

# New Emergency & Permanent Regulations Draft Summary

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The Maryland Cannabis Administration (MCA) is simultaneously promulgating identical emergency and proposed regulations to replace the emergency regulations adopted under COMAR 14.17.01–.22 on July 1, 2023. The emergency regulations were approved by the Joint Committee on Administrative, Executive, and Legislative Review (AELR) at a public hearing on June 7, 2024. This document is intended to provide guidance to licensees on when new provisions should be implemented.

Part of this action is to repeal in their entirety regulations under COMAR 10.62 Natalie M. LaPrade Medical Cannabis Commission. This summary explains how the MCA's revised regulations differ from <u>its current regulations</u> adopted on July 1, 2023.

Changes made in this draft and discussed below fall into two categories: (1) the transfer of COMAR 10.62 provisions and (2) policy adjustments made in response to internal review and external stakeholder engagement.

The transfer of COMAR 10.62 provisions is nonsubstantive, as it incorporates the text of regulations previously referenced in the emergency regulations. To ensure transferred regulations align with current policy and practice, MCA's subject matter experts offered language updates and clarifications to align regulations with current policy and practice. For the most part these do not involve meaningful policy changes. Text that was amended or deleted from what was transferred from COMAR 10.62 is explained in this section.

Changes that fall under the second category are a combination of nonsubstantive language clean-ups, clarifications, and policy adjustments. These changes amend text that was adopted under COMAR 14.17 or expand upon provisions transferred from COMAR 10.62. These are being proposed in response to discussions with external stakeholders, requests for clarification, and internal evaluations of the Maryland cannabis landscape since adult-use sales began on July 1st. Nonsubstantive language clean-ups and clarifications are not explained in this document.

# Transfer of COMAR 10.62 to COMAR 14.17 & Policy Updates

The emergency regulations adopted under COMAR 14.17 reference existing provisions under COMAR 10.62 for many components of the Maryland cannabis program, including but not limited to medical program, licensee, and ancillary business operations, as well as many aspects of enforcement, record keeping and inspections. This draft transfers language from Maryland Medical Cannabis Commission (MMCC) regulations under COMAR 10.62 to a location where it will be contained within new Maryland Cannabis Administration (MCA) regulations under COMAR 14.17.

To ensure transferred language reflects current policy and practice, MCA conducted a systematic review of all COMAR 10.62 provisions cited in the emergency regulations, in coordination with MCA's subject matter experts, i.e. Scientific Support; Office of Compliance & Regulation; and Public Health, Data, and Education. This process identified any needed language updates or clarifications, which are identified in the next section. After the Office of Policy & Government Affairs reviewed and refined these changes, then updated COMAR 10.62 language was drafted into COMAR 14.17. Generally speaking, provisions of COMAR 10.62 were copied verbatim into the same COMAR 14.17 regulations that referenced them in the emergency regulations; however in certain cases they were rearranged for clarity and concision.

When the permanent regulations under COMAR 14.17 are promulgated, the existing COMAR 10.62 regulations will be repealed in their entirety.

## Changes Made Throughout

Any terms or references in regulations transferred from COMAR 10.62 that are unique to the medical-only cannabis program were deleted or updated. These are as follows:

- Commission  $\rightarrow$  Administration
- Delete 'medical' as appropriate
- Remove and/or replace all references to 10.62, as applicable
- Change all terms describing METRC, e.g. inventory control, to 'seed-to-sale tracking system' and use this throughout.

# Changes made to COMAR 10.62 provisions

- COMAR 14.17.04.01 –Per <u>§ 36-301(f)</u>, certifying providers may not receive any sort of compensation from a licensee. As such, language from <u>COMAR 10.62.03.02</u> allowing certifying providers to request MCA approval for such compensation was not transferred to the new subtitle. **Effective immediately.**
- COMAR 14.17.04.02 and .04 MCA is no longer requiring patients or caregivers to obtain identification cards. At the point of sale, patients and caregivers may present their government-issued identification card and provide the patient's registration number. This draft incorporates other necessary language about patient identification card handling from COMAR <u>10.62.06.03–.07</u> into Regulation .02 of this chapter but deletes language

requiring patients and caregivers to obtain an MCA identification card. **Effective July 1**, **2024**.

- COMAR 14.17.04.07 Regarding the new condition approval process, <u>COMAR</u> <u>10.62.07.02</u> requires an annual public hearing to evaluate any petition to consider other medical conditions. Language has been amended to schedule this hearing as needed, not annually.
- COMAR 14.17.04.01 and .02 Overly detailed language regarding the application
  process for certifying providers and caregivers has been replaced with language
  instructing them to submit applications in the manner specified by the Administration. For
  reference, see <u>COMAR 10.62.03.01</u> and <u>COMAR 10.62.04.04</u>. This change was made
  for clarity and concision; website guidance and the application itself identify what
  information is required from these applicants.
- Each licensee's Discrepancy, Theft, or Diversion regulation requires a licensee to commence an investigation of and report a discrepancy to MCA within one business day of discovering the discrepancy. Additionally, language has been added to establish that failure to report a discrepancy within one business day may be used as evidence of diversion. The MCA intends to issue additional guidance and processes around discrepancy reporting. The MCA is advising that industry implement this process on or before July 1, 2024.
- COMAR 14.17.10.03D(7)(b)(iii) Language has been clarified to allow growers to dispose of samples after 18 months (or 6 months from expiration date). This is a cleanup to align with current procedures for processors, as described in <u>10.62.23.06</u>.
   Licensees may begin implementing this change immediately.
- Deleted requirement for licensees to have a second, independent alarm system for locations where records are stored, rooms that hold cannabis, and off-site record storage. Licensees may begin implementing this change immediately.
- Wherever used, the term 'non-public zone' has been deleted for the sake of clarity. This term is used to describe specific areas of licensed premises and how licensees should handle visitors to those areas. For <u>growers</u> and <u>processors</u>, this term was deleted without replacement as these facilities don't have public zones. Guests to any part of grower and processor premises should be treated as visitors (described below). For dispensaries, the term 'operations zone' is used to reference areas where visitors must be supervised in order to be consistent with organizational discussion in <u>COMAR</u> <u>10.62.27.08</u>.
- Visitors, as newly defined, must be 'continually, physically supervised' at all times while on the premises. Existing language only requires visual supervision. This change clarifies that video surveillance does not meet this requirement.

# **COMAR 14.17 Policy Adjustments & Clarifications**

Changes made in response to external stakeholder engagement will be flagged as such. If not otherwise noted, the change is a policy clean-up/clarification resulting from internal review.

## COMAR 14.17.01 Definitions

Several new definitions were added; tweaks to some existing definitions were made:

- Data network (i.e. OneStop) Defined the term to distinguish it from the seed-to-sale tracking system. It is used in reference to a dispensary's duty to query OneStop to verify an individual's patient status and other details.
- Electronic manifest Defined the term to distinguish it from the broader seed-to-sale tracking system. The electronic manifest records the chain of custody during a cannabis transfer or delivery and the term is used numerous times to describe procedures for these transactions.
- Neutral age screening Defined to align with the <u>Federal Trade Commission's definition</u>. In these regulations, it is used in the context of online orders; however, it can also be applied to MCA guidance regarding website advertising.
- Residence The term is used in the context of where cannabis may be delivered. Definition distinguishes between private dwellings and university campus housing.
- Visitor Defined to distinguish between individuals who visit licensed premises for the purpose of purchasing cannabis and guests who visit for other reasons, such as performing maintenance or repairs or touring the property.
- Increased plant size under 'home cultivation' definition from 6 to 8 inches. Licensees may begin implementing this change immediately.

## COMAR 14.17.02 General Regulations

- Regulation .02 Single Supply Chain for Cannabis Products Added blanket language to require all licensees to accurately track, tag or otherwise record inventory in the seed-tosale tracking system as specified in their specific chapters. This is an existing requirement; explicit language has been added for emphasis.
- Regulation .05 Technical Authority This draft incorporates by reference MCA's technical authority to further ensure that its guidance for laboratories and licensees is legally enforceable.

## COMAR 14.17.04 Medical Program

Highlights

 Regulation .06 Compassionate Use Fund – This regulation outlines parameters and procedures for a more robust Compassionate Use Fund, which reduces the cost of obtaining a medical assessment to determine the appropriateness of medical cannabis for Medicaid and Veterans Affairs participants. During a stakeholder listening session, patients and caregivers expressed support for using this program to support the written certification process. MCA is actively working to implement these provisions and aims to implement this process on or before July 1, 2024.

Other

- Regulation .05 Patient Accommodations In response to patient stakeholder input, regulations require dispensaries who opt to offer dedicated service lines to make a good faith effort to prioritize qualifying patients. The intent of this addition is to encourage dispensaries to prioritize any patients standing in line over adult-use consumers, in addition to providing the designated line. MCA is advising that industry implement this process on or before July 1, 2024.
- Regulation .08 Clinical Directors New language in this regulation exempts (1) a standard dispensary from appointing a clinical director until it has been licensed and operational for at least 24 months and (2) a micro dispensary from having a clinical director at any point.

## COMAR 14.17.05 Application Process and Issuance of Licenses

 Regulation .05 Issuance of a License or Rescission of a Conditional License – Add language requiring conditional licensees to notify the MCA when they have secured control of a proposed site and to demonstrate adequate capitalization within 6 months of being issued a conditional license. Additionally, language has been added to clarify that MCA may suspend, fine, restrict, or revoke a license if it is determined that a licensee has not complied with statements in the application.

## **General Licensee Chapters**

#### COMAR 14.17.06 Standard Licenses

- Regulation .04 Transfer of Ownership Interest in a License
  - .04B In response to industry stakeholder input, establish parity between publicly and privately held entities by eliminating the requirement to report a transfer of five percent or less for all entities unless the transfer is part of an employee compensation plan. Previously, private entities were required to report all transfers at least 30 days prior to the transfer, while public entities were exempt from reporting a transfer of ownership interest of five percent or less as long as the transfer does not convey a controlling interest. MCA intends to fully implement this process by July 1, 2024.
  - .04D Clarifies that, prior to a license being operational for at least five years, a proposed transfer may not convey to the transferee a controlling interest in the license at a later date.
  - .04E Allow, rather than require, MCA to deny a transfer if the proposed transferee or any owner is convicted of or plead no contest to a crime involving moral turpitude. MCA intends to fully implement this process by July 1, 2024.
  - .041 Require a licensee to conduct a full inventory of all cannabis and cannabis products prior to finalizing the transfer and in the manner prescribed by the

Administration. MCA is advising that industry implement this process on or before July 1, 2024.

- .04J In response to stakeholder input, added provisions for employee stock options program and reduced administrative burden on those types of transfers.
   MCA intends to fully implement this process by July 1, 2024.
- Regulation .05 Management Agreements Clarifies limitations for management agreements with regard to transfer of control. The MCA intends to implement these provisions immediately.

#### COMAR 14.17.07 Micro Licenses

- .07 Micro Dispensary License
  - In response to licensee stakeholder input, new language clarifies that:
    - For the purposes of micro dispensaries, an authorized service area includes the region in which the license was awarded.
    - Establishes activities that may be conducted outside of a licensee's authorized service area, including storage and transit for specific purposes.
    - Explicitly permits a licensee to petition the MCA for an expansion of authorized service areas and authorizes MCA to approve or deny such a request.

## COMAR 14.17.08 Laboratory Registration and Operations

• Regulation .07 State Cannabis Testing Laboratory – Authorizes the State Cannabis Testing Laboratory to establish pilot programs, including the ability to waive, reduce, or amend testing standards.

## COMAR 14.17.09 Other Cannabis Businesses

- Regulation .02 Cannabis Registrants Clarifies that the Administration may deny a registration for any good cause and that licensees may only contract with a cannabis business that is registered with the Administration.
- Regulation .03 Transport Service Operations Consolidate requirements for transportation between licensees and registrants. Transfers from 10.62.18.02–.06. Additionally, any registrants or licensees transporting edible cannabis products will be required to comply with edible cannabis transport requirements outlined in the processor edible regulations. Delivery procedures have been redrafted under COMAR 14.17.12.03 Micro Dispensary Operations. This draft presently reflects the prior statutory requirement that delivery operations by standard dispensaries and other ancillary businesses cease for medical patients by June 30, 2024. HB253 extends this authorization through June 30, 2025, which takes supremacy over the regulations put forward. MCA will align these dates in subsequent rulemaking.

## Licensee-Specific Chapters

All – below are changes made to all licensee chapters (COMAR 14.17.10, .11, and .12)

#### Highlights

• Each licensee chapter has a new, final regulation describing which processes it must describe in a standard operating procedure (SOP). This regulation also requires licensees to train agents on these processes and to have the SOP readily available for inspector review upon request. MCA is advising that industry develop and implement the relevant SOPs on or before July 1, 2024.

#### COMAR 14.17.10 Growers

#### Highlights

- Regulation .03D(5) Cannabis Grower Controls The proposed language adds a requirement for a licensee to notify the MCA within 24 hours of learning that a lab has determined a batch does not meet specifications. This requirement is to ensure that MCA is aware of potentially persistent test failures. MCA is advising that industry implement this requirement on or before July 1, 2024.
- Regulation .06 Product Reservations and Trade Practices Changes made to this
  regulation enable a grower to meet the trade practice requirements through distribution
  to both processors and dispensaries, as long as they distribute roughly equal amounts to
  each facility type. Additionally, it clarifies that licensees should prioritize distributions to
  social equity licensees over distributions to other licensees with non-shared ownership.
  Finally, it specifies that a social equity grower can meet the requirement by transfers to
  licensees with non-shared ownership, rather than requiring them to prioritize or
  accommodate other social equity licensees.

#### Other

- Added sink, scale, and sanitation requirements for creating usable products under Regulations .02H and .03B(2) and E. This is a clean-up to better organize all grower requirements under the grower-specific regulations.
- In Regulation .08, establishes that failure to report a discrepancy within one business day may be used by the Administration as evidence of diversion.

#### COMAR 14.17.11 Processors

#### Highlights

 Regulation .04C(2) Cannabis Product Processing – Requires a licensee to notify the MCA within 24 hours of learning that a lab has determined a lot does not meet specifications. This requirement is to ensure that MCA is aware of persistent test failures. MCA is advising that industry implement this requirement on or before July 1, 2024.

#### Other

- In Regulations .02G and .03F, added sink, scale, and sanitation requirements for creating usable products. This is a clean-up to better organize all processor requirements under the grower-specific regulations.
- In Regulations .03B(2), establishes that any products derived from hemp shall comply with testing, manufacturing, and packaging requirements established by MCA regulations.

#### COMAR 14.17.12 Dispensaries

#### Highlights

- Regulation .02
  - In response to dispensary stakeholders, allow a dispensary to choose to admit children younger than 8 years old to enter the licensed premises if they are accompanied by a qualifying patient or a registered caregiver. Licensees may begin implementing this change immediately.
  - In response to dispensary stakeholders, allow a licensee to request an exemption to the current requirement that cannabis inventory be locked in a secure room during operating hours and for two hours before and after operating hours. Licensees may begin implementing this change immediately.
  - In response to internal discussions and stakeholders, adds provisions for curbside & drive through, notably allowing this for all customers. Licensees may begin implementing this change immediately, after the required SOPs have been developed by the licensee.
  - Prohibits dispensaries from creating consumer profiles without consent. This policy has been in effect since it was explicitly clarified in an August 2023 bulletin; new regulation language codifies this existing policy.
- Regulation .03 Micro Dispensary Establishes requirements for micro dispensaries, including provisions for storage, delivery operations, vehicles, dispensing operations, and seed-to-sale tracking.
- Regulation .08 Online, Telephone, or Other Remote Orders
  - In response to dispensary stakeholders, signatures are no longer required to pick up online orders. Licensees may begin implementing this change immediately.
  - If a dispensary uses an online ordering system, it must (1) verify the consumer is at least 21 years old or that the individual is a qualifying patient or registered caregiver, (2) include a notice that a valid, government-issued photo identification card is required to receive the order; and (3) collect the name and date of birth of the individual submitting the order. The dispensary agent may only collect payment after confirming that the consumer's, qualifying patient's, or registered caregiver's identification card displays a name and date of birth that matches the information collected at the time of the order. MCA is advising that industry implement this requirement on or before July 1, 2024.

Regulation .09 Hours of Operations – In response to stakeholders, removes the 12-hour maximum on hours of operation. Additionally, the language now permits dispensaries to operate at any time between the hours of 8am and 11pm. Licensees may begin implementing this change immediately.

#### Other

- Regulation .04 Dispensary Operations Language has been added to require a licensed dispensary to conduct a physical inventory of its stock of cannabis and compare the physical inventory of stock with the stock reflected in seed-to-sale tracking system at least monthly. MCA is advising that industry implement this requirement on or before July 1, 2024.
- Regulation .06 Products Reservations and Trade Practices Clarifies that licensees should prioritize products produced by social equity licensees over those produced by licensees with non-shared ownership. Additionally, it specifies that a social equity dispensary can meet the requirement by making products produced by licensees with non-shared ownership available for sale, rather than requiring them to prioritize or accommodate other social equity licensees.

## COMAR 14.17.13 Cannabis Products

- Regulation .03 Product Reservations In response to industry input and after careful internal consideration, MCA is revising regulations to permit adult-use consumers to purchase concentrated cannabis products with a total weight of 1 gram or less. Infused pre-rolls are exempted from this product weight requirement. Additionally, adult-use consumers may purchase infused non-edible cannabis products regardless of potency. Licensees may begin implementing this change immediately.
- Regulation .07 Home Cultivation Products In response to dispensary stakeholder input, MCA increased the height and width limits for seedlings a dispensary may sell to a consumer or patient from six to eight inches. This marginal change aligns Maryland requirements with other states' requirements. Licensees may begin implementing this change immediately.
- Regulation .11 Usable Cannabis Products In response to dispensary stakeholder input, MCA increased bulk transfer limits in this draft from five to 50 pounds. Accordingly, it increased the limit on the quantity of usable cannabis in inventory at a given time for the purpose of creating usable cannabis products to 50 pounds. Individual package limits for transfers still may not exceed one pound. Licensees may begin implementing this change immediately.

# 14.17.14 Complaints, Enforcement, Record Keeping, and Inspections of Cannabis Businesses

Changes have been made throughout this chapter to enhance clarity through and to align regulatory text with current processes and statutory requirements. Substantive changes are noted below:

- Regulation .02 Records Reduce requirement for licensees to maintain records from five to two years. The seed-to-sale tracking system maintains records of all plants, testing, transfers, distributions, etc. indefinitely, minimizing the need for licensees to maintain independent records. Licensees may begin implementing this change immediately.
- Regulation .04D Discipline and Enforcement Authorizes the MCA to impose penalties for a material misstatement, omission, misrepresentation, or untruth by a licensee, registrant, or agent. This provision is already in place in the specific context of an inspection and is being broadened in this proposal. MCA intends to fully implement this process by July 1, 2024.
- Regulation .05F Fines and Suspension Proceedings Authorizes MCA to impose late fees. The purpose of this language is to encourage licensees to pay fines in a timely manner. Additionally, language has been added and revised through this regulation to clarify suspension proceedings under this chapter. MCA intends to fully implement this process by July 1, 2024.
- Regulation .06 Advertising Increases fines for advertising violations. Specifically, the fine for a second violation increases from \$5,000 to \$10,000 and the fine for a third violation is increasing from \$10,000 to \$25,000. Establishes a new, \$50,000 fine for any subsequent violation within 24 months of the initial violation. Additionally, it clarifies that any violation that occurred between May 3, 2023, and the effective date of these regulations counts for the purposes of calculating the appropriate fine. The purpose of this language is to improve compliance with State law regarding cannabis business advertising. Effective immediately for violations committed after June 7, 2024.

## COMAR 14.17.15 Cannabis Business Agents

- Regulation .02 Registration
  - Changes related to criminal history
    - .02D An agent must disclose to the MCA any convictions or pleas of no contest that occur after initial application. MCA is advising that industry implement this requirement on or before July 1, 2024.
    - .02E Authorizes, rather than requires MCA, to deny registration for an agent convicted of a crime involving moral turpitude to language. MCA intends to fully implement this process by July 1, 2024.

## COMAR 14.17.16 Cannabis Business Owners

- Regulation .01A Conditions of Ownership and Control
  - Clarifies an individual must be 21 years or older to hold any amount of ownership in a cannabis business with limited exceptions for ownership interests held in a trust for beneficiaries who aren't yet 21 years old.
  - Authorizes the MCA to force ownership divestment or impose other penalties, including the revocation of licensure, if an owner is convicted of or pleads no contest to a crime involving moral turpitude after initial licensure.

 Regulation .04B(2) Mandatory Reporting of Legal Actions – Requires an individual with ownership interest or control greater than 5 percent to report legal actions, including its filing of bankruptcy and a conviction of or no contest plea to a crime involving moral turpitude. MCA is advising that industry implement this requirement on or before July 1, 2024.

## COMAR 14.17.17 Receivership

To address and minimize confusion regarding what may be included in a security agreement, removes language regarding secured interest in a cannabis license and instead focuses on receivership actions to ensure a license transfer does not occur without Administration approval.

## COMAR 14.17.18 Packaging & Labeling

Highlights

Regulation .03D(2) – In response to dispensary and processor stakeholder input, MCA will allow nutrition information and itemizations of cannabinoids and terpenes, allergens, and non-cannabis ingredients to be placed on an inner layer, such as on a peel-and-reveal label. A nutrition label may alternatively be made available on the package through a link or QR code. Previously these were required to be placed on a package's outermost layer. Licensees may begin implementing this change immediately.

Other

- Regulation .04C In response to licensee stakeholders, permits the warning statements required for medical cannabis products to be applied on the personalized label.
   Licensees may begin implementing this change immediately.
- Regulation .02B(3) In response to licensee stakeholder input and to correct a drafting error, any soft sided package shall be four mil, not millimeters, or greater in thickness.
   This corrects a drafting error, and no implementation change should be required for licensees or MCA's process.
- Regulation .07A(1) In response to licensee stakeholder input, this draft aligns language with 36-203.1(C)(1)(ii) by limiting the prohibition on images of food, etc., resemblance to trademarked packaging of any commercially available candy, etc., and images, etc. used to advertise to children to only those that "may appeal to minors". The purpose of this change is to amend language that is more restrictive than statutory prohibitions. This corrects a drafting error, and no implementation change should be required for licensees or MCA's process.

## COMAR 14.17.19 Cannabis Research

Regulation .02D Research and Development – This regulation bolsters existing requirements for cannabis research and development by adding new provisions, including conformity with study protocols and MCA guidance, notifying MCA about any adverse events, notifying MCA about any changes to the study, and documentation of IRB approval. Finally, this regulation incorporates existing guardrails for edible cannabis research and development.

## COMAR 14.17.22 Hearings

Changes have been made throughout this chapter to enhance clarity and to align regulatory text with current processes and statutory requirements.