

SUMMARY OF PERMANENT RULE CHANGES - SEPTEMBER 2021

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH

CHAPTER 681. MEDICAL MARIJUANA REGULATIONS

1. **DESCRIPTION:**

OAC 310:681-1-4. Definitions

- Adds definition of “remediation” (same definition set forth in 63 O.S. § 427.2).
- Adds definition of “decontamination.”
- Modifies definition of “inventory tracking system” to make clear the system must account for the entire life span of medical marijuana and medical marijuana products, including testing samples thereof and medical marijuana waste.
- Adds definition of “organic.”
- Adds definition of “readily accessible.”

OAC 310:681-1-6. Proof of Residency

- Subsection (a)(7): Adds that an applicant’s Oklahoma Tax Returns from the preceding year may be used for proof of residency.

OAC 310:681-2-5. Term and renewal of medical marijuana patient and caregiver licenses

- Subsection (e)(2)-(3): Adds requirement that patients and caregiver licensees must obtain Department approval for changes that affect the licensee’s qualification for licensure. Creates a new provision that permits name changes and establishes documentation that must be submitted related to proof of identity and to establish a valid name change.
- Subsection (f): Revises misspelling.

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

- Subsection (d): Adds a reference to Appendix C, which establishes a schedule of fines for violations.

OAC 310:681-3-3. Transporter agent license

- Subsection (f)(2): Revises misspelling.

OAC 310:681-3-6. Inventory manifests

- Subsection (a): Changes the terminology “shipping manifests” to “inventory manifests” for uniformity throughout the rules.

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

- Subsection (a)(7): Clarifies that trade name must be updated and accurate in the licensee’s online OMMA account.

OAC 310:681-4-2. Licenses

- Subsection (c)(4): Revises misspelling.
- Subsection (e)(2): Updates citations.
- Subsection (f)(1): Clarifies research and education facilities shall not wholly assign, sale, or transfer the license to a new owner or another legal entity.

OAC 310:681-4-3. Applications

- Subsection (e)(2): Adds requirement that official documentation from the Secretary of State establishing the applicant’s trade name should accompany the application for a research facility license, if applicable.
- Subsection (f)(3): Adds requirement that official documentation from the Secretary of State establishing the applicant’s trade name should accompany the application for an education facility license, if applicable.

OAC 310:681-4-4. Inspections

- Subsection (a): Adds a reference to Appendix C, which establishes a schedule of fines for violations.
- Subsection (f): Adds a reference to Appendix C, which establishes a schedule of fines for violations.
- Subsection (h): Adds a reference to Appendix C for inspection violations not corrected within thirty (30) days, which creates a schedule of fines for violations.
- Subsection (i): Clarifies the Department may seek fines as set forth in Appendix C and any other administrative penalties authorized by law without allowing opportunity to correct a violation when the violation is not capable of being corrected.

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

- Subsection (e): Adds references to Appendix C, which establishes a schedule of fines for violations.
- Subsection (e)(8): Clarifies the Department may seek fines as set forth in Appendix C and any other administrative penalties authorized by law without allowing opportunity to correct a violation when the violation is not capable of being corrected.

OAC 310:681-4-6. Penalties

- Subsection (a): Clarifies it is a violation to not submit a timely, complete, and accurate monthly report and moves the fine to Appendix C, which establishes a schedule of fines for violations.
- Subsection (b): Moves the monetary penalties for fraudulent reports to Appendix C, which establishes a schedule of fines for violations.
- Subsection (c): Moves the monetary penalties for unlawful sales to Appendix C, which establishes a schedule of fines for violations.
- Subsection (f): Adds that penalties shall be assessed in the amounts set forth in Appendix C and failure to pay fines assessed within thirty (30) days results in non-renewal, suspension, and/or revocation of the license.

OAC 310:681-5-1.1. Responsibilities of the license holder

- Subsection (7): Clarifies that trade name must be updated and accurate in the licensee’s online OMMA account.

OAC 310:681-5-2. Licenses

- Subsection (c)(3): Revises misspellings.

- Subsection (e)(2): Establishes that licensees are allowed one name change request and establishes the information and documentation a medical marijuana business licensee must submit relating to the business name change. Updates citations.
- Subsection (f)(1): Clarifies business licenses may not be wholly assigned, sold, or transferred to a new owner or another legal entity.

OAC 310:681-5-3. Applications

- Subsection (e)(3): Adds requirement that official documentation from the Secretary of State establishing the applicant's trade name should accompany the application for a business license, if applicable.

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

- Adds that an applicant's Oklahoma Tax Returns from the may be used for proof of residency.

OAC 310:681-5-4. Inspections

- Subsection (a): Adds a reference to Appendix C, which establishes a schedule of fines for violations.
- Subsection (g): Adds a reference to Appendix C, which establishes a schedule of fines for violations.
- Subsection (i): Adds a reference to Appendix C for inspection violations not corrected within thirty (30) days, which creates a schedule of fines for violations.
- Subsection (j): Clarifies the Department may seek fines as set forth in Appendix C and any other administrative penalties authorized by law without allowing opportunity to correct a violation when the violation is not capable of being corrected.

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

- Subsection (a): Adds that processor sales or transfers to medical marijuana patients or caregivers is prohibited pursuant to 63 O.S. § 423(C), except that processors may process medical marijuana into concentrate on behalf of a licensed patient or caregiver for a fee.
- Subsection (b): Adds a new provision that would require a log to be kept for each occasion medical marijuana is processed into a concentrate for a medical marijuana patient or caregiver.
- Subsection (c): Adds provision clarifying that only the medical marijuana received from the licensed patient or caregiver may be processed into the concentrate.
- Subsection (d): Adds labeling requirements for the medical marijuana concentrate processed on behalf of a licensed patient or caregiver.
- Subsection (e): Adds requirement that processors store medical marijuana concentrate processed on behalf of a licensed patient under conditions and in manner that protects against contamination.
- Subsection (f): Adds provision clarifying medical marijuana concentrate processed for a licensed patient or caregiver are not subject to the testing requirements set forth in 63 O.S. § 427.17.
- Subsection (g): Adds provision clarifying sales not in accordance with this Section are unlawful sales.

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

- Subsection (b)(2): Clarifies that copies of sample field logs, patient processing logs, inventory manifests, transporter agent licenses 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.
- Subsection (b)(4): Creates requirement for a log documenting each instance a processor processed medical marijuana into a concentrate form on behalf of a licensed patient or caregiver.

- Subsection (e): Adds references to Appendix C, which creates a fine schedule for violations.
- Subsection (e)(8): Clarifies the Department may seek fines as set forth in Appendix C and any other administrative penalties authorized by law without allowing opportunity to correct a violation when the violation is not capable of being corrected.

OAC 310:681-5-6.1. Penalties

- Subsection (a): Clarifies it is a violation to not submit a timely, complete and accurate monthly report and moves the fines to Appendix C, which establishes a schedule of fines for violations.
- Subsection (b): Moves the monetary penalties for fraudulent reports to Appendix C, which establishes a schedule of fines for violations.
- Subsection (c): Moves the monetary penalties for unlawful sales to Appendix C, which establishes a schedule of fines for violations.
- Subsection (f): Establishes that penalties shall be assessed in the amounts set forth in Appendix C and failure to pay fines assessed within thirty (30) days results in non-renewal, suspension, and/or revocation of the license.

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

- 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

- Subsection (a): Prohibits consumption of alcohol or the smoking or vaping of medical marijuana on licensed premises. If the licensed premises is a residence, then consuming alcohol or the smoking or vaping of marijuana is prohibited in areas where operations of the business are conducted.
- Subsection (c): Clarifies no commercial licensee shall deliver medical marijuana or medical marijuana products to licensed patients or caregivers.
- Subsection (f): Clarifies this subsection applies to medical marijuana and not just products.
- Subsection (j): Adds prohibition clarifying that growers shall not possess, sell, or transfer medical marijuana products.
- Subsection (l): Clarifies that licensees shall only sell or otherwise transfer medical marijuana to Oklahoma-licensed medical marijuana businesses and that licensee shall not sell or purchase medical marijuana from out-of-state individuals or entities. Clarifies that dispensaries may sell medical marijuana and medical marijuana products to licensed patients and caregivers, and processors may process medical marijuana into a concentrate on behalf of a licensed patient or caregiver.

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

- 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. Adds that deceptive, false, or misleading packaging and labeling includes claims that a product is “organic” without approval from Federal Government or “pesticide free” when pesticides have been used on the medical marijuana or products. Adds prohibition that packages and labels cannot contain universal symbols from other states. Prohibits designing a label in a manner that would cause confusion regarding the package’s contents, potency or other required information. Adds

requirement that packaging and labeling contain current and accurate information that matches what is on file with the OMMA, including legal name, trade name and license number.

- 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.
- 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.
- 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 310:681-7-3. Advertising

- Subsection (b): Adds prohibition against representations by licensee that it is engaged in commercial services for which it is not licensed. Adds prohibition against advertisement that could cause licensed patients to believe medical marijuana was grown in another state.
- Subsection (c): Adds that deceptive, false, or misleading advertising includes claims that a product is “organic” without approval from Federal Government or “pesticide free” when pesticides have been used on the medical marijuana or products.

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

- 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.
- 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”).
- Subsection (f): Revised to add “Except as is authorized in these Rules” in recognition that proposed permanent rules establish process for retesting.
- 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.
- 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.
- 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 Subsection (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.

- 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.
- 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

- 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.

OAC 310:681-8-3. Sampling requirements and procedures

- 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.
- Subsection (a)(6): Requires samples to be clearly labeled with the following information: “Primary Sample” or “Reserve Sample,” name, license number, and batch number.
- Subsection (a)(7): Clarifies reserve sample shall only be used for quality control purposes or retesting in accordance with OAC 310:81-8-1(j).
- 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.
- Subsection (b): Nonsubstantive clean up changes.
- Subsection (e)(2): Prohibits a laboratory from withholding from a commercial licensee a COA reporting a failed test.
- 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.
- 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 within allowable threshold.
- Subsection (e)(6): Requires laboratory to immediately notify the Department in the form and manner prescribed by Department of any failed testing.

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

- Subsection (e): Establishes that licensees are allowed one name change request per year and establishes the information and documentation a licensee must submit relating to the business name.
- Subsection (f)(1): clarifies business licenses may not be wholly assigned, sold, or transferred to a new owner or another legal entity.

OAC 310:681-9-3. License applications

- Subsection (e)(3): Adds requirement that official documentation from the Secretary of State establishing the applicant’s trade name should accompany the application for a license if applicable.

OAC 310:681-9-5. License applications

- Subsection (a): Adds a reference to Appendix C, which establishes a schedule of fines for violations.
- Subsection (g): Adds a reference to Appendix C, which establishes a schedule of fines for violations.
- Subsection (i): Adds a reference to Appendix C for inspection violations not corrected within thirty (30) days, which creates a schedule of fines for violations.
- Subsection (j) Clarifies the Department may seek fines as set forth in Appendix C and any other administrative penalties authorized by law without allowing opportunity to correct a violation when the violation is not capable of being corrected.

OAC 310:681-9-6. Security Requirements

- Subsection (b): Removes requirement that waste receptacles be locked with commercial-grade II non-residential locks.

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

- Subsection (a): Adds references to Appendix C, which establishes a schedule of fines for violations.
- Subsection (a)(8): Clarifies the Department may seek fines as set forth in Appendix C and any other administrative penalties authorized by law without allowing opportunity to correct a violation when the violation is not capable of being corrected.

OAC 310:681-9-8. Penalties

- Subsection (a): Moves the monetary penalties for unlawful transfers to Appendix C, which establishes a schedule of fines for violations.
- Subsection (d): Establishes that penalties shall be assessed in the amounts set forth in Appendix C and failure to pay fines assessed within thirty (30) days results in non-renewal, suspension, and/or revocation of the license.

OAC 310:681-9-9. Waste disposal

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

Appendix C: Establishes a schedule of fines for various administrative offenses.