

Comments on August 2015 Proposed Rules 1 CCR 212-1

Introduction:

Americans for Safe Access (ASA) thanks the Colorado Marijuana Enforcement Division (MED) for the opportunity to comment on the Medical Marijuana Proposed Rules 1 CCR 212-1. ASA appreciates the effort the MED appears to making on behalf of ensuring that patients have access to medicine that is tested and labeled in a beneficial manner; however, we also have concerns that many of the proposed rule changes will prove to be onerous in practice.

Regulations that impose needlessly onerous tasks on those who produce, process, test, and sell medical marijuana products ultimately harm patients by making products more costly to produce which increase the point of sale price patients must pay, and potentially can cause shortages or discontinuation of products that patients have come to rely upon for their medical therapy. The cost of medical marijuana products is of very real concern to patients because health insurance does not provide coverage for medical marijuana therapy.

Almost paradoxically, the stringent rules may not be adequately enforced. ASA is concerned that the reliance upon local licensing authorities to conduct inspections may mean that product safety rules are consistently enforced. If the state and local governments are unable to adequately perform routine product safety inspections, the Division should consider allowing for third-party certification to help alleviate this issue. While ASA supports the proposed rules to prevent state licensing employees from quitting to immediately go to work on behalf of medical marijuana industry parties, this does not address the concern regarding enforcement.

ASA offers the following specific commentary on Proposed Rules 1 CCR 212-1.

M 103 Definitions

"Immature plant" means a nonflowering Medical Marijuana plant that is no taller than eight inches and no wider than eight inches produced from a cutting, clipping or seedling and that is in a growing container that is no larger than two inches wide and two inches tall that is sealed on the sides and bottom. Plants meeting these requirements are not attributable to a licensee's maximum allowable plant count, but must be fully accounted for in the Inventory Tracking System.

Comments: This is very limiting as to what may and may not be transported. Two inch pots mean that these plants will not even be sexed should they be from seed and will

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still be required to be in cubes if they are clones. Eight inch by eight inch plants are plenty small enough for transport without concern for them having value that would encourage diversion. Even at 8" x 8" a plant grown from seed will not be showing its sex. This regulation seems needlessly burdensome and the proposed change should be deleted.

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

B. Separation of Co-located Licensed Operations

5. *Testing Facilities. A co-located Medical Marijuana Testing Facility and Retail Marijuana Testing Facility shall maintain either physical or virtual separation of the facilities and marijuana and products being tested. Record keeping for the business operations and labeling of products must enable the Division and local licensing authority to clearly distinguish the inventories and business transactions of Medical Marijuana and Medical Marijuana-Infused Product and Retail Marijuana and Retail Marijuana Product.*

Comments: The term “virtual separation” is undefined, and therefore is confusing. Without clear guidance on what virtual separation means, there is no way the testing facilities can be certain that adhering to the virtual standard. Additionally, there is no standard for regulators to determine whether or not a testing facility is abiding by the rules regarding virtual separation.

Moreover, the regulation appears to be completely unnecessary. The equipment required to run these facilities is incredibly expensive and it seems to make sense to allow cannabis testing facilities to test both adult use and medical cannabis and cannabis derived products. Patients will not be harmed if the same equipment is used to test retail and medical marijuana. The cost savings of not having to needlessly purchase expensive duplicate equipment would benefit patients. Additionally, the ban on letting Medical Marijuana Testing Facilities test industrial hemp in M 703 seems needless for similar reasons.

We recommend strike this provision, but at the very least the Division should provide clear guidance on what “virtual separation” means.

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

C.5. Product Safety.

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

1. *A Medical Marijuana-Infused Products Manufacturer that manufactures Edible Medical Marijuana-Infused Product shall create and maintain standard production procedures and detailed manufacturing processes for each Edible Medical Marijuana-*

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Infused Product it manufactures. These procedures and processes must be documented and made available on the Licensed Premises for inspection by the Division, the Colorado Department of Public Health & Environment, and local licensing authorities.

2. A Medical Marijuana-Infused Products Manufacturer may determine a standard dose of THC for each Edible Medical Marijuana-Infused Product it manufactures. If a Medical Marijuana-Infused Products Manufacturer determines a standard dose for an Edible Medical Marijuana-Infused Product, that information must be documented in the product's standard production procedure.

3. For each Edible Medical Marijuana-Infused Product, the total amount of active THC contained within the product must be documented in the standard production procedures.

4. Universal Symbol Marking Requirements.

a. The following categories of Edible Medical Marijuana-Infused Products shall be marked, stamped, or otherwise imprinted with the Universal Symbol directly on the Medical Marijuana-Infused Product in a manner to cause the Universal Symbol to be distinguishable and easily recognizable.

i. Chocolate

ii. Soft confections

iii. Hard confections or lozenges

iv. Consolidated baked goods (e.g. cookie, brownie, cupcake, granola bar)

v. Pressed pills and capsules

b. The Universal Symbol marking shall:

i. Be located in the center of the Edible Medical Marijuana-Infused Product;

ii. Be of a size that covers at least 25% of one side of the Edible Medical Marijuana-Infused Product's surface, but not less than ¼ inch by ¼ inch; and

iii. Include the word "Medical" below the Universal Symbol.

c. If a Medical Marijuana-Infused Products Manufacturer demarks each individual dose of marijuana in an Edible Medical Marijuana-Infused Product, then the Universal Symbol and the word "Medical" shall be applied to each dose and in accordance with the requirements of subparagraph (C.5)(4)(b) of this rule M 604. d. Edible Medical Marijuana-Infused Products that are liquids, loose bulk goods (e.g. granola, cereals, popcorn), or powders, are exempt from the Universal Symbol marking requirements provided that they comply with the labeling and Child-Resistant Container packaging requirements of rule M 1004.5.

5. Remanufactured Products Prohibited. A Medical Marijuana-Infused Products Manufacturer shall not utilize a commercially manufactured food product as their Edible Medical Marijuana-Infused Product. The following exceptions to this prohibition

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apply:

- a. *A food product that was commercially manufactured specifically for use by the Medical Marijuana-Infused Products Manufacturer Licensee to infuse with marijuana shall be allowed. The Licensee shall have a written agreement with the commercial food product manufacturer that declares the food product's exclusive use by the Medical Marijuana Infused Products Manufacturer.*
 - b. *Commercially manufactured food products may be used as ingredients in a Medical Marijuana-Infused Products Manufacturer's Edible Medical Marijuana-Infused Product so long as: (1) they are used in a way that renders them unrecognizable as the commercial food product in the final Edible Medical Marijuana-Infused Product, and (2) the Medical Marijuana-Infused Products Manufacturer does not state or advertise to the consumer that the final Edible Medical Marijuana-Infused Product contains the commercially manufactured food product.*
6. *Trademarked Food Products. Nothing in this rule alters or eliminates a Medical Marijuana-Infused Products Manufacturer's responsibility to comply with the trademarked food product provisions required by the Medical Code per 12-43.3-404(11)(a-c), C.R.S.*

Comments: Generally speaking there is nothing wrong with having some sort of explicit notification on packaging to indicate that a produce contains THC. However, we are concerned with the way concept is being applied, and it may create difficulty and expense. Adding the labeling to each individual dose seems redundant and potentially difficult for manufacturers to implement. ASA recommends striking the individual dose demarcation requirements and recommends changing the background color from red (which is associated with stopping) to yellow (which is associated with proceed intelligently with appropriate caution).

M 704 – Medical Marijuana Testing Facilities: Personnel

- A. 2. *The laboratory director for a Medical Marijuana Testing Facility must meet one of the following qualification requirements:*
 - a. *The laboratory director must be a Medical Doctor (M.D.) licensed to practice medicine in Colorado and have at least three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body; or*
 - b. *The laboratory director must hold a doctoral degree in one of the natural sciences and have at least three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body; or*

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C. *The laboratory director must hold a master’s degree in one of the natural sciences and have at least five years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body.*

D. *Supervisory Analyst. Supervisory analysts must meet one of the qualifications for a laboratory director or have at least a bachelor’s degree in one of the natural sciences and three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body. A combination of education and experience may substitute for the three years of full-time laboratory experience.*

E. *Laboratory Testing Analyst*

1. *Educational Requirements. An individual designated as a testing analyst must meet one of the qualifications for a laboratory director or supervisory analyst or have at least a bachelor’s degree in one of the natural sciences and one year of full-time experience in laboratory testing.*

Comments:

ASA supports well-trained staff and directors however, this seems like a very high standard that has overly broad perimeters that could have unintended consequences. These are very rigid requirements for lab directors, supervisory analysts and testing analysts, but again creates an issue with undefined terms in the explicit requirements. The term “regulated laboratory environment” is not defined, is a university lab a “regulated laboratory environment”? If so, how will someone coming out of that environment, research dominate, qualify as having worked in a lab ...”in which methods were recognized by an accrediting body.” It is worth considering that testing reports used by the government are not generated using third party (accrediting body) validated methodology. These overly onerous requirements would exclude most cannabis experts coming out of academic careers such as Arno Hazekamp.

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

4. *Failed Potency Tests for Medical Marijuana Infused-Product*

a. *If the THC content of a Medical Marijuana Infused-Product is determined through testing not to be homogenous, then it shall be considered to have failed potency testing. A Medical Marijuana Infused-Product shall be considered not to be homogenous if 10% of the infused portion of the Medical Marijuana Infused-Product contains more than 20% of the total THC contained within entire Medical Marijuana Infused-Product.*

Comments: It seems unclear what homogenous means in the context of this regulation.

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For example, how can a brownie with nuts be homogeneous? If taking "10% of the infused products" means taking 1/10th of the product for testing, and if that 1/10th of the product is sampled and to have more than 20% of the expected value than under this rule it would be considered not to be homogenous. The primary concern with this language is that its specificity will encourage improper sampling techniques resulting in workarounds to pass this type of test. Additionally, this may be redundant with 10mg caps on products. We recommend striking this provision.

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

B., 1., a. A complete list of all non-organic pesticides, fungicides, and herbicides used during the cultivation of the Medical Marijuana.

Comments: CO has approved over 100 tolerance exempt pesticide products for use in the commercial production of cannabis plus 11 pesticide products that are not tolerance exempt. If these products were required to be labeled, then in the case of an adverse event/reaction there would be tracking available to document the connection. ASA recommends that this be changed to require the labeling of all non-tolerance exempt pesticides, fungicides, and herbicides used during cultivation. Note: this statement appears throughout the document and is a required labeling statement on all medical cannabis and medical cannabis infused products.

M 1501 – Medical Marijuana Testing Program – Contaminant Testing

B. Validation of Process – Contaminant Testing

1. Medical Marijuana. An Optional Premises Cultivation Operation’s cultivation process shall be deemed valid regarding Contaminants if every Harvest Batch that it produced during at least a six week period but no longer than a 12 week period passed all contaminant tests required by paragraph C of this rule. This must include at least 6 Test Batches that contain Samples from entirely different Harvest Batches.

Comments: Clarification is sought for what is means by, "produced during at least a six week period but no longer than a 12 week period". Does this period of time include plant growth or does it begin at the time of harvest? Beyond that, what happens if the crop needs to be sold from the cultivator to the manufacturer, say for fresh concentrate or juice production, before the 6 week period? This regulation needs further clarification or should be modified to take into account these considerations.

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