COLORADO
Department of Revenue
Enforcement Division - Marijuana
1707 Cole Blvd., Suite 300
Lakewood, CO 80401

December 18, 2017

INDUSTRY-WIDE BULLETIN: 17-09

RE: MEDICAL AND RETAIL RULES EFFECTIVE JANUARY 1, 2018 – REQUIRED TESTING

Dear Marijuana Industry Stakeholders:

Medical and Retail Marijuana Rules effective January 1, 2018, reflect several changes to testing requirements in the Medical (M) and Retail (R) 700 and 1500 Series rules. This Industry-wide Bulletin highlights several of those changes; however, Licensees should review all changes to these rules in advance of January 1, 2018 (available at: https://www.colorado.gov/pacific/enforcement/2017-med-rulemaking).

Samples and Test Batches (Rules M and R 1504, 1 CCR 212-1 and 1 CCR 212-2):

Amendments to Rules M and R 1504(A)(1) require Licensees to follow specific Sample collection protocols when submitting Test Batches for testing pursuant to Medical and Retail Marijuana Rules M and R 1501, 1503, and 1507. Those protocols will be published in the Colorado Department of Public Health and Environment's (CDPHE) Reference Library (found at https://tinyurl.com/y8p86vu3) by Wednesday, December 27, 2018.

In addition, under Rules M and R 1504 (B)(1-4), Samples that comprise a Test Batch must meet minimum size or amount requirements based on the category of marijuana and size of the Harvest or Production Batch from which a Sample was collected. The Samples collected may be composited into a single physical package and submitted as a single Test Batch. That single Test Batch may be submitted for multiple required tests. However, multiple Harvest or Production Batches may not be combined into a single Test Batch. The following scenario offers an example of compliant Sample collection and Test Batch submission for microbial contaminant and potency testing:

- A Retail Marijuana Cultivation (RMC) Licensee creates two Harvest Batches, each containing a different strain and each yielding five pounds of usable Retail Marijuana. Pursuant to Rules R 1501 and 1503, the RMC is required to subject both Harvest Batches to microbial contaminant testing and potency testing. The RMC will approach each Harvest Batch individually, by collecting from each Harvest Batch a minimum of eight separate, 0.5 gram, Samples of Retail Marijuana, following the protocols in the Reference Library. As a result, the RMC will possess two separate Test Batches, each weighing no less than four grams and reported on its own individual Metrc® package tag. The RMC may submit both Test Batches, one representing each Harvest Batch, to a licensed Retail Marijuana Testing Facility, for potency and microbial contaminant testing on each Test Batch. Accordingly, the Retail Marijuana Testing Facility will receive two separate Test Batches, each weighing four grams, each on their own Metrc® tag, to conduct a total of four tests.

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Ongoing Testing Following Process Validation (Rules M and R 1501 and 1503, 1 CCR 212-1 and 1 CCR 212-2):

Amendments to Rules M and R 1501 and 1503 increase the frequency of required testing for Licensees that have achieved process validation.

- Contaminant Testing Once Every 30 Days: Under Rules M and R 1501 (B)(4)-(5), Licensees that have achieved process validation must, at a minimum of once every 30 days, submit a single Test Batch representing a Harvest Batch and/or Production Batch for contaminant testing. Regardless of the number of Harvest and/or Production Batches that a Licensee possesses, if process validation is achieved, one Test Batch must be submitted for contaminant testing every 30 days. If during any 30-day window a Harvest or Production Batch is not available for testing, the next Harvest or Production Batch created must be subject to contaminant testing.

- Potency Testing Once Per Quarter: Under Rules M and R 1503 (B)(2) and (E)(4), Licensees that have achieved process validation must, at a minimum of once every quarter, submit a single Test Batch for each Medical and Retail Marijuana strain cultivated and each type of Medical Marijuana-Infused Product or Retail Marijuana Product produced for potency testing. If during any quarter a Harvest Batch for each strain or Production Batch for each type of Medical Marijuana-Infused Product or Retail Marijuana Product is not available for testing, the next Harvest Batch or Production Batch created for that strain or product must be subject to potency testing.

Residual Solvent Acceptable Limits (Rules M and R 712, 1 CCR 212-1 and 1 CCR 212-2):

Amendments to Rules M and R 712 (E)(3) change the acceptable limits of residual solvents that may be present in a Solvent-Based Concentrate.

- New Limits Apply February 1, 2018: Please note that Licensees will have until February 1, 2018 to comply with the new acceptable limits. This is intended to provide adequate time for Medical and Retail Testing Facilities to obtain required certification under the new acceptable limits, from which CDPHE and MED can verify that Testing Facilities are able to detect solvents at these limits. Until February 1, 2018, the current acceptable limits for required residual solvent testing will remain applicable and subject to enforcement.

- Required Re-Validation of Process for Retail Marijuana Products Manufacturing Facilities: Unless the new acceptable residual solvent limits results in a Material Change, a Retail Marijuana Products Manufacturing Facility that has achieved process validation need only subject the first three Production Batches of Solvent-Based Concentrates to residual solvent contaminant testing in order to maintain its process validation. However, if the new acceptable residual solvent limits requires a substantive revision to a Retail Marijuana Products Manufacturing Facility's

standard operating procedures for the production of Retail Marijuana Concentrate, this constitutes a Material Change requiring compliance with the procedures in Rule R 1501 (F)(1) in order to maintain process validation. This will require a Retail Marijuana Products Manufacturing Facility to subject two additional Production Batches of Solvent-Based Concentrate to residual solvent contaminant testing.

Mandatory Medical Microbial Contaminant and Residual Solvent Contaminant Testing Required Beginning February 1, 2018 (Rule M 1501, 1 CCR 212-1):

Proficiency testing for microbial contaminant and residual solvent contaminant testing has been established in all marijuana categories for all licensed Retail and Medical Marijuana Testing Facilities that are certified to test in those testing categories. To view which Testing Facilities have been certified in potency testing, please visit this webpage: https://www.colorado.gov/pacific/enforcement/med-licensed- facilities.

Pursuant to section 12-43.3-202(2.5)(c), C.R.S., with proficiency testing for microbial contaminant and residual solvent contaminant testing now established, the MED is implementing expanded mandatory microbial contaminant and residual solvent contaminant testing beginning February 1, 2018. On February 1, 2018, all Medical Marijuana Optional Premises Cultivations and Medical Marijuana-Infused Products Manufacturers are required to comply with Rules M 1501(C)(1) and (C)(3).

Mandatory testing of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Products applies to all Harvest and/or Production Batches created on or after February 1, 2018. Harvest and/or Production Batches created prior to February 1, 2018, are not subject to microbial contaminant and residual solvent contaminant testing requirements. Medical Marijuana Businesses should check the date of harvest or production of the Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product prior to accepting transfers to determine if contaminant testing is required. Mandatory Medical Marijuana contaminant testing is a matter of public health and safety and full compliance is expected by February 1, 2018.

Pesticide and Mycotoxin Contaminant Testing:

Requirements for Pesticide testing and mycotoxin contaminant testing in the Medical and Retail Marijuana Rules will not be implemented until proficiency testing is established and Medical and Retail Marijuana Testing Facilities are certified at sufficient capacity. In order to provide Medical and Retail licensees adequate time to comply with such requirements, MED will provide additional information regarding implementation of requirements for Pesticide and mycotoxin contaminant testing at a later date through an additional Industry Bulletin.

James Burack
Director