COLORADO
Department of Revenue
Always Help

Colorado Department of Revenue
Marijuana Enforcement Division

RULEMAKING WORK GROUP

SB19-224
Regulated Marijuana Sunset – Other Matters
Friday, September 13, 2019
1:00 p.m.

1707 Cole Blvd., Ste. 300
Lakewood, CO 80401

The materials contained herein are for purposes of stakeholder discussion and to solicit feedback to inform rulemaking required for implementation of Senate Bill 19-224. All summaries, outlines, and proposals are subject to amendment.

Questions: *Danielle Henry, Policy Advisor, DOR MED: danielle.henry@state.co.us*
Dominique Mendiola, Deputy Director, DOR MED: dominique.mendiola@state.co.us

Department of Revenue, Marijuana Enforcement Division

SB19-224 Work Group
Regulated Marijuana Sunset - Other Matters
September 13, 2019

AGENDA ITEM #1 – CONSUMER WASTE

Legislation Summary: Senate Bill 19-224 directs the State Licensing Authority to promulgate rules for marijuana consumer waste, including "[c]onditions under which a Licensee is authorized to collect marijuana consumer waste and transfer it to a person for the purposes of reuse or recycling in accordance with requirements established by the Department of Public Health and Environment ("CDPHE") pertaining to waste disposal and recycling."

Pursuant to SB19-224, **marijuana consumer waste** means "any component left after the consumption of a regulated marijuana product, including but not limited to containers, packages, cartridges, pods, cups, batteries, all-in-one disposable devices, and any other waste component left after the regulated marijuana is consumed as defined by rules promulgated by the State Licensing Authority."

Subject Areas for Rulemaking/Action Items:

Conditions established by rule must include:

- The person receiving marijuana consumer waste from a licensee is, to the extent required by law, registered with the CDPHE;
- Record-keeping requirements;
- Security measures related to the collection and transfer of marijuana consumer waste;
- Health and safety requirements, including requirements for the handling of marijuana consumer waste; and
- Processes associated with handling marijuana consumer waste, including destruction of any remaining regulated marijuana in the marijuana consumer waste.

Proposed Rules Handout:

- 3-240 – Collection of Marijuana Consumer Waste, Pages 11-12

CONTINUES ON NEXT PAGE

AGENDA ITEM #2 - INHALERS

Legislation Summary: Under Senate Bill 19-224, "[t]he State Licensing Authority shall treat a metered-dose inhaler the same as a vaporized delivery device for purposes of regulation and testing."

Subject Areas for Rulemaking/Action Items:

- Redefine intended uses for audited product and inhaled product.
- Testing requirements.
- Packaging and labeling requirements.

Proposed Rules Handout:

- 3-1010 – Packaging and Labeling: General Requirements Prior to Transfer to a Patient or Consumer, Pages 15-17
- 4-115 – Regulated Marijuana Testing Program: Sampling and Testing Program, Pages 19-21
- 5-325 – Medical Marijuana Products Manufacturer: Audited Product and Alternative Use Product, Pages 26-27
- 6-325 – Retail Marijuana Products Manufacturing Facility: Audited Product and Alternative Use Product, Pages 29-30

AGENDA ITEM #3 – "REDUNDANT" TESTING

Legislation Summary: Senate Bill 19-224 requires the promulgation of rules to prevent redundant testing of marijuana and marijuana concentrate, including but not limited to:

- Potency testing of marijuana allocated to extractions; and
- Residual solvent testing of marijuana concentrate when all inputs of the marijuana concentrate have passed residual solvent testing.

Subject Areas for Rulemaking/Action Items:

- Review mandatory testing provisions and identify those stage(s) of marijuana production and manufacturing most necessary for each particular test.
- Identify within the Rules M/R 1500 Series where certain risks of duplicate or redundant testing arise.
- Consider where process validation can be applied to more effectively address "redundant" testing concerns.

AGENDA ITEM #4 - SIGNAGE AND ADVERTISING

Legislation Summary: Senate Bill 19-224 establishes the following new defined terms:

- **Advertising** means the act of providing consideration for the publication, dissemination, solicitation, or circulation of visual, oral, or written communication to directly induce any person to patronize a particular medical marijuana business or retail marijuana business or purchase particular regulated marijuana. "Advertising" does not include packaging and labeling, consumer education materials, or branding.
- **Branding** means promotion of a business's brand through publicizing the medical marijuana business's or retail marijuana business's name, logo, or distinct design features of the brand.
- **Consumer education materials** means any informational materials that seek to educate consumers about regulated marijuana generally, including but not limited to education regarding the safe consumption of marijuana, regulated marijuana concentrate, or regulated marijuana products, provided it is not distributed or made available to individuals under twenty-one years of age.

SB19-224 maintains rulemaking authority related to signage and advertising, which includes:

- A prohibition on mass-market campaigns that have a high likelihood of reaching persons under 18 years of age for medical marijuana or 21 years of age for retail marijuana;
- Allow packaging and accessory branding;
- Prohibit health or physical benefit claims in advertising, merchandising, and packaging;
- Prohibit unsolicited pop-up advertising on the internet;
- Prohibit banner ads on mass market websites;
- Prohibit opt-in marketing that does not permit an easy and permanent opt-out feature; and
- Prohibit marketing directed toward location-based devices.

Subject Areas for Rulemaking/Action Items:

- Outdoor advertising/billboards
- 70% requirements
- Event sponsorships
- Review other state restrictions

Specific rules that will be incorporated/amended/eliminated:

- 3-700 Series, Pages 12-14

AGENDA ITEM #5 –TRANSITION PERMITS

Legislation Summary: Senate Bill 19-224 requires the promulgation of rules to establish requirements for transition permits for medical marijuana cultivation facilities and retail marijuana cultivation facilities, including but not limited to permit application requirements and restrictions of a transition permit. Under SB19-224, a medical or retail cultivation facility that has obtained an approved change of location from the State Licensing Authority may operate one license at two geographical locations for the purpose of transitioning operations from one location to another if:

- The total plants cultivated at both locations do not exceed any plant count limit imposed on the license by statute and rules;
- The licensed premises of both geographical locations comply with all surveillance, security, and inventory tracking requirements imposed by statute and rules;
- Both the transferring location and the receiving location track all plants virtually in transition in the seed-to-dale tracking system to ensure proper tracking for taxation and tracking purposes;
- Operation at both geographical locations does not exceed 180 days, unless for good cause shown; and
- The cultivation facility licensee obtains the proper state permit and local permit or license.
    - If the change of location is within the same local jurisdiction, the licensee must first obtain a transition permit from the state and, if required by the local jurisdiction, a transition permit or other form of approval.
    - If the change of location is to a different jurisdiction, the licensee must first obtain a license from the local jurisdiction where it intends to locate, a transition permit from the state, and, if required, a transition permit or other form of approval from the local jurisdiction where it intends to locate.

Subject Areas for Rulemaking/Action Items:

- Application requirements and restrictions of a transition permit.

Specific rules that will be incorporated/amended/eliminated:

- 2-205 – Fees, Page 7
- 2-255 – Change of Location of a Regulated Marijuana Business, Pages 10-11
- 5-205 – Medical Marijuana Cultivation Facility, Page 25
- 6-205 – Retail Marijuana Cultivation Facility, Page 29

AGENDA ITEM #6 – OTHER GENERAL SUNSET MATTERS

- **INDUSTRIAL HEMP PRODUCTS**
- **PREGNANCY WARNING**
- **IMMATURE PLANTS & SEED TRANSFERS**
- **LICENSE RENEWAL**

SB19-224 Work Group
Regulated Marijuana Sunset - Other Matters
September 13, 2019

This document is provided for purposes of stakeholder discussion to inform the Division's implementation of Senate Bill 19-224 ("Regulated Marijuana Sunset"). The information contained herein does not reflect the entirety of proposed rules for implementation of SB19-224, but rather is generally limited to those subject areas intended for stakeholder discussions in the Division's September 13, 2019 rulemaking work groups meetings. The Division will release updated materials prior to the next "Regulated Marijuana Sunset – Other Matters" work group meeting scheduled September 20, 2019.

Part 1 – General Applicability

1-115 – Definitions

Definitions. The following definitions of terms, in addition to those set forth in section 44-12-103, C.R.S., apply to all rules promulgated pursuant to the Retail Code, unless the context requires otherwise:

"Accelerator Cultivator" means a natural person qualified as an Accelerator Licensee pursuant to these rules and is licensed to cultivate on the Licensed Premises of a Retail Marijuana Cultivation Facility and to distribute Retail Marijuana to Retail Marijuana Products Manufacturers and Retail Marijuana Stores.

"Accelerator-Endorsed Licensee" means a Retail Marijuana Cultivation Facility Licensee or Retail Marijuana Products Manufacturer Licensee who has, pursuant to these rules, been endorsed to host and offer technical and capital support to an Accelerator Licensee operating on its Licensed Premises.

"Accelerator Licensee" means a natural person who has resided in a census tract designated by the Office of Economic Development and International Trade as an opportunity zone for five of the ten years prior to application and has not been the Beneficial Owner of a license issued pursuant to the Marijuana Code.

"Accelerator Manufacturer" means a natural person qualified as an Accelerator Licensee pursuant to these rules and is licensed to manufacture and distribute Retail Marijuana Concentrate and Retail Marijuana Product on the Licensed Premises of an Accelerator-Endorsed Manufacturer Licensee.

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

"Audited Product" means a Regulated Marijuana Product with an intended use of: (1) metered dose nasal spray, (2) ~~pressurized metered dose inhaler, (3)~~ vaginal administration, or (34) rectal administration. Audited Product types may raise public health concerns requiring additional safeguards and oversight. These product types may only be manufactured and Transferred by a Medical Marijuana Products Manufacturer in strict compliance with Rule M 607 or Retail Marijuana Products Manufacturer in strict compliance with Rule R 607. Prior to the first Transfer of an Audited Product to a Medical Marijuana Store, Medical Marijuana Cultivation Facility that has a Centralized Distribution Permit, Retail Marijuana Store or Retail Marijuana Cultivation Facility that has obtained a Centralized Distribution Permit, the Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer shall submit to the Division and, if

applicable, to the Local Licensing Authority or Local Jurisdiction an independent third-party audit verifying compliance with Rule M 607 or Rule R 607. All rules regarding Regulated Marijuana Product apply to Audited Product except where Rules M 607, 712, 1002-1, and 1003-1 and Rules R 607, 712, 1002-1, and 1003-1 apply different requirements.

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

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

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

a. Is a cosmetic, food, food additive, or herb;

b. Is for human use or consumption;

c. Contains any part of the hemp plant, including naturally occurring Cannabinoids, compounds, concentrates, extracts, isolates, resins, or derivatives; and

d. Contains a delta-9 tetrahydrocannabinol concentration of no more than three-tenths of one percent.

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

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

~~"Marijuana 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 Marijuana Research and Development Facility or another Medical Research and Development Cultivation, all for limited research purposes authorized pursuant to section 44-11-408, C.R.S. A Marijuana Research and Development Cultivation is a Licensed Research Business.~~

"Medical Marijuana" means marijuana that is grown and sold pursuant to the Marijuana Code and includes seeds and Immature Plants. Unless the context otherwise requires, Medical Marijuana ~~Concentrate is considered Medical Marijuana and is included in the term "Medical Marijuana" as used in these rules~~includes Medical Marijuana Concentrate and Medical Marijuana Products.

"Medical Marijuana 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 product, 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.~~

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

"Regulated Marijuana Business" means Medical Marijuana Businesses and Retail Marijuana Businesses.

"Regulated Marijuana Product" means Medical Marijuana Product and Retail Marijuana Product.

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

"Retail Marijuana Business" means a Retail Marijuana Store, a Retail Marijuana Cultivation Facility, a Retail Marijuana Products Manufacturer, a Retail Marijuana Testing Facility, a Retail Marijuana Business Operator, ~~or~~ a Retail Marijuana Transporter, an Accelerator Cultivator, an Accelerator Manufacturer, a Marijuana Hospitality Establishment, or a Retail Marijuana Hospitality and Sales Establishment.

Part 2 – Applications and Licenses

2-200 Series – Applications and Licenses Rules

2-205 – Fees

A. Regulated Marijuana Business Initial Application and License Fees.

1. Medical Marijuana Businesses.

License Type	**Application Fee**	**License Fee**
Medical Marijuana Store	$5,000.00	$2,000.00
Medical Marijuana Products Manufacturer	$1,000.00	$1,500.00
Medical Marijuana Cultivation Facility	$1,000.00	
Class 1 (1-500 plants)		$1,500.00
Class 2 (501-1,500 plants)		$1,000.00
Class 3 (1,501-3,000 plants)		$2,500.00
Expanded Production Management (for each class of 3,000 plants over Class 3)		$2,500.00 plus an additional $1,000 for each class of 3,000

		plants over Class 3.
Medical Marijuana Testing Facility	$1,000.00	$1,500.00
Medical Marijuana Transporter	$1,000.00	$4,400.00
Medical Marijuana Business Operator	$1,000.00	$2,200.00
Marijuana Research and Development Facility	$1,000.00	$1,500.00
~~Marijuana Research and Development Cultivation~~	~~$1,000.00~~	~~$1,500.00~~

2. Retail Marijuana Businesses.

License Type	**Application Fee**	**License Fee**
Retail Marijuana Store	$5,000.00	$2,000.00
Retail Marijuana Products Manufacturer	$5,000.00	$1,500.00
Retail Marijuana Cultivation Facility Tier 1 (1-1,800 plants)	$5,000.00	$1,500.00
Tier 2 (1,801-3,600 plants)		$1,000.00
Tier 3 (3,601-6,000 plants)		$2,000.00
Tier 4 (6,001-10,200 plants)		$4,000.00
Tier 5 (10,201-13,800 plants)		$6,000.00
Expanded Production Management (for each additional tier of 3,600 plants over Tier 5)		$6,000.00 plus an additional $1,000 for each tier of 3,600 plants over Tier 5
Retail Marijuana Testing Facility	$1,000.00	$1,500.00
Retail Marijuana Transporter	$1,000.00	$4,400.00
Retail Marijuana Business Operator	$1,000.00	$2,200.00

B. Regulated Marijuana Business Renewal Application and Fees.

1. Medical Marijuana Businesses.

License Type	**Application Fee**	**License Renewal Fee**
Medical Marijuana Center	$1,500.00	$300.00
Medical Marijuana Products Manufacturer	$1,500.00	
Medical Marijuana Cultivation Facility	$1,500.00	
Class 1 (1-500 plants)	$800.00	
Class 2 (501-1,500 plants)	$2,000.00	
Class 3 (1,501-3,000 plants)	$2,000.00 plus an additional $800 for each class of 3,000 plants over Class 3.	
Expanded Production Management (for each class of 3,000 plants over Class 3)		
Medical Marijuana Testing Facility	$1,500.00	
Medical Marijuana Transporter	$4,400.00	
Medical Marijuana Business Operator	$2,200.00	
Marijuana Research and Development Facility	$1,500.00	

2. Retail Marijuana Businesses.

License Type	**Application Fee**	**License Renewal Fee**
Retail Marijuana Store	$1,500.00	$300.00
Retail Marijuana Products Manufacturer	$1,500.00	
Retail Marijuana Cultivation Facility Tier 1 (1-1,800 plants)	$1,500.00	
Tier 2 (1,801-3,600 plants)	$800.00	
Tier 3 (3,601-6,000 plants)	$1,500.00	
	$3,000.00	

Tier 4 (6,001-10,200 plants)	$5,000.00	
Tier 5 (10,201-13,800 plants) Expanded Production Management (for each additional tier of 3,600 plants over Tier 5)	$5,000.00 plus an additional $800.00 for each tier of 3,600 plants over Tier 5	
Retail Marijuana Testing Facility	$1,500.00	
Retail Marijuana Transporter	$4,400.00	
Retail Marijuana Business Operator	$2,200.00	

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

1. Controlling Beneficial Owner Request for a Finding of Suitability.

   a. Colorado Resident Controlling Beneficial Owner - $800.00 per Natural Person

   b. Non-Resident Controlling Beneficial Owner - $5,000.00 per Natural Person

   c. For a Controlling Beneficial Owner that is an Entity, the Entity's request for finding of suitability must include either a $800.00 (Colorado resident) or a $5,000.00 (non-resident) fee for each of its Executive Officers and any person that indirectly Beneficially Owns ten percent or more of the Regulated Marijuana Business.

2. Owner License and Owner Identification Badge. A Person possessing an Owner License may be issued an Identification Badge. Only Controlling Beneficial Owners and Passive Beneficial Owners can obtain an Owner License.

   a. Controlling Beneficial Owner and any Passive Beneficial Owner Subject to a Finding of Suitability – License Fee. A Controlling Beneficial Owner or Passive Beneficial Owner who was found a suitable after November 1, 2019, and within the preceding 365 days, must pay a license fee of $75.00 prior to obtaining an Owner Identification Badge.

   b. Passive Beneficial Owner Application and License Fee. A Passive Beneficial Owner may, but is not required to, apply for an Owner License and Identification Badge. A Passive Beneficial Owner who has not obtained a finding of suitability after November 1, 2019, and within the preceding 365 days, must pay an initial application and license fee of $800.00 (Colorado resident) or $5,000.00 (non-resident) fee for each natural person or, if the Passive Beneficial Owner is an Entity, the Entity must pay the fee for each of its Executive Directors.

      i. Of the total Passive Beneficial Owner application and license fee, $75.00 is the license fee and the remaining $725.00 (Colorado resident) or $4,925.00 (non-resident) of the application fee. A Person submitting an application for a Passive Beneficial Owner license may submit the total fee of either $800.00 or $5,000.00 in one form of payment.

3. Owner License Renewal Fee. All Controlling Beneficial Owners and licensed Passive Beneficial Owners - $500.00.

D. Employee License – Initial Application and Renewal Fees.

1. Key License Initial Application and License Fee – $250.00

   a. Of the total Key License application and license fee, $225.00 is the application fee and $25.00 is the license fee. A Person submitting an application for a Key License may submit the total fee of $250.00 in one form of payment.

2. Support License Initial Application and License Fee – $75.00

   a. Of the total Support License application and license fee, $50.00 is the application fee and $25.00 is the license fee. A Person submitting an application for a Support License may submit the total fee of $75.00 in one form of payment.

3. Key and Support License Renewal Fee – $75.00

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

1. Natural Person – $225.00

2. Entity – $800.00

F. Other Fees. The following other fees apply:

1. Permits.

   a. Off Premises Storage Permit – $1,500.00

   b. Medical Marijuana Transporter and Retail Marijuana Transporter Off Premises Storage Permit – $2,200.00

   c. Centralized Distribution Permit Initial and Renewal Fee – $20.00

   d. R&D Co-Location Permit Initial and Renewal Fee – $50.00

   e. Transition Permit – $250.00

2. Regulated Marijuana Business Changes.

   a. Change of Controlling Beneficial Owner – Not involving a Publicly Traded Corporation – New Controlling Beneficial Owner(s) – $1,600.00

   b. Change of Entity Type/Jurisdiction – $800.00

   c. Change of Trade Name – $50.00

   d. Change of Location – $500.00

   e. Modification of Licensed Premises – $100.00

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

4. Responsible Vendor Provider Applications.

   a. Responsible Vendor Program Provider Initial Application – $850.00

   b. Responsible Vendor Program Provider Renewal Application – $350.00

5. Duplicate License, Identification Badge, or Certificate.

   a. Duplicate Business License – $20.00

   b. Duplicate Owner or Employee Identification Badge – $20.00

   c. Responsible Vendor Program Provider Duplicate Certificate – $50.00

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

2-225 – Renewal Application Requirements for All Licensees

A. License Periods.

1. Regulated Marijuana Business and Owner Licenses are valid for one year from the date of issuance.

2. Medical Marijuana Transporters, Retail Marijuana Transporters, and Employee Licenses are valid for two years from the date of issuance.

B. Division Notification Prior to Expiration.

1. The Division will send a notice of license renewal 90 days prior to the expiration of an existing license by first class mail to the Licensee's physical address of record.

2. Failure to receive the Division notification does not relieve the Licensee of the obligation to timely renew the license.

C. Renewal Deadline.

1. A Licensee ~~may~~ must apply for the renewal of an existing license ~~at least 30 days~~ prior to the License's expiration date. ~~A renewal application filed at least 30 days prior to expiration of the license is timely pursuant to subsection 24-4-104(7), C.R.S., and the Licensee may continue to operate until a Final Agency Order on the renewal application.~~

2. ~~If the Licensee files a renewal application less than 30 days prior to expiration, the Licensee must provide a written explanation detailing the circumstances surrounding the untimely filing. If the Division accepts the application, then~~A renewal application submitted to the Division prior to the license's expiration date shall be ~~the application is~~ deemed timely pursuant to subsection 24-4-104(7), C.R.S., and the Licensee may continue to operate until Final Agency Order on the renewal application.

D. If License Not Renewed Before Expiration. A license is immediately invalid upon expiration if the Licensee has not filed a renewal application and remitted all of the required application and license fees prior to the license expiration date. A Regulated Marijuana Business that fails to file a renewal application and remit all required application and license fees prior to the license expiration date must not operate unless it first obtains a new state license and any required local license.

~~1. If License Not Renewed Before Expiration. A license is immediately invalid upon expiration if the Licensee has not filed a renewal application and remitted all of the required application and license fees prior to the license expiration date. A Regulated Marijuana Business that fails to file a renewal application and remit all required application and license fees prior to the license expiration date must not operate unless it first obtains a new state license and any required local license.~~

~~2. Administratively Continued Regulated Marijuana License. In the event of a renewal application filed after the license expiration date, a Regulated Marijuana Business may not operate unless and until the Division informs the Regulated Marijuana Business Licensee that the license has been administratively continued. A Regulated Marijuana Business whose license has been administratively continued may continue to operate until Final Agency Order on the renewal application. Review of the renewal application will include, among other factors, a review of whether the Regulated Marijuana Business operated with an expired license.~~

~~3. The Division will not accept a renewal application filed more than 90 days after the expiration date of the license. A Regulated Marijuana Business license that expired over 90 days prior to submission of the Regulated Marijuana Business' renewal application may only submit a new initial license application to the State Licensing Authority.~~

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

A. Application Required Before Changing Location of Licensed Premises. A Regulated Marijuana Business must apply for and receive Division approval before changing the location of its Licensed Premises.

B. Application Requirements. A change of location application must include:

1. At least one signature of a Controlling Beneficial Owner and representation that the signing Controlling Beneficial Owner(s) is/are authorized to submit the application on behalf of the Regulated Marijuana Business.

2. Evidence the Local Licensing Authority and/or Local Jurisdiction in which the Regulated Marijuana Business proposes to move have approved the proposed new location.

3. The deed, lease, sublease, rental agreement, contract, or any other document(s) establishing the Licensee is, or will be, entitled to possession of the premises for which the application is made.

4. Legible and accurate floor plans for the proposed licensed Premises that complies with the requirements of the M/R 300 Series of these Rules. The floor plans must include a plan for the proposed Licensed Premises and a separate plan for the security/surveillance plan including camera location, number and direction of coverage. If the diagram is larger than 8.5 inches x 11 inches, the Applicant must also provide the diagram in a portable document format (.pdf).

C. Change of Location Permit Required.

1. A Regulated Marijuana Business cannot change the location of its Licensed Premises until it receives a change of location permit from the Division.

2. The permit is effective on the date of issuance, and the Licensee must, within 120 days, change the location of its Regulated Marijuana Business to the place specified in the change of location permit and at the same time cease to operate a Regulated Marijuana

Business at the former location. For good cause shown, the 120-day deadline may be extended an additional 120 days.

3. If the Regulated Marijuana Business does not change the location of its Licensed Premises within the time period granted by the Division, including any extension, the Regulated Marijuana Business must submit a new application, pay the change of location fee, and receive a new change of location permit prior to changing the location of its Licensed Premises.

4. A Regulated Marijuana Business cannot operate or exercise any of the privileges of its license(s) in both locations, unless a Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility has received a transition permit.

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

1. A Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility may apply for a transition permit and a change of location at the same time.

2. A Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility that has obtained a transition permit must comply with the following requirements:

a. The total plants cultivated at both locations do not exceed any plant count limit imposed on the Licensee by the Marijuana Code and these rules;

b. The Licensed Premises of both geographical locations comply with all surveillance, security, and inventory tracking requirements imposed by the Marijuana Code and these rules at the Rule 3-200 Series and 3-800 Series;

c. Both geographical locations shall track all Regulated Marijuana plants in transition in the Inventory Tracking System to ensure proper tracking for taxation purposes;

d. Operation at both geographical locations does not exceed 180 days, unless Licensee demonstrates good cause to extend the deadline an additional 180 days; and

e. The Licensee obtains a transition permit pursuant to this Rule and any local permit or license, as required by the Local Licensing Authority or Local Jurisdiction.

3. Change of Location in the Same Local Jurisdiction. If the change of location is within the same local jurisdiction, the Licensee must:

a. First obtain a transition permit pursuant to this Rule; and

b. If required by the Local Licensing Authority or Local Jurisdiction, a transition permit or other form of approval from the Local Licensing Authority or Local Jurisdiction.

4. Change of Location to a Different Local Jurisdiction. If the change of location is to a different local jurisdiction, the Licensee must:

a. First obtain a license from the Local Licensing Authority or Local Jurisdiction where the Licensee intends to locate;

b. The Licensee must obtain a transition permit pursuant to this Rule; and

c. If required by the Local Licensing Authority or Local Jurisdiction, a transition permit or other form of approval from the Local Licensing Authority or Local Jurisdiction for the local jurisdiction where it intends to locate.

5. Conduct at either location may be basis for fine, suspension, revocation, or other sanction against the License.

E. Violation Affecting Public Safety. It is a violation affecting public safety if a Regulated Marijuana Business changes the location of its Licensed Premises without first obtaining a change of location permit from the Division, and any required approval(s) from the Local Licensing Authority and/or Local Jurisdiction.

Part 3 – Regulated Marijuana Business Operations

3-100 Series – General Privileges and Limitations

3-200 Series – Licensed Premises

3-240 – Collection of Marijuana Consumer Waste

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

B. Medical Marijuana Stores, Retail Marijuana Stores, Marijuana Hospitality Businesses, and Retail Marijuana Hospitality and Sales Businesses may collect, reuse, and recycle Marijuana Consumer Waste in accordance with the requirements of this Rule 3-240.

C. Collection, Separation, and Processes.

1. Collection. A Licensee must comply with the following requirements when collecting Marijuana Consumer Waste pursuant to paragraph B of this Rule:

a. The Licensee utilizes receptacles that are sealed and designed to require specialized tools in order to open and access the contents of the receptacle;

b. All receptacles used for collection of Marijuana Consumer Waste shall be located within the Restricted Access Area of the Licensed Premises and shall be reasonably supervised by a Licensee to ensure any Marijuana Consumer Waste collected is only removed by a Licensee; and

c. All receptacles used for collection of Marijuana Consumer Waste shall be recorded on video surveillance.

d. All receptacles used for collection of Marijuana Consumer Waste shall be labeled. The label identify the receptacle as “Contains Marijuana Consumer Waste.”

2. Separation. Medical Marijuana Stores, Retail Marijuana Stores, Marijuana Hospitality Businesses, and Retail Marijuana Hospitality and Sales Businesses must separate electronic and battery components from the Marijuana Consumer Waste.

3. Processes. Medical Marijuana Stores, Retail Marijuana Stores, Marijuana Hospitality Businesses, and Retail Marijuana Hospitality and Sales Businesses must establish standard operating procedures that ensure at a minimum any remaining Regulated Marijuana in Marijuana Consumer Waste is removed and destroyed to the extent practicable.

D. Transfers of Marijuana Consumer Waste.

1. Medical Marijuana Stores, Retail Marijuana Stores, Marijuana Hospitality Businesses, and Retail Marijuana Hospitality and Sales Businesses may Transfer Marijuana Consumer Waste, excluding the electronic components and battery components, to a Person for purposes of recycling. Such Person shall be registered as required by the Colorado Department of Public Health and Environment's regulations at 6 CCR 1007-2, Part 1, Section 8.

2. Medical Marijuana Stores, Retail Marijuana Stores, Marijuana Hospitality Businesses, and Retail Marijuana Hospitality and Sales Businesses may Transfer the electronic and battery components of Marijuana Consumer Waste to a Person for purposes of recycling in accordance with the Colorado Department of Public Health and Environment's regulations at 6 CCR 1007-3.

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

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

3-300 Series – Health and Safety Regulations

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

3-500 Series – Responsible Vendor Program

3-600 Series – Transport and Storage

3-700 Series – Signage and Advertising

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

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

3-710 – The Term "Minor" as Used in the Retail Code and These Rules

The term "minor" as used in the Retail Code and these rules means an individual under the age of 21.

3-715 – Advertising: Television

A. Television Defined. As used in this rule, the term "television" means a system for transmitting visual images and sound that are reproduced on screens, and includes broadcast, cable, on-

demand, satellite, or internet programming. Television includes any video programming downloaded or streamed via the internet.

B. Television Advertising. A Retail Marijuana Establishment shall not utilize television Advertising unless the Retail Marijuana Establishment has reliable evidence that no more than 30 percent of the audience for the program on which the Advertising is to air is reasonably expected to be under the age of 21.

3-720 – Advertising: Radio

A. Radio Defined. As used in this rule, the term "radio" means a system for transmitting sound without visual images, and includes broadcast, cable, on-demand, satellite, or internet programming. Radio includes any audio programming downloaded or streamed via the internet.

B. Radio Advertising. A Retail Marijuana Establishment shall not engage in radio Advertising unless the Retail Marijuana Establishment has reliable evidence that no more than 30 percent of the audience for the program on which the Advertising is to air is reasonably expected to be under the age of 21.

3-725 – Advertising: Print Media

A Retail Marijuana Establishment shall not engage in Advertising in a print publication unless the Retail Marijuana Establishment has reliable evidence that no more than 30 percent of the publication's readership is reasonably expected to be under the age of 21.

3-730 – Advertising: Internet

A Retail Marijuana Establishment shall not engage in Advertising via the internet unless the Retail Marijuana Establishment has reliable evidence that no more than 30 percent of the audience for the internet web site is reasonably expected to be under the age of 21. *See also* Rule R 1114 – Pop-Up Advertising.

3-735 – Advertising: Targeting Out-of-State Persons Prohibited.

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

3-740 – Signage and Advertising: No Safety Claims Because Regulated by State Licensing Authority

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

3-745 – Signage and Advertising: No Safety Claims Because Tested by a Retail Marijuana Testing Facility

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

3-750 – Signage and Advertising: Outdoor Advertising

A. Local Ordinances. In addition to any requirements within these rules, a Retail Marijuana Establishment shall comply with any applicable local ordinances regulating signs and Advertising.

B. Outdoor Advertising Generally Prohibited. Except as otherwise provided in this rule, it shall be unlawful for any Retail Marijuana Establishment to engage in Advertising that is visible to members of the public from any street, sidewalk, park or other public place, including Advertising utilizing any of the following media: any billboard or other outdoor general Advertising device; any sign mounted on a vehicle, any hand-held or other portable sign; or any handbill, leaflet or flier directly handed to any person in a public place, left upon a motor vehicle, or posted upon any public or private property without the consent of the property owner.

C. Exception. The prohibitions set forth in this rule shall not apply to any fixed sign that is located on the same zone lot as a Retail Marijuana Establishment and that exists solely for the purpose of identifying the location of the Retail Marijuana Establishment and otherwise complies with any applicable local ordinances.

3-755 – Signage and Advertising: No Content That Targets Minors

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

3-760 – Advertising: Advertising via Marketing Directed Toward Location-Based Devices

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

3-765 – Pop-Up Advertising

A Retail Marijuana Establishment shall not utilize unsolicited pop-up Advertising on the internet.

3-770 – Advertising: Event Sponsorship

A Retail Marijuana Establishment may sponsor a charitable, sports, or similar event, but a Retail Marijuana Establishment shall not engage in Advertising at, or in connection with, such an event unless the Retail Marijuana Establishment has reliable evidence that no more than 30 percent of the audience at the event and/or viewing Advertising in connection with the event is reasonably expected to be under the age of 21.

3-800 Series – Inventory Tracking Requirements

3-900 Series – Business Records

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

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

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

1. Packaging of Regulated Marijuana Product. Every Regulated Marijuana Product shall be in a Child-Resistant Container at the time of Transfer to a Medical Marijuana Store or Retail Marijuana Store in accordance with the following packaging limits:

e. Audited Product. A Container holding Audited Product for rectal administration need not be Child-Resistant but must be placed into a Child-Resistant Container prior to Transfer to a patient. The Container containing Audited Product for administration by: (i) metered dose nasal spray~~,~~ or (ii) ~~pressurized metered dose inhaler, or (iii)~~ vaginal administration must be Child Resistant and labeled.

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

A. Applicability. This Rule establishes additional labeling requirements for Regulated Marijuana (except seeds and Immature plants), Medical Marijuana Concentrate, Retail Marijuana Concentrate, and Regulated Marijuana Product prior to Transfer to a patient or consumer. The labeling requirements in this Rule apply to all Containers immediately containing Regulated Marijuana, Medical Marijuana Concentrate, Retail Marijuana Concentrate, and Regulated Marijuana Product. These labeling requirements based on intended use are in addition to, not in lieu of, the requirements in Rule ~~R 1002-1~~3-1010.

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

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

a. Inhaled Product:

i. Flower or Trim (including pre-rolled joint and Kief);

ii. Solvent-Based Medical Marijuana Concentrate;

iii. Solvent-Based Retail Marijuana Concentrate;

iv. Water-Based Medical Marijuana Concentrate;

v. Water-Based Retail Marijuana Concentrate;

vi. Heat/Pressure-Based Medical Marijuana Concentrate;

vii. Heat/Pressure-Based Retail Marijuana Concentrate;

viii. Vaporizer cartridge/vaporizer pen~~;~~.

ix. Pressurized metered dose inhaler.

b. For Oral Consumption:

i. Food or drink infused with Medical Marijuana;

ii. Food or drink infused with Retail Marijuana;

iii. Medical Marijuana Concentrate intended to be consumed orally;

iv. Retail Marijuana Concentrate intended to be consumed orally;

iii. Pills and capsules;

iv. Tinctures.

c. Skin and Body Products:

i. Topical;

ii. Transdermal.

d. Audited Product:

i. Metered Dose Nasal Spray;

ii. ~~Pressurized Metered Dose Inhaler;~~

~~iii.~~ Vaginal Administration;

i~~v~~ii. Rectal Administration.

2. Inhaled Product. The "Inhaled Product" intended use may be used only for products intended for consumption by smoking or vaping where the product is heated or burned prior to consumption, or through use of a pressurized metered dose inhaler. The label(s) on all inhaled product intended use shall also include:

a. The potency statement required by Rule ~~R 1002-1~~3-1010 for: (1) flower (including pre-rolls and Kief), (2) Solvent-Based Medical Marijuana Concentrate, (3) Solvent-Based Retail Marijuana Concentrate, (4) Water-Based Medical Marijuana Concentrate, (5) Water-Based Retail Marijuana Concentrate, (6) Heat/Pressure-Based Medical Marijuana Concentrate, (7) Heat/Pressure-Based Retail Marijuana Concentrate shall be stated as the percentage of Total THC and CBD.

b. The potency statement required by Rule ~~R 1002-1~~3-1010 for vaporizer cartridges, ~~and~~ disposable vaporizer pens, and pressurized metered dose inhalers shall be stated as either the percentage of Total THC and CBD, or the number of milligrams of Total THC and CBD, per cartridge, ~~or~~ pen, or inhaler.

3. For Oral Consumption. The label(s) on all Edible Medical Marijuana Products and Edible Retail Marijuana Products, including but not limited to confections, liquids pills, capsules and tinctures, shall also include:

a. Potency Statement. The potency statement required by Rule ~~R 1002-1~~3-1010 shall be stated as: (1) milligrams of active THC and CBD per serving and (2) milligrams of active THC and CBD per Container where the Container contains more than one serving.

b. Additional Warning Statement Required. The following additional warning statement shall be included on the label on the Container or Marketing Layer for all Edible Medical Marijuana Product and Edible Retail Marijuana Product: **"The intoxicating effects of this product may be delayed by up to 4 hours.**"

c. Expiration/Use-By Date. A product expiration date, upon which the Edible Medical Marijuana Product or Edible Retail Marijuana Product will no longer be fit for consumption, or a use-by-date, upon which the Edible Medical Marijuana Product or Edible Retail Marijuana Product will no longer be optimally fresh. Once a label with an expiration or use-by date has been affixed to a Container containing an Edible Medical Marijuana Product or Edible Retail Marijuana Product and any Marketing Layer, a Licensee shall not alter that expiration or use-by date or affix a new label with a later expiration or use-by date.

d. Production Date. The date on which the Edible Medical Marijuana Product or Edible Retail Marijuana Product was produced which may be included in the Batch Number required by Rule ~~R 1002-1~~3-1010.

e. Statement Regarding Refrigeration. If an Edible Medical Marijuana Product or Edible Retail Marijuana Product is perishable, a statement that the product must be refrigerated.

4. Skin and Body Products (Topical and Transdermal). The "Skin and Body Products" intended use may be used only for products intended for consumption by topical or transdermal application, and must be intended for external use only. The label(s) on all skin and body products shall also include:

a. Topical Product Potency Statement. For topical product the potency statement required by Rule ~~R 1002-1~~3-1010 shall be stated as the number of milligrams of active THC and CBD per Container.

b. Transdermal Product Potency Statement. For transdermal product, the potency statement required by Rule ~~R 1002-1~~3-1010 shall be stated as the number of milligrams of active THC and CBD per transdermal product, and the total number of milligrams of active THC and CBD per Container.

c. Expiration/Use-By Date. A product expiration or use-by date, after which the skin and body product will no longer be fit for use. Once a label with an expiration or use-by date has been affixed to any Container holding a skin and body product and any Marketing Layer, a Licensee shall not alter that expiration or use-by date or affix a new label with a later expiration or use-by date.

d. Production Date. The date on which the skin and body product was produced which may be included in the Batch Number required by Rule ~~R 1002-1~~3-1010.

5. Audited Product. Packaging and labeling for all Audited Products: (i) metered dose nasal spray, (ii) ~~pressurized metered dose inhaler, (iii)~~ vaginal administration, or (i~~v~~ii) rectal administration shall include:

a. All packaging and labeling requirements required by ~~these R 1000-1 Rules~~this 3-1000 Series for Regulated Marijuana Products; except Rule ~~R~~ 607 controls where the context otherwise clearly requires.

b. Audited Product shall be packaged and labeled for Transfer to a patient or consumer prior to Transfer from a Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer.

c. Expiration/Use-By Date. A product expiration date that is appropriate for the Audited Product when stored at room temperature as verified by testing required by Rule ~~R~~ 607. Once a label with an expiration date has been affixed to a

Container containing and Audited Product, a Licensee shall not alter that expiration date, or affix a new label with a later expiration date.

d. Production Date. The date on which the Audited Product was produced, which may be included in the Batch Number required by Rule ~~R 1002-1~~3-1010.

C. No Other Intended Use Permitted. No intended use other than those identified in this Rule shall be identified on any label, except as permitted by an Alternative Use Designation approved by the State Licensing Authority pursuant to Rule ~~R~~ 607. Licensees shall accurately identify all intended use(s) from the exclusive list of intended uses in this Rule, or as required by the Alternative Use Designation, on the label.

1. Alternative Use Product. No Regulated Marijuana Business shall Transfer or accept an Alternative Use Product unless the Alternative Use Product received an Alternative Use Designation in accordance with Rule ~~R~~ 607 and complied with all the requirements of Rules ~~R~~ 607 and R ~~1001-1~~3-1005 through ~~1003-1~~3-1015, and with any additional packaging and labeling requirements identified in the Alternative Use Designation. At a minimum the label(s) on all Alternative Use Products shall include:

a. All packaging and labeling requirements applicable to the Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer by these ~~Rules R 1000-1~~3-1000 Series Rules unless inconsistent with the Alternative Use Designation in which case the Alternative Use Designation shall control.

b. Expiration/Use-By Date. A product expiration date that is appropriate for the Alternative Use Product when stored at room temperature as verified by a Medical Marijuana Testing Facility or Retail Marijuana Testing Facility. Once a label with an expiration date has been affixed to a Container containing Alternative Use Product, a Licensee shall not alter that expiration date, or affix a new label with a later expiration date.

c. Production Date. The date on which the Alternative Use Product was produced, which may be included in the Batch Number required by Rule ~~R 1002-1~~3-1010.

d. All other requirements identified by the Alternative Use Designation.

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

Part 4 – Regulated Marijuana Testing Program

4-110 – Regulated Marijuana Testing Program: Sampling Procedures

D. Industrial Hemp Product Sampling Procedures. Absent sampling and testing standards established by the Colorado Department of Public Health and Environment for the sampling and testing of Industrial Hemp Product, a Person Transferring an Industrial Hemp Product to a Licensee pursuant to the Marijuana Code and these Rules shall comply with the sampling and testing standards set forth in these 4-100 Series Rules – Regulated Marijuana Testing Program and as required by these Rules.

4-115 – Regulated Marijuana Testing Program: Sampling and Testing Program

D. Permissible Levels of Contaminants. If Regulated Marijuana or Regulated Marijuana Product is found to have a contaminant in levels exceeding those established as permissible under this Rule, then it shall be considered to have failed contaminant testing. Notwithstanding the permissible levels established in this Rule, the Division reserves the right to determine, upon good cause and reasonable grounds, that a particular Test Batch presents a risk to the public health or safety and therefore shall be considered to have failed a contaminant test.

1. Microbials (Bacteria, Fungus)

Substance	**Acceptable Limits Per Gram**	**Product to be Tested**
–Shiga-toxin producing Escherichia coli (STEC)*- Bacteria	< 1 Colony Forming Unit (CFU)	Regulated Marijuana Flower and trim; ~~Retail~~ Regulated Marijuana Products (other than Audited Product); Water-Based, Heat/Pressure-Based, and Food-Based Medical Marijuana Concentrate; Water-Based, Heat/Pressure-Based, and Food-Based Retail Marijuana Concentrate; Industrial Hemp Products
Salmonella species* – Bacteria	< 1 Colony Forming Unit (CFU)	
Total Yeast and Mold	< 10^4 Colony Forming Unit (CFU)	
	≤10^1 cfu/ml or ≤10^1 cfu/g	Pressurized metered dose inhaler; Vaporizer delivery device; Audited Product: administration by metered dose nasal spray~~, pressurized metered dose inhaler,~~ or vaginal administration
	≤10^2 cfu/ml or ≤10^2 cfu/g	Audited Product: rectal administration
Total aerobic microbial count	≤10^2 cfu/ml or ≤10^2 cfu/g	Pressurized metered dose inhaler; Vaporizer delivery device; Audited Product: administration by metered dose nasal spray~~, pressurized metered dose inhaler,~~ or vaginal administration
	≤10^3 cfu/ml or ≤10^3 cfu/g	Audited Product: rectal administration
Staphylococcus Aureus	Absent in 1 ml or 1 g	Pressurized metered dose inhaler; Vaporizer delivery device; Audited Product: administration by metered dose nasal spray~~, pressurized metered dose inhaler,~~ or vaginal administration

Pseudomonas aeruginosa	Absent in 1 ml or 1 g	Pressurized metered dose inhaler; Vaporizer delivery device; Audited Product: administration by metered dose nasal spray~~, pressurized metered dose inhaler,~~ or vaginal administration
Bile tolerant gram negative bacteria	Absent in 1 ml or 1 g	Pressurized metered dose inhaler; Vaporizer delivery device; Audited Product: administration by metered dose nasal spray ~~or pressurized metered dose inhaler~~
Candida albicans	Absent in 1 ml or 1 g	Audited Product: vaginal administration

*The Medical Marijuana Testing Facility or Retail Marijuana Testing Facility shall contact the Colorado Department of Public Health and Environment when STEC and Salmonella are detected beyond the acceptable limits.

2. Mycotoxins

Substance	**Acceptable Limits Per Gram**	**Product to be Tested**
Aflatoxins (B1, B2, G1, and G2)	< 20 parts per billion (PPB) (total of B1 + B2 + G1 + G2)	Solvent-Based Medical Marijuana Concentrate manufactured from Medical Marijuana flower or trim that failed microbial testing; Solvent-Based Retail Marijuana Concentrate manufactured from Retail Marijuana flower or trim that failed microbial testing
Ochratoxin A	< 20 parts per billion (PPB)	

3. Residual Solvents

Substance	**Acceptable Limits Per Gram**	**Product to be Tested**
Acetone	< 1,000 Parts Per Million (PPM)	Solvent-Based Medical Marijuana Concentrate; Solvent-Based Retail Marijuana Concentrate; Industrial Hemp Product
Butanes	< 1,000 Parts Per Million (PPM)	
Ethanol***	< 1,000 Parts Per Million (PPM)	
Heptanes	< 1,000 Parts Per Million (PPM)	
Isopropyl Alcohol	< 1,000 Parts Per Million (PPM)	
Propane	< 1,000 Parts Per Million (PPM)	
Benzene**	< 2 Parts Per Million (PPM)	

Toluene**	< 180 Parts Per Million (PPM)	
Pentane	< 1,000 Parts Per Million (PPM)	
Hexane**	< 60 Parts Per Million (PPM)	
Total Xylenes (m,p, o-xylenes)**	< 430 Parts Per Million (PPM)	
Any other solvent not permitted for use pursuant to Rules 5-315 and 6-315 ~~R 605~~.	None Detected	

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

***Note: Solvent-Based Medical Marijuana Concentrate and Solvent-Based Retail Marijuana Concentrate that exceeds the acceptable limit for ethanol may only be used in Medical Marijuana Concentrate or Medical Marijuana Product, or Retail Marijuana Concentrate or Retail Marijuana Product, which intended use is oral consumption, skin and body products, or Audited Product .

4. Metals

Substance	**Acceptable Limits Per Gram Based on Intended Use**	**Product to be Tested**
Metals (Arsenic, Cadmium, Lead and Mercury)	**Inhaled Product or Audited Product: administration by metered dose nasal spray ~~or pressurized metered dose inhaler~~** Lead – Max Limit: < .5 ppm Arsenic – Max Limit: < 0.2 ppm Cadmium – Max Limit: < 0.2 ppm Mercury – Max Limit: < 0.1 ppm	Regulated Marijuana Flower and trim; Water-Based, Food-Based, Heat/Pressure-Based, and Solvent-Based Medical Marijuana Concentrate; Water-Based, Food-Based, Heat/Pressure-Based Retail Marijuana Concentrate; ~~Retail~~ Regulated Marijuana Product; Pressurized Metered Dose Inhaler; Vaporizer delivery device; Audited Product
	Topical and/or Transdermal Lead – Max Limit: < 10 ppm Arsenic – Max Limit: < 3 ppm Cadmium – Max Limit: < 3 ppm Mercury – Max Limit: < 1 ppm	
	Oral Consumption or Audited Product: rectal or vaginal administration Lead – Max Limit: < 1 ppm Arsenic – Max Limit: < 1.5 ppm Cadmium – Max Limit: < 0.5 ppm Mercury – Max Limit: < 1.5 ppm	

5. Pesticides

Substance	Detection Limits	Product to be Tested
Abamectin (Avermectins: B1a & B1b)	< 0.07 Parts Per Million (PPM)	~~Retail~~ Regulated Marijuana flower and trim
Azoxystrobin	< 0.02 Parts Per Million (PPM)	

Bifenazate	< 0.02 Parts Per Million (PPM)	
Etoxazole	< 0.01 Parts Per Million (PPM)	
Imazalil	< 0.04 Parts Per Million (PPM)	
Imidacloprid	< 0.02 Parts Per Million (PPM)	
Malathion	< 0.05 Parts Per Million (PPM)	
Myclobutanil	< 0.04 Parts Per Million (PPM)	
Permethrin (mix of isomers)	< 0.04 Parts Per Million (PPM)	
Spinosad (Mixture of A and D)	< 0.06 Parts Per Million (PPM)	
Spiromesifen	< 0.03 Parts Per Million (PPM)	
Spirotetramat	< 0.02 Parts Per Million (PPM)	
Tebuconazole	< 0.01 Parts Per Million (PPM)	

6. Other Contaminants

Pesticide	If the Test Batch is found to contain banned prohibited Pesticide not listed in Paragraph (5) above, or the improper application of a permitted Pesticide, then that Test Batch shall be considered to have failed contaminant testing.
Chemicals	If the Test Batch is found to contain levels of any chemical that could be toxic if consumed or as applied, then the Division may determine that the Test Batch has failed contaminant testing.
Microbials	If the Test Batch is found to contain levels of any microbial that could be toxic if consumed or present, then the Division may determine that the Test Batch has failed contaminant testing.
Metals	If the Test Batch is found to contain levels of any metal that could be toxic if consumed or present then the Division may determine that the Test Batch has failed contaminant testing.

4-120 – Regulated Marijuana Testing Program: Contaminant Testing

E. Exemptions.

1. Medical Marijuana Concentrate.

a. A Medical Marijuana Products Manufacturer who combines multiple Production Batches of Solvent-Based Medical Marijuana Concentrate into a Production Batch of Solvent-Based Medical Marijuana Concentrate shall be considered exempt from residual solvent testing pursuant to this Rule and the 4-100 Series Rules only if all original Production Batches passed residual solvent testing. This does not apply if a solvent was introduced during the combination of the Production Batches.

b. A Production Batch of Medical Marijuana Concentrate shall be considered exempt from this Rule if the Medical Marijuana Products Manufacturer that produced it does not Transfer any portion of the Production Batch and uses the

entire Production Batch to manufacture Medical Marijuana Product, except that a Solvent-Based Medical Marijuana Concentrate must still be submitted for residual solvent contaminant testing. The manufactured Medical Marijuana Product shall be subject to mandatory testing under this Rule.

2. Retail Marijuana Concentrate.

a. A Retail Marijuana Products Manufacturer who combines multiple Production Batches of Solvent-Based Retail Marijuana Concentrate into a Production Batch of Solvent-Based Retail Marijuana Concentrate shall be considered exempt from residual solvent testing pursuant to this Rule and the 4-100 Series Rules only if all original Production Batches passed residual solvent testing. This does not apply if a solvent was introduced during the combination of the Production Batches.

b. A Production Batch of Retail Marijuana Concentrate shall be considered exempt from this Rule if the Retail Marijuana Products Manufacturer that produced it does not Transfer any portion of the Production Batch and uses the entire Production Batch to manufacture Retail Marijuana Product, except that a Solvent-Based Retail Marijuana Concentrate must still be submitted for residual solvent contaminant testing. The manufactured Retail Marijuana Product shall be subject to testing under this Rule.

4-125 – Regulated Marijuana Testing Program: Potency Testing

G. Exemption.

1. Medical Marijuana Allocated For Extraction. Any Medical Marijuana that will be allocated for extraction in the Inventory Tracking System shall be considered exempt from potency testing pursuant to this Rule and the 4-100 Series Rules.

2. Retail Marijuana Allocated for Extraction. Any Retail Marijuana that will be allocated for extraction in the Inventory Tracking System shall be considered exempt from potency testing pursuant to this Rule and the 4-100 Series Rules

Part 5 – Medical Marijuana Business License Types

5-100 Series – Medical Marijuana Stores

5-105 – Medical Marijuana Store: License Privileges

G. Performance-Based Incentives. A Medical Marijuana Store may compensate its employees using performance-based incentives, including sales-based performance-based incentives.

H. Authorized Transfers of Industrial Hemp Products. Effective July 1, 2020, a Medical Marijuana Store may Transfer Industrial Hemp Product to a patient only after it has confirmed:

1. That all Industrial Hemp Product has passed all required testing pursuant to the 4-100 Series Rules at a Medical Marijuana Testing Facility; and

2. That the Person Transferring the Industrial Hemp Product to the Medical Marijuana Store is registered with the Colorado Department of Public Health and Environment pursuant to section 25-5-426, C.R.S.

5-115 – Medical Marijuana Sales: General Limitations or Prohibited Acts

C. ~~Quantity Limitations On Transfers~~Sales Limitations. ~~During a single transaction to a patient, a Medical Marijuana Store and its employees are prohibited from Transferring:~~

1. ~~More than two ounces of Medical Marijuana unless the patient has designated the Medical Marijuana Store as his or her primary center and supplied it with documentation from the patient's physician allowing the patient more than two ounces of Medical Marijuana;~~.A Medical Marijuana Store and its employees shall not sell to a patient in a single business day, individually or in any combination:

   a. More than two ounces of medical marijuana flower;

   b. 40 grams of Medical Marijuana Concentrate; or

   c. Medical Marijuana Products containing a combined total of 20,000 mg.

2. Exception. A Medical Marijuana Store may sell Medical Marijuana flower in an amount that exceeds the sales limitation in subparagraph (C)(1) of this Rule only to a patient who has a physician recommendation for more than two ounces of Medical Marijuana flower and is registered with the Medical Marijuana Store.~~More than the patient's extended ounce count to a patient who designated the Medical Marijuana Store as his or her primary center and supplied it with documentation from the patient's physician allowing the patient more than two ounces of Medical Marijuana;~~

~~3. More than six Immature plants unless the patient has designated the Medical Marijuana Store as his or her primary center and supplied it with documentation from the patient's physician allowing the patient more than six plants;~~

~~4. More than half of the patient's extended plant count to a patient who has designated the Medical Marijuana Store as his or her primary center and supplied it with documentation from the patient's physician allowing the patient more than six plants.~~

~~5. More than six Medical Marijuana plant seeds unless the patient has designated the Medical Marijuana Store as his or her primary center and supplied it with documentation from the patient's physician allowing the patient more than six Medical Marijuana seeds. One Medical Marijuana plant is equivalent to one Medical Marijuana seeds.~~

~~J. Performance-Based Sales Incentives Prohibited. A Medical Marijuana Store shall not compensate its employees using performance-based sales incentives. Performance-based incentives that are not sales-based are acceptable. Examples of performance-based incentives that are not sales-based include recognition for providing quality information to patients, or the duration of the employee's employment with the Medical Marijuana Store.~~

5-120 – Point of Sale: Restricted Access Area

D. Pregnancy Warning. Medical Marijuana Stores must post, at all times and in a prominent place inside the Restricted Access Area, a warning that is at minimum three inches high and six inches wide that reads:

> **WARNING:** Using marijuana, in any form, while you are pregnant or breastfeeding passes THC to your baby and may be harmful to your baby. There is no known safe amount of marijuana use during pregnancy or breastfeeding.

5-200 Series – Medical Marijuana Cultivation Facility: License Privileges

5-205 – Medical Marijuana Cultivation Facility: License Privileges

F. Performance-Based Incentives. A Medical Marijuana Cultivation Facility may compensate its employees using performance-based incentives, including sales-based performance-based incentives. However, a Medical Marijuana Cultivation Facility may not compensate a Sampling Manager using Sampling Units. *See* Rule ~~M~~ 508 – Sampling Unit Protocols.

G. Authorized Sources of Medical Marijuana Seeds and Immature Plants. A Medical Marijuana Cultivation Facility shall only obtain Medical Marijuana seeds or Immature Plants from its own Medical Marijuana, properly Transferred Retail Marijuana cultivated at a Retail Marijuana Cultivation Facility with at least one identical Controlling Beneficial Owner, or properly transferred from another Medical Marijuana Business pursuant to the inventory tracking requirements in the~~is~~ Rule 3-800 Series~~, and as long as there is first a documented point-of-sale transaction at that Medical Marijuana Cultivation Facility's designated Medical Marijuana Store or Medical Marijuana Products Manufacturer~~.

I. Transition Permit. A Medical Marijuana Cultivation Facility may only operate at two geographical locations pursuant to Rule 2-255(D).

5-300 Series – Medical Marijuana Products Manufacturers

5-305 – Medical Marijuana Products Manufacturer: License Privileges

C. Manufacture of Medical Marijuana Product Authorized. A Medical Marijuana Products Manufacturer may manufacture, prepare, package, and label Medical Marijuana Product, whether in concentrated form or that are comprised of Medical Marijuana and other ingredients intended for use or consumption, such as Edible Medical Marijuana Products, ointments, or tinctures.

1. Industrial Hemp Product Authorized. Effective July 1, 2020, a Medical Marijuana Products Manufacturer may use Industrial Hemp Product as an ingredient in the manufacture and preparation of Medical Marijuana Product pursuant to this subparagraph (C)(1) of this Rule.

a. Prior to accepting and taking possession of any Industrial Hemp Product for use as an ingredient in a Medical Marijuana Product the Medical Marijuana Products Manufacturer shall verify the following:

i. That the Industrial Hemp Product has passed all testing required by Part 4 of these Rules at a Medical Marijuana Testing Facility; and

ii. That the Person Transferring the Industrial Hemp Product to the Medical Marijuana Products Manufacturer is registered with the Colorado Department of Public Health and Environment pursuant to section 25-5-426, C.R.S.

G. Performance-Based Incentives~~Compensation~~. A Medical Marijuana Products Manufacturer may compensate its employees using performance-based incentives, including sales-based performance-based incentives. However, a Medical Marijuana Products Manufacturer may not compensate a Sampling Manager using Sampling Units. *See* Rule ~~M~~ 606 – Sampling Unit Protocols.

5-325 – Medical Marijuana Products Manufacturer: Audited Product and Alternative Use Product

B. Audited Products – Mandatory Audit Prior to Transfer. Following submission of an independent third-party audit to the Division and to the Local Licensing Authority as required by this Rule, a Medical Marijuana Products Manufacturer may Transfer Audited Product with an intended use of: (1) metered dose nasal spray, (2) ~~pressurized metered dose inhaler, (3)~~ vaginal administration, or

(4) rectal administration to another Medical Marijuana Products Manufacturer, a Medical Marijuana Cultivation Facility that has obtained a Centralized Distribution Permit, or a Medical Marijuana Store.

D. Audited Product Requirements. Audited Product shall meet the following minimum product requirements:

1. All non-cannabis derived inactive ingredients contained in any Audited Product must be listed in, and the maximum concentration of all inactive ingredients in the final Audited Product must be less than or equal to the concentration listed in the Federal Food and Drug Administration Inactive Ingredients Database, https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm for:

   a. The inhalation route of administration for any Audited Product to be used in ~~either~~ a metered dose nasal spray ~~or a pressurized metered dose inhaler~~;

   b. The vaginal route of administration for any Audited Product to be used for vaginal administration; or

   c. The rectal route of administration for any Audited Product to be used for rectal administration.

   d. In the alternative, the State Licensing Authority, in consultation with the Colorado Department of Public Health and Environment, may approve an inactive ingredient upon a reasonable showing that such inactive ingredient has a well-established safety record for the intended route of administration. Such approval shall not be unreasonably withheld.

   e. If the Audited Product contains a fungicidal or bactericidal ingredient listed in, and with a concentration that is at or below the maximum concentration permitted in, the Federal Food and Drug Administration Inactive Ingredients Database, https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm, the Audited Product is not required to undergo microbial contaminant testing required by Rules M 712 and M 1501.

2. Required Product Development Testing. The Medical Marijuana Products Manufacturer must establish the Audited Product meets the following through independent third-party testing:

   a. The Audited Product must deliver the amount of each cannabinoid identified on the label throughout the entire volume of the Audited Product using the intended delivery device and in accordance with the instructions provided by the Medical Marijuana Products Manufacturer, as demonstrated by testing at a Medical Marijuana Testing Facility.

      i. For Audited Product with an intended use of ~~either~~ metered dose nasal spray ~~or pressurized metered dose inhaler~~, compliance with this requirement shall be established by test results verifying the delivered dose of each cannabinoid identified on the label using the methods described in The United States Pharmacopeia Physical Test and Determination Chapter 601, *Aerosols, Nasal Sprays, Metered-Dose Inhalers, and Dry Powder Inhalers*.

      ii. For Audited Product with an intended use of either vaginal administration or rectal administration, compliance with this testing requirement shall be

established by test results demonstrating that each cannabinoid identified on the label is within +/- 15% of the amount identified on the label.

b. The expiration date identified on the label of the Audited Product is appropriate when the Audited Product is stored at room temperature, as demonstrated by testing from a Medical Marijuana Testing Facility.

c. Identification of all non-cannabis derived ingredients and constituents in the Audited Product at concentrations of 1%, which verification is obtained from one or more of the following:

i. Testing by a Medical Marijuana Testing Facility;

ii. Testing by a laboratory that is ISO 17025 accredited but is not a Medical Marijuana Testing Facility, except that no Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana Product may be Transferred to such a laboratory; and/or

iii. One or more certificate(s) of analysis from the manufacturer of any ingredient or constituent included in the Audited Product.

5-400 Series – Medical Marijuana Testing Facilities

5-405 - Medical Marijuana Testing Facilities: License Privileges

C. Testing of Industrial Hemp Product Authorized.

1. A Medical Marijuana Testing Facility may accept and test samples Industrial Hemp Products.

2. Before a Medical Marijuana Testing Facility accepts a sample of Industrial Hemp Product, the Medical Marijuana Testing Facility shall verify that the Person submitting the sample is registered with the Colorado Department of Public Health and Environment pursuant to section 25-5-426, C.R.S.

3. A Medical Marijuana Testing Facility may only accept samples of Industrial Hemp Product that are tracked through the radio frequency identification-based inventory tracking system.

4. A Medical Marijuana Testing Facility shall be permitted to test Industrial Hemp Product only in the category(ies) that the Medical Marijuana Testing Facility is certified to perform testing in pursuant to Rule 5-415 – Medical Marijuana Testing Facilities: Certification Requirements.

5. A Medical Marijuana Testing Facility may provide the results of any testing performed on Industrial Hemp Product to the Person submitting the sample of Industrial Hemp Product.

6. Nothing in these rules shall be construed to require a Medical Marijuana Testing Facility to accept and/or test samples of Industrial Hemp Product.

5-410 – Medical Marijuana Testing Facilities: General Limitations or Prohibited Acts

I. Testing of Unregistered or Untracked Industrial Hemp Products Prohibited. A Medical Marijuana Testing Facility is authorized to accept or test Industrial Hemp Product only if (1) the entity

providing the Samples of Industrial Hemp Product is registered and regulated pursuant to Article 4 or Title 25, C.R.S., and (2) the Industrial Hemp Product is tracked in the Inventory Tracking System.

5-500 Series – Medical Marijuana Transporters

5-600 Series – Medical Marijuana Business Operators

5-700 Series – Marijuana Research and Development Facilities

Part 6 – Retail Marijuana Business License Types

6-100 Series – Retail Marijuana Stores

6-105 – Retail Marijuana Store: License Privileges

F. Performance-Based Incentives. A Retail Marijuana Store may compensate its employees using performance-based incentives, including sales-based performance-based incentives.

G. Authorized Transfers of Industrial Hemp Products. Effective July 1, 2020, a Retail Marijuana Store may Transfer Industrial Hemp Product to a consumer only after it has confirmed:

1. That all Industrial Hemp Product has passed all required testing pursuant to the 4-100 Series Rules at a Retail Marijuana Testing Facility; and

2. That the Person Transferring the Industrial Hemp Product to the Retail Marijuana Store is registered with the Colorado Department of Public Health and Environment pursuant to section 25-5-426, C.R.S.

6-110 – Retail Marijuana Sales: General Limitations or Prohibited Acts

~~M. A Retail Marijuana Store shall not compensate its employees using performance-based sales incentives. Performance-based incentives that are not sales-based are acceptable. Examples of performance-based incentives that are not sales-based include recognition for providing quality information to consumers, or the duration of the employee's employment with the Retail Marijuana Store.~~

6-115 – Point of Sale: Restricted Access Area

D. Pregnancy Warning. Retail Marijuana Stores must post, at all times and in a prominent place inside the Restricted Access Area, a warning that is at minimum three inches high and six inches wide that reads:

> **WARNING:** Using marijuana, in any form, while you are pregnant or breastfeeding passes THC to your baby and may be harmful to your baby. There is no known safe amount of marijuana use during pregnancy or breastfeeding.

6-200 Series – Retail Marijuana Cultivation Facilities

6-205 – Retail Marijuana Cultivation Facility: License Privileges

H. Authorized Sources of Retail Marijuana Seeds and Immature Plants. A Retail Marijuana Cultivation Facility shall only obtain Retail Marijuana seeds or Immature Plants from its own Retail Marijuana, properly Transferred Medical Marijuana cultivated at a Medical Marijuana Cultivation Facility with at least one identical Controlling Beneficial Owner, or properly transferred from

another Retail Marijuana Business pursuant to the inventory tracking requirements in ~~this Rule~~the Rule 3-800 Series.

J. Transition Permit. A Retail Marijuana Cultivation Facility may only operate at two geographical locations pursuant to Rule 2-255(D).

6-300 Series – Retail Marijuana Products Manufacturing Facilities

6-305 – Retail Marijuana Products Manufacturer: License Privileges

C. Manufacture of Retail Marijuana Product Authorized. A Retail Marijuana Products Manufacturer may manufacture, prepare, package, store, and label Retail Marijuana Product, whether in concentrated form or that are comprised of Retail Marijuana and other ingredients intended for use or consumption, such as Edible Retail Marijuana Products, ointments, or tinctures.

1. Industrial Hemp Product Authorized. Effective July 1, 2020, a Retail Marijuana Products Manufacturer may use Industrial Hemp Product as an ingredient in the manufacture and preparation of Retail Marijuana Product pursuant to this subparagraph (C)(1) of this Rule.

a. Prior to accepting and taking possession of any Industrial Hemp Product for use as an ingredient in a Retail Marijuana Product the Retail Marijuana Products Manufacturer shall verify the following:

i. That the Industrial Hemp Product has passed all testing required by Part 4 of these Rules at a Retail Marijuana Testing Facility; and

ii. That the Person Transferring the Industrial Hemp Product to the Retail Marijuana Products Manufacturer is registered with the Colorado Department of Public Health and Environment pursuant to section 25-5-426, C.R.S.

G. ~~Compensation~~Performance-Based Incentives. A Retail Marijuana Products Manufacturer may compensate its employees using performance-based incentives, including sales-based performance-based incentives. However, a Retail Marijuana Products Manufacturer may not compensate a Sampling Manager using Sampling Units. *See* Rule ~~R~~ 606 – Sampling Unit Protocols.

6-325 – Retail Marijuana Products Manufacturing Facility: Audited Product and Alternative Use Product

B. Audited Products – Mandatory Audit Prior to Transfer. Following submission of an independent third-party audit to the Division and, if applicable, to the Local Jurisdiction as required by this Rule, a Retail Marijuana Products Manufacturer may Transfer Audited Product with an intended use of: (1) metered dose nasal spray, (2) ~~pressurized metered dose inhaler, (3)~~ vaginal administration, or (34) rectal administration.

D. Audited Product Requirements. Audited Product shall meet the following minimum product requirements:

1. All non-cannabis derived inactive ingredients contained in any Audited Product must be listed in, and the maximum concentration of all inactive ingredients in the final Audited Product must be less than or equal to the concentration listed in the Federal Food and Drug Administration Inactive Ingredients Database, https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm for:

a. The inhalation route of administration for any Audited Product to be used in ~~either~~ a metered dose nasal spray ~~or a pressurized metered dose inhaler~~;

b. The vaginal route of administration for any Audited Product to be used for vaginal administration; or

c. The rectal route of administration for any Audited Product to be used for rectal administration.

d. In the alternative, the State Licensing Authority, in consultation with the Colorado Department of Public Health and Environment, may approve an inactive ingredient upon a reasonable showing that such inactive ingredient has a well-established safety record for the intended route of administration. Such approval shall not be unreasonably withheld.

e. If the Audited Product contains a fungicidal or bactericidal ingredient listed in, and with a concentration that is at or below the maximum concentration permitted in, the Federal Food and Drug Administration Inactive Ingredients Database, https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm, the Audited Product is not required to undergo microbial contaminant testing required by Rules ~~R~~ 712 and ~~R~~ 1501.

2. Required Product Development Testing. The Retail Marijuana Products Manufacturer must establish the Audited Product meets the following through independent third-party testing:

a. The Audited Product must deliver the amount of each cannabinoid identified on the label throughout the entire volume of the Audited Product using the intended delivery device and in accordance with the instructions provided by the Retail Marijuana Products Manufacturer, as demonstrated by testing at a Retail Marijuana Testing Facility.

i. For Audited Product with an intended use of ~~either~~ metered dose nasal spray ~~or pressurized metered dose inhaler~~, compliance with this requirement shall be established by test results verifying the delivered dose of each cannabinoid identified on the label using the methods described in The United States Pharmacopeia Physical Test and Determination Chapter 601, *Aerosols, Nasal Sprays, Metered-Dose Inhalers, and Dry Powder Inhalers*.

ii. For Audited Product with an intended use of either vaginal administration or rectal administration, compliance with this testing requirement shall be established by test results demonstrating that each cannabinoid identified on the label is within +/- 15% of the amount identified on the label.

b. The expiration date identified on the label of the Audited Product is appropriate when the Audited Product is stored at room temperature, as demonstrated by testing from a Retail Marijuana Testing Facility.

c. Identification of all non-cannabis derived ingredients and constituents in the Audited Product at concentrations of 1%, which verification is obtained from one or more of the following:

i. Testing by a Retail Marijuana Testing Facility;

ii. Testing by a laboratory that is ISO 17025 accredited but is not a Retail Marijuana Testing Facility, except that no Retail Marijuana, Retail Marijuana Concentrate, or Retail Marijuana Product may be Transferred to such a laboratory; and/or

iii. One or more certificate(s) of analysis from the manufacturer of any ingredient or constituent included in the Audited Product.

6-400 Series – Retail Marijuana Testing Facilities

6-405 – Retail Marijuana Testing Facilities: License Privileges

F. Testing of Industrial Hemp Product Authorized.

1. A Retail Marijuana Testing Facility may accept and test samples Industrial Hemp Products.

2. Before a Retail Marijuana Testing Facility accepts a sample of Industrial Hemp Product, the Retail Marijuana Testing Facility shall verify that the Person submitting the sample is registered with the Colorado Department of Public Health and Environment pursuant to section 25-5-426, C.R.S.

3. A Retail Marijuana Testing Facility may only accept samples of Industrial Hemp Product that are tracked through the radio frequency identification-based inventory tracking system.

4. A Retail Marijuana Testing Facility shall be permitted to test Industrial Hemp Product only in the category(ies) that the Retail Marijuana Testing Facility is certified to perform testing in pursuant to Rule 6-415 – Retail Marijuana Testing Facilities: Certification Requirements.

5. A Retail Marijuana Testing Facility may provide the results of any testing performed on Industrial Hemp Product to the Person submitting the sample of Industrial Hemp Product.

6. Nothing in these rules shall be construed to require a Retail Marijuana Testing Facility to accept and/or test samples of Industrial Hemp Product.

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

H. Testing of Unregistered or Untracked Industrial Hemp or Industrial Hemp Products Prohibited.

1. A Retail Marijuana Testing Facility is authorized to accept or test Industrial Hemp only if (1) the entity providing the Samples of Industrial Hemp is regulated by Article 61 of Title 35, C.R.S., (2) the Industrial Hemp is submitted by a registered cultivator, and (3) the Industrial Hemp is tracked through the radio frequency identification-based inventory tracking system approved by the Commissioner of the Colorado Department of Agriculture, pursuant to section 35-61-105.5, C.R.S.

2. A Retail Marijuana Testing Facility is authorized to accept or test Industrial Hemp Product only if (1) the entity providing the Samples of Industrial Hemp Product is registered and regulated pursuant to Article 4 or Title 25, C.R.S., and (2) the Industrial Hemp Product is tracked in the Inventory Tracking System.

6-500 Series – Retail Marijuana Transporters

6-600 Series – Retail Marijuana Business Operators

6-700 Series – Marijuana Hospitality Businesses

6-800 Series – Retail Marijuana Hospitality and Sales Businesses

6-900 Series – Retail Marijuana Accelerator Cultivators

6-1000 Series – Retail Marijuana Accelerator Manufacturers

Part 7 – Regulated Marijuana Transfers to Unlicensed Medical Research Facilities and Pesticide Manufacturers

Part 8 – Enforcement and Discipline

8-100 Series - Enforcement

8-200 Series - Discipline

PROPOSED REORGANIZATION OF COLORADO MARIJUANA RULES

1 CCR 212-3

September 13, 2019

Part 1 – GENERAL APPLICABILITY

- 1-105 – Engaging in Business
- 1-110 – Severability
- 1-115 – Definitions
- 1-120 – Declaratory Orders Concerning the Marijuana Code
- 1-125 – Computation of Time
- 1-130 – Subpoena Fees
- 1-135 – Instructions for Local Licensing Authorities and Local Jurisdictions
- 1-140 – Local Law Enforcement's Authority Not Impaired by Marijuana Code

Part 2 – LICENSING AND INTERESTS

- 2-100 SERIES - Applicability
  - 2-105 – Applicability
- 2-200 SERIES – Applications and License Rules
  - 2-205 – Fees
  - 2-210 – Duties of All Applicants and Licensees
  - 2-215 – All Applications Requirements
  - 2-220 – Initial Application Requirements for Regulated Marijuana Businesses
  - 2-225 – Renewal Application Requirements for All Licensees
  - 2-230 – Disclosure of Financial Interests in a Regulated Marijuana Business
  - 2-235 – Suitability
  - 2-240 – Factors Considered in Determining Reasonable Cause for Disclosure, Finding of Suitability, and Extension of 120 Day Deadline for Finding of Suitability
  - 2-245 – Change of Controlling Beneficial Owner Application or Notification
  - 2-250 – Regulated Marijuana Business that is a Publicly Traded Corporation – Notification of Non-Confidential Securities Filings
  - 2-255 – Change of Location of a Regulated Marijuana Business
  - 2-260 – Changing, Altering, or Modifying Licensed Premises
  - 2-265 – Owner and Employee License: License Requirements, Applications, Qualifications, and Privileges
  - 2-270 – Application Denial and Voluntary Withdrawal
  - 2-275 – Temporary Appointee Registrations for Court Appointees
  - 2-280 – Controlling Beneficial Owners that are Persons Prohibited, Unsuitable, Revoked, or Suspended; At Least One Controlling Beneficial Owner Holding a Valid Owner License Required; and Prohibited Third-Party Acts

Part 3 – REGULATED MARIJUANA BUSINESS OPERATIONS

- 3-100 SERIES – General Privileges and Limitations
  - 3-105 – Regulated Marijuana Businesses: Privileges Granted
  - 3-110 – Consumption Prohibited
  - 3-115 – Transporter Transfer Restrictions
- 3-200 SERIES – Licensed Premises
  - 3-205 – Limited Access Areas

- 3-210 – Possession of Licensed Premises
- 3-215 – Regulated Marijuana Businesses – Shared Licensed Premises and Operational Separation
- 3-220 – Security Alarms and Lock Standards
- 3-225 – Video Surveillance
- 3-230 – Waste Disposal
- 3-235 – Transfer of Fibrous Waste
- 3-240 – Marijuana Consumer Waste
- 3-245 – Selling and Serving Regulated Marijuana
- 3-250 – Accelerator Endorsements

- 3-300 SERIES – Health & Safety Regulations
  - 3-305 – Local Safety Inspections
  - 3-310 – General Sanitary Requirements
  - 3-315 – Independent Health and Safety Audit
  - 3-320 – Contaminated Product
  - 3-325 – Prohibited Chemicals
  - 3-330 – Cultivation of Regulated Marijuana: Specific Health and Safety Requirements
  - 3-335 – Production of Regulated Marijuana Products: Specific Health and Safety Requirements
  - 3-340 – Violation Affecting Public Safety
- 3-400 SERIES – Acceptable Forms of Identification for Regulated Marijuana Sales
  - 3-405 – Identification
- 3-500 SERIES – Responsible Vendor Program
  - 3-505 – General Standards for a Regulated Marijuana Business Designated A Responsible Vendor
  - 3-510 – General Standards for Responsible Vendor Program Provider
  - 3-515 – Certification Training Program Standards
  - 3-520 – Certification Training Class Core Curriculum
- 3-600 SERIES – Transport and Storage
  - 3-605 – Transport: All Regulated Marijuana Businesses
  - 3-610 – Off-Premises Storage of Regulated Marijuana and Regulated Marijuana Product: All Regulated Marijuana Businesses
  - 3-615 – Regulated Marijuana Delivery Permits
- 3-700 SERIES – Signage & Advertising
  - 3-705 – Advertising General Requirement: No Deceptive, False, or Misleading Statements
  - 3-710 – The Term “Minor” as Used in the Marijuana Code and These Rules
  - 3-715 – Advertising: Television
  - 3-720 – Advertising: Radio
  - 3-725 – Advertising: Print Media
  - 3-730 – Advertising: Internet
  - 3-735 – Advertising: Targeting Out-of-State Persons Prohibited
  - 3-740 – Signage and Advertising: No Safety Claims Because Regulated by State Licensing Authority
  - 3-745 – Signage and Advertising: No Safety Claims Because Tested by a Medical Marijuana Testing Facility or Retail Marijuana Testing Facility
  - 3-750 – Signage and Advertising: Outdoor Advertising
  - 3-755 – Signage and Advertising: No Content That Targets Minors
  - 3-760 – Advertising: Advertising via Marketing Directed Toward Location-Based Devices
  - 3-765 – Pop-Up Advertising
  - 3-770 – Advertising: Event Sponsorship
- 3-800 SERIES – Inventory Tracking Requirements

- 3-805 – Regulated Marijuana Businesses: Inventory Tracking System
- 3-810 – Minimum Tracking Requirements
- 3-815 – Transport Manifest Required
- 3-820 – Input into Inventory Tracking System Required
- 3-825 – Inventory Must Be Reconciled Daily
- 3-830 – Sampling Unit Tracking Requirements
- 3-835 – Medical Marijuana Testing Facilities and Retail Marijuana Testing Facilities: Specific Tracking Requirements

- 3-900 SERIES – Business Records
  - 3-905 – Business Records Required
  - 3-910 – Reporting and Transmittal of Taxes
  - 3-915 – Independent Audit May Be Required
  - 3-920 – Regulated Marijuana Business Reporting Requirements
  - 3-925 – Department Information Access
- 3-1000 SERIES – Labeling, Packaging, and Product Safety
  - 3-1005 – Packaging and Labeling: Minimum Requirements Prior to Transfer to a Regulated Marijuana Business
  - 3-1010 – Packaging and Labeling: General Requirements Prior to Transfer to a Patient or Consumer
  - 3-1015 – Additional Labeling Requirements Prior to Transfer to a Patient or Consumer

Part 4 – REGULATED MARIJUANA TESTING PROGRAM

- 4-105 – Regulated Marijuana Testing Program: Mandatory Testing
- 4-110 – Regulated Marijuana Testing Program: Sampling Procedures
- 4-115 – Regulated Marijuana Testing Program: Sampling and Testing Program
- 4-120 – Regulated Marijuana Testing Program: Contaminant Testing
- 4-125 – Regulated Marijuana Testing Program: Potency Testing
- 4-130 – Regulated Marijuana Testing Program: Costs
- 4-135 – Regulated Marijuana Testing Program: Contaminated Product and Failed Test Results

Part 5 – MEDICAL MARIJUANA LICENSE TYPES

- 5-100 SERIES – Medical marijuana stores
  - 5-105 – Medical Marijuana Store: License Privileges
  - 5-110 – Registration of a Primary Medical Marijuana Store
  - 5-115 – Medical Marijuana Sales: General Limitations and Prohibited Acts
  - 5-120 – Point of Sale: Restricted Access Area
- 5-200 SERIES – Medical marijuana cultivation facilities
  - 5-205 – Medical Marijuana Cultivation Facility: License Privileges
  - 5-210 – Medical Marijuana Cultivation Facility: General Limitations and Prohibited Acts
  - 5-215 – Medical Marijuana Cultivation Facility: Testing
  - 5-220 – Medical Marijuana Cultivation Facility: Medical Marijuana Concentrate Production
  - 5-225 – Medical Marijuana Cultivation Facility: Production Management
  - 5-230 – Sampling Unit Protocols
- 5-300 SERIES – Medical marijuana products manufacturer
  - 5-305 – Medical Marijuana Products Manufacturer: License Privileges
  - 5-310 – Medical Marijuana Products Manufacturer: General Limitations and Prohibited Acts
  - 5-315 – Medical Marijuana Products Manufacturer: Medical Marijuana Concentrate Production

- 5-320 – Sampling Unit Protocols
- 5-325 – Medical Marijuana Products Manufacturer: Audited Product and Alternative Use Product

- 5-400 SERIES – Medical marijuana testing facility
  - 5-405 – Medical Marijuana Testing Facilities: License Privileges
  - 5-410 – Medical Marijuana Testing Facilities: General Limitations and Prohibited Acts
  - 5-415 – Medical Marijuana Testing Facilities: Certification Requirements
  - 5-420 – Medical Marijuana Testing Facilities: Personnel
  - 5-425 – Medical Marijuana Testing Facilities: Standard Operating Procedure Manual
  - 5-430 – Medical Marijuana Testing Facilities: Analytical Processes
  - 5-435 – Medical Marijuana Testing Facilities: Proficiency Testing
  - 5-440 – Medical Marijuana Testing Facilities: Quality Assurance and Quality Control
  - 5-445 – Medical Marijuana Testing Facilities: Chain of Custody
  - 5-450 – Medical Marijuana Testing Facilities: Records Retention
  - 5-455 – Medical Marijuana Testing Facilities: Notification of Medical Marijuana Business
- 5-500 SERIES – Medical marijuana transporters
  - 5-505 – Medical Marijuana Transporter: License Privileges
  - 5-510 – Medical Marijuana Transporter: General Limitations and Prohibited Acts
- 5-600 SERIES – Medical marijuana business operators
  - 5-605 – Medical Marijuana Business Operator: License Privileges
  - 5-610 – Medical Marijuana Business Operator: General Limitations and Prohibited Acts
  - 5-615 – Medical Marijuana Business Operator: Employee Licenses for Personnel
  - 5-620 – Medical Marijuana Business Operator: Business Records Required
- 5-700 SERIES – Marijuana Research and Development Facilities
  - 5-705 – Marijuana Research and Development Facilities: License Privileges
  - 5-710 – Marijuana Research and Development Facilities: General Limitations and Prohibited Acts
  - 5-715 – Marijuana Research and Development Facilities: Project Approval
  - 5-720 – Marijuana Research and Development Facilities: Authorized Research Activities
  - 5-725 – Marijuana Research and Development Facilities: Testing
  - 5-730 – Marijuana Research and Development Facilities: Production Management and Possession Limits

<u>Part 6</u> – RETAIL MARIJUANA LICENSE TYPES

- 6-100 SERIES – Retail marijuana stores
  - 6-105 – Retail Marijuana Store: License Privileges
  - 6-110 – Retail Marijuana Sales: General Limitations and Prohibited Acts
  - 6-115 – Point of Sale: Restricted Access Area
- 6-200 SERIES – Retail marijuana cultivation facilities
  - 6-205 – Retail Marijuana Cultivation Facility: License Privileges
  - 6-210 – Retail Marijuana Cultivation Facility: General Limitations and Prohibited Acts
  - 6-215 – Retail Marijuana Cultivation Facility: Medical Marijuana Concentrate Production
  - 6-220 – Retail Marijuana Cultivation Facility: Production Management
  - 6-225 – Sampling Unit Protocols
- 6-300 SERIES – Retail marijuana products manufacturer
  - 6-305 – Retail Marijuana Products Manufacturer: License Privileges
  - 6-310 – Retail Marijuana Products Manufacturer: General Limitations and Prohibited Acts
  - 6-315 – Retail Marijuana Products Manufacturer: Medical Marijuana Concentrate Production
  - 6-320 – Sampling Unit Protocols
  - 6-325 – Retail Marijuana Products Manufacturer: Audited Product and Alternative Use Product

- 6-400 SERIES – Retail marijuana testing facility
    - 6-405 – Retail Marijuana Testing Facilities: License Privileges
    - 6-410 – Retail Marijuana Testing Facilities: General Limitations and Prohibited Acts
    - 6-415 – Retail Marijuana Testing Facilities: Certification Requirements
    - 6-420 – Retail Marijuana Testing Facilities: Personnel
    - 6-425 – Retail Marijuana Testing Facilities: Standard Operating Procedure Manual
    - 6-430 – Retail Marijuana Testing Facilities: Analytical Processes
    - 6-435 – Retail Marijuana Testing Facilities: Proficiency Testing
    - 6-440 – Retail Marijuana Testing Facilities: Quality Assurance and Quality Control
    - 6-445 – Retail Marijuana Testing Facilities: Chain of Custody
    - 6-450 – Retail Marijuana Testing Facilities: Records Retention
    - 6-455 – Retail Marijuana Testing Facilities: Notification of Retail Marijuana Business
- 6-500 SERIES – Retail marijuana transporters
    - 6-505 – Retail Marijuana Transporter: License Privileges
    - 6-510 – Retail Marijuana Transporter: General Limitations and Prohibited Acts
- 6-600 SERIES – Retail marijuana business operators
    - 6-605 – Retail Marijuana Business Operator: License Privileges
    - 6-610 – Retail Marijuana Business Operator: General Limitations and Prohibited Acts
    - 6-615 – Retail Marijuana Business Operator: Employee Licenses for Personnel
    - 6-620 – Retail Marijuana Business Operator: Business Records Required
- 6-700 SERIES – Retail marijuana accelerator cultivator license
    - 6-705 – Retail Marijuana Accelerator Cultivation: License Privileges
    - 6-710 – Retail Marijuana Accelerator Cultivation: General Limitations and Prohibited Acts
- 6-800 SERIES – Retail marijuana accelerator manufacturer license
    - 6-705 – Retail Marijuana Accelerator Manufacturer: License Privileges
    - 6-710 – Retail Marijuana Accelerator Manufacturer: General Limitations and Prohibited Acts
- 6-900 SERIES – Licensed Hospitality Businesses
    - 6-905 – Licensed Hospitality Businesses: General Provisions
    - 6-910 – Licensed Hospitality Businesses: Additional Health and Safety Regulations
    - 6-915 – Licensed Hospitality Businesses: Operation Within a Retail Food Establishment
    - 6-920 – Retail Marijuana Hospitality and Sales Businesses: Additional License Privileges
    - 6-925 – Retail Marijuana Hospitality and Sales Businesses: General Limitations and Prohibited Acts
    - 6-930 – Marijuana Hospitality Business: Limited Access Area
    - 6-935 – Marijuana Hospitality Business: Requirements for Mobile Licensed Premises

Part 7 – REGULATED MARIJUANA TRANSFERS TO UNLICENSED ENTITIES

- 7-105 – Medical Marijuana Transfers to Medical Research Facilities
- 7-110 – Retail Marijuana Transfers to Medical Research Facilities
- 7-115 – Pesticide Manufacturers

Part 8 – ENFORCEMENT & DISCIPLINE

- 8-100 SERIES – Enforcement
    - 8-105 – Duties of Employees of State Licensing Authority
    - 8-110 – Requirements for Inspections and Investigations, Searches, Administrative Holds, and Such Additional Activities as May Become Necessary from Time to Time
    - 8-115 – Disposition of Unauthorized Regulated Marijuana
    - 8-120 – Written Warnings and Assurances of Voluntary Compliance

- 8-125 – Investigative Subpoenas
- 8-130 – Administrative Warrants

- 8-200 SERIES – Discipline
  - 8-205 – Disciplinary Process: Non-Summary Suspension
  - 8-210 – Summary Suspension
  - 8-215 – Suspension Process: Regular and Summary Suspensions
  - 8-220 – Administrative Hearings
  - 8-225 – Administrative Subpoenas
  - 8-230 – Administrative Hearing Appeals/Exceptions to Initial Decision
  - 8-235 – Penalties
  - 8-240 – Confidential Information and Former State Licensing Authority Employees