  5. Maintain records of mass spectrometric tuning;
  6. Establish written criteria for an acceptable mass-spectrometric tune;
  7. Document corrective actions if a mass-spectrometric tune is unacceptable;
  8. Monitor analytic analyses to check for contamination and carry-over;
  9. Use selected ion monitoring within each run to assure that the laboratory compare ion ratios and retention times between calibrators, controls and specimens for identification of an analyte;
  10. Use an internal standard for qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;
  11. Document the monitoring of the response (area or peak height) for the internal standard to ensure consistency overtime of the analytical system;
  12. Define the criteria for designating qualitative results as positive;
  13. When a library is used to qualitatively match an analyte, the relative retention time and mass spectra from a known standard or control must be run on the same system before reporting the results; and
  14. Evaluate the performance of the instrument after routine and preventive maintenance (e.g. clipping or replacing the column or cleaning the source) prior to analyzing subject samples.
- C. Immunoassays. A Medical Marijuana Testing Facility using Immunoassays must:
1. Perform and document preventive maintenance as required by the manufacturer;
  2. Ensure that records are maintained and readily available to the staff operating the equipment;
  3. Validate any changes or modifications to a manufacturer's approved assays or testing methods when a sample is not included within the types of samples approved by the manufacturer; and
  4. Define acceptable separation or measurement units (absorbance intensity or counts per minute) for each assay, which must be consistent with manufacturer's instructions.
- D. Thin Layer Chromatography ("TLC"). A Medical Marijuana Testing Facility using TLC must:
1. Apply unextracted standards to each thin layer chromatographic plate;
  2. Include in their written procedure the preparation of mixed solvent systems, spray reagents and designation of lifetime;
  3. Include in their written procedure the storage of unused thin layer chromatographic plates;

4. Evaluate, establish, and document acceptable performance for new thin layer chromatographic plates before placing them into service;
  5. Verify that the spotting technique used precludes the possibility of contamination and carry-over;
  6. Measure all appropriate RF values for qualitative identification purposes;
  7. Use and record sequential color reactions, when applicable;
  8. Maintain records of thin layer chromatographic plates; and
  9. Analyze an appropriate matrix blank with each batch of specimens analyzed.
- E. High Performance Liquid Chromatography ("HPLC"). A Medical Marijuana Testing Facility using HPLC must:
1. Perform and document preventive maintenance as required by the manufacturer;
  2. Ensure that records are maintained and readily available to the staff operating the equipment;
  3. Monitor and document the performance of the HPLC instrument each day of testing;
  4. Evaluate the performance of new columns before use;
  5. Create written standards for acceptability when eluting solvents are recycled;
  6. Use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified when available or appropriate for the assay; and
  7. Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system.
- F. Liquid Chromatography Mass Spectroscopy ("LC/MS"). A Medical Marijuana Testing Facility using LC/MS must:
1. Perform and document preventive maintenance as required by the manufacturer;
  2. Ensure that records are maintained and readily available to the staff operating the equipment;
  3. Maintain records of mass spectrometric tuning;
  4. Document corrective actions if a mass-spectrometric tune is unacceptable;
  5. Use an internal standard with each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;
  6. Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system;

7. Compare two transitions and retention times between calibrators, controls and specimens within each run;
  8. Document and maintain records when changes in source, source conditions, eluent, or column are made to the instrument; and
  9. Evaluate the performance of the instrument when changes in: source, source conditions, eluent, or column are made prior to reporting test results.
- G. Other Analytical Methodology. A Medical Marijuana Testing Facility using other methodology or new methodology must:
1. Implement a performance based measurement system for the selected methodology and validate the method following good laboratory practices prior to reporting results. Validation of other or new methodology must include when applicable, but is not limited to:
    - a. Verification of Accuracy
    - b. Verification of Precision
    - c. Verification of Analytical Sensitivity
    - d. Verification of Analytical Specificity
    - e. Verification of the LOD
    - f. Verification of the LOQ
    - g. Verification of the Reportable Range
    - h. Identification of Interfering Substances
  2. Validation of the other or new methodology must be documented.
  3. Prior to use, other or new methodology must have a standard operating procedure approved and signed by the laboratory director.
  4. Testing analysts must have documentation of competency assessment prior to testing samples.
  5. Any changes to the approved other or new methodology must be revalidated and documented prior to testing samples.

### **M 707 – Basis and Purpose**

The statutory authority for this rule is found at subsection 12-43.3-202(2)(a)(I) and section 12-43.3-405, C.R.S. The purpose of this rule is to establish a proficiency testing program for Medical Marijuana Testing Facilities.

### **M 707 – Medical Marijuana Testing Facilities: Proficiency Testing**

This rule shall be effective on July 1, 2016.

- A. Proficiency Testing Required. A Medical Marijuana Testing Facility must participate in a proficiency testing program for each approved category in which it seeks certification.
- B. Participation in Designated Proficiency Testing Event. If required by the Division as part of certification, the Medical Marijuana Testing Facility must have successfully participated in a proficiency test in the category for which it seeks certification, within the preceding 12 months.
- C. Continued Certification. To maintain continued certification, a Medical Marijuana Testing Facility must participate in the designated proficiency testing program with continued satisfactory performance as determined by the Division as part of certification.
- D. Analyzing Proficiency Testing Samples. A Medical Marijuana Testing Facility must analyze Proficiency Testing Samples using the same procedures with the same number of replicate analyses, standards, testing analysts and equipment as used for product testing.
- E. Proficiency Testing Challenge Attestation. The laboratory director and all testing analysts that participated in a proficiency test must sign corresponding attestation statements.
- F. Laboratory Director Must Review Results. The laboratory director must review and evaluate all proficiency test results.
- G. When Remedial Action Required. A Medical Marijuana Testing Facility must take and document remedial action when a score of less than 100% is achieved during a proficiency test. Remedial action documentation must include a review of Samples tested and results reported since the last successful proficiency testing challenge.
- H. What Constitutes Successful or Unsatisfactory Participation in Proficiency Testing Event. Successful participation is the positive identification of 80% of the target analytes that the Medical Marijuana Testing Facility reports to include quantitative results when applicable. Any false positive results reported will be considered an unsatisfactory score for the proficiency testing event.
- I. Consequence of Unsuccessful Participation in Proficiency Testing Event. Unsuccessful participation in a proficiency test may result in limitation, suspension or revocation of certification.

#### **M 708 – Basis and Purpose**

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 quality assurance and quality assurance standards for a Medical Marijuana Testing Facility.

#### **M 708 – Medical Marijuana Testing Facilities: Quality Assurance and Quality Control**

This rule shall be effective on July 1, 2016.

- A. Quality Assurance Program Required. A Medical Marijuana Testing Facility must establish, monitor, and document the ongoing review of a quality assurance program that is sufficient to identify problems in the laboratory preanalytic, analytic and postanalytic systems when they occur and must include, but is not limited to:
  - 1. Review of instrument preventive maintenance, repair, troubleshooting and corrective actions documentation must be performed by the laboratory director or designated supervisory analyst on an ongoing basis to ensure the effectiveness of actions taken over time;

2. Review by the laboratory director or designated supervisory analyst of all ongoing quality assurance; and
  3. Review of the performance of validated methods used by the Medical Marijuana Testing Facility to include calibration standards, controls and the Standard Operating Procedures used for analysis on an ongoing basis to ensure quality improvements are made when problems are identified or as needed.
- B. Quality Control Measures Required. A Medical Marijuana Testing Facility must establish, monitor and document on an ongoing basis the quality control measures taken by the laboratory to ensure the proper functioning of equipment, validity of standard operating procedures and accuracy of results reported. Such quality control measures must include, but shall not be limited to:
1. Documentation of instrument preventive maintenance, repair, troubleshooting and corrective actions taken when performance does not meet established levels of quality;
  2. Review and documentation of the accuracy of automatic and adjustable pipettes and other measuring devices when placed into service and annually thereafter;
  3. Cleaning, maintaining and calibrating as needed the analytical balances and in addition, verifying the performance of the balance annually using certified weights to include three or more weights bracketing the ranges of measurement used by the laboratory;
  4. Annually verifying and documenting the accuracy of thermometers using a NIST traceable reference thermometer;
  5. Recording temperatures on all equipment when in use where temperature control is specified in the standard operating procedures manual, such as water baths, heating blocks, incubators, ovens, refrigerators, and freezers;
  6. Properly labeling reagents as to the identity, the concentration, date of preparation, storage conditions, lot number tracking, expiration date and the identity of the preparer;
  7. Avoiding mixing different lots of reagents in the same analytical run;
  8. Performing and documenting a calibration curve with each analysis using at minimum three calibrators throughout the reporting range;
  9. For qualitative analyses, analyzing, at minimum, a negative and a positive control with each batch of samples analyzed;
  10. For quantitative analyses, analyzing, at minimum, a negative and two levels of controls that challenge the linearity of the entire curve;
  11. Using a control material or materials that differ in either source or, lot number, or concentration from the calibration material used with each analytical run;
  12. For multi-analyte assays, performing and documenting calibration curves and controls specific to each analyte, or at minimum, one with similar chemical properties as reported in the analytical run;
  13. Analyzing an appropriate matrix blank and control with each analytical run, when available;

14. Analyzing calibrators and controls in the same manner as unknowns;
15. Documenting the performance of calibration standards and controls for each analytical run to ensure the acceptability criteria as defined in the Standard Operating Procedure is met;
16. Documenting all corrective actions taken when unacceptable calibration, control, and standard or instrument performance does not meet acceptability criteria as defined in the Standard Operating Procedure;
17. Maintaining records of validation data for any new or modified methods to include; accuracy, precision, analytical specificity (interferences), LOD, LOQ, and verification of the linear range; and
18. Performing testing analysts that follow the current Standard Operating Procedures Manual for the test or tests to be performed.

### **M 709 – Basis and Purpose**

The statutory authority for this rule is found at subsection 12-43.3-202(2.5)(I) and section 12-43.3-405, C.R.S. The purpose of this rule is to establish chain of custody standards for a Medical Marijuana Testing Facility. In addition, it establishes the requirement that a Medical Marijuana Testing Facility follow an adequate chain of custody for Samples it maintains.

### **M 709 – Medical Marijuana Testing Facilities: Chain of Custody**

This rule shall be effective on July 1, 2016.

General Requirements. A Medical Marijuana Testing Facility must establish an adequate chain of custody and Sample requirement instructions that must include, but not be limited to;

1. Issue instructions for the minimum Sample requirements and storage requirements;
2. Document the condition of the external package and integrity seals utilized to prevent contamination of, or tampering with, the Sample;
3. Document the condition and amount of Sample provided at the time of receipt;
4. Document all persons handling the original Samples, aliquots, and extracts;
5. Document all transfers of Samples, aliquots, and extracts referred to another certified Medical Marijuana Testing Facility Licensee for additional testing or whenever requested by a client;
6. Maintain a current list of authorized personnel and restrict entry to the laboratory to only those authorized;
7. Secure the Laboratory during non-working hours;
8. Secure short and long-term storage areas when not in use;
9. Utilize a secured area to log-in and aliquot Samples;
10. Ensure Samples are stored appropriately; and

11. Document the disposal of Samples, aliquots, and extracts.

### **Basis and Purpose – M 710**

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

### **M 710 – Medical Marijuana Testing Facilities: Records Retention**

This rule shall be effective on July 1, 2016.

- A. General Requirement. A Medical Marijuana Testing Facility must maintain all required business records. See Rule M901 - Business Records Required.
- B. Specific Business Records Required: Three Year Retention. A Medical Marijuana Testing Facility must establish processes to preserve records for a minimum of three years that includes, but is not limited to;
  1. Test Results;
  2. Quality Control and Quality Assurance Records;
  3. Standard Operating Procedures;
  4. Personnel Records;
  5. Chain of Custody Records;
  6. Proficiency Testing Records; and
  7. Analytical Data to include printouts generated by the instrumentation.
- C. Specific Business Records Required: Five Year Retention. A Medical Marijuana Testing Facility must establish processes to preserve records for a minimum of five years of testing to include, accession numbers, specimen type, raw data of calibration standards and curves, controls and subject results, final and amended reports, acceptable reference range parameters, and identification of analyst and date of analysis.

### **Basis and Purpose – M 711**

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

### **M 711 – Reporting**

**This rule shall be effective on July 1, 2016.**

Required Procedures. A Medical Marijuana Testing Facility must establish procedures to ensure that results are accurate, precise and scientifically valid prior to reporting that include the following processes;

1. Report quantitative results that are only above the lowest concentration of calibrator or standard used in the analytical run;

2. Verify results that are below the lowest concentration of calibrator or standard and above the LOQ by using a blank and a standard that falls below the expected value of the analyte in the sample in duplicate prior to reporting a quantitative result;
3. Qualitatively report results below the lowest concentration of calibrator or standard and above the LOD as either trace or using a non-specific numerical designation;
4. Adequately document the available external chain of custody information;
5. Ensure all final reports contain the name and location of the Medical Marijuana Testing Facility Licensee, name and unique identifier of sample, submitting client, sample received date, date of report, type of specimen tested, test result, units of measure, and any other information or qualifiers needed for interpretation when applicable to the test method and results being reported, to include any identified and documented discrepancies;
6. Provide the final report to the submitting client in a timely manner; and
7. Provide copies of final reports to the Division when results of tested samples exceed maximum levels of allowable contamination within 72 hours of obtaining the final result.

### **Basis and Purpose – M 712**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.4-203(2.5)(a)(I), 12-43.3-202(2)(a)(XIV), 12-43.4-202(2)(a)(XI), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(IV), 12-43.3-202(2)(a)(XX), and 12-43.3-405, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to establish the portion of the Division's mandatory testing and 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**

- A. Division Authority. The Division may elect to require that a Test Batch be submitted to a specific Medical Marijuana Testing Facility for testing to verify compliance, perform investigations, compile data or address a public health and safety concern.
- B. Test Batches
  1. 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. Medical Marijuana Infused-Product. A Medical Marijuana Testing Facility must establish a standard number of finished product(s) it requires to be included in each Test Batch of Medical Marijuana Infused-Product for every type of test that it conducts.
- C. Rejection of Test Batches and Samples
  1. A Medical Marijuana Testing Facility may not accept a Test Batch that is smaller than its standard minimum amount.

2. A Medical Marijuana Testing Facility may not accept a Test Batch or Sample that it knows was not taken in accordance with these rules or any additional Division sampling procedures or was not collected by Division personnel.
- D. Notification of Medical Marijuana Business. 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

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

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

\*\* 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

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

4. Other Contaminants

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

5. Division Notification. 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. Cannabinoids Potency Profiles. A Medical Marijuana Testing Facility may test and report results for any cannabinoid provided the test is conducted in accordance with the Division's Medical Marijuana Testing Facility Certification Policy Statement.
2. Reporting of Results
  - a. For potency tests on Medical Marijuana and Medical Marijuana Concentrate, results must be reported by listing a single percentage concentration for each cannabinoid that represents an average of all samples within the Test Batch.
  - b. For potency tests conducted on Medical Marijuana Infused-Product, results must be reported by listing the total number of milligrams contained within a single Medical Marijuana-Infused Product unit for sale for each cannabinoid and affirming the THC content is homogenous.
3. Dried Flower. All potency tests conducted on Medical Marijuana must occur on dried and cured Medical Marijuana that is ready for sale.
4. Failed Potency Tests for Medical Marijuana Infused-Product
  - a. If the THC content of a Medical Marijuana Infused-Product is determined through testing not to be homogenous, then it shall be considered to have failed potency testing. A Medical Marijuana Infused-Product shall be considered not to be homogenous if 10% of the infused portion of the Medical Marijuana Infused-Product contains more than 20% of the total THC contained within entire Medical Marijuana Infused-Product.
5. Potency Variance. A potency variance of no more than plus or minus 15% is allowed.

**M 800 Series – Transport and Storage**

**Basis and Purpose – M 801**

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

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

- A. Persons Authorized to Transport. The only Persons authorized to transport Medical Marijuana, Medical Marijuana Vegetative plants, or Medical Marijuana-Infused Product are those individuals licensed by the State Licensing Authority pursuant to section 12-43.3-401, C.R.S.; including Owners 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. Transport Between Licensed Premises.
1. 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.
  2. 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.
1. 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.
  2. Medical Marijuana Vegetative Plants. 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. Motor Vehicle Required. 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. Documents Required During Transport. 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. Use of Colorado Roadways. 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
1. Final Weighing and Packaging. 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. Preparation in Limited Access Area. 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. Sealed packages or Containers must be placed in Shipping Containers. The contents of Shipping Containers shall be easily accessible and may be inspected by the State Licensing Authority, local licensing authorities, and state and local law enforcement agency for a purpose authorized by the Medical Code or for any other state or local law enforcement purpose.
- G.5 Required RFID Tags for Medical Marijuana Vegetative Plants. Each Medical Marijuana Vegetative plant that is transported pursuant to this rule must have a RFID tag affixed to it prior to transport.
- H. Creation of Records and Inventory Tracking
1. Use of Inventory Tracking System -Generated Transport Manifest.
    - a. Medical Marijuana or Medical Marijuana-Infused Product. 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.
    - a.1 Use of a Medical Marijuana Transporter. In addition to subsubparagraph (H)(1)(a), Licensees shall also follow the requirements of this subsubparagraph (H)(1)(a.1) when a Licensee utilizes the services of a Medical Marijuana Transporter.
      - i. When a Medical Marijuana Center, Optional Premises Cultivation Operation, Medical Marijuana-Infused Products Manufacturer, or Medical Marijuana Testing Facility utilizes a Medical Marijuana Transporter for transporting its Medical Marijuana or Medical Marijuana-Infused Products, the originating Licensee shall input the requisite information on the Inventory Tracking System-generated transport manifest for the final destination Licensee who will be receiving the Medical Marijuana or Medical Marijuana-Infused Products.

- ii. A Medical Marijuana Transporter is prohibited from being listed as the final destination Licensee.
  - iii. A Medical Marijuana Transporter shall not alter the information of the final destination Licensee after the information has been entered on the Inventory Tracking System-generated transport manifest by the originating Medical Marijuana Center, Optional Premises Cultivation Operation, Medical Marijuana-Infused Products Manufacturer, or Medical Marijuana Testing Facility.
  - iv. If the Medical Marijuana Transporter is not delivering the originating Licensee's Medical Marijuana or Medical Marijuana- Infused Product directly to the final destination Licensee, the Medical Marijuana Transporter shall communicate to the originating Licensee which of the Medical Marijuana Transporter's Licensed Premises or off-premises storage facilities will receive and temporarily store the Medical Marijuana or Medical Marijuana-Infused Product. The originating Licensee shall input the Medical Marijuana Transporter's location address and license number on the Inventory Tracking System-generated transport manifest.
- b. Medical Marijuana Vegetative Plants.
- i. Licensees who transport Medical Marijuana Vegetative plants shall create an Inventory Tracking System-generated transport manifest to reflect inventory that leaves the originating Licensed Premises to be transported to the destination Licensed Premises due to a change of location approved by the Division pursuant to rule M 206, or a one-time transfer pursuant to rule M 211.
  - ii. Medical Marijuana Transporters are permitted to transport Medical Marijuana Vegetative Plants on behalf of other Licensees due to a change of location approved by the Division pursuant to rule M 206, or a one-time transfer pursuant to rule M 211. The Medical Marijuana Transporter shall transport the Medical Marijuana Vegetative Plants directly from the originating Licensed Premises to the final destination Licensed Premises without any stops in between.
2. Copy of Transport Manifest to 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;
  - c. Name, location address, and license number of the destination Medical Marijuana Business(es), or the destination Retail Marijuana Establishment in the event of a one-time transfer;

- c.1 Name, location address, and license number of the Medical Marijuana Transporter if applicable pursuant to M 801(H)(1)(a.1)(iv).
  - d. Product name and quantities (by weight or unit) of each product to be delivered to each specific destination location(s);
  - e. Arrival date and estimated time of arrival;
  - f. Delivery vehicle make and model and license plate number; and
  - g. Name, Occupational License number, and signature of the Licensee accompanying the transport.
- I. Inventory Tracking. In addition to all the other tracking requirements set forth in these rules, a Medical Marijuana Business shall be responsible for all the procedures associated with the tracking of inventory that is transported between Licensed Premises. See Rule M 901 – Business Records Required.
- 1. Responsibilities of Originating Licensee.
    - a. Medical Marijuana or Medical Marijuana-Infused Product. Prior to departure, the originating Medical Marijuana Business shall adjust its records to reflect the removal of Medical Marijuana or Medical Marijuana-Infused Product. The scale used to weigh product to be transported shall be tested and approved in accordance with measurement standards established in 35-14-127,, C.R.S. Entries to the records shall note the Inventory Tracking System-generated transport manifest and shall be easily reconciled, by product name and quantity, with the applicable transport manifest.
    - b. Medical Marijuana Vegetative Plants. Prior to departure, the originating Optional Premises Cultivation Operation shall adjust its records to reflect the removal of Medical Marijuana Vegetative plants. Entries to the records shall note the Inventory Tracking System-generated transport manifest and shall be easily reconciled, by product name and quantity, with the applicable transport manifest.
  - 2. Responsibilities of 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. Medical Marijuana Transporters shall comply with all requirements of this subsubparagraph (I)(2)(a) except that they are not required to weigh Medical Marijuana or Medical Marijuana-Infused Products.
    - 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. Discrepancies. 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. Adequate Care of Perishable Medical Marijuana-Infused Product. A Medical Marijuana Business must provide adequate refrigeration for perishable Medical Marijuana-Infused Product during transport.

### **Basis and Purpose – M 802**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(l), 12-43.3-202(1)(h), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XVIII.6) 12-43.3-202(2)(a)(XX), and 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.

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

- A. Off-premises Storage Permit Authorized. A Medical Marijuana Center, Medical Marijuana-Infused Products Manufacturer, and an Optional Premises Cultivation Operation may only store Medical Marijuana or Medical Marijuana-Infused Product in their Licensed Premises or in their one permitted off-premises storage facility. Medical Marijuana Transporters are allowed to have more than one permitted off-premises storage facility.
- B. Permitting. To obtain a permit for an off-premises storage facility, a Medical Marijuana Business must apply on current Division forms and pay any applicable fees. 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.
- C. Extension of Licensed Premises. 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. Limitation on Inventory to be Stored. 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 the particular Medical Marijuana Business's finished goods inventory. The aforementioned Licensees may not share the premises with, nor store inventory belonging to, a Retail Marijuana Establishment or Medical Marijuana Business that is not commonly-owned.
- E. Restrictions. 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. Display of Off-premises Storage Permit and License. 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. Security in Storage Facility. A permitted off-premises storage facility must meet all video and security requirements applicable to a Licensed Premises.
- I. Transport to or from a Permitted Off-premises Storage Facility. 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 and from a permitted off-premises storage facility.
- J. Inventory Tracking. In addition to all the other tracking requirements set forth in these rules, a 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. Inventory Tracking System Access and Scale. Every permitted off-premises storage facility must have an Inventory Tracking System terminal and a scale tested and approved in accordance with measurement standards established in 35-14-127,, C.R.S.
- L. Adequate Care of Perishable Medical Marijuana-Infused Product. A Medical Marijuana Business must provide adequate refrigeration for perishable Medical Marijuana-Infused Product and shall utilize adequate storage facilities and transport methods.
- M. Consumption Prohibited. 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 901**

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

### **M 901 – Business Records Required**

#### **A. General Requirements**

1. A Medical Marijuana Business must maintain the information required in this rule in a format that is readily understood by a reasonably prudent business person.
2. Each Medical Marijuana Business shall retain all books and records necessary to fully account for the business transactions conducted under its license for the current year and three preceding calendar years.

- a. On premises records: The Medical Marijuana Business' books and records for the preceding six months (or complete copies of such records) must be maintained on its Licensed Premises at all times.
  - b. On- or off-premises records: Books and records associated with older periods may be archived on or off of the Licensed Premises.
3. The books and records must fully account for the transactions of the business and must include, but shall not be limited to:
- a. Current Employee List – This list must provide the full name and Occupational License number of each employee and all non-employee Owners, who work at a Medical Marijuana Business.
    - i. Once the functionality is developed, each Licensed Premises shall enter the full name and Occupational license number of every employee that works on the premises into the Inventory Tracking System. The Licensed Premises shall update its list of employees in the Inventory Tracking System within 10 days of an employee commencing or ceasing employment on the premises.
  - b. Secure Facility Information – For its Licensed Premises and any associated permitted off-premises storage facility, a Medical Marijuana Business must maintain the business contact information for vendors that maintain video surveillance systems and Security Alarm Systems.
  - c. Licensed Premises – Diagram of all approved Limited Access Areas and any permitted off-premises storage facilities.
  - d. Visitor Log – List of all visitors entering Limited Access Areas or Restricted Access Areas.
  - e. All records normally retained for tax purposes.
- B. Loss of Records and Data. Any loss of electronically-maintained records shall not be considered a mitigating factor for violations of this rule. Licensees are required to exercise due diligence in preserving and maintaining all required records.
- C. Violation Affecting Public Safety. Violation of this rule may constitute a license violation affecting public safety.
- D. Records Related to Inventory Tracking. A Medical Marijuana Business must maintain accurate and comprehensive inventory tracking records that account for, reconcile, and evidence all inventory activity for Medical Marijuana from either seed or Immature Plant stage until the Medical Marijuana or Medical Marijuana-Infused Product is destroyed or sold to another Medical Marijuana Business or a patient.
- E. Records Related to Transport. A Medical Marijuana Business must maintain adequate records for the transport of all activities related to Medical Marijuana and Medical Marijuana-Infused Product. See Rule M 801 – Transport of Medical Marijuana or Medical Marijuana-Infused Product.
- F. Provision of Requested Records to the Division. A Licensee must provide on-demand access to on-premises records following a request from the Division during normal business hours or hours of apparent operation, and must provide access to off-premises records within three business days following a request from the Division.

### **Basis and Purpose – M 902**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XVII), and 12-43.3-202(2)(a)(XX), C.R.S. All Medical Marijuana Centers must collect and remit sales tax on all retail sales made pursuant to the licensing activities. The purpose of this rule is to clarify when such taxes must be remitted to the Colorado Department of Revenue.

### **M 902 – Reporting and Transmittal of Taxes**

Sales and Use Tax Returns Required. All state and state-collected sales and use tax returns must be filed, and all taxes must be remitted to the Department of Revenue, on or before the 20<sup>th</sup> day of the month following the reporting month. For example, a January return and remittance will be due to the Department of Revenue by February 20<sup>th</sup>. If the due date (20<sup>th</sup> of the month) falls on a weekend or holiday, the next business day is considered the due date for the return and remittance.

### **Basis and Purpose – M 903**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XVII), and 12-43.3-202(2)(a)(XX), C.R.S. To effectively enforce and implement the Medical Code, the State Licensing Authority must mandate a Licensee-paid audit when necessary. This rule explains when an audit may be deemed necessary and sets forth possible consequences of a Licensee's refusal to cooperate or pay for the audit.

### **M 903 – Independent Audit May Be Required**

#### **A. State Licensing Authority May Require Independent Audit**

1. When the State Licensing Authority deems it necessary, it may require a Medical Marijuana Business to undergo an audit by an independent accountant. The scope of the audit may include, but need not be limited to, financial transactions and inventory control measures.
2. In such instances, the Division may attempt to mutually agree upon the selection of the independent accountant with a Medical Marijuana Business. However, the Division always retains the right to select the independent accountant regardless of whether a mutual agreement can be reached. The independent accountant shall be a certified public accountant licensed by, and in good standing with, the Colorado State Board of Accountancy.
3. The Medical Marijuana Business will be responsible for all direct costs associated with the independent audit.

#### **B. When Independent Audit Is Necessary.** The State Licensing Authority has discretion to determine when an audit by an independent accountant is necessary. The following is a non-exhaustive list of examples that may justify an independent audit:

1. A Medical Marijuana Business does not provide requested records to the Division;
2. The Division has reason to believe that the Medical Marijuana Business does not properly maintain its business records;
3. A Medical Marijuana Business has a prior violation related to recordkeeping or inventory control;
4. A Medical Marijuana Business has a prior violation related to diversion.

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

#### **Basis and Purpose – M 904**

The statutory authority for this rule is found at subsections 12-43.3-201(5), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(d), 12-43.3-202(1)(h), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XVII), 12-43.3-202(2)(a)(XX), 12-43.3-310(12), and 12-43.3-901(2), C.R.S. The State Licensing Authority must know the individuals serving as managers of Medical Marijuana Businesses. Accordingly, this rule reiterates the statutory mandate that a Medical Marijuana Business must report any management change to the Division prior to the change. The rule also clarifies that a Medical Marijuana Business must save a copy of any management change report to the Division and that failure to follow this rule can result in discipline.

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

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

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

#### **M 904 – Medical Marijuana Business Reporting Requirements**

- A. Manager Change Must Be Reported.
  1. When Required. A Medical Marijuana Business shall provide the Division a written report prior to any change in manager occurs.
  2. Licensee Must Maintain Record of Reported Change. A Medical Marijuana Business must also maintain a copy of this written report with its business records.
  3. Consequence of Failure to Report. Failure to report a change in a timely manner may result in discipline.

- B. Reporting of Crime on the Licensed Premises or Otherwise Related to a Medical Marijuana Business. A Medical Marijuana Business and all Licensees employed by the Medical Marijuana Business shall report to the Division any discovered plan or other action of any Person to (1) commit theft, burglary, underage sales, diversion of marijuana or marijuana product, or other crime related to the operation of the subject Medical Marijuana Business; or (2) compromise the integrity of the Inventory Tracking System. A report shall be made as soon as possible after the discovery of the action, but not later than 14 days. Nothing in this paragraph (B) alters or eliminates any obligation a Medical Marijuana Business or Licensee may have to report criminal activity to a local law enforcement agency.

### **Basis and Purpose – M 905**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b), 12-43.3-202(1)(d), 12-43.3-202(2)(a)(XVII), 12-43.3-202(2)(a)(XVIII), 12-43.3-202(2)(a)(XX), and 12-43.3-307(1)(g), C.R.S. See also articles 21, 22, 26 and 28.8 of title 39, C.R.S. The purpose of this rule is to clarify the Division's authority to provide taxation divisions within the Department copies of or access to reports or other information obtained from or regarding a Licensee, for the purpose of ensuring accurate and complete filing of tax returns and payment of sales 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 1000 Series – Labeling, Packaging, and Product Safety**

#### **Basis and Purpose – M 1001**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), and 12-43.3-202(2)(a)(XX), C.R.S. Extensive labeling and secure packaging of Medical Marijuana and Medical Marijuana-Infused Product is of statewide concern. The purpose of this rule, and other rules in this series, is to ensure that all Medical Marijuana and Medical Marijuana-Infused Product are sold and delivered to lawful patients in packaging that is not easily opened by children. This rule also clarifies packaging and labeling terms that will be used throughout this rule and rules in the same series to ensure that Coloradoans are adequately informed.

#### **M 1001 – Packaging Requirements: General Requirements**

#### **Rule M 1001 is repealed effective October 1, 2016**

Packaging of Medical Marijuana and Medical Marijuana-Infused Product by a Medical Marijuana Center. A Medical Marijuana Center must ensure that all Medical Marijuana and Medical Marijuana-Infused Product is placed within a Container prior to sale to a consumer. If the Container is not Child-Resistant, the Medical Marijuana Center must place the Container within an Opaque and Resealable Exit Package that is Child-Resistant.

### Basis and Purpose – M 1001.5

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(l), 12-43.3-202(1)(h), 12-43.3-202(2)(a)(VI), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), 12-43.3-202(2)(a)(XX), 12-43.3-403(3), 12-43.3-404(5), and 12-43.3-901(4)(b), C.R.S. The State Licensing Authority finds it essential to regulate and establish labeling and secure packaging requirements for Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana Infused-Product. The purpose of this rule, and the rules in this series, is to ensure that all Medical Marijuana and Medical Marijuana Infused-Product are sold and delivered to lawful consumers in packaging that is not easily opened by children. Further, the State Licensing Authority believes based on written and oral comments it received through the rulemaking process that prohibiting labels that appeal to or are intended to target individuals under the age of 21 and requiring child-resistant packaging is of a state wide concern and would assist in limiting exposure and diversion to minors. One of the State Licensing Authority's primary goals is to prevent use of Medical Marijuana by children who are not registered Medical Marijuana patients. The State Licensing Authority has a compelling state interest in the reduction and prevention of accidental marijuana consumption by children. This can be achieved through avoidance of packaging designed to appeal to children and avoidance of use of the word "candy" on packaging, labeling and product. Children generally have a strong attraction to and interest in candy. "Candy" is one of the first words children learn to speak. Children rely upon packaging to deduce a product's contents. "Candy" is not medicine. This rule is in the interest of the health of the people of Colorado and is necessary for the stringent and comprehensive administration of the Medical Code. The State Licensing Authority is adopting this rule as a narrowly-tailored way to reduce or prevent accidental ingestion of Medical Marijuana or Medical Marijuana-Infused Products by children and others.

### M 1001.5 – Labeling and Packaging Requirements: General Applicability

- A. Ship Product Ready for Sale. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer may package smaller quantities of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana Infused-Product in a Container prior to transport, provided the Containers are placed within a larger package that has an RFID tag and all required labels affixed to it. This larger package of Containers may serve as the Shipping Container. Licensees shall ensure that either each package of Medical Marijuana or Medical Marijuana-Infused Product placed within a Shipping Container has an RFID tag and all required labels affixed to each package, or the Shipping Container itself must have an RFID tag and all required labels affixed to it for the Medical Marijuana or Medical Marijuana-Infused Product contained within the Shipping Container. If the Licensee elects to place the RFID tag and all required labels on the Shipping Container, the Shipping Container shall contain only one package, Harvest Batch, or Production Batch of Medical Marijuana or Medical Marijuana-Infused Product. If a Shipping Container holds multiple packages, each individual package shall be affixed with an RFID tag and all required labels. See Rule M 309 – Inventory Tracking System and Rule M 801 – Transport of Medical Marijuana and Medical Marijuana Infused-Product.
- B. Inventory Tracking Compliance.
  1. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer must package all Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana Infused-Product in accordance with all Inventory Tracking System rules and procedures.
- C. Packaging May Not Be Designed to Appeal to Children. A Medical Marijuana Business shall not place any content on a Container holding Medical Marijuana, Medical Marijuana Concentrate, or a Medical Marijuana Infused-Product in a manner that specifically targets individuals under the age of 21, including but not limited to, cartoon characters or similar images.
- D. Health and Benefit Claims. Labeling text on a Container may not make any false or misleading statements regarding health or physical benefits to the consumer.

- E. Font Size. Labeling text on a Container must be no smaller than 1/16 of an inch.
- F. Use of English Language. Labeling text on a Container must be clearly written or printed and in the English language.
- G. Unobstructed and Conspicuous. Labeling text on a Container must be unobstructed and conspicuous. A Licensee may affix multiple labels to a Container, provided that none of the information required by these rules is completely obstructed.
- H. Use of the Word(s) “Candy” and/or “Candies” Prohibited.
  - 1. Licensees shall not use the word(s) “candy” and/or “candies” on the product, packaging or labeling for Medical Marijuana or Medical Marijuana-Infused Product.
  - 2. Notwithstanding the requirements of subparagraph (H)(1), a licensed Medical Marijuana Business whose Identity Statement contains the word(s) “candy” and/or “candies” shall be permitted to place its Identity Statement on Medical Marijuana and/or Medical Marijuana-Infused Product packaging and labeling.

### **Basis and Purpose – M 1002**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to ensure that the labeling on each Container of Medical Marijuana and Medical Marijuana-Infused Product includes necessary and relevant information for consumers, is easily accessible to consumers, and is clear and noticeable. This rule also ensures that Medical Marijuana and Medical Marijuana-Infused Products labeling does not include health and physical benefit claims.

### **M 1002 – Labeling Requirements: General Requirements**

#### **Rule M 1002 is repealed effective October 1, 2016**

- A. Labeling Required. All Medical Marijuana and Medical Marijuana-Infused Product sold, transferred, or otherwise provided to a consumer must be in a Container that is labeled with all required information, see Rules M 1001 – Packaging Requirements: General Requirements, M 1003 – Labeling Requirements: Specific Requirements, Medical Marijuana and Medical Marijuana-Infused Product and M 1004 – Labeling Requirements: Specific Requirements, Edible Medical Marijuana-Infused Product, and that specifically excludes certain text.
- B. Health and Benefit Claims. Labeling text on a Container may not make any false or misleading statements regarding health or physical benefits to the consumer.
- C. Font Size. Labeling text on a Container must be no smaller than 1/16 of an inch.
- D. Use of English Language. Labeling text on a Container must be clearly written or printed and in the English language.
- E. Unobstructed and Conspicuous. Labeling text on a Container must be unobstructed and conspicuous. A Licensee may affix multiple labels to a Container, provided that none of the information required by these rules is completely obstructed.

### Basis and Purpose – M 1002.5

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.3-402(7), 12-43.3-404(5), 12-43.3-404(10), and 12-43.3-901(4)(b), C.R.S. The purpose of this rule is to ensure that every Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer label each package and Container of Medical Marijuana with all of the necessary and relevant information for the receiving Medical Marijuana Business. In addition, this rule clarifies basic packaging requirements. The State Licensing Authority wants to ensure the regulated community employs proper labeling techniques for all Medical Marijuana as this is a public health and safety concern.

### M 1002.5 – Packaging and Labeling of Medical Marijuana by an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer

- A. Packaging of Medical Marijuana by an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer. Every Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer must ensure that all Medical Marijuana is placed within a sealed package that has no more than ten pounds of Medical Marijuana within it prior to transport or transfer of any Medical Marijuana to another Medical Marijuana Business. The package shall be affixed with an RFID tag in accordance with rule M 1001.5(A).
- B. Labeling of Medical Marijuana Packages by an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer. Every Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer must ensure that a label(s) is affixed to every package holding Medical Marijuana that includes all of the information required by this rule prior to transport or transfer to another Medical Marijuana Business.
  1. Required Information. Every Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer must ensure the following information is affixed to every package holding Medical Marijuana:
    - a. The license number of the Optional Premises Cultivation Operation where the Medical Marijuana was grown;
    - b. The Harvest Batch Number(s) assigned to the Medical Marijuana;
    - c. The net weight, using a standard of measure compatible with the Inventory Tracking System, of the Medical Marijuana prior to its placement in the package; and
    - d. A complete list of all nonorganic pesticides, fungicides, and herbicides used during the cultivation of the Medical Marijuana.
  2. Required Potency Statement. For each package of Medical Marijuana, the potency of at least the Medical Marijuana's THC and CBD shall be included on a label that is affixed to the package. The potency shall be expressed as a range of percentages that extends from the lowest percentage to the highest percentage of concentration for each cannabinoid listed, from every test conducted on that strain of Medical Marijuana cultivated by the same Optional Premises Cultivation Operation within the last six months.
  3. Required Contaminant Testing Statement.

- a. When All Required Contaminant Tests Are Not Performed. If a Medical Marijuana Testing Facility did not test a Harvest Batch for microbials, mold, mildew, and filth, then the package shall be labeled with the following statement: **“The marijuana contained within this package has not been tested for contaminants.”** Except that when an Optional Premises Cultivation Operation has successfully validated its process regarding contaminants pursuant to rule M 1501, then the package instead shall be labeled with the following statement: **“The marijuana contained within this package complies with the mandatory contaminant testing required by rule M 1501.”**
  - b. When All Required Contaminant Tests Are Performed and Passed. If a Medical Marijuana Testing Facility tested a Harvest Batch for microbials, mold, mildew, and filth, and the required test(s) passed, then the package shall be labeled with the following statement: **“The marijuana contained within this package complies with the mandatory contaminant testing required by rule M 1501.”**
  - c. Nothing in this rule permits a Medical Marijuana Business to transfer, wholesale, or sell Medical Marijuana that has failed contaminant testing and has not subsequently passed the additional contaminant testing required by rule M 1507(B).
- C. Labeling of Medical Marijuana Containers by an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer. If an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer packages Medical Marijuana within a Container that is then placed within a larger package, each Container must be affixed with a label(s) containing all of the information required by Rule M 1002.5(B), except that the net weight statement required by Rule M 1002.5(B)(1)(c) shall be based upon the weight in the Container and not the larger package or Shipping Container.

### Basis and Purpose – M 1003

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to ensure that each Container of Medical Marijuana and Medical Marijuana-Infused Product includes necessary and relevant labeling information for consumers.

### M 1003 – Labeling Requirements: Specific Requirements, Medical Marijuana and Medical Marijuana-Infused Product

#### Rule M 1003 is repealed effective October 1, 2016

- A. Labels Required. No Licensee shall sell, transfer, or give away any Medical Marijuana that does not contain a Label with a list of all ingredients, including all chemical additives, including but not limited to nonorganic pesticides, herbicides, and fertilizers that were used in its cultivation and production. The label must also list:
1. The Batch Number or numbers assigned by the Optional Premises Cultivation Operation to the marijuana plant or plants from which the Medical Marijuana contained within the Container was harvested; and
  2. A complete list of solvents and chemicals used in the creation of any Medical Marijuana concentrate.

- B. Medical Marijuana Container Labeling Must Include the Following Information:
1. The license number of the Optional Premises Cultivation Facility, if different than the Medical Marijuana Center's license number, identifying where the Medical Marijuana within the Container was grown;
  2. The license number of the Medical Marijuana Center that sold the Medical Marijuana to the patient;
  3. The date of sale; and
  4. The patient registry number of the purchaser.
- C. Medical Marijuana-Infused Product Container Labeling Must Include the Following Information:
1. The license number of the Medical Marijuana Business(es) where the Medical Marijuana used to manufacture the Medical Marijuana-Infused Product within the Container was grown;
  2. The license number of the Medical Marijuana Center that sold the Medical Marijuana-Infused Product to the patient;
  3. The following statement: "This product contains medical marijuana and was produced without regulatory oversight for health, safety or efficacy and there may be health risks associated with the consumption of the product."
  4. For Medical Marijuana-Infused Product, the product identity and net weight statements must appear on the portion of the label displayed to the patient.
  5. When a Medical Marijuana-Infused Product is made specifically for a designated patient, the label of that product shall state the patient's Medical Marijuana Registry number.
  6. The list of ingredients and company name statements must be conspicuously listed on the Medical Marijuana-Infused Product package.
  7. A nutrition facts panel may be required if nutritional claims are made on the label of any Medical Marijuana-Infused Product.
- D. Minimum print size. The minimum print size for each of the required statements for non-infused products and for each of the required statements for Medical Marijuana-Infused Product is 1/16 inch. The size of the characters in the net weight statement is determined by the area of the principal display panel and may be greater than 1/16 inch.

**Basis and Purpose – M 1003.5**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.3-402(7), 12-43.3-404(5), 12-43.3-404(10), 12-43.3-404(11)(b-c), and 12-43.3-901(4)(b), C.R.S. The purpose of this rule is to ensure that every Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer labels each package and Container of Medical Marijuana Concentrate with all of the necessary and relevant information for the receiving Medical Marijuana Business. In addition, this rule clarifies basic packaging requirements. The State Licensing Authority wants to ensure the regulated community employs proper labeling techniques for all Medical Marijuana Concentrate because it is a public health and safety concern.

**M 1003.5 – Packaging and Labeling of Medical Marijuana Concentrate by an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer**

- A. Packaging of Medical Marijuana Concentrate by an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer. Every Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer must ensure that all Medical Marijuana Concentrate is placed within a sealed package that has no more than one pound of Medical Marijuana Concentrate within it prior to transport or transfer to another Medical Marijuana Business. The package shall be affixed with an RFID tag in accordance with rule M 1001.5(A).
- B. Labeling Medical Marijuana Concentrate Package by an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer. Every Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer must ensure that a label(s) is affixed to every package holding Medical Marijuana Concentrate that includes all of the information required by this rule prior to transport or transfer to another Medical Marijuana Business.
1. Required Information. Every Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer must ensure the following information is affixed to every package holding Medical Marijuana Concentrate:
    - a. The license number(s) of the Optional Premises Cultivation Operation(s) where the Medical Marijuana used to produce the Medical Marijuana Concentrate was grown;
    - b. The license number of the Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer that produced the Medical Marijuana Concentrate;
    - c. The Production Batch Number assigned to the Medical Marijuana Concentrate contained within the package;
    - d. The net weight, using a standard of measure compatible with the Inventory Tracking System, of the Medical Marijuana Concentrate prior to its placement in the package;
    - e. A complete list of all nonorganic pesticides, fungicides, and herbicides used during the cultivation of the Medical Marijuana used to produce the Medical Marijuana Concentrate contained within; and
    - f. A complete list of solvents and chemicals used to create the Medical Marijuana Concentrate.
  2. Required Potency Statement. For each package of Medical Marijuana Concentrate, the potency of at least the Medical Marijuana Concentrate's THC and CBD shall be included on a label that is affixed to the package. The potency shall be expressed in milligrams for each cannabinoid.
  3. Required Contaminant Testing Statement.
    - a. When All Required Contaminant Tests Are Not Performed.



### Basis and Purpose – M 1004

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to ensure that each Container of an Edible Medical Marijuana-Infused Product includes necessary and relevant information for patients.

### M 1004 – Labeling Requirements: Specific Requirements, Medical Marijuana-Infused Product

#### Rule M 1004 is repealed effective October 1, 2016

- A. Ingredient List. A list of all ingredients used to manufacture the Edible Medical Marijuana-Infused Product; which may include a list of any potential allergens contained within, or used in the manufacture of, the Medical Marijuana-Infused Product.
- B. Statement Regarding Refrigeration. A statement that the Medical Marijuana-Infused Product, if perishable, must be refrigerated.
- C. Statement of Expiration Date. A product expiration date, for perishable Medical Marijuana-Infused Product, upon which the product will no longer be fit for consumption, or a use-by-date, upon which the product will no longer be optimally fresh. Once a label with a use-by or expiration date has been affixed to a Container of a Medical Marijuana-Infused Product, a Licensee shall not alter that date or affix a new label with a later use-by or expiration date.

### Basis and Purpose – M 1004.5

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.3-402(2)(a)(I-III), 12-43.3-402(7), 12-43.4-404(5), 12-43.4-404(10), 12-43.4-404(11), and 12-43.3-901(4)(b), C.R.S. The purpose of this rule is to ensure that every Medical Marijuana-Infused Products Manufacturer labels each package and Container holding a Medical Marijuana Infused-Product with all of the necessary and relevant information for the receiving Medical Marijuana Business. In addition, this rule clarifies basic packaging requirements. The State Licensing Authority wants to ensure the regulated community employs proper packaging and labeling techniques for each Medical Marijuana Infused-Product because it is a public health and safety concern. 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 for correct labeling. The acceptable potency variance has been set at plus or minus 15% to comport with the potency variance mandated by the Retail Code.

Product safety requirements are being adopted to aid in making Medical Marijuana-Infused Products more readily identifiable to the general public 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 standard portions for its products or to provide a mechanism with the product for accurately measuring a standard portion.

### M 1004.5 – Packaging and Labeling Requirements of a Medical Marijuana Infused-Product by a Medical Marijuana-Infused Products Manufacturer

- A. Packaging of Medical Marijuana Infused-Product by a Medical Marijuana-Infused Products Manufacturer

1. General Standard. Every Medical Marijuana-Infused Products Manufacturer must ensure that each Container holding a Medical Marijuana Infused-Product is placed in a package prior to transport or transfer to another Medical Marijuana Business. The package shall be affixed with an RFID tag in accordance with rule M 1001.5(A).
  2. Edible Medical Marijuana Infused-Product.
    - a. Every Medical Marijuana-Infused Products Manufacturer must ensure that each Edible Medical Marijuana Infused-Product is packaged within a Child-Resistant Container prior to transport or transfer to another Medical Marijuana Business.
    - b. If the Edible Medical Marijuana-Infused Product contains multiple portions then it must be packaged in a Child-Resistant Container that maintains its Child-Resistant effectiveness for multiple openings
  3. Medical Marijuana Infused-Product that is not Edible Medical Marijuana Infused-Product. Every Medical Marijuana-Infused Products Manufacturer must ensure that each Medical Marijuana Infused-Product that is not an Edible Medical Marijuana Infused-Product is individually packaged within a Container prior to transport or transfer to another Medical Marijuana Business.
- B. Labeling of Medical Marijuana Infused-Product Containers by a Medical Marijuana-Infused Products Manufacturer. A Medical Marijuana-Infused Products Manufacturer must ensure that a label(s) is affixed to every Container holding a Medical Marijuana Infused-Product that includes all of the information required by this rule prior to transport or transfer to another Medical Marijuana Business.
1. Required Information (General). Every Medical Marijuana-Infused Products Manufacturer must ensure the following information is affixed to every Container holding a Medical Marijuana Infused-Product:
    - a. The license number(s) of the Optional Premises Cultivation Operation(s) where the Medical Marijuana used to produce the Medical Marijuana Infused-Product was grown;
    - b. The Production Batch Number(s) of Medical Marijuana Concentrate(s) used in the production of the Medical Marijuana Infused-Product.
    - c. The license number of the Medical Marijuana-Infused Products Manufacturer that produced the Medical Marijuana Infused-Product.
    - d. A net weight statement.
    - e. The Production Batch Number(s) assigned to the Medical Marijuana Infused-Product.
    - f. A statement about whether the Container is Child-Resistant.
    - h. The Identity Statement and Standardized Graphic Symbol of the Medical Marijuana-Infused Products Manufacturer that manufactured the Medical Marijuana Infused-Product. A Licensee may elect to have its Identity Statement also serve as its Standardized Graphic Symbol for purposes of complying with this rule. The Licensee shall maintain a record of its Identity Statement and Standardized Graphic Symbol and make such information available to the State Licensing Authority upon request;

- i. The Universal Symbol, which must be located on the front of the Container and no smaller than  $\frac{1}{2}$  of an inch by  $\frac{1}{2}$  of an inch, and the following statement which must be labeled directly below the Universal Symbol: "Contains Marijuana. For Medical Use Only. Keep out of the reach of children."
- j. The following warning statements:
  - i. **"There may be health risks associated with the consumption of this product."**
  - ii. **"This product contains marijuana and its potency was tested with an allowable plus or minus 15% variance pursuant to 12-43.3-202(2.5)(a)(I)(E), C.R.S."**
  - iii. **"This product was produced without regulatory oversight for health, safety, or efficacy."**
  - iv. **"There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant."**
- k. A complete list of all nonorganic pesticides, fungicides, and herbicides used during the cultivation of the Medical Marijuana used to produce the Medical Marijuana Infused-Product.
- l. A complete list of solvents and chemicals used in the creation of any Medical Marijuana Concentrate that was used to produce the Medical Marijuana Infused-Product.
- m. Required Potency Statement. This subsubparagraph (B)(1)(m) of rule M 1004.5 shall become effective October 1, 2017. Each Container holding a Medical Marijuana-Infused Product shall be labeled with the potency of at least the Medical Marijuana-Infused Product's THC and CBD. The potency shall be expressed in milligrams for each cannabinoid. The potency shall be labeled either:
  - i. In a font size that is at least two font sizes larger than the surrounding label text and also not less than 10 point font, bold, and enclosed within an outlined shape such as a circle or square; or
  - ii. Highlighted with a bright color such as yellow.
- 2. Required Information (Edible Medical Marijuana Infused-Product). Every Medical Marijuana-Infused Products Manufacturer must ensure that the following information or statement is affixed to every Container holding an Edible Medical Marijuana Infused-Product:
  - a. Ingredient List. A list of all ingredients used to manufacture the Edible Medical Marijuana Infused-Product; which shall include a list of any potential allergens contained within.
  - b. Statement Regarding Refrigeration. If the Edible Medical Marijuana Infused-Product is perishable, a statement that the Edible Medical Marijuana Infused-Product must be refrigerated.

- c. Statement of Production Date. The date on which the Edible Medical Marijuana Infused-Product was produced.
  - d. Statement of Expiration Date. A product expiration date, for perishable Edible Medical Marijuana Infused-Product, upon which the product will no longer be fit for consumption, or a use-by-date, upon which the product will no longer be optimally fresh. Once a label with a use-by or expiration date has been affixed to a Container holding an Edible Medical Marijuana Infused-Product, a Licensee shall not alter that date or affix a new label with a later use-by or expiration date.
3. Permissive Information (Edible Medical Marijuana Infused-Product). Every Medical Marijuana-Infused Products Manufacturer may affix a label(s) with the following information to every Container holding an Edible Medical Marijuana Infused-Product:
  - a. The Medical Marijuana Infused-Product's compatibility with dietary restrictions.
  - b. A nutritional fact panel.
4. Required Potency Statement.
  - a. Every Medical Marijuana-Infused Products Manufacturer must ensure that a label is affixed to the Container that includes at least the Medical Marijuana Infused-Product's THC and CBD content.
  - b. Nothing in this rule permits a Medical Marijuana Business to transfer, wholesale, or sell Medical Marijuana Infused-Product that has failed potency testing and has not subsequently passed the additional potency testing required by rule R 1507(C).
5. Required Contaminant Testing Statement.
  - a. When All Required Contaminant Tests Are Not Performed. If a Medical Marijuana Testing Facility did not test a Production Batch of Medical Marijuana Infused-Product for microbials, mold, and mildew, then the Container shall be **labeled** with the following statement: **"The Medical Marijuana Infused-Product contained within this package has not been tested for contaminants."** Except that when a Medical Marijuana-Infused Products Manufacturer has successfully validated its process regarding contaminants for the particular Medical Marijuana Infused-Product pursuant to rule M 1501, then the Container instead shall be labeled with the following statement: **"The Medical Marijuana Infused-Product contained within this package complies with the mandatory contaminant testing required by rule M 1501."**
  - b. When All Contaminant Tests Are Performed and Passed. If a Medical Marijuana Testing Facility tested a Production Batch of Medical Marijuana Infused-Product for microbials, mold, and mildew, and the required test(s) passed, then the Container shall be labeled with the following statement: **"The Medical Marijuana Infused-Product contained within this package complies with the mandatory contaminant testing required by rule M 1501."**
  - c. Nothing in this rule permits a Medical Marijuana Business to transfer, wholesale, or sell Medical Marijuana Infused-Product that has failed contaminant testing and has not subsequently passed the additional contaminant testing required by rule M 1507(B).

- D. Labeling of Medical Marijuana Infused-Product Shipping Containers or Packages by Medical Marijuana-Infused Products Manufacturer. Prior to transporting or transferring any Medical Marijuana Infused-Product to another Medical Marijuana Business, a Medical Marijuana Manufacturing Products Facility must ensure that a label is affixed to a Shipping Container or package holding Medical Marijuana Infused-Product that includes all of the information required by this rule. A Medical Marijuana-Infused Products Manufacturer must include the following information on every Shipping Container or package:
1. The number of Containers holding a Medical Marijuana Infused-Product within the Shipping Container or package; and
  2. The license number of the Medical Marijuana-Infused Products Manufacturer(s) that produced the Medical Marijuana Infused-Product within the Shipping Container or package.

**Basis and Purpose – M 1005**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.3-402(2)(a), 12-43.3-402(6), 12-43.3-402(7), and 12-43.3-901(4)(b), C.R.S. The purpose of this rule is to ensure that the labeling on each Container of Medical Marijuana includes necessary and relevant information for patients, does not include health and physical benefit claims, is easily accessible to patients, and is clear and noticeable. The State Licensing Authority wants to ensure the regulated community employs proper labeling techniques for all Medical Marijuana because it is a public health and safety concern. 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 for correct labeling. The acceptable potency variance has been set at plus or minus 15% to comport with the potency variance mandated by the Retail Code.

**M 1005 – Packaging and Labeling of Medical Marijuana by a Medical Marijuana Center**

- A. Packaging of Medical Marijuana by a Medical Marijuana Center.
1. A Medical Marijuana Center must ensure that all Medical Marijuana is placed within a Container prior to sale to a consumer. If the Container is not Child-Resistant, the Medical Marijuana Center must place the Container within an Exit Package that is Child-Resistant.
  2. Except that when a patient provides written documentation signed by his or her physician attesting to the fact that it would be unreasonably difficult for the patient to open packaging that is Child-Resistant:
    - a. A Medical Marijuana Center shall not be required to package the Medical Marijuana in a Child-Resistant Container for sale to the patient; and
    - b. A Medical Marijuana Center shall not be required to utilize a Child-Resistant Exit Package for the patient.
    - c. If the Medical Marijuana is packaged in a Child-Resistant Container, a Medical Marijuana Center may defeat the Medical Marijuana's Child-Resistant packaging on behalf of the patient, so long as the Medical Marijuana remains with the packaging after the Child-Resistant properties have been defeated.

- B. Labeling of Medical Marijuana by a Medical Marijuana Center. A Medical Marijuana Center must affix all of the information required by this rule to every Container in which Medical Marijuana is placed no later than at the time of sale to a patient:
1. A Medical Marijuana Center must include the following information on every Container:
    - a. The license number(s) of the Optional Premises Cultivation Operation(s) where the Medical Marijuana was grown;
    - b. The license number of the Medical Marijuana Center that sold the Medical Marijuana to the patient;
    - c. The Identity Statement and Standardized Graphic Symbol of the Medical Marijuana Center that sold the Medical Marijuana to the consumer. A Licensee may elect to have its Identity Statement also serve as its Standardized Graphic Symbol for purposes of complying with this rule. The Licensee shall maintain a record of its Identity Statement and Standardized Graphic Symbol and make such information available to the State Licensing Authority upon request;
    - d. The Harvest Batch Number(s) assigned to the Medical Marijuana within the Container;
    - e. The date of sale to the patient;
    - f. The patient registry number of the purchaser;
    - g. The net weight, in grams to at least the tenth of a gram, of the Medical Marijuana prior to its placement in the Container;
    - h. The following warning statements:
      - i. "There may be health risks associated with the consumption of this product."
      - ii. "This marijuana's potency was tested with an allowable plus or minus 15% variance pursuant to 12-43.3-202(2.5)(a)(I)(E), C.R.S."
      - iii. "There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant."
    - i. A complete list of all nonorganic pesticides, fungicides, and herbicides used during the cultivation of the Medical Marijuana.
    - j. The Universal Symbol, which must be located on the front of the Container and no smaller than  $\frac{1}{2}$  of an inch by  $\frac{1}{2}$  of an inch, and the following statement which must be labeled directly below the Universal Symbol: "Contains Marijuana. For Medical Use Only. Keep out of the reach of children."

2. Required Potency Statement. This subparagraph (B)(2) of rule M 1005 shall be repealed on October 1, 2017. For each Harvest Batch of Medical Marijuana packaged within a Container, the Medical Marijuana Center shall ensure the potency of at least the Medical Marijuana's THC and CBD is included on a label that is affixed to the Container. The potency shall be expressed as a range of percentages that extends from the lowest percentage to the highest percentage of concentration for each cannabinoid listed, from every test conducted on that strain of Medical Marijuana cultivated by the same Optional Premises Cultivation Operation within the last six months.
- 2.1. Required Potency Statement. This subparagraph (B)(2.1) of rule M 1005 shall become effective on October 1, 2017. For each Harvest Batch of Medical Marijuana packaged within a Container, the Medical Marijuana Center shall ensure the potency of at least the Medical Marijuana's THC and CBD is included on a label that is affixed to the Container. The potency shall be expressed as a range of percentages that extends from the lowest percentage to the highest percentage of concentration for each cannabinoid listed, from every test conducted on that strain of Medical Marijuana cultivated by the same Optional Premises Cultivation Operation within the last six months. The potency shall be labeled either:
  - a. In a font size that is at least two font sizes larger than the surrounding label text and also not less than 10 point font, bold, and enclosed within an outlined shape such as a circle or square; or
  - b. Highlighted with a bright color such as yellow.
3. Required Contaminant Testing Statement.
  - a. When All Required Contaminant Tests Are Not Performed. If a Medical Marijuana Testing Facility did not test a Harvest Batch for microbials, mold, mildew, and filth, then a Medical Marijuana Center must ensure that a label is affixed to a Container holding any Medical Marijuana from that Harvest Batch with the following statement: **"The marijuana contained within this package has not been tested for contaminants."** Except that when an Optional Premises Cultivation Operation has successfully validated its process regarding contaminants pursuant to rule M 1501, then the Container instead shall be labeled with the following statement: **"The marijuana contained within this package complies with the mandatory contaminant testing required by rule M 1501."**
  - b. When All Required Contaminant Tests Are Performed and Passed. If a Medical Marijuana Testing Facility tested a Harvest Batch for microbials, mold, mildew, and filth, and all the required test(s) passed, then the Container shall be labeled with the following statement: **"The marijuana contained within this package complies with the mandatory contaminant testing required by rule M 1501."**
  - c. Nothing in this rule permits a Medical Marijuana Business to transfer, wholesale, or sell Medical Marijuana that has failed contaminant testing and has not subsequently passed the additional contaminant testing required by rule M 1507(B).

## Basis and Purpose – M 1006

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), 12-43.3-202(2)(a)(XX), 12-43.3-402(2)(a)(I-III), 12-43.4-202(2.5)(a)(I), 12-43.3-402(2)(a), 12-43.3-402(6), 12-43.3-404(5), 12-43.3-404(10), and 12-43.3-901(4)(b), C.R.S. The purpose of this rule is to ensure that the labeling on each Container holding a Medical Marijuana Infused-Product includes necessary and relevant information for consumers, does not include health and physical benefit claims, is easily accessible to consumers, and is clear and noticeable. In addition, this rule clarifies basic packaging requirements. The State Licensing Authority wants to ensure the regulated community employs proper packaging and labeling techniques for each Medical Marijuana Infused-Product because this is a public health and safety concern. 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 for correct labeling. The acceptable potency variance has been set at plus or minus 15% to comport with the potency variance mandated by the Retail Code.

## M 1006 – Packaging and Labeling of Medical Marijuana Infused-Product by a Medical Marijuana Center

### A. Packaging Requirements for a Medical Marijuana Center.

1. Beginning December 1, 2016, a Medical Marijuana Center shall not purchase, take possession of, or sell Medical Marijuana-Infused Product that does not comply with rules M 604 and M 1004.5.
2. A Medical Marijuana Center must ensure that each Medical Marijuana Infused-Product is placed within a Container prior to sale to a consumer. If the Container is not Child-Resistant, the Medical Marijuana Center must place the Container within an Exit Package that is Child-Resistant.
3. Except that when a patient provides written documentation signed by his or her physician attesting to the fact that it would be unreasonably difficult for the patient to open packaging that is Child-Resistant:
  - a. If the Medical Marijuana-Infused Product is packaged in a Child-Resistant Container, a Medical Marijuana Center may defeat the Medical Marijuana-Infused Product's Child-Resistant packaging on behalf of the patient, so long as the Medical Marijuana-Infused Product remains with the packaging after the Child-Resistant properties have been defeated; or
  - b. If the Medical Marijuana-Infused Product is not packaged in a Child-Resistant Container, a Medical Marijuana Center shall not be required to package the Medical Marijuana-Infused Product in a Child-Resistant Container for sale to the patient; and
  - c. A Medical Marijuana Center shall not be required to utilize a Child-Resistant Exit Package for the patient.

- ### B. Labeling of Medical Marijuana Infused-Product by a Medical Marijuana Center. Every Medical Marijuana Center must ensure that a label(s) is affixed to every Exit Package at the time of sale to a consumer that includes all of the information required by this rule. If an Exit Package is not required pursuant to subparagraph (A)(2) of this rule M 1006, and the Medical Marijuana Center elects not to provide one, then the Medical Marijuana Center must ensure the labels required by this rule are affixed to each Container of Medical Marijuana Infused-Product no later than at the time of sale to a consumer.

1. Required Information.
  - a. The license number of the Medical Marijuana Center that sold the Medical Marijuana Infused-Product to the consumer;
  - b. The Identity Statement and Standardized Graphic Symbol of the Medical Marijuana Center that sold the Medical Marijuana Infused-Product to the consumer. A Licensee may elect to have its Identity Statement also serve as its Standardized Graphic Symbol for purposes of complying with this rule. The Licensee shall maintain a record of its Identity Statement and Standardized Graphic Symbol and make such information available to the State Licensing Authority upon request;
  - c. The date of sale to the consumer;
  - d. The patient registry number of the purchaser;
  - e. The following warning statements:
    - i. **“There may be health risks associated with the consumption of this product.”**
    - ii. **“This product contains marijuana and its potency was tested with an allowable plus or minus 15% variance pursuant to 12-43.3-202(2.5)(a)(I)(E), C.R.S.”**
    - iii. **“This product was produced without regulatory oversight for health, safety, or efficacy.”**
    - iv. **“There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant.”**
  - f. The Universal Symbol, which must be located on the front of the Container or Exit Package as appropriate and no smaller than ½ of an inch by ½ of an inch, and the following statement which must be labeled directly below the Universal Symbol: “Contains Marijuana. For Medical Use Only. Keep out of the reach of children.”.
  - g. Required Potency Statement. This subparagraph (B)(1)(g) of rule M 1006 shall become effective October 1, 2017. Each Container holding a Medical Marijuana-Infused Product shall be labeled with the potency of at least the Medical Marijuana-Infused Product’s THC and CBD. The potency shall be expressed in milligrams for each cannabinoid. The potency shall be labeled either:
    - i. In a font size that is at least two font sizes larger than the surrounding label text and also not less than 10 point font, bold, and enclosed within an outlined shape such as a circle or square; or
    - ii. Highlighted with a bright color such as yellow.

**Basis and Purpose – M 1007**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.4-402(2)(a)(I-III), 12-43.4-402(6), 12-43.4-404(5), 12-43.3-404(10), and 12-43.3-901(4)(b), C.R.S. The purpose of this rule is to ensure that the labeling on each Container holding a Medical Marijuana Concentrate includes necessary and relevant information for patients, does not include health and physical benefit claims, is easily accessible to patients, and is clear and noticeable. In addition, this rule clarifies basic packaging requirements. The State Licensing Authority wants to ensure the regulated community employs proper labeling techniques to each Medical Marijuana Concentrate as this is a public health and safety concern. 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 for correct labeling. The acceptable potency variance has been set at plus or minus 15% to comport with the potency variance mandated by the Retail Code.

**M 1007 – Packaging and Labeling of Medical Marijuana Concentrate by a Medical Marijuana Center**

A. Packaging of Medical Marijuana Concentrate by an Optional Premises Cultivation Operation.

1. A Medical Marijuana Center must ensure that all Medical Marijuana Concentrate is placed within a Container prior to sale to a consumer. If the Container is not Child-Resistant, the Medical Marijuana Center must place the Container within an Exit Package that is Child-Resistant.
2. Except that when a patient provides written documentation signed by his or her physician attesting to the fact that it would be unreasonably difficult for the patient to open packaging that is Child-Resistant:
  - a. A Medical Marijuana Center shall not be required to package the Medical Marijuana Concentrate in a Child-Resistant Container for sale to the patient; and
  - b. A Medical Marijuana Center shall not be required to utilize a Child-Resistant Exit Package for the patient.
  - c. If the Medical Marijuana Concentrate is packaged in a Child-Resistant Container, a Medical Marijuana Center may defeat the Medical Marijuana Concentrate's Child-Resistant packaging on behalf of the patient, so long as the Medical Marijuana Concentrate remains with the packaging after the Child-Resistant properties have been defeated.

B. Labeling of Medical Marijuana Concentrate by Medical Marijuana Centers. Every Medical Marijuana Center must ensure that a label(s) is affixed to every Container holding Medical Marijuana Concentrate that includes all of the information required by this rule no later than at the time of sale to a consumer:

1. Every Medical Marijuana Center must ensure the following information is affixed to every Container holding a Medical Marijuana Concentrate:
  - a. The license number(s) of the Optional Premises Cultivation Operation(s) where the Medical Marijuana used to produce the Medical Marijuana Concentrate within the Container was grown;
  - b. The license number of the Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer that produced the Medical Marijuana Concentrate;

- c. The Production Batch Number assigned to the Medical Marijuana Concentrate;
  - d. The license number of the Medical Marijuana Center that sold the Medical Marijuana Infused-Product to the consumer;
  - e. The net weight, in grams to at least the tenth of a gram, of the Medical Marijuana Concentrate prior to its placement in the Container;
  - f. The date of sale to the consumer;
  - g. The patient registry number of the purchaser;
  - h. The following warning statements:
    - i. **“There may be health risks associated with the consumption of this product.”**
    - ii. **“This product contains marijuana and its potency was tested with an allowable plus or minus 15% variance pursuant to 12-43.3-202(2.5)(a)(I)(E), C.R.S.”**
    - iv. **“This product was produced without regulatory oversight for health, safety, or efficacy.”**
    - v. **“There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant.”**
  - i. The Universal Symbol, which must be located on the front of the Container and no smaller than ½ of an inch by ½ of an inch, and the following statement which must be labeled directly below the Universal Symbol: “Contains Marijuana. For Medical Use Only. Keep out of the reach of children.”
  - j. A complete list of all nonorganic pesticides, fungicides, and herbicides used during the cultivation of the Medical Marijuana used to produce the Medical Marijuana Concentrate; and
  - k. A complete list of solvents and chemicals used to produce the Medical Marijuana Concentrate.
2. Required Potency Statement. This subparagraph (B)(2) of rule M 1007 shall be repealed on October 1, 2017. For each Production Batch of Medical Marijuana Concentrate packaged within a Container, the Medical Marijuana Center shall ensure the potency of at least the Medical Marijuana Concentrate’s THC and CBD is included on a label that is affixed to the Container. The potency shall be expressed in milligrams for each cannabinoid.
- 2.1. Required Potency Statement. This subparagraph (B)(2.1) of rule M 1007 shall become effective October 1, 2017. Each Container holding a Medical Marijuana Concentrate shall be labeled with the potency of at least the Medical Marijuana Concentrate’s THC and CBD. The potency shall be expressed in milligrams for each cannabinoid. The potency shall be labeled either:

- a. In a font size that is at least two font sizes larger than the surrounding label text and also not less than 10 point font, bold, and enclosed within an outlined shape such as a circle or square; or
  - b. Highlighted with a bright color such as yellow.
3. Required Contaminant Testing Statement.
- a. When All Required Contaminant Tests Are Not Performed.
    - i. Solvent-Based Medical Marijuana Concentrate. If a Medical Marijuana Testing Facility did not test a Production Batch of Solvent-Based Medical Marijuana Concentrate for residual solvents, mold, and mildew, then the Container shall be labeled with the following statement: **“The Medical Marijuana Concentrate contained within this package has not been tested for contaminants.”** Except that when a Medical Marijuana-Infused Products Manufacturer has successfully validated its process regarding contaminants pursuant to rule M 1501, then the Container instead shall be labeled with the following statement: **“The Medical Marijuana Concentrate contained within this package complies with the mandatory contaminant testing required by rule M 1501.”**
    - ii. Food- and Water-Based Medical Marijuana Concentrate. If a Medical Marijuana Testing Facility did not test a Production Batch of Food- or Water-Based Medical Marijuana Concentrate for microbials, mold, and mildew, then the Container shall be labeled with the following statement: **“The Medical Marijuana Concentrate contained within this package has not been tested for contaminants.”** Except that when an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer has successfully validated its process regarding contaminants pursuant to rule M 1501, then the Container instead shall be labeled with the following statement: **“The Medical Marijuana Concentrate contained within this package complies with the mandatory contaminant testing required by rule M 1501.”**
  - b. When All Required Contaminant Tests Are Performed and Passed.
    - i. Solvent-Based Medical Marijuana Concentrate. If a Medical Marijuana Testing Facility tested a Production Batch of Solvent-Based Medical Marijuana Concentrate for residual solvents, mold, and mildew, and the required test(s) passed, then the Container shall be labeled with the following statement: **“The Medical Marijuana Concentrate contained within this package complies with the mandatory contaminant testing required by rule M 1501.”**
    - ii. Food- and Water-Based Medical Marijuana Concentrate. If a Medical Marijuana Testing Facility tested a Production Batch for microbials, mold, and mildew, and the required test(s) passed, then the Container shall be labeled with the following statement: **“The Medical Marijuana Concentrate contained within this package complies with the mandatory contaminant testing required by rule M 1501.”**

- c. Nothing in this rule permits a Medical Marijuana Business to transfer, wholesale, or sell Medical Marijuana Concentrate that has failed contaminant testing and has not subsequently passed the additional contaminant testing required by rule M 1507(B).

**M 1100 Series – Signage and Advertising**

**M 1101 – General Requirement: False and Misleading Statements**

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)(a)(VI), 12-43.3-202(2)(a)(XX), 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)(I), 12-43.3-202(2)(a)(XX), 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.

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**Basis and Purpose – M 1104**

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

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**Basis and Purpose – M 1107**

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)(II), and 12-43.3-901(4)(b), 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), 12-43.3-202(2)(a)(XX), 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 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.

**Basis and Purpose – M 1109**

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)(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)(a)(XX), 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), 12-43.3-202(2)(a)(XX), 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 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.

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**Basis and Purpose – M 1112**

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)(II), and 12-43.3-901(4)(b), 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.

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**Basis and Purpose – M 1113**

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)(II)(F), and 12-43.3-901(4)(b), 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), 12-43.3-202(2)(a)(XX), 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), 12-43.3-202(2)(a)(XX), 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 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 1200 Series – Enforcement**

### **Basis and Purpose – M 1201**

The statutory authority for this rule is found at subsections 12-43.3-201(4), 12-43.3-201(5), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(d), 12-43.3-202(2)(a)(II), and 12-43.3-202(2)(a)(XX), and sections 16-2.5-101, 16-2.5-121, and 16-2.5-124.5, C.R.S. The purpose of this rule is to allow for officers and employees of the Division to investigate all aspects of the Licensees to ensure the fair, impartial, stringent, and comprehensive administration of the Medical Code and rules promulgated pursuant to it.

### **M 1201 – Duties of Employees of the State Licensing Authority**

#### **A. Duties of Director**

1. The State Licensing Authority may delegate an act required to be performed by the State Licensing Authority related to the day-to-day operation of the Division to the Director.
2. The Director may authorize Division employees to perform tasks delegated from the State Licensing Authority.

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- B. Duties of Division Investigators. The State Licensing Authority, the Department's Senior Director of Enforcement, the Director, and Division investigators shall have all the powers of any peace officer to:
1. Investigate violations or suspected violations of the Medical Code and any rules promulgated pursuant to it. Make arrests, with or without warrant, for any violation of the Medical Code, any rules promulgated pursuant to it, Article 18 of Title 18, C.R.S., any other laws or regulations pertaining to Medical Marijuana in this state, or any criminal law of this state, if, during an officer's exercise of powers or performance of duties pursuant to the Medical Code, probable cause exists that a crime related to such laws has been or is being committed;
  2. Serve all warrants, summonses, subpoenas, administrative citations, notices or other processes relating to the enforcement of laws regulating Medical Marijuana and Medical Marijuana-Infused Product;
  3. Assist or aid any law enforcement officer in the performance of his or her duties upon such law enforcement officer's request or the request of other local officials having jurisdiction;
  4. Inspect, examine, or investigate any premises where the Licensee's Medical Marijuana or Medical Marijuana-Infused Product are grown, stored, cultivated, manufactured, tested, distributed, or sold, and any books and records in any way connected with any licensed activity;
  5. Require any Licensee, upon demand, to permit an inspection of Licensed Premises during business hours or at any time of apparent operation, marijuana equipment, and marijuana accessories, or books and records; and, to permit the testing of or examination of Medical Marijuana or Medical Marijuana-Infused Product;
  6. Require Applicants to submit complete and current applications and fees and other information the Division deems necessary to make licensing decisions and approve material changes made by the Applicant or Licensee;
  7. Conduct investigations into the character, criminal history, and all other relevant factors related to suitability of all Licensees and Applicants for Medical Marijuana licenses and such other Persons with a direct or indirect interest in an Applicant or Licensee, as the State Licensing Authority may require; and
  8. Exercise any other power or duty authorized by law.
- C. Duties of State Licensing Authority and Division Employees.
1. Employees shall maintain the confidentiality of State Licensing Authority and Division records and information. For confidentiality requirements of State Licensing Authority and Division employees who leave the employment of the State Licensing Authority, see rule M 1308 - Confidential Information and Former State Licensing Authority Employees.
  2. Pursuant to subsection 12-43.3-201(4), C.R.S., State Licensing Authority employees with regulatory oversight responsibilities for marijuana businesses licensed by the State Licensing Authority shall not work for, represent, or provide consulting services to or otherwise derive pecuniary gain from a marijuana business licensed by the State Licensing Authority or other business entity established for the primary purpose of providing services to the marijuana industry for a period of six months following his or her last day of employment with the State Licensing Authority.

3. Pursuant to subsection 12-43.3-201(5), C.R.S., disclosure of confidential records or information in violation of the provisions of the Medical Code constitutes a class 1 misdemeanor.

**Basis and Purpose – M 1202**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(IV), and 12-43.3-202(2)(a)(XX), C.R.S. This rule explains that Licensees must cooperate with Division employees when they are acting within the normal scope of their duties and that failure to do so may result in sanctions. It also explains the administrative hold process, the handling of inventory subject to administrative hold and under investigation and the process for voluntary surrender of Medical Marijuana and Medical Marijuana-Infused Product.

**M 1202 – Requirement for Inspections and Investigations, Searches, Administrative Holds, Voluntary Surrenders and Such Additional Activities as May Become Necessary from Time to Time**

**A. Applicants and Licensees Shall Cooperate with Division Employees**

1. Applicants and Licensees must cooperate with employees of the Division who are conducting inspections or investigations relevant to the enforcement of laws and regulations related to the Medical Code.
2. No Applicant or Licensee shall by any means interfere with, obstruct or impede the State Licensing Authority or any employee of the Division from exercising their duties under the provisions of the Medical Code and all rules promulgated pursuant to it. This would include, but is not limited to:
  - a. Threatening force or violence against an employee or investigator of the Division, or otherwise endeavoring to intimidate, obstruct, or impede employees or investigators of the Division, their supervisors, or any peace officers from exercising their duties. The term “threatening force” includes the threat of bodily harm to such individual or to a member of his or her family;
  - b. Denying investigators of the Division access to premises where the Licensee’s Medical Marijuana or Medical Marijuana-Infused Product are grown, stored, cultivated, manufactured, tested, distributed, or sold during business hours or times of apparent activity;
  - c. Providing false or misleading statements;
  - d. Providing false or misleading documents and records;
  - e. Failing to timely produce requested books and records required to be maintained by the Licensee; or
  - f. Failing to timely respond to any other request for information made by a Division employee or investigator in connection with an investigation of the qualifications, conduct or compliance of an Applicant or Licensee.

B. Administrative Hold

1. To prevent destruction of evidence, diversion or other threats to public safety, while permitting a Licensee to retain its inventory pending further investigation, a Division investigator may order an administrative hold of Medical Marijuana or Medical Marijuana-Infused Product pursuant to the following procedure:
  - a. If during an investigation or inspection of a Licensee, a Division investigator develops reasonable grounds to believe certain Medical Marijuana or Medical Marijuana-Infused Product constitute evidence of acts in violation of the Medical Code or rules promulgated pursuant to it, or otherwise constitute a threat to the public safety, the Division investigator may issue a notice of administrative hold of any such Medical Marijuana or Medical Marijuana-Infused Product. The notice of administrative hold shall provide a documented description of the Medical Marijuana or Medical Marijuana-Infused Product to be subject to the administrative hold and a concise statement that is promptly issued and approved by the Director or his or her designee regarding the reasons for issuing the administrative hold.
  - b. Following the issuance of a notice of administrative hold, the Division will identify the Medical Marijuana or Medical Marijuana-Infused Product subject to the administrative hold in the Inventory Tracking System. The Licensee shall continue to comply with all tracking requirements. See Rule M 309 – Medical Marijuana Business: Inventory Tracking System.
  - c. The Licensee shall completely and physically segregate the Medical Marijuana or Medical Marijuana-Infused Product subject to the administrative hold in a Limited Access Area of the Licensed Premises under investigation, where it shall be safeguarded by the Licensee.
  - d. While the administrative hold is in effect, the Licensee is prohibited from selling, giving away, transferring, transporting, or destroying the Medical Marijuana or Medical Marijuana-Infused Product subject to the administrative hold except as otherwise authorized by these Rules.
  - e. While the administrative hold is in effect, the Licensee must safeguard the Medical Marijuana and Medical Marijuana-Infused Product subject to the administrative hold and must fully comply with all security requirements including but not limited to surveillance, lock and alarm requirements set forth in the Medical Code and the rules of the State Licensing Authority. See Rule M 1309 Administrative Warrants.
  - f. Nothing herein shall prevent a Licensee from voluntarily surrendering Medical Marijuana or Medical Marijuana-Infused Product that is subject to an administrative hold, except that the Licensee must follow the procedures set forth below for voluntary surrender of Medical Marijuana or Medical Marijuana-Infused Product.
  - g. Nothing herein shall prevent a Licensee from the continued possession, cultivation, or harvesting of the Medical Marijuana subject to the administrative hold. All Medical Marijuana or Medical Marijuana-Infused Product subject to an administrative hold must be put into separate Harvest Batches.

- h. At any time after the initiation of the administrative hold, the Division may lift the administrative hold pending the administrative process, or seek other appropriate relief.

C. Voluntary surrender of Medical Marijuana or Medical Marijuana-Infused Product

1. A Licensee, prior to a Final Agency Order and upon mutual agreement with the Division, may elect to voluntarily surrender any Medical Marijuana or Medical Marijuana-Infused Product to the Division.
  - a. Such voluntary surrender may require destruction of any Medical Marijuana or Medical Marijuana-Infused Product in the presence of a Division investigator and at the Licensee's expense, and
  - b. The individual signing the Division's voluntary surrender form on behalf of the Licensee must certify that the individual has authority to represent and bind the Licensee.
2. The voluntary surrender form may be utilized in connection with a stipulated agency order through which the Licensee waives the right to hearing and any associated rights.
3. The voluntary surrender form may be utilized even if the Licensee does not waive the right to hearing and any associated rights, with the understanding that the outcome of the hearing does not impact the validity of the voluntary surrender.
4. A Licensee, after a Final Agency Order and upon mutual agreement with the Division, may elect to voluntarily surrender any marijuana or marijuana product to the Division.
  - a. The Licensee must complete and return the Division's voluntary surrender form within 15 calendar days of the date of the Final Agency Order.
  - b. Such voluntary surrender may require destruction of any marijuana or marijuana product in the presence of a Division investigator and at the Licensee's expense.
  - c. The individual signing the Division's voluntary surrender form on behalf of the Licensee must certify that the individual has authority to represent and bind the Licensee.

**Basis and Purpose - M 1203**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(II), 12-43.3-202(2)(a)(IV), and 12-43.3-202(1)(b)(XX), and section 12-43.3-602, C.R.S. The purpose of this rule is to provide guidance following either an agency decision or under any circumstances where the licensee is ordered to surrender and/or destroy unauthorized Medical Marijuana and unauthorized Medical Marijuana-Infused Product. This rule also provides guidance as to the need to preserve evidence during agency investigations or subject to agency order.

**M 1203 – Disposition of Unauthorized Medical Marijuana**

- A. After a Final Agency Order Mandates the Destruction of Medical Marijuana or Medical Marijuana-Infused Product. If the State Licensing Authority issues a Final Agency Order pursuant to section 12-43.3-602, C.R.S., that mandates the destruction of some or all of the Licensee's unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product, the Licensee may:

1. Voluntarily Surrender. The Licensee may voluntarily surrender to the Division all of its unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product that are described in the Final Agency Order in accordance with the provisions of Rule M 1202.
  2. Seek a Stay. The licensee may file a petition for a stay of the Final Agency Order with the Denver District Court within 15 days of the Final Agency Order.
  3. Take No Action. If the Licensee does not either (1) voluntarily surrender its unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product as set forth in Subsection (A)(1)(a) of this Rule; or (2) properly seek a stay of the Final Agency Order as set forth in section A.1.b. of this rule, the Division will enter the Licensed Premises and seize and destroy the unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product that are the subject of the Final Agency Order.
- B. General Requirements Applicable To All Licensees Following Final Agency Order To Destroy Unauthorized Medical Marijuana or Unauthorized Medical Marijuana-Infused Product. The following requirements apply regardless of whether the Licensee voluntarily surrenders its unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product, seeks a stay of agency action, or takes no action:
1. The 15 day period set forth in section 12-43.3-602, C.R.S., and this rule shall include holidays and weekends.
  2. During the period of time between the issuance of the Final Agency Order and the destruction of unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product, the Licensee shall not sell, destroy, or otherwise let any unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product that are subject to the Final Agency Order leave the Licensed Premises unless specifically authorized by the State Licensing Authority or a court of competent jurisdiction.
  3. During the period of time between the issuance of the Final Agency Order and the destruction of unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product, the Licensee must safeguard any unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product in its possession or control and must fully comply with all security requirements including but not limited to surveillance, lock and alarm requirements set forth in the Medical Code and the rules of the State Licensing Authority.
  4. Unless the State Licensing Authority otherwise orders, the Licensee may cultivate, water, or otherwise care for any unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product that are subject to the Final Agency Order during the period of time between the issuance of the Final Agency Order and the destruction of the unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product.
  5. If a district attorney notifies the Division that some or all of the unauthorized Medical Marijuana or Medical Marijuana-Infused Product is involved in an investigation, the Division shall not destroy the unauthorized Medical Marijuana or Medical Marijuana-Infused Product until approved by the district attorney.

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**Basis and Purpose - M 1204**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(I), 12-43.3-202(2)(a)(II), 12-43.3-202(2)(a)(IV), and 12-43.3-202(2)(a)(XX), C.R.S. This rule explains that the Director of the Division may exercise discretion to accept an assurance of voluntary compliance. It also explains the evidentiary value of an assurance of voluntary compliance should a licensee not comply with the agreement.

**M 1204 – Assurance of Voluntary Compliance**

- A. The Director of the Division may accept an assurance of voluntary compliance regarding any act or practice alleged to violate the Medical Code, or the rules and regulations thereunder, from a person who has engaged in, is engaging in, or is about to engage in such acts or practices.
- B. The assurance must be in writing and may include a stipulation for the voluntary payment of the cost commensurate with the acts or practices and an amount necessary to restore money or property which may have been acquired by the alleged violator because of the acts or practices.
- C. An assurance of voluntary compliance may not be considered an admission of a violation for any purpose; however, proof of failure to comply with the assurance of voluntary compliance is prima facie evidence of a violation of the Medical Code, or the rules and regulation thereunder.
- D. The State Licensing Authority may approve or review an assurance of voluntary compliance.

**M 1300 Series – Discipline**

**Basis and Purpose – M 1301**

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(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 clarify how the disciplinary process for non-summary license suspensions and license revocations is initiated.

**M 1301 – Disciplinary Process: Non-Summary Suspensions**

- A. How a Disciplinary Action is Initiated
  - 1. If the State Licensing Authority, on its own initiative or based on a complaint, has reasonable cause to believe that a Licensee has violated the Medical Code, any rule promulgated pursuant to it, or any of its orders, the State Licensing Authority shall issue and serve upon the Licensee an Order to Show Cause (administrative citation) as to why the Licensee's license should not be suspended, revoked, restricted, fined, or subject to other disciplinary sanction.
  - 2. The Order to Show Cause shall identify the statute, rule, regulation, or order allegedly violated, and the facts alleged to constitute the violation. The order shall also provide an advisement that the license could be suspended, revoked, restricted, fined, or subject to other disciplinary sanction, should the charges contained in the notice be sustained upon final hearing.
- B. Disciplinary Hearings. Disciplinary hearings will be conducted in accordance with Rule M 1304 – Administrative Hearings.
- C. Renewal. The issuance of an Order to Show Cause does not relieve the Licensee of the obligation to timely comply with all license renewal requirements.

## **Basis and Purpose – M 1302**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(a), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(c), 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 – Summary Suspensions**

### **A. How a Summary Suspension Action is Initiated**

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

### **B. Duration of Summary Suspension. Unless lifted by the State Licensing Authority, the Summary Suspension Order shall remain in effect until issuance of a Final Agency Order.**

### Basis and Purpose – M 1303

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 s24-4-104(4)(a), and sections 12-43.3-601 and 24-4-105, C.R.S. The State Licensing Authority recognizes that if Licensees are not able to care for their products during a period of active suspension, then their plants could die, their edible products could deteriorate, and their on-hand inventory may not be properly maintained. Accordingly, this rule was written to clarify that Licensees whose licenses are summarily suspended may care for on-hand inventory, manufactured products, and plants during the suspension (unless the State Licensing Authority does not allow such activity), provided the Licensed Premises and all Medical Marijuana and Medical Marijuana-Infused Product are adequately secured. In addition, the rule clarifies what activity is always prohibited during such suspension.

### M 1303 – Suspension Process: Regular and Summary Suspensions

A. Signs Required During Active Suspension. Every Licensee whose License has been suspended, whether summarily or after an administrative hearing, shall post two notices in conspicuous places, one on the exterior and one on the interior of its premises, for the duration of the suspension. The notices shall at least 17 inches in length and 11 inches in width containing lettering not less 1/2" in height.

1. For suspension following issuance of a Final Agency Order, the sign shall be in the following form:

NOTICE OF SUSPENSION  
MEDICAL MARIJUANA LICENSES ISSUED  
FOR THESE PREMISES HAVE BEEN  
SUSPENDED BY ORDER OF THE STATE LICENSING AUTHORITY  
FOR VIOLATION OF THE COLORADO MEDICAL MARIJUANA CODE

2. For a summary suspension pending issuance of a Final Agency Order, the sign shall be in the following form:

NOTICE OF SUSPENSION  
MEDICAL MARIJUANA LICENSES ISSUED  
FOR THESE PREMISES HAVE BEEN  
SUSPENDED BY ORDER OF THE STATE LICENSING AUTHORITY  
FOR ALLEGED VIOLATION OF THE COLORADO MEDICAL MARIJUANA  
CODE

Any advertisement or posted signs that indicate that the premises have been closed or business suspended for any reason other than by the manner described in this rule shall be deemed a violation of these rules.

**B. Prohibited Activity During Suspension**

1. Unless otherwise ordered by the State Licensing Authority, during any period of suspension the Licensee shall not permit the acquisition, purchase, selling, serving, giving away, distribution, manufacture, sampling, testing, transfer, or transport of Medical Marijuana or Medical Marijuana-Infused Product on the Licensed Premises, nor allow patients to enter the Licensed Premises.
2. Unless otherwise ordered by the State Licensing Authority, during any period of suspension the Licensee may continue to possess, maintain, cultivate or harvest Medical Marijuana or Medical Marijuana-Infused Product on the Licensed Premises. The Licensee must fully account for all such Medical Marijuana and Medical Marijuana-Infused Product in the Inventory Tracking System. The Licensee must safeguard any Medical Marijuana or Medical Marijuana-Infused Product in its possession or control. The Licensee must fully comply with all security requirements including but not limited to surveillance, lock and alarm requirements set forth in the Medical Code and the rules of the State Licensing Authority.

**C. Removal and Destruction of Marijuana and Marijuana-Infused Product. Medical Marijuana and Medical Marijuana-Infused Product shall not be removed from the Licensed Premises or destroyed unless and until:**

1. The provisions described in section 12-43.3-602, C.R.S., related to the proper destruction of unauthorized marijuana are met, and the State Licensing Authority orders forfeiture and destruction. See also Rule M 1203 – Disposition of Unauthorized Medical Marijuana;
2. The Licensee has voluntarily surrendered the Medical Marijuana or Medical Marijuana-Infused Product in accordance with Rule M 1202(C) – voluntary surrender;
3. The State Licensing Authority has seized the Medical Marijuana or Medical Marijuana-Infused Product pursuant to an Administrative Warrant. See Rule M 1309 - Administrative Warrant.

**D. Renewal. The issuance of a suspension or an Order of Summary Suspension does not relieve the Licensee of the obligation to timely comply with all license renewal requirements.**

**Basis and Purpose – M 1304**

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

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## M 1304 – Administrative Hearings

### A. General Procedures

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

### B. Requesting a Hearing

1. A Denied Applicant that has been served with a Notice of Denial may request a hearing within 60 days of the service of the Notice of Denial by making a written request for a hearing to the Division. The request must be submitted by United States mail or by hand delivery. Email or fax requests will not be considered. The request must be sent to the mailing address of the Division's headquarters, as listed on the Division's website. Include "Attn: Hearing Request" in the mailing address. The written request for a hearing must be received by the Division within the time stated in the Notice of Denial. An untimely request for hearing will not be considered.
2. A Denied Applicant that timely requests a hearing following issuance of a Notice of Denial shall be served with a Notice of Grounds for Denial, and shall be entitled to a hearing regarding the matters addressed therein.
3. A Respondent that has been served with an Order to Show Cause shall be entitled to a hearing regarding the matters addressed therein.

### C. When a Responsive Pleading is Required

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

D. Hearing Notices

1. Notice to Set. The Division shall send a notice to set a hearing to the Denied Applicant or Respondent in writing by first-class mail to the last mailing address of record.
2. Notice of Hearing. The Hearings Division shall notify the Division and Denied Applicant or Respondent of the date, place, time and nature of the hearing regarding denial of the license application or whether discipline should be imposed against the Respondent's license at least 30 days prior to the date of such hearing, unless otherwise agreed to by both parties. This notice shall be sent to the Denied Applicant or Respondent in writing by first-class mail to the last mailing address of record. Hearings shall be scheduled and held as soon as is practicable.
  - a. If an Order of Summary Suspension has issued, the hearing on the Order to Show Cause will be scheduled and held promptly.
  - b. Continuances may be granted for good cause, as described in this rule, shown. A motion for a continuance must be timely.
  - c. For purposes of this rule, good cause may include but is not limited to: death or incapacitation of a party or an attorney for a party; a court order staying proceedings or otherwise necessitating a continuance; entry or substitution of an attorney for a party a reasonable time prior to the hearing, if the entry or substitution reasonably requires a postponement of the hearing; a change in the parties or pleadings sufficiently significant to require a postponement; a showing that more time is clearly necessary to complete authorized discovery or other mandatory preparation for the hearing; or agreement of the parties to a settlement of the case which has been or will likely be approved by the final decision maker. Good cause normally will not include the following: unavailability of counsel because of engagement in another judicial or administrative proceeding, unless the other proceeding was involuntarily set subsequent to the setting in the present case; unavailability of a necessary witness, if the witness' testimony can be taken by telephone or by deposition; or failure of an attorney or a party timely to prepare for the hearing.

E. Prehearing Matters Generally

1. Prehearing Conferences Once a Hearing is Set. Prehearing conferences may be held at the discretion of the hearing officer upon request of any party, or upon the hearing officer's own motion. If a prehearing conference is held and a prehearing order is issued by the hearing officer, the prehearing order will control the course of the proceedings. Such prehearing conferences may occur by telephone.
2. Depositions. Depositions are generally not allowed; however, a hearing officer has discretion to allow a deposition if a party files a written motion and can show why such deposition is necessary to prove its case. When a hearing officer grants a motion for a deposition, C.R.C.P. 30 controls. Hearings will not be continued because a deposition is allowed unless (a) both parties stipulate to a continuance and the hearing officer grants the continuance, or (b) 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. Witnesses. The name, mailing address, and telephone number of any witness whom the party may call at hearing, together with a detailed statement of the expected testimony.
  - b. Experts. The name, mailing address, and brief summary of the qualifications of any expert witness a party may call at hearing, together with a statement that details the opinions to which each expert is expected to testify. These requirements may be satisfied by the incorporation of an expert's resume or report containing the required information.
  - c. Exhibits. A description of any physical or documentary evidence to be offered into evidence at the hearing. Exhibits should be identified as follows: Division using numbers and Denied Applicant or Respondent using letters.
  - d. Stipulations. A list of all stipulations of fact or law reached, as well as a list of any additional stipulations requested or offered to facilitate disposition of the case.
4. Prehearing Statements Binding. The information provided in a party's prehearing statement shall be binding on that party throughout the course of the hearing unless modified to prevent manifest injustice. New witnesses or exhibits may be added only if: (1) the need to do so was not reasonably foreseeable at the time of filing of the prehearing statement; (2) it would not unduly prejudice other parties; and (3) it would not necessitate a delay of the hearing.
5. Consequence of Not Filing a Prehearing Statement Once a Hearing is Set. If a party does not timely file a prehearing statement, the hearing officer may impose appropriate sanctions including, but not limited to, striking proposed witnesses and exhibits.

F. Conduct of Hearings

1. The hearing officer shall cause all hearings to be electronically recorded.
2. The hearing officer may allow a hearing, or any portion of the hearing, to be conducted in real time by telephone or other electronic means. If a party is appearing by telephone, the party must provide actual copies of the exhibits to be offered into evidence at the hearing to the hearing officer when the prehearing statement is filed.
3. The hearing officer shall administer oaths to all witnesses at hearing. The hearing officer may question any witness.
4. The hearing, including testimony and exhibits, shall be open to the public unless otherwise ordered by the hearing officer in accordance with a specific provision of law.
  - a. Reports and other information that would otherwise be confidential pursuant to Subsection 12-43.3-202(1)(d), C.R.S., may be introduced as exhibits at hearing.

- b. Any party may move the hearing officer to seal an exhibit or order other appropriate relief if necessary to safeguard the confidentiality of evidence.

5. Court Rules.

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

6. Exhibits.

- a. All documentary exhibits must be paginated by the party offering the exhibit into evidence.
- b. The Division shall use numbers to mark its exhibits.
- c. The Denied Applicant or Respondent shall use letters to mark its exhibits.

- 7. The hearing officer may proceed with the hearing or enter default judgment if any party fails to appear at hearing after proper notice.

G. Post Hearing. After considering all the evidence, the hearing officer shall determine whether the proponent of the order has proven its case by a preponderance of the evidence, and shall make written findings of evidentiary fact, ultimate conclusions of fact, conclusions of law, and a recommendation. These written findings shall constitute an Initial Decision subject to review by the State Licensing Authority pursuant to the Colorado Administrative Procedure Act and as set forth in Rule 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. Marijuana Enforcement Division Representation. The Division shall be represented by the Colorado Department of Law.

### Basis and Purpose – M 1305

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(2)(a)(V), 12-43.3-202(a)(XIX), and 12-43.3-202(2)(a)(XX), and section 24-4-105, C.R.S. The purpose of this rule is to establish how all parties, including pro se parties, can obtain subpoenas during the administrative hearing process.

### M 1305 – Administrative Subpoenas

- A. Informal Exchange of Documents Encouraged. Parties are encouraged to exchange documents relevant to the Notice of Denial or Order to Show Cause prior to requesting subpoenas. In addition, to the extent practicable, parties are encouraged to secure the voluntary presence of witnesses necessary for the hearing prior to requesting subpoenas.
- B. Hearing Officer May Issue Subpoenas
1. A party or its counsel may request the hearing officer to issue subpoenas to secure the presence of witnesses or documents necessary for the hearing or a deposition, if one is allowed.
  2. Requests for subpoenas to be issued by the hearing officer must be delivered in Person or by mail to the office of the Department of Revenue – Hearings Division, 1881 Pierce St. #106, Lakewood, CO 80214. Subpoena requests must include the return mailing address, and phone and facsimile numbers of the requesting party or its attorney.
  3. Requests for subpoenas to be issued by the hearing officer must be made on a “Request for Subpoena” form authorized and provided by the Hearings Division. A hearing officer shall not issue a subpoena unless the request contains the following information:
    - a. Name of Denied Applicant or Respondent;
    - b. License or application number;
    - c. Case number;
    - d. Date of hearing;
    - e. Location of hearing, or telephone number for telephone check-in;
    - f. Time of hearing;
    - g. Name of witness to be subpoenaed; and
    - h. Mailing address of witness (home or business).
  4. A request for a subpoena *duces tecum* must identify each document or category of documents to be produced.
  5. Requests for subpoenas shall be signed by the requesting party or their counsel.
  6. The hearing officer shall issue subpoenas without discrimination, as set forth in section 24-4-105(5), C.R.S. If the reviewing hearing officer denies the issuance of a subpoena, or alters a subpoena in any material way, specific findings and reasons for such denial or alteration must be made on the record, or by written order incorporated into the record.

C. Service of Subpoenas

1. Service of any subpoena is the duty of the party requesting the subpoena.
2. All subpoenas must be served at least two business days prior to the hearing.

D. Subpoena Enforcement

1. Any subpoenaed witness, entity, or custodian of documents may move to quash the subpoena with the hearing officer.
2. A hearing officer may quash a subpoena if he or she finds on the record that compliance would be unduly burdensome or impracticable, unreasonably expensive, or is unnecessary.

**Basis and Purpose – M 1306**

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(2)(a)(V), 12-43.3-202(a)(XIX), and 12-43.3-202(2)(a)(XX), and section 24-4-105, C.R.S. The purpose of this rule is to establish how parties may appeal a hearing officer's Initial Decision pursuant to the Administrative Procedure Act.

**M 1306 – Administrative Hearing Appeals/Exceptions to Initial Decision**

- A. Exception(s) Process. Any party may appeal an Initial Decision to the State Licensing Authority pursuant to the Colorado Administrative Procedure Act by filing written exception(s) within 30 days after the date of mailing of the Initial Decision to the Denied Applicant or Respondent and the Division. The written exception(s) shall include a statement giving the basis and grounds for the exception(s). Any party who fails to properly file written exception(s) within the time provided in these rules shall be deemed to have waived the right to an appeal. A party shall serve a copy of the exception(s) on all parties. The address of the State Licensing Authority is: State Licensing Authority, 1375 Sherman Street, 4<sup>th</sup> Floor, Denver, CO 80203.
- B. Designation of Record. Any party that seeks to reverse or modify the Initial Decision of the hearing officer shall file with the State Licensing Authority, within 20 days from the mailing of the Initial Decision, a designation of the relevant parts of the record and of the parts of the hearing transcript which shall be prepared, and advance the costs therefore. A copy of this designation shall be served on all parties. Within ten days thereafter, any other party or the Division may also file a designation of additional parts of the transcript of the proceedings which is to be included and advance the cost therefore. No transcript is required if the review is limited to a pure question of law. A copy of this designation of record shall be served on all parties.
- C. Deadline Modifications. The State Licensing Authority may modify deadlines and procedures related to the filing of exceptions to the Initial Decision upon motion by either party for good cause shown.
- D. No Oral Argument Allowed. Requests for oral argument will not be considered.

## **Basis and Purpose – M 1307**

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(2)(a)(V), 12-43.3-202(a)(XIX), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to establish guidelines for enforcement and penalties that will be imposed by the State Licensing Authority for non-compliance with Medical Code, section 18-18-406.3(7), C.R.S., or any other applicable rule. The State Licensing Authority considered the type of violation and the threat of harm to the public versus purely administrative harm when setting the penalty structure. Based upon public testimony and a written commentary, Rule M 1307.A was amended to include additional license violations affecting public safety and Rule M 1307.C.1 was added.

## **M 1307 – Penalties**

- A. Penalty Schedule. The State Licensing Authority will make determinations regarding the type of penalty to impose based on the severity of the violation in the following categories:
1. License Violations Affecting Public Safety. This category of violation is the most severe and may include, but is not limited to, Medical Marijuana sales to non-patients, consuming marijuana on the Licensed Premises, Medical Marijuana sales in excess of the relevant transaction limit, permitting the diversion of Medical Marijuana outside the regulated distribution system, possessing medical marijuana inventory or medical marijuana-infused products inventory obtained from outside the regulated distribution system or from an unauthorized source, misstatements or omissions in the Inventory Tracking System, failure to continuously escort a visitor in a Limited Access Area, violations related to co-located Medical Marijuana Businesses and Retail Marijuana Establishments, failure to maintain books and records to fully account for all transactions of the business, or packaging or labeling violations that directly impact patient safety. Violations of this nature generally have an immediate impact on the health, safety, and welfare of the public at large. The range of penalties for this category of violation may include license suspension, a fine per individual violation, a fine in lieu of suspension of up to \$100,000, and/or license revocation depending on the mitigating and aggravating circumstances. Sanctions may also include restrictions on the license.
  2. License Violations. This category of violation is more severe than a license infraction but generally does not have an immediate impact on the health, safety and welfare of the public at large. License violations may include but are not limited to, advertising and/or marketing violations, packaging or labeling violations that do not directly impact patient safety, failure to maintain minimum security requirements, failure to keep and maintain adequate business books and records, minor or clerical errors in the inventory tracking procedures. The range of penalties for this category of violation may include a written warning, license suspension, a fine per individual violation, a fine in lieu of suspension of up to \$50,000, and/or license revocation depending on the mitigating and aggravating circumstances. Sanctions may also include restrictions on the license.
  3. License Infractions. This category of violation is the least severe and may include, but is not limited to, failure to display required badges, unauthorized modifications of the premises of a minor nature, or failure to notify the State Licensing Authority of a minor change in ownership. The range of penalties for this category of violation may include a verbal or written warning, license suspension, a fine per individual violation, and/or a fine in lieu of suspension of up to \$10,000 depending on the mitigating and aggravating circumstances. Sanctions may also include restrictions on the license.

B. Other Factors

1. The State Licensing Authority may take into consideration any aggravating and mitigating factors surrounding the violation which could impact the type or severity of penalty imposed.
2. The penalty structure is a framework providing guidance as to the range of violations, suspension description, fines, and mitigating and aggravating factors. The circumstances surrounding any penalty imposed will be determined on a case-by-case basis.
3. For all administrative offenses involving a proposed suspension, a Licensee may petition the State Licensing Authority for permission to pay a monetary fine, within the provisions of section 12-43.3-601, C.R.S., in lieu of having its license suspended for all or part of the suspension.

**Basis and Purpose – M 1308**

The statutory authority for this rule is found at subsections 12-43.3-201(4), 12-43.3-201(5), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(d), 12-43.3-202(2)(a)(II), 12-43.3-202(2)(a)(V), 12-43.3-202(2)(a)(VI), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to assure Licensees do not use unauthorized confidential information at any time and do not engage the services of former State Licensing Authority or Division employees with regulatory oversight responsibilities for licensed marijuana businesses for the first 6 months following State Licensing Authority or Division employment.

**M 1308 –Confidential Information and Former State Licensing Authority Employees**

- A. Misdemeanor if Disclosed. Disclosure of confidential records or information in violation of the Medical Code constitutes a class 1 misdemeanor pursuant to subsection 12-43.3-201(5), C.R.S.
1. Licensees, and employees or agents of a Licensee, shall not obtain or utilize confidential information the Licensee, employee or agent is not lawfully entitled to acquire or possess through use or misuse of Division processes or Division-approved systems. For confidentiality requirements of State Licensing Authority and Division employees, see rule M 1201 – Duties of Employees of the State Licensing Authority.
  2. Any Licensee, and any employee or agent of a Licensee, who is authorized to access the Division's Inventory Tracking System and/or have access to confidential information derived from Division sources, shall utilize the confidential information only for a purpose authorized by the Division or these Rules.
  3. All Licensees, and all employees and agents of Licensees, shall not use the Inventory Tracking System for any purpose other than tracking the Licensee's Medical Marijuana and Medical Marijuana-Infused Product.
- B. Six-Month Prohibition from Working with Former State Licensing Authority Employees. State Licensing Authority or Division employees with regulatory oversight responsibilities for Medical Marijuana Businesses or Retail Marijuana Establishments are prohibited from working for, representing, or providing consulting services to or otherwise deriving pecuniary gain from a Licensee for a period of six months following his or her last day of employment with the State Licensing Authority or Division.
1. Any Licensee who utilizes, employs, consults, seeks advice from, or contracts with a former employee of the State Licensing Authority or the Division prior to the conclusion of the six-month period shall be in violation of the Medical Code.

2. Any Licensee who possesses, utilizes or re-discloses confidential information obtained from a former State Licensing Authority or Division employee at any time shall be in violation of the Medical Code.

### **Basis and Purpose – M 1309**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(II), 12-43.3-202(2)(a)(IV), 12-43.3-202(a)(X), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to establish the circumstances under which the Division may seek from a district court an administrative warrant to search and/or seize marijuana and marijuana products. The Division has encountered circumstances that would have justified such a warrant. Establishing the criteria under which the Division may seek an administrative warrant will give fair notice to the regulated community regarding the types of violations that would lead to a request for an administrative warrant.

### **M 1309 – Administrative Warrants**

- A. Criteria. The Division may seek from a district court an administrative search warrant authorizing search and seizure in circumstances in which the Division makes a proper showing that:
  1. A Licensee has refused entry of Division investigators during business hours or times of apparent activity;
  2. A Licensee subject to an administrative hold or summary suspension has failed to comply with applicable rules; or
  3. A Licensee otherwise has acted in a manner demonstrating disregard for the Medical Code and the State Licensing Authority's rules or that threatens the public health, safety, and welfare.
- B. Affidavit. When seeking an administrative search warrant, the Division will supply the district court with a sworn affidavit explaining the bases for seeking the warrant.
- C. Seized Property. If the Division seizes marijuana, neither the Division nor the State Licensing Authority shall cultivate or care for any seized marijuana or marijuana products. The Division may seek from the district court an order to destroy any such marijuana or marijuana products.

### **M 1400 Series – Division, Local Licensing Authority, and Law Enforcement Procedures**

#### **Basis and Purpose – M 1401**

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. This rule gives general instructions regarding Medical Marijuana Businesses administrative matters to local jurisdictions and clarifies for such entities what the Division and State Licensing Authority will do in certain instances. The rule also reaffirms that local law enforcement's authority to investigate and take any necessary action with regard to Medical Marijuana Businesses remains unaffected by the Medical Code or any rules promulgated pursuant to it.

#### **M 1401 – Instructions for Local Licensing Authorities and Law Enforcement Officers**

- A. Division Protocol for Medical Marijuana Businesses
  1. The Division shall forward a copy of all new Medical Marijuana Business applications to the relevant local licensing authority.

2. The Division shall notify the relevant local licensing authority when an application for a Medical Marijuana Business is either approved or denied. This includes new business applications, renewal business applications, change of location applications, transfer of ownership applications, premises modification applications, and off-premises storage permit applications.
  3. Conditioned on Local Approval. Any license issued or renewed by the Division for a Medical Marijuana Business shall be conditioned upon relevant local licensing authority approval of the application.
- B. Local Licensing Authority Protocol for Medical Marijuana Businesses
1. As soon as practicable, a local licensing authority that has prohibited the operation of Medical Marijuana Businesses shall inform the Division, in writing, of such prohibition and shall include a copy of the applicable ordinance or resolution.
  2. If a local licensing authority will authorize the operation of Medical Marijuana Businesses, it shall inform the Division of the local point-of-contact on Medical Marijuana regulatory matters. The local jurisdiction shall include, at minimum, the name of the division or branch of local government, the mailing address of that entity, and telephone number.
  3. Local licensing authorities may impose separate local licensing requirements related to the time, place, and manner of Medical Marijuana Businesses, and shall otherwise determine if an application meets those local requirements.
  4. The relevant local licensing authority shall notify the Division, in writing, of whether an application for a Medical Marijuana Business complies with local restrictions and requirements, and whether the application is approved or denied based on that review. If a local licensing authority makes any written findings of fact, a copy of those written findings shall be included with the notification.
- C. Local Licensing Authority Inspections. The relevant local licensing authorities and their investigators may inspect Medical Marijuana Businesses during all business hours and other times of apparent activity, for the purpose of inspection or investigation.
- D. Local Licensing Authority Powers. Nothing in these rules shall be construed to limit the authority of local licensing authorities as established by the Medical Code or otherwise by law.
- E. Local Law Enforcement's Authority Not Impaired by Medical Code. Nothing in the Medical Code or any rules promulgated pursuant to it shall be construed to limit the ability of local police departments, sheriffs, or other state or local law enforcement agencies to investigate unlawful activity in relation to a Medical Marijuana Business and such agencies shall have the ability to run a Colorado Crime Information Center criminal history check of an Applicant or Licensee during an investigation of unlawful activity related to Medical Marijuana or a Medical Marijuana Business. This includes, but is not limited to, inspecting and investigating Medical Marijuana Businesses to ensure they are in compliance with all local licensing authority regulations related to time, place, and manner.

## 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)(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), 12-43.3-402(6), 12-43.3-402(7), 12-43.3-404(4), and 12-43.3-404(10), C.R.S. The purpose of this rule is to protect the public health and safety by establishing the contaminant testing and related process validation portion of the Division's Medical Marijuana sampling and testing program.

### M 1501 – Medical Marijuana Testing Program – Contaminant Testing

- A. 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
1. 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.
1. Microbial Contaminant Testing. Each Harvest Batch of Medical Marijuana and Production Batch of Water- or Food-Based Medical Marijuana Concentrate and Medical Marijuana-Infused Product must be tested for microbial contamination by a Medical Marijuana Testing Facility. The microbial contamination test must include, but need not be limited to, testing to determine the presence of Salmonella sp. and shiga-toxin producing Escherichia coli., and the amount of total yeast and mold.
  2. Repealed.

3. Residual Solvent Contaminant Testing. Each Production Batch of Solvent-Based Medical Marijuana Concentrate produced by a Medical Marijuana-Infused Products Manufacturer must be tested for residual solvent contamination by a Medical Marijuana Testing Facility. The residual solvent contamination test must include, but need not be limited to, testing to determine the presence of, and amounts present of, butane, heptanes, benzene\*, toluene\*, hexane\*, and xylenes\*. \* Note: These solvents are not approved for use. Testing is required for these solvents due to their possible presence in the solvents approved for use per rule M 605.
- D. Additional Required Tests. The Division may require additional tests to be conducted on a Harvest Batch or Production Batch prior to an Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer wholesaling, transferring, or processing into a Medical Marijuana Concentrate or Medical Marijuana-Infused Product any Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product from that Harvest Batch or Production Batch. Additional tests may include, but need not be limited to, screening for Pesticide, chemical contaminants or other types of biological contaminants, microbials, molds, metals, or residual solvents.
- E. Exemptions
1. 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. Material Change Re-validation. 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. Pesticide. 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. Solvents. 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. Notification. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer that makes a Material Change must notify the Medical Marijuana Testing Facility that conducts contaminant testing on the first five Harvest Batches or Production Batches produced using the new standard operating procedures.

- d. Testing Required Prior to Wholesale, Transfer or Processing. When a Harvest Batch or Production Batch is required to be submitted for testing pursuant to this rule, the Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer that produced it may not wholesale, transfer or process into a Medical Marijuana Concentrate or Medical Marijuana-Infused Product any of the Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product from that Harvest Batch or Production Batch.
  2. Failed Contaminant Testing Re-Validation. If a Sample the Division requires to be tested fails contaminant testing, the Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer shall follow the procedures in paragraph B of rule M 1507 for any package, Harvest Batch, or Production Batch from which the failed Sample was taken. The Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer shall also submit three additional Test Batches of the Medical Marijuana or Medical Marijuana-Infused Product for contaminant testing by a Medical Marijuana Testing Facility within no more than 30 days. If any one of the three submitted Test Batches fails contaminant testing, the Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer shall re-validate its process for contaminants.
  3. 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. Violation Affecting Public Safety. 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)(XI), 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), 12-43.3-402(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 mandatory testing portion of the Division's Medical Marijuana sampling and testing program.

### **M 1502 – Medical Marijuana Testing Program – Mandatory Testing**

- 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.
1. 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, 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.

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- B. Methods for Determining Required Testing.
1. Random Testing. The Division may require Samples to be submitted for testing through any one or more of the following processes: random process, risk-based process or other internally developed process, regardless of whether a Medical Marijuana Business's process has been validated.
  2. Inspection or Enforcement Tests. 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. Beta Testing. 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. Minimum Testing Standards. 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. Additional Sample Types. 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, 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. Violation Affecting Public Safety. Failure to comply with this rule may constitute a license violation affecting public safety.

### Basis and Purpose – M 1503

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)(XX), 12-43.3-202(2.5)(a)(I), 12-43.3-402(6), 12-43.3-402(7), 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 potency testing and related process validation portion of the Division's Medical Marijuana sampling and testing program.

### M 1503 – Medical Marijuana Testing Program – Potency Testing

**Rule M 1503 shall be effective beginning July 1, 2016.**

#### A. Potency Testing – General.

1. Test Batches. A Test Batch submitted for potency testing may only be comprised of Samples that are of the same strain of Medical Marijuana or from the same Production Batch of Medical Marijuana Concentrate or Medical Marijuana-Infused Product.
2. Cannabinoid Profile. A potency test conducted pursuant to this rule must at least determine the level of concentration of THC, THCA, CBD, CBDA and CBN.

#### B. Potency Testing for Medical Marijuana.

1. Initial Potency Testing. An Optional Premises Cultivation Operation must have potency tests conducted by a Medical Marijuana Testing Facility on four Harvest Batches, created a minimum of one week apart, for each strain of Medical Marijuana that it cultivates.
  - a. The first potency test must be conducted on each strain prior to the Optional Premises Cultivation Operation wholesaling, transferring or processing into a Medical Marijuana Concentrate any Medical Marijuana of that strain.
  - b. All four potency tests must be conducted on each strain no later than December 1, 2016 or six months after the Optional Premises Cultivation Operation begins cultivating that strain, whichever is later.
2. Ongoing Potency Testing. After the initial four potency tests, an Optional Premises Cultivation Operation shall have each strain of Medical Marijuana that it cultivates tested for potency at least once every six months.

#### C. Potency Testing for Medical Marijuana Concentrate. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer must have a potency test conducted by a Medical Marijuana Testing Facility on every Production Batch of Medical Marijuana Concentrate that it produces prior to wholesaling, transferring or processing into a Medical Marijuana-Infused Product any of the Medical Marijuana Concentrate from that Production Batch.

#### D. Potency Testing for Medical Marijuana-Infused Product

1. Potency Testing Required for Medical Marijuana-Marijuana Infused Product. A Medical Marijuana-Infused Products Manufacturer shall have potency tests conducted by a Medical Marijuana Testing Facility on every Production Batch of Medical Marijuana Infused-Product that it produces prior to transferring or wholesaling any of the Medical Marijuana-Infused Product from that Production Batch.

2. Required Tests. Potency tests conducted on Medical Marijuana-Infused Product must determine the level of concentration of the required cannabinoids and whether or not THC is homogeneously distributed throughout the product.
  3. Partially Infused Medical Marijuana-Infused Products. If only a portion of a Medical Marijuana-Infused Product is infused with Medical Marijuana, then the Medical Marijuana-Infused Products Manufacturer must inform the Medical Marijuana Testing Facility of exactly which portions of the Medical Marijuana-Infused Product are infused and which portions are not infused.
- E. Validation of Process - Potency and Homogeneity – Edible Medical Marijuana-Infused Products Containing 100 Milligrams or Less of THC.
1. A Medical Marijuana-Infused Products Manufacturer may process validate potency and homogeneity for each type of Edible Medical Marijuana-Infused Product that it manufactures so long as the Edible Medical Marijuana-Infused Product contains 100 milligrams or less of THC.
  2. A Medical Marijuana-Infused Products Manufacturer's production process for a particular type of Edible Medical Marijuana-Infused Product shall be deemed valid regarding potency and homogeneity if every Production Batch that it produces for that particular type of Edible Medical Marijuana-Infused Product during at least a four week period but no longer than an eight week period passes all potency tests required by rule M 1503(D)(2). 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 a Medical Marijuana-Infused Products Manufacturer has successfully obtained process validation for potency and homogeneity for a particular type of Edible Medical Marijuana-Infused Product that it produces, the process validation shall be effective for one year from the date of the last passing test required to satisfy the process validation requirements.
- F. Violation Affecting Public Safety. 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)(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), 12-43.3-402(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**

- A. Collection of Samples
1. 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.
  2. 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 Samples of Medical Marijuana or Medical Marijuana-Infused Product for the purpose of circumventing contaminant testing detection limits or potency testing requirements. The Sample(s) collected and submitted for testing must be representative of the Harvest Batch or Production Batch being tested. A violation of this sub-paragraph (A)(3) shall be considered a license violation affecting public safety.
- B. Samples for Test Batches of Medical Marijuana and Medical Marijuana Concentrate. Each Test Batch of Medical Marijuana or Medical Marijuana Concentrate must be comprised of a representative selection of Samples.
1. 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 and combined into one Test Batch.
    - 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 and combined into one Test Batch.
    - c. 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 and combined into one Test Batch.
    - 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 and combined into one Test Batch.
    - 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 and combined into one Test Batch.
    - f. For Test Batches comprised of Harvest Batches or Production Batches weighing 100 pounds or more, 29 separate Samples must be taken and combined into one Test Batch.
  2. Multiple Harvest Batches or Production Batches. 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. Finished Product. Test Batches of Medical Marijuana-Infused Product must be comprised of finished product that is packaged for sale.
  2. Multiple Production Batches. 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 its sole discretion, to assign a Medical Marijuana Testing Facility to test the Sample.
- E. Violation Affecting Public Safety. Failure to comply with this rule may constitute a license violation affecting public safety.

### **Basis and Purpose – M 1505**

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)(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), 12-43.3-402(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 rules governing Test Batches for the Division's Medical Marijuana sampling and testing program.

### **M 1505 – Medical Marijuana Testing Program – Test Batches**

**Rule M 1505 shall be effective beginning July 1, 2016.**

- A. No Combination of Product Types. A Test Batch may not be a combination of any two or three of the following: Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product.
- B. Combining Samples.
  - 1. Harvest Batches and Production Batches. The Division will generally permit an Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer to combine Samples from any number of Harvest Batches or Production Batches created within a 7 day period into a single Test Batch for any contaminant testing required by rule. However, the Division may elect, at its sole discretion, to require a Test Batch to be comprised of Samples from only one Harvest Batch, Production Batch or a specifically identified quantity of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product.
  - 2. Packages. The Division will generally permit a Medical Marijuana Business to combine Samples from any number of packages of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product into a single Test Batch for any contaminant testing required by rule. However, the Division may elect, at its sole discretion, to require a Test Batch to be comprised of Samples from only one package or a specifically identified quantity of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Production.
- C. Same Processes
  - 1. General Applicability. All Harvest Batches or Production Batches combined into a single Test Batch must be cultivated or produced using the same standard operating procedure.
  - 2. Medical Marijuana. All Harvest Batches of Medical Marijuana combined into a single Test Batch must be cultivated using the same Pesticide and other agricultural chemicals. If an Optional Premises Cultivation Operation applies a Pesticide or other agriculture chemicals to only a specific set of plants, then Samples from those plants must be placed within a separate Test Batch.

3. Medical Marijuana Concentrate. All Production Batches of Medical Marijuana Concentrate combined into a single Test Batch must be of the same category and produced using the same extraction methods and combination of solvents.
  4. Medical Marijuana-Infused Product. All Production Batches of Medical Marijuana-Infused Product combined into a single Test Batch must be of the exact same product type and made using the same ingredients.
- D. Failed Contaminant Testing. If a Test Batch fails a contaminant test, then each Harvest Batch or Production Batch that was combined into that Test Batch shall be considered to have failed contaminant testing. See Rule R 1507.
- E. Violation Affecting Public Safety. Failure to comply with this rule may constitute a license violation affecting public safety.

### **Basis and Purpose – M 1506**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2.5)(a)(I), 12-43.3-402(6), and 12-43.3-404(10), C.R.S. The purpose of this rule is to protect the public health and safety by establishing rules requiring Medical Marijuana Business's to cover certain costs associated with the Division's Medical Marijuana sampling and testing program.

### **M 1506 – Medical Marijuana Testing Program – Costs**

**Rule M 1506 shall be effective beginning July 1, 2016.**

Costs. The cost for all sampling and tests conducted pursuant to these rules shall be the financial responsibility of the Medical Marijuana Business that is required to submit the Sample for testing.

### **Basis and Purpose – M 1507**

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)(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), 12-43.3-402(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 rules governing the quarantining of potentially contaminated product and the destruction of product that failed contaminant or potency testing for the Division's Medical Marijuana sampling and testing program.

### **M 1507 – Medical Marijuana Testing Program – Contaminated Product and Failed Test Results**

- A. Quarantining of Product.
1. If the Division has reasonable grounds to believe that a particular Harvest Batch, Production Batch, package or quantity of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product is contaminated or presents a risk to public safety, then the Division may require a Medical Marijuana Business to quarantine it until the completion of the Division's investigation, which may include the receipt of any test results.
  2. If a Medical Marijuana Business is notified by the Division or a Medical Marijuana Testing Facility that a Test Batch failed a contaminant or potency test, then the Medical Marijuana Business shall quarantine any Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product from any package, Harvest Batch or Production Batch combined into that Test Batch and must follow the procedures established pursuant to paragraphs B and/or C of this rule.

3. Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product that has been quarantined pursuant to this rule must be physically separated from all other inventory and may not be sold, wholesaled, transferred or processed into a Medical Marijuana Concentrate or Medical Marijuana-Infused Product.
- B. Failed Contaminant Testing: All Contaminant Testing Except Microbial Testing of Medical Marijuana Flower or Trim. If a Medical Marijuana Business is notified by the Division or a Medical Marijuana Testing Facility that a Test Batch failed contaminant testing, then for each package, Harvest Batch or Production Batch combined into that Test Batch the Medical Marijuana Business must either:
1. Destroy and document the destruction of the package, Harvest Batch or Production Batch that it possesses, See Rule M 307 – Waste Disposal; or
  2. Decontaminate the portion of the package, Harvest Batch or Production Batch that it possesses, if possible, and create two new Test Batches, each containing the requisite number of Samples, and have those Test Batches tested for the identified contaminant by the same or different Medical Marijuana Testing Facility.
    - a. If both new Test Batches pass the required contaminant testing, then any Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product from any package, Harvest Batch or Production Batch included in that Test Batch may be sold, wholesaled, transferred or processed into a Medical Marijuana Concentrate or Medical Marijuana-Infused Product.
    - b. If one or both of the Test Batches do not pass contaminant testing, then the Medical Marijuana Business must destroy and document the destruction of the entire portion of the package, Harvest Batch or Production Batch included in that Test Batch that it possesses. See Rule M 307 – Waste Disposal.
- B.1. Failed Contaminant Testing: Microbial Testing of Medical Marijuana Flower or Trim. If an Optional Premises Cultivation Operation is notified by the Division or a Medical Marijuana Testing Facility that a Test Batch of Medical Marijuana flower or trim failed microbial testing, then for each package or Harvest Batch combined into that Test Batch the Medical Marijuana Business must either:
1. Destroy and document the destruction of the package or Harvest Batch, See Rule M 307 – Waste Disposal; or
  2. The Optional Premises Cultivation Operation may transfer all packages or Harvest Batches associated with the failed Test Batch to a Medical Marijuana-Infused Products Manufacturer for processing the particular Medical Marijuana into a Solvent-Based Medical Marijuana Concentrate.
    - a. The Solvent-Based Medical Marijuana Concentrate shall be manufactured entirely from the Medical Marijuana flower or trim that failed microbial testing. No other Medical Marijuana shall be included in the Solvent-Based Medical Marijuana Concentrate manufactured pursuant to subparagraph (B.1)(2) of this rule R 1507.

- b. The Solvent-Based Medical Marijuana Concentrate that was manufactured out of the Medical Marijuana flower or trim that failed microbial testing shall undergo all required testing for contaminants pursuant to rule M 1501 – Medical Marijuana Testing Program – Contaminant Testing, for potency pursuant to rule M 1503 – Medical Marijuana Testing Program – Potency Testing, and any other testing required or allowed by the Medical Marijuana Rules or Medical Marijuana Code.
    - c. If the Solvent-Based Medical Marijuana Concentrate that was manufactured out of the Medical Marijuana flower or trim that failed microbial testing fails contaminant testing, the Optional Premises Cultivation Operation shall destroy and document the destruction of the entire portion of the Production Batch(es) associated with the Solvent-Based Medical Marijuana Concentrate that failed contaminant testing, See Rule M 307 – Waste Disposal.
- C. Failed Potency Testing. If a Medical Marijuana Business is notified by the Division or a Medical Marijuana Testing Facility that a Test Batch of Medical Marijuana-Infused Product failed potency testing, then for the package or Production Batch from which that Test Batch was produced the Medical Marijuana Business must either:
  - 1. Destroy and document the destruction of the entire portion of the package or Production Batch that it possesses, See Rule M 307 – Waste Disposal; or
  - 2. Attempt corrective measures, if possible, and create two new Test Batches and have those Test Batches tested for potency by the same or different Medical Marijuana Testing Facility.
    - a. If both new Test Batches pass potency testing, then any Medical Marijuana-Infused Product from the Production Batch included in the Test Batch may be sold, wholesaled or transferred.
    - b. If one or both of the Test Batches fail potency testing, then the Medical Marijuana-Infused Products Manufacturer must destroy and document the destruction of the entire portion of the package or Production Batch that it possesses. See Rule M 307 – Waste Disposal.
- D. Violation Affecting Public Safety. 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)(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 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, Liens, and Secured Interests 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. A Medical Marijuana Transporter shall not place or hold a lien or secured interest on 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 7 days from receiving it at its Licensed Premises or off-premises storage facility. The total allowable 7 day storage duration begins and applies regardless of which of the Medical Marijuana Transporter's premises receives the Medical Marijuana or Medical Marijuana-Infused Product first, ie. the Medical Marijuana Transporter's Licensed Premises, or any of its off-premises storage facilities.

- 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 Licensed Premises or in transport vehicles.
- H. A Medical Marijuana Transporter shall receive Medical Marijuana and Medical Marijuana-Infused Product from the originating Licensee packaged in the way that it is intended to be delivered to the final destination Licensee. The Medical Marijuana Transporter shall deliver the Medical Marijuana and Medical Marijuana-Infused Product in the same, unaltered packaging to the final destination Licensee.
- I. Opening of Sealed Packages or Containers and Re-Packaging Prohibited. A Medical Marijuana Transporter shall not open sealed packages or Containers of Medical Marijuana or Medical Marijuana-Infused Product. Medical Marijuana Transporters are prohibited from re-packaging Medical Marijuana or Medical Marijuana-Infused Product.
- J. Temperature-Controlled Transport Vehicles. A Medical Marijuana Transporter shall utilize temperature-controlled transport vehicles when necessary to prevent spoilage of the transported Medical Marijuana and Medical Marijuana-Infused Product.
- K. Damaged or Refused Product. Any damaged Medical Marijuana or Medical Marijuana-Infused Product that is undeliverable to the final destination Medical Marijuana Business, or any Medical Marijuana or Medical Marijuana-Infused Product that is refused by the final destination Medical Marijuana Business shall be transported back to the originating Medical Marijuana Business.

**Basis and Purpose – M 1603**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(l), 12-43.3-202(1)(h), 12-43.3-202(2)(a)(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 Transporter must have the ability to reconcile its transported 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.
1. 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.
  4. All information on the Inventory Tracking System generated transport manifests must be accurate.

### **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)(XII), 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., and section 12-43.3-406, 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 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:
1. That any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with Medical Marijuana 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;
  2. That hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Hand-washing facilities shall be located in the Licensed Premises and where good sanitary practices require employees to wash 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 Medical Marijuana or Medical Marijuana-Infused Product shall conform to hygienic practices while on duty, including but not limited to:
    - a. Maintaining adequate personal cleanliness;
    - b. Washing hands thoroughly in an adequate hand-washing area(s) before starting work and at any other time when the hands may have become soiled or contaminated; and
    - c. 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, 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.
2. 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.

### **M 1700 Series – Medical Marijuana Business Operators**

#### **Basis and Purpose – M 1701**

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

#### **M 1701 – Medical Marijuana Business Operator: Registration Privileges**

- A. Privileges Granted. A Medical Marijuana Business Operator shall only exercise those privileges granted to it by the Medical Code, the rules promulgated pursuant thereto and the State Licensing Authority. A Medical Marijuana Business Operator may exercise those privileges only on behalf of the Medical Marijuana Business(es) it operates. A Medical Marijuana Business shall not contract to have more than one Medical Marijuana Business Operator providing services to the Medical Marijuana Business at any given time.
- B. Licensed Premises of the Medical Marijuana Business(es) Operated. A separate registration is required for each specific Medical Marijuana Business Operator, and each such registered Medical Marijuana Business Operator may operate one or more other Medical Marijuana Business(es). A Medical Marijuana Business Operator shall not have its own Licensed Premises, but shall maintain its own place of business, and may exercise the privileges of a Medical Marijuana Business Operator at the Licensed Premises of the Medical Marijuana Business(es) it operates.

- C. Entities Eligible to Hold Medical Marijuana Business Operator Registration. A Medical Marijuana Business Operator registration may be held only by a business entity, including, but not limited to, a corporation, limited liability company, partnership or sole proprietorship.
- D. Separate Place of Business. A Medical Marijuana Business Operator shall designate and maintain a place of business separate from the Licensed Premises of any Medical Marijuana Business(es) it operates. A Medical Marijuana Business Operator's separate place of business shall not be considered a Licensed Premises, and shall not be subject to the requirements applicable to the Licensed Premises of other Medical Marijuana Businesses, except as set forth in Rules M 1702 and 1704. Possession, storage, use, cultivation, manufacture, sale, distribution, or testing of Medical Marijuana or Medical Marijuana-Infused Product is prohibited at a Medical Marijuana Business Operator's separate place of business.
- E. Agency Relationship and Discipline for Violations. A Medical Marijuana Business Operator and each of its Direct Beneficial Interest Owners required to hold an Associated Key License, as well as the agents and employees of the Medical Marijuana Business Operator, shall be agents of the Medical Marijuana Business(es) the Medical Marijuana Business Operator is contracted to operate, when engaged in activities related, directly or indirectly, to the operation of such Medical Marijuana Business(es), including for purposes of taking administrative action against the Medical Marijuana Business being operated. See § 12-43.4-601(1), C.R.S. Similarly, a Medical Marijuana Business Operator and its Direct Beneficial Interest Owners required to hold an Associated Key License, as well as the officers, agents and employees of the Medical Marijuana Business Operator, may be disciplined for violations committed by the Direct Beneficial Interest Owners, agents or employees of the Medical Marijuana Business acting under their direction or control. A Medical Marijuana Business Operator may also be disciplined for violations not directly related to a Medical Marijuana Business it is operating.
- F. Compliance with Applicable State and Local Law, Ordinances, Rules and Regulations. A Medical Marijuana Business Operator, and each of its Direct Beneficial Interest Owners, agents and employees engaged, directly or indirectly, in the operation of the Medical Marijuana Business(es) it operates, shall comply with all state and local laws, ordinances, rules and regulations applicable to the Medical Marijuana Business(es) being operated.

### **Basis and Purpose – M 1702**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(a), 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX) and 12-43.3-401(d), C.R.S. The purpose of this rule is to clarify those acts that are limited in some fashion, or prohibited, by a Medical Marijuana Business Operator.

### **M 1702 – Medical Marijuana Business Operators: General Limitations or Prohibited Acts**

- A. Prohibited Financial Interest. A Person who is a Direct Beneficial Interest Owner or an Indirect Beneficial Interest Owner of a Medical Marijuana Business Operator shall not be a Direct Beneficial Interest Owner or Indirect Beneficial Interest Owner of, or otherwise have a direct or indirect financial interest in, a Medical Marijuana Business operated by the Medical Marijuana Business Operator. Except that such Person shall have the right to compensation for services provided in accordance with these rules.
- B. Sale of Marijuana Prohibited. A Medical Marijuana Business Operator is prohibited from selling, distributing, or transferring Medical Marijuana or Medical Marijuana-Infused Product to another Medical Marijuana Business or a consumer, except when acting as an agent of a Medical Marijuana Business(es) operated by the Medical Marijuana Business Operator.

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- C. Consumption Prohibited. A Medical Marijuana Business Operator, and its Direct Beneficial Interest Owners, agents and employees, shall not permit the consumption of marijuana or marijuana products at its separate place of business.
- D. Inventory Tracking System. A Medical Marijuana Business Operator, and any of its Direct Beneficial Interest Owners, agents or employees engaged in the operation of the Medical Marijuana Business(es) it operates, must use the Inventory Tracking System account of the Medical Marijuana Business(es) it operates, in accordance with all requirements, limitations and prohibitions applicable to the Medical Marijuana Business(es) it operates.
- E. Compliance with Requirements and Limitations Applicable to the Medical Marijuana Business(es) Operated. In operating any other Medical Marijuana Business(es), a Medical Marijuana Business Operator, and its Direct Beneficial Interest Owners, agents and employees, shall comply with all requirements, limitations and prohibitions applicable to the type(s) of Medical Marijuana Business(es) being operated, under state and local laws, ordinances, rules and regulations, and may be disciplined for violation of the same.
- F. Inventory Tracking System Access. A Medical Marijuana Business may grant access to its Inventory Tracking System account to the Direct Beneficial Interest Owners who are required to hold Associated Key Licenses, as well as the licensed agents and employees of a Medical Marijuana Business Operator having duties related to Inventory Tracking System activities of the Medical Marijuana Business(s) being operated.
1. The Direct Beneficial Interest Owners, agents and employees of a Medical Marijuana Business Operator granted access to a Medical Marijuana Business's Inventory Tracking System account, shall comply with all Inventory Tracking System rules.
  2. At least one Direct Beneficial Interest Owner of a Medical Marijuana Business being operated by a Medical Marijuana Business Operator must be an Inventory Tracking System Trained Administrator for the Medical Marijuana Business's Inventory Tracking System account. That Inventory Tracking System Trained Administrator shall control access to its Inventory Tracking System account, and shall promptly terminate the access of the Medical Marijuana Business Operator's Direct Beneficial Interest Owners, agents and employees:
    - a. When its contract with the Medical Marijuana Business Operator expires by its terms;
    - b. When its contract with the Medical Marijuana Business Operator is terminated by any party; or
    - c. When it is notified that the registration of the Medical Marijuana Business Operator, or a specific Direct Beneficial Interest Owner, agent or employee of the Medical Marijuana Business Operator, has expired, or has been suspended or revoked.

- G. Limitations on Use of Documents and Information Obtained from Medical Marijuana Businesses. A Medical Marijuana Business Operator, and its agents and employees, shall maintain the confidentiality of documents and information obtained from the other Medical Marijuana Business(es) it operates, and shall not use or disseminate documents or information obtained from a Medical Marijuana Business it operates for any purpose not authorized by the Medical Code and the rules promulgated pursuant thereto, and shall not engage in data mining or other use of the information obtained from a Medical Marijuana Business to promote the interests of the Medical Marijuana Business Operator or its Direct Beneficial Interest Owners, Indirect Beneficial Interest Owners, agents or employees, or any Person other than the Medical Marijuana Business it operates.
- H. Form and Structure of Allowable Agreement(s) Between Operators and Owners. Any agreement between a Medical Marijuana Business and a Medical Marijuana Business Operator:
1. Must acknowledge that the Medical Marijuana Business Operator, and its Direct Beneficial Interest Owners, agents and employees who are engaged, directly or indirectly, in operating the Medical Marijuana Business, are agents of the Medical Marijuana Business being operated, and must not disclaim an agency relationship;
  2. May provide for the Medical Marijuana Business Operator to receive direct remuneration from the Medical Marijuana Business, including a portion of the profits of the Medical Marijuana Business being operated, subject to the following limitations:
    - a. The portion of the profits to be paid to the Medical Marijuana Business Operator shall be commercially reasonable, and in any event shall not exceed the portion of the net profits to be retained by the Medical Marijuana Business being operated;
    - b. The Medical Marijuana Business Operator, and any Person associated with the Medical Marijuana Business Operator, shall not be granted, and may not accept:
      - i. a security interest in the Medical Marijuana Business being operated, or in any assets of the Medical Marijuana Business;
      - ii. an ownership or membership interest, shares, or shares of stock, or any right to obtain any direct or indirect beneficial ownership interest in the Medical Marijuana Business being operated, or a future or contingent right to the same, including but not limited to options or warrants;
    - c. The Medical Marijuana Business Operator, and any person associated with the Medical Marijuana Business Operator, shall not guarantee the Medical Marijuana Business's debts or production levels.
  3. Shall permit the Medical Marijuana Business being operated to terminate the contract with the Medical Marijuana Business Operator at any time, with or without cause;
  4. Shall be contingent on approval by the Division; and
  5. Shall not be materially amended without advance written approval from the Division.

- I. A Medical Marijuana Business Operator may engage in dual operation of a Medical Marijuana Business and a Retail Marijuana Establishment at a single location, to the extent the Medical Marijuana Business being operated is permitted to do so pursuant to subsection 12-43.4-401(2)(a), C.R.S., and the Medical Marijuana Business Operator shall comply with the rules promulgated pursuant to the Medical Code and the Retail Code, including the requirement of obtaining a valid license as a Retail Marijuana Establishment Operator.

### **Basis and Purpose – M 1703**

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

### **M 1703 – Medical Marijuana Business Operators: Occupational Licenses for Personnel**

- A. Occupational Licenses Required. All natural persons who are Direct Beneficial Interest Owners, and all natural persons who are agents and employees, of a Medical Marijuana Business Operator that are actively engaged, directly or indirectly, in the operation of one or more other Medical Marijuana Business(es), including but not limited to all such persons who will come into contact with Medical Marijuana or Medical Marijuana-Infused Product, who will have to access Limited Access Areas, or who will have access to the Inventory Tracking System account of the Medical Marijuana Business(es) being operated as part of their duties, must have a valid Occupational License.
  1. Associated Key Licenses. All natural persons who are Direct Beneficial Interest Owners in a Medical Marijuana Business Operator must have a valid Associated Key License, associated with the Medical Marijuana Business Operator registration. Such an Associated Key License shall satisfy all licensing requirements for work related to the business of the Medical Marijuana Business Operator and for work performed on behalf of, or at the Licensed Premises of, the Medical Marijuana Business(es) operated by the Medical Marijuana Business Operator.
  2. Key Licenses. All other natural persons who are agents or employees of a Medical Marijuana Business Operator that are actively engaged, directly or indirectly, in the operation of other Medical Marijuana Businesses, must hold a Key License. The Key License shall satisfy all licensing requirements for work related to the business of the Medical Marijuana Business Operator and for work at the Licensed Premises of, or on behalf of, the Medical Marijuana Business(es) operated by the Medical Marijuana Business Operator.
- B. Occupational Licenses Not Required. Occupational Licenses are not required for Indirect Beneficial Interest Owners of a Medical Marijuana Business Operator, Qualified Limited Passive Investors who are Direct Beneficial Interest Owners of a Medical Marijuana Business Operator, or for natural persons who will not come into contact with Medical Marijuana or Medical Marijuana-Infused Product, will not have access to Limited Access Area(s) of the Medical Marijuana Business(es) being operated, and will not have access to the Inventory Tracking System account of the Medical Marijuana Business(es) being operated.

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

### **Basis and Purpose – M 1704**

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

### **M 1704 – Medical Marijuana Business Operators: Business Records Required**

- A. General Requirement. A Medical Marijuana Business Operator must maintain all required business records as set forth in Rule R 901 - Business Records Required, except that:
1. A Medical Marijuana Business Operator is not required to maintain secure facility information, diagrams of its designated place of business, or a visitor log for its separate place of business, because a Medical Marijuana Business Operator will not come into contact with Medical Marijuana or Medical Marijuana-Infused Product at its separate place of business; and
  2. A Medical Marijuana Business Operator is not required to maintain records related to inventory tracking, or transport, because a Medical Marijuana Business Operator is prohibited from engaging in activities on its own behalf that would require inventory tracking or transport. All records relating to inventory tracking activities and records related to transport pertaining to the Medical Marijuana Business(es) operated by the Medical Marijuana Business Operator shall be maintained at the Licensed Premises of such Medical Marijuana Business(es).
- B. All records required to be maintained shall be maintained at the Medical Marijuana Business Operator's separate place of business, and not at the Licensed Premises of the Medical Marijuana Business(es) it operates.

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### **Editor's Notes**

#### **History**

Entire rule emer. rule eff. 08/19/2010; expired 12/17/2010.

Entire rule eff. 12/30/2010.

Entire rule eff. 07/01/2011.

Entire rule eff. 10/15/2013.

Rules M 103, M 307, M 407, M 504, M 506, M 604-M 605 eff. 03/02/2014.

Rules M 207-M 210, M 235-M 236 emer. rules eff. 07/01/2014; expired 10/28/2014. Rule M 234 emer. rule repealed eff. 07/01/2014; expired 10/28/2014.

Rules M 103, M 402-M 403, M 1001, M 1003 emer. rules eff. 08/01/2014.

Rules M 207-M 210, M 235-M 236 emer. rules eff. 10/28/2014; Rule M 234 emer. rule repealed eff. 10/28/2014.

Rules M 103, M 207-M 210, M 235-M 236, M 402-M 403, M 408, M 605, M 1001, M 1003, M 1204 eff. 10/30/2014; Rule M 234 rule repealed eff. 10/30/2014.

Rules M 103-M 104, M 106, M 201-M 206, M 210-M 211, M 231-M 231.5, M 233, M 235-M 236, M 301-M 302, M 304, M 307-M 309, M 401, M 403, M 501, M 505, M 601, M 604-M 605, M 700-M 712, M 801-M 802, M 901, M 904, M 1001-M 1007, M 1201-M 1203, M 1301-M 1304, M 1308-M 1309, M 1500-M 1507 eff. 11/30/2015.

Rules M 207-M 210 emer. rules eff. 11/30/2015.

Rules M 207-M 210 emer. rules eff. 03/24/2016.

Rules M 207-M 210, M 231.5, M 235, M 236 eff. 07/01/2016.

Rules M 201, M 207-M 210, M 235, M 236 emer. rules eff. 12/22/2016.

Rules M 100-M 1100, M 1300, M 1500-M 1700 eff. 01/01/2017.

Rules M 106, M 201, M 207-M 210, M 235, M 236 eff. 04/14/2017.

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