STATE OF COLORADO

DEPARTMENT OF REVENUE
State Capitol Annex
1375 Sherman Street, Room 409
Denver, Colorado 80261
Phone (303) 866-5610
Fax (303) 866-2400

John W. Hickenlooper
Governor

Michael S. Hartman
Executive Director

Colorado Department of Revenue
Marijuana Enforcement Division

Emergency Rules

Revised Rules, Medical Marijuana, 1 CCR 212-1

Rule M 103 – Definitions

Rule M 201 – Application Process

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

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

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

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

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

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

Rule M 1307 - Penalties

Rule M 1702 – Medical Marijuana Business Operators: General Limitation or Prohibited Acts

Rule M 1901 – Licensed Research Businesses: License Privileges

Rule M 1902 – Licensed Research Businesses: General Limitations or Prohibited Acts

Rule M 1903 – Licensed Research Businesses: Inventory Tracking

Rule M 1905 – Licensed Research Businesses: Authorized Research Activities

New Rules, Medical Marijuana, 1 CCR 212-1

Rule M 253 – Temporary Appointee Registrations for Court Appointees

Revised Rules, Retail Marijuana, 1 CCR 212-2

Rule R 103 – Definitions

Rule R 201 – Application Process

Rule R 210 – Schedule of Other Application Fees: All Licenses

Rule R 304.1 – Medical Marijuana Business and Retail Marijuana Establishment- Shared Licensed Premises and Operational Separation

Rule R 501 – Retail Marijuana Cultivation Facility: License Privileges

Rule R 503 – Retail Marijuana Cultivation Facility: Inventory Tracking System

Rule R 505 – Retail Marijuana Cultivation Facilities: Retail Marijuana Concentrate Production

Rule R 601 – Retail Marijuana Products Manufacturing Facilities: License Privileges

Rule R 1307 - Penalties

Rule R 1702 – Retail Marijuana Business Operators: General Limitations or Prohibited Acts

New Rules, Retail Marijuana, 1 CCR 212-2

Rule R 253 – Temporary Appointee Registrations for Court Appointees

Statement of Emergency Justification and Adoption

Pursuant to sections 24-4-103, 12-43.3-202, and 12-43.4-202, C.R.S, I, Michael S. Hartman, Executive Director of the Department of Revenue and State Licensing Authority, hereby adopt the aforementioned revised Medical Marijuana and Retail Marijuana Rules, which are attached hereto.

Section 24-4-103(6), C.R.S., authorizes the State Licensing Authority to issue an emergency rule if the State Licensing Authority finds that the immediate adoption of the rule is imperatively necessary to comply with a state law or for the preservation of public health, safety, or welfare and compliance with the requirements of section 24-4-103, C.R.S., would be contrary to the public interest.

I find: (1) the immediate adoption of these revised rules is necessary to comply with the statutory mandates of the Medical Marijuana Code, sections 12-43.3-101 to -1102, C.R.S., and Retail Marijuana Code, sections 12-43.4-101 to -1101, C.R.S.; (2) the immediate adoption of these revised rules is necessary to preserve the public health, safety, and welfare; and (3) compliance with the notice and public hearing requirements of section 24-4-103, C.R.S., would be contrary to the public interest.

Statutory Authority

The statutory authority for the attached revised and new Medical Marijuana Rules is identified in the statement of basis and purpose preceding each rule, and includes subsections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(a), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(X), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-202(2)(a)(XXII), 12-43.3-202(2)(a)(XXIII), 12-43.3-401(1.5), 12-43.3-403(4), and 12-43.3-404(2), C.R.S., and sections 12-43.3-104, 12-43.3-201, 12-43.3-310, 12-43.3-311, 12-43.3-501, and 12-43.3-502, C.R.S.

The statutory authority for the attached revised and new Retail Marijuana Rules is identified in the statement of basis and purpose preceding each rule, and includes subsections 12-43.4-202(2)(a), 12-43.4-202(2)(e), 12-43.4-202(3)(a)(II), 12-43.4-202(3)(a)(XIX), 12-43.4-202(3)(a)(XX), 12-43.4-

202(3)(a)(XXI), 12-43.4-202(3)(b)(VIII), 12-43.4-202(3)(b)(IX); 12-43.4-304(1), 12-43.4-401(1.5), 12-43.4-403(7), 12-43.4-404(1)(b), and 12-43.4-404(2), C.R.S., and sections 12-43.4-103, 12-43.4-104, 12-43.4-201, 12-43.4-309, 12-43.4-310, 12-43.3-501, and 12-43.3-502, C.R.S.; and Colorado Constitution Article XVIII, Subsection 16(5)(a)(II).

Purpose

The purposes of the revisions and/or additions to the aforementioned Medical Marijuana Rules, 1 CCR 212-1, and Retail Marijuana Rules, 1 CCR 212-2, are to establish requirements and procedures to implement the following legislation, all of which became effective immediately upon the Governor's signature pursuant to a safety clause:

House Bill 18-1280

House Bill 1280 requires persons appointed by a court to take possession of, operate, manage, or control a Medical Marijuana Business or Retail Marijuana Establishment to notify the State Licensing Authority and apply for a finding of suitability. Further, it requires the State Licensing Authority, upon notification of such court appointments, to issue a temporary registration to the court appointee. The amended M and R 100, 200, and 1700 Series Rules establish definitions, fees, procedures, and temporary registration requirements for persons authorized by court order to take possession of, operate, manage, or control a Medical Marijuana Business or Retail Marijuana Establishment.

House Bill 18-1389

House Bill 1389 establishes a centralized distribution permit to be issued to Medical Marijuana Optional Premises Cultivation Operations ("Medical Cultivation") and Retail Marijuana Cultivation Facilities ("Retail Cultivation"), authorizing temporary storage of medical and retail marijuana, concentrate, and product, for the purpose of transfer to the permit holder's commonly-owned Medical Marijuana Centers and Retail Marijuana Stores. The amended M and R 100 and 500 Series Rules establish definitions, fees, requirements, and procedures for Medical Cultivations and Retail Cultivations applying for and issued a Centralized Distribution Permit.

Senate Bill 18-271

Senate Bill 271 authorizes Marijuana Research and Development Facility and Marijuana Research and Development Cultivation ("Licensed Research Businesses") to share licensed premises with a Medical Marijuana-Infused Products Manufacturer and Retail Marijuana Products Manufacturing Facility. Under prior law, such co-location was restricted, as medical and retail marijuana products could only be prepared on a licensed premises used exclusively for the manufacture and preparation of medical and retail products and using equipment exclusively for the manufacture and preparation of such products. As a result, research activities of a Licensed Research Business could not occur at the same premises of a medical or retail manufacturing licensee, and the rules had not to date set forth the process for a Licensed Research Business to share a licensed premises with other types of Medical Marijuana Businesses and Retail Marijuana Establishments. The amended M and R 100 200, 300, 600, and 1300 Series Rules, and amended M 1900 Series Rules, establish fees, requirements, and procedures for Licensed Research Businesses sharing a licensed premises with another Medical Marijuana Business or a Retail Marijuana Establishment.

Further, Senate Bill 271 authorizes the State Licensing Authority to establish requirements for transfer of marijuana by Licensed Research Businesses. The amended M 1900 Series Rules permit the transfer of Immature Plants to other Medical Marijuana Businesses, so long as the plants have not been exposed to prohibited chemicals.

Effective Date of Emergency Rules and Permanent Rulemaking

Following the adoption of these emergency rules, the State Licensing Authority will file a permanent rulemaking notice. Permanent rulemaking proceedings will include the opportunity for substantial stakeholder and public participation

The attached emergency rules are effectively immediately upon adoption. Medical Rule M 253 and Retail Rule R 253 are hereby adopted, and the prior versions of Medical Rules M 103, 201, 210, 304.1, 501, 503, 601, 1307, 1702, 1901, 1902, 1903, and 1905 1 CCR 212-1, and Retail Rules R 103, 201, 210, 304.1, 501, 503, 601, 1307, and 1702, 1 CCR 212-2, are hereby amended by the emergency rules attached hereto. The attached emergency rules remain in effect until their expiration date, 120 from the date of adoption, or until replaced by rules promulgated pursuant to the permanent rulemaking process.

Michael S. Hartman
Executive Director
Colorado Department of Revenue
State Licensing Authority

6/18/18
Date

COLORADO
Department of Revenue
Enforcement Division - Marijuana

June 18, 2018

Emergency Medical Marijuana Rules, 1 CCR 212-1

M 100 Series – General Applicability

Basis and Purpose – M 103

The statutory authority for this rule includes but is not limited to sections 12-43.3-104, 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a), 12-43.3-202(2)(a)(XX), C.R.S. , 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, an indirect financial interest, a lease agreement, secured or unsecured loan, or security interest in fixtures or equipment with a direct nexus to the cultivation, manufacture, Transfer, transportation, or testing of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product. A Person who provides funding for a Research Project conducted by a Licensed Research Business is an Affiliated Interest for the Licensed Research Business, unless that Person is a Direct Beneficial Interest Owner or an Indirect Beneficial Interest Owner. 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, and any Person who controls or is positioned so as to enable the exercise of control over a Medical Marijuana Business. Each shareholder, officer, director, member, or

partner of a Closely Held Business Entity that is a Direct Beneficial Interest Owner and any Person who controls or is positioned as to enable the exercise of control over a Medical Marijuana Business 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.

"Centralized Distribution Permit" means a permit issued to an Optional Premises Cultivation Operation pursuant to section 12-43.3-403, C.R.S., authorizing temporary storage of Medical Marijuana Concentrate and Medical Marijuana-Infused Product received from a Medical Marijuana-Infused Products Manufacturer for the sole purpose of Transfer to commonly owned Medical Marijuana Centers. For purposes of a Centralized Distribution Permit only, the term "commonly owned" means at least one natural person has a minimum of five percent ownership in both the Optional Premises Cultivation Operation possessing the Centralized Distribution Permit and the Medical Marijuana Center.

"Child-Resistant" means special packaging that is:

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

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

c. Resealable for any product intended for more than a single use or containing multiple servings.

"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 intellectual property with a direct nexus to the cultivation, manufacture, Transfer, or testing of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product. A Commercially Reasonable Royalty must be limited to specific intellectual property the Commercially Reasonable Royalty Interest Holder owns or is otherwise authorized to license or to a product or line of products. A Commercially Reasonable Royalty will not be approved where it could cause reasonable consumer confusion or violate any federal copyright, trademark, or patent law or regulation. The Commercially Reasonable Royalty shall provide for compensation to the Commercially Reasonable Royalty Holder as a percentage of gross revenue or gross profit. The royalty payment must be at a reasonable percentage rate. To determine

whether the percentage rate is reasonable, the Division will consider the totality of the circumstances, including but not limited to the following factors:

a. The percentage of royalties received by the recipient for the licensing of the intellectual property.

b. The rates paid by the Licensee for the use of other intellectual property.

c. The nature and scope of the license, as exclusive or non-exclusive; or as restricted or non-restricted in terms of territory or with respect to whom the product may be sold.

d. The licensor's established policy and marketing program to maintain his intellectual property monopoly by not licensing others or by granting licenses under special conditions designed to preserve that monopoly.

e. The commercial relationship between the recipient and Licensee, such as, whether they are competitors in the same territory in the same line of business.

f. The effect of selling the intellectual property in promoting sales of other products of the Licensee; the existing value of the intellectual property to the recipient as a generator of sales of his non-intellectual property items; and the extent of such derivative sales.

g. The duration of the term of the license for use of the intellectual property.

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

i. The utility and advantages of the intellectual property over products or businesses without the intellectual property.

j. The nature of the intellectual property; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the intellectual property.

k. The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the intellectual property.

l. The portion of the realizable profit that should be credited to the intellectual property as distinguished from non-intellectual property elements, the manufacturing process, business risks, or significant features or improvements added by the Licensee.

"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 receptacle directly containing Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product that is labeled according to the requirements in Rules M 1001 *et. seq*. or Rules M 1001-1 *et seq*.

"Court Appointee" means a Person appointed by a court as a receiver, personal representative, executor, administrator, guardian, conservator, trustee, or similarly situated Person; acting in accordance with section 12-43.3-401(1.5), C.R.S., and these rules; and authorized by court order to take possession of, operate, manage, or control a Medical Marijuana Business.

"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 for which the intended use is oral consumption, 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 an Opaque bag or other similar Opaque covering provided at the point of sale, in which Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product already in a Container is placed. If Medical Marijuana flower, trim, or seeds are placed into a Container that is not Child-Resistant, then the Exit Package must be Child-Resistant.

"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, 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.

"Finished Marijuana" means post-harvest Medical Marijuana including flower and trim that has been harvested for more than 90 days or that has completed the curing and drying process according to the Optional Premises Cultivation Operation's written standard operating procedures that were last submitted to the Division. Standard operating procedures for curing and drying may provide a curing and drying period that is longer than 90 days but any such period must be commercially reasonable and shall not exceed 12 months. Among other factors, the Division may consider the Optional Premises Cultivation Operation's prior business years' business transactions to determine whether the Optional Premises Cultivation Operation's standard operating procedures are commercially reasonable.

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

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

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

"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.

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

"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 and accredited college or university.

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

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 patient at a Medical Marijuana Center, Transferred to a Medical Research Facility, Transferred to a Pesticide Manufacturer, destroyed by a Medical Marijuana Business or used in a Research Project by a Licensed Research Business.

"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 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 Usermust 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 central to the Medical Marijuana Business' operation. An individual holding a Key License has the highest level of responsibility. An example of a Key Licensee includes, but is not limited to, managers.

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

"Licensed Research Business" means a Marijuana Research and Development Facility or a Marijuana Research and Development Cultivation.

"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, Transferred, or processed for Transfer, 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.

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

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

"Marketing Layer" means that packaging in addition to the Container that is the outermost layer visible to the consumer at the point of sale. The Marketing Layer is optional, but if used by a Licensee in addition to the required Container, it must be labeled according to the requirements in Rules M 1001 *et. seq*. or Rules M 1001-1 *et. seq*.

"Marijuana Research and Development Cultivation" means a Person that is licensed pursuant to the Medical Code to grow, cultivate, and possess Medical Marijuana, and to Transfer Medical Marijuana to a Medical Research and Development Facility or another Medical Research and Development Cultivation, all for limited research purposes authorized pursuant to section 12-43.3-408, C.R.S. A Marijuana Research and Development Cultivation is a Licensed Research Business.

"Marijuana Research and Development Facility" means a Person that is licensed pursuant to the Medical Code to possess Medical Marijuana for limited research purposes authorized pursuant to section 12-43.3-408, C.R.S. A Marijuana Research and Development Facility is a Licensed Research Business.

"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. Unless the context otherwise requires, Medical Marijuana Concentrate is considered Medical Marijuana and is included in the term Medical Marijuana as used in these rules.

"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, a Medical Marijuana Transporter, a Marijuana Research and Development Facility, or a Marijuana Research and Development Cultivation.

"Medical Marijuana Business Operator" means an entity that holds a registration or license from the State Licensing Authority to provide professional operational services to one or more Medical Marijuana Businesses, other than Licensed Research Businesses, for direct remuneration from the Medical Marijuana Business(es), which may include compensation based upon a percentage of the profits of the Medical Marijuana Business(es) being operated. A Medical Marijuana Business Operator may contract with Medical Marijuana Business(es) to provide operational services. A Medical Marijuana Business Operator's contract with a Medical Marijuana Business does not in and of itself constitute ownership. The Medical Code and rules apply to all Medical Marijuana Business Operators regardless of whether such operator holds a registration or license. Any reference to "license" or "licensee" shall mean "registration" or "registrant" when applied to a Medical Marijuana Business Operator that holds a registration issued by the State Licensing Authority.

"Medical Marijuana 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, Solvent-Based Medical Marijuana Concentrate, and Heat/Pressure-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 testing and research on Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product.

"Medical Marijuana Transporter" means a Person that is licensed to transport Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product from one Medical Marijuana Business to another Medical Marijuana Business or to a Medical Research Facility or Pesticide Manufacturer, and to temporarily store the transported Medical Marijuana and Medical Marijuana-Infused Product at its licensed premises, but is not authorized to sell, give away, buy, or receive complimentary Medical Marijuana, Medical Marijuana Concentrate, or Medical

Marijuana-Infused Product under any circumstances. A Medical Marijuana Transporter does not include a Licensee that transports its own Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product.

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

"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 a Direct Beneficial Interest 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."

"Pesticide Manufacturer" means a Person who: (1) manufactures, prepares, compounds, propagates, or processes any Pesticide or device or active ingredient used in producing a Pesticide; (2) who possesses an establishment number with the U.S. Environmental Protection Agency pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136 *et. seq.*; (3) who conducts research to establish safe and effective protocols, including but not limited

to establishing efficacy and toxicity, for the use of Pesticides on Medical Marijuana; (4) who has applied for and received any necessary license, registration, certifications, or permits from the Colorado Department of Agriculture pursuant to the Pesticide Act, section 35-9-101 *et. seq*., C.R.S., and/or the Pesticide Applicators' Act, sections 35-10-101 *et seq*., C.R.S.; (5) who is authorized to conduct business in the State of Colorado; and (6) who has physical possession of the location in the State of Colorado where its research activities occur. A Pesticide Manufacturer is neither a Medical Marijuana Business, a Retail Marijuana Establishment, nor a Licensee.

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

"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.

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

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

"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.

"R&D Co-Location Permit" means a permit issued to a Licensed Research Business authorizing it to co-locate with a commonly owned Medical Marijuana-Infused Products Manufacturer, Retail Marijuana Products Manufacturing Facility, Medical Marijuana Optional Premises Cultivation Operation, and Retail Marijuana Cultivation Facility pursuant to Rule M 1901. A separate R&D Co-Location Permit is required for each location at which a Licensed Research Business seeks to share a single Licensed Premises.

"RFID" means Radio Frequency Identification.

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

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

"Research Project" means a discrete scientific endeavor to answer a research question or a set of research questions. A Research Project must include a description of a defined protocol, clearly articulated goal(s), defined methods and outputs, and a defined start and end date. The description must demonstrate that the Research Project will comply with all requirements in the M 1900 Series. All research and development conducted by a Licensed Research Business must be conducted in furtherance of an approved Research Project.

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

"Restricted Access Area" means a designated and secure area within a Licensed Premises in a Medical Marijuana Center where Medical Marijuana, Medical Marijuana Concentrate, 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 but not limited

to Retail Marijuana Concentrate that is cultivated, manufactured, distributed, or sold by a licensed Retail Marijuana Establishment. "Retail Marijuana" does not include industrial hemp, nor does it include fiber produced from stalks, oil, or cake made from the seeds of the plant, sterilized seed of the plant which is incapable of germination, or the weight of any other ingredient combined with marijuana to prepare topical or oral administrations, food, drink, or other product. Unless the context otherwise requires, Retail Marijuana Concentrate is considered Retail Marijuana and is included in the term "Retail Marijuana" as used in these rules.

"Retail Marijuana Concentrate" means a specific subset of Retail Marijuana that was produced by extracting Cannabinoids from Retail Marijuana. Categories of Retail Marijuana Concentrate include Water-Based Retail Marijuana Concentrate, Food-Based Retail Marijuana Concentrate, Solvent-Based Retail Marijuana Concentrate, and Heat/Pressure-Based Retail Marijuana Concentrate.

"Retail Marijuana Cultivation Facility" means an entity licensed to cultivate, prepare, and package Retail Marijuana and Transfer Retail Marijuana to Retail Marijuana Establishments, Medical Research Facilities, and Pesticide Manufacturers, 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 Establishment 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 Transfer Retail Marijuana and Retail Marijuana Product to other Retail Marijuana Products Manufacturing Facilities, Retail Marijuana Stores, Medical Research Facilities, and Pesticide Manufacturers, 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 Transfer 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 testing and research on Retail Marijuana, Retail Marijuana Concentrate, and Retail Marijuana Products.

"Retail Marijuana Transporter" means a Person that is licensed to transport Retail Marijuana, Retail Marijuana Concentrate, and Retail Marijuana Products from one Retail Marijuana Establishment to another Retail Marijuana Establishment or to a Medical Research Facility or Pesticide Manufacturer, and to temporarily store the transported Retail Marijuana, Retail Marijuana Concentrate, and Retail Marijuana Products at its Licensed Premises, but is not authorized to sell, give away, buy, or receive complimentary Retail Marijuana, Retail Marijuana

Concentrate, or Retail Marijuana Products under any circumstances. A Retail Marijuana Transporter does not include a Licensee that transports and distributes its own Retail Marijuana, Retail Marijuana Concentrate, or Retail Marijuana Products.

"Sample" means any item collected from a Medical Marijuana Business and provided to a Medical Marijuana Testing Facility for testing. 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. A Shipping Container is used solely for the transport of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product between Medical Marijuana Businesses, a Medical Research Facility, or a Pesticide Manufacturer.

"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 Transfer 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. A Support Licensee is a Person with less decision-making authority than a Key Licensee and who is reasonably supervised by a Key Licensee or an Associated Key Licensee. Examples of individuals who need this type of license include, but are not limited to, sales clerks or cooks.

"Temporary Appointee Registration" means a registration issued to a Court Appointee pursuant to section 12-43.3-401(1.5)(b), C.R.S.

"THC" means tetrahydrocannabinol.

"THCA" means tetrahydrocannabinolic acid.

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

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

"Transfer(s)(ed)(ing)" means to grant, convey, hand over, assign, sell, exchange, donate, or barter, in any manner or by any means, with or without consideration, any Medical Marijuana,

Medical Marijuana Concentrate, or Medical Marijuana-Infused Product from one Licensee to another Licensee or to a patient. A Transfer includes the movement of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product from one Licensed Premises to another, even if both premises are contiguous, and even if both premises are owned by a single entity or individual or group of individuals, and also includes a virtual Transfer that is reflected in the Inventory Tracking System, even if no physical movement of the Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product occurs.

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

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

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

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

M 200 Series – Licensing and Interests

Basis and Purpose – M 201

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

M 201 – Application Process

A. General Requirements

1. All applications for licenses or registrations authorized pursuant to subsections 12-43.3-401(1)~~(a)-(h)~~ and (1.5), 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 Rule M 207 – Schedule of Application Fees: Medical Marijuana Businesses; Rule M 208 – Schedule of Business License and Registration Fees: Medical Marijuana Businesses; Rule M 209 – Schedule of Business Renewal License and Registration Fees: Medical Marijuana Businesses; Rule M 210 – Schedule of Other Application Fees: All Licensees; Rule M 235 – Schedule of License Fees: Individuals; and Rule 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 organization 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; and

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 Establishment 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.

f. At a minimum, each Applicant for a Court Appointee finding of suitability required by Rule M 253(A)(2), shall provide, at the time of application, the following information:

i. A copy of the order appointing the Court Appointee;

ii. A statement affirming the Court Appointee complied with the certification required by section 12-43.3-401(1.5)(a), C.R.S.;

iii. If the Court Appointee is an entity, a complete list of all individuals responsible for taking possession of, operating, managing, or controlling the licensed Medical Marijuana Business; and

iv. A complete list of all Medical Marijuana Businesses and Retail Marijuana Establishments and the respective dates during which the Court Appointee is currently serving, or has previously served, as a receiver, personal representative, executor, administrator, guardian, conservator, trustee, or similarly situated Person.

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 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, of for any other state or local law enforcement purpose or as otherwise required by law.

E. Division Application Management and Local Licensure.

1. Repealed.

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.

Basis and Purpose – M 210

The statutory authority for this rule includes but is not limited to sections 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), 12-43.3-104, 12-43.3-310, 12-43.3-401, 12-43.3-501, 12-43.3-502, 12-43.3-1101, ~~and~~ 12-43.3-1102, and 12-43.3-202(2)(a)(XXII), 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

4. Change of Trade Name - $50.00

5. Change of Location Application Fee - $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

14. Licensed Research Business Research Project Proposal - $500.00

15. Temporary Appointee Registration finding of suitability

a. Individual - $225.00

b. Entity - $800.00

16. Centralized Distribution Permit - $20.00

17. R&D Co-Location Permit - $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 253

The statutory authority for this rule includes, but is not limited to, sections 12-43.3-202 and 12-43.3-401, C.R.S. The purpose of this rule is to establish procedures and requirements for any Person appointed by a court as a receiver, personal representative, executor, administrator, guardian, conservator, trustee, or similarly situated Person acting in accordance with section 12-43.3-401(1.5), C.R.S., and authorized by court order to take possession of, operate, manage, or control a Medical Marijuana Business.

M 253 – Temporary Appointee Registrations for Court Appointees

A. For Court Appointees appointed on or after May 15, 2018, the effective date of House Bill 18-1280:

1. Notice to the State and Local Licensing Authorities. Within seven days of accepting an appointment as a Court Appointee pursuant to section 12-43.3-401(1.5), C.R.S., (or within seven days of June 18, 2018, the effective date of this Rule M 253, whichever is later), such Court Appointee shall file a notice to the State Licensing Authority and the applicable local licensing authority on a form prescribed by the State Licensing Authority. The notice shall be accompanied by a copy of the order appointing the Court Appointee and a statement affirming that the Court Appointee complied with the certification required by section 12-43.3-401(1.5)(a), C.R.S. If the Court Appointee is an entity, the notice shall identify all individuals responsible for taking possession of, operating,

managing, or controlling the licensed Medical Marijuana Business. Each notice shall identify at least one such individual.

2. Application for Finding of Suitability. Within 14 days of accepting an appointment as a Court Appointee pursuant to section 12-43.3-401(1.5), C.R.S., (or within 14 days of June 18, 2018, the effective date of this Rule M 253, whichever is later), each Court Appointee shall file an application for a finding of suitability with the State Licensing Authority on forms prescribed by the State Licensing Authority. Each entity and individual for whom a notice was filed pursuant to Rule M 253(A) shall file an application for a finding of suitability. The Division may in its discretion rely upon a recent licensing background investigation for Court Appointees that currently hold a license or Temporary Appointee Registration issued by the State Licensing Authority, and may waive all or part of the application fee accordingly.

3. Effective date. The Temporary Appointee Registration shall issue following the State Licensing Authority's receipt of the notice required by Rule M 253(A)(1), and shall be deemed effective as of the date of the court appointment.

B. For Court Appointees appointed prior to May 15, 2018, the effective date of House Bill 18-1280:

1. Any receiver, personal representative, executor, administrator, guardian, conservator, trustee, or similarly situated Person authorized by court order to take possession of, operate, manage, or control a Medical Marijuana Business prior to May 15, 2018, the effective date of House Bill 18-1280, shall be deemed a Court Appointee.

2. Notice to the State and Local Licensing Authorities and Application for Finding of Suitability. Any such Court Appointee appointed by a court prior to May 15, 2018, shall, within 14 days of June 18, 2018, the effective date of this Rule M 253, file notice of the appointment with the State Licensing Authority and the applicable local licensing authority, and file an application for a finding of suitability with the State Licensing Authority, in accordance with Rule M 253(A)(2). The notice and application shall include a copy of the order appointing the Person, but need not include a statement affirming that the Person complied with the certification required by section 12-43.3-401(1.5)(a), C.R.S.

3. Effective date. The Temporary Appointee Registration for a Court Appointee appointed prior to May 15, 2018, the effective date of House Bill 18-1280, shall be deemed effective May 15, 2018.

C. Temporary Appointee Registration.

1. Entities. If the Court Appointee is an entity, such entity shall receive a Temporary Appointee Registration. Additionally, each such entity must identify all individuals responsible for taking possession of, operating, managing, or controlling the Medical Marijuana Business, and all such individuals shall also receive a Temporary Appointee Registration, which shall be treated as an Associated Key License except where contrary to the provisions of this Rule M 253 or section 12-43.3-401(1.5), C.R.S. Each Court Appointee that is an entity must identify at least one such individual.

2. Individuals. If the Court Appointee is an individual, such individual's Temporary Appointee Registration shall be treated as an Associated Key License except where contrary to the provisions of this Rule M 253 or section 12-43.3-401(1.5), C.R.S.

3. Other employees. Any other individual working under the direction of a Court Appointee who possesses, cultivates, manufactures, tests, dispenses, sells, serves, transports, researches, or delivers Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product as permitted by privileges granted under a Medical Marijuana

Business license must have a valid Occupational License of the type required for the duties that individual will perform. *See* Rules M 103 and 233.

4. Licensed Premises. A Court Appointee shall not establish an independent Licensed Premises, but shall be authorized to exercise the privileges of the Temporary Appointee Registration within the Licensed Premises of the Medical Marijuana Business for which it is appointed.

5. Medical Code and rules applicable. Court Appointees shall be subject to the terms of the Medical Code and the rules promulgated pursuant thereto. Except where inconsistent with section 12-43.3-401(1.5), C.R.S., or this Rule M 253, the State Licensing Authority may take any action with respect to a Temporary Appointee Registration that it could take with respect to any license issued under the Medical Code. In any action involving a Temporary Appointee Registration, these rules shall be read as including the terms "registered", "registration", "registrant" or any other similar terms in lieu of "licensed", "licensee", and any other similar terms as the context requires when applied to a Temporary Appointee Registration.

D. Disciplinary actions.

1. Suspension, revocation, or other disciplinary action regarding a Medical Marijuana Business. In addition to any other basis for suspension, revocation, or other disciplinary action, a Medical Marijuana Business's license may, pursuant to section 12-43.3-202(1)(a), 12-43.3-401(1.5)(b), and 12-43.3-601(1), C.R.S., be suspended, revoked, or subject to other disciplinary action based upon its Court Appointee's violations of the Medical Code, the rules promulgated pursuant thereto, the terms, conditions, or provisions of the Temporary Appointee Registration issued by the State Licensing Authority, or any order of the State Licensing Authority. Such disciplinary action may occur even after the Temporary Appointee Registration is expired or surrendered, if the action is based upon an act or omission that occurred while the Temporary Appointee Registration was active.

2. Suspension, revocation, or other disciplinary action regarding a Temporary Appointee Registration. In addition to any other basis for suspension, revocation, or other disciplinary action, a Temporary Appointee Registration may, pursuant to section 12-43.3-202(1)(a), 12-43.3-401(1.5)(b), and 12-43.3-601(1), C.R.S., be suspended, revoked, or subject to other disciplinary action based upon the Court Appointee's failure to obtain a finding of suitability or violations of the Medical Code, the rules promulgated pursuant thereto, the terms, conditions, or provisions of the Temporary Appointee Registration issued by the State Licensing Authority, or any order of the State Licensing Authority. Such disciplinary action may occur even after the Temporary Appointee Registration is expired or surrendered, if the action is based upon an act or omission that occurred while the Temporary Appointee Registration was active.

3. Suitability. If the State Licensing Authority denies an application for a finding of suitability because the Court Appointee failed to timely apply for a finding of suitability, failed to provide all information requested by the Division in connection with an application for a finding of suitability, or was found to be unsuitable, the State Licensing Authority may pursue disciplinary action as set forth in Rule M 253(D)(1)-(2) and (4).

4. Court Appointee's responsibility to notify the appointing court. The Court Appointee shall notify the appointing court of any action taken against the Temporary Appointee Registration by the State Licensing Authority pursuant to sections 12-43.3-601 or 24-4-104, C.R.S., within two business days. Such actions include, without limitation, the issuance of an Order to Show Cause, the issuance of an Administrative Hold, the issuance of an Order of Summary Suspension, the issuance of an Initial Decision by the

Department's Hearings Division, or the issuance of a Final Agency Order by the State Licensing Authority. The Court Appointee shall forward a copy of such notification to the Division at the same time the notification is made to the appointing court.

E. Expiration and renewal.

1. Conclusion of a Court Appointee's court appointment. A Court Appointee's Temporary Appointee Registration shall expire upon the conclusion of a Court Appointee's court appointment. Each Court Appointee and each Medical Marijuana Business that has a Court Appointee shall notify the State Licensing Authority within two business days of the date on which a Court Appointee's court appointment ends, whether due to termination of the appointment by the court, substitution of another Court Appointee, closure of the court case, or otherwise. For a Court Appointee that is appointed in connection with multiple court cases, the notice shall be filed with the State Licensing Authority with respect to each such case.

2. Annual renewal. If it has not yet expired pursuant to Rule M 253(E)(1), each Temporary Appointee Registration shall be valid for one year, after which it shall be subject to annual renewal in accordance with the Medical Code and rules promulgated pursuant thereto. If a Court Appointee is appointed in connection with multiple court cases, the Temporary Appointee Registration is subject to annual renewal unless all such appointments have ended, whether due to termination of the appointments by the courts, substitution of other Court Appointees, closure of the court cases, or otherwise.

3. Other termination. A Temporary Appointee Registration may be valid for less than the applicable term if surrendered, revoked, suspended, or subject to similar action.

F. Medical Marijuana Business Operators as Court Appointees. By virtue of its privileges of licensure, a Medical Marijuana Business Operator and its Associated Key Licensees may serve as Court Appointees without a Temporary Appointee Registration subject to the following terms:

1. Notice to the State Licensing Authority of appointment. The Medical Marijuana Business Operator and its Associated Key Licensees shall be responsible for notifying the State Licensing Authority within seven days of any court appointment to serve as a receiver, personal representative, executor, administrator, guardian, conservator, trustee, or similarly situated Person and take possession of, operate, manage, or control a Medical Marijuana Business. Such notice shall be accompanied by a copy of the order making the appointment, and shall identify each Medical Marijuana Business regarding which the Medical Marijuana Business Operator is appointed.

2. Notice to the court of State Licensing Authority action. The Medical Marijuana Business Operator and its Associated Key Licensee(s) shall be responsible for notifying the appointing court of any action taken against the Medical Marijuana Business Operator license or the Associated Key license by the State Licensing Authority pursuant to sections 12-43.3-601 or 24-4-104, C.R.S., within two business days. Such actions include, without limitation, the issuance of an Order to Show Cause, the issuance of an Administrative Hold, the issuance of an Order of Summary Suspension, the issuance of an Initial Decision by the Department's Hearings Division, or the issuance of a Final Agency Order by the State Licensing Authority. The Medical Marijuana Business Operator and its Associated Key Licensee(s) shall forward a copy of such notification to the Division at the same time the notification is made to the appointing court.

M 300 Series – The Licensed Premises

Basis and Purpose – M 304.1

The statutory authority for this Rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(X), 12-43.3-202(2.5)(a)(I)(A)-(F), 12-43.4-104(1)(a)(V), 12-43.4-202(b), 12-43.4-401(2), 12-43.4-404(2), 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 a Retail Marijuana Establishment operation.

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

A. Co-Located Medical Marijuana Centers and Retail Marijuana Stores.

1. Medical Marijuana Center that authorizes patients that are over the age of 21. A Medical Marijuana Center that authorizes only Medical Marijuana patients who are over the age of 21 years to be on the Licensed Premises may also hold a Retail Marijuana Store license and operate at the same location under the following circumstances:

   a. The relevant local licensing authority and local jurisdiction permit a dual operation at the same location;

   b. The Medical Marijuana Center and Retail Marijuana Store are commonly owned;

   c. The Medical Marijuana Center and Retail Marijuana Store shall maintain physical or virtual separation between (i) Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana-Infused Product, and other Medical Marijuana-related inventory and (ii) Retail Marijuana, Retail Marijuana Concentrate, Retail Marijuana Products, and other Retail Marijuana-related inventory;

   d. The Medical Marijuana Center and Retail Marijuana Store shall maintain separate displays between (i) Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana-Infused Product, and other Medical Marijuana-related inventory and (ii) Retail Marijuana, Retail Marijuana Concentrate, Retail Marijuana Products, and other Retail Marijuana-related inventory;

   e. Record-keeping, inventory tracking, packaging, and labeling for the Medical Marijuana Center and Retail Marijuana Store shall enable the Division and local licensing authority to clearly distinguish the inventories and business transactions of the Medical Marijuana Center from the inventories and business transactions of the Retail Marijuana Store; and

   f. The Medical Marijuana Center shall post and maintain signage the clearly conveys that persons under the age of 21 years may not enter.

2. Medical Marijuana Center that authorizes patients under the age of 21. A Medical Marijuana Center that authorizes Medical Marijuana Patients under the age of 21 years to be on the premises may operate in the same location with a Retail Marijuana Store under the following circumstances:

   a. The relevant local licensing authority and local jurisdiction permit a dual operation at the same location;

b. The Medical Marijuana Center and Retail Marijuana Store are commonly owned;

c. The Medical Marijuana Center and the Retail Marijuana Store maintain physical separation, including separate entrances and exits, between their respective Restricted Access Areas;

d. No point of sale operations occur at any time outside the physically separated Licensed Premises;

e. All Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product in a Restricted Access Area must be physically separated from all Retail Marijuana, Retail Marijuana Concentrate, and Retail Marijuana Product in a Restricted Access Area, and such physical separation must include separate entrances and exits;

f. Any display areas shall be located in the physically separated Restricted Access Areas;

g. In addition to the physically separated sales and display areas, the Medical Marijuana Center and Retail Marijuana Store shall maintain physical or virtual separation for storage of Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana-Infused Product and other Medical Marijuana-related inventory from storage of Retail Marijuana, Retail Marijuana Concentrate, Retail Marijuana Products and other Retail Marijuana-related inventory; and

h. Record-keeping, inventory tracking, packaging, and labeling for the Medical Marijuana Center and Retail Marijuana Store shall enable the Division and local licensing authority to clearly distinguish the inventories and business transactions of the Medical Marijuana Center from the inventories and business transactions of the Retail Marijuana Store.

B. Co-located Optional Premises Cultivation Operation and Retail Marijuana Cultivation Facility. An Optional Premises Cultivation Operation and a Retail Marijuana Cultivation Facility may share a single Licensed Premises and operate at the same location under the following circumstances:

1. The relevant local licensing authority and local jurisdiction permit a dual operation at the same location;

2. The Optional Premises Cultivation Operation and the Retail Marijuana Cultivation Facility are commonly owned;

3. The co-located Optional Premises Cultivation Operation and Retail Marijuana Cultivation Facility shall maintain either physical or virtual separation between (i) Medical Marijuana and Medical Marijuana Concentrate and (ii) and Retail Marijuana and Retail Marijuana Concentrate; and

4. Record keeping, inventory tracking, packaging and labeling for the Optional Premises Cultivation Operation and Retail Marijuana Cultivation Facility must enable the Division and relevant local licensing authority to clearly distinguish the inventories and business transactions of the Optional Premises Cultivation Operation from the Retail Marijuana Cultivation Facility.

C. Co-located Medical Marijuana-Infused Products Manufacturer and Retail Marijuana Products Manufacturing Facility. A Medical Marijuana-Infused Products Manufacturer and a Retail Marijuana Products Manufacturing Facility may share a single Licensed Premises and operate at the same location under the following circumstances:

1. The relevant local licensing authority and local jurisdiction permit a dual operation at the same location;

2. The Medical Marijuana-Infused Products Manufacturer and the Retail Marijuana Products Manufacturing Facility are commonly owned;

3. The Medical Marijuana-Infused Products Manufacturer and Retail Marijuana Products Manufacturing Facility shall maintain either physical or virtual separation between (i) Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana-Infused Products and other Medical Marijuana-related inventory and (ii) Retail Marijuana, Retail Marijuana Concentrate, Retail Marijuana Products and other Retail Marijuana-related inventory. Nothing in this Rule prohibits a co-located Retail Marijuana Products Manufacturing Facility and Medical Marijuana-Infused Products Manufacturer from sharing raw ingredients in bulk, for example flour or sugar, except Retail Marijuana and Medical Marijuana may not be shared under any circumstances; and

4. Record keeping, inventory tracking, packaging and labeling for the Medical Marijuana-Infused Products Manufacturer and Retail Marijuana Products Manufacturing Facility must enable the Division and local licensing authority to clearly distinguish the inventories and business transactions of the Medical Marijuana-Infused Product Manufacturer from the Retail Marijuana Product Manufacturing Facility.

D. Co-located Medical Marijuana Testing Facility and Retail Marijuana Testing Facility. A Medical Marijuana Testing Facility and a Retail Marijuana Testing Facility may share a single Licensed Premises and operate at the same location under the following circumstances:

1. The relevant local licensing authority and local licensing jurisdiction permit dual operation at the same location;

2. The Medical Marijuana Testing Facility and Retail Marijuana Testing Facility are identically owned;

3. The Medical Marijuana Testing Facility and Retail Marijuana Testing Facility shall maintain either physical or virtual separation between (i) Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana-Infused Product and other Medical Marijuana-related inventory and (ii) Retail Marijuana, Retail Marijuana Concentrate, Retail Marijuana Products and other Retail Marijuana-related inventory; and

4. Record keeping, inventory tracking, packaging and labeling for the Medical Marijuana Testing Facility and Retail Marijuana Testing Facility must enable the Division and local licensing authority to clearly distinguish the inventories and business transactions of the Medical Marijuana Testing Facility from the Retail Marijuana Testing Facility.

E. Co-Located Medical Marijuana Transporter and Retail Marijuana Transporter. A Medical Marijuana Transporter and a Retail Marijuana Transporter may share a single Licensed Premises and operate dual transporting, logistics, and temporary storage business operation at the same location under the following circumstances:

1. The relevant local licensing authority and local licensing jurisdiction permit dual operation at the same location;

2. The Medical Marijuana Transporter and Retail Marijuana Transporter are identically owned;

3. The Medical Marijuana Transporter and Retail Marijuana Transporter shall maintain either physical or virtual separation between (i) Medical Marijuana, Medical Marijuana

Concentrate, Medical Marijuana-Infused Products, and other Medical Marijuana-related inventory and (ii) Retail Marijuana, Retail Marijuana Concentrate, Retail Marijuana Products and other Retail Marijuana-related inventory; and

4. Record keeping, inventory tracking, packaging and labeling for the Medical Marijuana Transporter and Retail Marijuana Transporter must enable the Division and local licensing authority to clearly distinguish the inventories and business transactions of the Medical Marijuana Transporter from the Retail Marijuana Transporter.

F. Co-Located Licensed Research Business. A Licensed Research Business may share a single Licensed Premises and operate at the same location as other Medical Marijuana Businesses or Retail Marijuana Establishments to the extent permitted by the Licensed Research Business's R&D Co-Location Permit and otherwise in compliance with all applicable rules. See Rule M 1900 Series.

G. Violation of this Rule may be considered a violation affecting public safety.

500 Series – Medical Marijuana Optional Premises Cultivation Operation: License Privileges

Basis and Purpose – M 501

The statutory authority for this rule includes but is not limited to sections 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)(XXIII), 12-43.4-401(4), 12-43.3-310, 12-43.4-402, 12-43.3-403(4), 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 304.1 – 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. In addition, an Optional Premises Cultivation Operation may share a single Licensed Premises with and operate at the same location as a Licensed Research Business so long as: each business or business entity holds a separate license; the Licensed Research Business obtains an R&D Co-Location Permit; both the Licensed Research Business and the Optional Premises Cultivation Operation comply with all terms and conditions of the R&D Co-Location Permit; and both the Licensed Research Business and the Optional Premises Cultivation Operation comply with all applicable rules. *See* Rule M 1900 Series.

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 Transfers. A Medical Marijuana Optional Premises Cultivation Operation may only Transfer Medical Marijuana and Water-Based Medical Marijuana Concentrate 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.

1. A Medical Marijuana Optional Premises Cultivation Operation is also authorized to Transfer Medical Marijuana to a Licensed Research Business pursuant to section 12-

43.3-408, C.R.S., a Medical Research Facility pursuant to section 25-1.5-106.5, C.R.S., or Pesticide Manufacturer pursuant to section 12-43.3-202(1)(h)(II), C.R.S. Until such Transfer, any Finished Marijuana at the Optional Premises Cultivation Operation shall count against the possession limits for the Medical Marijuana Center the Optional Premises Cultivation Operation is designated to pursuant to section 12-43.3-403, C.R.S. See Rule M 403(A.5).

2. An Optional Premises Cultivation shall not Transfer Flowering plants or Vegetative plants to any Person except as authorized pursuant to Rule M 801.

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 or the Rule M 1000-1 Series – Labeling, Packaging, and Product Safety, and securely sealed in a tamper-evident manner.

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 is a Medical Marijuana Business and the transportation order is delivered to a licensed Medical Marijuana Business, Medical Research Facility, or Pesticide Manufacturer. Nothing in this Rule prevents a Medical Marijuana Optional Premises Cultivation from transporting its own Medical Marijuana.

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

H. Authorized Sources of Medical Marijuana Seeds and Immature Plants. A Medical Marijuana Optional Premises Cultivation Operation shall only obtain Medical Marijuana seeds or Immature Plants from its own Medical Marijuana or properly transferred from another Medical Marijuana Business pursuant to the inventory tracking requirements in this Rule, and as long as there is first a documented point-of-sale transaction at that Optional Premises Cultivation Operation's designated Medical Marijuana Center or Medical Marijuana-Infused Products Manufacturer.

I. Centralized Distribution Permit. An Optional Premises Cultivation Operation may apply to the State Licensing Authority for a Centralized Distribution Permit for authorization to temporarily store Medical Marijuana Concentrate and Medical Marijuana-Infused Product received from a Medical Marijuana-Infused Products Manufacturer for the sole purpose of Transfer to commonly owned Medical Marijuana Centers.

1. For purposes of a Centralized Distribution Permit only, the term "commonly owned" means at least one natural person has a minimum of five percent ownership in both the Optional Premises Cultivation Operation possessing a Centralized Distribution Permit and the Medical Marijuana Center to which the Medical Marijuana Concentrate and Medical Marijuana-Infused Product will be Transferred.

2. To apply for a Centralized Distribution Permit, an Optional Premises Cultivation Operation may submit an addendum to its new or renewal application or a separate addendum prior to a renewal application on forms prepared by the Division to request a Centralized Distribution Permit. The Optional Premises Cultivation Operation shall send a copy of its Centralized Distribution addendum to the local licensing authority in the jurisdiction in which the Centralized Distribution Permit is proposed at the same time it submits the addendum to the State Licensing Authority.

3. An Optional Premises Cultivation Operation that has been issued a Centralized Distribution Permit may accept Transfers of Medical Marijuana Concentrate and Medical Marijuana-Infused Product from a Medical Marijuana-Infused Products Manufacturer for

the sole purpose of temporary storage and Transfer to commonly owned Medical Marijuana Centers.

a. An Optional Premises Cultivation Operation may only accept Medical Marijuana Concentrate and Medical Marijuana-Infused Product that is packaged and labeled for sale to a patient pursuant to the Rule M 1000 Series and Rule M 1000-1 Series.

b. An Optional Premises Cultivation Operation storing Medical Marijuana Concentrate and Medical Marijuana-Infused Product pursuant to a Centralized Distribution Permit shall not store such Medical Marijuana Concentrate or Medical Marijuana-Infused Product on the Optional Premises Cultivation Operation's Licensed Premises for more than 90 days from the date of receipt.

c. All Transfers of Medical Marijuana Concentrate and Medical Marijuana-Infused Product by an Optional Premises Cultivation Operation shall be without consideration.

4. All security and surveillance requirements that apply to an Optional Premises Cultivation Operation apply to activities conducted pursuant to the privileges of a Centralized Distribution Permit.

Basis and Purpose – M 503

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(h), 12-43.3-202(2)(a)(XX), and 12-43.3-403~~(3)~~, C.R.S. The purpose of this rule is to eliminate diversion of Medical Marijuana.

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

A. Minimum Tracking Requirement. An Optional Premises Cultivation Operation must use the Inventory Tracking System to ensure its inventories are identified and tracked from the point Medical Marijuana is Propagated from seed or cutting to the point when it is delivered to a Medical Marijuana Business, Medical Research Facility, or Pesticide Manufacturer. See Rule M 309, Medical Marijuana Business: Inventory Tracking System. An Optional Premises Cultivation Operation shall track all Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product possessed pursuant to a Centralized Distribution Permit in the Inventory Tracking System from the point it is received to the point of Transfer to its commonly owned Medical Marijuana Center. *See* Rule M 501 – Medical Marijuana Optional Premises Cultivation Operation: License Privileges. 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* Rule M 901 – Business Records Required.

1. An Optional Premises Cultivation Operation is prohibited from accepting any Medical Marijuana 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 to the Optional Premises Cultivation Operation.

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 506

The statutory authority for this rule includes but is not limited to sections 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) - (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: or the Optional Premises Cultivation Operation has been issued a Centralized Distribution Permit and is in possession of the Medical Marijuana Concentrate in compliance with Rule M 501(I).

2. Notwithstanding subparagraph (C)(1) of this Rule M 505, an Optional Premises Cultivation Operation shall be permitted to possess Solvent-Based Medical Marijuana Concentrate only when the possession is due to the Transfer of Medical Marijuana flower or trim that failed microbial testing to a Medical Marijuana-Infused Products Manufacturing Facility for processing into a Solvent-Based Medical Marijuana Concentrate, and the Medical Marijuana-Infused Products Manufacturing Facility Transfers the resultant Solvent-Based Medical Marijuana Concentrate back to the originating Optional Premises Cultivation Operation.

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 includes but is not limited to sections 12-43.3-202(1)(b)(I) , 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I)(A-F), 12-43.3-202(2)(a)(XXIII), 12-43.3-403, 12-43.3-404(2), 12-43.3-406(1)(c), 12-43.3-406(4)(b), and 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 single Licensed Premises and operate at the same 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. In addition, a Licensed Research Business may share a single Licensed Premises with and operate at the same location as a Medical Marijuana-Infused Products Manufacturer so long as: each business or business entity holds a separate license; the Licensed Research Business obtains an R&D Co-Location Permit; both the Licensed Research Business and the Medical Marijuana-Infused Products Manufacturer comply with all terms and conditions of the R&D Co-Location Permit; and both the Licensed Research Business and the Medical Marijuana-Infused Products Manufacturer comply with all applicable rules. *See* Rule M 1900 Series.

C. Authorized Transfers. A Medical Marijuana-Infused Products Manufacturer ~~may only~~is authorized to Transfer Medical Marijuana, Medical Marijuana-Infused Product, and Medical Marijuana Concentrate as follows:

1. ~~(1)~~ Medical Marijuana Concentrate and Medical Marijuana-Infused Product.

a. A Medical Marijuana-Infused Products Manufacturer may Transfer its own Medical Marijuana-Infused Product and Medical Marijuana Concentrate to Medical Marijuana Centers, other Medical Marijuana-Infused Products Manufacturers, Licensed Research Businesses, Medical Research Facilities, and Pesticide Manufactures.~~;~~

b. A Medical Marijuana-Infused Products Manufacturer may Transfer its own Medical Marijuana-Infused Product and Medical Marijuana Concentrate to an Optional Premises Cultivation Operation that has been issued a Centralized Distribution Permit.

i. Prior to any Transfer pursuant to this Rule M 601(C)(1)(b), a Medical Marijuana-Infused Products Manufacturer shall verify the Optional Premises Cultivation Operation possesses a valid Centralized Distribution Permit. *See* Rule M 501 – Medical Marijuana Optional Premises Cultivation Operation: License Privileges.

ii. For any Transfer pursuant to this Rule M 601(C)(1)(b), A Medical Marijuana-Infused Products Manufacturer shall only Transfer Medical Marijuana-Infused Product and Medical Marijuana Concentrate that is packaged and labeled for sale to a patient. *See* Rule M 1000 Series and Rule M 1000-1 Series.

2. ~~(2)~~Medical Marijuana.

a. A Medical Marijuana-Infused Products Manufacturer may Transfer Medical Marijuana that was not cultivated at its own Optional Premises Cultivation to another Medical Marijuana-Infused Products Manufacturer.

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 Medical Marijuana-Infused 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. Repealed.

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 Medical Marijuana Transporter for transportation of its Medical Marijuana-Infused Product or Medical Marijuana Concentrate so long as the place where transportation orders are taken is a licensed Medical Marijuana Business and the transportation order is delivered to a Medical Marijuana Business, Medical Research Facility, or Pesticide Manufacturer. Nothing in this Rule prevents a Medical Marijuana-Infused Products Manufacturer from transporting its own Medical Marijuana or Medical Marijuana Concentrate.

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

M 1300 Series – Discipline

Basis and Purpose – M 1307

The statutory authority for this rule includes but is not limited to sections 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 12-43.3-202(2)(a)(XXII), 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, violations related to R&D Co-Location Permits, 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.

C. Mitigating and Aggravating Factors. The State Licensing Authority may consider mitigating and aggravating factors when considering the imposition of a penalty. These factors may include, but are not limited to:

1. Any prior violations that the Licensee has admitted to or was found to have engaged in.

2. Good faith measures by the Licensee to prevent the violation, including the following:

   a. Proper supervision;

   b. Regularly-provided and documented employee training, provided the Licensee demonstrates all reasonable training measures were delivered prior to the Division's investigation;

   c. Standard operating procedures established prior to the Division's investigation, and which include procedures directly addressing the conduct for which imposition of a penalty is being considered; and

   d. Previously established and maintained responsible-vendor designation pursuant to Rule M 408.

3. Licensee's past history of success or failure with compliance checks.

4. Corrective action(s) taken by the Licensee related to the current violation or prior violations.

5. Willfulness and deliberateness of the violation.

6. Likelihood of reoccurrence of the violation.

7. Circumstances surrounding the violation, including, but not limited to, Licensee self-reported violation(s) of the Medical Code or rules promulgated pursuant to the Medical Code; and

8. Owner or manager is the violator or has directed an employee or other individual to violate the Medical Code or rules promulgated pursuant to the Medical Code.

M 1700 Series – Medical Marijuana Business Operators

Basis and Purpose – M 1702

The statutory authority for this rule includes but is not limited to sections 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. Financial Interest. A Person who is a Direct Beneficial Interest Owner or an Indirect Beneficial Interest Owner of a Medical Marijuana Business Operator may also be a Direct Beneficial Interest Owner, an Indirect Beneficial Interest Owner or otherwise hold a direct or indirect financial interest in another Medical Marijuana Business so long as that interest complies with all other requirements of these rules. A Medical Marijuana Business may be operated by a Medical Marijuana Business Operator where each has one or more Direct Beneficial Interest Owners or Indirect Beneficial Interest Owners in common. A Person may receive compensation for services provided by a Medical Marijuana Business Operator in accordance with these rules.

B. Sale of Marijuana Prohibited. A Medical Marijuana Business Operator is prohibited from selling, distributing, or transferring Medical Marijuana or Medical Marijuana-Infused Product to another Medical Marijuana Business or a consumer, except when acting as an agent of a Medical Marijuana Business(es) operated by the Medical Marijuana Business Operator.

C. 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 license or 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 shall not be granted, and may not accept:

i. a security interest in the Medical Marijuana Business being operated, or in any assets of the Medical Marijuana Business;

ii. an ownership or membership interest, shares, or shares of stock, or any right to obtain any direct or indirect beneficial ownership interest in the Medical Marijuana Business being operated, or a future or contingent right to the same, including but not limited to options or warrants;

c. The Medical Marijuana Business Operator shall not guarantee the Medical Marijuana Business's debts or production levels.

3. Shall permit the Medical Marijuana Business being operated to terminate the contract with the Medical Marijuana Business Operator at any time, with or without cause;

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.

J. Any Medical Marijuana Business Operators and the Medical Marijuana Business Operator's Associated Key Licensee(s) that are appointed by a court to serve as a receiver, personal representative, executor, administrator, guardian, conservator, trustee, or similarly situated Person and take possession of, operate, manage, or control a Medical Marijuana Business must comply with Rule M 253(F).

M 1900 Series –Licensed Research Businesses

Basis and Purpose - M 1901

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX), 12-43.3-202(2)(a)(XXII), 12-43.3-202(2)(a)(XXIII), 12-43.3-404(2), 12-43.3-405(1), ~~and~~ 12-43.3-408, 12-43.4-202(3)(a)(XXI), and 12-43.4-404(2)(b), C.R.S. The purpose of this rule is to establish that it is unlawful for Licensed Research Businesses to exercise any privilege other than those granted by the State Licensing Authority. The purpose of this rule also is to clarify the distinct privileges granted to Marijuana Research and Development Facilities and Marijuana Research and Development Cultivations.

M 1901 – Licensed Research Businesses: License Privileges

A. Privileges Applicable to any Licensed Research Business.

1. Privileges Granted. A Licensed Research Business shall only exercise those privileges granted to it by the State Licensing Authority.

2. Licensed Premises. A Licensed Research Business may share a Licensed Premises ~~only~~ with a commonly owned Medical Marijuana Testing Facility. Additionally, a Licensed Research Business with a Co-Location Permit may share a Licensed Premises with a commonly owned Medical Marijuana-Infused Products Manufacturer, Retail Marijuana Products Manufacturing Facility, Medical Marijuana Optional Premises Cultivation Operation, or Retail Marijuana Cultivation Facility.

   a~~i~~. If a Licensed Research Business shares its Licensed Premises with a commonly owned Medical Marijuana Testing Facility, the Licensees shall physically segregate all Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product used for research purposes in order to prevent contamination or any other effect on Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product submitted to the Medical Marijuana Testing Facility for testing.

   b. If a Licensed Research Business shares its Licensed Premises with a commonly owned Medical Marijuana-Infused Products Manufacturer, Retail Marijuana Products Manufacturing Facility, Medical Marijuana Optional Premises Cultivation Operation, or Retail Marijuana Cultivation Facility, the Licensed Research Business must first obtain an R&D Co Location Permit for that Licensed Premises and must comply with all terms and conditions of the R&D Co-Location Permit.

3. Authorized Sources of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product. A Licensed Research Business may receive or obtain Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product from only the following sources:

   a~~i~~. An Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer may Transfer Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to a Licensed Research Business.

   b~~ii~~. Marijuana Research and Development Cultivations. A Marijuana Research and Development Cultivation may Transfer Medical Marijuana to other Licensed Research Businesses.

B. Privileges Applicable to Marijuana Research and Development Cultivations.

1. Cultivation of Marijuana Authorized. A Marijuana Research and Development Cultivation may grow, cultivate, possess, and Transfer Medical Marijuana for use in research only.

2. Production of Marijuana Concentrate. A Marijuana Research and Development Cultivation and an Optional Premises Cultivation Operation are subject to the same restrictions concerning Medical Marijuana Concentrate production. Therefore, a Licensed Research Business may produce Medical Marijuana Concentrate only as allowed by, and in conformance with, Rule M 506(A)-(B).

3. Authorized Marijuana Transport. A Marijuana Research and Development Cultivation is authorized to utilize a licensed Medical Marijuana Transporter for transportation of Medical Marijuana to other Licensed Research Businesses so long as the place where transportation orders are taken and delivered is a Licensed Research Business. Nothing in this rule prevents a Marijuana Research and Development Cultivation from transporting its own Medical Marijuana to other Licensed Research Businesses.

C. R&D Co-Location Permit. A Licensed Research Business may obtain an R&D Co-Location Permit to operate at the same Licensed Premises as a commonly owned Medical Marijuana-Infused Products Manufacturer, Retail Marijuana Products Manufacturing Facility, Medical Marijuana Optional Premises Cultivation Operation, or Retail Marijuana Cultivation Facility under the following circumstances:

1. The Licensed Research Business must apply on current Division forms and pay any applicable fees.

2. A Licensed Research Business may only apply for and hold an R&D Co-Location Permit if the relevant local licensing authority and local jurisdiction allow for Licensed Research Businesses to operate at the same location as the specified Medical Marijuana Business or Retail Marijuana Establishment. Any R&D Co-Location Permit issued by the Division is conditioned upon the Licensed Research Business's receipt of all required local licensing authority and local jurisdiction approvals or acknowledgements.

3. The Licensed Research Business and the specified Medical Marijuana Business or Retail Marijuana Establishment shall be commonly owned.

4. Prior to operating in the same Licensed Premises pursuant to an R&D Co-Location Permit, the Licensed Research Business shall submit a co-location plan and standard operating procedures to the Division. The co-location plan and standard operating procedures shall demonstrate protocols to prevent cross-contamination and protect public health and safety, including but not limited to:

a. Standards and controls for maintaining physical separation between the Licensed Research Business's research activities and the cultivating or manufacturing activities of the co-located Medical Marijuana Business or Retail Marijuana Establishment; and

b. Standards and controls for maintaining physical separation between the Licensed Research Business's Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Products and the co-located Medical Marijuana Business's or Retail Marijuana Establishment's Medical Marijuana, Retail

Marijuana, Medical Marijuana Concentrate, Retail Marijuana Concentrate, Medical Marijuana-Infused Products, and Retail Marijuana Products.

5. The Division may consult with the Colorado Department of Public Health and Environment in reviewing the co-location plan and standard operating procedures, and determining whether the co-location plan and standard operating procedures demonstrate protocols to prevent cross-contamination and protect public health and safety.

6. Modifying the co-location plan and standard operating procedures shall be considered a material change to the Licensed Premises. See Rule M 303 – Changing, Altering, or Modifying the Licensed Premises.

7. Record keeping, inventory tracking, packaging and labeling for the Licensed Research Business and co-located Medical Marijuana Business or Retail Marijuana Establishment must enable the Division, local licensing authority, and local jurisdiction to clearly distinguish the inventory, transactions, and activities of the Licensed Research Business from the inventory, transactions, and activities of the co-located Medical Marijuana Business or Retail Marijuana Establishment.

Basis and Purpose - M 1902

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX), 12-43.3-202(2)(a)(XXII), 12-43.3-202(2)(a)(XXIII), 12-43.3-310(7), 12-43.3-405(1), ~~and~~ 12-43.3-408, and 12-43.4-202(3)(a)(XXI), C.R.S. The purpose of this rule is to clarify those acts that are prohibited, or limited in some fashion, by a Licensed Research Business.

M 1902 – Licensed Research Businesses: General Limitations or Prohibited Acts

A. Restrictions Applicable to Any Licensed Research Business.

1. Packaging and Labeling Standards Required. A Licensed Research Business is prohibited from Transferring to a Licensee or any other Person Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product that is not packaged and labeled in accordance with these rules. *See* Rule M 1000-1 Series – Labeling, Packaging, and Product Safety.

   a~~i~~. Unless the Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product was subject to contaminant testing required by the Medical Marijuana Code and these rules, a Licensed Research Business shall disclose to any individual Person receiving Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product as part of an approved Research Project that the Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product has not been subject to mandatory contaminant testing.

2. Transfers to Individuals. A Licensed Research Business is prohibited from Transferring Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to any individual, unless as part of an approved Research Project.

3. Consumption Prohibited. A Licensed Research Business shall not permit the consumption of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product on its Licensed Premises, unless the consumption is~~as~~ part of an approved Research Project and the Licensed Research Business does not share a Licensed Premises with a Medical Marijuana ~~Testing Facility~~Business or a Retail Marijuana Establishment.

4. Transporter Restrictions. A Licensed Research Business shall not sell or give away Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to a Medical Marijuana Transporter, and shall not buy or receive complimentary Medical Marijuana, Medical Marijuana Concentrate, or Medical-Marijuana Infused Product from a Medical Marijuana Transporter.

5. Worker Health and Safety. A Licensed Research Business shall comply with all applicable federal, state, and local laws regarding worker health and safety.

6. Performance Incentives. A Licensed Research Business may not use performance incentives to compensate its employees, agents, or contractors who will conduct research, development, or testing.

7. Licensure and Research Projects. A Licensed Research Business shall not engage in any research activities until the State Licensing Authority or its delegate approves both (1) its business license application, pursuant to Rule M 201, and (2) one or more Research Project(s), pursuant to Rule M 1904.

   ai. A Licensed Research Business may submit its business license application prior to or in conjunction with its Research Project application. Except that the Licensed Research Business may not engage in any research activities except in conjunction with an approved Research Project.

   bii. If a Licensed Research Business's license expires or is suspended or revoked, the Licensee shall immediately cease all activities associated with the privileges of licensure, including but not limited to research.

B. Restrictions Applicable to- Licensed Research BusinessesMarijuana Research and Development Cultivations.

1. Transfer Restriction. A Licensed Research Business Marijuana Research and Development Cultivation may only Transfer Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to: a Licensed Research Business, a Medical Marijuana Testing Facility for testing, or to any individual person as part of an approved Research Project.

   a. A Medical Marijuana Testing Facility for testing;

   b. A natural person as part of and in compliance with the conditions of an approved Research Project;

   c. In the case of Medical Marijuana cultivated at the Licensed Premises of the Marijuana Research and Development Cultivation, to another Licensed Research Business; or

   d. In the case of an Immature Plant that has not been exposed to a chemical prohibited by Rule M 504(F) and (H), to another Medical Marijuana Business.

C. Repealed.Restrictions Applicable to Marijuana Research and Development Facilities.

1. Transfer Restriction. A Marijuana Research and Development Facility may only Transfer Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to an individual person as part of an approved Research Project or to a Medical Marijuana Testing Facility for testing.

Basis and Purpose - M 1903

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX), and 12-43.3-202(2)(a)(XXII), and 12-43.3-408, C.R.S. The purpose of this rule is to require all Licensed Research Businesses to track all inventory from the point it is Propagated or received to the point when it is destroyed, used in a Research Project, or, if permitted, Transferred to another Licensed Research Business or another Medical Marijuana Business~~Testing Facility~~. The purpose of this rule is also to eliminate diversion of Medical Marijuana.

M 1903 – Licensed Research Businesses: Inventory Tracking

A. Minimum Tracking Requirement. A Licensed Research Business must use the Inventory Tracking System to ensure its inventories are identified and tracked from the point Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product is propagated or received to the point when it is destroyed, used in a Research Project, or, if permitted, Transferred to another Licensed Research Business or another Medical Marijuana Business~~Testing Facility~~. *See also* Rule M 309 - Medical Marijuana Business: Inventory Tracking System. A Licensed Research Business must have the ability to reconcile its inventory records generated from the Inventory Tracking System with the associated transaction history and sale receipts or other Transfer documentation. *See also* Rule M 901 – Business Records Required.

1. A Licensed Research Business is prohibited from accepting any Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product without receiving a valid transport manifest generated from the Inventory Tracking System.

2. A Licensed Research Business must immediately input all Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product delivered to its Licensed Premises and account for all RFID tags into the Inventory Tracking System at the time of delivery.

3. A Licensed Research Business must reconcile its transaction history and on-hand Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product to the Inventory Tracking System at the close of business each day.

Basis and Purpose - M 1905

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX), 12-43.3-202(2)(a)(XXII), 12-43.3-405(1), and 12-43.3-408(2), C.R.S. The purpose of this rule to establish the limited research purposes authorized for Licensed Researched Businesses. The purpose of this rule is also to establish additional requirements for Research Projects involving human subjects and animal subjects, as well as restrictions on the use of Pesticides. The rule also establishes reporting requirements and explains when the State Licensing Authority may require a Licensed Research Business to undergo an audit of its research activities.

M 1905 – Licensed Research Businesses: Authorized Research Activities

A. Authorized Research. A Licensed Research Business is authorized to engage in the following research at its Licensed Premises:

1. Chemical Potency and Composition Levels.

2. Clinical Investigations of Marijuana-Derived Products.

3. Efficacy and Safety of Administering Marijuana as Part of Medical Treatment.

4. Genomic Research.

5. Horticultural Research.

6. Agricultural Research.

7. Marijuana-Affiliated Products or Systems. A marijuana-affiliated product or system includes products or systems such as marijuana delivery systems and cultivation or processing equipment.

B. Pesticide Research. A Licensed Research Business shall not engage in any research activities involving Pesticides unless the Licensed Research Business has applied for and received any necessary license, registration, certification, or permit from the Colorado Department of Agriculture pursuant to the Pesticide Act, sections 35-9-101 *et seq.,* C.R.S., and/or the Pesticide Applicators' Act, sections 35-10-101 *et seq.*, C.R.S.

1. A Licensed Research Business engaged in research activities involving Pesticide shall at all times comply with the Pesticide Act, sections 35-9-101 *et seq.*, C.R.S., Pesticide Applicators' Act, sections 35-10-101 *et seq.*, C.R.S., and all rules promulgated pursuant thereto.

C. Research Involving Human Subjects. A Licensed Research Business shall not conduct any research involving human subjects unless all aspects of its proposed Research Project have been reviewed and approved by an Institutional Review Board that is registered and in good standing with Office for Human Research Protections, U.S. Department of Health and Human Services.

1. A Licensed Research Business shall include proof of approval and ongoing oversight and review by an Institutional Review Board as part of its Research Project proposal. A Research Project may be approved conditioned upon subsequent Institutional Review Board approval. A Licensee shall not engage in any Research Project involving human subjects until it receives approval by the Institutional Review Board and its Research Project is approved. A Licensed Research Business conducting research involving human subjects shall also comply with any ongoing monitoring required by the Institutional Review Board.

2. A Licensed Research Business conducting research involving human subjects shall at all times comply with the U.S. Department of Health and Human Services' requirements for protection of human research subjects, including additional safeguards necessary for vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, 45 C.F.R. part 46, and all other relevant federal and/or state laws and regulations regarding research on human subjects, as well as all prevailing ethical standards and requirements for research involving human subjects.

3. A Licensed Research Business conducting research involving human subjects shall obtain informed consent from any individual participating in such research prior to the individual's participation in the research. A Licensed Research Business shall comply with U.S. Food and Drug Administration requirements for informed consent and additional safeguards for children in clinical investigations, 21 C.F.R. part 50, as part of approval and ongoing oversight and review by an Institutional Review Board.

D. Research Involving Animal Subjects. A Licensed Research Business shall not conduct any research involving animal subjects as defined in the Animal Welfare Act, 7 U.S.C. § 2132(g) unless the Licensed Research Business is registered with the U.S. Department of Agricultural pursuant to the Animal Welfare Act, 7 U.S.C. §§ 2131 *et seq.*

1. A Licensed Research Business shall include proof of its current registration with the U.S. Department of Agriculture as part of its Research Project proposal. Failure to be registered with the U.S. Department of Agriculture shall be grounds for denial of Research Project proposal involving animal subjects.

2. A Licensed Research Business shall at all times treat animal subjects as defined in the Animal Welfare Act, 7 U.S.C. § 2132(g) involved in research humanely and consistent with all relevant federal and/or state laws and regulations, as well as all prevailing ethical standards and requirements for research on such animals.

E. Research Involving Testing of Marijuana. A Licensed Research Business may only engage in research regarding the testing of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product if the following criteria are met:

1. Testing Qualifications. A Licensed Research Business must meet one of the following standards:

a. The Licensed Research Business also holds a Medical Marijuana Testing Facility license and has been certified pursuant to Rule M 703;

b. The Licensed Research Business is accredited to the International Organization for Standardization/International Electrotechnical Commission 17025:2005 Standard, or any subsequent superseding ISO 17025 standard; or

c. The Licensed Research Business is part of an institution of higher education whose protocols have been approved by the Colorado Department of Public Health and Environment.

2. A Licensed Research Business proposing to engage in research regarding the testing Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product shall include in its Research Project proposal documentation establishing its testing qualification pursuant to Paragraph (E)(1) of this Rule. *See* Rule M 1904 – Licensed Research Businesses: Project Approval.

F. ~~No~~ Transfers of Marijuana Used in Research. A Licensed Research Business shall not Transfer to any Person any Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product unless such Transfer is authorized under Rule M 1902 ~~that has been used by the Licensee for research~~. ~~Unless otherwise provided by the State Licensing Authority~~Otherwise, a Licensed Research Business shall at the conclusion of its research destroy all remaining Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product subject to the Licensed Research Business's approved Research Project. Unless otherwise provided, a Research Project will be deemed concluded on its defined end date as provided in the Licensed Research Business's Research Project proposal that was submitted to and approved by the Division. The Licensed Research Business shall ensure destruction of such remaining Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product is destroyed in conformance with Rule M 307.

G. Periodic Reporting. A Licensed Research Business shall submit to the Division a report regarding the status of approved Research Projects every 6 months following the Division's approval of its Research Project.

1. The periodic reports shall address the Licensed Research Business's compliance and progress with its approved Research Project.

2. The periodic reports shall include any protocol changes or reported protocol deviations, as well as enrollment numbers and adverse events for studies involving human subjects.

3. If the Licensed Research Business is conducting its Research Project in whole or in part with a Public Institution or Public Money, the Division shall submit the Licensed Research Business's periodic reports to the Scientific Advisory Council for review.

4. If an adverse event occurs, the Licensed Research Business shall immediately notify the Division of the adverse event on the form prepared by the Division.

H. Suspension or Revocation of Project Approval. Research Project approval is subject to revocation or suspension if the Licensed Research Business's research has materially diverged from the Licensed Research Business's approved Research Project, violates the Medical Marijuana Code or the rules promulgated thereto, or presents a risk to public health and safety. *See* Rule M 1300 Series – Discipline.

I. Reporting of Research Results. A Licensed Research Business shall supply the Division with copies of all final reports, findings, or documentation regarding the outcomes of approved Research Projects.

J. Independent Research Audit. The State Licensing Authority in its discretion may at any time require that a Licensed Research Business undergo an audit of its research activities.

1. Circumstances Justifying Independent Research Audit. The following is a non-exhaustive list of examples that may justify an independent research audit:

a. The Division has reasonable grounds to believe that the Licensed Research Business is in violation of one or more of the requirements set forth in these rules or other applicable statutes or regulations;

b. The Division has reasonable grounds to believe that the Licensed Research Business's research activities present a danger to the public health and/or safety; or

c. The Division has reasonable grounds to believe that the Licensed Research Business has been or is engaged in research activities that have not received prior Division approval.

2. Selection of An Independent Consultant. The Division and the Licensed Research Business may attempt to mutually agree upon the selection of an independent consultant to perform a research audit. However, the Division always retains the authority to select the independent consultant regardless of whether mutual agreement can be reached.

3. Costs. The Licensed Research Business subject to an independent research audit will be responsible for all costs associated with the independent research audit, including but not limited to the auditor's fees.

4. Compliance Required. A Licensed Research Business must pay for and timely cooperate with the State Licensing Authority's requirement that it undergo an independent research audit in conformance with this Rule.

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