OAC 310:681—Summary of 2020 Emergency Rule Changes

OAC 310:681-1-4. Definitions

- Adds definition of "remediation" (same definition set forth in 63 O.S. § 427.2) and definition of "decontamination."

OAC 310:681-5-6. Inventory tracking, records, reports, and audits

- Pg. 45, Subsection (b)(2): Clarifies that copies of sample field logs and documents related to transportation and sampling are included in the types testing records business licensees have to maintain. By including these documents in the list, they must be kept onsite and readily available for seven years.

OAC 310:681-5-10. Medical marijuana waste disposal

- Pg. 52, Subsection (b)(1)-(3): Creates a new provision that would require commercial licensees to create and maintain (for five years) a disposal log that must be signed and attested to under penalty of perjury. Under current law, commercial licensees may dispose of root balls, stems, fan leaves, seeds, and stalks on their own but must send all other medical marijuana waste to a waste disposal facility. Documentation will help OMMA Compliance monitor disposal and dissuade diversion of plant material.

OAC 310:681-5-18. Prohibited Acts

- Pg. 54, Subsection (k): Clarifies that licensees shall only sell or otherwise transfer medical marijuana to Oklahoma-licensed medical marijuana businesses and that licensee shall not sell medical marijuana to out-of-state individuals or entities.

OAC 310:681-7-1. Labeling and Packaging

- Pg. 56, Subsection (d): Adds prohibition that packages and labels cannot contain the OSDH or OMMA logo. Compliance inspectors have found several instances where this is occurring.
- Pg. 56, Subsection (e): Adds requirements for labels of non-edible products so they are more uniform with edibles and provide important information such as name, license number, batch number, quantity, and ingredients. These items are essential information for a patient to have access to in the event of a recall.
- Pg. 56-57, Subsection (f): Adds basic labeling requirements for wholesale transfers between growers and/or processors, which include name, license number, batch number, date of harvest or production, and a statement that the medical marijuana has passed testing or failed testing and is being transferred for remediation purposes only.
- Pg. 57, Subsection (g): Adds requirement that growers and processors store medical marijuana and products under conditions and in manner that protects against contamination and deterioration. Also requires it to be stored in fully sealed/closed receptacles when not in use.

OAC 310:681-8-1. Testing standards and thresholds

- Pg. 58-59, Subsections (c): Clarifies that samples must be collected and labeled in accordance with applicable statutes and these Rules. Strikes duplicative language that was intended to be struck during prior rulemaking.
- Pg. 58, Subsection (d): Authorizes growers to sell/transfer and processors to purchase/process a harvest batch that has failed microbiological testing for remediation purposes only. Strikes and moves language requiring dispensaries to maintain copies of Certificates of Analysis (COAs).
- Pg. 59, Subsection (h): Expands and clarifies the duty of growers, processors, and dispensaries to obtain and retain (for two years) copies of COAs for all medical marijuana and products they purchase. Requires growers and processors to provide these copies to the Department immediately upon request and to other licensees who request copies in order to be in compliance

with these requirements. Also requires growers and processors to notify the Department when their medical marijuana or products fail testing.

- Pg. 61-62, Subsection (j): Establishes process for retesting harvest and production batches that fail testing. Requires the reserve sample to be used for retesting and outlines protocol for collection of a new sample if the reserve sample is not sufficient. Allows retesting to be limited to the category of analyte that failed initial testing; limits costs by not requiring full panel retesting. If retest gives passing results, requires second retest to confirm safety and suitability of medical marijuana or product. Requires any batch that does not have two successful tests for each analyte to be remediated, decontaminated, or disposed.
- Pg. 62, Subsection (k): Allows for harvest or production batches that have been remediated or decontaminated and have failed testing to be retested in accordance with the new retesting procedures established in (j). Prohibits further decontamination of production batches that failed retesting and allows for harvest batches that have been decontaminated and failed testing for microbials to be disposed of or remediated.
- Pg. 63, Subsection (l): Authorizes growers to sell/transfer to a processor and processor to purchase/process a harvest batch that has failed microbiological testing for remediation purposes only. Clarifies that the production batch must be fully tested. Prohibits processors from selling medical marijuana from the harvest batch that failed testing.
- Pg. 63-64, Subsections (m)-(r): Changes term "remediation" to "decontamination" to reflect the fact that the definition of "remediation" in 63 O.S. § 427.2 limits the definition of remediation to the processing of a harvest batch that has failed microbiological testing into a solvent-based concentrate.

OAC 310:681-8-2. General operating requirements and procedures

- Pg. 65, Subsection (b): Establishes requirement that a testing laboratory shall only report COAs for analytes the laboratory conducted that are within the scope of the testing laboratory's accreditation; clarifies laboratories may outsource testing and report those results on a COA but must identify the laboratory that conducted the testing.
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OAC 310:681-8-3. Sampling requirements and procedures.

- Pg. 68-69, Subsection (a)(1)(A) and (a)(11): Establishes requirement that samplers must be trained on the testing laboratory's sampling protocols and that commercial licensees must document such training.
- Pg. 68, Subsection (a)(6): Requires samples to be clearly labeled with the following information: "Primary Sample" or "Reserve Sample"; name, license number, and batch number.
- Pg. 69, Subsection (a)(9): Requires the sample field log to list the title and version of the laboratory's standard operating procedure that was followed when collecting the sample.
- Pg. 71, Subsection (e)(2): Prohibits a laboratory from withholding from a commercial licensee a COA reporting a failed test.
- Pg. 71, Subsection (e)(3): Clarifies that COAs must contain the required information even in "electronic form" and requires COAs to contain definitions of any abbreviated terms.
- Pg. 71-72, Subsection (e)(4): Requires COAs to clearly and conspicuously list "Pass" or "Fail" in font size no smaller than the size of 12 point Times New Roman font. Cannot be listed in fine print or footnotes. Also requires actual limits of analytes detected to be listed, even if below allowable threshold.
- Pg. 72, Subsection (e)(6): Requires laboratory to immediately notify the Department in the form and manner prescribed by Department of any failed testing.

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OAC 310:681-9-9. Waste disposal

- Pg. 85, Subsection (a): Requires commercial licensees to submit waste to a waste disposal facility within 90 days.