# TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 681. MEDICAL MARIJUANA REGULATIONS

#### **RULEMAKING ACTION:**

**EMERGENCY** adoption

#### **RULES:**

Subchapter 1. General Provisions

310:681-1-2 [AMENDED]

310:681-1-4 [AMENDED]

310:681:1-6 [AMENDED]

310:681-1-7 [AMENDED]

310:681-1-9.1 [AMENDED]

Subchapter 2. Medical Marijuana Licenses

310:681-2-1 [AMENDED]

310:681-2-3 [AMENDED]

310:681-2-5 [AMENDED]

310:681-2-8 [AMENDED]

Subchapter 3. Transporter License

310:681-3-1 [AMENDED]

310:681-3-2 [AMENDED]

310:681-3-3 [AMENDED]

310:681-3-4 [AMENDED]

Subchapter 4. Research Facilities and Education Facilities

310:681-4-2 [AMENDED]

310:681-4-3 [AMENDED]

310:681-4-4 [AMENDED]

310:681-4-5 [AMENDED]

Subchapter 5. Medical Marijuana Businesses

310:681-5-1.1 [AMENDED]

310:681-5-2 [AMENDED]

310:681-5-2.1 [NEW]

310:681-5-3 [AMENDED]

310:681-5-3.1 [AMENDED]

310:681-5-3.2 [AMENDED]

310:681-5-4 [AMENDED]

310:681-5-4.1 [NEW]

310:681-5-6 [AMENDED]

310:681-5-6.1 [AMENDED]

310:681-5-8 [AMENDED]

310:681-5-8.1 [AMENDED]

310:681-5-11 [AMENDED]

310:681-5-12 [AMENDED]

310:681-5-14 [NEW]

310:681-5-17 [AMENDED]

310:681-5-18 [AMENDED]

Subchapter 7. Packaging, Labeling, and Advertising

310:681-7-1 [AMENDED]

Subchapter 8. Laboratory Testing

310:681-8-1 [AMENDED]

310:681-8-2 [AMENDED]

310:681-8-3 [AMENDED]

310:681-8-4 [AMENDED]

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Subchapter 9. Waste Disposal Facilities
   310:681-9-1 [AMENDED]
   310:681-9-2 [AMENDED]
   310:681-9-3 [AMENDED]
   310:681-9-4 [AMENDED]
   310:681-9-6 [AMENDED]
   310:681-9-7 [AMENDED]
   Appendix C [REVOKED]
   Appendix C [NEW]
   Appendix D [NEW]
   Appendix E [NEW]
AUTHORITY:
   Commissioner of the Oklahoma State Department of Health; 63 O.S. § 1-104
ADOPTION:
   July 21, 2022
EFFECTIVE:
   Immediately upon Governor's approval
EXPIRATION:
   Effective through September 14, 2023, unless superseded by another rule or disapproved by the
Legislature.
SUPERSEDED EMERGENCY ACTIONS:
Superseded rules:
   Subchapter 1. General Provisions
   310:681-1-2 [AMENDED]
   310:681-1-4 [AMENDED]
   310:681:1-6 [AMENDED]
   310:681-1-7 [AMENDED]
   310:681-1-9.1 [AMENDED]
   Subchapter 2. Medical Marijuana Licenses
   310:681-2-3 [AMENDED]
   310:681-2-5 [AMENDED]
   310:681-2-8 [AMENDED]
   Subchapter 3. Transporter License
   310:681-3-1 [AMENDED]
   310:681-3-2 [AMENDED]
   310:681-3-3 [AMENDED]
   310:681-3-4 [AMENDED]
   310:681-3-6 [AMENDED]
   Subchapter 4. Research Facilities and Education Facilities
   310:681-4-2 [AMENDED]
   310:681-4-3 [AMENDED]
   310:681-4-4 [AMENDED]
   310:681-4-5 [AMENDED]
   Subchapter 5. Medical Marijuana Businesses
   310:681-5-1.1 [AMENDED]
   310:681-5-2 [AMENDED]
   310:681-5-2.1 [NEW]
   310:681-5-3 [AMENDED]
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310:681-5-3.1 [AMENDED] 310:681-5-3.2 [AMENDED] 310:681-5-4 [AMENDED] 310:681-5-4.1 [NEW]

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310:681-5-6 [AMENDED]
   310:681-5-6.1 [AMENDED]
   310:681-5-8 [AMENDED]
   310:681-5-8.1 [AMENDED]
   310:681-5-11 [AMENDED]
   310:681-5-12 [AMENDED]
   310:681-5-14 [NEW]
   310:681-5-18 [AMENDED]
   Subchapter 7. Packaging, Labeling, and Advertising
   310:681-7-1 [AMENDED]
   Subchapter 8. Laboratory Testing
   310:681-8-1 [AMENDED]
   310:681-8-2 [AMENDED]
   310:681-8-3 [AMENDED]
   Subchapter 9. Waste Disposal Facilities
   310:681-9-1 [AMENDED]
   310:681-9-2 [AMENDED]
   310:681-9-3 [AMENDED]
   310:681-9-4 [AMENDED]
   310:681-9-6 [AMENDED]
   310:681-9-7 [AMENDED]
   Appendix C [REVOKED]
   Appendix C [NEW]
   Appendix D [NEW]
   Appendix E [NEW]
Gubernatorial approval:
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November 23, 2021

#### **Register publication:**

39 Ok Reg 271

#### **Docket number:**

21-858

#### **INCORPORATIONS BY REFERENCE:**

#### FINDING OF EMERGENCY:

The proposed emergency rules: implement legislative changes mandated by HB 3208, SB 1511, and SB 1726; implement legislative changes mandated by SB 1033, HB 2646 and HB 2272; add new requirements in statute under 63 OS. § 425 et seq., 63 O.S. § 427.2 et seq., and 63 O.S. § 427.14b et seq.; and address changes and/or new requirements in statute under 63 O.S. § 420 et seq., 63 O.S. § 427.1 et seq., and 63 O.S. § 427a et seq. The proposed emergency rules also add in new requirements to implement the State inventory tracking system pursuant to 63 O.S. § 427.13. The emergency rules are intended to ensure the safety of medical marijuana and medical marijuana products sold to consumers and to prevent inversion and diversion and unlawful distribution of medical marijuana and medical marijuana products. Permanent rules implementing the requirements set forth in the new legislation cannot be promulgated until 2023.

#### **GIST/ANALYSIS:**

The amendments reflect new requirements that commercial growers are prohibited from being within 1,000 feet of a school as required under SB 1511. The distance is measured from the property line of the school to the property line of the commercial grower. The rules amend the Definition section to add technology centers to the definition of public school. Language is also added providing for a moratorium as to the processing and issuing new medical marijuana business licenses for dispensaries, processors, and growers beginning August 1, 2022.

The rules amend the Definitions section to add new terms and corresponding definitions for terms in the new and amended sections of Chapter 681. The rules add and define hazardous and nonhazardous processor license as authorized by HB 2646. Specifically, a processor utilizing any chemical in the extraction process that is defined as hazardous under 29 CFR 1910.1200 is required to obtain a hazardous processor license. Preschools are removed from the definitions of public and private schools, as provided for in HB 2646. The amendments reflect the statutory requirements for the distance between a school and a medical marijuana dispensaries and/or waste facilities that become effective on November 1, 2021 per HB 2646. Most records are now required to be maintained for seven (7) years as provided in HB 2646. The rules add the following fees as authorized by HB 2646: a \$20 license reprint fee for patient licenses and transporter agent licenses; a \$500 fee for a material change that would affect qualifications for licensure; a \$500 late renewal fee if licensees wish to renew a license that has been expired for no longer than nighty (90) days; and other fines penalties specifically provided for under HB 2646. Possession limits and transaction limits are updated to be consistent with HB 2646. Laboratories, research facilities, and education facilities are now also given a complimentary transportation license, and this language is added throughout the rules reflecting the ability of these commercial licensees to transport medical marijuana and medical marijuana product. The rules provide regulatory requirements for the State inventory tracking system. The rules also require that commercial licensees track inventory, cultivation, manufacturing and transactions for the purpose of reporting the information to the Department. The rules add language that a rejected application shall be corrected within thirty (30) days and that if the application is resubmitted with errors not clerical or typographical in nature the application shall be denied unless the Department determines otherwise, pursuant to HB 2646. The thirty (30) day grace period for licensees to liquidate marijuana after their license expires, is revoked, suspended or surrendered has been removed per HB 2646. The rules allow for the Department to perform inspections to ensure qualifications for licensure, and they remove the requirement to provide twenty-four (24) hours' notice consistent with HB 2646. The rules allow the Department to issue an Order for Disciplinary Action that will become final within 30 days if a hearing is not requested. Language is added providing for emergency cease and desist authority per HB 2646. The rules allow dispensaries to display samples of medical marijuana in a sample container for patients to smell and handle, and provide requirements on how dispensaries may display and properly label the samples. The amendments also include the addition of the ability for growers and dispensaries to make and package noninfused pre-rolls that do not exceed one (1) gram. In doing so, the rules include: new definitions for "grower", "dispensary", "infused" and "noninfused pre-rolls"; new testing requirements for pre-rolls and kief; new sampling requirements for pre-rolls and final medical marijuana products; changes in batch sizes to be in line with new statutory changes; and changes in the definitions of "final medical marijuana product" and "nonliquid medical marijuana product" to clearly reflect the batch size permissible for all medical marijuana and medical marijuana products. The rules include implementation for embargoing and recalling medical marijuana or medical marijuana products that may be harmful or unsafe for human consumption or tested above allowable thresholds.

#### **CONTACT PERSON:**

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DUE TO EXCESSIVE LENGTH OF THESE RULES (AS DEFINED IN OAC 655:10-7-12), THE FULL TEXT OF THESE RULES WILL NOT BE PUBLISHED. THE RULES ARE AVAILABLE FOR PUBLIC INSPECTION AT THE OKLAHOMA STATE DEPARTMENT OF HEALTH, 123 ROBERT S. KERR AVENUE, OKLAHOMA CITY, OKLAHOMA 73102 AND AT THE SECRETARY OF STATE'S OFFICE OF ADMINISTRATIVE RULES. THE FOLLOWING SUMMARY HAS BEEN PREPARED PURSUANT TO 75 O.S., SECTION 255(B):

#### **SUMMARY**

#### **OAC 310:681-1-4. Definitions**

Adds definition of "actively operating" or "actively conducting business operations."

Adds definition of "error in measurement."

Adds definition of "error in measurement allowance." Adds definition of "integration" or "integrated." Revises definition of "inventory tracking system" or "State inventory tracking system" to be consistent with the definition in 63 O.S. § 427.2.

Revises definition of "marijuana" to reflect changes made to the statutory definition in 63 O.S. § 427.2.

Revises definition of "medical marijuana waste" to reflect changes made to the statutory definition in 63 O.S. § 427.2.

Adds definition of "nonoperational."

Adds definition of "openly in existence."

Revises definition of "Public School" to reflect changes made to the statutory definition in 63 O.S. § 427.2.

Adds definition of "publicly traded company."

Adds definition of "RFID."

Adds definition of "seed-to-sale tracking system."

Adds definition of "wholesale package."

Adds definition of "working towards operation status".

#### OAC 310:681-2-3. Applications for caregiver's license

Subsection (e)(2): Adds language that caregivers "shall not charge a medical marijuana patient licensee for cultivating medical marijuana in excess of actual costs incurred in cultivating the medical marijuana."

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

Subsection (d): Adds language requiring each warehouse location of a commercial transporter applicant or licensee to be inspected and approved by the Department prior to use.

#### OAC 310:681-3-6. Inventory manifests

Subsection (a): Replaces "an electronic inventory management system" with the "State's inventory tracking system in accordance with OAC 310:681-5-6(d)" to be consistent with 63 O.S. § 427.16(H).

#### OAC 310:681-4-2 Licenses

Subsection (f)(1): Removes language prohibiting research and education facilities from transferring licenses.

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

Subsection (a)(6): adds language clarifying that data submitted to the Department through the State's inventory tracking system will satisfy monthly reporting requirements.

Subsection (c)(5): adds language requiring commercial licensees to maintain written standard operating procedures.

Subsection (d)(1)-(3): Adds language and requirements for reporting of required data and information into the State's inventory tracking system pursuant to 63 O.S. § 427.3(D)(8) and § 427.13(B).

Subsection (e): Adds language requiring commercial licensees use a seed to sale tracking system or integrate their seed to sale tracking system with the State's inventory tracking system. Clarifies that if the commercial licensee's seed to sale system does not integrate or share all required information with the State's inventory tracking system, the commercial license is required to ensure all required information is reported directly to the State's inventory tracking system.

Subsection (f)(1)-(8): Adds new language for reporting of required data and information into the State's inventory tracking system, including requirements related to the purchase and use of RFID tags in order to track medical marijuana and medical marijuana product through all stages of the life

span of the plant and product. Adds requirement relating to the use of RFID tags in the context of wholesale packages.

Subsection (g)(1)-(8): Adds new language and requirements for commercial licensees' inventory tracking system administrators and employee users to access the State's inventory tracking system. Subsection (h): Creates a new provision governing reporting requirements in the context of loss of access to the State's inventory tracking system both due to circumstances beyond and within commercial licensees' control.

Subsection (i): Clarifies audits conducted by the Department ensure the accuracy of information and data reported to the Department.

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

Subsection (9): Clarifies that commercial licensees are financially responsible for the costs of compliance and inventory tracking and that the Department will not contribute to, fund or subsidize compliance or tracking expenses incurred by commercial licensees.

#### OAC 310:681-5-2. Licenses.

Subsection (e)(2)(D)(i)-(vii) Creates new provision allowing a medical marijuana grower, processor, and commercial transporter to submit a request and required documentation to the Department to add a publicly traded company as an owner of up to forty percent (40%) of the equity interest of an existing medical marijuana grower, processor, or commercial transporter that has been licensed for at least eighteen (18) months and is operating in good standing pursuant to 63 O.S. § 427.15a. Subsection (f): removes language prohibiting business licensees from transferring licenses.

# OAC 310:681-5-2.1. Objection by municipality.

Subsection (a)(1)-(2): Creates new provisions allowing municipal governments to object prior to an initial renewal or transfer of ownership of a medical marijuana dispensary that the municipality determines is operating contrary to the required setback distance from a school pursuant to 63 O.S. § 426.1(E)(2)-(5).

# **OAC 310:681-5-3.** Applications.

Subsection (e)(6): Adds new language reflecting the change in measurement of the distance between a medical marijuana grow and a school pursuant to 63 O.S. § 425(G)(2).

Subsection (h): Adds the new subsection; adds new language to establish a moratorium on processing and issuing licenses for commercial dispensaries, processors, and grows.

Subsection (e)(6): Adds new language reflecting the change in measurement of the distance between a medical marijuana dispensary and a school pursuant to 63 O.S. § 425(G).

Subsection (e)(10): Adds reference to additional documents required under OAC 310:681-5-

2(e)(2)(c) for a medical marijuana grower, processor or transporter to add a publicly traded company as an owner.

#### **OAC 310:681-5-4.** Inspections.

Subsection (d): Creates new provisions requiring the Department conduct on-site inspections of warehouse locations owned by medical marijuana transporter applicants and licensees prior to use of the warehouse location pursuant to 63 O.S. § 427.16.

#### OAC 310:681-5-4.1. Operational status visit.

Subsection (a)(1)-(3): Creates new provisions requiring the Department conduct on-site visits at licensed growers, processors and dispensaries to verify operational status and providing an 180 day grace period pursuant to 63 O.S. § 427.6(K).

Subsection (b): Creates new provisions requiring the Department to conduct follow up on-site visits at licensed growers, processors and dispensaries to verify operational status if the licensee was not

operational at the initial visit pursuant to 63 O.S. § 427.6(K). Adds language allowing discretionary second grace period and requiring the Department move for revocation if licensee is non-operational and second grace period is not granted.

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

Subsection (a)(4): Adds language clarifying that submission of information and data to the State's inventory tracking system is required and will satisfy the monthly reporting requirements upon implementation.

Subsection (b)(6): Creates a new provision adding written standard operating procedures to the list of records commercial licensees are required to keep onsite and maintained for seven (7) years. Subsection(d)(1)-(3): Adds language and requirements for reporting required data and information into the State's inventory tracking system pursuant to 63 O.S. § 427.3(D)(8) and § 427.13(B). Subsection(e): Adds language requiring commercial licensees use a seed to sale tracking system or integrate their seed to sale tracking system with the State's inventory tracking system. Clarifies that if the commercial licensee's seed to sale system does not integrate or share all required information with the State's inventory tracking system, the commercial license is required to ensure all required information is reported directly to the State's inventory tracking system.

Subsection(f)(1)-(8): Adds new language and requirements for reporting required data and information into the State's inventory tracking system, including requirements related to the purchase and use of RFID tags in order to track medical marijuana and medical marijuana products through all stages of the life span of the plant and product. Adds requirement relating to the use of RFID tags in the context of wholesale packages.

Subsection (g)(1)-(8): Adds new language and requirements for commercial licensees' inventory tracking system administrators and employee users to access the State's inventory tracking system. Subsection (h): Creates a new provision governing reporting requirements in the context of loss of access to the State's inventory tracking system both due to circumstances beyond and within commercial licensees' control.

Subsection (i): Clarifies audits conducted by the Department ensure the accuracy of information and data reported to the Department.

#### OAC 310:681-5-11. Attestation confirming or denying foreign financial interest.

Subsection (a)-(c): Creates new requirements for medical marijuana businesses to submit an attestation to the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control disclosing the existence of any foreign financial interests pursuant to 63 O.S. § 427.15.

#### **OAC 310:681-5-18.** Prohibited Acts.

Subsection (m): Adds prohibition on the transfer, purchase, sale of medical marijuana or medical marijuana products not properly inputted or tracked in the State's inventory tracking system after implementation.

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

Subsection (e)(3): Creates new requirement that RFID tags not obscure required label and packaging requirements.

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

Subsection (d)(3)-(4): Adds requirement that laboratories maintain and properly store reserve samples for at least thirty (30) days.

#### **OAC 310:681-9-1.** Waste disposal.

Subsection (b): Adds language reflecting that as of November 1, 2021 there will be no limit to the number of medical marijuana waste disposal licenses pursuant to 63 O.S. §430(A).

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

Subsection (f): Removes prohibition on transfer of waste disposal facility licenses and permits.

#### OAC 310:681-9-3. License applications.

Subsection (e)(5): Changes distance measurement between waste disposal facility and school from "property line" to "front entrance" in the context of supporting documentation that must be submitted with applications for waste disposal facility licenses.

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

Subsection (b)(1)-(3): Creates new requirements for reporting required data and information into the State's inventory tracking system pursuant to 63 O.S. § 427.3(D)(8) and § 427.13(B).

Subsection (c): Adds language requiring commercial licensees use a seed to sale tracking system or integrate their seed to sale tracking system with the State's inventory tracking system. Clarifies that if the commercial licensee's seed to sale system does not integrate or share all required information with the State's inventory tracking system, the commercial license is required to ensure all required information is reported directly to the State's inventory tracking system.

Subsection (d)(1)-(8): Adds new language and requirements for reporting required data and information into the State's inventory tracking system, including requirements related to the purchase and use of RFID tags in order to track medical marijuana and medical marijuana products through all stages of the life span of the plant and product. Adds requirement relating to the use of RFID tags in the context of wholesale packages.

Subsection (e)(1)-(7): Adds new language and requirements for commercial licensees' inventory tracking system administrators and employee users to access the State's inventory tracking system. Subsection (f): Creates a new provision governing reporting requirements in the context of loss of access to the State's inventory tracking system both due to circumstances beyond and within commercial licensees' control.

PURSUANT TO THE ACTIONS DESCRIBED HEREIN, THE FOLLOWING EMERGENCY RULES ARE CONSIDERED PROMULGATED AND EFFECTIVE UPON APPROVAL BY THE GOVERNOR AS SET FORTH IN 75 O.S. § 253(F):

#### **SUBCHAPTER 1. GENERAL PROVISIONS**

# 310:681-1-2. Regulatory program established

- (a) A regulatory program is hereby established under the Oklahoma State Department of Health in the OMMA, and the initiation, administration, regulation, and enforcement of such program shall be the responsibility of the OMMA or its designee.
- (b) All license applications, inquiries, and other correspondence shall be directly electronically submitted to and received and processed by the Oklahoma State Department of Health by the OMMA division or its designee, except as is otherwise required by law or expressly permitted in writing by the Department.
- (c) All applications and forms provided for under this Chapter are available on the Oklahoma State Department of Health's OMMA website at http://omma.ok.gov/.
- (d) The Oklahoma State Department of Health is located at <del>1000 N.E. 10 Street</del> <u>123 Robert S Kerr Ave</u>, Oklahoma City, Oklahoma, 731<del>17</del>02.

#### 310:681-1-4. Definitions

The following words and terms, when used in this Chapter, shall have the following meaning, unless the context clearly indicates otherwise:

"Actively operating" or "Actively conducting business operations" means a commercial licensee

that possesses, sells, purchases or transfers medical marijuana and/or medical marijuana products to or from its licensed premises in a regular or seasonal capacity.

"Advertising" means the act of providing consideration for the publication, dissemination, solicitation, or circulation of visual, oral, or written communication to induce directly or indirectly any person to patronize a particular medical marijuana business or to purchase any particular medical marijuana or medical marijuana products. "Advertising" includes marketing but does not include packaging and labeling.

"Alcoholic beverage" has the same meaning as set forth in 37A O.S. § 1-103 ('alcoholic beverage' means alcohol, spirits, beer and wine as those terms are defined under 37A O.S. § 1-103 "and also includes every liquid or solid, patented or not, containing alcohol, spirits, wine or beer and capable of being consumed as a beverage by human beings").

"Applicant" means the natural person or entity in whose name a license would be issued.

"Application status" means the status of a submitted application and includes the following:

- (A) "Submitted" means the application has been submitted but a review is not yet complete;
- (B) "Rejected" means the application has been reviewed but contains one or more errors requiring correction by the applicant at no additional fee before a final determination on the application can be made. "Rejected" does not mean the application is denied;
- (C) "Approved" means the application has been approved and that a license will be issue and mailed to the applicant; and
- (D) "Denied" means the applicant does not meet the qualifications under Oklahoma law and this Chapter for a license.

"Authority" or "OMMA" means the Oklahoma Medical Marijuana Authority, a division of the Oklahoma State Department of Health.

"Batch number" means a unique numeric or alphanumeric identifier assigned prior to any testing to allow for inventory tracking and traceability.

"Business license" means a license issued by the Department to a medical marijuana dispensary, grower, processor, testing laboratory, or transporter.

"Cannabinoid" means any of the chemical compounds that are active principles of marijuana.

"Caregiver" means a family member or assistant who regularly looks after a licensed patient whom a physician certifies is homebound or needs assistance.

"CFR" means the Code of Federal Regulations, the compilation of the general and permanent rules published in the Federal Register by the executive departments and agencies of the federal government which is published by the U.S. Government Printing Office. Citations in this Chapter to the CFR refer sequentially to the Title, Part and Section numbers.

"Child-resistant" means packaging that is:

- (A) Designed or constructed to be significantly difficult for children under five (5) years of age to open and not difficult for normal adults to use properly as defined by 16 CFR § 1700.15 (1995) and 16 CFR § 1700.20 (1995); and
- (B) Opaque so that the outermost packaging does not allow the product to be seen without opening the packaging material; and
- (C) Resealable to maintain its child-resistant effectiveness for multiple openings for any product intended for more than a single use or containing multiple servings.

"Clone" means a non-flowering plant cut from a mother plant that is capable of developing into a new plant and has shown no signs of flowering.

"COA" means certificate of analysis.

"Commercial license" means any license issued to an individual or entity that is not a patient, caregiver, or transporter agent.

"Commercial licensee" means an individual or entity issued a commercial license and does not mean a patient, caregiver, or transporter agent.

"Commissioner" means the State Commissioner of Health of the Oklahoma State Department of Health.

"Complete(d) application" means a document prepared in accordance with Oklahoma law, these

Rules, and the forms and instructions provided by the Department including any supporting documentation required by the Department and the license fee.

"**Decontamination**" means a process that attempts to remove or reduce to an acceptable level a contaminant exceeding an allowable threshold set forth in these Rules in a harvest batch or production batch.

"Department" means the Oklahoma State Department of Health or its agent or designee.

"**Dispense**" means the retail selling of medical marijuana or <u>medical</u> marijuana products that are packaged and labeled in accordance with the law to a licensed patient, the licensed patient's parent(s) or legal guardian(s) if licensed patient is a minor, or a licensed caregiver.

"Dispensary" or "Commercial Dispensary" means an individual or entity that has been issued a medical marijuana business license by the Department, which allows the dispensary to purchase medical marijuana or medical marijuana products from a licensed processor, grower, or dispensary; to sell medical marijuana and medical marijuana products to a licensed patient, to a licensed caregiver, and to the licensed patient's parent(s) or legal guardian(s) if licensed patient is an minor, and a licensed caregiver; to prepare and package noninfused pre-rolled medical marijuana with a net weight that does not exceed one (1) gram to sell to medical marijuana patients and caregivers; and to sell, transfer, and transport or contract with a commercial transporter to transport medical marijuana or medical marijuana products to another licensed dispensary, a research facility, and an educational facility; and to transfer to testing laboratories.

"**Dispose**" or "**Disposal**" means the final disposition of medical marijuana waste by either a process which renders the waste unusable and unrecognizable through physical destruction or a recycling process.

"Disqualifying criminal conviction" means:

- (A) Any non-violent felony conviction within last two (2) years of submitting an application to the Department;
- (B) Any violent felony conviction for an offense listed in 57 O.S. § 571(2) within last five (5) years of submitting an application to the Department; or
- (C) Incarceration for any reason during submission of application to the Department.

"Education facility" means an individual or entity that has been issued a license by the Department to operate a facility providing training and education to individuals involving the cultivation, growing, harvesting, curing, preparing, packaging, or testing of medical marijuana, or the production, manufacture, extraction, processing, packaging, or creation of medical-marijuana-infused products or medical marijuana products for the limited education and research purposes permitted under state and federal law and these Rules; to transfer, by sale or donation, medical marijuana grown within its operation to licensed research licensees; and to transfer to licensed testing laboratories.

"Entity" means an individual, sole proprietorship, a general partnership, a limited partnership, a limited liability company, a trust, an estate, an association, a corporation, or any other legal or commercial entity.

"Entrance to a private or public school" means an opening, such as a door, passage, or gate, that allows access to any public or private schools, including school buildings, facilities, or other indoor and outdoor properties utilized for classes or school activities.

"Error in measurement" means a mistake made by the Department or a municipality in the setback measurement process where either the distance between a medical marijuana dispensary and a school is miscalculated due to mathematical error or the methods used to measure the setback distance is inconsistent with 63 O.S. § 425(G).

"Error in measurement allowance" means an allowance of an error in measurements of the distance between a medical marijuana dispensary and a school up to and including five hundred (500) feet when remeasured after an original license has been issued.

"Final product" or "Final medical marijuana product" means any finished medical marijuana product that has been infused with a concentrate or that has been further processed and is in the form in which it will be sold to medical marijuana patients and caregivers, meaning no other ingredients or additives will be infused or otherwise added into the product. Examples may include topicals, tinctures, cookies, brownies, candies, gummies, beverages, or chocolate.

"Flower" means the reproductive organs of the marijuana or cannabis plant referred to as the bud or parts of the plant that are harvested and used to consume for consumption in a variety of medical marijuana products.

"**Flowering**" means the reproductive state of the marijuana or cannabis plant in which there are physical signs of flower or budding out of the nodes of the stem.

"Food" has the same meaning as set forth in 63 O.S. § 1-1101 ('food' means (1) articles used for food or drink for man, (2) chewing gum, and (3) articles used for components of any such article) and set forth in the Oklahoma Administrative Code ("OAC") OAC 310:257-1-2 and OAC 310:260-1-6 ("'food' means any raw, cooked, or processed edible substance, ice, beverage or ingredient used or intended for use or for sale in whole or in part for human consumption").

"Grower" or "Commercial grower" means an individual or entity that has been issued a medical marijuana business license by the Department, which allows the grower to grow, harvest, dry, cure, package medical marijuana and noninfused pre-rolled medical marijuana with a net weight that does not exceed one (1) gram, to sell, transfer, and transport or contract with a commercial transporter for the transport of medical marijuana in accordance with Oklahoma law and this Chapter to a dispensary, processor, grower, research facility, education facility, or testing laboratory.

"Harvest Batch" means a specifically identified quantity of usable medical marijuana, no greater than ten (10) pounds, not to exceed harvest batch sizes allowable under OAC 310:681-8-1(b), that is uniform in strain, cultivated utilizing the same cultivation practices, harvested at the same time from the same location, and dried or cured under uniform conditions.

"Hazardous processor license" means a license issued to a medical marijuana processor that performs an extraction method that utilizes chemicals considered hazardous by the OSHA Hazard Communication Standard under 29 CFR § 1910.1200.

"Immature plant" means a nonflowering marijuana plant that has not demonstrated signs of flowering.

"Indirect beneficial owner" means an individual or entity who indirectly, through any contract, arrangement, understanding, relationship or otherwise, owns ten percent (10%) or more of the equity interests of a grower, processor, or dispensary.

"Information panel" has the same definition as set forth in 21 CFR § 101.2 and means "that part of the label immediately contiguous and to the right of the principal display panel as observed by an individual facing the principal display panel."

"Infused pre-roll" means pre-rolled medical marijuana into which cannabis concentrate, extracts, derivatives, or other ingredients have been incorporated.

"Integration" or "Integrated" means a third-party vendor's software application or a software service that has been fully validated to share inventory tracking or other data directly with the State inventory tracking system via a secure Application Programming Interface ("API").

"Inventory tracking system" or "State inventory tracking system" means a the required tracking system established by the Department that accounts for medical marijuana from either the seed or immature plant stage until the medical marijuana or medical marijuana product is sold to a patient at a medical marijuana dispensary, transferred to a medical marijuana research facility, disposed of in accordance with these Rules, or used in a research project by a medical marijuana research facility, meaning that the State's inventory tracking system accounts from the entire life span of medical marijuana and medical marijuana products, including any testing samples thereof and medical marijuana waste.

"Kief" means the resinous trichomes of marijuana that have been separated from the marijuana plant.

"Label" carries the same definition as set forth in 63 O.S. § 1-1101 and means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this article that any word, statement, or other information appearing on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if there be any, of the retail package of such article, or is easily legible through the outside container or wrapper.

"License" means a state issued license or other state issued documentation proving the holder of such license is a member of a state-regulated medical marijuana program.

- "License number" means the unique multi-character identifier issued and printed upon each license.
- "Licensee" means any natural born person or entity that holds a medical marijuana license provided for in this Chapter, excluding inmates of any local, county, state, or federal correctional facility or jail.
  - "Licensed Packager" means as used in 63 O.S. § 422(C) a processor.
- "Licensed premises" means the premises specified in an application for a medical marijuana business, research facility, education facility, or waste disposal facility that is owned or in lawful possession of the licensee and within which the licensee is authorized to operate.
  - "Lot" means the food produced during a period of time indicated by a specific code.
- "Marijuana" means the same as the term that is defined in 63 O.S. § 2-101 and shall not include any plant or material containing delta-8 or delta-10 tetrahydrocannabinol which is grown, processed or sold pursuant to the provisions of the Oklahoma Industrial Hemp Program.
- "Material change" means any change that would affect the qualifications for licensure of an applicant or licensee.
  - "Mature plant" means harvestable female marijuana plant that is flowering.
  - "Medicaid" means the program that is also commonly known in Oklahoma as "SoonerCare."
- "Medical marijuana" means marijuana that is grown, processed, dispensed, tested, possessed, or used for a medical purpose.
- "Medical marijuana business" means an individual or entity licensed by the Department as a medical marijuana dispensary, grower, processor, testing laboratory, or transporter.
- "Medical marijuana concentrate" ("Concentrate") means a substance obtained by separating cannabinoids from any part of the marijuana plant by physical or chemical means, so as to deliver a product with a cannabinoid concentration greater than the raw plant material from which it is derived. Categories of concentrate include water-based medical marijuana concentrate, food-based medical marijuana concentrate, solvent-based concentrate, and heat- or pressure-based medical marijuana concentrate as those terms are defined in the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.
- "Medical marijuana product" means a product that contains cannabinoids that have been extracted from plant material or the resin therefrom by physical or chemical means and is intended for administration to a licensed patient, including but not limited to concentrates, oils, tinctures, edibles, pills, topical forms, gels, creams, and other derivative forms, except that this term does not include live plant forms.
- "Medical marijuana research" means research on medical marijuana and medical marijuana products for public purposes, including the advancement of (A) Public health policy and public safety policy, (B) Agronomic and horticultural best practices, and (C) Medical and pharmacopoeia best practices. For purposes of this Chapter, this term does not include biomedical and clinical research that is subject to federal regulations and institutional oversight and shall not be subject to Department oversight.
  - "Medical marijuana waste" means
    - (A) unused, surplus, returned or out-of-date marijuana; recalled marijuana; unused marijuana; plant debris of the plant of the genus cannabis, including dead plants and all unused plant parts, except the term shall not include <u>seeds</u>, roots, stems, stalks and fan leaves,
    - (B) all product which is deemed to fail laboratory testing and cannot be remediated or decontaminated, or
    - (C) all products and inventory from commercial licensees that:
      - (i) have gone out of business;
      - (ii) are not subject to the provisions of Section 1560 of Title 12 of the Oklahoma Statute; and
      - (iii) are unable to lawfully transfer or sell the product and inventory to another commercial licensee.
  - "Minor" means any natural person younger than eighteen (18) years of age.
- "Mother plant" means a marijuana plant that is grown or maintained for the purpose of generating clones, and that will not be used to produce plant material for sale to a processor or dispensary.
- "Municipality" means the same definition as set forth in the Oklahoma Municipal Code, 11 O.S. § 1-102, and "means any incorporated city or town."

"Nonhazardous processor license" means a license issued by the Department to a processor that will not perform any processing or extraction methods that utilize a chemical considered hazardous by the OSHA Hazard Communication Standard under 29 CFR § 1910.1200.

"Noninfused pre-roll" means pre-rolled medical marijuana that consist only of flower, shake, or trim, and may include unflavored paper, a filter, tip, or cone. This product shall not include marijuana concentrates, extracts, derivatives, or any other ingredients.

"Nonliquid medical marijuana product" means a substance obtained by separating cannabinoids that have been extracted from plant material by physical or chemical means and is not a liquid, meaning that it does not conform to a container in which it is placed. Examples include wax, budder, shatter, and hash.

"Nonoperational" means a commercial licensee that cannot provide proof that it is actively operating or working towards operational status.

"Officer of a corporate entity" or "Principal officer" means an officer identified in the corporate bylaws, articles of organization or other organizational documents, or in a resolution of the governing body.

"Officer of a municipality" means the same definition as set forth in the Oklahoma Municipal Code, 11 O.S. § 1-102, and means any person who is elected to an office in municipal government or is appointed to fill an unexpired term of an elected office, and the clerk and the treasurer whether elected or appointed.

"Oklahoma resident" or "Resident" means an individual who can provide proof of residency as required by OAC 310:681-1-6 (relating to proof of residency) or OAC 310:681-5-3.1 (relating to proof of residency for commercial business licensees).

"Oklahoma uniform symbol" or "Universal symbol" means the image, established by the Department and made available to commercial licensees through the OMMA website, which indicates the package contains medical marijuana or medical marijuana products with THC and must be printed at least one-half inch in size by one-half inch in size in the color designated by the Department.

"Openly in existence" means any building, location, or structure on a school site that has visible outward markings indicating the building, location, or structure was operating as a school which would serve as sufficient notice of the existence of the school or a reason for further inquiry on the part of the medical marijuana dispensary license applicant. "Openly in existence" shall not mean any school that operated secretly or discreetly without any signs or other markings on any building, location, or structure on the school site, undeveloped land or a structure owned by a school that was not openly used and marked as a school site, or any school site that was established after the medical marijuana dispensary had been established and licensed by the Department.

"**Organic**" means the same as the term defined in the National Organic Program codified at 7 CFR § 205.2. This includes the terms "organically produced" as set forth in 7 U.S.C. § 6502(15) and "100 percent organic" and "made with organic (specified ingredients or food group(s))" as set forth in 7 CFR § 205.102.

"Out-of-state medical marijuana patient license" means an unexpired medical marijuana patient license issued by another U.S. state, which is the substantial equivalent of the Oklahoma medical marijuana patient license issued pursuant to OAC 310:681-2-1 and OAC 310:681-2-2.

"Owner" means, except where the context otherwise requires, a direct beneficial owner, including, but not limited to, all persons or entities as follows:

- (A) All shareholders owning an interest of a corporate entity and all officers of a corporate entity;
- (B) All partners of a general partnership;
- (C) All general partners and all limited partners that own an interest in a limited partnership;
- (D) All members that own an interest in a limited liability company;
- (E) All beneficiaries that hold a beneficial interest in a trust and all trustees of a trust;
- (F) All persons or entities that own interest in a joint venture;
- (G) All persons or entities that own an interest in an association;
- (H) The owners of any other type of legal entity; and
- (I) Any other person holding an interest or convertible note in any entity which owns, operates, or

manages a licensed medical marijuana facility.

"Package" or "Packaging" means any container or wrapper that a medical marijuana business may use for enclosing or containing medical marijuana or medical marijuana products, except that "package" or "packaging" shall not include any carry-out bag or other similar container.

"Patient" or "Licensed patient" means a person that has been properly issued a medical marijuana license pursuant to Oklahoma law and these Rules.

#### "Pesticide" means

- (A) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or
- (B) any substance or mixture of substances intended for use as a plant regulator, defoliant or desiccant. "Pesticide" shall not include any article that is a "new animal drug" as designated by the United States Food and Drug Administration.

"Physician" or "Oklahoma Physician" means a doctor of medicine, a doctor of osteopathic medicine, or a doctor of podiatric medicine who holds a valid, unrestricted and existing license to practice in the State of Oklahoma.

"Plant material" means the leaves, stems, buds, and flowers of the marijuana plant, and does not include seedlings, seeds, clones, stalks, or roots of the plant or the weight of any non-marijuana ingredients combined with marijuana.

"Political subdivision" means any county or municipal governments.

"Preschool" means a public early childhood education program offered under 70 O.S. §§ 11-103.7 and 1-114 (B) or similar program offered by a private school whose primary purpose is to offer educational (or academic) instruction. Preschool does not include a homeschool, daycare, or child care facility licensed under the Oklahoma Child Care Facilities Licensing Act, 10 O.S. § 401 et seq.

"Principal display panel" has the same definition as set forth in 21 CFR § 101.1 and "means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale."

"Private school" means a <u>an preschool</u>, elementary, middle, or high school maintained by private individuals, religious organizations, or corporations, funded, at least in part, by fees or tuition, and open only to pupils selected and admitted based on religious affiliations or other particular qualifications. "Private school" shall not include a homeschool, daycare, or child care facility licensed under the Oklahoma Child Care Facilities Licensing Act, 10 O.S. § 401 et seq.

"Process" means to distill, extract, manufacture, prepare, or otherwise produce a medical marijuana product.

"Processor" or "Commercial Processor" means an individual or entity that has been issued a medical marijuana business license by the Department, which allows the processor to: purchase medical marijuana or medical marijuana products from a grower or processor; process, package, sell, transfer, and transport or contract with a commercial transporter to transport medical marijuana and medical marijuana products that they processed to a licensed dispensary, processor, or testing laboratory in accordance with Oklahoma law and this Chapter; and process medical marijuana received from a licensed patient into a medical marijuana concentrate, for a fee. Processors will receive either a hazardous processor license or a non-hazardous processor license based on the type of chemicals the processor will be utilizing in the extraction process in accordance with these Rules.

#### "Production batch" means

- (A) Any amount of medical marijuana concentrate <u>or nonliquid medical marijuana products</u>, not to exceed<del>ten (10) pounds</del> <u>production batch sizes allowable under OAC 310:681-8-1(b)</u>, of the same category and produced using the same extraction methods, standard operating procedures, and an identical group of harvest batch of medical marijuana; and
- (B) Any amount of finished medical marijuana product, not to exceed ten (10) pounds production batch sizes allowable under OAC 310:681-8-1(b), of the same exact type, produced using the same ingredients, standard operating procedures, and same production batch of medical marijuana concentrate or same harvest batch of medical marijuana.

"Public institution" means any entity established or controlled by the federal government, state

government, or a local government or municipality, including, but not limited, institutions of higher education and related research institutions.

"Publicly traded company" means a business entity organized under the laws of the United States or Canada where the domicile for the business entity permits the sale of marijuana and such business entity has a class of securities that are registered and traded for investment pursuant to the Securities Exchange Act of 1934 or listed and traded for investment on a reputable recognized foreign stock exchange or foreign market.

"Public money" means any funds or money obtained from any governmental entity, including, but not limited to, research grants.

"**Public school**" means a <u>an preschool</u>, elementary, middle, high school, or <u>technology center school</u> established under state law, regulated by the local state authorities in the various political subdivisions, funded and maintained by public taxation, and open and free to all children of the particular district where the school is located.

"Quality assurance laboratory" means a laboratory designated by the Department to conduct surveillance of testing laboratories for compliance purposes.

"Readily accessible" means that a licensee can immediately produce the documentation upon the Department's request.

"Registered to conduct business" means any individual or entity that is required under Oklahoma law to register with the Oklahoma Secretary of State and/or the Oklahoma Tax Commission and has provided sufficient proof to the Department of its good standing with such.

"Remediation" means the process by which the medical marijuana flower or trim, which has failed microbial testing, a harvest batch or production batch that fails testing is processed into solvent based medical marijuana concentrate undergoes a procedure to remedy the harvest batch or production batch failure and is tested retested in accordance with Oklahoma law and these Rules.

"Research project" means a discrete scientific endeavor to answer a research question or a set of research questions related to medical marijuana and is required for a medical marijuana research license.

"Research facility" means an individual or entity that has been issued a license by the Department to grow, cultivate, possess, and transfer to testing laboratories, and to transfer by sale or donation to other licensed research facilities, medical marijuana for the limited research purposes permitted under state and federal law and these Rules.

"Retailer" or "Retail marijuana establishment" as used in 63 O.S. § 420 et seq. means an entity licensed by the State Department of Health as a medical marijuana dispensary.

"Revocation" means the Department's final decision in accordance with the Oklahoma Administrative Procedures Act, 75 O.S. § 250 et seq., that any license issued by the Department pursuant to Oklahoma law and this Chapter is rescinded.

"RFID" means Radio Frequency Identification.

"Rules" means, unless otherwise indicated, the rules as adopted and set forth in OAC 310:681.

"Sampler" means a person who is employed by or is an owner of a licensed laboratory, grower, or processor and is authorized by that employer to collect samples in accordance with the testing laboratory's standard operating procedures and these Rules.

"Seedling" means a marijuana plant that has no flowers.

"Seed-to-sale tracking system" means an electronic inventory tracking system utilized by a commercial licensee to track inventory, any steps through the process of cultivating or manufacturing medical marijuana and/or medical products, transactions with other licensees, testing, and other required information for the purpose of reporting that information to the Department in accordance with Oklahoma law, rules, and regulations.

"Shipping container" means a hard-sided container with a lid or other enclosure that can be secured into place. A shipping container is used solely for the transport of medical marijuana, medical marijuana concentrate, or medical marijuana products between medical marijuana businesses, a medical marijuana research facility, or a medical marijuana education facility.

"State question" means Oklahoma State Question No. 788 and Initiative Petition Number 412.

"Strain" means the elassification name given to a particular variety of medical marijuana or cannabis plants in either pure sativa, indica, afghanica, ruderalis, or hybrid varieties that is based on a combination of factors which may include, but is not limited to, botanical lineage, appearance, chemical profile, and accompanying effects. An example of a "strain" would be "OG Kush" or "Pineapple Express".

"Terpenoids" means isoprenes that are the aromatic compounds found in cannabis, including, but not limited to: limonene, myrcene, pinene, linalool, eucalyptol,  $\Delta$ -terpinene,  $\beta$ -caryophyllene, caryophyllene oxide, nerolidol and phytol.

"**Testing laboratory**" or "**Laboratory**" means a public or private laboratory licensed pursuant to state law and these Rules to conduct testing and research on medical marijuana and medical marijuana products.

"THC" means tetrahydrocannabinol, which is the primary psychotropic cannabinoid formed by decarboxylation of naturally <u>occurring</u> testrahydrocannabinolic acid, which generally occurs by exposure to heat.

"Transporter" or "Commercial Transporter" means an individual or entity issued a medical marijuana commercial license by the Department, which allows the transporter to transport, store, and distribute, but not take ownership of, medical marijuana and medical marijuana products to and from the licensed premises of commercial licensee. As used in this Chapter, "Transporter" or "Commercial Transporter" does not mean licensed commercial growers, processors, and dispensaries, laboratories, research facilities, and education facilities who are automatic holders of transporter licenses.

"Transporter Agent" means an agent, employee, officer, or owner of commercial transporter, grower, processor, or dispensary, laboratory, research facility, or education facility who has been issued a transporter agent license by the Department to transport medical marijuana and medical marijuana products on behalf of the said commercial transporter, grower, processor, or dispensary, laboratory, research facility, and education facility.

"Transporter license" means a medical marijuana business license issued by the Department either (A) automatically to commercial growers, processors, and dispensaries, laboratories, research facilities, and education facilities upon approval of a business license, or (B) to commercial transporters solely for the transportation, storage, and distribution of medical marijuana and medical marijuana products.

"Usable medical marijuana" means the dried leaves, flowers, oils, vapors, waxes, and other portions of the marijuana plant and any mixture or preparation thereof, excluding seed, roots, stems, stalks, and fan leaves.

"Waste disposal facility" means an individual or entity that has been issued a medical marijuana waste disposal facility license by the Department to dispose of medical marijuana waste as authorized in Oklahoma law and these Rules.

"Waste disposal facility license" means a license issued by the Department to possess, transport, and dispose of medical marijuana waste. The waste disposal facility license shall be issued to the location submitted by the applicant that is first approved by the Department.

"Waste disposal facility permit" means a permit issued by the Department to a waste disposal licensee to possess, transport, and dispose of medical marijuana waste at the location submitted on the permit application. Waste disposal facility permits shall be required for each approved facility operated by a waste disposal facility licensee.

"Wholesale package" means medical marijuana from the same harvest batch or multiple units of medical marijuana product from the same production batch that are combined together as a single unit for the purpose of RFID tagging and are transported to a single commercial licensee.

"Working towards operational status" means a commercial licensee that:

- (A) Has applied for any additional permits, registrations, or licenses required by the Department or another Oklahoma agency, organization, or political subdivision to lawfully conduct operations at the licensed premises and is awaiting issuance of such permit(s), registration(s), or other license(s);
- (B) Is performing construction or other material changes to the licensed premises in preparation of operations at the licenses premises;
- (C) Is <u>onboarding</u> or training initial staff in preparation of operations at the licensed premises;

- (D) Is in the process of purchasing or is awaiting receipt of delivery of physical materials essential to operations at the licensed premises, such as furniture or equipment; or
- (E) Any additional actions determined to be sufficient by the Department.

#### **310:681-1-6. Proof of residency**

- (a) Applicants shall establish their current Oklahoma residency through submission of an electronic copy or digital image in color of one of the following unexpired documents:
  - (1) An Oklahoma issued driver's license;
  - (2) An Oklahoma Identification Card;
  - (3) An Oklahoma voter identification card;
  - (4) A utility bill for the calendar month preceding the date of application, excluding cellular telephone, television, and internet bills;
  - (5)(4) A residential property deed to property in the State of Oklahoma;
  - (6)(5) A current rental agreement for residential property located in the State of Oklahoma; or
  - (7)(6) The preceding year's Oklahoma Tax Return showing the applicant as an Oklahoma taxpayer; or
  - (8)(7) Other documentation that the Department deems sufficient to establish residency.
- (b) Documents submitted should provide a valid residential address. Documents listing addresses of P.O. Boxes are not sufficient proof of residency and will be rejected.

### **310:681-1-7. Proof of identity**

- (a) All applicants for non-commercial licenses shall establish their identity through submission of an electronic copy or digital image in color of one of the following unexpired documents:
  - (1) An Oklahoma issued driver's license or Real ID;
  - (2) An Oklahoma Identification Card;
  - (3) A United States Passport or other photo identification issued by the United States government;
  - (4) A tribal identification card approved for identification purposes by the Oklahoma Department of Public Safety; or
  - (5) Other documentation that the Department deems sufficient to establish identity.
- (b) All commercial license applicants shall establish their identity through submission of an electronic copy or digital image in color of one of the following unexpired documents:
  - (1) Front and back of an Oklahoma issued driver's license or Real ID;
  - (2) Front and back of an Oklahoma Identification Card or Real ID;
  - (3) A United States Passport or other photo identification issued by the United States government;
  - (4) A tribal identification card approved for identification purposes by the Oklahoma Department of Public Safety; or
  - (5) Other documentation that the Department deems sufficient to establish identity.

#### 310:681-1-9.1. Recommending physician standards

- (a) Any Physician, before making a recommendation for medical marijuana under these provisions, shall be in "good standing" with their licensure board the State Board of Medical Licensure and Supervision or the State Board of Osteopathic Examiners. Physicians in residency or other graduate medical training do not meet the definition of Physician under this Subchapter and any recommendation for a patient medical marijuana license will be rejected by the Department.
- (b) When recommending a medical marijuana license, a physician shall use the accepted standards a reasonable and prudent physician would follow when recommending any medication to a patient.
- (c) A physician shall not be located at the same physical address of a dispensary.

# SUBCHAPTER 2. MEDICAL MARIJUANA LICENSES

# 310:681-2-1. Application for patient license

(a) The application for a patient license shall be on the Department issued form and shall include at a minimum:

- (1) The applicant's first name, middle name, last name and suffix, if applicable;
- (2) The applicant's valid mailing address;
- (3) The applicant's date of birth;
- (4) The applicant's telephone number and email address;
- (5) The signature of the applicant attesting the information provided by the applicant is true and correct; and
- (6) The date the application was signed.
- (b) An application must be submitted within thirty (30) days of signature or it will be rejected by the Department.
- (c) A complete application shall include the following documentation or the application will be rejected:
  - (1) Documents establishing the applicant is an Oklahoma resident as established in OAC 310:681-1-6 (relating to proof of residency).
  - (2) Documents establishing proof of identity as established in OAC 310:681-1-7 (relating to proof of identity).
  - (3) A digital photograph as established in OAC 310:681-1-8 (relating to applicant photograph).
  - (4) A certification and recommendation from an Oklahoma Physician dated within thirty (30) days of the date of submission of the application to the Department, on the form provided by the Department, which includes the following:
    - (A) The physician's name and medical license number including an identification of the physician's license type;
    - (B) Office address on file with the physician's licensing board;
    - (C) Telephone number on file with the physician's licensing board;
    - (D) The patient/applicant's date of birth;
    - (E) The physician's signed and dated attestation of the following:
      - (i) The physician has established a medical record and has a bona fide physician-patient relationship;
      - (ii) The physician has determined the presence of a medical condition(s) for which the patient/applicant is likely to receive therapeutic or palliative benefit from use of medical marijuana;
      - (iii) The patient/applicant is recommended a medical marijuana license according to the accepted standards a reasonable and prudent physician would follow for recommending or approving any medication as described at OAC 310:681-1-9.1 (relating to recommending physician standards);
      - (iv) If applicable, the patient/applicant is homebound and unable to ambulate sufficiently to allow them to regularly leave their residence; and the physician believes the patient/applicant would benefit from having a caregiver with a caregiver's license designated to manage the patient's medical marijuana on the patient's behalf;
      - (v) The information provided by the physician in the certification is true and correct; and
      - (vi) Stating the method by which the physician verified the patient's identity as provided in OAC 310:681-1-7 (relating to proof of identity).
- (d) Payment of the application fee as established in 63 O.S. § 420 et seq. is required unless the applicant is insured by Medicaid or Medicare.
  - (1) If the applicant is insured by Medicaid or Medicare, the applicant must provide a copy of their insurance card or other acceptable verification.
  - (2) Upon receipt of this verification the Department may attempt to verify the applicant is currently insured by the insuring agency.
  - (3) If the Department is unable to verify the insurance, the application shall be rejected until verification is obtained.
  - (4) All applicants who are verified as being insured by Medicaid or Medicare shall pay a reduced application fee as established in 63 O.S. § 420 et seq.
  - (5) Application fees are nonrefundable.
- (e) An applicant who can demonstrate his or her status as a one-hundred-percent-disabled veteran shall

pay a reduced application fee of \$20.00 and shall have the opportunity to submit the license application and payment by means other than solely online and in a manner approved by the Department. In order to qualify, an applicant must submit with his or her application a letter or other official documentation from the U.S. Department of Veteran Affairs or an agency of the U.S. Department of Defense, signed within six (6) months of submission of the application, establishing that the applicant is a veteran with a service disability and stating the percent of the disability is one-hundred percent. Such letter or documentation must be signed within six (6) months of submission of the application unless documentation submitted demonstrates the individual's status as a permanent one-hundred-percent-disabled veteran.

(f) An applicant who can meet the requirements for a patient license established in OAC 310:681-2-1 but whose physician recommendation for medical marijuana is only valid for sixty (60) days shall be issued a short-term medical marijuana license. A short-term medical marijuana license shall be valid for sixty (60) days. The initial license and renewal fee shall be \$100.00, unless the applicant can prove he or she is insured by Medicaid or Medicare in accordance with OAC 310:681-2-1(d) or is a one-hundred-percent-disabled veteran in accordance with OAC 310:681-2-1(e), in which case applicant shall pay a reduced fee of \$20.00.

# 310:681-2-3. Application for caregiver's license

- (a) Applications for a caregiver's license for caregivers of a licensed patient may be made at any time during the term of the patient license.
- (b) Only one caregiver's license shall be issued for each patient license, except in the case of a licensed patient under the age of eighteen (18) whereby two (2) parents and/or legal guardians may be recognized as the minor's caregivers, if such minor is homebound.
- (c) A caregiver's application will be accepted for a patient who has a physician's attestation that the patient is homebound or does not have the capability to self-administer or purchase medical marijuana due to developmental disability or physical or cognitive impairment and would benefit by having a designated caregiver to manage medical marijuana on the behalf of the patient as provided in OAC 310:681-2-1(c)(4)(E)(iv).
- (d) The caregiver's application shall be made on a form provided by the Department and shall include the following:
  - (1) All information and documentation for the caregiver provided for in OAC 310:681-2-1(a) and (c) except there shall be no medical certification from an Oklahoma Physician nor fee assessed for a caregiver's license;
  - (2) A signed and dated attestation from the patient license holder or patient applicant, or the patient's parent(s) or legal guardian(s) if patient is under eighteen (18) years of age, appointing the caregiver as their designee under this provision. If the patient license holder is incapacitated or subject to legal guardianship, a durable medical power of attorney or a court order for guardianship may be submitted and the person appointed to act under that document may execute the notarized statement; and
  - (3) The patient license number shall be included in the application.
- (e) A caregiver issued and in possession of a valid, unexpired OMMA caregiver license may exercise the same rights as the medical marijuana patient license holder for whom he or she is designated caregiver, except that:
  - (1) A caregiver may not use the medical marijuana or medical marijuana products obtained on behalf of the medical marijuana patient license holder; and
  - (2) A caregiver may only exercise cultivation rights on behalf of up to five (5) medical marijuana patient license holders and shall not charge a medical marijuana patient licensee for cultivating medical marijuana in excess of actual costs incurred in cultivating the medical marijuana.
- (f) A caregiver shall immediately notify the Department in a manner prescribed by the Department if the medical marijuana patient license holder for whom he or she is designated caregiver is deceased.

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

(a) Patient License Term. Medical marijuana patient licenses issued under OAC 310:681-2-1 and OAC

- 310:681-2-2 shall be for a term of two (2) years from the date of issuance, unless the physician recommendation is terminated by the physician, the medical marijuana patient license holder is deceased, or the license is revoked by the Department or voluntarily surrendered by the patient.
- (b) **Short-term patient license term.** Short-term medical marijuana patient licenses issued under OAC 310:681-2-1(f) and OAC 310:681-2-2(g) shall be for a term of sixty (60) days from the date of issuance, unless the physician recommendation is terminated by the physician, the short-term patient license holder is deceased, or the license is revoked by the Department or voluntarily surrendered by the patient.
- (c) Caregiver license term. Caregiver's licenses may not extend beyond the expiration date of the underlying patient license regardless of the issue date.
- (d) **Temporary patient license term**. Temporary patient licenses issued under OAC 310:681-2-4 shall be for a term of thirty (30) days from the date of issuance, unless the temporary patient license holder is deceased or the license is revoked by the Department or voluntarily surrendered by the patient; however, temporary patient licenses may not extend beyond the expiration date of the underlying out-of-state medical marijuana patient license.

# (e) Change in information.

- (1) All patient and caregiver licensees shall ensure that all information and records maintained in the licensee's online OMMA license account are complete, accurate, and updated in a timely manner.
- (2) Patient and caregiver licensees shall obtain Department approval for any changes that affect the licensee's qualifications for licensure.
- (3) Patient and caregiver licensees submitting a name change request must provide information and documentation relating to proof of identity, including but not limited to the following:
  - (A) Documents establishing proof of identity as established in OAC 310:681-1-7 (relating to proof of identity); and
  - (B) A marriage license, divorce decree, or other documentation the Department deems sufficient to establish a valid name change.
- (f) **Renewal**. It is the responsibility of the license holder to renew the license, with all applicable documentation, prior to the date of expiration of the license by following the procedures provided in OAC 310:681-2-1, 310:681-2-2, 310:681-2-3, and/or 310:681-2-4. The Department may refuse to renew a license of a patient or caregiver for the following:
  - (1) Failure to meet the requirements for licensure set forth in 63 O.S. § 420 et seq; the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.; or OAC 310:681.
  - (2) Noncompliance with 63 O.S. § 420 et seq.; the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.; the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq.; or OAC 310:681.
- (g) **Renewal fee**. The fee for renewal shall be the fee established in statute or under this Chapter for the license. Application fees are nonrefundable.

# (h) Surrender of license.

- (1) A licensed patient or caregiver may voluntarily surrender a license to the Department at any time.
- (2) If a licensee voluntarily surrenders a license, the licensee shall:
  - (A) Return the license to the Department;
  - (B) Submit a surrender license form provided by the Department; and
  - (C) Submit proof of the licensee's identity through submission of documentation identified in OAC 310:681-1-7 (relating to Proof of Identity).
- (3) Patient and caregiver surrender forms and any other documentation or information submitted by a patient or caregiver shall be confidential.

#### (i) Physician termination.

(1) A recommending physician who determines the continued use of medical marijuana by the patient no longer meets the requirements for possession of a license may notify the Department of the physician's intent to terminate the physician recommendation by submitting a physician termination form provided by the Department signed within thirty (30) days of submission. A physician termination renders the patient license <u>immediately</u> null and void <u>without the right to an individual proceeding</u>.

- (2) The Department shall then immediately terminate the patient license. If the physician fails to comply with any further requests for information or documentation that the Department deems necessary to validate the physician termination, the Department may refuse to terminate the patient license.
- (3) The Department shall not terminate a minor patient license unless both recommending physicians have submitted a physician termination form.
- (4) Notice and a right to hearing shall be provided to the patient in accordance with the Oklahoma-Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq., and the Oklahoma-Administrative Procedures Act, 75 O.S. § 250 et seq.
- (j) License revocation and suspension. Except as otherwise provided in applicable Oklahoma law and these Rules, procedures for nonrenewal, revocation, and suspension of licenses are stated in the Oklahoma Administrative Procedures Act, 75 O.S. § 250 et seq. These procedures provide for the licensee to receive notice and to have the opportunity to be present at a hearing and to present evidence in his or her defense. The Commissioner of Health or his or her designee may promulgate an administrative order revoking or suspending the license, dismissing the matter, or providing for other relief as allowed by law. At any time after the action is filed against the licensee, the Department and the licensee may dispose of the matter by consent order or stipulation. Orders are appealable in accordance with the Oklahoma Administrative Procedures Act, 75 O.S. § 250 et seq.
- (k) Patient license reprint. All medical marijuana patient licensees may request a reprint of their license in the event the physical license is lost, destroyed, or otherwise misplaced by the licensee. The medical marijuana patient licensee shall be charged a \$20.00 fee for the license reprint.

#### **310:681-2-8.** Possession limits

- (a) A patient who has been issued and is in possession of an OMMA medical marijuana license is legally authorized to:
  - (1) Consume marijuana legally;
  - (2) Legally possess up to three (3) ounces (84.9 grams) of marijuana on their person;
  - (3) Legally possess six mature marijuana plants and the harvested marijuana therefrom;
  - (4) Legally possess six seedling plants;
  - (5) Legally possess (1) ounce (28.3 grams) of concentrated marijuana;
  - (6) Legally possess seventy-two (72) ounces (2,037.6 grams) of edible marijuana; and
  - (7) Legally possess up to eight (8) ounces (226.4 grams) of marijuana in their residence-; and
  - (8) Legally possess seventy-two (72) ounces of topical marijuana.
- (b) These possession limits are cumulative and a licensed patient or caregiver may possess at one time the totality of the items listed in this Section.

#### SUBCHAPTER 3. TRANSPORTER LICENSE

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

- (a) A medical marijuana transporter license shall be issued to qualifying applicants for grower, processor, or dispensary, laboratory, research facility, or education facility licenses at the time of approval. This license shall enable licensed growers, processors, and dispensaries, laboratories, research facilities, and education facilities through their licensed transporter agents to transport medical marijuana or medical marijuana products to other commercial licensees. This license shall not authorize licensed growers, processors, or dispensaries, laboratories, research facilities, or education facilities to transport, store, or distribute medical marijuana or medical marijuana products on behalf of other medical marijuana licensees.
- (b) A medical marijuana commercial transporter license shall be issued as an independent business license to applicants meeting the requirements set forth in OAC 310:681-5-3, OAC 310:681-5-3.1, and OAC 310:681-5-3.2. This license shall be subject to the same restrictions and obligations as any commercial licensee and shall enable the commercial transporter to:
  - (1) transport, store, and distribute medical marijuana and medical marijuana products on behalf of

other commercial licensees;

- (2) contract with multiple commercial licensees; and
- (3) maintain multiple warehouses at licensed premises that are approved by the Department for the purpose of temporarily storing and distributing medical marijuana and medical marijuana products.
- (c) A commercial transporter applicant or licensee must obtain and submit to the Department for each warehouse location a certificate of compliance issued by the political subdivision where the licensed premises is to be located certifying compliance with the categories listed in 63 O.S. § 426.1(E), and the licensed premises shall meet security requirements applicable to a medical marijuana business.
- (d) A commercial transporter shall be responsible for any and all medical marijuana and medical marijuana products within its custody, control, or possession. A commercial transporter applicant or licensee must have each warehouse location inspected and approved by the Department prior to its use.
- (e) No person or entity shall transport or otherwise transfer any medical marijuana or medical marijuana products without both a valid transporter license and a valid transporter agent license. A commercial transporter shall be responsible for any and all medical marijuana and medical marijuana products within its custody, control, or possession.
- (f) No person or entity shall transport or otherwise transfer any medical marijuana or medical marijuana products without both a valid transporter license and a valid transporter agent license.

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

- (a) With the exception of a lawful transfer between medical marijuana businesses that are licensed to operate at the same physical address, All all medical marijuana and medical marijuana products shall be transported:
  - (1) In a locked shipping container, shielded from public view, and clearly labeled "Medical Marijuana or Derivative"; and
  - (2) In a secured area of the vehicle that is not accessible by the driver during transit.
- (b) All vehicles used to transport medical marijuana and medical marijuana products shall be:
  - (1) Equipped with active Global Positioning System (GPS) trackers, which shall not be mobile cellular devices and which shall be capable of storing and transmitting GPS data; and
  - (2) Insured at or above the legal requirements in Oklahoma.
- (c) Commercial transporters, growers, processors, and dispensaries, <u>laboratories</u>, <u>research facilities</u>, and <u>education facilities</u> shall maintain updated and accurate records and information on all vehicles engaged in the transport of medical marijuana or medical marijuana products, including GPS data and records. Such records and information shall be kept at the licensed premises <u>for at least seven (7) years</u> and shall be readily accessible.
- (d) Licensed transporter agents shall carry a copy of the commercial transporter license or the grower, processor, or dispensary, laboratory, research facility, or education facility transportation license, and the transporter agent's license while transporting medical marijuana. Penalties for violations of this subsection shall include fines in the amounts set forth in Appendix C against the individual transporter and the employing commercial transporter, grower, processor, or dispensary, laboratory, research facility, or education facility for whom the transporting agent is transporting medical marijuana or medical marijuana products at the time of the violation.
- (e) Commercial licensees and transporter agents shall implement appropriate security measures to deter and prevent the theft and diversion of marijuana during transportation.
- (f) Commercial transporters and transporter agents shall comply with all applicable motor vehicle laws.
- (g) In addition to any other penalties established by law, the Department may revoke the transporter agent license of any transporter agent who knowingly violates any provision of 63 O.S. § 427.16.
- (h) In addition to any other penalties established by law, the Department may revoke or suspend the transporter license of any commercial transporter who knowingly aids or facilitates a transporter agent in the violation of any provision of 63 O.S. § 427.16.

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

- (a) **License required.** Only agents, employees, officers, or owners of commercial transporters, growers, processors, or dispensaries, laboratories, research facilities, or education facilities who are issued a transporter agent license by the Department shall be qualified to transport medical marijuana or medical marijuana products.
- (b) **Application fee**. Either the individual applicant for a transporter agent license or the business licensee employing the applicant shall submit the transporter agent license application or any renewal application to the Department on a form and in a manner prescribed by the Department, along with the annual application fee of \$10025.00 as established in the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.
- (c) **Submission.** The application for a transporter agent license shall be on the Department prescribed form and shall include at a minimum:
  - (1) The applicant's first name, middle name, last name, and suffix, if applicable;
  - (2) The applicant's residential address and valid mailing address;
  - (3) The applicant's date of birth;
  - (4) The applicant's telephone number and email address;
  - (5) The applicant's Oklahoma driver license number and expiration date;
  - (6) An affidavit of lawful presence signed by the transporter agent applicant;
  - (7) An attestation that the transporter agent applicant shall not divert medical marijuana or medical marijuana products to any entity or individual that is not lawfully entitled to possess;
  - (8) An attestation that the transporter agent understands and/or has been notified that the business licensee identified as the employer in the application may terminate the transporter agent license at any time; and
  - (9) An attestation that the information provided in the application is true and correct.
- (d) Supporting documentation. A complete application shall include the following documentation:
  - (1) A copy of the applicant's valid, unexpired Oklahoma driver license;
  - (2) Documents establishing the applicant is an Oklahoma resident as established in OAC 310:681-5-3.1 1-6 (relating to proof of residency for business licensees);
  - (3) A digital photograph as established in OAC 310:681-1-8 (relating to applicant photograph).
  - (4) An employment verification form prescribed by the Department verifying the applicant's employment with a commercial transporter, grower, processor, or dispensary, laboratory, research facility, or education facility; and
  - (5) A criminal background check conducted by the Oklahoma State Bureau of Investigation establishing that the applicant does not have a disqualifying criminal conviction.
- (e) **License term**. A transporter agent license shall be valid for one year, unless the license is deactivated by the business licensee employing the transporter agent, voluntarily surrendered, or revoked by the Department. Transporter agent licenses shall not extend beyond the expiration, surrender, or revocation of the business license of the commercial transporter, grower, processor, or dispensary, laboratory, research facility, or education facility employing the transporter agent.
- (f) **Renewal**. It is the responsibility of the license holder to renew the license, with all applicable documentation, prior to the date of expiration of the license by following the procedures provided in OAC 310:681-3-3. The Department may refuse to renew a license of a transporter agent for the following:
  - (1) Failure to meet the requirements for licensure set forth in the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq., or OAC 310:681.
  - (2) Noncompliance with 63 O.S. § 420 et seq.; the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.; the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq.; or OAC 310:681.
- (g) License reprints. Transporter agents may request a reprint of their license in the event the physical license is lost, destroyed, or otherwise misplaced by the licensee. The transporter agent shall be charged a \$20.00 fee for the license reprint.

#### 310:681-3-4. Employer deactivation of transporter agent license

(a) Commercial transporters, growers, processors, or dispensaries, laboratories, research facilities, or

education facilities employing a transporter agent shall notify the Department within fourteen (14) days in the manner and on the form prescribed by the Authority when a transporter agent ceases to work as a transporter, and the transporter agent license shall be deactivated. This deactivation shall not be subject to appeal.

(b) The commercial transporter, grower, processor, or dispensary, laboratory, research facility, or education facility is responsible for destroying or returning to the Department any deactivated transporter agent license.

#### 310:681-3-6. Inventory manifests

- (a) Commercial transporters, growers, processors, and dispensaries, laboratories, research facilities, and education facilities shall utilize an electronic inventory management system the State inventory tracking system in accordance with OAC 310:681-5-6(d) to create and maintain inventory shipping manifests documenting all transport of medical marijuana and medical marijuana products throughout the State of Oklahoma.
- (b) When transporting medical marijuana or medical marijuana products, commercial transporters, growers, processors, and dispensaries shall provide copies of the inventory manifests to each originating and receiving licensee at the time the product changes hands.
  - (1) The copy of the inventory manifest to be left with the originating licensee shall include, at a minimum:
    - (A) The license number, business name, address, and contact information of the originating licensee:
    - (B) The license number, business name, address, and contact information of the commercial transporter, grower, processor, or dispensary, laboratory, research facility, or education facility transporting the medical marijuana if such licensee is not the originating licensee;
    - (C) A complete inventory of the medical marijuana and medical marijuana products to be transported, including the quantities by weight or unit of each type of medical marijuana and medical marijuana products and the batch number(s);
    - (D) The date of transportation and the approximate time of departure;
    - (E) Printed names, signatures, and transporter agent license numbers of personnel accompanying the transport;
    - (F) Notation of the commercial transporter, grower, processor, <del>or</del> dispensary, <u>laboratory</u>, <u>research</u> facility, or education facility authorizing the transport; and
    - (G) The license number(s), business name(s), address(es), and contact information for all end point recipients.
  - (2) The copy of the inventory manifest to be left with the receiving licensee shall include, at a minimum:
    - (A) The license number, business name, address, and contact information for the receiving licensee:
    - (B) The license number, business name, address, and contact information of the originating licensee;
    - (C) The license number, business name, address, and contact information of the commercial transporter, grower, processor, or dispensary, laboratory, research facility, or education facility transporting the medical marijuana if such licensee is not the originating licensee;
    - (D) A complete inventory of the medical marijuana and medical marijuana products delivered to the receiving licensee, including the quantities by weight or unit of each type of medical marijuana and medical marijuana products and the batch number(s);
    - (E) The date and estimated time of arrival;
    - (F) The printed names, signatures, and transporter agent license numbers of the personnel accompanying the transport; and
    - (G) The printed names, titles, and signatures of any personnel accepting delivery on behalf of the receiving licensee.
- (c) A separate inventory manifest shall be prepared for each licensee receiving the medical marijuana or

medical marijuana products.

- (d) Commercial transporters, processors, growers, and dispensaries, laboratories, research facilities, or education facilities shall also maintain copies of all inventory manifests in accordance with OAC 310:681-5-6(b).
- (e) Inventory manifests should reflect a complete chain of custody of any and all medical marijuana and medical marijuana products being transported, including all instances in which the medical marijuana and medical marijuana products are stored at a commercial transporter warehouse.
- (f) Originating and receiving licensees shall maintain copies of inventory manifests and inventory records logging the quantity of medical marijuana or medical marijuana products received for at least three (3) seven (7) years from the date of receipt.
- (g) An inventory manifest shall not be altered after departing from the originating licensee's premises, except to make the following changes:
  - (1) for The addition of the printed names, titles, and signatures of any personnel accepting delivery on behalf of the receiving licensee.
  - (2) Documenting any refusal to accept delivery of medical marijuana or medical marijuana products or if delivery of the medical marijuana or medical marijuana products is impossible, which shall include, at minimum:
    - (A) The license number, business name, address, and contact information of the licensee to which the medical marijuana or medical marijuana products were to be delivered;
    - (B) A complete inventory of the medical marijuana or medical marijuana products being returned, including batch number;
    - (C) The date and time of attempted delivery and the refusal;
    - (D) Documentation establishing the medical marijuana or medical marijuana products were returned in accordance with OAC 310:681-3-6(i).
- (h) A receiving licensee shall refuse to accept any medical marijuana or medical marijuana products that are not accompanied by an inventory manifest.
- (i) If a receiving licensee refuses to accept delivery of any medical marijuana and/or medical marijuana product or if delivery of the medical marijuana or medical marijuana is impossible; (1) The the medical marijuana and/or medical marijuana products shall be immediately returned to originating licensee who retains legal ownership of the products; and the refusal shall be fully documented in accordance with OAC 310:681-3-6(g)(2).
  - (2) The refusal shall be fully documented in the inventory manifests, which should include, at a minimum:
    - (A) The license number, business name, address, and contact information of the licensee to which the medical marijuana or medical marijuana products were to be delivered;
    - (B) A complete inventory of the medical marijuana or medical marijuana products being returned, including batch number;
    - (C) The date and time of the refusal; and
    - (D) Documentation establishing the medical marijuana or medical marijuana products were returned in accordance with OAC 310:681-3-6(i)(1).

#### SUBCHAPTER 4. RESEARCH FACILITIES AND EDUCATION FACILITIES

#### 310:681-4-2. Licenses

- (a) **Timeframe.** Research facility and education facility licenses shall be issued for a twelve (12) month period expiring one (1) year from the date of issuance. The license may be issued upon receipt of a completed application, payment of application fee, and verification by the Department the individual or entity complies with the requirements set forth in Oklahoma law and this Chapter.
- (b) **Location.** Research facility and education facility licenses shall only be valid for a single location at the address listed on the application. If a single research project will occur in multiple locations, a separate research facility or education facility license shall be required for each location.
- (c) Renewal of license.

- (1) It is the responsibility of the license holder to renew the license, with all applicable documentation, prior to the date of expiration of the license by following the procedures provided in OAC 310:681-4-3.
- (2) Before renewing a license, the Department may require further information and documentation to determine the licensee continues to meet the requirements set forth in Oklahoma law and these Rules. Once a certificate of compliance is properly submitted showing full compliance, no additional certificate of compliance will be required for license renewal unless a change of use or occupancy occurs, or other change that would require additional inspection, licensure, or permitting by the state or municipality.
- (3) If the research conducted by a research facility licensee includes a public institution or public money, the Department shall review any reports made by the licensee to determine if the research continues to meet qualifications in state law and these Rules.
- (4) The Department may refuse to renew a license of a research or education facility for the following:
  - (A) Failure to meet the requirements for licensure set forth in 63 O.S. § 420 et seq; the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.; or OAC 310:681.
  - (B) Noncompliance with 63 O.S. § 420 et seq.; the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.; the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq.; or OAC 310:681.
- (5) Upon the determination that a licensee has not met the requirements for renewal, the Department shall provide written notice to the licensee. The notice shall provide an explanation for the denial of the renewal application.
- (6) A commercial licensee that attempts to renew its license after the expiration date of the license shall pay a nonrefundable late renewal fee in the amount of \$500.00 to reinstate the license once processed. A license that has been expired for more than ninety (90) days shall not be renewed.
- (d) **Liquidation of products**. A research facility or education facility licensee whose license is not renewed, or whose license is revoked, suspended, or voluntarily surrendered, shall cease all operations immediately upon expiration of the license and shall liquidate or dispose of all medical marijuana and medical marijuana products in accordance with OAC 310:681-5-2(d).

# (e) Change in information.

- (1) Licensees shall notify the Department in writing within fourteen (14) days of any changes in contact information by electronically submitting a change request in accordance with the Department's instructions.
- (2) Licensees shall obtain Department approval prior to for any material changes that affect the licensee's qualifications for licensure. Licensees shall notify submit a material change request to the Department in writing in advance of any material change that may affect the licensee's qualifications for licensure by electronically submitting a change request, along with any relevant documentation and fees, in accordance with the Department's instructions. When submitting a material change request, the licensee will be required to pay a \$500.00 nonrefundable fee. Except as is otherwise authorized by the Department, licensees are limited to one location change request and one ownership change request per year of licensure.
  - (A) Medical marijuana research and education licensees submitting a location change must provide the information and documentation required in OAC 310:681-4-3 relating to locations, including but not limited to the following:
    - (i) A certificate of compliance as required in OAC 310:681-4-3(e)(1) on a form prescribed or otherwise authorized by the Department that is issued by the political subdivision where the licensed premises is to be located certifying compliance with the categories listed in 63 O.S. § 426.1(E); and
    - (ii) Any further documentation the Department determines is necessary to ensure the business licensee is still qualified under Oklahoma law and this Chapter to obtain a business license.
  - (B) Medical marijuana research and education licensees submitting an ownership change request must provide the information and documentation required in OAC 310:681-4-3 relating to

owners, including but not limited to the following:

- (i) If applicable, a list of all owners and principal officers of the applicant and supporting documentation as set forth in OAC 310:681-4-3(e)(3);
- (ii) Documents required under OAC 310:681-4-3(e)(4) establishing that the applicant; and the members, managers, and board members if applicable; and seventy-five percent (75%) of the research facility's or education facility's ownership interests are Oklahoma residents as required in the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.;
- (iii) For public institutions seeking a research seeking a research facility license, a background check for each principal investigator and co-principal investigator; and
- (iv) Any further documentation the Department determines is necessary to ensure the business licensee is still qualified under Oklahoma law and this Chapter to obtain a business license.
- (3) Licensees shall notify the Department prior to any changes that affect the initial research project and/or curriculum, including funding, in a manner prescribed by the Department. If the research will be conducted with a public institution or public money, the licensee shall supply any documentation or information the Department determines is necessary to determine whether any change to the research project and/or curriculum constitutes a material change. If there is a material change, the Department may deny the change and require the licensee to submit a new application.

### (f) Transfer of license.

- (1) Research facility and education facility licenses shall not be wholly assigned, sold, or otherwise transferred to a new owner(s) or another legal entity(ies).
- (2) Licenses shall not be changed from one license type to another.
- (3)(2) Licenses are limited to the research project(s) approved by the Department and shall not be transferred to any other research project, research, or curriculum.
- (g) **Surrender of license**. A research facility or education facility licensee may voluntarily surrender a license to the Department at any time in accordance with 310:681-5-2(g).

#### 310:681-4-3. Applications

- (a) **Application fee**. An applicant for a research facility or education facility license, or renewal thereof, shall submit to the Department a completed application on a form and in a manner prescribed by the Department, along with the application fee as established in 63 O.S. § 420 et seq. and the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.
- (b) **Submission**. The application shall be on the Department prescribed form and shall include the following information about the establishment:
  - (1) Name of the establishment;
  - (2) Physical address of the establishment, including the county in which any licensed premises will be located;
  - (3) GPS coordinates of the establishment;
  - (4) Phone number and email of the establishment; and
  - (5) Hours of operation for any licensed premises.
- (c) **Individual applicant**. The application for a research facility or education facility license made by an individual on his or her own behalf shall be on the Department prescribed form and shall include at a minimum:
  - (1) The applicant's first name, middle name, last name, and suffix if applicable;
  - (2) The applicant's residence address and valid mailing address;
  - (3) The applicant's date of birth;
  - (4) The applicant's telephone number and email address;
  - (5) Indication of the type of research to be conducted;
  - (6) Indication of any public money involved in the research and/or curriculum, if applicable;
  - (7) An attestation that the information provided by the applicant is true and correct;
  - (8) An attestation that any licensed premises shall not be located on tribal lands;

- (9) An attestation that the research project does not involve biomedical or clinical research subject to federal regulations and institutional oversight, which is exempt from Department regulations, and that research facility and education facility licenses granted by the Department are only issued for the research and/or curriculum described and approved in the application;
- (10) An attestation that the use of any public funds or involvement of any public institution for research purposes must be disclosed at the time of application and that additional information and documentation regarding the research and/or curriculum may be required to be submitted during and after the application submission;
- (11) An attestation that the applicant adheres to 45 CFR § 46 (Protection of Human Subjects under United States Law) regulations; and
- (12) A statement signed by the applicant pledging not to divert marijuana to any individual or entity that is not lawfully entitled to possess marijuana.
- (d) **Application on behalf of an entity**. In addition to requirements of Subsection (c), an application for a research facility or education facility license made by an individual on behalf of an entity shall include:
  - (1) An attestation that applicant is authorized to make application on behalf of the entity;
  - (2) Full name of organization;
  - (3) Trade name, if applicable;
  - (4) Type of business organization;
  - (5) Mailing address;
  - (6) Telephone number and email address;
  - (7) The name, residence address, and date of birth of each owner, if applicable; and
  - (8) The name and residence address of each principal investigator or principal officer, if applicable.
- (e) **Supporting documentation for research facility applicants**. Each application for a research facility shall be accompanied by the following documentation:
  - (1) A certificate of compliance on a form prescribed or otherwise authorized by the Department that is issued by the political subdivision where the licensed premises is to be located certifying compliance with the categories listed in 63 O.S. § 426.1(E);
  - (2) If applicable, official documentation from the Secretary of State establishing the applicant's trade name;
  - (3) If applicable, a list of all owners and principal officers of the applicant and supporting documentation, including, but not limited to: certificate of incorporation, bylaws, articles of organization, operating agreement, certificate of limited partnership, resolution of a board of directors, or other similar documents;
  - (4) If applicable, documents establishing the applicant; and the members, managers, and board members; and seventy-five percent (75%) of the applicant's ownership interests are Oklahoma residents as required in accordance with OAC 310:681-1-6. This requirement shall not apply to research facility applicants that are public institutions or Oklahoma non-profit entities registered with the Oklahoma Secretary of State.
  - (5) The applicant shall submit a full description of the research including the following:
    - (A) Defined protocol;
    - (B) Clearly articulated goals;
    - (C) Defined methods and outputs;
    - (D) Defined start and end date; and
    - (E) Funding source(s); and
  - (6) Any further documentation or information the Department determines is necessary to ensure the applicant is qualified under Oklahoma law and these Rules to obtain a research facility license.
- (f) **Supporting documentation for education facility applicants.** Each application for an education facility license shall be accompanied by the following documentation:
  - (1) A certificate of compliance on a form prescribed or otherwise authorized by the Department that is issued by the political subdivision where the licensed premises is to be located certifying compliance with the categories listed in 63 O.S. § 426.1(E);
  - (2) An application for an education facility must include non-profit registration with the Oklahoma

Secretary of State;

- (3) If applicable, official documentation from the Secretary of State establishing the applicant's trade name:
- (4) If research is being conducted the applicant shall submit a full description of the research including the following:
  - (A) Defined protocol;
  - (B) Clearly articulated goals;
  - (C) Defined methods and outputs;
  - (D) Defined start and end date; and
  - (E) Funding source(s)
- (5) If applicable, the education facility applicant must submit the curriculum and/or a description of the curricula that will be used; and
- (6) Any further documentation or information the Department determines is necessary to ensure the applicant is qualified under Oklahoma law and these Rules to obtain an education facility license.

# (g) Supporting documentation for public research or education.

- (1) Research facility and education facility licensees may contract to perform research and/or education in conjunction with a public higher education research institution. If the research will be conducted with a public institution or public money, the Department shall review the research project and/or curriculum of the applicant to determine if it meets additional requirements in accordance with the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq. The applicant shall supply all relevant information and documentation to establish that the research or education meets these additional requirements. The Department shall review the research or education project to assess:
  - (A) The quality, study design, value, or impact of the project;
  - (B) Whether the applicant has the appropriate personnel, expertise, facilities, infrastructure, funding, and human, animal, or other approvals in place to successfully conduct the project; and
  - (C) Whether the amount of marijuana to be grown by the applicant is consistent with the scope and goals of the project.
- (2) To assess these criteria, research facility and education facility applications for research or education involving public institutions or public money shall include:
  - (A) A description of how public institutions and public funds will be utilized in the research or education;
  - (B) A full description of the research project to include:
    - (i) Abstract;
    - (ii) Study problem or curriculum;
    - (iii) Rationale, including identification of the need, gaps, benefits, advance best practices, public policy or safety
    - (iv) Literature review, including a bibliography of all referenced materials;
    - (v) Study or curriculum objectives;
    - (vi) Research method; and
    - (vii) Ethical considerations.
  - (C) An overview of the amount of marijuana to be purchased, grown, or cultivated, and an explanation for the amount to be purchased or grown;
  - (D) Contract(s) and agreement(s) with public institutions involved in the research and sources of public funds supporting the research;
  - (E) Documentation of applicant's ability to successfully implement the research project and/or curriculum to include:
    - (i) Curriculum vitae or resumes for all principal investigators and co-principal investigators;
    - (ii) Organizational chart; and
    - (iii) Description of the funding source(s).
  - (F) Any further documentation or information the Department determines is necessary to ensure the applicant is qualified under Oklahoma law and these Rules.

- (h) **Incomplete application**. Failure to submit a complete application with all required information and documentation shall result in a rejection of the application. The Department shall notify the applicant via email through the electronic application account of the reasons for the rejection—, and the applicant shall have thirty (30) days from the date of notification to correct and complete the application without an additional fee. If the applicant fails to correct and complete the application within the thirty (30) day period, the application shall expire. Unless the Department determines otherwise, an application that has been resubmitted but is still incomplete or contains errors that are not clerical or typographical in nature shall be denied.
- (i) **Review process**. Research facility and education facility license approval shall be assessed by a procedural review process as determined by the Department.
- (j) **Application denial**. If the Department determines that the research or education project does not meet the requirements of state law or these Rules, the application shall be denied.

#### 310:681-4-4. Inspections

- (a) Submission of an application for a medical marijuana research license and educational facility license constitutes permission for entry to and inspection of any licensed premises during hours of operation and other reasonable times. Refusal to permit or impeding such entry or inspection shall constitute grounds for administrative penalties, which may include but are not limited to fines as set forth in Appendix C and the denial, nonrenewal, suspension, and/or revocation of a license.
- (b) The Department may perform two on-site inspections per calendar year of the licensed research facility or education facility to determine, assess, and monitor compliance with applicable Oklahoma law and these Rules or ensure qualifications for licensure.
- (c) The Department may conduct additional inspections to ensure correction of or investigate violations of applicable Oklahoma law and these Rules.
- (d) The Department shall refer all complaints alleging criminal activity or other violations of Oklahoma law that are made against a licensee to appropriate Oklahoma state or local law enforcement or regulatory authorities. Except for license information concerning licensed patients, the Department may share confidential information to assist other agencies in ensuring compliance with applicable laws, rules and regulations.
- (e) If the Department discovers what it reasonably believes to be criminal activity or other violations of Oklahoma law during an inspection, the Department may refer the matter to appropriate Oklahoma state or local law enforcement or regulatory authorities for further investigation.
- (f) The Department may review any and all records of a licensee and may require and conduct interviews with such persons or entities and persons affiliated with such entities, for the purpose of determining compliance with Department rules and applicable laws. Failure to make documents or other requested information available to the Department and/or refusal to appear or cooperate with an interview shall constitute grounds for administrative penalties, which may include but are not limited to fines as set forth in Appendix C and the denial, nonrenewal, suspension, and/or revocation of a license. All records shall be kept on-site and readily accessible.
- (g) If the Department identifies a violation of 63 O.S. § 420 et seq., the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.; or these Rules during an inspection of the licensee, the Department shall take administrative action in accordance with Oklahoma law, including the Oklahoma Administrative Procedures Act, 75 O.S. §§ 250 et seq.
- (h) Except as otherwise provided in Oklahoma law or these Rules, correctable violations identified during an inspection shall be corrected within thirty (30) days of receipt of a written notice of violations. If a licensee fails to correct violations within thirty (30) days, the licensee will be subject to a fine in the amount set forth in Appendix C for each violation and any other administrative action and penalty authorized by law.
- (i) The Department may assess fines in the amounts set forth in Appendix C and seek any other administrative penalties authorized by law against a licensee without providing opportunity to correct when the violation is not capable of being corrected.

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

- (a) **Monthly reports**. Research facility licensees shall submit monthly reports to the Department, which shall include:
  - (1) The amount of marijuana purchased from medical marijuana businesses and research facilities in pounds;
  - (2) The amount of medical marijuana grown and used for research in pounds;
  - (3) The amount of marijuana waste in pounds;
  - (4) If necessary, a detailed explanation of why any marijuana cannot be accounted for as having been purchased, used for research, or maintained in current inventory; and
  - (5) Any information the Department determines is necessary to ensure that all marijuana grown in Oklahoma is accounted for as required under 63 O.S. § 420 et seq. the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.
  - (6) Upon implementation, submission of information and data to the Department through the State inventory tracking system will be required in accordance with the Oklahoma Medical Marijuana Protection Act, 63 O.S. § 427.1 et seq., and these Rules, and submission of information and data to the Department through the State inventory tracking system shall be sufficient to satisfy monthly reporting requirements.
- (b) **Transfer or sale**. A research facility licensee and an educational facility licensee may only transfer, by sale or donation, marijuana grown within its operation to medical marijuana research licensees. Research facility and education facility licensees shall keep records for every transaction related to the donation or sale of marijuana. Records related to the donation or sale shall include at a minimum the following:
  - (1) The name and license number of the medical marijuana researcher licensee that purchased or received the medical marijuana;
  - (2) The address and phone number of each recipient;
  - (3) The type of marijuana donated or sold;
  - (4) The amount of marijuana donated or sold in pounds; and
  - (5) The date of the donation or sale.
- (c) **Records**. Pursuant to the Department's audit and inspection responsibilities, research facility and education facility licensees shall keep onsite and readily accessible, either in paper or electronic form, a copy of the records listed below. Except as otherwise specifically provided in Oklahoma law and this Chapter, all records shall be maintained for at least seven (7) years from the date of creation.
  - (1) Business records, which may include but are not limited to employee records, organizational documents or other records relating to the governance and structure of the licensee, manual or computerized records of assets and liabilities, monetary transactions, tax records, journals, ledgers, and supporting documents, including agreements, checks, invoices, receipts, and vouchers.
  - (2) As applicable, any documents related to the processing, preparation, <u>transportation</u>, <u>sampling</u>, and/or testing of medical marijuana and medical marijuana products, including but not limited to <u>sample filed logs</u>, lab reports, testing records, equipment inspections, training materials, and standard operating procedures.
  - (3) Documentation of every instance in which medical marijuana was sold or otherwise transferred to or purchased or otherwise obtained from another licensee, which shall include, but is not limited to:
    - (A) The name, license number, address, and phone number of all licensees involved in each transaction; and
    - (B) The quantity and type of medical marijuana or medical marijuana products involved in each transaction;
    - (C) The batch number of the medical marijuana or medical marijuana products involved in each transaction:
    - (D) The date of each transaction:
    - (E) The monetary value of the medical marijuana or medical marijuana products involved in each transaction, including the total sale or purchase amounts;
    - (F) All point-of-sale and tax records; and

- (G) All inventory manifests and other documentation relating to the transport of medical marijuana and medical marijuana products.
- (4) Any and all documents relating to the disposal or destruction of medical marijuana, medical marijuana products, and medical marijuana waste.
- (d) Inventory tracking system. Pursuant to 63 O.S. § 427.3(D)(8) and 63 O.S. § 427.13(B), Each each research facility and education facility commercial licensee shall use the State inventory seed to-sale tracking system established by the Department by inputting inventory tracking data required to be reported to the Department directly into the State inventory tracking system or by utilizing a seed-to-sale tracking system that integrates with the Department established system at the time of its implementation State inventory tracking system. All commercial licensees must have an inventory tracking system account activated to lawfully operate and must ensure all information is reported to the Department accurately and in real time or after each individual sale in accordance with 63 O.S. § 427.13(B)(1) and these Rules. The system utilized by each licensee shall be a system that: All commercial licensees shall ensure the following information and data are accurately tracked and timely reported to the Department through the State inventory tracking system:
  - (1) Documents the <u>The</u> chain of custody of all medical marijuana and medical marijuana products, including every transaction with another licensee, patient, or caregiver; including, but not limited to:
    - (A) The name address, license number, and phone number of the medical marijuana business that cultivated, manufactured, sold, purchased, or otherwise transferred the medical marijuana or medical marijuana product(s);
    - (B) The type, item, strain, and category of medical marijuana or medical marijuana product(s) involved in the transaction;
    - (C) The weight, quantity, or other metric required by the Department, of the medical marijuana or medical marijuana product(s) involved in the transaction;
    - (D) The batch number of the medical marijuana or medical marijuana product(s);
    - (E) The total amount spent in dollars;
    - (F) All point-of-sale records as applicable;
    - (G) Transportation information documenting the transport of medical marijuana or medical marijuana product(s) as required under OAC 310:681-3-6(b);
    - (H) Testing results and information;
    - (I) Waste records and information;
    - (J) Marijuana excise tax records, if applicable;
    - (K) RFID tag number(s);
  - (2) Establishes ongoing inventory controls and procedures for the conduct of inventory reviews and comprehensive inventories of medical marijuana and medical marijuana products for traceability which shall enable the licensee to detect any diversion, theft, or loss in a timely manner;
  - (3) Identifies and allows for tracking and documentation of the <u>The</u> entire life span of a licensee's stock of medical marijuana and medical marijuana products, including, at a minimum:
    - (A) when When medical marijuana seeds or clones are planted;
    - (B) when When medical marijuana plants are harvested and/or destroyed;
    - (C) when When medical marijuana is transported, or otherwise transferred, sold, stolen, diverted, or lost;
    - (D) a complete inventory of all medical marijuana; seeds; plant tissue; clones; usable marijuana; trim; leaves; other plant matter; and medical marijuana products When medical marijuana changes form, including, but not limited to, when it is planted, cultivated, processed, and infused into a final product;
    - (E) all samples sent to a testing laboratory or used for internal quality testing or other purposes <u>A</u> complete inventory of all medical marijuana; seeds; plant tissue; clones; useable marijuana; trim; shake; leaves; other plant matter; and medical marijuana products;
  - (F) All samples sent to a testing laboratory or used for internal quality testing or other purposes; (4) In event of a serious adverse event or recall, is capable of tracking medical marijuana or medical marijuana product from a patient back to the source of the medical marijuana or medical marijuana

#### product; and

- (5) Tracks medical marijuana using an assigned batch number and bar code.
- (3) Any further information the Department determines is necessary to ensure all medical marijuana and medical marijuana products are accurately and fully tracked throughout the entirety of the lifespan of the plant and product.
- (e) Seed-to-sale tracking system. A commercial licensee shall use a seed-to-sale tracking system or integrate its own seed-to-sale tracking system with the State inventory tracking system established by the Department. If a commercial licensee uses a seed-to-sale tracking system that does not integrate with the State inventory tracking system, or does integrate but does not share all required information, the commercial licensee shall ensure all required information is reported directly into the State inventory tracking system.

Audits. The Department may perform on site audits of all research facility and education facility licensees to ensure the accuracy of the research facility's monthly reports and to ensure that all marijuana grown in Oklahoma is accounted for. Submission of an application for a research facility or education facility license constitutes permission for entry to any licensed premises and auditing of the licensee during hours of operation and other reasonable times. Refusal to permit the Department entry or refusal to permit the Department to inspect all books and records shall constitute grounds for administrative penalties, which may include, but are not limited to, fines as set forth in Appendix C and the denial, nonrenewal, suspension, and/or revocation of a license.

- (1) The Department may review any and all records and information of a research facility or education facility licensee and may require and conduct interviews with such persons or entities and persons affiliated with such licensees, for the purpose of determining compliance with Department rules and applicable laws. Failure to make documents or other requested information available to the Department and/or refusal to appear or cooperate with an interview shall constitute grounds for administrative penalties, which may include, but are not limited to, fines as set forth in Appendix C and the denial, nonrenewal, suspension, and/or revocation of a license, or any other remedy or relief provided under law. All records shall be kept on site and readily accessible.
- (2) Licensees shall comply with all written requests from the Department to produce or provide access to records and information within ten (10) business days.
- (3) If the Department identifies a violation of 63 O.S. § 420 et seq., the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.; or these Rules during an audit of the licensee, the Department shall take administrative action against the licensee in accordance with Oklahoma law, including the Oklahoma Administrative Procedures Act, 75 O.S. § 250 et seq.
- (4) The Department may refer all complaints alleging criminal activity or other violations of Oklahoma law that are made against a licensee to appropriate Oklahoma state or local law enforcement or regulatory authorities.
- (5) If the Department discovers what it reasonably believes to be criminal activity or other violations of Oklahoma law during an audit, the Department may refer the matter to appropriate Oklahoma state or local law enforcement or regulatory authorities for further investigation.
- (6) Except as is otherwise provided in Oklahoma law or these Rules, correctable violations identified during an audit shall be corrected within thirty (30) days of receipt of a written notice of violation.
- (7) If a licensee fails to correct violations within thirty (30) days, the licensee will be subject to a fine in the amount set forth in Appendix C for each violation and any other administrative action and penalty authorized by law.
- (8) The Department may assess fines in the amounts set forth in Appendix C and seek any other administrative penalties authorized by law against a licensee without providing opportunity to correct when the violation is not capable of being corrected.

#### (f) Inventory tracking system requirements

- (1) At a minimum, commercial licensees shall track, update, and report inventory after each individual sale to the Department in the State inventory tracking system.
- (2) All commercial licensees must ensure all on-premises and in-transit medical marijuana and medical marijuana product inventories are reconciled each day in the State inventory tracking system

- at the close of business, if not already done.
- (3) Commercial licensees are required to use RFID tags from a Department-approved supplier for the State inventory tracking system. Each Licensee is responsible for the cost of all RFID tags and any associated vendor fees.
  - (A) A commercial licensee shall ensure its inventories are properly tagged and that a RFID tag is properly assigned to medical marijuana, medical marijuana products, and medical marijuana waste as required by the Department.
  - (B) A commercial licensee shall ensure it has an adequate supply of RFID tags at all times. If a commercial licensee is unable to account for unused RFID tags, the commercial licensee must report to the Department and the State inventory tracking system vendor within forty-eight (48) hours.
  - (C) RFID tags must contain the legal name and correct license number of the commercial licensee that ordered them. Commercial licensees are prohibited from using another licensee's RFID tags.
    (D) Prior to a plant reaching a point where it is able to support the weight of the RFID tag and
  - attachment strap, the RFID tag may be securely fastened to the stalk or other similarly situated position approved by the Department.
  - (E) When the plant becomes able to support the weight of the RFID tag, the RFID tag shall be securely fastened to a lower supporting branch. The RFID tag shall remain affixed for the entire life of the plant until disposal.
  - (F) Mother plants must be tagged before any cuttings or clones are generated therefrom.
  - (G) If a RFID tag gets destroyed, stolen, or falls off of a medical marijuana plant, the licensee must ensure a new RFID tag is placed on the medical marijuana plant and the change of the RFID tag is properly reflected in the State inventory tracking system.
  - (H) Commercial licensees shall not reuse any RFID tag that has already been affixed to any regulated medical marijuana or medical marijuana products.
- (4) Each wholesale package of medical marijuana must have a RFID tag during storage and transfer and may only contain one harvest batch of medical marijuana.
- (5) Prior to transfer, commercial licensees shall ensure that each immature plant is properly affixed with an RFID tag if the plant was not previously tagged in accordance with these Rules.
- (6) Commercial licensees' inventory must have a RFID tag properly affixed to all medical marijuana products during storage and transfer in one of the following manners:
  - (A) Individual units of medical marijuana products shall be individually affixed with a RFID tag; or
  - (B) Medical marijuana products may only be combined in a single wholesale package using one RFID tag if all units are from the same production batch.
- (7) If any medical marijuana or medical marijuana products are removed from a wholesale package, each individual unit or new wholesale package must be separately tagged.
- (8) All packages of medical marijuana waste shall have a RFID tag affixed and the contents of the waste package shall be reported in the State inventory tracking system.

#### (g) Inventory tracking system administrators and users.

- (1) A commercial licensee must have at least one owner, or manager, who is an inventory tracking system administrator.
- (2) The inventory tracking system administrator must attend and complete all required inventory tracking system training.
- (3) If at any point, the inventory tracking system administrator for a licensee changes, the commercial licensee shall change or assign a new inventory tracking system administrator within thirty business days.
- (4) Commercial licensees shall maintain an accurate and complete list of all inventory tracking system administrators and employee users.
- (5) Commercial licensees shall ensure that all owners and employees that are granted inventory tracking system account access for the purpose of conducting inventory tracking functions are trained and authorized before the owners or employees may access the State inventory tracking system.

- (6) All inventory tracking system users shall be assigned an individual account in the State inventory tracking system.
- (7) Any individual entering data into the State inventory tracking system shall only use the inventory tracking system account assigned specifically to that individual. Each inventory tracking system administrator and inventory tracking system user must have unique log-in credentials that shall not be used by any other person.
- (8) Within three (3) business days, commercial licensees must remove access for any inventory tracking system administrator or user from their accounts if any such individual no longer utilizes the State inventory tracking system or is no longer employed by the commercial licensee.
- (h) Loss access to State inventory tracking system. If at any time a commercial licensee loses access to the State inventory tracking system due to circumstances beyond the commercial licensee's control, the commercial licensee shall keep and maintain records detailing all inventory tracking activities that were conducted during the loss of access. Once access is restored, all inventory tracking activities that occurred during the loss of access must be immediately entered into the State inventory tracking system. If a commercial licensee loses access to the State inventory tracking system due to circumstances within its control, the commercial licensee may not perform any business activities that would be required to be reported into the State inventory tracking system until access is restored and reporting is resumed; any transfer, sale, or purchase of medical marijuana or medical marijuana products shall be an unlawful sale. (i) **Audits**. The Department may perform on-site audits of all research facility and education facility licensees to ensure the accuracy of information and data reported to the Department and to ensure that all marijuana grown in Oklahoma is accounted for. Submission of an application for a research facility or education facility license constitutes permission for entry to any licensed premises and auditing of the licensee during hours of operation and other reasonable times. Refusal to permit the Department entry or refusal to permit the Department to inspect all books and records shall constitute grounds for and administrative penalties, which may include, but are not limited to, fines as set forth in Appendix C and the denial, nonrenewal, suspension, and/or revocation of a license.
  - (1) The Department may review any and all records and information of a research facility or education facility licensee and may require and conduct interviews with such persons or entities and persons affiliated with such licensees, for the purpose of determining compliance with Department Rules and applicable laws. Failure to make documents or other requested information available to the Department and/or refusal to appear or cooperate with an interview shall constitute grounds for administrative penalties, which may include, but are not limited to, fines as set forth in Appendix C and the denial, nonrenewal, suspension, and/or revocation of a license, or any other remedy or relief provided under law. All records shall be kept on-site and readily accessible.
  - (2) Licensees shall comply with all written requests from the Department to produce or provide access to records and information within ten (10) business days.
  - (3) If the Department identifies a violation of 63 O.S. § 420 et seq., the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.; or these Rules during an audit of the licensee, the Department shall take administrative action against the licensee in accordance with Oklahoma law, including the Oklahoma Administrative Procedures Act, 75 O.S. § 250 et seq.
  - (4) The Department may refer all complaints alleging criminal activity or other violations of Oklahoma law that are made against a licensee to appropriate Oklahoma state or local law enforcement or regulatory authorities.
  - (5) If the Department discovers what it reasonably believes to be criminal activity or other violations of Oklahoma law during an audit, the Department may refer the matter to appropriate Oklahoma state or local law enforcement or regulatory authorities for further investigation.
  - (6) Except as is otherwise provided in Oklahoma law or these Rules, correctable violations identified during an audit shall be corrected within thirty (30) days of receipt of a written notice of violation.

    (7) If a licensee fails to correct violations within thirty (30) days, the licensee will be subject to a fine in the amount set forth in Appendix C for each violation and any other administrative action and penalty authorized by law.
  - (8) The Department may assess fines in the amounts set forth in Appendix C and seek any other

administrative penalties authorized by law against a licensee without providing opportunity to correct when the violation is not capable of being corrected.

#### SUBCHAPTER 5. MEDICAL MARIJUANA BUSINESSES

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

Upon acceptance of the license issued by the Department, the license holder in order to retain the license shall:

- (1) Post the license or permit in a location in the licensed premises that is conspicuous;
- (2) Comply with the provisions in this Chapter;
- (3) Allow representatives of the Department access to the medical marijuana business as specified under OAC 310:681-5-4 and OAC 310:681-5-6(e);
- (4) Comply with directives of the Department including time frames for corrective actions specified in inspection reports, audit reports, notices, orders, warnings, and other directives issued by the Department in regard to the license holder's medical marijuana business or in response to community emergencies;
- (5) Accept notices issued and served by the Department according to law;
- (6) Be subject to the administrative, civil, injunctive, and criminal remedies authorized in law for failure to comply with this Chapter or a directive of the Department, including time frames for corrective actions specified in inspection reports, audit reports, notices, orders, warnings, and other directives:
- (7) Ensure that all information and records maintained in the licensee's online OMMA license account—including the hours of operation for all licensed premises, trade name, and a valid mailing address, if applicable—are complete, accurate, and updated in a timely manner in accordance with these Rules; and
- (8) If applicable, submit the annual renewal application and pay all renewal license and late fees, if any-:
- (9) Bear the financial responsibility for all compliance and inventory tracking obligations and responsibilities set forth in Oklahoma statutes and these Rules. The Department will not contribute to, fund, or subsidize any commercial licensee's compliance or tracking expenses. Nothing herein shall be construed to require the Department to contribute to, subsidize, or fund in any way a commercial licensee's compliance or tracking expenses; and
- (10) If multiple commercial licensees are located at the same location, each commercial license must ensure that all inventory is separately and properly tracked, accounted for, and physically and distinctly separated from the inventory of any other commercial licensee such that licensees and the Departments are readily able to distinguish as to which licensee each item of medical marijuana and medical marijuana products belongs.

#### 310:681-5-2. Licenses

- (a) **Timeframe**. A medical marijuana business license shall be issued for a twelve (12) month period expiring one (1) year from the date of issuance. The license may be issued upon receipt of a completed application, payment of application fee, and verification by the Department the individual or entity complies with the requirements set forth in Oklahoma law and this Chapter.
- (b) **Location**. A business license issued to a grower, processor, dispensary, or testing laboratory shall only be valid for a single location at the address listed on the application. A transporter license shall only be valid at the physical locations that have been submitted to and approved by the Department and are listed on the application.

# (c) Renewal of license.

- (1) It is the responsibility of the license holder to renew the license, with all applicable documentation, prior to the date of expiration of the license by following the procedures provided in OAC 310:681-5-3.
- (2) Before renewing a license, the Department may require further information and documentation

and may require additional background checks to determine the licensee continues to meet the requirements set forth in Oklahoma law and these Rules. Once a certificate of compliance is properly submitted showing full compliance, no additional certificate of compliance will be required for license renewal unless a change of use or occupancy occurs, or other change that would require additional inspection, licensure, or permitting by the state or municipality.

- (3) The Department may refuse to renew a license of a medical marijuana business for the following: (A) Failure to meet the requirements for licensure set forth in 63 O.S. § 420 et seq; the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.; or OAC 310:681.
  - (B) Noncompliance with 63 O.S. § 420 et seq.; the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.; the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq.; or OAC 310:681.
- (4) Upon the determination that a licensee has not met the requirements for renewal, the Department shall provide written notice to the licensee. The notice shall provide an explanation for the denial of the renewal application.
- (5) A commercial licensee that attempts to renew its license after the expiration date of the license shall pay a nonrefundable late renewal fee in the amount of \$500.00 to reinstate the license once processed and approved by the Department. A license that has been expired for more than ninety (90) days shall not be renewed.
- (d) **Liquidation of products.** A medical marijuana business licensee whose license is not renewed, or whose license is revoked, suspended, or voluntarily surrendered, shall cease all operations immediately upon expiration of the license and shall dispose of any medical marijuana or medical marijuana products in accordance with OAC 310:681-5-10 that were not liquidated prior to licensure expiration in accordance with Oklahoma law and these Rules.
  - (1) A medical marijuana business has thirty (30) days from date of expiration, revocation, suspension, or surrender of a business license to liquidate and transfer all medical marijuana or medical marijuana products to another medical marijuana business that (1) the medical marijuana business may lawfully sell to and (2) is licensed to possess such medical marijuana or medical marijuana products.
  - (2) Any medical marijuana or medical marijuana products not liquidated in accordance with OAC 310:681-5-2(d)(1) shall be disposed of as specified under OAC 310:681-5-10.

## (e) Change in information.

- (1) Licensees shall notify the Department in writing within fourteen (14) days of any changes in contact information by electronically submitting a change request in accordance with the Department's instructions.
- (2) Licensees shall obtain Department approval prior to for any material changes that affect the licensee's qualifications for licensure. Licensees shall submit a material change request to notify the Department in writing in advance of any material change that may affect the licensee's qualifications for licensure by electronically submitting a change request, along with any relevant documentation and fees, in accordance with the Department's instructions. When submitting a material change request, the licensee will be required to pay a \$500.00 nonrefundable fee. Except as is otherwise authorized by the Department, licensees are limited to one location change request, one name change request, and one ownership change request per year of licensure.
  - (A) Medical marijuana business licensees submitting a location change must provide the information and documentation required in OAC 310:681-5-3 relating to locations, including but not limited to the following:
    - (i) If applicable, proof as required in OAC 310:681-5-3(e)(6) that the location of the dispensary or grower is at least one thousand (1,000) feet from any public and private school;
    - (ii) A certificate of compliance as required in OAC 310:681-5-3(e)(8) on a form prescribed or otherwise authorized by the Department that is issued by the political subdivision where the licensed premises is to be located certifying compliance with the categories listed in 63 O.S. § 426.1(E); and
    - (iii) Any further documentation the Department determines is necessary to ensure the business licensee is still qualified under Oklahoma law and this Chapter to obtain a business

license.

- (B) Medical marijuana business licensees submitting an ownership change request must provide the information and documentation required in OAC 310:681-5-3 relating to owners, including but not limited to the following:
  - (i) A list of all owners and principal officers of the commercial applicant and supporting documentation as set forth in OAC 310:681-5-3(e)(1);
  - (ii) An affidavit of lawful presence for each new owner;
  - (iii) Documents required under OAC 310:681-5-3(e)(7) establishing that the applicant; and the members, managers, and board members if applicable; and seventy-five percent (75%) of the commercial applicant's ownership interests are Oklahoma residents as required in the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.;
  - (iv) A background check in accordance with OAC 310:681-1-5; and
  - (v) Any further documentation the Department determines is necessary to ensure the business licensee is still qualified under Oklahoma law and this Chapter to obtain a business license.
- (C) A medical marijuana business licensee submitting a name change request must provide the information and documentation required in OAC 310:681-5-3 relating to the business name, including, but not limited to, the following:
  - (i) A certificate of good standing from the Oklahoma Secretary of State issued within thirty (30) days of submission of the application;
  - (ii) If applicable, official documentation from the Secretary of State establishing the applicant's trade name;
  - (iii) If applicable, an electronic copy or digital image in color of a sales tax permit issued by the Oklahoma Tax Commission;
  - (iv) A list of all owners and principal officers of the licensee under the new name and supporting documentation as set forth in OAC 310:681-5-3(e)(1);
  - (v) Documents establishing that seventy-five (75%) of the ownership of the licensee under the new name are Oklahoma residents in accordance with OAC 310:681-5-3(e)(7); and
  - (vi) Any further documentation the Department determines is necessary to ensure the business licensee is still qualified under Oklahoma law and this Chapter to obtain a business license.
- (D) Medical marijuana growers, processors, or commercial transporters that have held a valid medical marijuana business license for at least eighteen (18) months and are operating in good standing may submit an ownership change request to add a publicly traded company as an owner. The publicly traded company shall not own more than forty percent (40%) of the equity in the existing medical marijuana grower, processor, or commercial transporter. The following documentation must be provided:
  - (i) If applicable, a certificate of good standing from the Oklahoma Secretary of State issued within thirty (30) days of submission of the application.
  - (ii) A list of all owners, excluding all shareholders of the publicly traded company, and principal officers of the commercial applicant and supporting documentation as set forth in OAC 310:681-5-3(e)(1);
  - (iii) Documents required under OAC 310:681-5-3(e)(6) establishing that the applicant; and the members, managers, and board members if applicable; and seventy-five percent (75%) of the grower, processor, or transporter applicant's ownership interests, excluding the publicly traded company, are Oklahoma residents as required in the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.

# (f) Transfer of license.

- (1) Business licenses may not be wholly assigned or otherwise transferred to a new owner(s) or another legal entity(ies).
- (2) Licenses may not be changed from one license type to another.

### (g) Surrender of license.

(1) A licensee may voluntarily surrender a license to the Department at any time.

- (2) If a licensee voluntarily surrenders a license, the licensee shall:
  - (A) Return the license to the Department;
  - (B) Submit on a form prescribed by the Department a report to the Department including the reason for surrendering the license; contact information following the close of business; the person or persons responsible for the close of the business; and where business records will be retained:
  - (C) Submit proof of the licensee's identity through submission of documentation identified in OAC 310:681-1-7 (relating to Proof of Identity); and
  - (D) Liquidate or dispose of any medical marijuana or medical marijuana products remaining in the possession of the licensee in accordance with OAC 310:681-5-2(d) and OAC 310:681-5-10.

### 310:681-5-2.1 Objection by municipality

Prior to the initial renewal or transfer of a license, a municipal government may object to the continued licensure of a medical marijuana dispensary if the municipal government determines the medical marijuana dispensary is operating contrary to the required setback distance after taking into account the error in measurement allowance.

- (1) To object to the initial renewal or transfer of a license, the municipal government shall submit the following documentation:
  - (A) An objection in a form and manner as determined by the department;
  - (B) A municipal resolution finding that the medical marijuana dispensary is located within the prohibited setback distance from a school;
  - (C) Documentation establishing that the school in question was openly in existence prior to the medical marijuana dispensary being licensed;
  - (D) Documentation of the measured distance from the school to the marijuana dispensary utilizing the method for determining the setback distance applicable to the front door of the medical marijuana dispensary less the error in measurement allowance.
- (2) If the Department determines a medical marijuana dispensary is operating contrary to the required setback distance from a school, including the error in measurement allowance, the Department may deny the renewal or transfer of license and move for revocation of the license.

### 310:681-5-3. Applications

- (a) **Application fee**. An applicant for a medical marijuana business, or renewal thereof, shall submit to the Department a completed application on a form and in a manner prescribed by the Department, along with the application fee as established in 63 O.S. § 420 et seq. and the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.
- (b) **Submission**. Applications for a business license will be accepted by the Department no earlier than sixty (60) days from the date that the State Question is approved by the voters of the State of Oklahoma. The application shall be on the Department prescribed form and shall include the following information about the establishment:
  - (1) Name of the establishment;
  - (2) Physical address of the establishment, including the county in which any licensed premises will be located;
  - (3) GPS coordinates of the establishment:
  - (4) Phone number and email of the establishment; and
  - (5) Hours of operation for any licensed premises.
- (c) **Individual applicant**. The application for a business license made by an individual on his or her own behalf shall be on the Department prescribed form and shall include at a minimum:
  - (1) The applicant's first name, middle name, last name and suffix if applicable;
  - (2) The applicant's residence address and valid mailing address;
  - (3) The applicant's date of birth;
  - (4) The applicant's telephone number and email address;
  - (5) An attestation that the information provided by the applicant is true and correct;

- (6) An attestation that any licensed premises shall not be located on tribal lands;
- (7) An attestation that the business has obtained all applicable local licenses and permits for all licensed premises;
- (8) An attestation that no individual with ownership interest in the business is a sheriff, deputy sheriff, police officer, prosecuting officer, an officer or employee of OMMA, or an officer or employee of a municipality in which the commercial entity is located; and
- (9) A statement signed by the applicant pledging not to divert marijuana to any individual or entity that is not lawfully entitled to possess marijuana.
- (d) **Application on behalf of an entity**. In addition to requirements of Subsection (c), an application for a business license made by an individual on behalf of an entity shall include:
  - (1) An attestation that applicant is authorized to make application on behalf of the entity:
  - (2) Full name of organization;
  - (3) Trade name, if applicable;
  - (4) Type of business organization;
  - (5) Mailing address;
  - (6) Telephone number and email address; and
  - (7) The name, residence address, and date of birth of each owner and each member, manager, and board member, if applicable.
- (e) **Supporting documentation**. Each application shall be accompanied by the following documentation:
  - (1) A list of all owners and principal officers of the business applicant and supporting documentation, including, but not limited to: certificate of incorporation, bylaws, articles of organization, operating agreement, certificate of limited partnership, resolution of a board of directors, or other similar documents;
    - (2) If applicable, a certificate of good standing from the Oklahoma Secretary of State issued within thirty (30)days of submission of the application;
    - (3) If applicable, official documentation from the Secretary of State establishing the applicant's trade name:
    - (4) If applicable, an electronic copy or digital image in color of a sales tax permit issued by the Oklahoma Tax Commission;
    - (5) An Affidavit of Lawful Presence for each owner;
    - (6) If a licensed dispensary or grower, proof that the location of the dispensary is at least one thousand (1,000) feet from a public or private school. For a dispensary, The distance specified shall be measured in a straight line from any entrance of any public and private school to the nearest point of the location of the dispensary the nearest property line of such public school or private school to the nearest perimeter wall of the licensed premise of such medical marijuana dispensary. For a grower, the distance specified shall be measured in a straight line from the nearest property line of such public school or private school to the nearest property line of the the licensed premises of such medical marijuana commercial grower. For the purposes of this subsection, a school shall not include a property owned, used, or operated by a public or private school that is not used for classroom instruction on core curriculum, such as an administrative building, athletic facility, ballpark, field, or stadium, unless such property is located on the same campus as a building used for classroom instruction on core curriculum; and
    - (7) Documents establishing the applicant; and the members, managers, and board members if applicable; and seventy-five percent (75%) of the commercial applicant's ownership interests are Oklahoma residents as required in the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.
      - (A) Applicants seeking to renew a commercial license issued prior to the enactment of the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq., shall submit documentation establishing proof of residency in accordance with OAC 310:681-1-6 (relating to proof of residency);
      - (B) All other applicants shall submit documentation establishing proof of residency in accordance with OAC 310:681-5-3.1 (relating to proof of residency for business licenses).

- (8) <u>If applicable</u>, a A certificate of compliance on a form prescribed or otherwise authorized by the Department that is issued by the political subdivision where the licensed premises is to be located certifying compliance with the categories listed in 63 O.S. § 426.1(E);
- (9) If applicable, accreditation documentation, including documentation of enrollment in analyte-specific proficiency testing results, showing applicants meet requirements stated in OAC 310:681-8-2(a): and
- (10) Any further documentation the Department determines is necessary to ensure the commercial applicant is qualified under Oklahoma law and this Chapter to obtain a commercial license. If a licensed grower, processor or transporter has added or is seeking to add a publicly traded company as an owner, additional documentation as required under OAC 310:681-5-2(e)(2)(C) to show the grower, processor, or transporter applicants meet the requirements stated in 63 O.S. § 427.15a;
- (11) If applicable, a list of all chemicals a processor will utilize to process marijuana;
- (12) If applicable, safety data sheets for every chemical a processor will utilize to process marijuana; and
- (13) Any further documentation the Department determines is necessary to ensure the commercial applicant is qualified under Oklahoma law and this Chapter to obtain a commercial license.
- (f) **Incomplete application**. Failure to submit a complete application with all required information and documentation shall result in a rejection of the application. The Department shall notify the applicant via email through the electronic application account of the reasons for the rejection, and the applicant shall have thirty (30) days from the date of notification to correct and complete the application without an additional fee. If the applicant fails to correct and complete the application within the thirty (30) day period, the application shall expire. <u>Unless the Department determines otherwise</u>, an application that has been resubmitted but is still incomplete or contains errors that are not clerical or typographical in nature shall be denied.
- (g) **Status update letter**. If a delay in processing has occurred, the Department shall notify the applicant via email of the delay and the reason for the delay.
- (h) **Moratorium.** Beginning August 1, 2022, and ending August 1, 2024, there shall be a moratorium on processing and issuing new medical marijuana business licenses for dispensaries, processors, and growers. The Authority will review and process applications received on or before August 1, 2022. The Executive Director of the Authority may terminate the moratorium prior to August 1, 2024, upon a determination that all pending license reviews, inspections, or investigations have been completed. The moratorium shall not apply to:
  - (1) The renewal of a medical marijuana business license for dispensaries, processors, or growers;
  - (2) The issuance of a medical marijuana business license necessitated by a change in the ownership or location of a dispensary, processor, or grower; or
  - (3) The issuance or renewal of a testing laboratory, transporter, education facility, research, or waste disposal license.

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

- (a) Applicants shall provide sufficient documentation establishing either:
  - (1) Oklahoma residency for at least two (2) years immediately preceding the application submission date; or
  - (2) Five (5) years continuous Oklahoma residency during the twenty-five (25) years immediately preceding the application submission date.
- (b) Applicants shall establish residency through submission of electronic copies or digital images in color of a combination of the following documents establishing residency for the entire span of the applicable time period:
  - (1) An unexpired Oklahoma-issued driver license or Real ID;
  - (2) An Oklahoma identification card;
  - (3) An Oklahoma voter identification card;
  - (4) Utility bills, excluding cellular telephone and Internet bills;

- (5)(4) Residential property deeds or other official documentation establishing proof of ownership of Oklahoma residential property;
- (6)(5) Rental agreements for residential property located in the State of Oklahoma;
- (7)(6) Oklahoma Tax Returns showing the applicant as an Oklahoma taxpayer; or
- (8)(7) Other documentation the Department deems necessary and/or sufficient to establish residency.

# 310:681-5-3.2. Persons prohibited from holding a commercial license

- (a) A medical marijuana commercial license shall not be issued to, renewed, or held by:
  - (1) An applicant who has failed to pay the required application or renewal fee;
  - (2) A corporation, if the criminal history of any its officers, directors, or stockholders has a disqualifying criminal conviction;
  - (3) An owner under twenty-five (25) years of age;
  - (4) An owner of any commercial licensee who, during a period of licensure or at the time of any commercial license application, has failed to:
    - (A) File any taxes, interest, or penalties due related to a medical marijuana business; or
    - (B) Pay any taxes, interest, or penalties due related to a medical marijuana business.
  - (5) A sheriff, deputy sheriff, police officer, prosecuting officer, officer or employee of OMMA, or officer or employee of a municipality in which the commercial licensee is located; and
  - (6) A person whose authority to be a caregiver as defined in this Chapter is revoked by the Department for violations of Oklahoma law or these Rules. For purposes of this Subsection, revoked by the Department shall not include termination of a caregiver license based solely on a patient's withdrawal of caregiver designation.
  - (7) A person who was involved in the management or operation of any commercial licensee that, after the initiation of a disciplinary action, has had a medical marijuana license revoked, not renewed, or surrendered during the five (5) years preceding submission of the application and for the following violations:
    - (A) unlawful sales or purchases;
    - (B) any fraudulent acts, falsification of records or misrepresentation to the Department, medical marijuana patient licensees, caregiver licensees, or medical marijuana business licensees;
    - (C) any grossly inaccurate or fraudulent reporting;
    - (D) threatening or harming any medical marijuana patient, caregiver, medical practitioner, or employee of the Department;
    - (E) knowingly or intentionally refusing to permit the Department access to premises or records;
    - (F) using prohibited, hazardous substance for processing in a residential area;
    - (G) criminal acts relating to the operation of a medical marijuana business; or
    - (H) any violation that endangers public health and safety or product safety, including, but not limited to, failure to test medical marijuana or medical marijuana products in accordance with these rules, failure to assist in a recall or embargo, or failure to adhere to any order or directive by the Department that may endanger public health and safety.
- (b) Any license issued to an individual or entity listed above shall be subject to revocation.

#### 310:681-5-4. Inspections

- (a) Submission of an application for a medical marijuana commercial license constitutes permission for entry to and inspection of any licensed premises and any vehicles on the licensed premises used for the transportation of medical marijuana and medical marijuana products during hours of operation and other reasonable times. Refusal to permit or impeding such entry or inspection shall constitute grounds for administrative penalties, which may include but are not limited to fines as set forth in Appendix C and the denial, nonrenewal, suspension, and/or revocation of a license.
- (b) The Department may perform two on-site inspections per calendar year of each licensed grower, processor, dispensary, or commercial transporter to determine, assess, and monitor compliance with applicable Oklahoma law and these Rules or ensure qualifications for licensure.
- (c) The Department shall conduct one on-site inspection of a testing laboratory applicant prior to licensure

- and one up to two (2) on-site inspection annually thereafter. The inspection prior to initial licensure may include proficiency testing, and shall be conducted to ensure all application materials are accurate and the applicant meets all requirements in 63 O.S. § 427.17 and these Rules.
- (d) The Department may conduct additional inspections to ensure correction of or investigate violations of applicable Oklahoma law and these Rules. Such inspections may be unannounced if the Department believes notice will result in the destruction of evidence. The Department shall conduct one (1) on-site inspection of each warehouse location of a medical marijuana transporter applicant or licensee prior to approving the location for use to ensure all information and documentation is true and correct and to determine if the proposed warehouse location meets all requirements of 63 O.S. § 427.16 and these Rules. (e) The Department shall refer all complaints alleging criminal activity or other violations of Oklahoma
- (e) The Department shall refer all complaints alleging criminal activity or other violations of Oklahoma law that are made against a licensee to appropriate Oklahoma state or local law enforcement or regulatory authorities. The Department may conduct additional inspections to ensure correction of or investigate violations of applicable Oklahoma law and these Rules.
- (f) If the Department discovers what it reasonably believes to be criminal activity or other violations of Oklahoma law during an inspection, the Department may refer the matter to appropriate Oklahoma state or local law enforcement or regulatory authorities for further investigation. The Department shall refer all complaints alleging criminal activity or other violations of Oklahoma law that are made against a licensee to appropriate Oklahoma state or local law enforcement or regulatory authorities.
- (g) The Department may review any and all records of a licensee and may require and conduct interviews with such persons or entities and persons affiliated with such entities, for the purpose of determining compliance with Department rules and applicable laws. Licensees shall be afforded at least twenty-four-hours' notice to secure legal representation prior to any interviews. Failure to make documents or other requested information available to the Department and/or refusal to appear or cooperate with an interview-shall constitute grounds for administrative penalties, which may include, but are not limited to, fines asset forth in Appendix C and the denial, nonrenewal, suspension, and/or revocation of a license. All records shall be kept on site and readily accessible. If the Department discovers what it reasonably believes to be criminal activity or other violations of Oklahoma law during an inspection, the Department may refer the matter to appropriate Oklahoma state or local law enforcement or regulatory authorities for further investigation. Except for license information concerning licensed patients, the Department may share confidential information to assist other agencies in ensuring compliance with applicable laws, Rules, and regulations.
- (h) If the Department identifies a violation of 63 O.S. § 420 et seq., the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.; and these Rules during an inspection of the business licensee, the Department shall take administrative action in accordance with Oklahoma law, including the Oklahoma Administrative Procedures Act, 75 O.S. §§ 250 et seq. The Department may review any and all records of a licensee and may require and conduct interviews with such persons or entities and persons affiliated with such entities, for the purpose of determining compliance with Department Rules and applicable laws. Failure to make documents or other requested information available to the Department and/or refusal to appear or cooperate with an interview shall constitute grounds for administrative penalties, which may include, but are not limited to, fines as set forth in Appendix C and the denial, nonrenewal, suspension, and/or revocation of a license. All records shall be kept on-site and readily available.
- (i) Except as otherwise provided in Oklahoma law or these Rules, correctable violations identified during an inspection shall be corrected within thirty (30) days of receipt of a written notice of violations. If the Department identifies a violation of 63 O.S. § 420 et seq., the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq., and these Rules during an inspection of the licensed business, the Department shall take administrative action in accordance with Oklahoma law, including the Oklahoma Administrative Procedures Act, 75 O.S. § 250 et seq. If a licensee fails to correct violations within thirty (30) days, the licensee will be subject to a fine in the amount set forth Appendix C for each violation and any other administrative action and penalty authorized by law.
- (j) The Department may assess fines in the amounts set forth in Appendix C and seek any other administrative penalties authorized by law against a licensee without providing opportunity to correct

when the violation is not capable of being corrected. The Department may suspend or revoke a license for failure to pay any fine or monetary penalty lawfully assessed by the Department against the licensee.

(k) If a licensee fails to correct violations within thirty (30) days, the licensee will be subject to a fine of \$500.00 for each deficiency and any other administrative action and penalty authorized by law.

### 310:681-5-4.1. Operational status visit

- (a) Initial operational status visit for Growers, Processors, and Dispensaries. Effective September 1, 2021, the Department shall begin scheduling on-site visits at licensed growers, processors, and dispensaries for the purposes of verifying whether the licensed grower, processor, or dispensary is actively operating or is working towards becoming operational.
  - (1) Initial operational status visits shall be scheduled and shall occur within the first one hundred eighty (180) days after issuance of a medical marijuana grower, medical marijuana processor, or medical marijuana dispensary license.
  - (2) Each operational status visit shall be performed on-site at the licensed premises on file with the Department.
  - (3) If, at the time of the initial operational status visit, the grower, processor, or dispensary being inspected fails to provide proof to the Department that the licensee is actively operating or working towards operational status, the Department shall grant the grower, processor, or dispensary a grace period of one hundred eighty (180) additional days from the date of their initial operational status visit to become operational.
- (b) Follow-up operational status visits. Upon the expiration of an operational status visit grace period, the Department shall perform a follow-up inspection of the licensed grower, licensed processor, or licensed dispensary for the purposes of verifying whether the licensed grower, processor, or dispensary has begun actively operating or is continuing to work towards becoming operational.
  - (1) Follow-up operational status visits shall be scheduled upon expiration of the grace period.
  - (2) Each follow-up operational status visit shall be performed on-site at the licensed premises on file with the Department.
  - (3) If, at the time of the follow-up operational status visit, the grower, processor, or dispensary fails to provide proof to the Department that the medical marijuana commercial licensee is actively operating or is continuing to work towards becoming operational, the Department may elect to grant an additional grace period of one hundred eighty (180) days to become operational. However, if granted, such grace period shall not extend beyond the one-year term of the license.
    - (A) If the Department does not grant a grower, processor, or dispensary a secondary grace period, the Department shall seek revocation of the grower, processor, or dispensary license.
      (B) If, after conducting a follow-up visit, the Department grants a secondary grace period, a grower, processor, or dispensary shall be afforded an additional term of one hundred eighty (180) days to become operational. Upon expiration of the secondary grace period, if a grower, processor, or dispensary has failed to provide proof to the Department that operations have commenced, the Department shall seek revocation of the grower, processor, or dispensary license. A third operational status visit of the licensed premises shall be at the discretion of the Department in making such a determination but shall not be required.

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

- (a) **Monthly reports**. Licensed growers, processors, and dispensaries shall complete a monthly report on a form and in a manner prescribed by the Department. These reports shall be deemed untimely if not received by the Department by the fifteenth (15th) of each month for the preceding month.
  - (1) Dispensary reports shall include:
    - (A) The amount of marijuana purchased in pounds;
    - (B) The amount of marijuana sold or otherwise transferred in pounds;
    - (C) The amount of marijuana waste in pounds;
    - (D) If necessary, a detailed explanation of why any medical marijuana product purchased by the licensee cannot be accounted for as having been sold or still remaining in inventory;

- (E) Total dollar amount of all sales to medical marijuana patients and caregivers;
- (F) Total dollar amount of all taxes collected from sales to medical marijuana patients and caregivers; and
- (G) Any information the Department determines is necessary to ensure that all marijuana grown in Oklahoma is accounted for as required under 63 O.S. § 420 et seq. and the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.
- (2) Grower reports shall include:
  - (A) The amount of marijuana harvested in pounds;
  - (B) The amount of marijuana purchased in pounds;
  - (C) The amount of marijuana sold or otherwise transferred in pounds;
  - (D) The amount of drying or dried marijuana on hand;
  - (E) The amount of marijuana waste in pounds;
  - (F) If necessary, a detailed explanation of why any marijuana cannot be accounted for as having been sold, disposed of, or maintained in current inventory;
  - (G) Total dollar amount of all sales; and
  - (H) Any information the Department determines is necessary to ensure that all marijuana grown in Oklahoma is accounted for as required under 63 O.S. § 420 et seq. and the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.
- (3) Processor reports shall include:
  - (A) The amount of marijuana purchased in pounds;
  - (B) The amount of marijuana sold or otherwise transferred in pounds;
  - (C) The amount of medical marijuana manufactured or processed in pounds;
  - (D) If necessary, a detailed explanation of why any marijuana cannot be accounted for as having been purchased, sold, processed, or maintained in current inventory;
  - (E) The amount of marijuana waste in pounds; and
  - (F) Any information the Department determines is necessary to ensure that all marijuana grown in Oklahoma is accounted for as required under 63 O.S. § 420 et seq. and the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.
- (4) <u>Upon implementation</u>, <u>Submission</u> of information and data to the Department through the seed-to-sale tracking system established by the Department, or a seed-to-sale tracking system that-integrates with the Department established system, <u>State inventory tracking system will be required</u> in accordance with the Oklahoma Medical Marijuana Protection Act, 63 O.S. § 427.1 et seq., and these Rules, and submission of the information and data to the <u>Department through the State inventory tracking system</u> shall be sufficient to satisfy monthly reporting requirements.
- (b) **Records**. Pursuant to the Department's audit and inspection responsibilities, medical marijuana business shall keep onsite and readily accessible, either in paper or electronic form, a copy of the records listed below. Except as otherwise specifically provided in Oklahoma law and this Chapter, all records shall be maintained for at least seven (7) years from the date of creation.
  - (1) Business records, which may include but are not limited to employee records, organizational documents or other records relating to the governance and structure of the licensee, manual or computerized records of assets and liabilities, monetary transactions, tax records, journals, ledgers, and supporting documents, including agreements, checks, invoices, receipts, and vouchers.
  - (2) As applicable, any documents related to the cultivation, processing, preparation, transportation, sampling, and/or testing of medical marijuana and medical marijuana products, including but not limited to sample field logs, patient processing logs, <u>safety data sheets and inventory for each chemical utilized by a processor</u>, inventory manifests, transporter agent licenses, <u>lab reports COAs</u>, testing records, equipment inspections, training materials, and standard operating procedures.
  - (3) Except as otherwise provided in this Subsection, documentation of every instance in which medical marijuana was sold or otherwise transferred to or purchased or otherwise obtained from another licensee, which shall include, but is not limited to:
    - (A) The name, license number, address, and phone number of all licensees involved in each transaction; and

- (B) The quantity and type of medical marijuana or medical marijuana products involved in each transaction;
- (C) The batch number of the medical marijuana or medical marijuana products involved in each transaction;
- (D) The date of each transaction;
- (E) The monetary value of the medical marijuana or medical marijuana products involved in each transaction, including the total sale or purchase amounts;
- (F) All point-of-sale and tax records; and
- (G) All inventory manifests and other documentation relating to the transport of medical marijuana and medical marijuana products.
- (4) For processors processing medical marijuana directly on behalf of a patient or caregiver, a log documenting each instance in which the processor processed medical marijuana received from a licensed patient into a concentrate form on behalf of the licensed patient, which shall include, but is not limited to, the following information:
  - (A) The patient and, if applicable, caregiver license number;
  - (B) The date the processor received the medical marijuana from the patient or caregiver;
  - (C) The weight of medical marijuana received from the patient;
  - (D) The weight or amount of concentrate produced, along with the weight of any excess medical marijuana, if applicable; and
  - (E) The date the concentrate was returned to the patient or caregiver.
- (5) Any and all documents relating to the disposal or destruction of medical marijuana, medical marijuana products, and medical marijuana waste.
- (6) Commercial licensees must also have the following documentation readily available on the licensed premise:
  - (A) the square footage of the licensed premises;
  - (B) a diagram of the licensed premises;
  - (C) if applicable, the number and type of lights at the licensed premise of a commercial grower;
  - (D) if applicable, the number, type and production capacity of equipment located at the licensed premise of a commercial processor;
  - (E) the names, addresses and telephone numbers of employees or agents of a medical marijuana business;
  - (F) employment manuals and standard operating procedures for the medical marijuana business; and
  - (G) any other information the Department deems reasonably necessary.
- (c) **Patient information.** Records containing private patient or caregiver information shall not be retained by a medical marijuana business commercial licensee for more than sixty (60) days without the patient's or caregiver's consent shall comply with all relevant state and federal laws. "Private patient information" means personally identifiable information, such as the patient name, address, date of birth, social security number, telephone number, email address, photograph, and financial information. This term does not include the patient's medical marijuana license number, which shall be retained by the business and provided to the Department upon request for compliance and public health purposes, including the verification of lawful sales or patient traceability in the event of product recall.
- (d) Inventory tracking system. Pursuant to 63 O.S. § 427.3(D)(8) and 63 O.S. § 427.13(B), Each each business commercial licensee shall use the seed to sale State inventory tracking system established by the Department or by inputting inventory tracking data required to be reported to the Department directly into the State inventory tracking system or by utilizing a seed-to-sale tracking system that integrates with the State inventory tracking system Department established system at the time of its implementation. The system utilized by each licensee shall be a system that: All commercial licensees must have an inventory tracking system account activated to lawfully operate and must ensure all information is reported to the Department accurately and in real time or after each individual sale in accordance with 63 O.S. § 427.13(B)(1) and these Rules. All commercial licensees shall ensure the following information and data are accurately tracked and timely reported to the Department though the State inventory tracking system:

- (1) Documents the <u>The</u> chain of custody of all medical marijuana and medical marijuana products, including every transaction with another commercial licensee, patient, or caregiver; including but not limited to:
  - (A) The name, address, license number, and phone number of the medical marijuana business that cultivated, manufactured, sold, purchased, or otherwise transferred the medical marijuana or medical marijuana product(s);
  - (B) The type, item, strain, and category of medical marijuana or medical marijuana product(s) involved in the transaction;
  - (C) The weight, quantity, or other metric required by the Department, of the medical marijuana or medical marijuana product(s) involved in the transaction;
  - (D) The batch number of the medical marijuana or medical marijuana product(s);
  - (E) The total amount spent in dollars;
  - (F) All point-of-sale records as applicable;
  - (G) Transportation information documenting the transport of medical marijuana or medical marijuana product(s) as required under OAC 310:681-3-6(b);
  - (H) Testing results and information;
  - (I) Waste records and information;
  - (J) Marijuana excise tax records, if applicable;
  - (K) RFID tag number(s);
- (2) Establishes ongoing inventory controls and procedures for the conduct of inventory reviews and comprehensive inventories of medical marijuana and medical marijuana products for traceability which shall enable the licensee to detect any diversion, theft, or loss in a timely manner;
- (3) Identifies and allows for tracking and documentation of the <u>The</u> entire life span of a licensee's stock of medical marijuana and medical marijuana products, including, at a minimum, <u>notifying the</u> Department:
  - (A) When medical marijuana seeds or clones are planted;
  - (B) When medical marijuana plants are harvested and/or destroyed;
  - (C) When medical marijuana is transported, <u>or otherwise transferred</u>, sold, stolen, diverted, or lost;
  - (D) A complete inventory of all medical marijuana; seeds; plant tissue; clones; usable marijuana; trim; leaves; other plant matter; and medical marijuana products; When medical marijuana changes form, including, but not limited to, when it is planted, cultivated, processed, and infused into a final form product;
  - (E) All samples sent to a testing laboratory or used for internal quality testing or other purposes; A complete inventory of all medical marijuana; seeds; plant tissue; clones; usable marijuana; trim; shake; leaves; other plant matter; and medical marijuana products;
  - (F) All samples sent to a testing laboratory or used for internal quality and testing or other purposes;
- (4) In event of a serious adverse event or recall, is capable of tracking medical marijuana or medical marijuana product from a patient back to the source of the medical marijuana or medical marijuana product; and
- (5)(3) Tracks medical marijuana using an assigned batch number and bar code. Any further information the Department determines is necessary to ensure all medical marijuana and medical marijuana products are accurately and fully tracked throughout the entirety of the lifespan of the plant and product.
- (e) Audits. The Department may perform on site audits of all commercial licensees to ensure the accuracy of the monthly reports and to ensure that all marijuana grown in Oklahoma is accounted for. Submission of an application for a medical marijuana commercial license constitutes permission for entry to any licensed premises and auditing of the commercial licensee during hours of operation and other reasonable times. Refusal to permit the Department entry or refusal to permit the Department to inspect all books and records shall constitute grounds for administrative penalties, which may include, but are not limited to, fines as set forth in Appendix C and the denial, nonrenewal, suspension, and/or revocation of a

license. Seed-to-sale tracking system. A commercial licensee shall use a seed-to-sale tracking system or integrate its own seed-to-sale tracking system with the State inventory tracking system established by the Department. If a commercial licensee uses a seed-to-sale tracking system that does not integrate with the State inventory tracking system, or does integrate but does not share all required information, the commercial licensee shall ensure all required information is reported directly into the State inventory tracking system.

- (1) The Department may review any and all records and information of a commercial licensee and may require and conduct interviews with such persons or entities and persons affiliated with such licensees, for the purpose of determining compliance with Department rules and applicable laws. Failure to make documents or other requested information available to the Department and/or refusal to appear or cooperate with an interview shall constitute grounds for administrative penalties, which may include, but is not limited to, fines as set forth in Appendix C and the denial, nonrenewal, suspension, and/or revocation of a license or any other remedy or relief provided under law. All records shall be kept on site and readily accessible.
- (2) Commercial licensees shall comply with all written requests from the Department to produce or provide access to records and information within ten (10) business days.
- (3) If the Department identifies a violation of 63 O.S. § 420 et seq., the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.; or these Rules during an audit of the commercial licensee, the Department shall take administrative action against the licensee in accordance with the Oklahoma law, including the Oklahoma Administrative Procedures Act, 75 O.S. § 250 et seq.
- (4) The Department may refer all complaints alleging criminal activity or other violations of Oklahoma law that are made against a commercial licensee to appropriate Oklahoma state or local law enforcement or regulatory authorities.
- (5) If the Department discovers what it reasonably believes to be criminal activity or other violations of Oklahoma law during an audit, the Department may refer the matter to appropriate Oklahoma state or local law enforcement or regulatory authorities for further investigation.
- (6) Except as is otherwise provided in Oklahoma law or these Rules, correctable violations identified during an audit shall be corrected within thirty (30) days of receipt of a written notice of violation.
- (7) If a licensee fails to correct violations within thirty (30) days, the licensee will be subject to a fine in the amount set forth in Appendix C for each violation and any other administrative action and penalty authorized by law.
- (8) The Department may assess fines in the amounts set forth in Appendix C and seek any other administrative penalties authorized by law against a licensee without providing opportunity to correct when the violation is not capable of being corrected.

### (f) Inventory Tracking System Requirements.

- (1) At a minimum, commercial licensees shall track, update, and report inventory after each individual sale to the Department in the State inventory tracking system.
- (2) All commercial licensees must ensure all on-premises and in-transit medical marijuana and medical marijuana product inventories are reconciled each day in the State inventory tracking system at the close of business, if not already done.
- (3) Commercial licensees are required to use RFID tags from a Department-approved supplier for the State Inventory Tracking System. Each Licensee is responsible for the cost of all RFID tags and any associated vendor fees.
  - (A) A commercial licensee shall ensure its inventories are properly tagged and that a RFID tag is properly assigned to medical marijuana, medical marijuana products, and medical marijuana waste as required by the Department.
  - (B) A commercial licensee shall ensure it has an adequate supply of RFID tags at all times. If a commercial licensee is unable to account for unused RFID tags, the commercial licensee must report to the Department and the State inventory tracking system vendor within forty-eight (48) hours.
  - (C) RFID tags must contain the legal name and correct license number of the commercial licensee that ordered them. Commercial licensees are prohibited from using another licensee's RFID tags.

- (D) Prior to a plant reaching a point where it is able to support the weight of the RFID tag and attachment strap, the RFID tag may be securely fastened to the stalk or other similarly situated position approved by the Department.
- (E) When the plant becomes able to support the weight of the RFID tag, the RFID tag shall be securely fastened to a lower supporting branch. The RFID tag shall remain affixed for the entire life of the plant until disposal.
- (F) Mother plants must be tagged before any cuttings or clones are generated therefrom.
- (G) If a RFID tag gets destroyed, stolen, or falls off of a medical marijuana plant, the licensee must ensure a new RFID tag is placed on the medical marijuana plant and the change of the RFID tag is properly reflected in the State inventory tracking system.
- (H) Commercial licensees shall not reuse any RFID tag that has already been affixed to any regulated medical marijuana or medical marijuana products.
- (4) Each wholesale package of medical marijuana must have a RFID tag during storage and transfer and may only contain one harvest batch of medical marijuana.
- (5) Prior to transfer, commercial licensees shall ensure that each immature plant is properly affixed with an RFID tag if the plant was not previously tagged in accordance with these Rules.
- (6) Commercial licensees' inventory must have a RFID tag properly affixed to all medical marijuana products during storage and transfer in one of the following manners:
  - (A) Individual units of medical marijuana products shall be individually affixed with a RFID tag; or
  - (B) Medical marijuana products may only be combined in a single wholesale package using one RFID tag if all units are from the same production batch.
- (7) If any medical marijuana or medical marijuana products are removed from a wholesale package, each individual unit or new wholesale package must be separately tagged.
- (8) All packages of medical marijuana waste shall have a RFID tag affixed and the contents of the waste package shall be reported in the State inventory tracking system.

## (g) Inventory tracking system administrators and users.

- (1) A commercial licensee must have at least one owner, or manager, who is an inventory tracking system administrator.
- (2) The inventory tracking system administrator must attend and complete all required inventory tracking system training.
- (3) If at any point, the inventory tracking system administrator for a commercial licensee changes, the commercial licensee shall change or assign a new inventory tracking system administrator within thirty business days.
- (4) Commercial licensees shall maintain an accurate and complete list of all inventory tracking system administrators and employee users.
- (5) Commercial licensees shall ensure that all owners and employees that are granted inventory tracking system account access for the purpose of conducting inventory tracking functions are trained and authorized before the owners or employees may access the State inventory tracking system.
- (6) All inventory tracking system users shall be assigned an individual account in the State inventory tracking system.
- (7) Any individual entering data into the State inventory tracking system shall only use the inventory tracking system account assigned specifically to that individual. Each inventory tracking system administrator and inventory tracking system user must have unique log-in credentials that shall not be used by any other person.
- (8) Within three (3) business days, commercial licensees must remove access for any inventory tracking system administrator or user from their accounts if any such individual no longer utilizes the State inventory tracking system or is no longer employed by the commercial licensee.
- (h) Loss of use of the State inventory tracking system. If at any time a commercial licensee loses access to the State inventory tracking system due to circumstances beyond the commercial licensee's control, the commercial licensee shall keep and maintain records detailing all inventory tracking activities that were conducted during the loss of access. Once access is restored, all inventory tracking activities

that occurred during the loss of access must be immediately entered into the State inventory tracking system. If a commercial licensee loses access to the State inventory tracking system due to circumstances within its control, the commercial licensee may not perform any business activities that would be required to be reported into the State inventory tracking system until access is restored and reporting is resumed; any transfer, sale, or purchase of medical marijuana or medical marijuana products shall be an unlawful sale.

- (i) Audits. The Department shall perform on-site audits of all commercial licensees to ensure the accuracy of information and data reported to the Department and to ensure that all marijuana grown in Oklahoma is accounted for. Submission of an application for a medical marijuana commercial license constitutes permission for entry to any licensed premises and auditing of the commercial licensee during hours of operation and other reasonable times. Refusal to permit the Department entry or refusal to permit the Department to inspect all books and records shall constitute grounds for and administrative penalties, which may include, but are not limited to, fines as set forth in Appendix C and the denial, nonrenewal, suspension, and/or revocation of a license.
  - (1) The Department may review any and all records and information of a commercial licensee and may require and conduct interviews with such persons or entities and persons affiliated with such licensees, for the purpose of determining compliance with Department Rules and applicable laws. Failure to make documents or other requested information available to the Department and/or refusal to appear or cooperate with an interview shall constitute grounds for nonrenewal, suspension, or revocation of a license or any other remedy or relief provided under law. All records shall be kept onsite and readily accessible.
  - (2) Commercial licensees shall comply with all written requests from the Department to produce or provide access to records and information within ten (10) business days.
  - (3) If the Department identifies a violation of 63 O.S. § 420 et seq., the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq., or these Rules during an audit of the commercial licensee, the Department shall take administrative action against the licensee in accordance with the Oklahoma law, including the Oklahoma Administrative Procedures Act, 75 O.S. § 250 et seq. (4) The Department may refer all complaints alleging criminal activity or other violations of
  - Oklahoma law that are made against a commercial licensee to appropriate Oklahoma state or local law enforcement or regulatory authorities.
  - (5) If the Department discovers what it reasonably believes to be criminal activity or other violations of Oklahoma law during an audit, the Department may refer the matter to appropriate Oklahoma state or local law enforcement or regulatory authorities for further investigation. Except for license information concerning licensed patients, the Department may share confidential information to assist other agencies in ensuring compliance with applicable laws, Rules and regulations.
  - (6) Except as is otherwise provided in Oklahoma law or these Rules, correctable violations identified during an audit shall be corrected within thirty (30) days of receipt of a written notice of violation.

    (7) If a licensee fails to correct violations within thirty (30) days the licensee will be subject to a fine
  - (7) If a licensee fails to correct violations within thirty (30) days, the licensee will be subject to a fine of \$500.00 for each violation and any other administrative action and penalty authorized by law.
- (j) All monthly report, inventory tracking and seed-to-sale information, data, and records submitted to the Department are treated as confidential records and are exempt from the Oklahoma Open Records Act.

#### 310:681-5-6.1. Penalties

- (a) Failure to file timely reports. If a commercial licensee fails to submit a timely, complete, and accurate required monthly report and fails to correct such deficiency within thirty (30) days of the Department's written notice, the licensee shall be subject to a fine in the amount set forth in Appendix C for each violation and any other administrative action and penalty authorized by law.
- (b) **Inaccurate reports**. Within any two (2) year period of time, if a licensee has submitted one (1) or more reports containing gross errors that cannot reasonably be attributed to normal human error, licensee shall be subject to a fine in the amount set forth in Appendix C for each violation and any other administrative action and penalty authorized by law.
- (c) Unlawful purchase and sale.

- (1) Within any two (2) year period of time, if the licensee has made an unlawful purchase or sale of medical marijuana, the licensee shall be subject to a fine in the amount set forth in Appendix C for each violation and any other administrative action and penalty authorized by law.
- (2) The Department may revoke the license at any time regardless of the number of the offense upon a showing that the violation was willful or grossly negligent.
- (d) **Noncompliance and criminal activity**. Commercial licenses and transporter agent licenses shall be subject to nonrenewal, revocation, suspension, monetary penalties, and any other penalty authorized by law upon a determination by the Department that the licensee has not complied with applicable Oklahoma law or this Chapter, or upon official notification to the Department that the licensee has engaged in criminal activity in violation of Oklahoma law.
- (e) Administrative penalties. Procedures for administrative penalties against a licensee are stated in the Oklahoma Administrative Procedures Act, 75 O.S. § 250 et seq. These procedures provide for the licensee to receive notice and to have the opportunity to be present at a hearing and to present evidence in his or her defense. The Commissioner of Health or his or her designee may promulgate an administrative order revoking or suspending the license, dismissing the matter, or providing for other relief as allowed by law. At any time after the action is filed against the commercial licensee, the Department and the licensee may dispose of the matter by consent order or stipulation. Orders are appealable in accordance with the Oklahoma Administrative Procedures Act, 75 O.S. § 250 et seq.
- (f) **Fines.** Monetary penalties shall be assessed in the amounts set forth in Appendix C. Failure to pay any fine within thirty (30) days of assessment of the fine shall result in nonrenewal, suspension, and/or revocation of the license.
- (g) Administrative Order. In addition to any other remedies provided by law, the Department may issue a written order to any licensee the Department has reason to believe has violated Oklahoma law or these regulations, and to whom the Department has served, not less than thirty (30) days previously, a written notice of violation of such statutes or rules.
  - (1) The written order shall state with specificity the nature of the violation. The Department may impose any disciplinary action authorized under by law including, but not limited, nonrenewal, suspension, revocation and the assessment of monetary penalties.
  - (2) Any order issued pursuant to the provisions of this section shall become a final order unless, not more than thirty (30) days after the order is served to the licensee, the licensee requests an administrative hearing in accordance with these Rules. Upon such request, the Department shall promptly initiate administrative proceedings.
- (h) Emergency Cease and Desist. If the Department finds that an emergency exists requiring immediate action in order to protect the health or welfare of the public, the Department may issue an order, without providing notice or hearing, stating the existence of said emergency and requiring that action be taken by the commercial licensee as the Department deems necessary to meet the emergency. Such action may include, but is not limited to, ordering the commercial licensee to immediately cease and desist operations. The order shall be effective immediately upon issuance and commercial licensees shall immediately comply with the provisions of the order. The Department may assess a penalty not to exceed ten thousand dollars (\$10,000.00) per day of noncompliance with the order. In assessing such penalty, the Department shall consider the seriousness of the violation and efforts taken by the commercial licensee to comply with applicable requirements. Upon application to the Department, the licensee shall be offered a hearing within ten (10) days of issuance of the order.

### 310:681-5-8. Composition of food safety standards board medical marijuana advisory council

- (a) The Food Safety Standards Board Medical Marijuana Advisory Council shall be comprised of twelve (12) Oklahoma residents appointed by the Commissioner of Health and shall serve at the pleasure of the Commissioner of Health. Additionally, the Department may appoint up to eight (8) additional members in accordance with 63 O.S. § 427.23(B). Each member should be a marijuana industry expert with unique qualifications related to food safety standards for processing and handling of medical marijuana and may be appointed from areas including, but not limited to, the following:
  - (1) State marijuana industry association representation;

- (2) Laboratory scientist or representative;
- (3) Director or designee of the Oklahoma Department of Mental Health and Substance Abuse Services;
- (4) Director or designee of the Oklahoma Department of Agriculture, Food and Forestry;
- (5) Director or designee of Oklahoma Center for Poison and Drug Information;
- (6) Director or designee of the Oklahoma ABLE Commission;
- (7) Director or designee of the Oklahoma Board of Pharmacy;
- (8) Director or designee of the Oklahoma State Medical Association or Physician;
- (9) Director or designee of the Oklahoma Board of Osteopathic Physicians;
- (10) Director or designee of the Department of Environmental Quality;
- (11) Director or designee Oklahoma Bureau of Narcotics and Dangerous Drugs;
- (12) Director or designee of the Oklahoma Board of Medical Licensure;
- (13) Designee of any Oklahoma public health agency; or
- (14) Food processor/manufacturer.
- (b) The Food Safety Standards Board Medical Marijuana Advisory Council (the "Board") shall by August 27, 2018 submit, and the Department shall make available, standards related to the handling and processing of medical marijuana and medical marijuana products. The Board shall review, and submit if necessary, recommendations regarding rule promulgation related to the handling and processing of medical marijuana and medical marijuana products and all aspects of the cultivation and manufacture of medical marijuana products.

## 310:681-5-8.1. Food safety standards for processors

- (a) **Purpose**. This Section sets forth the food safety standards that processors must comply with in the preparation, production, manufacturing, processing, handling, packaging, and labeling of edible medical marijuana products.
- (b) **Existing law**. This Section does not relieve licensed processors of any obligations under existing laws, rules, and regulations, including 63 O.S. § 1-1101 et seq., OAC 310:257, and OAC 310:260, to the extent they are applicable and do not conflict with 63 O.S. § 420 et. seq.
  - (1) The sale, offer to sell, dispense or release into commerce of any food or confection under a name, label, or brand when the name, label, or brand either precisely or by slang term or popular usage, is the name, label, or brand of marijuana is not prohibited.
  - (2) Marijuana used in food shall be considered an additive, a component, and/or an edible substance.
  - (3) Marijuana shall not be considered a deleterious, poisonous, or nonnutritive substance, and the use of marijuana, alone, in food shall not make such food adulterated or misbranded.
- (c) **Updated law**. In the event the Oklahoma Board of Health or the Commissioner of Health amends OAC 310:257 or OAC 310:260, adopts new food safety rules, or incorporates into Oklahoma law updated federal food safety standards, including Title 21 of the Code of Federal Regulations, licensed processors shall comply with such rules to the extent they are applicable and do not conflict with 63 O.S. § 420 et seq., 63 O.S. § 427.1 et seq., or these <u>rules</u> <u>Rules</u>.
- (d) **Board meetings**. The Food Safety Standards Board Medical Marijuana Advisory Council shall meet as regularly as its members deem necessary to review Oklahoma food safety laws and these rules Rules and to take action, including amending and/or adding recommended standards to the Oklahoma Board of Health or the Commissioner of Health. In addition, the Medical Marijuana Advisory Council may recommend rules to the State Commissioner of Health relating to all aspects regarding the safe cultivation and manufacturing of medical marijuana products.
- (e) **Labeling and packaging**. Labels and packages for food containing marijuana shall comply with all applicable requirements in existing Oklahoma law, rules, and regulations, and any laws incorporated therein by reference, to the extent they do not conflict with 63 O.S. § 420.
  - (1) 21 CFR Part 101, as of August 22, 2018, is hereby incorporated by reference into this Section to the extent it is applicable and does not conflict with 63 O.S. § 420 et seq. and 63 O.S. § 427.1 et seq.
  - (2) Existing requirements for principal display panels or information panels include:
    - (A) Name and address of the business;

- (B) Name of the food;
- (C) Net quantity or weight of contents;
- (D) Ingredients list
- (E) Food allergen information; and
- (F) Nutrition labeling, if required under 21 CFR § 101.9.
- (3) In addition, principal display panels or information panels must contain:
  - (A) List of cannabis ingredients;
  - (B) The batch of marijuana;
  - (C) The strain of marijuana (optional);
  - (D) THC dosage in milligrams per unit; and
  - (E) The lot code.
- (4) Nutrient content, health, qualified health and structure/function claims must comply with the Food and Drug Administration ("FDA") Food Labeling Guide.
- (5) Packaging must contain the statement, "For accidental ingestion call 1-800-222-1222."
- (6) All packages and individually-packaged product units, including but not limited to those from bulk packaging, must contain the Oklahoma uniform symbol in clear and plain sight. The Oklahoma uniform symbol must be printed at least one-half inch by one-half inch in size in color.
- (7) In order to comply with OAC 310:681-7-1(d)(4) and this Section, a label must contain a warning that states, "Women should not use marijuana or medical marijuana products during pregnancy because of the risk of birth defects or while breastfeeding."
- (f) **Recommended HACCP**. A Hazard Analysis and Critical Control Plan ("HACCP"), as set forth under 21 CFR Part 120, shall be recognized as a standardized best practice to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Processors are encouraged to adopt a HACCP to help ensure compliance with existing Oklahoma food safety laws, particularly OAC 310:260-3-6.
- (g) Private homes; living or sleeping quarters.
  - (1) A private home, a room used as living or sleeping quarters, or an area directly opening into a room used as living or sleeping quarters may not be used for conducting processing operations.
  - (2) Living or sleeping quarters located on the premises of a processor such as those provided for lodging registration clerks or resident managers shall be separated from rooms and areas used for food establishment operations by complete partitioning and solid self-closing doors.

# 310:681-5-11. Attestation confirming or denying foreign financial interests.

- (a) All licensed medical marijuana businesses shall submit an attestation to the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control ("OBNDD") confirming or denying the existence of any foreign financial interests in the medical marijuana business in accordance with 63 O.S. § 427.15 and OBNDD rules and regulations.
- (b) The Department shall immediately revoke the medical marijuana business license of any medical marijuana business licensee that fails to submit such attestation to OBNDD in accordance with the law. (c) A medical marijuana business that submits a complete and approved attestation to OBNDD within sixty (60) days of revocation of its license may be eligible to seek reinstatement of its license.

### 310:681-5-12. Marijuana transaction limitations

- (a) A single transaction by a dispensary with a patient, or the parent(s) or legal guardian(s) if patient is under eighteen (18) years of age, or caregiver shall be limited to three (3) ounces or eighty-four and ninetenths (84.9) grams of marijuana, one (1) ounce or twenty-eight and three-tenths (28.3) grams of marijuana concentrate, seventy-two (72) ounces or two thousand thirty-seven and six-tenths (2,037.6) grams of edible medical marijuana products, six (6) mature plants, and/or six (6) seedling plants.
- (b) A single transaction between a processor and patient, or the parent(s) or legal guardian(s) if patient is younger than eighteen (18) years of age, for the processing of medical marijuana concentrate shall be limited to one (1) ounce of medical marijuana concentrate.
- (c) Medical marijuana businesses shall verify and ensure that all medical marijuana transactions are

conducted with medical marijuana patient, caregiver, or commercial license holders in accordance with the law and shall take all reasonable steps necessary to prevent the sale or other transfer of medical marijuana and medical marijuana products to a person or entity who does not hold a valid, unexpired license issued by the Department under 63 O.S. §420 et seq., the Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq., the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq., and this Chapter.

- (1) Verification of all licenses shall include, at a minimum: name; valid, unexpired license number; and expiration date.
- (2) In addition to the items required in Subsection (c)(1) above, verification of licenses issued to individuals shall include verification of the photo of the licensee.
- (d) Any transaction not in accordance with this Section will constitute an unlawful purchase and sale as set forth in OAC 310:681-5-6.1 (relating to penalties).

#### 310:681-5-14. Handling of medical marijuana by dispensary

(a) A medical marijuana dispensary may display samples of marijuana of no more than three (3) grams in each separate sample display cases, jars, or other sample containers protected by a plastic or metal mesh screen to allow medical marijuana patients and caregivers to smell and handle the various strains sold by a medical marijuana dispensary. The sample shall only be used for display purposes and cannot be offered for retail sale. The medical marijuana dispensary shall dispose of the sample in accordance with these Rules.

- (b) Each display case, jar, or other container must be labeled with the following information:
  - (1) licensee name that grew the medical marijuana;
  - (2) strain name;
  - (3) batch number; and
  - (4) the following statement: "Sample: not for retail sale."

# 310:681-5-17. Entry to licensed premises

(a) No minors under the age of eighteen (18) may enter licensed premises unless the minor is accompanied by under the supervision of his or her parent or legal guardian at all times while on the licensed premises.

#### 310:681-5-18. Prohibited acts

- (a) No commercial licensee shall allow the consumption of alcohol or the smoking or vaping of medical marijuana or medical marijuana products on the licensed premises, except that if the licensed premises is a residence, a commercial licensee shall only be prohibited from consuming alcohol or the smoking or vaping of medical marijuana in areas of the licensed premises where operations of the business are conducted.
- (b) No commercial licensee shall employ any person under the age of eighteen (18).
- (c) No-commercial licensee shall allow for or provide the delivery of medical marijuana or medical marijuana products to licensed patients or caregivers.
- (d) No dispensary shall allow any physician to be located, maintain an office, write recommendations, or otherwise provide medical services to patients at the same physical address as a dispensary.
- (e) No commercial licensee shall engage in advertising prohibited under OAC 310:681-7-3.
- (f) No commercial licensee shall sell or offer to sell medical marijuana or medical marijuana product by means of any advertisement or promotion that includes any statement, representation, symbol, depiction, or reference, directly or indirectly, which would reasonably be expected to induce minors to purchase or consume marijuana or medical marijuana products.
- (g) No commercial licensee shall falsify or misrepresent any documents, forms, or other materials or information submitted to the Department.
- (h) No commercial licensee shall threaten or harm a patient, medical practitioner, or an employee of the Department.
- (i) No commercial licensee shall fail to adhere to any acknowledgment, verification, or other

representation made to the Department.

- (j) No licensed grower shall possess, sell or otherwise transfer, or offer to sell or otherwise transfer medical marijuana products.
- (k) No licensee shall operate or otherwise use any extraction equipment or processes utilizing butane, propane, carbon dioxide or any potentially hazardous material in residential property.
- (1) Licensees shall only not sell or otherwise transfer, purchase, obtain, or otherwise accept the transfer of medical marijuana or medical marijuana products from an any individual or entity that is not an Oklahoma-licensed medical marijuana business, except that licensed dispensaries may sell medical marijuana and medical marijuana products to licensed patients and caregivers and a processor may process medical marijuana directly on behalf of a licensed patient or caregiver in accordance with 310:681-5-5. No licensee shall purchase or sell medical marijuana or medical marijuana products to or from any unlicensed individual or entity.
- (m) After implementation of the State inventory tracking system, no licensee shall sell or otherwise transfer, purchase, obtain or otherwise accept the transfer of medical marijuana or otherwise accept the transfer of medical marijuana or medical marijuana products that are not properly inputted and tracked in the State inventory tracking system in accordance with Oklahoma law and regulations.
- (n) Medical marijuana growers and dispensaries shall not make or package infused pre-rolls.
- (o) Medical marijuana growers and dispensaries shall not make or package pre-rolls that exceed one (1) gram.
- (p) Licensees shall not allow any other entity or person to use their OMMA license number who is not an owner, employee, or authorized contractor of the commercial licensee while conducting business on behalf of that commercial licensee.
- (q) No commercial licensee shall make, sell, transfer, or offer to sell any alcoholic beverage that has been infused with medical marijuana or medical marijuana products.
- (r) Growers shall not purchase, make, sell, transfer, or otherwise obtain any medical marijuana products except growers may package and sell noninfused pre-rolls and kief in accordance with these Rules.
- (s) Dispensaries shall not package or alter packaging or labeling of medical marijuana or medical marijuana products except for the following reasons:
  - (1) Dispensaries are authorized to package and sell noninfused pre-rolled marijuana;
  - (2) Dispensaries, or employees thereof, may handle loose or nonpackaged medical marijuana to be placed in packaging for retail sale consistent with Oklahoma law and these Rules, including packaging and labeling requirements in OAC 310:681-7-1(d)-(e);
  - (3) Dispensaries may apply barcodes, qr codes, or other inventory tracking tags and labels. These items shall not obscure required label and packaging requirements; and
  - (4) Dispensaries must place medical marijuana or medical marijuana products into a child-resistant exit package at the point of transfer to a patient or caregiver if those items are not already in child-resistant packaging.

#### SUBCHAPTER 7. PACKAGING, LABELING, AND ADVERTISING

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

- (a) **Prohibition on sale or transfer.** Commercial licensees shall not sell, distribute, or otherwise transfer medical marijuana and medical marijuana products that are not packaged and labeled in accordance with the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq., and these Rules.
- (b) **Nonacceptance or return.** A dispensary shall refuse to accept or shall return to the licensee transferring medical marijuana or medical marijuana products to the dispensary, any medical marijuana or medical marijuana products that are not packaged and labeled in accordance with the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq., and these Rules. The business licensee who sold or otherwise transferred the nonconforming medical marijuana or medical marijuana products shall accept such return. If circumstances are such that the dispensary cannot return or refuse to accept the nonconforming medical marijuana or medical marijuana products, the dispensary shall dispose of the nonconforming medical marijuana and medical marijuana products in accordance with the Oklahoma

Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq., and these Rules.

- (c) **Documentation.** A dispensary shall document any such return, nonacceptance, or disposal, and such documentation shall include at a minimum:
  - (1) The license number, name, contact information, and address of the licensee who sold or otherwise transferred the nonconforming medical marijuana or medical marijuana products to the dispensary;
  - (2) A complete inventory of the medical marijuana and medical marijuana products to be returned or disposed, including the batch number;
  - (3) The reason for the nonacceptance, return, or disposal; and
  - (4) The date of the nonacceptance, return, or disposal.
- (d) **General requirements**. The following general label and packaging requirements, prohibitions, and exceptions shall apply to all medical marijuana and medical marijuana products being transferred or sold to a dispensary or by a dispensary:
  - (1) Labels, packages, and containers shall not be attractive to minors and shall not contain any content that reasonably appears to target children, including toys, cartoon characters, and similar images. Packages should be designed to minimize appeal to children and shall not depict images other than the business name logo of the medical marijuana producer and image of the product.
  - (2) Packaging must contain a label that reads: "Keep out of reach of children."
  - (3) All medical marijuana and medical marijuana products must be packaged in child-resistant containers at the point of sale or other transfer to a patient, a patient's parent or legal guardian if patient is a minor, or a caregiver.
  - (4) Label must contain a warning that states "Women should not use marijuana or medical marijuana products during pregnancy because of the risk of birth defects."
  - (5) Packages and labels shall not contain any deceptive, false or misleading statements. For purposes of this section, information that is deceptive, false, or misleading includes:
    - (i) (A) Any indication that the medical marijuana or medical marijuana product is organic, unless the National Organic Program (Section 6517 of the federal Organic Foods Production Act of 1990 (7 U.S.C. Section 6501 et seq.)) authorizes organic certification and designation for marijuana and marijuana products. This includes variants of the word "organic" such as "organix" and "organique."
    - (ii) (B) Any indication that the medical marijuana or medical marijuana product is "Pesticide-free," unless the medical marijuana or a medical-marijuana product was grown, harvested, processed, and dispensed without any pesticide.
  - (6) No medical marijuana or medical marijuana products shall be intentionally or knowingly packaged or labeled so as to cause a reasonable patient confusion as to whether the medical marijuana or medical marijuana product is a trademarked product.
  - (7) No medical marijuana or medical marijuana products shall be packaged or labeled in a manner that violates any federal trademark law or regulation.
  - (8) Packages and labels shall not make any claims or statements that the medical marijuana or medical marijuana products provide health or physical benefits to the patient.
  - (9) Packages and labels shall not contain the logo of the Oklahoma State Department of Health or the Oklahoma Medical Marijuana Authority.
  - (10) Packages and labels shall not contain any universal symbols from another state, any statements that the medical marijuana was grown in another state, or any depictions, symbols, or other information that could cause a reasonable patient to be confused as to the state of origin of the medical marijuana or medical marijuana product.
  - (11) Labels shall be designed and applied in a manner that does not cause patient confusion regarding the package's contents, potency, or other required information. In the event that any package or immediate container of medical marijuana or medical marijuana product is relabeled, all prior labels must be removed in entirety prior to the new label being applied. Covering an initial label with an updated label is prohibited.
  - (12) All packaging and labeling must contain current and accurate information on file with the

Authority, including, but not limited to, the licensee's legal name, trade name, and license number. (13) Packages and labels shall be considered inaccurate if the difference in percentage of the cannabinoid and/or total THC claimed to be present on a package or label is plus or minus fifteen percent (15%) of the percentage on the COA. For example, bulk order packaging that identifies a THC amount as 100mg would be inaccurate if the COA for that production batch indicated a THC content of less than 85mg or more than 115mg.

# (e) Label requirements for sales to dispensaries or by dispensaries.

- (1) Labels on medical marijuana and medical marijuana products being transferred or sold to a dispensary or by a dispensary shall contain, at a minimum, the following information:
  - (A) The name and license number of the grower, <u>dispensary</u>, or processor who is selling or otherwise transferring the medical marijuana or medical marijuana products to the dispensary;
  - (B) Name of the medical marijuana or medical marijuana product;
  - (C) The batch number of the medical marijuana or medical marijuana product;
  - (D) Net quantity or weight of contents;
  - (E) Ingredients list;
  - (F) The Oklahoma Uniform Symbol in the manner and form prescribed by the Department;
  - (G) THC potency on the COA for that batch;
  - (H) Total Terpenoid potency terpenoid content in the manner precribed by the Department; and
  - (I) The statement, "This product has been tested for contaminants."
- (2) Labels for edible medical marijuana products shall also meet the requirements set forth in OAC 310:681-5-8.1.
- (3) As applicable, RFID tags shall not obscure required label and packaging requirements.
- (f) Label requirements for sales between growers and/or processors. All medical marijuana and medical marijuana products sold or otherwise transferred between growers and/or processors shall be labeled and the label shall contain, at a minimum, the following information:
  - (1) Name and license number of the grower or processor who is selling or otherwise transferring the medical marijuana or medical marijuana product;
  - (2) The batch number of the medical marijuana or medical marijuana product;
  - (3) Date of harvest or production; and
  - (4) A statement that the medical marijuana or medical marijuana products have passed testing or statement that the medical marijuana failed testing and is being transferred to a processor for purposes of remediation.

### (g) Storage requirements for growers and processors.

- (1) Growers and processors shall store medical marijuana and medical marijuana products under conditions and in a manner that protects the medical marijuana and medical marijuana products from physical and microbial contamination and deterioration.
- (2) When not in use, medical marijuana and medical marijuana products shall be stored in receptacles that are capable of being fully closed and sealed and are kept fully closed and sealed.

## SUBCHAPTER 8. LABORATORY TESTING

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

- (a) **Purpose**. To ensure the suitability and safety for human consumption of medical marijuana and medical marijuana products, growers and processors are required to test medical marijuana and medical marijuana products for microbials, mycotoxins, residual solvents, pesticides, THC and cannabinoid potency, terpenoid potency type and concentration, heavy metals, foreign materials and filth, and water activity and moisture content in accordance with the following standards and thresholds. No laboratory may test medical marijuana without a valid, unexpired testing laboratory license issued by the Department. A licensed laboratory shall only send samples for testing to another licensed laboratory. (b) **Batches**.
  - (1) **Batch size.** Growers shall separate all harvested medical marijuana into harvest batches not to exceed ten (10) fifteen (15) pounds with the exception of any plant material to be sold to a licensed

- processor for the purposes of turning the plant material into concentrate which may be separated into harvest batches of no more than fifty (50) pounds. Processors shall separate all medical marijuana product lots into production batches not to exceed ten (10) pounds four (4) liters of liquid medical marijuana concentrate or nine (9) pounds for nonliquid medical marijuana products, and for final medical marijuana products no greater than one-thousand (1,000) grams of THC.
- (2) **Research and Development ("R&D") testing.** Growers and processors may submit samples for research and development testing. R&D testing may be performed by a licensed laboratory in accordance with these Rules:
  - (A) Passing R&D test results. If a sample submitted to a laboratory passes a R&D test, it shall not constitute a pass for the purposes of compliance with required testing under OAC 310:681-8-1(i); (B) Failing R&D test results. If a sample submitted to a laboratory fails a R&D test, laboratories shall clearly note in the State's inventory tracking system and on any COA created for an R&D sample that the test results are for R&D purposes only; and
  - (C) Growers and processors shall ensure that any R&D testing done under this subsection is appropriately documented and identified in the State's inventory tracking system.
- (c) **Frequency**. Growers and processors shall ensure samples from each harvest batch and production batch are collected, labeled, and tested in accordance with the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq., and these Rules.

## (d) Prohibitions.

- (1) Growers shall not sell or otherwise transfer any medical marijuana from any medical marijuana harvest batch until samples of the harvest batch have passed all tests in accordance with this Subchapter, except that growers may sell or otherwise transfer harvest batches that have failed microbiological testing to processors for decontamination or remediation in accordance with OAC 310:681-8-1(1)(2). Remediated and decontaminated medical marijuana only may be returned to the originating license commercial grower.
- (2) Processors shall not purchase or otherwise obtain, process, sell, or otherwise transfer any medical marijuana or medical marijuana products from any medical marijuana harvest batch or production batch until samples of the harvest batch or production batch have passed all tests in accordance with this Subchapter, except that processors may purchase or otherwise obtain and process harvest batches that have failed testing for the purpose of remediation only in accordance with OAC 310:681-8-1(1)(2).
- (3) Dispensaries shall not purchase, accept transfer of, or otherwise transfer any medical marijuana or medical marijuana products that have not passed all tests in accordance with this Subchapter.
- (e) **Department required testing**. The Department may require a medical marijuana commercial business to submit a sample of medical marijuana, medical marijuana concentrate, or medical marijuana product to a licensed testing laboratory or upon demand. The costs for all sampling and tests conducted pursuant to these rules shall be the financial responsibility of the business licensee the quality assurance laboratory upon demand when the Department has reason to believe the medical marijuana is unsafe for patient consumption or inhalation or has not been tested in accordance with Oklahoma law and these regulations. The Department may also require a medical marijuana business to periodically submit samples of medical marijuana or medical marijuana products to the quality assurance laboratory no more than twice a year for quality assurance purposes. The licensee shall provide the samples or units of medical marijuana or medical marijuana products at its own expense but shall not be responsible for the costs of testing.
- (f) **Prohibited transfers.** Except as is authorized in these Rules, growers, processors, and dispensaries shall dispose of and shall not use, sell, or otherwise transfer any medical marijuana or medical marijuana products that exceed any testing thresholds or fail to meet any other standards or requirements set forth in this Subchapter.

## (g) Embargo and Recall.

(1) **Embargo.** In the event that any medical marijuana or medical marijuana products product is found by either a testing laboratory or the quality assurance laboratory that to exceed the allowable testing

thresholds or that otherwise fail to meet standards set forth in this Subchapter are sold or otherwise transferred, the following shall occur under these Rules; or which otherwise contains analytes which may be poisonous, deleterious to health or otherwise unsuitable or unsafe for human consumption; or where such medical marijuana or medical marijuana product is in violation of applicable laws, rules or regulations, the following shall occur by commercial licensees:

- (1)(A) Any commercial licensee with knowledge of such event shall immediately notify the Department;.
- (2)(B) All such medical marijuana and medical marijuana products in the possession of a commercial licensee shall be immediately recalled; and affixed with an electronic tag, physical tag and/or other appropriate marking or hold, including a hold in the State's inventory tracking system, giving notice of the reason that the medical marijuana or medical marijuana product is subject to embargo. The affixed tag(s) and/or electronic hold shall further warn all persons not to remove or dispose of the medical marijuana or medical marijuana product by sale, donation, or otherwise transfer without permission of the Authority. It shall be unlawful for any person to remove or dispose of the embargoed medical marijuana or medical marijuana products without permission of the Authority.
- (C) The Authority, upon determination that any medical marijuana or medical marijuana product tests result exceed allowable thresholds, is in violation of applicable laws, rules or regulations, or is otherwise poisonous, deleterious to health or unsafe for consumption may institute an action in a district court of competent jurisdiction for the condemnation and destruction of the medical marijuana or medical marijuana product in accordance with 63 O.S. § 427.24.
- (D) The Authority, upon determination that any medical marijuana or medical marijuana product meets the requirements of applicable laws, rules or regulations, or otherwise is not poisonous, deleterious to health or unsafe shall remove the embargo.
- (E) In the event any medical marijuana or medical marijuana products subject to an embargo is sold or otherwise transferred, such embargoed medical marijuana or medical marijuana products shall be recalled in accordance with these Rules.
- (3)(F) Every commercial licensee who is in possession or has ever had possession of such embargoed medical marijuana or medical marijuana products shall assist in the immediate recall embargo.
- (2) **Recall.** In the event that any medical marijuana or medical marijuana products that exceed allowable testing thresholds, are the subject of an embargo, or a derivative thereof, or that otherwise fail to meet standards set forth in this Subchapter are sold or otherwise transferred, the following shall occur:
  - (A) Any commercial licensee with knowledge of such event shall immediately notify the Department:
  - (B) All such medical marijuana and medical marijuana products shall be immediately recalled and cannot be sold or otherwise transferred; and
  - (C) Every commercial licensee who is in possession or has ever had possession of such medical marijuana or medical marijuana products shall assist in the immediate recall, including, but not limited to, the following:
    - (i) Undertake necessary measures to ensure any affected medical marijuana or medical marijuana products are not transferred;
    - (ii) Create a distribution list of all commercial licensees that received the medical marijuana or medical marijuana products subject to the recall, including the licensee's name, license number, address and contact information;
    - (iii) Create a list identifying all medical marijuana or medical marijuana products subject to the recall, including the category of medical marijuana or medical marijuana products, product description, net contents, batch number, and, if applicable, the name and license number of the commercial licensee that cultivated or manufactured the medical marijuana or medical marijuana product subject to the recall;
    - (iv) Provide notice to all affected licensees and consumers once identified;

- (v) Communicate with the Department regarding the status of the recall and immediately provide all required information and documentation to the Department within forty-eight (48) hours unless granted additional time by the Department.
- (vi) The Licensee's failure to timely comply with the provisions of this subsection and/or provide required information and documentation to the Department may result in revocation, suspension, and monetary penalties. The Department may also issue a public recall notice, at any time, if it determines it is necessary to protect the public's health safety and welfare.
- (D) The commercial licensee whose harvest or production batch is being recalled, and who bears responsibility for the recall, shall bear the costs for disposal of all medical marijuana waste subject to the recall in accordance with Oklahoma law and these Rules.

#### (h) Retention of test results and records.

- (1) Prior to accepting any sale or transfer of any medical marijuana, growers shall obtain copies of any and all certificates of analysis (COAs) for every test conducted on the harvest batch(es) of the medical marijuana.
- (2) Prior to accepting any sale or transfer of any medical marijuana or medical marijuana products, processors shall obtain copies of any and all COAs for every test conducted on the harvest batch(es) of the medical marijuana or production batch(es) of the medical marijuana products.
- (3) Prior to accepting any sale or transfer of medical marijuana, dispensaries shall obtain copies of any and all COAs for every test conducted on the harvest batch(es);
- (4) Prior to accepting any sale or transfer of medical marijuana products, dispensaries shall obtain copies of any and all COAs for every test conducted on the production batch(es);
- (5) Commercial licensees shall maintain copies of any and all COAs for at least two (2) seven (7) years and these records must be kept onsite and readily accessible.
- (6) Growers and processors shall immediately provide copies of COAs to the Department upon request and to any medical marijuana licensee upon request when the purpose of such request is compliance with this Section.
- (7) Growers and processors shall, in the manner and form prescribed by the Department, provide notification to the Department of any medical marijuana or medical marijuana products that have failed testing. Such notification shall include copies of the applicable COAs.
- (8) For the purposes of this subsection, submission of a COA into the State's inventory tracking system is sufficient to meet a commercial licensee's requirements to report and maintain such records.
- (i) **Allowable thresholds.** If changes to this Subsection require a change in methodology, proficiency testing enrollment, or accreditation the medical marijuana testing laboratory has up to ninety (90) days to comply.
  - (1) **Microbiological testing**. Harvest batch samples and production batch samples shall be tested for microbial limits as set forth in Appendix A.
  - (2) Mycotoxins. Production batch samples shall be tested for mycotoxins as set forth in Appendix A.
  - (3) **Residual solvents and chemical residue**. Production batch samples shall be tested for residual solvents and chemical residue as set forth in Appendix A. If the cannabis concentrate used to make an infused product was tested for solvents and chemical residue and test results indicate the lot was within established limits, then the infused product does not require additional testing for solvents and chemical residue.

#### (4) Metals.

- (A) All harvest batch and production batch samples shall be tested for heavy metals, which shall include but is not limited to lead, arsenic, cadmium, and mercury.
- (B) Test results shall meet thresholds set forth in Appendix A.
- (C) If the cannabis concentrate used to make an infused product was tested for metals and test results indicate the lot was within established limits, then the infused product does not require additional testing for metals. However, pre-rolls must still undergo additional testing for metals.
- (5) **Pesticide residue**. All harvest batch and production batch samples shall be tested for the following pesticides, and shall not exceed the associated limits:

(A) Spiromesifen	< 0.2 ppm
(B) Spirotetramat	< 0.2 ppm
(C) Tebuconazole	< 0.4 ppm
(D) Etoxazole	< 0.2 ppm
(E) Imazalil	< 0.2 ppm
(F) Imidacloprid	< 0.4 ppm
(G) Malathion	< 0.2 ppm
(H) Myclobutanil	< 0.2 ppm
(I) Azoxystrobin	< 0.2 ppm
(J) Bifenazate	< 0.2 ppm
(K) Abamectin (Avermectins: B1a & B1b)	
(L) Permethrin (mix of isomers)	

(M) Spinosad (Mixture of A and D)
 (6) Potency. Processors and growers shall test harvest batch and production batch samples for levels of total THC and terpenoid potency type and concentration.

< 0.5 ppm < 0.2 ppm

- (7) **Foreign materials and filth**. Growers and processors shall inspect all medical marijuana and medical marijuana products for contaminants and filth.
  - (A) Contaminants include any biological or chemical agent, foreign matter, or other substances not intentionally added to medical marijuana or medical marijuana products that may compromise safety or suitability.
  - (B) The surface area of each sample shall not contain more than two percent (2%) of foreign organic material.
  - (C) Samples shall not contain any presence of inorganic material, including but not limited to plastic, glass, and metal shavings.
  - (D) Inspection records shall indicate a continual process of physical inspection has taken place for all batches.

## (8) Water activity and moisture content.

- (A) All harvest batch samples shall be tested to determine the level of water activity and the percentage of moisture content. This subsection shall not apply to harvest batches that are flash frozen.
- (B) A harvest batch sample shall be deemed to have passed water activity testing if the water activity does not exceed 0.65 Aw. The laboratory shall report the result of the water activity test, to two significant figures, on the certificate of analysis (COA) and indicate "pass" or "fail" on the COA.
- (C) A harvest batch sample shall be deemed to have passed moisture content testing if the moisture content does not exceed fifteen percent (15.0%). The laboratory shall report the result of the moisture content test to the nearest tenth of one percent, by weight, of the dry sample on the COA and indicate "pass" or "fail" on the COA.
- (j) **Retesting.** If a harvest or production batch fails any analyte testing, the harvest or production batch may be retested in accordance with the following:
  - (1) The reserve sample shall be used first for all retesting. If there is not enough reserve sample for any additional tests required under this Subsection, a new sample may be collected. The new sample must be a representative sample of the batch and shall be gathered in accordance with these Rules.
  - (2) The retest may be limited to testing for the category of analyte that has failed testing. For example, if a primary sample fails pesticide testing, testing of the reserve sample may be limited to pesticide testing.
  - (3) If the first retest fails testing for the same analyte that failed the initial test, the harvest or production batch must either be remediated or decontaminated in accordance with the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq., and these Rules, or must be disposed of in accordance with the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq. and these Rules.
  - (4) If the first retest(s) passes testing, a second retest shall be conducted to confirm the product does

not exceed allowable thresholds and is safe to consume. If the second retest also passes for the same analyte, the batch may be processed, sold, or otherwise transferred. If the second retest fails for the same analyte that failed the initial test, the harvest or production batch must either be remediated or decontaminated in accordance with the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq., and these Rules, or must be disposed of in accordance with the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq. and these Rules.

- (5) If during the first retest, a harvest batch or production batch fails testing for an analyte that passed initial testing, the harvest batch or production batch must pass testing for that analyte during the second retest.
- (6) Any harvest batch or production batch that is retested and does not have two (2) successful tests for each analyte must either be remediated or decontaminated in accordance with the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq., and these Rules, or must be disposed of in accordance with the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq. and these Rules.

# (k) Remediation, decontamination, and retesting, general.

- (1) If a sample fails testing under this Subchapter, the harvest batch or production batch from which the sample was taken:
  - (A) May be remediated or decontaminated in accordance with these Rules; or
  - (B) If it is not or cannot be remediated or decontaminated under these Rules, it must be disposed in accordance with the Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq. and these Rules.
- (2) A harvest batch or production batch that has been remediated or decontaminated must be fully tested and successfully pass all the analyses required under this Subchapter. If the harvest batch or production batch fails to pass testing after remediation or decontamination, the harvest batch or production batch must be either disposed of in accordance with the Waste Management Act, 63 O.S. § 427a et seq. and these Rules or retested in accordance with OAC 310:681-8-1(j) with the following exceptions:
  - (A) Any harvest batch that has been decontaminated and fails retesting for microbials must be either remediated or disposed of in accordance with these Rules.
  - (B) Any production batch that has been decontaminated and fails retesting shall not be further decontaminated.
- (3) Growers and processors may remediate failed harvest batches or production batches providing the remediation method does not impart any toxic or deleterious substance to the usable medical marijuana or medical marijuana products. Any remediation methods or remediation solvents used on medical marijuana or medical marijuana products must be disclosed to the testing laboratory.
- (4) Growers and processers must, as applicable:
  - (A) Have detailed procedures for remediation and decontamination processes to remove microbiological contaminants and foreign materials, and for reducing the concentration of solvents.
  - (B) Prior to retesting, provide to the testing laboratory a document specifying how the product was remediated or decontamination. This document shall be retained by the laboratory together with other testing documentation.
  - (C) Document all re-sampling, re-testing, decontamination, remediation, and/or disposal of marijuana or marijuana-derived products that fail laboratory testing under these Rules.
- (5) At the request of the grower or processor, the Department may authorize a re-test to validate a failed test result on a case-by-case basis. All costs of the re-test will be borne by the grower or the processor requesting the re-test.
- (6) Growers and processors must inform a laboratory prior to samples being taken that the harvest batch or production batch has failed testing and is being re-tested after undergoing remediation or decontamination.

### (1) Remediation, decontamination, and retesting, microbiological impurities testing.

(1) If a sample from a harvest batch or production batch fails microbiological contaminant testing, the

batch may be used to make a cannabinoid concentrate or extract if the processing method effectively decontaminates the batch.

- (2) A grower may only sell or otherwise transfer a harvest batch that has failed microbiological contaminant testing to a processor and only for the purpose of remediation. The processor shall either remediate the harvest batch by processing it into a solvent-based concentrate or shall dispose of the batch in accordance with these Rules. Any production batches resulting from the remediation must be tested in accordance with OAC 310:681-8-1(k). Processors shall not sell any medical marijuana from any harvest batch that has failed testing. Harvest batches that have failed microbial testing may be sent to a processor for decontamination of microbial contaminants and returned to the grower.
- (3) If a sample from a batch of a cannabinoid concentrate or extract fails microbiological contaminant testing, the batch may be further processed, if the processing method effectively decontaminates the batch, such as a method using a hydrocarbon-based solvent or a CO2 closed-loop system.
- (4) A batch that is remediated or decontaminated in accordance with this Subsection of this section must be sampled and tested in accordance with these rules and must be tested, if not otherwise required for that product, for microbiological contaminants, residual solvents and processing chemicals and residual pesticides.
- (5) A batch that fails microbiological contaminant testing after undergoing a decontamination process in accordance with subsection (1) or (2) of this section must be disposed in accordance with the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq., and these Rules.

## (m) Decontamination and retesting, residual solvent and processing chemicals testing.

- (1) If a sample from a batch fails residual solvent and processing chemicals testing, the batch may be decontaminated using procedures that would reduce the concentration of solvents to less than the action level.
- (2) A batch that is decontaminated in accordance with subsection (1) must be sampled and retested for solvents in accordance with these Rules and must be tested, if not otherwise required for that product under these rules, for pesticides.
- (3) A batch that fails residual solvent and processing chemicals testing and is not decontaminated or is decontaminated and fails retesting must be disposed in accordance with the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq., and these Rules.

## (n) Decontamination and retesting, foreign materials testing.

- (1) If a sample from a batch of usable marijuana fails foreign materials testing, the batch from which the sample was taken may be remediated to reduce the amount of foreign materials to below action levels.
- (2) A batch that undergoes decontamination as described in subsection (1) must be sampled and tested in accordance with these Rules.

# (o) Remediation, decontamination and retesting, residual pesticide testing.

- (1) If a sample from a batch fails residual pesticide testing, the batch may not be remediated or decontaminated and must be disposed in accordance with the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq., and these Rules.
- (2) The Department may report to the Oklahoma Department of Agriculture all test results showing samples failing residual pesticide testing.

# (p) Remediation, decontamination and retesting, heavy metals testing.

- (1) If a sample from a batch fails heavy metals testing, the batch may not be remediated or decontaminated and must be disposed in accordance with the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq., and these Rules.
- (2) The Department may report to the Oklahoma Department of Environmental Quality all test results showing samples failing heavy metals testing.

# (q) Remediation, decontamination and retesting, mycotoxin testing.

- (1) If a sample from a batch fails mycotoxins testing, the batch may not be remediated or decontaminated and must be disposed in accordance with the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq., and these Rules.
- (r) Decontamination and resting retesting, water activity and moisture content.

- (1) If a harvest batch sample fails water activity and/or moisture content testing, the harvest batch may be further dried and cured by the grower.
- (2) A harvest batch that undergoes decontamination as described in subsection (1) must be sampled and tested in accordance with these Rules. If the harvest batch passed initial testing for residual solvents and chemical residue, metals, and/or pesticides, then the harvest batch does not require additional testing for those testing categories.
- (3) If a harvest batch that fails microbial testing and water activity and/or moisture content testing, the harvest batch does not need to be further dried and cured by the grower before being transferred to a processor for remediation in accordance with OAC 310:681-8-1(1).

# (s) Testing of noninfused pre-rolls and kief.

- (1) **Pre-rolls.** Growers, processors and dispensaries may create noninfused pre-rolls in accordance with Oklahoma law and these Rules.
  - (A) Growers, processors and dispensaries may create noninfused pre-rolls from flower, shake, or trim collected from multiple harvest batches. The plant material must be homogenized into a new batch not exceed fifteen (15) pounds. Noninfused pre-rolls created by a grower, processor or dispensary are subject to the same testing requirements of a harvest batch under OAC 310:681-8-1(i).
  - (B) Growers, processors and dispensaries may create noninfused pre-rolls from flower, shake, or trim collected from a single harvest batch. If the noninfused flower, shake or trim come from a single harvest that has passed full compliance testing, growers must conduct additional testing on the pre-rolls only for heavy metals, filth and contaminants, and potency.
- (2) **Kief.** Growers and processors may collect kief from multiple harvest batches. The kief must be homogenized into a new batch not exceed fifteen (15) pounds. Kief collected by a grower or processor is subject to the same testing requirements of a harvest batch under OAC 310:681-8-1(i).

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

- (a) Laboratory accreditation. A laboratory that submits an application to become a licensed testing laboratory prior to January 1, 2020 must have made application for accreditation to ANSI/ASQ National Accreditation Board, American Association for Laboratory Accreditation (A2LA), Perry Johnson Laboratory Accreditation (PJLA), or any other accrediting entity using the ISO/IEC Standard 17025, at the time of application. Application for accreditation must be made to one of these entities in both chemistry and biology, or cannabis. A laboratory that submits an application to become a licensed testing laboratory on or after January 1, 2020 must be accredited by ANSI/ASQ National Accreditation Board, American Association for Laboratory Accreditation (A2LA), Perry Johnson Laboratory Accreditation (PJLA), or any other accrediting entity using the ISO/IEC Standard 17025. The accreditation must befrom one of these entities in both chemistry and biology, or cannabis. All medical marijuana testing laboratories shall obtain accreditation by any accreditation Cooperation ("ILAC"), prior to applying for and receiving a medical marijuana testing laboratory license. The accreditation must be from one of these entities in both chemistry and biology, or cannabis. Renewal of any medical marijuana testing laboratory license shall be contingent upon maintaining accreditation in accordance with these Rules.
- (b) **Testing limited to scope of accreditation.** Upon accreditation, a testing laboratory shall only report test results on COAs for the testing of analytes the laboratory conducted that are within the scope of the testing laboratory's accreditation. A lab may outsource testing and report those results on a COA but must identify the testing laboratory that actually conducted the testing.
- (c) <u>Proficiency testing</u> <u>External quality control program testing</u>. The laboratory shall be subject to <u>proficiency testing</u> an external quality control program administered by the Department or its designee. <u>at a frequency Frequency of external quality control</u> and at times testing is to be determined by the Department or its designee.
  - (1) The laboratory shall cooperate with the Department or its designee for purposes of conducting proficiency external quality control testing. The Department or its designee may require submission

- of samples from the licensed laboratory for purposes of proficiency external quality control testing. (2) The quality assurance laboratory shall obtain reserve samples from licensed laboratories for the purposes of proficiency external quality control testing, which shall occur at a minimum of three (3) times per year for regular monitoring. The Department or the quality assurance laboratory may require additional proficiency external quality control tests to ensure correction of or investigate violations of Oklahoma law and these Rules.
- (3) If the Department determines on the basis of a proficiency testing that the laboratory has not satisfactorily identified the presence, quantity, or other relevant factor(s) pertaining to a given analyte, the Department may revoke the license, require additional tests, and/or require remedial actions to be taken by the laboratory. A result outside of the target range of any analyte in an external quality control sample event shall be deemed an unsatisfactory result. Each unsatisfactory result shall be evaluated by the licensed laboratory and corrective measure identified. The evaluation and completion of corrective measures shall be documented and signed by the laboratory director. The laboratory must then demonstrate its ability to achieve the target value.
- (4) If a laboratory fails its proficiency testing for an analyte, the batch testing results since the last proficiency test for that analyte must be re-evaluated. The laboratory director shall assess and implement necessary procedures to ensure risks to public safety are mitigated following failed proficiency testing results. More than 20% unsatisfactory results in any external quality control testing event shall be deemed unsuccessful participation in the external quality control program. Unsuccessful participation in external quality control testing for two testing events in a row, or 2 out of 3 events, may result in suspension or revocation of a laboratory license.
- (5) Failure to participate in any external quality control testing shall be deemed unsuccessful participation in the external quality control program.
- (6) If a laboratory fails its external quality control testing for an analyte, the batch testing results since the last external quality control test for that analyte must be re-evaluated. The laboratory director shall assess and implement necessary procedures to ensure risks to public safety are mitigated following failed external quality control testing results.
- (d) **Conflict of interest**. A person who is a direct beneficial owner or an indirect beneficial owner of a licensed laboratory. A licensed testing laboratory shall establish policies to prevent the existence of or appearance of undue commercial, financial, or other influences that may diminish the competency, impartiality, and integrity of the testing processes or results of the laboratory. At a minimum, employees, owners, or agents of a licensed laboratory who participate in any aspect of the analysis and results of a sample are prohibited from improperly influencing the testing process, improperly manipulating data, or improperly benefiting from any ongoing financial, employment, personal, or business relationship with the medical marijuana business licensee that provided the sample. A medical marijuana testing laboratory shall not test samples for any medical marijuana business in which an owner, employee or agent of the medical marijuana testing laboratory has any form of ownership or financial interest in the medical marijuana business.
- (e) **Safety standards**. Licensed laboratories must comply with Occupational Safety and Health Administration (OSHA) Standard 29 CFR § 1910.1450.
- (f) **Personnel**. A licensed laboratory shall not operate unless a medical laboratory director is on site during operational hours. Personnel of a licensed laboratory shall meet the following minimum requirements:
  - (1) A medical laboratory director must possess a bachelor's degree in the chemical, environmental, biological sciences, physical sciences or engineering, with at least twenty-four (24) college semester credit hours in chemistry and at least two (2) years of experience in the environmental analysis of representative inorganic and organic analytes for which the laboratory will be performing. A master's degree or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience. The medical laboratory director shall be responsible for the development of and adherence to all pre-analytic, analytic, and post-analytic procedures, and the implementation of a quality system that assures reliable test results and regulatory compliance.
  - (2) Analysts must possess a bachelor's degree applicable to a laboratory testing environment, with a

minimum of two (2) years of experience, or an associate's degree and five (5) years of applicable experience.

- (3) Ancillary personnel must possess a high school diploma or equivalent.
- (4) A licensed laboratory shall notify the Department within seven (7) business days after any change of the laboratory's director occurs.

# (g) Equipment.

- (1) Equipment used for analysis must have a Limit of Detection (LOD) capable of detecting the quantities at or below 50% of the thresholds listed in OAC 310:681-8-1(h) and Appendix A.
- (2) Equipment used for the analysis of test samples shall be adequately inspected, cleaned, and maintained. Equipment used for the generation or measurement of data shall be adequately tested and calibrated on an appropriate schedule, as applicable.
- (3) Laboratory operations shall document procedures setting forth in sufficient detail the methods and schedules to be used in the routine inspection, cleaning, maintenance, testing, and calibration of equipment, and shall specify, as appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The procedures shall designate the personnel responsible for the performance of each operation.
- (4) Records shall be maintained of all inspection, maintenance, testing, and calibrating operations. These records shall include the date of the operation, the person who performed it, the written procedure used, and any deviations from the written procedure. All deviations must be reviewed and approved by the medical laboratory director. Records shall be kept of non-routine repairs performed on equipment. Such records shall document the nature of the repair, how and when the need for the repair was discovered, and any remedial action taken in response to the repair. A written assessment of the validity of the results obtained previous to the failure must be made. Documentation of any repeat testing performed must also be maintained. Any non-routine repair must be reported to and reviewed by the quality assurance laboratory.
- (5) Computer systems used for the analysis of samples, retention of data, sample tracking, calibration scheduling, management of reference standards, or other critical laboratory management functions shall ensure that electronic records, electronic signatures, and handwritten signatures executed to electronic records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

### (h) Data storage.

- (1) The laboratory shall ensure that all raw data, documentation, protocols, and final reports associated with analysis of a test sample are retained for at least two (2) seven (7) years from the date of completion of analysis.
- (2) The laboratory shall designate an individual as responsible for records maintenance. Only authorized personnel may access the maintained records.
- (3) The laboratory shall maintain the records identified in this section:
  - (A) In a manner that allows retrieval, as needed;
  - (B) Under conditions of storage that minimize deterioration throughout the retention period; and
  - (C) In a manner that prevents unauthorized alteration.
- (i) **Materials to be maintained on premises**. The laboratory shall maintain on its premises, and shall promptly present to the Department upon request:
  - (1) Personnel documentation including, but not limited to employment records, job descriptions, education, and training requirements of the laboratory, and documentation of education and training provided to staff for the purpose of performance of assigned functions;
  - (2) Policies concerning laboratory operations, business licensing, and security procedures;
  - (3) Any policies, protocol, or procedures for receipt, handling, and disposition of samples of usable marijuana;
  - (4) Equipment information detailing the type of equipment used, inspection policies and practices, testing and calibration schedules and records, and standards for cleaning and maintenance of equipment:
  - (5) Reagents, solutions, and reference policies including, but not limited to standards for labeling,

storage, expiration, and re-qualification dates and records;

- (6) Reference standards, acquired or internally produced, including the certificate of analysis;
- (7) Sample analysis procedures including, but not limited to procedures for the use of only primary or secondary standards for quantitative analyses;
- (8) Documentation demonstrating that the analytical methods used by the laboratory are appropriate for their intended purpose; that staff is competent in the process; and that deviations from approved standards of practice do not occur without proper authorization;
- (9) Policies for data recording, review, storage, and reporting that include, but are not limited to standards to ensure that:
  - (A) Data are recorded in a manner consistent with applicable Oklahoma law and these Rules, and are reviewed to verify that applicable standards of practice, equipment calibration, and reference standards were applied before reporting;
  - (B) All data, including raw data, documentation, protocols, and reports are retained in accordance with applicable Oklahoma law and these rules; and
  - (C) Reports are the property of the business or individual who provided the sample, and reports meet the requirements of this rule.
- (10) Documentation showing the laboratory complies with OSHA Standard 29 CFR § 1910.1450; and
- (11) Such other materials as the Department may require.
- (j) **Department access to materials and premises**. The laboratory shall promptly provide the Department or the Department's designee access to a report of a test, and any underlying data, that is conducted on a sample. The laboratory shall also provide access to the Department or the Department's designee to laboratory premises, and to any material or information requested by the Department, for the purpose of determining compliance with the requirements of applicable Oklahoma law and these rules.
- (k) Reporting of accreditation and proficiency testing results. The laboratory shall submit to the Department, within thirty (30) days of an accrediting entity's assessment, the results of any proficiency testing or an accrediting entity's audit, including the findings and any corrective action required following the assessment.
- (1) Licensed premises standards. The laboratory must be constructed, arranged and maintained in a way that ensures the laboratory premises, ventilation and utilities are sufficient for conducting all phases of the testing process:
  - (1) Work area should be arranged to minimize problems in specimen handling, examination and testing, and reporting of test results. Workbench space must be sufficient for the performance of testing, including, but not limited to, adequate lighting, water, gas, vacuum, and electrical outlets.

    Instruments, equipment, and computer systems should be placed in locations where their operation is not affected adversely by physical or chemical factors, such as heat, humidity, direct sunlight, vibrations, power fluctuations, or fumes from acid or alkaline solutions. Equipment tops should not be used as a workbench space;
  - (2) Lighting or backgrounds as appropriate for visual interpretation of test results;
  - (3) There is a system in place which ensures that the ventilation system properly removes vapors, fumes, and excessive heat as appropriate for the type of testing done in the laboratory;
  - (4) There is an adequate, stable electrical source maintained at each testing location that meets the power requirements for each piece of equipment;
  - (5) The Laboratory is designed to minimize contamination of samples, equipment, instruments, reagents and supplies. Laboratories performing molecular amplification procedures must have a mechanism to detect cross-contamination of specimens; and
  - (6) Reagents must be prepared in an area that is separate, as applicable, from where specimens are processed, prepared, amplified, and detected to prevent contamination.

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

- (a) **General requirements**. Samples must be collected, handled, stored, and disposed of in accordance with this Section. Individuals collecting samples are called "Samplers."
  - (1) Samplers shall:

- (A) Follow the approved standard operating procedures of the laboratory that will be testing the samples collected
- (B) Be trained on how to collect samples in accordance with the standard operating procedures of the laboratory(ies) that will be conducting the testing on the samples collected;
- (C) Have access to a copy of the laboratory's standard operating procedures while they are collecting the samples; and
- (D) Follow inventory manifest requirements set forth in these Rules.
- (2) Samplers shall collect samples at the location of the grower or processor.
- (3) A licensed laboratory must either utilize a licensed commercial transporter to transport samples or obtain a commercial transporter license in order to transport samples from the grower or processor to the laboratory.
- (4) All commercial transporters, growers, or processors or dispensaries transporting samples to a laboratory shall be prohibited from storing samples at any location other than the laboratory facility. All samples must be delivered the day of collection.
- (5) (4) Samples shall only be collected from harvest batches and production batches in final form. For purpose of this Subsection, "final form" means the form medical marijuana or a medical marijuana product is in when sold or transferred.
- (6) (5) The sampler shall collect both a primary sample and a reserve sample from each harvest batch and production batch. The sample shall be clearly and conspicuously labeled, and the label shall include at least the following information:
  - (A) Whether the sample is the "Primary Sample" or "Reserve Sample";
  - (B) The name and license number of grower or processor from whom the sample was taken; and
  - (C) The batch number of the harvest batch or production batch from which the sample was taken.
- (7) (6) The primary sample and reserve sample shall be stored separately and analyzed separately. The reserve sample shall only be used for quality control purposes or for retesting in accordance with OAC 310:681-8-1(j).
- (8) (7) Samples shall be transported and subsequently stored at the laboratory in a manner that prevents degradation, contamination, and tampering. If the medical marijuana or medical marijuana product specifies on the label how the product shall be stored, the laboratory shall store the sample as indicated on the label.
- (9) The sampler shall create and use a sample field log to record the following information for each sample. The field log shall include, at a minimum, the following information:
  - (A) Laboratory's name, address, and license number;
  - (B) Title and version of the laboratory's standard operating procedure(s) followed when collecting the sample;
  - (C) Sampler's name(s) and title(s);
  - (D) Date and time sampling started and ended;
  - (E) Grower's, or processor's or dispensary's name, address, and license number;
  - (F) Batch number of the batch from which the sample was obtained;
  - (G) Sample matrix;
  - (H) Total batch size, by weight or unit count;
  - (I) Total weight or unit count of the primary sample;
  - (J) Total weight or unit count of the reserve sample;
  - (K) The unique sample identification number for each sample;
  - (L) Name, business address, and license number of the person who transports the samples to the laboratory;
  - (M) Requested analyses;
  - (N) Sampling conditions, including temperature;
  - (O) Problems encountered and corrective actions taken during the sampling process, if any; and
  - (P) Any other observations from sampling, including major inconsistencies in the medical marijuana color, size, or smell.
- (10) The laboratory shall maintain inventory manifest documentation listed in OAC 310:681-3-6 and

utilize an electronic inventory management system that meets the requirements set forth in OAC 310:681-5-6(d) for each sample that the laboratory collects, transports, and analyzes.

- (11) Commercial licensees shall document all employee training on a testing laboratory's standard operating procedures.
- (12) Commercial licensees must maintain the documentation required in these rules for at least two-(2) seven (7) years and must provide that information to the Department upon request.

# (b) Sample size.

- (1) To obtain a representative sample of a harvest batch, a total of 0.5% of the batch shall be collected from different areas of the batch following the laboratory's approved protocol. The sample shall then be homogenized and aliquoted into a primary sample and reserve sample, which shall be equal in amounts. The primary sample and reserve sample shall be in the amounts specified in the laboratory's standard operating procedure. Any amounts left over after aliquoting may be returned to the harvest batch
- (2) To obtain a representative sample of a processed batch that is well mixed or homogeneous by its nature, a sampler shall obtain an amount sufficient to be aliquoted into a primary sample and a reserve sample, which shall be equal in amount. If the batch is of not homogeneous or is of unknown homogeneity, then 0.5% of the batch shall be collected from different portions of the batch following the laboratory's approved protocol. The sample shall then be homogenized and aliquoted into a primary sample and reserve sample, which shall be equal in amount. The primary sample and reserve sample shall be in the amounts specified in the laboratory's standard operating procedure. Any amount left over after aliquoting may be returned to the production batch.
- (3) To obtain a representative sample of a final medical marijuana product batch, samples shall be collected in accordance with the table in Appendix D.
- (4) To obtain a representative sample of pre-rolls, samples shall be collected in accordance with the table in Appendix E.

## (c) Sampling standard operating procedures.

- (1) Samples collected must be representative of the entire batch to ensure accurate microbiological analysis and foreign material assessments.
- (2) Sample protocol shall be approved by the laboratory director. The laboratory shall develop and implement written sampling policies and procedures that are appropriate for each test method and each type of matrix to be tested and that are consistent with these regulations. Sampling procedures must describe the laboratory's method for collection, preparation, packaging, labeling, documentation, and transport of samples from each matrix type the laboratory tests.
- (3) The sampling standard operating procedures (SOP) shall include at least the following information:
  - (A) A step-by-step guide for obtaining samples from each matrix type the laboratory samples;
  - (B) Protocols for ensuring that contaminants are not introduced during sampling, including protocols relating to the sanitizing of equipment and tools, protective garb, and sampling containers;
  - (C) Accepted test sample types;
  - (D) Minimum test sample size;
  - (E) Recommended test sample containers;
  - (F) Test sample labeling;
  - (G) Transport and storage conditions, such as refrigeration, as appropriate to protect the physical and chemical integrity of the sample;
  - (H) Other requirements, such as use of preservatives, inert gas, or other measures designed to protect sample integrity; and
  - (I) Chain-of-custody documentation for each sample in accordance with OAC 310:681-5-6.
- (4) The sampling SOP shall be signed and dated by the medical laboratory director and shall include any revision dates and authors. The laboratory director's signature denotes approval of the plan.
- (5) The laboratory shall retain a controlled copy of the sampling SOP on the laboratory premises and ensure that the sampling SOP is accessible to the sampler in the field during sampling.

- (d) **Sample handling, storage and disposal**. A laboratory shall establish sample handling procedures for the tracking of test samples through the analytical process (by weight, volume, number, or other appropriate measure) to prevent diversion.
  - (1) The laboratory shall store each test sample under the appropriate conditions appropriate to protect the physical and chemical integrity of the sample.
  - (2) Analyzed test samples consisting of medical marijuana or medical marijuana products shall be held in a controlled access area pending destruction or other disposal.
  - (3) Any portion of a medical marijuana or medical marijuana product test sample that is not destroyed during analysis shall be: Reserve samples shall be maintained and properly stored by the laboratory for at least thirty (30) days.
    - (A) Returned to the licensed individual or entity that provided the sample after the required retention period for reserve samples;
    - (B) Transported to a state or local law enforcement office; or
    - (C) Disposed of in accordance with OAC 310:681-5-10 (relating to medical marijuana wastedisposal).
  - (4) After the required thirty (30) day storage period, any portion of a medical marijuana or medical marijuana product test sample that is not destroyed during analysis shall be:
    - (A) Returned to the licensed individual or entity that provided the sample after the required retention period for reserve samples;
    - (B) Transported to a state or local law enforcement office; or
    - (C) Disposed of in accordance with OAC 310:681-5-10 (relating to medical marijuana waste disposal).

## (e) Data reporting.

- (1) The laboratory shall generate a certificate of analysis (COA) for each primary sample that the laboratory analyzes.
- (2) The laboratory shall issue the COA to the requester within two (2) business days after technical and administrative review of analysis has been completed. A laboratory shall not withhold a COA reporting a failed test from the requester for any reason.
- (3) All COAs, whether in paper or electronic form, shall contain, at minimum, the following information:
  - (A) The name, address, license number, and contact information of the laboratory that conducted the analysis;
  - (B) If the laboratory sends a sample to another laboratory for testing, the reference laboratory must be identified as having performed that test;
  - (C) The name, address, and license number of the requester;
  - (D) The description of the type or form of the test sample (leaf, flower, powder, oil, specific edible product, etc.) and its total primary sample weight in grams, reported to the nearest gram;
  - (E) The unique sample identifier;
  - (F) Batch number of the batch from which the sample was obtained;
  - (G) Sample history, including the date collected, the date received by the laboratory, and the date(s) of sample analyses and corresponding testing results, including units of measure where applicable;
  - (H) The analytical methods used, including at a minimum identification of the type of analytical equipment used (e.g., GC, HPLC, UV, etc.);
  - (I) The reporting limit for each analyte tested;
  - (J) Any compounds detected during the analyses of the sample that are not among the targeted analytes and are unknown, unidentified, tentatively identified or known and injurious to human health if consumed, if any;
  - (K) The identity of the supervisory or management personnel who reviewed and verified the data and results and ensured that data quality, calibration, and other applicable requirements were met; and
  - (L) Definitions of any abbreviated terms.

- (4) The laboratory shall report test results for each primary sample on the COA as follows:
  - (A) When reporting quantitative results for each analyte, the laboratory shall use the appropriate units of measurement as required under this chapter and indicate "pass" or "fail";
  - (B) When reporting qualitative results for each analyte, the laboratory shall indicate "pass" or "fail";
  - (C) "Pass" and "Fail" must be clear, conspicuous, and easily identifiable in a font size no less than the size of 12 pt font in Times New Roman and shall not be in fine print or footnotes;
  - (D) When reporting results for any analytes that were detected below the analytical method limit of quantitation (LOQ), indicate "<LOQ" and list the results for analytes that were detected above the LOQ but below the allowable limit; and
  - (E) Indicate "NT" for not tested for any test that the laboratory did not perform.
- (5) Upon detection of any compounds during the analyses of the sample that are not among the targeted analytes and are unknown, unidentified, tentatively identified, or known and injurious to human health if consumed, laboratories shall notify the Department immediately and shall submit to the Department a copy of the COA containing those compounds as required in OAC 310:681-8-3(e)(3)(I). The Department may require a processor, or grower, or dispensary to submit samples for additional testing, including testing for analytes that are not required by these Rules, at the licensee's expense. The licensee shall provide the samples or units of medical marijuana or medical marijuana products at its own expense but shall not be responsible for the costs of testing.
- (6) When a laboratory determines that a harvest batch or production batch has failed any required testing, the laboratory shall immediately notify the Department in the manner and form prescribed by the Department on its website and shall submit a copy of the COA to the Department within two (2) business days. Submission of this information to the Department through the seed to sale tracking system established by the Department or a seed to sale tracking system that integrates with the Department established system State's inventory tracking system shall be sufficient to satisfy this reporting requirement.

#### 310:681-8-4. Laboratory quality assurance and quality control

- (a) **Laboratory Quality Assurance (LQA) program**. The medical laboratory director shall develop and implement an LQA program to ensure the reliability and validity of the analytical data produced by the laboratory.
  - (1) The LQA program shall, at minimum, include a written LQA manual that addresses the following:
    - (A) Quality control procedures, including remedial actions;
    - (B) Laboratory organization and employee training and responsibilities;
    - (C) LQA criteria for acceptable performance;
    - (D) Traceability of data and analytical results;
    - (E) Instrument maintenance, calibration procedures, and frequency;
    - (F) Performance and system audits;
    - (G) Steps to change processes when necessary;
    - (H) Record retention;
    - (I) Test procedure standardization; and
    - (J) Method validation, including, but not limited to, accuracy, precision, sensitivity, cross-over, LOD, linearity, and measurement of uncertainty.
  - (2) The laboratory director shall annually review, amend if necessary, and approve the LQA program and manual when:
    - (A) The LQA program and manual are created; and
    - (B) There is a change in methods, laboratory equipment, or the supervisory or management laboratory employee overseeing the LQA program.

## (b) Laboratory quality control samples.

- (1) The laboratory shall use laboratory quality control (LQC) samples in the performance of each analysis according to the specifications in this section.
- (2) The laboratory shall analyze LQC samples in the same manner as the laboratory analyzes samples

of medical marijuana and medical marijuana products.

- (3) The laboratory shall use negative and positive controls for microbial testing.
- (4) The following quality control samples must be run every 20 samples in an analytic run:
  - (A) Method blank;
  - (B) Continuing calibration verification (CCV);
  - (C) Laboratory replicate sample; and
  - (D) Matrix spike sample or matrix spike duplicate sample.
- (5) If the result of the analyses is outside the specified acceptance criteria in Appendix B, the laboratory shall determine the cause and take steps to remedy the problem until the result is within the specified acceptance criteria. Samples after the last acceptable run must be re-tested.
- (6) The laboratory shall generate a LQC sample report for each analytical run that includes LQC parameters, measurements, analysis date, and matrix. The results must fall within the criteria set forth in Appendix B.

# (c) Reagents, solutions, and reference standards.

- (1) Reagents, solutions, and reference standards shall be:
  - (A) Secured in accordance with the laboratory's storage policies; labeled to indicate identity, date received or prepared, and expiration or requalification date; and, where applicable, concentration or purity, storage requirements, and date opened;
  - (B) Stored under appropriate conditions to minimize degradation or deterioration of the material; and
  - (C) Used only within the item's expiration or requalification date.
- (2) Deteriorated or outdated reagents and solutions shall be properly disposed, in compliance with all federal, state and local regulations.
- (3) The laboratory may acquire commercial reference standards for cannabinoids and other chemicals or contaminants, for the exclusive purpose of conducting testing for which the laboratory is approved. The laboratory may elect to produce reference standards in-house (internally). When internally produced, the laboratory shall utilize standard analytical techniques to document the purity and concentration of the internally produced reference standards. The laboratory is authorized to obtain marijuana or marijuana-derived product from a licensed non-profit producer for this purpose.
- (4) The laboratory shall obtain or, for internally-produced standards, shall create a certificate of analysis (COA) for each lot of reference standard. Each COA shall be kept on-file and the lot number of the reference standard used shall be recorded in the documentation for each analysis, as applicable.

#### SUBCHAPTER 9. WASTE DISPOSAL FACILITIES

## 310:681-9-1. License or permit required

- (a) No person or entity shall operate a medical marijuana waste disposal facility without first obtaining a license from the Department pursuant to the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq., other applicable Oklahoma law, including regulations of the Oklahoma Department of Environmental Quality, and the Rules in this Chapter. Only a person who is in compliance with the requirements of Oklahoma law and these Rules shall be entitled to receive or retain such a license or permit.
- (b) The Department shall not, for the first year of the licensure program, until November 1, 2021, issue more than ten (10) waste disposal facility licenses. The Department shall have the authority to develop and utilize criteria, standards, and preferred qualifications for the selection of licensees and timing of licensure as it deems appropriate and reasonable. Beginning November 1, 2021, there shall be no limit to the number of medical marijuana waste disposal licenses issued by the Department.
- (c) All license and permit applications shall be complete and accurate in every detail, shall include all attachments or supplemental information required by the forms supplied by the Department, and shall be accompanied by full remittance of the entire application fee. Any misstatements, omissions, misrepresentations, or untruths made in the application shall be grounds for administrative action against the licensee by the Department.

- (d) All licenses and permits shall be on forms prescribed by the Department.
- (e) Application fees are nonrefundable.
- (f) Upon issuance of a waste disposal facility license, each waste disposal facility licensee shall automatically receive a waste disposal transportation license. Medical marijuana waste disposal facility licensees shall ensure that a copy of the waste disposal transportation license is inside any vehicles used for transporting medical marijuana waste during transportation.

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

- (a) **Timeframe**. Waste disposal facility licenses and permits shall be issued for a twelve (12) month period expiring one (1) year from the date of issuance. The license or permit may be issued upon receipt of a completed application, payment of application fee, and verification by the Department the individual or entity complies with the requirements set forth in Oklahoma law and this Chapter.
- (b) **Location**. Waste disposal facility licenses and permits shall only be valid for a single location at the address listed on the application.

#### (c) Renewal of license or permit

- (1) It is the responsibility of the license holder to renew the license and any associated permits, with all applicable documentation, prior to the date of expiration of the license or permit by following the procedures provided in OAC 310:681-9-3 and OAC 310:681-9-4.
- (2) Before renewing a license or permit, the Department may require further information and documentation to determine if the licensee continues to meet the requirements set forth in Oklahoma law and these Rules.
- (3) The Department may refuse to renew a license or permit of a medical marijuana waste facility for the following:
  - (A) Failure to meet the requirements for licensure or permits set forth in the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq., or OAC 310:681.
  - (B) Noncompliance with 63 O.S. § 420 et seq.; the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.; the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq.; or OAC 310:681.
- (4) Upon the determination that a licensee has not met the requirements for renewal, the Department shall provide written notice to the licensee. The notice shall provide an explanation for the denial of the renewal application.

#### (d) Disposal of waste upon termination of license/permit.

- (1) A waste disposal facility licensee whose license is not renewed, or whose license is revoked, suspended, or voluntarily surrendered, shall immediately cease all operations at all licensed and permitted locations upon expiration of the license and shall immediately either dispose of any medical marijuana waste remaining in its possession or transfer such medical marijuana waste to another licensed medical marijuana waste disposal facility licensee.
- (2) A waste disposal facility licensee whose permit is not renewed, or whose permit is revoked, suspended, or voluntarily surrendered, shall cease all operations at the permitted location immediately upon expiration of the permit and shall immediately take one of the following actions:
  - (A) Dispose of any medical marijuana waste remaining in its possession at the permitted location;
  - (B) Transfer such medical marijuana waste to another permitted location belonging to the same licensed medical marijuana waste disposal facility licensee; or
  - (C) Transfer such medical marijuana waste to another licensed medical marijuana waste disposal facility licensee.

### (e) Change in information.

- (1) Licensees shall notify the Department in writing within fourteen (14) days of any changes in contact information by electronically submitting a change request in accordance with the Department's instructions.
- (2) Licensees shall obtain Department approval prior to for any material changes that affect the licensee's qualifications to receive a license or permit for licensure. Licensees shall notify submit a

material change request to the Department in writing in advance of any material change that may affect the licensee's qualifications for licensure by electronically submitting a change request, along with any relevant documentation and fees, in accordance with the Department's instructions. When submitting a material change request, the licensee will now be required to pay a \$500.00 nonrefundable fee. Except as is otherwise authorized by the Department, licensees are limited to one location change request, one ownership change request, and one name change request per year of licensure.

- (A) Medical marijuana waste licensees submitting a location change for any licensed or permitted location must provide the information and documentation required in OAC 310:681-9-4 relating to locations, including but not limited to the following:
  - (i) Proof as required in OAC 310:681-9-4(c)(1) that the location of the waste facility is at least one thousand (1,000) feet from any public or private school; and
  - (ii) Any further documentation the Department determines is necessary to ensure the business licensee is still qualified under Oklahoma law and this Chapter to obtain a business license.
- (B) Medical marijuana business licensees submitting an ownership change request must provide the information and documentation required in OAC 310:681-9-3 relating to owners, including but not limited to the following:
  - (i) An list of all owners and principal officers of the commercial applicant and supporting documentation as set forth in OAC 310:681-9-3(e)(1);
  - (ii) An affidavit of lawful presence for each new owner;
  - (iii) Documents required under OAC 310:681-9-3(e)(5) establishing that the applicant; and the members, managers, and board members if applicable; and seventy-five percent (75%) of the commercial applicant's ownership interests are Oklahoma residents as required in the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.;
  - (iv) Background checks in accordance with OAC 310:681-1-5; and
  - (v) Any further documentation the Department determines is necessary to ensure the business licensee is still qualified under Oklahoma law and this Chapter to obtain a business license.
- (C) A medical marijuana business licensee submitting a name change request must provide the information and documentation required in OAC 310:681-5-3 relating to the business name, including but not limited to the following:
  - (i) A certificate of good standing from the Oklahoma Secretary of State issued within thirty
  - (30) days of submission of the application as required under OAC 310:681-5-3(e)(2);
  - (ii) If applicable, official documentation from the Secretary of State establishing the applicant's trade name;
  - (iii) If applicable, an electronic copy or digital image in color of a sales tax permit issued by the Oklahoma Tax Commission;
  - (iv) A list of all owners and principal officers of the licensee under the new name and supporting documentation as set forth in OAC 310:681-5-3(e)(1);
  - (v) Documents establishing that seventy-five (75%) of the ownership of the licensee under the new name are Oklahoma residents in accordance with OAC 310:681-5-3(e)(6); and
  - (vi) Any further documentation the Department determines is necessary to ensure the business licensee is still qualified under Oklahoma law and this Chapter to obtain a business license.

#### (f) Transfer of license or permit.

- (1) Waste disposal facility licenses and permits may not be wholly assigned or otherwise transferred to a new owner(s) or another legal entity(ies).
- (2) Licenses may not be changed from one license type to another.
- (g) **Surrender of license or permit**. A waste disposal facility licensee may voluntarily surrender a license or permit to the Department at any time in accordance with OAC 310:681-5-2(g). If a waste disposal facility license is surrendered, all associated permitted locations will be surrendered.
- (h) **Revocation of license or permit**. If a waste disposal facility license is revoked, all associated permitted locations will be revoked.

#### 310:681-9-3. License applications

- (a) **Application fee**. An applicant for a waste disposal facility license, or renewal thereof, shall submit to the Department a completed application on a form and in a manner prescribed by the Department, along with the application fee as established in 63 O.S. § 420 et seq. and the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq.
- (b) **Submission**. The application shall be on the Department prescribed form and shall include the following information about the establishment:
  - (1) Name of the establishment;
  - (2) Physical address of the establishment, including the county in which any licensed premises will be located:
  - (3) GPS coordinates of the establishment;
  - (4) Phone number and email of the establishment;
  - (5) Hours of operation for any licensed premises;
  - (6) Type of waste facility; and
  - (7) Proposed number and location of additional waste disposal facilities associated with the applicant.
- (c) **Individual applicant**. The application for a waste disposal facility license made by an individual on his or her own behalf shall be on the Department prescribed form and shall include at a minimum:
  - (1) The applicant's first name, middle name, last name, and suffix if applicable;
  - (2) The applicant's residence address and valid mailing address;
  - (3) The applicant's date of birth;
  - (4) The applicant's telephone number and email address;
  - (5) An attestation that the information provided by the applicant is true and correct;
  - (6) An attestation that any licensed premises shall not be located on tribal lands; and
  - (7) A statement signed by the applicant pledging not to divert marijuana to any individual or entity that is not lawfully entitled to possess marijuana.
- (d) **Application on behalf of an entity**. In addition to requirements of Subsection (c), an application for a waste facility license made by an individual on behalf of an entity shall include:
  - (1) An attestation that applicant is authorized to make application on behalf of the entity;
  - (2) Full name of organization;
  - (3) Trade name, if applicable;
  - (4) Type of business organization;
  - (5) Mailing address;
  - (6) Telephone number and email address; and
  - (7) The name, residence address, and date of birth of each owner and each member, manager, and board member, if applicable.
- (e) **Supporting documentation**. Each application shall be accompanied by the following documentation:
  - (1) A list of all persons and/or entities that have an ownership interest in the entity;
  - (2) If applicable, a certificate of good standing from the Oklahoma Secretary of State;
  - (3) If applicable, official documentation from the Secretary of State establishing the applicant's trade name;
  - (4) An Affidavit of Lawful Presence for each owner;
  - (5) Proof that the proposed location of the waste disposal facility is a least one thousand (1,000) feet from a public or private school. The distance specified shall be measured from any entrance of the school to the nearest property line point front entrance of the facility;
  - (6) Documents establishing the applicant, the members, managers, and board members, if applicable, and seventy-five percent (75%) of the ownership interests are Oklahoma residents as established in 63 O.S. § 420 et seq., and OAC 310:681-1-6 (relating to proof of residency);
  - (7) Proof of sufficient liability insurance. Liability insurance or a letter of insurability from the insurance company shall be provided by the applicant and shall apply to sudden and nonsudden bodily injury and property damage on, below, and above the surface of the facility. Such insurance

shall be maintained for the period of operation of the facility during operation and after closing. Sufficient liability insurance means that the licensee shall maintain at all times insurance coverage with at least the following minimum limits:

- (A) Commercial General Liability: \$5,000,000.00 each occurrence;
- (B) Pollution Legal Liability: \$5,000,000.00 each occurrence;
- (8) Relevant waste permit(s) from the Oklahoma Department of Environmental Quality or the Oklahoma Department of Agriculture; and
- (9) Any further documentation the Department determines is necessary to ensure the applicant is qualified under Oklahoma law and this Chapter to obtain a waste disposal facility license.
- (f) **Incomplete application**. Failure to submit a complete application with all required information and documentation shall result in a rejection of the application. The Department shall notify the applicant via email through the electronic application account of the reasons for the rejection.

#### 310:681-9-4. Permit applications

- (a) **Application fee**. An applicant for a waste disposal facility permit, or renewal thereof, shall submit to the Department a completed application on a form and in a manner prescribed by the Department, along with the application fee as established in 63 O.S. § 420 et seq. and the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq. A waste disposal facility permit application shall be submitted after and associated with an approved waste disposal facility license application.
- (b) **Submission**. The application shall be on the Department prescribed form and shall include the following information about the establishment:
  - (1) Name and license number of the waste disposal facility licensee associated with the permit;
  - (2) Physical address of the establishment, including the county in which any licensed premises will be located;
  - (3) GPS coordinates of the establishment;
  - (4) Phone number and email of the establishment;
  - (5) Hours of operation of the establishment.
  - (6) Mailing address of the establishment;
  - (7) An attestation that the information provided by the applicant is true and correct;
  - (8) An attestation that any licensed premises shall not be located on tribal lands;
  - (9) A statement signed by the applicant pledging not to divert marijuana to any individual or entity that is not lawfully entitled to possess marijuana; and
  - (10) An attestation that applicant is authorized to make application on behalf of the entity.
- (c) **Supporting documentation**. Each application shall be accompanied by the following documentation:
  - (1) Proof that the proposed location of the waste disposal facility is a least one thousand (1,000) feet from a public or private school. The distance specified shall be measured from any entrance of the school to the nearest property line point front entrance of the facility;
  - (2) Proof of sufficient liability insurance. Liability insurance shall be provided by the applicant and shall apply to sudden and nonsudden bodily injury and property damage on, below, and above the surface of the facility. Such insurance shall be maintained for the period of operation of the facility and shall provide coverage for damages resulting from operation of the facility during operation and after closing. Sufficient liability insurance means that the licensee shall maintain at all times insurance coverage with at least the following minimum limits:
    - (A) Commercial General Liability: \$5,000,000.00;
    - (B) Pollution Legal Liability: \$5,000,000.00 each occurrence;
  - (3) Relevant waste permit(s) from the Oklahoma Department of Environmental Quality; and
  - (4) Any further documentation the Department determines is necessary to ensure the commercial applicant is qualified under Oklahoma law and this Chapter to obtain a waste disposal facility license.
- (d) **Incomplete application.** Failure to submit a complete application with all required information and documentation shall result in a rejection of the application. The Department shall notify the applicant via email through the electronic application account of the reasons for the rejection.

#### 310:681-9-6. Security requirements

- (a) **General requirements**. All licensed entities shall provide effective controls and procedures to guard against theft and diversion of medical marijuana and medical marijuana products. In order to determine whether a registrant has provided effective controls against diversion, the licensee shall adhere to the security requirements as set forth by these Rules.
- (b) **Storage**. OMMA licensed entities shall dispose of medical marijuana waste using a medical marijuana waste disposal facility licensed by the Department. The licensee shall dispose of all medical marijuana waste in a secure waste receptacle that is locked with commercial-grade locks. The receptacle shall be kept in a safe and secure location with limited access.

## (c) Transport.

- (1) Medical marijuana waste facilities shall transport medical marijuana waste in accordance with the following:
  - (A) All medical marijuana waste shall be transported:
    - (i) In a locked shipping container, shielded from public view and clearly labeled "Medical Marijuana Waste"; and
    - (ii) In a secured area of the vehicle that is not accessible by the driver during transit.
  - (B) All vehicles used to transport medical marijuana and medical marijuana products shall be:
    - (i) Equipped with active Global Positioning System (GPS) trackers, which shall not be mobile cellular devices and which shall be capable of storing and transmitting GPS data; and
    - (ii) Insured at or above the legal requirements in Oklahoma.
  - (C) Medical marijuana waste facilities shall maintain updated and accurate records and information on all vehicles engaged in the transport of medical marijuana waste, including GPS data and records. Such records and information shall be kept at the licensed premises and shall be readily accessible.
  - (D) Medical marijuana waste facilities shall implement appropriate security measures to deter and prevent the theft and diversion of medical marijuana waste during transportation.
  - (E) Medical marijuana waste facilities shall comply with all applicable motor vehicle laws.
- (2) Waste disposal facilities who render the medical marijuana unusable and unrecognizable at the collection site shall transport the processed medical marijuana waste in accordance with the following:
  - (A) All vehicles used to transport medical marijuana and medical marijuana products shall be insured at or above the legal requirements in Oklahoma.
  - (B) Medical marijuana waste facilities shall maintain updated and accurate records and information on all vehicles engaged in the transport of medical marijuana waste. Such records and information shall be kept at the licensed premises and shall be readily accessible.
  - (C) Medical marijuana waste facilities shall comply with all applicable motor vehicle laws.
- (d) **Documentation**. The medical marijuana business, research facility, and education facility licensees transferring the medical marijuana waste for disposal shall document in the electronic inventory system all waste placed in the secure container and transferred to the medical marijuana waste facility licensee. The inventory manifest for transport of medical marijuana waste shall also contain this information and shall adhere to OAC 310:681-9-6(c). Each person authorized by the waste facility licensee to transport to a waste disposal facility shall maintain records before and during transport and at the waste disposal facility. Electronic inventory should match the inventory manifest form prior to travel and upon arrival at the disposal facility.
  - (1) The copy of the inventory manifest to be left with the business, research facility, or education facility licensee include the following:
    - (Å) The license number, business name, address and contact information of the business, research facility, or education facility licensee;
    - (B) The license number, business name, address and contact information of the waste disposal facility licensee;
    - (C) A complete inventory of the medical marijuana waste to be transported, including quantities

by weight or unit of the medical marijuana waste;

- (D) The date of transportation and approximate time of departure;
- (E) Printed names and signatures of personnel accompanying the transportation of the medical marijuana waste; and
- (F) Notation of the business, research facility, or education facility from which the medical marijuana waste was collected.
- (2) The copy of the inventory manifest to be retained by the medical marijuana waste facility shall include, at a minimum:
  - (A) The license number, business name, address and contact information of the business, research facility, or education facility licensee(s) from which the waste was collected;
  - (B) The license number, business name, address and contact information of the waste disposal facility licensee;
  - (C) A complete inventory of the medical marijuana waste collected, including quantities by weight or unit of the medical marijuana waste;
  - (D) The date and time of arrival; and
  - (E) The printed names and signatures of personnel accompanying the transportation of the medical marijuana waste.
- (e) **Records and reporting**. Reporting the loss of in-transit shipments is the responsibility of the waste disposal facility licensee. Any losses shall be reported to the Department immediately in writing and through the electronic inventory system. Every inventory and other record required shall be kept by the licensee available for at least two (2) seven (7) years from the date of such inventory or record, for inspecting and copying.

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

- (a) **Audits**. The Department may perform on-site audits of all waste disposal facility licensees and permitted locations to ensure that all marijuana grown in Oklahoma is accounted for. Submission of an application for a medical marijuana waste disposal facility license constitutes permission for entry to any licensed premises and auditing of the licensee during hours of operation and other reasonable times. Refusal to permit the Department entry or refusal to permit the Department to inspect all books and records shall constitute grounds for administrative penalties, which may include, but is not limited to, fines as set forth in Appendix C and the denial, nonrenewal, suspension, and/or revocation of a license or permit.
  - (1) The Department may review any and all records and information of a waste disposal facility licensee and may require and conduct interviews with such persons or entities and persons affiliated with such licensees, for the purpose of determining compliance with Department rules and applicable laws. Failure to make documents or other requested information available to the Department and/or refusal to appear or cooperate with an interview shall constitute grounds for administrative penalties, which may include, but are not limited to, fines as set forth in Appendix C and the denial, nonrenewal, suspension, and/or revocation of a license or any other remedy or relief provided under law. All records shall be kept on-site and readily accessible.
  - (2) Waste disposal facility licensees shall comply with all written requests from the Department to produce or provide access to records and information within ten (10) business days.
  - (3) If the Department identifies a violation of the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq., other applicable Oklahoma law, or these Rules during an audit of the licensee, the Department shall take administrative action against the licensee in accordance with the Oklahoma law, including the Oklahoma Administrative Procedures Act, 75 O.S. § 250 et seq.
  - (4) The Department may refer all complaints alleging criminal activity or other violations of Oklahoma law that are made against a waste disposal licensee to appropriate Oklahoma state or local law enforcement or regulatory authorities.
  - (5) If the Department discovers what it reasonably believes to be criminal activity or other violations of Oklahoma law during an audit, the Department may refer the matter to appropriate Oklahoma state or local law enforcement or regulatory authorities for further investigation.

- (6) Except as is otherwise provided in Oklahoma law or these Rules, correctable violations identified during an audit shall be corrected within thirty (30) days of receipt of a written notice of violation.
- (7) If a licensee fails to correct violations within thirty (30) days, the licensee will be subject to a fine in the amount set forth in Appendix C for each violation and any other administrative action and penalty authorized by law.
- (8) The Department may assess fines in the amounts set forth in Appendix C and seek any other administrative penalties authorized by law against a licensee without providing opportunity to correct when the violation is not capable of being corrected.
- (b) Inventory tracking system. Each waste disposal facility Pursuant to 63 O.A. § 427.3(D)(8) and 63 O.S. § 427.13(B), each commercial licensee shall use the seed to sale State inventory tracking system established by the Department or a seed-to-sale tracking system that integrates with the Department-established system at the time of its implementation by inputting inventory tracking data required to be reported to the Department directly into the State inventory tracking system or by utilizing a seed-to-sale tracking system that integrates with the State inventory tracking system. All commercial licensees must have an inventory tracking system account activated to lawfully operate and must ensure all information is reported to the Department accurately and in real time or after each individual sale in accordance with 63 O.S. § 427.13(B)(1) and these Rules. All commercial licensees shall ensure the following information and data are accurately tracked and timely reported to the Department through the State inventory tracking system The system utilized by each licensee shall be a system that:
  - (1) Documents the <u>The</u> chain of custody of all medical marijuana and medical marijuana products, including every transaction with another commercial licensee; <u>patient or caregiver</u>, including but not limited to:
    - (A) The name, address, license number and phone number of the medical marijuana business that cultivated, manufactured, sold, purchased, or otherwise transferred the medical marijuana or medical marijuana product(s);
    - (B) The type, item, strain, and category of medical marijuana or medical marijuana product(s) involved in the transaction;
    - (C) The weight, quantity, or other metric required by the Department, of the medical marijuana or medical marijuana product(s) involved in the transaction;
    - (D) The batch number of the medical marijuana or medical marijuana product(s);
    - (E) The total amount spent in dollars;
    - (F) All point-of-sale records as applicable;
    - (G) Transportation information documenting the transport of medical marijuana or medical marijuana product(s) as required under OAC 310:681-3-6(b);
    - (H) Testing results and information;
    - (I) Waste records and information;
    - (J) Marijuana excise tax records, if applicable;
    - (K) RFID tag number(s);
  - (2) Establishes ongoing inventory controls and procedures for the conduct of inventory reviews and comprehensive inventories of medical marijuana and medical marijuana products for traceability which shall enable the licensee to detect any diversion, theft, or loss in a timely manner;
  - (3) Identifies and allows for tracking and documentation of the <u>The</u> entire life span of a licensee's stock of medical marijuana and medical marijuana products, including, at a minimum, notifying the Department:
    - (A) when When medical marijuana seeds or clones are planted;
    - (B) when When medical marijuana plants are harvested and/or destroyed;
    - (C) when When medical marijuana is transported, or otherwise transferred sold, stolen, diverted, or lost:
    - (D) a complete inventory of all medical marijuana; seeds; plant tissue; clones; usable marijuana; trim; leaves; other plant matter; and medical marijuana products; When medical marijuana changes form, including, but not limited to, when it is planted, cultivated, processed, and infused into a final form product;

- (E) all samples sent to a testing laboratory or used for internal quality testing or other purposes; <u>A</u> complete inventory of all medical marijuana; seeds; plant tissue; clones; usable marijuana; trim; shake; leaves; other plant matter; and medical marijuana products; and
- (4) Tracks medical marijuana using an assigned batch number and bar code.
- (3) Any further information the Department determines is necessary to ensure all medical marijuana and medical marijuana products are accurately and fully tracked throughout the entirety of the life span of the plant and product.
- (c) Seed-to-sale tracking system. A commercial licensee shall use a seed-to-sale tracking system or integrate its own seed-to-sale tracking system with the State inventory tracking system established by the Department. If a commercial licensee uses a seed-to-sale tracking system that does not integrate with the State inventory tracking system, or does integrate but does not share all required information, the commercial licensee shall ensure all required information is reported directly into the State inventory tracking system.

#### (d) Inventory tracking system requirements.

- (1) At a minimum, commercial licensees shall track, update and report its inventory after each individual sale to the Department in the State inventory tracking system.
- (2) All commercial licensees must ensure all on-premises and in-transit medical marijuana and medical marijuana product inventories are reconciled each day in the State inventory tracking system at the close of business, if not already done.
- (3) Commercial licensees are required to use RFID tags from a Department-approved supplier for the State Inventory Tracking System. Each Licensee is responsible for the cost of all RFID tags and any associated vendor fees.
  - (A) A commercial licensee shall ensure its inventories are properly assigned to medical marijuana, medical marijuana products, and medical marijuana waste as required by the Department.
  - (B) A commercial licensee shall ensure it has an adequate supply of RFID tags at all times. If a commercial licensee is unable to account for unused RFID tags, the commercial licensee must report to the Department and the State inventory tracking system vendor within forty-eight (48) hours.
  - (C) RFID tags must contain the legal name and correct license number of the commercial licensee that ordered them. Commercial licensees are prohibited from using another licensee's RFID tags.
  - (D) Prior to a plant reaching a point where it is able to support the weight of the RFID tag and attachment strap, the RFID tag may be securely fastened to the stalk or other similarly situated position approved by the Department.
  - (E) When the plant becomes able to support the weight of the RFID tag, the RFID tag shall be securely fastened to a lower supporting branch. The RFID tag shall remain affixed for the entire life of the plant until disposal.
  - (F) Mother plants must be tagged before any cuttings or clones are generated therefrom.
  - (G) If a RFID tag gets destroyed, stolen, or falls off of a medical marijuana plant, the licensee must ensure a new RFID tag is placed on the medical marijuana plant and the change of the RFID tag is properly reflected in the State inventory tracking system.
  - (H) Commercial licensees shall not reuse any RFID tag that has already been affixed to any regulated medical marijuana or medical marijuana products.
- (4) Each wholesale package of medical marijuana must have a RFID tag during storage and transfer and may only contain one harvest batch of medical marijuana.
- (5) Prior to transfer, commercial licensees shall ensure that each immature plant is properly affixed with an RFID tag if the plant was not previously tagged in accordance with these Rules.
- (6) Commercial licensees' inventory must have a RFID tag properly affixed to all medical marijuana products during storage and transfer in one of the following manners:
  - (A) Individual units of medical marijuana products shall be individually affixed with a RFID tag; or
  - (B) Marijuana products may only be combined in a single wholesale package using one RFID tag

- if all units are from the same production batch.
- (7) If any medical marijuana or medical marijuana products are removed from a wholesale package, each individual unit or new wholesale package must be separately tagged.
- (8) All packages of medical marijuana waste shall have a RFID tag affixed and the contents of the waste package shall be reported in the State inventory tracking system.

#### (e) Inventory tracking system administrators and users.

- (1) The inventory tracking system administrator must attend and complete all required inventory tracking system training.
- (2) If at any point, the inventory tracking system administrator for a licensee changes, the commercial licensee shall change or assign a new inventory tracking system administrator within thirty business days.
- (3) Commercial licensees shall maintain an accurate and complete list of all inventory tracking system administrators and employee users.
- (4) Commercial Licensees shall ensure that all owners and employees that are granted inventory tracking system account access for the purpose of conducting inventory tracking functions are trained and authorized before the owners or employees may access the State inventory tracking system.
- (5) All inventory tracking system users shall be assigned an individual account in the State inventory tracking system.
- (6) Any individual entering data into the State inventory tracking system shall only use the inventory tracking system account assigned specifically to that individual. Each inventory tracking system administrator and inventory tracking system user must have unique log-in credentials that shall not be used by any other person.
- (7) Within three (3) business days, commercial licensees must remove access for any inventory tracking system administrator or user from their accounts if any such individual no longer utilizes the State inventory tracking system or is no longer employed by the commercial licensee.
- (f) Loss of access to State inventory tracking system. If at any time a commercial licensee loses access to the State inventory tracking system due to circumstances beyond the commercial licensee's control, the commercial licensee shall keep and maintain records detailing all inventory tracking activities that were conducted during the loss of access. Once access is restored, all inventory tracking activities that occurred during the loss of access must be immediately entered into the State inventory tracking system. If a commercial licensee loses access to the inventory tracking system due to circumstances within its control, the commercial licensee may not perform any business activities that would be required to be reported into the State inventory tracking system until access is restored and reporting is resumed; any transfer, sale, or purchase of medical marijuana or medical marijuana products would be an unlawful sale.

# APPENDIX C. SCHEDULE OF FINES [REVOKED] APPENDIX C. SCHEDULE OF FINES [NEW]

OFFENSE	FINE AMOUNT	Citation
Failure to carry copy of both transporter license and transporter agent license while transporting medical marijuana or medical marijuana products	\$50 per violation – transporter agent  \$500 per violation – commercial transporter, grower, processor, or dispensary	OAC 310:681-3-1(e)-(f); 63 O.S. § 427.16(E)
Unauthorized individual in vehicle transporting marijuana	\$1,000 per violation	OAC 310:681-3-1(e)-(f)
Recordkeeping violations	\$500 per violation	OAC 310:681-3-2(c); OAC 310:681-3-6; OAC 310:681-4-5; OAC 310:681-5-5(b); OAC 310:681-5-10(b); OAC 310:681-5-10(c); OAC 310:681-8-1(h); OAC 310:681-8-1(h); OAC 310:681-8-2(g); OAC 310:681-8-2(g); OAC 310:681-8-2(h); OAC 310:681-8-2(i); OAC 310:681-8-3(a); OAC 310:681-8-3(c)(5); OAC 310:681-9-6(c); OAC 310:681-9-6(c); OAC 310:681-9-6(e)
Failure to ensure information and records in OMMA online account are complete, accurate, and updated in timely manner	\$500 per violation	OAC 310:681-4-1.1(7); OAC 310:681-4-2(e); OAC 310:681-5-1.1(7); OAC 310:681-5-2(e)

Refusal to permit Department access to licensed premises	\$5,000 per violation	OAC 310:681-4-4(a); OAC 310:681-5-4(a); OAC 310:681-9-5(a); 63 O.S. § 427.6(E)(7)
Failure to make documents or other requested information available to the Department	\$500 per violation	OAC 310:681-4-5(c)&(e); OAC 310:681-5-4(g); OAC 310:681-5-6(b)&(e); OAC 310:681-9-5(g); OAC 310:681-9-7(a); 63 O.S. § 427.6(E)(7)
Failure to appear for or cooperate with an interview	\$500 per violation	OAC 310:681-4-4(f); OAC 310:681-4-5(e); OAC 310:681-5-4(g); OAC 310:681-5-6(e)(1); OAC 310:681-9-5(g)(1); OAC 310:681- 9-7(a)(1)
Failure to maintain documents onsite and readily accessible	\$500 per violation	OAC 310:681-4-4(f); OAC 310:681-4-5(c); OAC 310:681-4-5(e)(1); OAC 310:681-5-4(g); OAC 310:681-5-6(b); OAC 310:681-5-6(e)(1); OAC 310:681-9-5(g); OAC 310:681-9-7(a)(1); 63 O.S. § 427.6(B)(3)
Inventory tracking violations	\$500 per violation	OAC 310:681-4-5; OAC 310:681-5-6; OAC 310:681-9-7(b); 63 O.S. § 427.13.
Unlawful purchase or sale	\$1,000 – First violation \$5,000 – Any additional violation	OAC 310:681-4-6(c); OAC 310:681-5-6.1(c); 63 O.S. § 427.6(G).

Monthly report violations	\$500 per violation	OAC 310:681-5-6.1(a); 63 O.S. §§ 421-423
Inaccurate reporting	\$5,000 - first violation \$10,000 - Any additional violation	OAC 310:681-5-6.1(b); 63 O.S. § 427.6(G)
Packaging & labeling violations	\$500 per violation	OAC 310:681-5-8.1(e); OAC 310:681-71; OAC 310:681-7-2; 63 O.S. § 427.18
Failure to notify the Department of actual loss, theft, and/or diversion	\$1,000 per violation	OAC 310:681-5-13; 63 O.S. § 427.6(E)(5)
Prohibited onsite consumption of alcohol	\$500 per violation	OAC 310:681-5-18(a)
Prohibited onsite smoking/vaping of medical marijuana	\$500 per violation	OAC 310:681-5-18(a)
Employment of persons younger than 18	\$500 per violation	OAC 310:681-5-18(b)
Delivery of medical marijuana or medical marijuana products to patients	\$1,000 per violation	OAC 310:681-5-18(c)
Physician located in or providing medical services to patients at the same physical address of dispensary	\$1,000 per violation	OAC 310:681-5-18(d)

Falsification or misrepresentations on any documents, forms, or other materials or information submitted to the Department	\$5,000 per violation	OAC 310:681-5-18(g)
Threatening or harming a patient, medical practitioner, or employee of the Department	\$5,000 per violation	OAC 310:681-5-18(h)
Failure to adhere to acknowledgment, verification, or other representation made to Department	\$1,000 per violation	OAC 310:681-5-18(i)
Possession, sale, or transfer of medical marijuana products by a grower	\$1,000 – First violation \$5,000 – Any additional violation	OAC 310:681-5-18(j)
Use of extraction equipment or processing utilizing butane, propane, carbon dioxide, or other potentially hazardous material in residential property	\$5,000 per violation	OAC 310:681-5-18(k)
Acceptance, purchase, sale, or transfer of improperly packaged or labeled medical marijuana or medical marijuana product by a business licensee	\$500 per violation	OAC 310:681-7-1 (b); 63 O.S. § 427.18(B)
Advertising violations	\$500 per violation	OAC 310:681-7-3; 63 O.S. § 427.21

Use or sale or other transfer of medical marijuana or medical marijuana products exceeding allowable testing thresholds	\$1,000 – First violation \$5,000 – Any additional violation	OAC 310:681-8-1(d); 63 O.S. § 427.17(V)	
Failure to assist Department in a recall	\$5,000 per violation	OAC 310:681-8-1(g)	
Reporting test result for testing outside scope of accreditation	\$1,000 per violation	OAC 310:681-8-2(b)	
Improper influencing of testing process, improper manipulation of data, or improper benefit by a testing laboratory employee, owner, or agent.	\$5,000 per violation	OAC 310:681-8-2(d); 63 O.S. § 427.17(M)	
Improper manipulation of test systems, including but not limited to, quality control, calibration data, and test validation.	\$5,000 per violation	OAC 310:681-8-2(d); 63 O.S. §427.17(M)	
Testing performed by unqualified personnel	\$1,000 per violation	OAC 310:681-8-2(f); 63 O.S. § 427.17(N)(10)	
Operation of licensed testing laboratory without medical laboratory director onsite \$1,000 per violation		OAC 310:681-8-2(f)	

Any inspection or audit violation not specifically listed above	\$500 per violation	63 O.S. § 427.6(E)-(F)
Diversion to an unauthorized minor	\$2,500 – First violation \$5,000 and termination of license – Any additional violation	63 O.S. § 427.6(I)
Any other violation not listed above for which disciplinary action can be taken under 63 O.S. § 427.6(E).	\$500 per violation	63 O.S. § 427.6(E)-(F)

# APPENDIX D. SAMPLE COLLECTION FOR FINAL MEDICAL MARIJUANA PRODUCTS $[\mbox{\rm NEW}]$

Minimum Number of Sample Increments Required to be submitted for Testing	Fi	Final Products Products (Sample Increment = 1 Serving)  Maximum Batch Size= 1000 Grams				
	Number of Servings within Production Batch	Minimum Number of Packaged Unitsfor a 5- Serving Unit*	Minimum Number of Packaged Units for a for a 10- Serving Unit*	Minimum Number of Packaged Units for a 20- Serving Unit*	Minimum Number of Packaged Units for a 100- Serving Unit*	
5	0 - 99	2	2	2	2	
8	100 - 999	2	2	2	2	
15	1000 - 4999	3	2	2	2	
22	5000 - 9999	5	3	2	2	
33	10000 - 49999	7	4	2	2	
43	50000 - 99999	9	5	3	3	
53	100000 - 249999	11	6	3	3	
80	250000 or more	16	8	4	4	

APPENDIX E. SAMPLE COLLECTION FOR PRE-ROLLS [NEW]

Minimum Number of	Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana (Sample Increment 0.25 g)				
Sample Increments Required to be submitted for testing	Number of Pre-Rolls within Production Batch	Minimum Number of Pre-Rolls to submit for a < or = 0.25 g Pre- Roll*	Minimum Number of Pre-Rolls to submit for a 0.50 g Pre- Roll)*	Minimum Number of Pre-Rolls to submit for a 1.00 g Pre- Roll*	Minimum Number of Pre- Rolls to submit for a 2.00 g Pre- Roll*
5	0 - 99	5	3	2	2
8	100 - 999	8	4	2	2
15	1000 - 4999	15	8	4	2
22	5000 - 9999	22	11	6	3
33	10000 - 49999	33	17	9	5
43	50000 - 99999	43	22	11	6
53	100000 - 249999	53	27	14	7