

OAC 310:681—Summary of 2020-2021 Permanent Rule Changes

310:681-1-4. Definitions

- Adds definition of “remediation” (same definition set forth in 63 O.S. § 427.2) and definition of “decontamination.” (Carry-over from proposed 2020 emergency rules.)
- Revises definition of “Inventory tracking system” to ensure it captures the entire life span of medical marijuana and medical marijuana products, including testing samples and medical marijuana waste.
- Adds definition of “Organic” to mean the same as the term defined in the National Organic Program codified at 7 C.F.R. § 205.2 and includes the related terms, “organically produced,” “100 percent organic,” and “made with organic (specified ingredients or food group(s))” as set forth in 7 U.S.C. § 6502(15) and 7 C.F.R. § 205.102.
- Adds definition of “Readily accessible” to mean “that a licensee can immediately produce the documentation upon the Department’s request.”

310:681-1-6. Proof of residency

- Adds preceding year’s Oklahoma tax return as documentation that can be submitted to establish residency.

310:681-2-5. Term and renewal of medical marijuana license

- Revises heading of section to be “Term and renewal of medical marijuana patient and caregiver licenses.”
- Clarifies that changes affecting a patient’s or caregiver’s qualification for licensure must be approved by the Department. Outlines documentation that must be submitted for approval of a name change.

310:681-3-1. License for transportation of medical marijuana

- Clarifies that all occupants in a vehicle transporting medical marijuana or medical marijuana products shall hold a valid and active transporter agent license.

310:681-3-2. Requirements for transportation of marijuana

- Transfers fines amounts to Appendix C, a newly-created appendix setting forth a schedule of fines. Fine amounts of \$50 against the transporter agent and \$500 against the transporter licensee remain the same.

310:681-3-6. Inventory manifests

- Changes “shipping manifests” to “inventory manifests” to ensure consistency in terminology.

310:681-4-1.1. Responsibilities of the license holder

- Clarifies that trade name is an item that licensees are required to keep updated in their online OMMA accounts.

310:681-4-2. Licenses

- Clarifies that assignments, sales, or other transfers of entire ownership of a research or educational facility license is not permitted.

310:681-4-3. Applications

- Adds requirement that an applicant intending to operate under a trade name submit official documentation from the Secretary of State of the trade name, which is required to be filed with the Secretary of State pursuant to 18 O.S. § 1140.

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310:681-4-4. Inspections

- Adds monetary penalty for refusal to permit entry by the Department for an inspection. Fine amount set forth in Appendix C is \$5,000.
- Adds monetary penalty for refusal to cooperate with interview. Fine amount set forth in Appendix C is \$500.
- Moves monetary penalty of \$500 per inspection violation to Appendix C.
- Clarifies that Department may seek fines for non-correctable violations without providing 30 days' notice and opportunity to correct.

310:681-4-5. Inventory tracking, records, reports, and audits

- Revises heading and adds “audits” to be consistent with similar heading in other subchapters.
- Adds monetary penalty for refusal to permit entry by the Department for an inspection. Fine amount set forth in Appendix C is \$5,000.
- Adds monetary penalty for refusal to permit access to books and records. Fine amount set forth in Appendix C is \$500.
- Moves monetary penalty of \$500 per audit violation to Appendix C.
- Clarifies that Department may seek fines for non-correctable violations without providing 30 days' notice and opportunity to correct.

310:681-4-6. Penalties

- Clarifies monetary penalty of \$500 for failure to submit timely, complete, and accurate monthly reports and moves fine amount to Appendix C.
- Moves fine amounts for fraudulent reports and unlawful purchases and sales to Appendix C.
- Adds that monetary penalties shall be assessed in amounts set forth in Appendix C and that failure to pay a fine within 30 days will result nonrenewal, suspension, and/or revocation of license.

310:681-5-1. Responsibilities of the license holder

- Clarifies that trade name is an item that licensees are required to keep updated in their online OMMA accounts.

OAC 310:681-5-2. Licenses

- Clarifies that assignments, sales, or other transfers of entire ownership of a business license is not permitted.
- Allows for one name change request to be submitted to the Department per year of licensure and sets forth documentation necessary to establish the name change.

310:681-5-3. Applications

- Adds requirement that an applicant intending to operate under a trade name submit official documentation from the Secretary of State of the trade name, which is required to be filed with the Secretary of State pursuant to 18 O.S. § 1140.

310:681-5-3.1. Proof of residency for commercial licensees

- Adds Oklahoma tax return as document that can be submitted to establish residency.

310:681-5-4. Inspections

- Adds monetary penalty for refusal to permit entry by the Department for an inspection. Fine amount set forth in Appendix C is \$5,000.

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- Adds monetary penalty for refusal to cooperate with interview. Fine amount set forth in Appendix C is \$500.
- Moves monetary penalty of \$500 per inspection violation to Appendix C.
- Clarifies that Department may seek fines for non-correctable violations without providing 30 days' notice.

310:681-5-5. Processing medical marijuana on behalf of a patient or caregiver

- New section setting forth regulations for the processing of homegrow on behalf of a patient or caregiver.
- Requires processor to maintain a log of the transactions.
- Makes clear that processor can only use the patient's or caregiver's medical marijuana and cannot include any medical marijuana from other sources.
- Requires the concentrate to be labeled with patient and caregiver license number, processor name and license number, date processed, and the Oklahoma uniform symbol.
- Requires medical marijuana and concentrate to be maintained on premises in a manner that protects it from contamination.
- Clarifies concentrate is not required to be tested.
- Makes any transaction not in accordance with this section an unlawful sale.

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

- Clarifies that copies of sample field logs and documents related to transportation and sampling are included in the types of testing records business licensees have to maintain. (Carry-over from proposed 2020 emergency rules.)
- Clarifies that business licensees must maintain records related to cultivation of medical marijuana, patient processing logs, inventory manifests, and transporter agent licenses.
- Requires processors to maintain a log documenting all processing of homegrow on behalf of patient or caregiver. Log must include patient and caregiver license number, date processor received medical marijuana, weight of marijuana received, weight or amount of concentrate produced, weight of any excess medical marijuana, and the date the concentrate was provided to the patient or caregiver.
- Adds monetary penalty for refusal to permit access to books and records. Fine amount set forth in Appendix C is \$500.
- Moves monetary penalty of \$500 per audit violation to Appendix C.
- Clarifies that the Department may seek fines for non-correctable violations without providing 30 days' notice and opportunity to correct.

OAC 310:681-5-6.1. Penalties

- Clarifies monetary penalty of \$500 for failure to submit timely, complete, and accurate monthly reports and moves fine amount to Appendix C.
- Moves fine amounts for fraudulent reports and unlawful purchases and sales to Appendix C.
- Adds that monetary penalties shall be assessed in amounts set forth in Appendix C and that failure to pay a fine within 30 days will result nonrenewal, suspension, and/or revocation of license.

OAC 310:681-5-10. Medical marijuana waste disposal (Carry-over from proposed 2020 emergency rules)

- 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

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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

- Extends prohibition on the consumption of alcohol and the smoking or vaping of medical marijuana to areas adjacent to the licensed premises that are under control of the licensee.
- Clarifies all commercial licensees are prohibited from delivering to patients or caregivers.
- In accordance with 63 O.S. § 422, adds prohibition against growers possessing, selling, or offering to sell medical marijuana products.
- Clarifies that licensees shall only sell or otherwise transfer medical marijuana to Oklahoma-licensed medical marijuana businesses and that licensees shall not sell medical marijuana to out-of-state individuals or entities. (Carry-over from proposed 2020 emergency rules.)

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

- Adds prohibition that packages and labels cannot contain the OSDH or OMMA logo. Compliance inspectors have found several instances where this is occurring. (Carry-over from proposed 2020 emergency rules.)
- 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. (Carry-over from proposed 2020 emergency rules.)
- 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. (Carry-over from proposed 2020 emergency rules.)
- Adds requirement that growers and processors store medical marijuana and products under conditions and in a manner that protects against contamination and deterioration. Also requires it to be stored in fully sealed/closed receptacles when not in use. (Carry-over from proposed 2020 emergency rules.)
- States use of the term “organic” on packaging or labeling is deceptive, false, or misleading unless the federal Organic Foods Production Act of 1990 authorized organic certification and designation for medical marijuana and medical marijuana products.
- States use of “Pesticide-free” on packaging or labeling is deceptive, false, or misleading unless the medical marijuana or medical marijuana product was grown, harvested, processed, and dispensed without any pesticides.
- Prohibits packages and labels from containing any universal symbols from another state, statements that medical marijuana was grown in another state, and any other statement that would cause a patient to be confused as to the origin of the medical marijuana or medical marijuana product.
- Prohibits labels from being designed or applied in a way that causes patient confusion. In the event an item needs to be relabeled, requires removal of initial label in its entirety.
- Requires packaging and labeling to contain current and accurate information that is on file with the Authority.

OAC 310:681-7-3. Advertising

- Prohibits advertising representing that a licensee is engaged in medical marijuana commercial services for which the licensee is not licensed.

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- Prohibits advertising that could cause a reasonable patient to be confused as to the state of origin of medical marijuana or medical marijuana product.
- States use of the term “organic” in advertising is deceptive, false, or misleading unless the federal Organic Foods Production Act of 1990 authorized organic certification and designation for medical marijuana and medical marijuana products.
- States use of “Pesticide-free” in advertising is deceptive, false, or misleading unless the medical marijuana or medical marijuana product was grown, harvested, processed, and dispensed without any pesticides.

OAC 310:681-8-1. Testing standards and thresholds (All changes carried over from proposed 2020 emergency rules)

- 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.
- 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).
- 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.
- 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.
- 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.
- 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.
- 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

- 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. (Carry-over from proposed 2020 emergency rules)

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OAC 310:681-8-3. Sampling requirements and procedures (Carried over from emergency rules)

- Establishes requirement that samplers must be trained on the testing laboratory’s sampling protocols and that commercial licensees must document such training.
- Requires samples to be clearly labeled with the following information: “Primary Sample” or “Reserve Sample”; name, license number, and batch number.
- 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.
- Prohibits a laboratory from withholding from a commercial licensee a COA reporting a failed test.
- Clarifies that COAs must contain the required information even in “electronic form” and requires COAs to contain definitions of any abbreviated terms.
- Requires COAs to clearly and conspicuously list “Pass” or “Fail” in Times New Roman font and size no smaller than 12-point. Cannot be listed in fine print or footnotes. Also requires actual limits of analytes detected to be listed, even if below allowable threshold.
- Requires laboratory to immediately notify the Department in the form and manner prescribed by Department of any failed testing.

OAC 310:681-9-2. Licenses and permits

- Clarifies that assignments, sales, or other transfers of entire ownership of waste licenses and permits are not permitted.
- Allows for one name change request to be submitted to the Department per year of licensure and sets forth documentation necessary to establish the name change.

OAC 310:681-9-3. License applications

- Adds requirement that an applicant intending to operate under a trade name submit official documentation from the Secretary of State of the trade name, which is required to be filed with the Secretary of State pursuant to 18 O.S. § 1140.

OAC 310:681-9-5. Inspections

- Adds monetary penalty for refusal to permit entry by the Department for an inspection. Fine amount set forth in Appendix C is \$5,000.
- Adds monetary penalty for refusal to cooperate with interview. Fine amount set forth in Appendix C is \$500.
- Moves monetary penalty of \$500 per inspection violations to Appendix C.
- Clarifies that Department may seek fines for non-correctable violations without providing 30 days’ notice.

OAC 310:681-9-6. Security requirements

- Removes requirement that commercial licensees use commercial-grade II non-residential locks on waste receptacles.

OAC 310:681-9-7. Audits and inventory

- Adds monetary penalty for refusal to permit entry by the Department for an inspection. Fine amount set forth in Appendix C is \$5,000.
- Adds monetary penalty for refusal to permit access to books and records. Fine amount set forth in Appendix C is \$500.
- Moves monetary penalty of \$500 per audit violation to Appendix C.

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- Clarifies that Department may seek fines for non-correctable violations without providing 30 days' notice and opportunity to correct.

OAC 310:681-9-8. Penalties

- Clarifies monetary penalty of \$500 for failure to submit timely, complete, and accurate monthly reports and moves fine amount to Appendix C.
- Moves fine amounts for fraudulent reports and unlawful purchases and sales to Appendix C.
- Adds that monetary penalties shall be assessed in amounts set forth in Appendix C and that failure to pay a fine within 30 days will result nonrenewal, suspension, and/or revocation of license.

OAC 310:681-9—9. Waste disposal (Carry over from 2020 proposed emergency rule)

- Requires commercial licensees to submit waste to a waste disposal facility within 90 days.

Appendix C. Schedule of Monetary Penalties

- Establishes fine amounts for violations.